IN THE UNITED STATES DISTRICT COURT FOR THE

[[1]]

[[2]],

Plaintiffs, **Case No.: [[3]]**

v.

[[4]],

John and Jane Does 1-10

Defendants.

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

For the Complaint, Plaintiff **[INSERT YOUR NAME]**, proceeding *pro se* states, all upon information and belief:

INTRODUCTORY STATEMENT

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[1] **INSERT THE NAME OF THE DISTRICT COURT YOU ARE SUING IN.**

[2] **INSERT YOUR NAME(S).**

[3] **LEAVE THIS BLANK UNTIL YOU FILE WITH THE COURT, AND WHEN THE COURT PROVIDES YOU A CASE NUMBER, INSERT THAT HERE.**

[4] **INSERT NAME OF PERSON AND/OR ENTITIES YOU ARE SUING. THIS WILL DEPEND ON A) THE GOVERNMENT MANDATE WHICH IMPACTS YOU (TO DETERMINE WHO WILL BE KNOWN IN THIS DOCUMENT AS THE "Government Defendant(s)"), B) YOUR EMPLOYER (WHO WILL BE KNOWN IN THIS DOCUMENT AS THE "EMPLOYER DEFENDANT"), AND C) THE PEOPLE AT YOUR EMPLOYER WHO ARE ASSISTING YOUR EMPLOYER CARRY OUT ITS ACTS AGAINST YOU, THE "NATURAL PERSON DEFENDANTS"). FOR EXAMPLE, IF THE GOVERNMENT MANDATE THAT IMPACTS YOU IS THE CMS MANDATE, THE FOLLOWING WOULD BE THE Government Defendant(s): "Xavier Becerra, Secretary, U.S. Department of Health and Human Services; United States Department of Health and Human Services; Chiquita Brooks-Lasure; Centers for Medicare and Medicaid Services".**

a. By the spring of 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, had spread across the globe. Since then, and because of the federal government's "Operation Warp Speed," three separate coronavirus vaccines have been developed and approved more swiftly than any other vaccines in our nation's history. The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-BioNTech COVID-19 Vaccine ("BioNTech Vaccine") on December 11, 2020.[5] Just one week later, FDA issued a second EUA for the Modern COVID-19 Vaccine ("Moderna Vaccine").[6] FDA issued its most recent EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine") on February 27, 2021 (the only EUA for a single shot vaccine).[7]

b. FDA fully approved the Pfizer Comirnaty Vaccine ("Comirnaty Vaccine") on August 23, 2021. Though both are affiliated with Pfizer, the BioNTech Vaccine and the Comirnaty Vaccines are legally distinguishable.

c. The EUA statute, 21 U.S.C. § 360bbb-3, explicitly states that anyone to whom an EUA product is administered must be informed of the option to accept or to refuse it, as well as alternatives to the product and the risks and benefits of receiving it.

d. The Government Defendant(s) (as defined below) has promulgated **[INSERT THE TYPE OF MANDATE, WHETHER CMS, OSHA, FEDERAL CONTRACTOR, ETC. AND INSERT A DESCRIPTION OF THE SAME. THE TYPE OF**

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[5] *Pfizer-BioNTech Vaccine FAQ*, FDA, bit.ly/3i4Yb4e (last visited August 26, 2021).

[6] *Moderna, About Our Vaccine*, bit.ly/2Vl4lUF (last visited August 26, 2021).

[7] *EUA for Third COVID-19 Vaccine*, FDA, bit.ly/3xc4ebk (last visited August 26, 2021).

MANDATE WILL ALSO DETERMINE THE NAME OF THE Government Defendant(s) YOU WILL BE SUING, WHICH WILL THEN HAVE TO BE INSERTED IN THE CAPTION ABOVE WHERE IT INDICATES DEFENDANTS AND IN A PARAGRAPH BELOW UNDER ALLEGATIONS, WHERE IT INDICATES AND DESCRIBES DEFENDANTS. WE HAVE PREPARED A DESCRIPTION OF EACH OF THE MANDATES, WHICH WE WILL PROVIDE TO YOU UPON REQUEST OR WILL BE AVAILABLE IN ANOTHER DOCUMENT LOCATED AT THE WEBPAGE YOU LOCATED THIS DOCUMENT, WHICH YOU CAN INSERT HERE. AS AN EXAMPLE, LANGUAGE MIGHT BE USED FOR THE CMS MANDATE: "On August 18, 2021, Centers for Medicare & Medicaid Services ("CMS") announced that it would be issuing a regulation that all nursing home staff would have to be vaccinated against COVID-19 as a requirement for LTC facilities participating with the Medicare and Medicaid programs. Subsequently, on September 9, 2021, CMS announced that this requirement would be extended to nearly all Medicare and Medicaid- certified providers and suppliers. The stated reason for these actions were CMS's aim to support increasing vaccination rates among staff working in all facilities, providers, and certified suppliers that participate in Medicare and Medicaid. On November 5, 2021, CMS published an IFC with comment period (86 FR 61555), entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," revising the infection control requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. Thus, according to the timetable set forth in the Centers for Medicare & Medicaid Services (Center for

Clinical Standards and Quality/Quality Safety, Safety & Oversight Group Memorandum, Ref: QSO-22-07-ALL, from Directors of Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG) to State Survey Agency Directors, dated December 28, 2021 ("QSO-22-07-ALL", attached hereto as Attachment E) within 60 days from December 28, 2021, 100% of staff of most Medicare- and Medicaid-certified providers and suppliers must (for these providers and suppliers to participate in the Medicare and Medicaid programs) have received the necessary doses to complete a Covid-19 vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC], the "Government Action".

e. Via the Government Action, and in coordination, cooperation and/or conspiracy with the Government Defendant(s) and the Natural Person Defendants (as defined below), each sharing the common purpose of subjecting the Plaintiff (and others in a similar position) to the same, the Employer Defendant issued and commenced to execute COVID-19 related directives (the "Directives") which Directives include **[INSERT ALL THAT YOUR EMPLOYER IS REQUIRING YOU TO DO REGARDING COVID-19 THAT YOU OBJECT TO. AN EXAMPLE YOU MIGHT USE, BUT ONLY INCLUDE WHAT UNEQUIVOCALLY APPLIES TO YOU, IS THE FOLLOWING: "A) Mandating that Plaintiff inject into his/her body a COVID-19 Vaccine (which is under only an Emergency Use Authorization or for which the legality and enforceability of an Approval has not been sufficiently confirmed), without any regard to and in fact, in direct contravention to the will of, the**

Plaintiff, without any regard to the fact that Plaintiff has, via previous infection with COVID-19, acquired natural immunity to COVID-19 (via, among other things, the body's natural production of antibodies effective against COVID-19) which is at least as effective against COVID-19 as vaccine acquired immunity, and in willful and reckless disregard to the fact that the administration of a COVID-19 vaccine to Plaintiff as a person previously infected with COVID-19 might pose a significant threat to the health and the very life of the Plaintiff; B) Mandating that Plaintiff undergo regular testing for COVID-19, at uncompensated (and, in some regards, significant) cost in terms of money, time and/or physical discomfort to Plaintiff, without any regard to and in fact, in direct contravention to the will of, the Plaintiff, and without any regard to the fact that Plaintiff has, via previous infection with COVID-19, acquired natural immunity to COVID-19 (via, among other things, the body's natural production of antibodies effective against COVID-19) which is at least as effective against COVID-19 as vaccine acquired immunity; C) Mandating that the Plaintiff utilize a mask at all times at uncompensated (and, in some regards, significant) cost in terms of money, time and/or physical discomfort to Plaintiff, without any regard to and in fact, in direct contravention to the will of, the Plaintiff, and without any regard to the fact that Plaintiff has, via previous infection with COVID-19, acquired natural immunity to COVID-19 (via, among other things, the body's natural production of antibodies effective against COVID-19) which is at least as effective against COVID-19 as vaccine acquired immunity].

f. The Government Action and the Directives are inextricably linked and intertwined, operate in vital support of the other, cannot achieve their common purpose without the other, and thus, constitute one *de facto* project/enterprise, that is, the "Government Action/Directives".

g. According to the Government Action/Directives, all employees of the Employer Defendant (such as Plaintiff) must have either been fully vaccinated or have received one of a two-dose series by certain dates set by the Government Action/Directives, unless they obtain a religious or medical exemption, both of which are limited in nature and application.

h. Those employees of the Employer Defendant who do not comply with the Government Action/Directives face potential disciplinary action, including termination of employment.

i. **Plaintiff has already contracted and fully recovered from COVID-19. As a result, he/she[8] has naturally acquired immunity, confirmed unequivocally by recent SARS-CoV-2 antibody tests. [IN ORDER TO FILE THIS COMPLAINT IN COURT IN ITS PRESENT FORM, YOU MUST HAVE THIS TEST ADMINISTERED UPON YOU AND CONFIRM THAT YOU HAVE NATURALLY ACQUIRED IMMUNITY. IF YOU DO NOT (OR CANNOT), YOU MUST NOT FILE THIS COMPLAINT IN COURT ALLEGING YOU HAVE NATURALLY ACQUIRED IMMUNITY BECAUSE, OTHERWISE, YOU RISK COMMITTING PERJURY. YOU MUST, IN THAT CASE, HAVE A LAWYER**

[8] The document includes several places where you may, if you so desire, insert your preferred pronoun.

REVISE THIS COMPLAINT TO ENSURE THAT YOU DO NOT RUN AFOUL OF PERJURY LAWS.]

j. **Plaintiff's doctor, Dr. [INSERT THE NAME OF YOUR DOCTOR], has advised him/her that it is *medically unnecessary* to undergo a vaccination procedure at this point (which fact also renders the procedure and any attendant risks medically unethical). [IN ORDER TO FILE THIS COMPLAINT IN COURT IN ITS PRESENT FORM, YOU MUST LOCATE A DOCTOR WHO CAN ETHICALLY DETERMINE, AND PROVIDE YOU WITH A LETTER STATING, THAT IT IS "*medically unnecessary* for [INSERT YOUR NAME] to undergo a vaccination procedure at this point". IF YOU DO NOT (OR CANNOT), YOU MUST NOT FILE THIS COMPLAINT IN COURT WITH THIS PROVISION ALLEGING THAT YOU HAVE BEEN ADVISED BY A DOCTOR THAT "it is *medically unnecessary* to undergo a vaccination procedure at this point" BECAUSE, OTHERWISE, YOU RISK COMMITTING PERJURY. YOU MUST, IN THAT CASE, HAVE A LAWYER REVISE THIS COMPLAINT TO ENSURE THAT YOU DO NOT RUN AFOUL OF PERJURY LAWS.]**

k. Yet, if Plaintiff follows his/her doctor's advice and elects not to take the vaccine, he/she faces adverse disciplinary consequences. In short, the Government Action/Directives is unmistakably coercive and cannot reasonably be considered anything other than an unlawful ""Mandatory COVID-19 Vaccination Directive".

l. Given Plaintiff's naturally acquired immunity, Government Defendant(s) (and the Employer Defendant and Natural Persons Defendants operating in coordination,

cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) cannot establish that the Government Action/Directives (forcing Plaintiff either to be vaccinated **[IF A COVID TEST IS PART OF THE DIRECTIVE, INSERT "and/or regularly tested for COVID-19" AND IF THERE ARE OTHER REQUIREMENTS OF THE DIRECTIVE, INSERT THEM HERE]** or to suffer adverse professional consequences) is necessary to achieve a compelling state interest that overrides the Plaintiff's fundamental right to bodily integrity and other constitutional rights, and cannot establish that the Government Action/Directives in their present form are narrowly tailored to achieve any compelling purpose and use the least restrictive means to achieve the purpose.

m. Naturally acquired immunity is at least as robust and durable as that attained through the most effective vaccines (some observers estimate that it is much more robust and durable), and it is significantly more protective than some of the inferior vaccines that the Defendants consider acceptable under the Government Action/Directives. Studies further indicate that naturally acquired immunity is significantly longer lasting than that acquired through the best vaccines. As a result, the Government Action/Directives is designed to nullify informed consent and infringes upon Plaintiff's rights under the Ninth and Fourteenth Amendments to the United States Constitution, including without limitation, his/her rights under the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

n. The modern approach on Equal Protection jurisdiction, pioneered by *Skinner v. Oklahoma,* 316 U.S. 535 (1942) (law permitting the compulsory sterilization of criminals is unconstitutional as it violates a person's rights given under the Fourteenth

Amendment of the Constitution, specifically the Equal Protection Clause, as well as the Due Process Clause), is that a higher level of judicial scrutiny, that is "strict scrutiny" is triggered by purported discrimination that involves "fundamental rights" (such as, in *Skinner*, the right to procreation). The Supreme Court in *Skinner* explains, "We are dealing with legislation that involves one of the basic civil rights of man. Marriage and procreation are fundamental to the very existence and survival of the race."… "there is no redemption for the individual whom the law touches. Any experiment which the state conducts is to his irreparable injury. He is forever deprived of a basic liberty"… "We advert to them merely in emphasis of our view that strict scrutiny of the classification which a state makes in a sterilization law is essential, lest unwittingly, or otherwise, invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws". *Skinner,* 316 U.S. at 541.

o. The Plaintiff maintains that his/her right to bodily integrity, to determine free of any coercion what may nor may not be injected into his/her body (especially when that which is to be injected involves a novel technology that some observers might consider experimental, is known to have caused injury to others, and is known to specifically pose a potential danger to those who have naturally acquired immunity such as Plaintiff) is also a fundamental right. Plaintiff notes that, as was the case in *Skinner*, one cannot be simply unvaccinated, and any potential injuries from a vaccination cannot be undone.

p. Plaintiff maintains that his/her right to bodily integrity is a right so entirely fundamental that it is beyond question, as it is incorporated into the very concept of the fundamental right to self defense and the seminal statement of the American Creed derived from the United States Declaration of Independence: "We hold these truths to be self evident; that

all men are created equal; that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the Pursuit of Happiness…". Plaintiff furthermore notes that, in its original form, as drafted by Thomas Jefferson, this read "We hold these truths to be sacred & undeniable; that all men are created equal & independent, that from equal creation they derive rights inherent & unalienable, among which are the preservation of life, & liberty, & the pursuit of happiness", [9] and thus, there is no other right so central, so fundamental to the very concept of Equal Protection than that of the fundamental right to one's bodily integrity.

q. Plaintiff is of the view, thus, that strict scrutiny of the classification which a state makes in a matter impacting his/her bodily integrity, such as the Government Action/Directives "is essential, lest unwittingly, or otherwise, invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws". *See Skinner*, 316 U.S. at 541.

r. Under the Strict Scrutiny Standard, triggered by a government law or regulation impacting a fundamental right, the government must demonstrate that the law or regulation is necessary to achieve a "compelling state interest". The government must also demonstrate that the law is "narrowly tailored" to achieve the compelling purpose, and uses the "least restrictive means" to achieve the purpose.

s. Unvaccinated individuals such Plaintiff, who have contracted COVID-19 and have antibodies, must not be treated differently than vaccinated individuals, lest it violate the Equal Protection Clause, because the compelling government interest (to stop the spread

[9] American Sphinx, The Character of Thomas Jefferson, Joseph J. Ellis, Vintage Books, 1998, p. 10.

of COVID) can be met by a more narrowly tailored, less restrictive means to achieve the same purpose (that is, treat natural immunity like vaccination).

t. The Defendants have cooperated, coordinated and conspired, each sharing a common purpose with one another, to deny the Plaintiff his/her rights under the Equal Protection Clause of the 14th Amendment, and thus the Government Defendant(s), the Employer Defendant and the Natural Person Defendants are jointly and severally liable to Plaintiff pursuant to 42 U.S.C. § 1983.

u. In her book, The Miner's Canary: Enlisting Race, Resisting Power, Transforming Democracy, the recently deceased Harvard Law Professor Lani Guinier and University of Texas Law Professor Gerald Torres "champion reform from below through 'public policy movements' - - reforms based on initiatives that are begun by minority groups but move beyond racial issues because they address the needs of other disadvantaged groups" poor white, felons, housewives arrested for traffic offenses, even citizens being taxed to build new prison."[10] and, Plaintiff would argue, people in his/her position.

v. Thus, it is significant to the instant matter that, in a case dating back to the Civil Rights Era, *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970), the Supreme Court explained under what conditions *both private actors and public actors* might be liable under 42 U.S.C. § 1983 for a violation of the Equal Protection Clause of the Fourteenth Amendment. In that case, a white school teacher had been arrested for vagrancy by police upon leaving a restaurant where she had been refused service when she was in the company of her students, who were black. She filed a complaint under 42 U.S.C. §

[10] Books in Brief: 'The Miner's Canary', Allen D. Boyer, *The New York Times*, April 21, 2002 (Last retrieved January 10, 2022).

1983 alleging that the refusal of service and her arrest was the result of a conspiracy between the restaurant and the police and violated the Equal Protection Clause of the Fourteenth Amendment to the Constitution.

w. In an opinion delivered by Justice Harlan, the Supreme Court explained:

> *A. CONSPIRACIES BETWEEN PUBLIC OFFICIALS AND PRIVATE PERSONS -- GOVERNING PRINCIPLES*
>
> *The terms of § 1983 make plain two elements that are necessary for recovery. First, the plaintiff must prove that the defendant has deprived him of a right secured by the "Constitution and laws" of the United States. Second, the plaintiff must show that the defendant deprived him of this constitutional right "under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory." This second element requires that the plaintiff show that the defendant acted "under color of law."* [Footnote 4]
>
> As noted earlier, we read both counts of petitioner's complaint to allege discrimination based on race in violation of petitioner's equal protection rights. [Footnote 5] Few principles of law are more firmly stitched into our constitutional fabric than the proposition that a State must not discriminate against a person because of his race or the race of his companions, or in any way act to compel or encourage racial segregation. [Footnote 6] *Although this is a lawsuit against a private party, not the State or one of its officials, our cases make clear that petitioner will have made out a violation of her Fourteenth Amendment rights and will be entitled to relief under § 1983 if she can prove* that a Kress employee, in the course of employment, and a Hattiesburg policeman *somehow reached an understanding* to deny Miss Adickes service in the Kress store, or to cause her subsequent arrest because she was a white person in the company of Negroes.
>
> *The involvement of a state official in such a conspiracy plainly provides the state action essential to show a direct violation of petitioner's Fourteenth Amendment equal protection rights, whether or not the actions of the police were officially authorized, or lawful;* Monroe v. Pape, 365 U. S. 167 (1961); see United States v. Classic, 313 U. S. 299, 313 U. S. 326 (1941); Screws v.

United States, 325 U. S. 91, 325 U. S. 107-111 (1945); Williams v. United States, 341 U. S. 97, 341 U. S. 99-100 (1951). *Moreover, a private party involved in such a conspiracy, even though not an official of the State, can be liable under § 1983.*

"*Private persons, jointly engaged with state officials in the prohibited action, are acting 'under color' of law for purposes of the statute. To act 'under color' of law does not require that the accused be an officer of the State. It is enough that he is a willful participant in joint activity with the State or its agents,*"

United States v. Price, 383 U. S. 787, 383 U. S. 794 (1966). [Footnote 7]

Adickes v. S. H. Kress & Co., 398 U.S. 150-152.

B. STATE ACTION -- 14TH AMENDMENT VIOLATION

For petitioner to recover under the substantive count of her complaint, she must show a deprivation of a right guaranteed to her by the Equal Protection Clause of the Fourteenth Amendment. Since the "action inhibited by the first section of the Fourteenth Amendment is only such action as may fairly be said to be that of the States," Shelley v. Kramer, 334 U. S. 1, 334 U. S. 13 (1948), we must decide, for purposes of this case, the following "state action" issue: is there sufficient state action to prove a violation of petitioner's Fourteenth Amendment rights if she shows that Kress refused her service because of a state-enforced custom compelling segregation of the races in Hattiesburg restaurants?

In analyzing this problem, it is useful to state two polar propositions, each of which is easily identified and resolved. On the one hand, the Fourteenth Amendment plainly prohibits a State itself from discriminating because of race. On the other hand, § 1 of the Fourteenth Amendment does not forbid a private party, not acting against a backdrop of state compulsion or involvement, to discriminate on the basis of race in his personal affairs as an expression of his own personal predilections. As was said in Shelley v. Kraemer, supra, § 1 of "[t]hat Amendment erects no shield against merely private conduct, however discriminatory or wrongful." 334 U.S. at 334 U. S. 13.

At what point between these two extremes a State's involvement in the refusal becomes sufficient to make the private refusal to serve a violation of the Fourteenth Amendment is far from clear

under our case law. *If a State had a law requiring a private person to refuse service because of race, it is clear beyond dispute that the law would violate the Fourteenth Amendment, and could be declared invalid and enjoined from enforcement. Nor can a State enforce such a law requiring discrimination through either convictions of proprietors who refuse to discriminate,* or trespass prosecutions of patrons who, after being denied service pursuant to such a law, refuse to honor a request to leave the premises. [Footnote 40]

The question most relevant for this case, however, is a slightly different one. *It is whether the decision of an owner of a restaurant to discriminate on the basis of race under the compulsion of state law offends the Fourteenth Amendment.* Although this Court has not explicitly decided the Fourteenth Amendment state action issue implicit in this question, underlying the Court's decisions in the sit-in cases is the notion that *a State is responsible for the discriminatory act of a private party when the State, by its law, has compelled the act. As the Court said in Peterson v. City of Greenville, 373 U. S. 244, 373 U. S. 248 (1963):*

"*When the State has commanded a particular result, it has saved to itself the power to determine that result, and thereby, 'to a significant extent' has 'become involved' in it.*"

Moreover, there is much support in lower court opinions for the conclusion that *discriminatory acts by private parties done under the compulsion of state law offend the Fourteenth Amendment.* In Baldwin v. Morgan, supra, the Fifth Circuit held that

"*[t]he very act of posting and maintaining separate [waiting room] facilities when done by the [railroad] Terminal as commanded by these state orders is action by the state.*"

The Court then went on to say:

"As we have pointed out above, the State may not use race or color as the basis for distinction. *It may not do so by direct action or through the medium of others who are under State compulsion to do so.*"

Id. at 755-756 (emphasis added). We think the same principle governs here.

> *For state action purposes, it makes no difference, of course, whether the racially discriminatory act by the private party is compelled by a statutory provision or by a custom having the force of law -- in either case, it is the State that has commanded the result by its law. Without deciding whether less substantial involvement of a State might satisfy the state action requirement of the Fourteenth Amendment, we conclude that petitioner would show an abridgment of her equal protection right if she proves that Kress refused her service because of a state-enforced custom of segregating the races in public restaurants*. [Emphasis Added]
>
> *Adickes v. S. H. Kress & Co*., 398 U.S. 169-171

x. That the Employer Defendant and the Natural Person Defendants are "jointly engaged with" the Government Defendant(s) "in the prohibited action" is clear from the facts set forth above and **[THE FOLLOWING BOLDED LANGUAGE IS ONLY APPLICABLE TO THE CMS MANDATES. IF THE GOVERNMENT ACTION/ DIRECTIVES/MANDATE WHICH YOU ARE SUBJECT TO ARE DIFFERENT, YOU WILL REQUIRE DIFFERENT PROOF OF YOUR COMPANY'S WORKING TOGETHER WITH THE GOVERNMENT THAT RISES TO THE LEVEL OF COORDINATION, CONSPIRACY, ETC., OR AT LEAST WOULD DEMONSTRATE IT "is a willful participant in joint activity with the State or its agents," TO GET YOU VACCINATED AGAINST YOUR WILL. YOU KNOW YOUR EMPLOYER AND THEIR ACTIVITIES BEST, AND, USING THE ITALICIZED LANGUAGE FROM *Adickes v. S. H. Kress & Co.*, 398 U.S. 169-171 SET FORTH IN THE ABOVE PARAGRAPH AS A GUIDE, YOU MUST LAY OUT THE FACTS THAT PROVE YOUR CASE, USING CONCRETE EXAMPLES FROM YOUR EXPERIENCE. IF THE CMS MANDATE APPLIES TO YOU, AND ONLY IF IT APPLIES TO YOU, MAY YOU USE THE FOLLOWING LANGUAGE. HOWEVER, EVEN IF SUCH IS THE CASE, YOU**

MUST DEVELOP THIS SECTION FURTHER, USING CONCRETE EXAMPLES FROM YOUR EXPERIENCE. THIS IS YOUR OPPORTUNITY TO TELL A FEDERAL JUDGE WHAT HAS BEEN DONE TO YOU, AND ONLY YOU CAN ENSURE THAT THIS PART, WHICH IS VERY IMPORTANT, IS DONE CORRECTLY, BECAUSE ONLY YOU ARE LIVING YOUR EXPERIENCE, DAY TO DAY.], moreover, by the Centers for Medicare & Medicaid Services (Center for Clinical Standards and Quality/Quality Safety, Safety & Oversight Group Memorandum, Ref: QSO-22-07-ALL, from Directors of Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG) to State Survey Agency Directors, dated December 28, 2021 ("QSO-22-07-ALL", attached hereto as Attachment E).

y. QSO-22-07-ALL specifies how each State Agency Director at the Government Defendant(s) is to work with entities in Employer Defendant's position, over a period of 30 to 90 days, to ensure that 100% of those in Plaintiff's position are vaccinated in accordance with the Government Action. In general, as long as the Employer Defendant and the Natural Person Defendants show steady efforts to comply with the Government Defendant(s)'s denial of the Plaintiff's rights under the Equal Protection Clause of the Fourteenth Amendment, they will suffer no penalties. Thus, the Government Defendant(s) readily admits to its active involvement in the very operations of the Employer Defendant's business, via direct contact with and influence over, the Natural Person Defendants charged with executing such operations, to ensure that the Government Action/Directives are realized to their perfection (the ultimate vaccination of 100% of the employees of

the Employer Defendant, other than those with a valid exception). Moreover, the Employer Defendant and the Natural Person Defendants are incentivized to coordinate, cooperate, and conspire with the Government Defendant(s) (and do so) to ensure that the Government Action/Directives are realized to their perfection (the ultimate vaccination of 100% of the employees of the Employer Defendant, other than those with a valid exception). The Employer Defendant and the Natural Person Defendants are literally paid by the Government Defendant(s) to do so, and they accept that payment in exchange for their thus rendered services to the Government Defendant(s).

z. That the Employer Defendant (and, thus, the remaining Defendants) are the willful participants in a joint activity is also suggested by the fact that, as pointed out several times during the January 7, 2022 oral arguments on the Government Action at the United States Supreme Court, there was no opposition to the Government Action submitted to the Court by anybody in the position of the Employer Defendant. They did not oppose the Government Action, because they approved of the Government Action.

aa. The reason they might have approved (and conspired) are manifold, but one reason might be that the Employer Defendant and the Natural Person Defendants' economic and related interests, via for example, common shareholders, interlocking directorates and common sources of financing, are closely aligned with the large pharmaceutical companies who stand to benefit from the consumption of vaccines. Natural Person Defendants, of course, might consider future employment opportunities with large pharmaceutical companies and the Government

Defendant(s). Interactions among all Defendants stemming from the real-world application of "Regulatory Capture" theory to the pharmaceutical/medical industry in which all Defendants operate must also be considered.

bb. Even beyond its constitutional defects, Defendants' unlawful Government Action/ Directives are irreconcilable with and frustrate the objectives of the statute governing administration of medical products authorized for emergency use only. Accordingly, the Government Action/Directives violate the EUA statute and must be enjoined.

cc. In a highly publicized opinion recently made public, the U.S. Department of Justice's Office of Legal Counsel ("OLC") argues that public and private entities can lawfully mandate that their employees receive one of the EUA vaccines.[11] Nevertheless, Congress never assigned any role to OLC to administer the EUA statute. The OLC Opinion, as explained in detail in Count III below, is also deeply flawed on multiple additional legal grounds.

dd. Regardless of whether Pfizer recently received full FDA approval for the Comirnaty Vaccine, the remaining vaccines "approved" for use by Defendants have not. As Pfizer itself acknowledges, the Comirnaty Vaccine is not widely available in the United States. Moreover, despite Pfizer's attempts to create equivalence between its BioNTech and Comirnaty Vaccines, the two are legally distinguishable. Thus, even after the Comirnaty Vaccine's approval, the Government Action/Directives still essentially force individuals, including Plaintiff and those similarly situated, to take one of the EUA vaccines.

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[11] Evan Perez & Tierney Sneed, Federal Law Doesn't Prohibit COVID-19 Vaccine Requirements, Justice Department Says, CNN (July 26, 2021), available at https://cnn.it/3iWxH42, last visited (August 26, 2021).

ee. In sum, the Government Action/Directives violate *both* the constitutional *and* federal statutory rights of Plaintiff and those similarly situated because it undermines their bodily integrity and autonomy and conditions their employment on their willingness to take a medically unnecessary vaccine. Forcing Plaintiff and others to take this vaccine will provide no discernible, let alone compelling, benefit either to Plaintiff or to the Defendants. Although obtaining the vaccine could raise Plaintiff's antibody levels even higher, her levels are already high enough to be equivalent to or better than most vaccinated people, so any augmented benefit would be negligible and above and beyond that required of, and attainable by, most vaccinated people. Plaintiff invokes this Court's Article III and inherent powers to insulate him/her from this pressure and to vindicate his/her constitutional and statutory rights.

GENERAL ALLEGATIONS

PARTIES

1. Plaintiff **[INSERT YOUR NAME]** is a **[INSERT YOUR POSITION AT DEFENDANT]** at Employer Defendant. Plaintiff resides in **[INSERT YOUR CITY OR TOWN, AND STATE OF RESIDENCE],** and works in **[INSERT THE CITY, TOWN AND STATE WHERE YOU WORK, AS THIS IS WHERE THE ACTS COMPLAINED OF ARE OCCURRING, AND THIS WILL BE THE BASIS FOR DETERMINING THE FEDERAL DISTRICT COURT YOU CAN SUE IT]** which is located in the **[INSERT THE NAME OF THE FEDERAL DISTRICT COURT YOU ARE SUING IN, WHICH YOU WILL ALSO INDICATE IN THE CAPTION ON THE FIRST PAGE. YOU MUST WORK IN THE DISTRICT THAT PERTAINS TO THAT COURT TO FILE THIS COMPLAINT IN THAT COURT, OR FIND AND**

ANNOUNCE IN THIS COMPLAINT ANOTHER REASON TO ESTABLISH YOUR RIGHT TO SUE IN THAT COURT].

2. Government Defendant(s) **[INSERT NAME OF AGENCY RESPONSIBLE FOR THE GOVERNMENT ACTION/MANDATE]** is **[INSERT OFFICIAL DESCRIPTION OF THE AGENCY]** located at **[INSERT PRIMARY ADDRESS OF THE AGENCY]. [IF THERE IS MORE THAN ONE AGENCY, OR HEAD OF AGENCY, ADD THEM ALL IN A SEPARATE PARAGRAPH ALONG THE SAME LINES AS THIS PARAGRAPH AS "Government Defendant(s) #1", "Government Defendant(s) # 2", ETC., AND REFER TO THEM AS "Government Defendant(s)" EACH MANDATE WILL HAVE DIFFERENT GOVERNMENT DEFENDANTS, AS EXPLAINED ELSEWHERE IN THIS DOCUMENT, BUT AS AN EXAMPLE, IN THE CASE OF THE CMS MANDATE, the Government Defendants would be: Xavier Becerra, Secretary, U.S. Department of Health and Human Services; United States Department of Health and Human Services; Chiquita Brooks-Lasure; Centers for Medicare and Medicaid Services].**

3. Employer Defendant **[INSERT NAME OF YOUR EMPLOYER WHO IS OBLIGATING YOU UNDER THE GOVERNMENT ACTION/MANDATE/ DIRECTIVES]** is **[INSERT A DESCRIPTION OF WHAT THE Employer Defendant IS, FOR EXAMPLE "a public research institution" or "a manufacturer of automobiles"]** located at **[INSERT PRIMARY ADDRESS OF YOUR EMPLOYER].**

4. Natural Person Defendant **[INSERT NAME OF YOUR SUPERVISORS, HUMAN RESOURCES PERSON, OR ANYONE ELSE AT YOUR EMPLOYER WHO IS OBLIGATING YOU PURSUANT TO THE GOVERNMENT ACTION/**

MANDATE/DIRECTIVES] is **[INSERT HIS/HER POSITION AT Employer Defendant]** of Employer Defendant. He **[OR SHE]** is sued in his **[OR HER]** official capacity. **[IF THERE IS MORE THAN ONE NATURAL PERSON WHO YOU PLAN ON SUING, ADD THEM ALL IN A SEPARATE PARAGRAPH ALONG THE SAME LINES AS THIS PARAGRAPH AS "NATURAL PERSON DEFENDANT #1", "NATURAL PERSON DEFENDANT # 2", ETC., AND REFER TO THEM AS "NATURAL PERSON DEFENDANTS"].**

5. John and Jane Does 1-10 are as-yet-unidentified Defendants involved in setting the policy embodied in the Government Action/Directives.

STATUTORY AND NONSTATUTORY JURISDICTION AND VENUE

6. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331, and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. That is because the claims here arise under the Constitution and statutes of the United States and because Plaintiff seeks prospective redress against persons acting under color of law (state actors in their official capacity, and private actors working in conspiracy with them), to end the deprivation of his/her rights, privileges, and immunities secured by the Constitution and federal law.

7. Venue for this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

STATEMENT OF FACTS

I. THE GOVERNMENT ACTION/DIRECTIVES

8. Government Defendant(s) has promulgated **[INSERT THE TYPE OF**

MANDATE, WHETHER CMS, OSHA, FEDERAL CONTRACTOR, ETC - WE HAVE A DESCRIPTION OF THE MAJOR MANDATES AND WILL PROVIDE THEM TO YOU UPON YOUR REQUEST OR IN A SEPARATE DOCUMENT AT THE PLACE ON OUR WEB PAGE YOU RECEIVED THIS DOCUMENT FROM, FOR YOUR INSERTION HERE. THE MANDATE APPLICABLE TO YOU WILL ALSO DETERMINE WHO THE Government Defendant(s) WILL BE, WHICH YOU WILL ENTER AT THE PROPER PLACE IN THE CAPTION ON THE FRONT PAGE, AND IN PARAGRAPH 2, GENERAL ALLEGATIONS, PARTIES, ABOVE. AS AN EXAMPLE, THE FOLLOWING LANGUAGE MIGHT BE USED FOR THE CMS MANDATE: "On August 18, 2021, Centers for Medicare & Medicaid Services ("CMS") announced that it would be issuing a regulation that all nursing home staff would have to be vaccinated against COVID-19 as a requirement for LTC facilities participating with the Medicare and Medicaid programs. Subsequently, on September 9, 2021, CMS announced that this requirement would be extended to nearly all Medicare and Medicaid- certified providers and suppliers. The stated reason for these actions were CMS's aim to support increasing vaccination rates among staff working in all facilities, providers, and certified suppliers that participate in Medicare and Medicaid. On November 5, 2021, CMS published an IFC with comment period (86 FR 61555), entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," revising the infection control requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. Thus, according to the timetable set forth in the Centers for Medicare & Medicaid Services (Center for

Clinical Standards and Quality/Quality Safety, Safety & Oversight Group Memorandum, Ref: QSO-22-07-ALL, from Directors of Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG) to State Survey Agency Directors, dated December 28, 2021 ("QSO-22-07-ALL", attached hereto as Attachment E) within 60 days from December 28, 2021, 100% of staff of most Medicare- and Medicaid-certified providers and suppliers must (for these providers and suppliers to participate in the Medicare and Medicaid programs) have received the necessary doses to complete a Covid-19 vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC]], the "Government Action".

9. Via the Government Action, and in coordination, cooperation and/or conspiracy with the Government Defendant(s) and the Natural Person Defendants, each sharing the common purpose of subjecting the Plaintiff (and others in a similar position) to the same, the Employer Defendant issued and commenced to execute COVID-19 related directives (the "Directives") which Directives include **[INSERT ALL THAT YOUR EMPLOYER IS REQUIRING YOU TO DO REGARDING COVID-19 THAT YOU OBJECT TO. AN EXAMPLE YOU MIGHT USE, BUT ONLY INCLUDE WHAT UNEQUIVOCALLY APPLIES TO YOU, IS THE FOLLOWING: "A) Mandating that Plaintiff inject into his/her body a COVID-19 Vaccine (which is under only an Emergency Use Authorization or for which the legality and enforceability of an Approval has not been sufficiently confirmed), without any regard to and in fact, in direct contravention to the will of, the Plaintiff, without any regard to the fact that**

Plaintiff has, via previous infection with COVID-19, acquired natural immunity to COVID-19 (via, among other things, the body's natural production of antibodies effective against COVID-19) which is at least as effective against COVID-19 as vaccine acquired immunity, and in willful and reckless disregard to the fact that the administration of a COVID-19 vaccine to Plaintiff as a person previously infected with COVID-19 might pose a significant threat to the health and the very life of the Plaintiff; B) Mandating that Plaintiff undergo regular testing for COVID-19, at uncompensated (and, in some regards, significant) cost in terms of money, time and/ or physical discomfort to Plaintiff, without any regard to and in fact, in direct contravention to the will of, the Plaintiff, and without any regard to the fact that Plaintiff has, via previous infection with COVID-19, acquired natural immunity to COVID-19 (via, among other things, the body's natural production of antibodies effective against COVID-19) which is at least as effective against COVID-19 as vaccine acquired immunity; C) Mandating that the Plaintiff utilize a mask at all times at uncompensated (and, in some regards, significant) cost in terms of money, time and/or physical discomfort to Plaintiff, without any regard to and in fact, in direct contravention to the will of, the Plaintiff, and without any regard to the fact that Plaintiff has, via previous infection with COVID-19, acquired natural immunity to COVID-19 (via, among other things, the body's natural production of antibodies effective against COVID-19) which is at least as effective against COVID-19 as vaccine acquired immunity].

10. The Government Action and the Directives are inextricably linked and intertwined, operate in vital support of the other, cannot achieve their common purpose

without the other, and thus, constitute one *de facto* project/enterprise, that is, the "Government Action/Directives".

11. As a result of the Government Action/Directives, the Plaintiff has or will be negatively impacted in his/her body and/or economy as follows: **[INSERT HOW YOU WILL BE DAMAGED BY THE WHAT THE DEFENDANTS ARE OBLIGATING YOU AND YOURS TO DO REGARDING THE VACCINES – NOT MERELY THE THREAT TO YOU PHYSICALLY, ETC., BUT THE THREAT TO YOU ECONOMICALLY, SOCIALLY, ETC. PUT IN EVERYTHING THAT YOU FEEL YOU WILL BE HURT BY THE DEFENDANTS OBLIGATION TO TAKE THE VACCINE. FEEL FREE TO HAVE THIS PORTION GO ON FOR SEVERAL PAGES, SINCE THIS IS YOUR CHANCE TO TELL THE COURT EXACTLY HOW YOU ARE BEING HURT BY THE DEFENDANTS AND WHY – THIS IS A VERY IMPORTANT PART OF YOUR COMPLAINT.]**

II. BACKGROUND PERTAINING TO THE CORONAVIRUS PANDEMIC AND COVID-19 VACCINES

12. The novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, is a contagious virus spread mainly from person-to-person, including through the air.

13. It is well settled that the coronavirus presents a significant risk primarily to individuals aged 70 or older and those with comorbidities such as obesity and diabetes. Bhattacharya and Kulldorff Joint Decl.[12] ¶¶ 10-14 ("Joint Decl.", Attachment A). *See* Smiriti Mallapaty, *The Coronavirus Is Most Deadly If You Are Older and Male*, NATURE (Aug. 28, 2020) (individuals under 50 face a negligible threat of a severe medical outcome

[12] Taken from a separate litigation involving persons with no connection to Plaintiff, but with similar scientific concerns deemed relevant to the instant litigation, and made under oath by these individuals, Stanford University Professor of Medicine Jay Bhattacharya and Harvard Professor Martin Kulldorff.

from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car).

14. In fact, a meta-analysis published by the WHO concluded that the survival rate for COVID-19 patients under 70 years of age was 99.95%. Joint Decl. ¶ 12.

15. CDC estimates that the survival rate for young adults between 20 and 49 is 99.95%, and for people ages 50-64 is 99.4%. Joint Decl. ¶ 12.

16. A seroprevalence study of COVID-19 in Geneva, Switzerland, reached a similar conclusion, estimating a survival rate of approximately 99.4% for patients between 50 and 64 years old, and 99.95% for patients between 20 and 49. Joint Decl. ¶ 13.

17. FDA has approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3. FDA issued an EUA for the BioNTech Vaccine on December 11, 2020.

- Just one week later, FDA issued an EUA for the Moderna Vaccine.
- FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.
- The Comirnaty Vaccine received full FDA approval on August 23, 2021.
- In a footnote to its "Fact Sheet for Health Care Providers," FDA states that Comirnaty "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." (emphasis added). FDA, "Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers)," (Aug. 23, 2021) (Attachment C) (relating to both the BioNTech Vaccine and Comirnaty Vaccine).
- The Comirnaty Vaccine is not widely available due to limited supply, as Pfizer also notes that "there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA." (Attachment C). See also FDA, FDA Approves First COVID-19 Vaccine, (Aug. 23, 2021), available at https://www.fda.gov/news-events/press-announcements/fda-approves-first- covid-19-vaccine (last visited Aug. 25, 2021).

18. The EUA status of the vaccines that are available at present in the United States

means that FDA has not yet fully approved them but permits their conditional use nonetheless due to exigent circumstances.

19. The standard for EUA review and approval is lower than that required for full FDA approval.

20. Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control. *See* CDC, *Vaccine Testing and the Approval Process* (May 1, 2014), *available at* https://bit.ly/3rGkG2s (last visited August 26, 2021).

21. The third phase typically takes place over years, because it can take that long for a new vaccine's side effects to manifest. *Id*.

22. The third phase must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. *Id*.

23. Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.

24. FDA must then determine, based on "substantial evidence," that the medical product is effective and that the benefits outweigh its risks when used according to the product's approved labeling. *See* CDC, *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19* (Oct. 22, 2020), *available at* bit.ly/3x4vN6s (last visited August 26, 2021).

25. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic." FDA, Emergency Use Authorization for Vaccines Explained (Nov.

20, 2020), available at bit.ly/3x8wImn (last visited August 26, 2021).

26. EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for FDA approval or clearance. *See id*. 28.

27. The EUA statute states that individuals to whom the product is administered must be informed: (1) that the Secretary has authorized emergency use of the product; (2) of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown; and (3) 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. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

28. Studies of immunizations outside of clinical-trial settings began in December 2020, following the first EUA for a COVID vaccine.

29. None of the precise EUA vaccines approved for use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Indeed, trials conducted so far have *specifically excluded* survivors of previous COVID-19 infections. Noorchashm Decl.[13] ¶ 28. ("Noorchashm Decl.", Attachment B).

30. Recent research indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Noorchashm Decl. ¶¶ 21-26; Joint Decl. ¶ 28.

31. The heightened risk of adverse effects results from "preexisting immunity to

[13] Taken from a separate litigation involving persons with no connection to Plaintiff, but with similar scientific concerns deemed relevant to the instant litigation, and made under oath by this individual, a Doctor Noorchashm.

SARS- Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Angeli *et al.*, *SARS-CoV-2 Vaccines: Lights and Shadows*, 88 EUR. J. INTERNAL MED. 1, 8 (2021).

32. Naturally acquired immunity developed after recovery from COVID-19 provides broad protection against severe disease from subsequent SARS-CoV-2 infection. Joint Decl. ¶¶ 15-24.

33. Multiple extensive, peer-reviewed studies comparing naturally acquired and vaccine-acquired immunity have concluded overwhelmingly that the former provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (BioNTech and Moderna). Joint Decl. ¶¶ 18-23.

34. These studies confirm the efficacy of natural immunity against reinfection with COVID-19 and show that almost all reinfections are less severe than first-time infections and almost never require hospitalization. Joint Decl. ¶ 18-24.

35. A study from Israel released mere days ago found that vaccinated individuals had 13.1 times greater risk of testing positive, 27 times greater risk of symptomatic disease, and around 8.1 times greater risk of hospitalization than unvaccinated individuals with naturally acquired immunity. Joint Decl. ¶ 20.

36. The authors concluded that the "study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [BioNTech's research name] two-dose vaccine-induced immunity." Joint Decl. ¶ 20.

37. Recent Israeli data found that those who had received the BioNTech Vaccine were

6.72 times *more likely* to suffer a subsequent infection than those with natural immunity. David Rosenberg, *Natural Infection vs Vaccination: Which Gives More Protection*? ISRAELNATIONALNEWS.COM (Jul. 13, 2021), *available at* https:// www.israelnationalnews.com/ News/News.aspx/309762 (last visited Aug. 26, 2021).

38. Israeli data also indicates that the protection BioNTech grants against infection is short-lived compared to natural immunity and degrades significantly faster. In fact, as of July 2021, vaccine recipients from January 2021 exhibited only 16% effectiveness against infection and 16% protection against symptomatic infection, increasing linearly until reaching a level of 75% for those vaccinated in April. *See* Nathan Jeffay, *Israeli, UK Data Offer Mixed Signals on Vaccine's Potency Against Delta Strain*, THE TIMES OF ISRAEL (July 22, 2021), *available at* bit.ly/3xg3uCg (last visited Aug. 26, 2021).

39. Those who received a second dose of the BioNTech Vaccine between January and April of this year were determined to have 39% protection against infection and 41% protection against symptomatic infection. The large number of breakthrough infections likely was the result of waning vaccine protection in the face of the Delta variant's spread. *See* Carl Zimmer, *Israeli Data Suggests Possible Waning in Effectiveness of Pfizer Vaccine*, THE NEW YORK TIMES (July 23, 2021); Kristen Monaco, *Pfizer Vax Efficacy Dips at 6 Months*, MEDPAGE TODAY (July 29, 2021), *available at* https://bit.ly/2VheBxw (last visited Aug. 26, 2021).

40. A CDC/IDSA clinician call on July 29, 2021, summarized the current state of the knowledge regarding the comparative efficacy of natural and vaccine immunity. The presentation reviewed three studies that directly compared the efficacy of prior infection

versus mRNA vaccine treatment and concluded "the protective effect of prior infection was similar to 2 doses of a COVID-19 vaccine."

41. Given that there is currently *more* data on the durability of naturally acquired immunity than there is for vaccine immunity, researchers rely on the expected durability of naturally acquired immunity to predict that of vaccine immunity. Joint Decl. ¶ 23.

42. Indeed, naturally and vaccine-acquired immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response. Joint Decl. ¶ 16.

43. The level of antibodies in the blood of those who have natural immunity was initially the benchmark in clinical trials for determining the efficacy of vaccines. Joint Decl. ¶ 16. 45.

44. Studies have demonstrated prolonged immunity with respect to memory T and B cells, bone marrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B cells following a COVID-19 infection. Joint Decl. ¶ 17; Dr. Harvey Risch, Yale School of Medicine, interview ("Risch interview"), *Laura Ingraham Discusses How Medical Experts Are Increasing Vaccine Hesitancy* (July 26, 2021), *available at* https://bit.ly/3zOL6Sx (last visited July 27, 2021).

45. T-cells last "quite a while," but B-cells migrate to the bone marrow and last even longer. Risch interview.

46. New variants of COVID-19 resulting from the virus's mutation do not escape the natural immunity developed by prior infection from the original strain of the virus. Joint Decl. ¶¶ 29-33.

47. In fact, vaccine immunity only targets the spike-protein of the original Wuhan

variant, whereas natural immunity recognizes the full complement of SARS-CoV-2 proteins and thus provides protection against a greater array of variants. Noorchashm Decl. ¶ 17.

48. While the CDC and the media have touted a study from Kentucky as proof that those with naturally acquired immunity should get vaccinated, that conclusion is unwarranted. As Drs. Bhattacharya and Kulldorff explain, although individuals with naturally acquired immunity who received a vaccine showed increased antibody levels, "[t]his does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths." Joint Decl. ¶ 37.

49. Similarly, Dr. Noorchashm explains that this study did not actually compare the appropriate groups. Instead of comparing individuals who had naturally-acquired immunity only to those who were only vaccinated, the study compared those with naturally-acquired immunity only to those who had naturally-acquired immunity *and* received the vaccine. Furthermore, the study "did not address or attempt to quantify the magnitude of risk and adverse effects in its comparison groups." Noorchashm Decl. ¶¶ 29-31.

50. In short, contrary to the claims of the CDC and the media, this study did *not* establish a valid reason to vaccinate individuals with naturally-acquired immunity. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31.

51. The Janssen Vaccine provides immunity protection of somewhere between 66% and 85%, far below that conferred by natural immunity. Joint Decl. ¶ 16; Noorchashm Decl. ¶ 15.

52. The Chinese Sinovac Vaccine has been approved by WHO, which itself

determined that this vaccine prevented *symptomatic* disease in just 51% of those who received it. *See WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WHO.INT (June 1, 2021), *available at* bit.ly/3yitIW7 (last visited Aug. 26, 2021).

53. Other clinical studies have found that the Sinovac Vaccine offers even lower levels of protection against infection. For instance, a study of Brazilian healthcare workers determined a mere 50.39% efficacy in preventing infection. *See* Elizabeth de Faria et al., *Performance of Vaccination with Coronavac[14]in a Cohort of Healthcare Workers (HCW)—Preliminary Report*, MEDRXIV (Apr. 15, 2021), *available at* https://www.medrxiv.org/ content/10.1101/ 2021.04.12.21255308v1 (last visited Aug. 26, 2021).

54. Real-world evidence also suggests that the Sinovac Vaccine provides only minimal protection against the Delta variant. See Alexander Smith, China on 'High Alert' as Variant of Covid-19 Spreads to 5 Provinces, NBCNEWS.COM (July 30, 2021), available at nbcnews.to/2VcK3NB (last visited Aug. 27, 2021); Chao Deng, As Delta Variant Spreads, China Lacks Data on Its Covid-19 Vaccines, WALL ST. J. (July 9, 2021), available at on.wsj.com/3rMjlXW (last visited Aug. 27, 2021); Matt D.T. Hitchings, et al., Effectiveness of CoronaVac in the Setting of High SARS-Cov-2 P.1 Variant Transmission in Brazil: A Test- Negative Case-Control Study, THE LANCET (July 25, 2021), available at bit.ly/3C6F41J (last visited Aug. 26, 2021).

55. The Sinopharm Vaccine also is from China and is WHO-approved. Although its

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[14] Sinovac and Coronavac are the same. *See* WHO, *Who Validates Sinovac COVID-19 Vaccine For Emergency Use,* (June 1, 2021), *available at* https://www.who.int/news/item/01-06-2021- who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy- recommendations (last visited Aug. 26, 2021).

reported level of efficacy against symptomatic infection has been reported as reasonably high (78%), real-world experience has generated severe doubts about the accuracy of that estimate. Because of the Sinopharm Vaccine's poor performance, several countries have stopped using it. *See* Yaroslav Trofimov & Summer Said, Bahrain, *Facing a Covid Surge, Starts Giving Pfizer Boosters to Recipients of Chinese Vaccine*, WALL ST. J. (June 2, 2021), *available at* on.wsj.com/3ljM0lX (last visited Aug. 26, 2021).

56. The COVISHIELD vaccine, manufactured by the Serum Institute of India and South Korea's SK Bioscience Co., Ltd., is also WHO-approved and thus recognized as adequate to satisfy MSU's Policy. The WHO itself reported a mere 70.42% efficacy against *symptomatic* COVID-19 infection, which fell to 62.10% in individuals who received two standard doses. *See Recommendation on Emergency Use Listing on COVISHIELD Submitted by SIIPL*, WHO (Feb. 26, 2021), *available at* bit.ly/3rNjnPo (last visited Aug. 26, 2021); *Recommendation for an Emergency Use Listing of AZD1222 Submitted by AstraZeneca AB and Manufactured by SK Bioscience Co. Ltd.*, WHO (Feb. 23, 2021), *available at* bit.ly/3yiQD3s (last visited Aug. 26, 2021). These vaccines have not been approved by the FDA for use in the United States.

57. Early data also suggests that naturally acquired immunity may provide greater protection against both the Delta and Gamma variants than that achieved through vaccination. A recent analysis of an outbreak among a small group of mine workers in French Guiana found that 60% of fully vaccinated miners suffered breakthrough infections compared to *zero* among those with natural immunity. Nicolas Vignier, et al., *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinate Gold Miners, French Guiana, 2021*, 27(10) EMERG. INFECT. DIS. (Oct. 2021), *available at* https://

wwwnc.cdc.gov/eid/article/27/10/21-1427_article (last visited Aug. 26, 2021).

58. In this vein, the CDC recently reported that "new scientific data" indicated that vaccinated people who experienced breakthrough infections carried similar viral loads to the unvaccinated (but not naturally immune), leading the CDC to infer that vaccinated people transmit the virus at concerning levels. *See CDC Reversal on Indoor Masking Prompts Experts to Ask, "Where's the Data?"*, WASHINGTON POST (July 28, 2021), *available at* wapo.st/2THpmIQ (last visited Aug. 26, 2021). For example, 74% of cases in a Cape Cod outbreak occurred in vaccinatedindividuals, again demonstrating that the vaccines are inferior to natural immunity when it comes to preventing infection. *See* Molly Walker, *CDC Alarmed: 74% of Cases in Cape Cod Cluster Were Among the Vaxxed*, MEDPAGE TODAY (July 30, 2021), *available at* bit.ly/2V6X3UP (last visited Aug. 26, 2021).

59. Many experts believe that the solution to "breakthrough" cases (individuals who become infected after vaccination or a prior infection) is treating patients with a therapeutic intervention—not mandating vaccines for everyone, which will not solve the disease problem for the reasons discussed above. The availability and effectiveness of therapeutics thus bear on the validity of state actors' (such as MSU) claims that a vaccine mandate is necessary to protect the public health. *See* Risch interview.

60. [THE FOLLOWING PARAGRAPH MAY ONLY BE INSERTED IF YOUR WORK DOES NOT INVOLVE THE CARE OF HIGH-RISK INDIVIDUALS, AND IF IT DOES INVOLVE THE CARE OF HIGH-RISK INDIVIDUALS, YOU MUST DELETE THIS PARAGRAPH] As Drs. Bhattacharya and Kulldorff have explained, there is no legitimate public-health rationale to require proof of vaccination to

participate in activities that do not involve care for high-risk individuals:

> **Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated — especially recovered COVID patients – pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero and natural immunity, which provides benefits that are at least as strong[.] At the same time, the requirement for ... proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice.**
>
> **Joint Decl. ¶¶ 50-51.**

III. COVID-19 VACCINES CAN CAUSE SIDE EFFECTS, INCLUDING SEVERE ADVERSE REACTIONS

61. Though the COVID-19 vaccines appear to be relatively safe at a population level, like all medical interventions, they carry a risk of side effects. Those side effects include common, temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and nausea. More rarely, they can cause serious side effects that result in hospitalization or death. Joint Decl. ¶¶ 25-26.

62. The vaccines could cause other side effects that remain unknown at this time due to their relatively recent development. Joint Decl.¶¶ 26-27.

63. Put differently, as a matter of simple logic, one cannot be certain about the long-term effects of a vaccine that has not been in existence for the long term and thus cannot have been studied over a span of years. For that reason, "[a]ctive investigation to check for safety problems is still ongoing." Joint Decl. ¶ 26.

IV. PLAINTIFF HAS ROBUST NATURALLY ACQUIRED IMMUNITY TO COVID-19

64. Plaintiff **[INSERT YOUR NAME]** is **[INSERT A DESCRIPTION OF YOUR POSITION (INCLUDING, WITHOUT LIMITATION, A DESCRIPTION OF YOUR DUTIES AND RESPONSIBILITIES) AT EMPLOYER DEFENDANT, HOW LONG**

YOU HAVE BEEN THERE, AND ANY OTHER RELEVANT DETAILS REGARDING YOUR EMPLOYMENT] at Employer Defendant.

65. Plaintiff has robust naturally acquired immunity to COVID-19, as demonstrated by the fact that: **[INSERT A DESCRIPTION OF HOW YOU CAN PROVE YOU HAVE NATURALLY ACQUIRED IMMUNITY (I.E, INSERT DATES THAT YOU HAD COVID AND/OR THAT YOU RECOVERED FROM COVID, PROOF YOU HAD COVID - FOR EXAMPLE, A DESCRIPTION OF YOUR SYMPTOMS, DATES OF ANTIBODY - TESTS WHICH YOU MUST INCLUDE AS AN ATTACHMENT HERETO, AND REFER TO AS (Attachment D)].**

66. **[YOU MUST TAKE THIS TEST IN ORDER TO INCLUDE THIS PARAGRAPH, AND IN ORDER TO USE THIS COMPLAINT IN ITS PRESENT FORM. IF YOU DO NOT, YOU CANNOT INCLUDE THIS PARAGRAPH IN THE COMPLAINT WITHOUT COMMITTING PERJURY, AND THIS COMPLAINT WILL NOT BE EFFECTIVE IN ITS PRESENT FORM, AS IT IS BASED ON HAVING NATURAL IMMUNITY, AND SO YOU MUST HIRE AN ATTORNEY TO REVISE THIS COMPLAINT TO SEEK OTHER POTENTIAL ARGUMENTS] His/ her recent semi-quantitative antibodies screening test established that his/her level of immune protection remains high and his/her spike antibody level is highly likely to be above the minimum necessary to provide adequate protection against re- infection from the SARS-CoV-2 virus.**

67. Thus, as is the case with someone in a similar position, undergoing a full vaccination course would be medically unnecessary, create a risk of harm to him/her, and provide insignificant or no benefit either to the Plaintiff or their community. Noorchashm

Decl. ¶ 12.

68. Dr. Noorchashm explains that substantial scientific literature demonstrates that, while the COVID-19 vaccines carry the possibility of side effects, as do all medical procedures, the risk of harm is greater to those who have recovered from the disease. Noorchashm Decl. ¶¶12 -28.

69. Accordingly, as is the case with someone in a similar position, mandating that Plaintiff receive a COVID-19 vaccine violates the rules of medical ethics. Noorchashm Decl. ¶¶ 8-35.

70. Plaintiff has real, substantial, and legitimate concerns about taking a COVID-19 vaccine in light of his/her natural immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves. Norris Decl. ¶ 15-17.

71. There are other employees of Employer Defendant who are similarly situated, e.g., they previously contracted COVID-19, they have naturally acquired immunity, and they have real, substantial, and legitimate concerns about taking the COVID-19 vaccine in light of their naturally acquired immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves.

CLAIMS FOR RELIEF

COUNT I: DEPRIVATION OF RIGHTS UNDER THE EQUAL PROTECTION CLAUSE OF THE FOURTEENTH AMENDMENT TO THE U.S. CONSTITUTION

72. Plaintiff realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

73. Plaintiff either must receive a COVID-19 vaccine or face disciplinary action, including loss of employment. Accordingly, Plaintiff's personal autonomy is being infringed upon.

74. By threatening adverse professional and personal consequences, the Government Action/Directives not only directly and palpably harm Plaintiff's bodily autonomy and dignity, but it forces him/her to endure the stress and anxiety of choosing between her employment—upon which his/her family relies—and his/her health.

75. The risk-avoidance benefits that the Government Action/Directives provide, compared to the restrictions and intrusive options offered to Plaintiff, are disproportionate.

76. Similarly, given that naturally acquired immunity confers equal or greater protection than that provided by the vaccines, the Government Action/Directives is not merely arbitrary and irrational (which it clearly is) but violates the Equal Protection Clause under the Fourteenth Amendment to the Constitution.

77. There is no indication that the Government Action/Directives are tailored to account for its impact on those who have acquired natural immunity.

78. Given Plaintiff's naturally acquired immunity, Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)), cannot establish a compelling governmental interest in overriding the personal autonomy and constitutional rights of Plaintiff by, via their combined and coordinated efforts, in conspiracy with one another and with the shared purpose of, forcing Plaintiff either to be vaccinated **[IF A COVID TEST IS PART OF THE DIRECTIVE, INSERT "and/or regularly tested for COVID-19" AND IF THERE ARE OTHER REQUIREMENTS OF THE DIRECTIVE, INSERT THEM HERE]** or to suffer adverse professional consequences.

79. Naturally acquired immunity is at least as robust and durable as that attained

through the most effective vaccines, and it is significantly more protective than some of the inferior vaccines that Defendant(s), including, without limitation, Employer Defendant, accept. Studies further indicate that naturally acquired immunity is significantly longer lasting than that acquired through the best vaccines. As a result, the Government Action/ Directives are designed to nullify informed consent and infringe upon Plaintiff's rights, under the Ninth and Fourteenth Amendments to the United States Constitution.

80. The modern approach on Equal Protection jurisdiction, pioneered by *Skinner v. Oklahoma,* 316 U.S. 535 (1942) (law permitting the compulsory sterilization of criminals is unconstitutional as it violates a person's rights given under the Fourteenth Amendment of the Constitution, specifically the Equal Protection Clause, as well as the Due Process Clause), is that a higher level of judicial scrutiny, that is "strict scrutiny" is triggered by purported discrimination that involves "fundamental rights" (such as, in *Skinner*, the right to procreation). The Supreme Court in *Skinner* explains, "We are dealing with legislation that involves one of the basic civil rights of man. Marriage and procreation are fundamental to the very existence and survival of the race."… "there is no redemption for the individual whom the law touches. Any experiment which the state conducts is to his irreparable injury. He is forever deprived of a basic liberty"… "We advert to them merely in emphasis of our view that strict scrutiny of the classification which a state makes in a sterilization law is essential, lest unwittingly, or otherwise, invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws". *Skinner,* 316 U.S. at 541.

81. The Plaintiff maintains that his/her right to bodily integrity, to determine free of any coercion what may nor may not be injected into his/her body (especially when that

which is to be injected involves a novel technology that some observers might consider experimental, is known to have caused injury to others, and is known to specifically pose a potential danger to those who have naturally acquired immunity such as Plaintiff) is also a fundamental right. Plaintiff notes that, as was the case in *Skinner*, one cannot be simply unvaccinated, and any potential injuries from a vaccination cannot be undone.

82. Plaintiff maintains that his/her right to bodily integrity is a right so entirely fundamental that it is beyond question, as it is incorporated into the very concept of the fundamental right to self defense and the seminal statement of the American Creed derived from the United States Declaration of Independence: "We hold these truths to be self evident; that all men are created equal; that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the Pursuit of Happiness…". Plaintiff furthermore notes that, in its original form, as drafted by Thomas Jefferson, this read "We hold these truths to be sacred & undeniable; that all men are created equal & independent, that from equal creation they derive rights inherent & unalienable, among which are the preservation of life, & liberty, & the pursuit of happiness", [15] and thus, there is no other right so central, so fundamental to the very concept of Equal Protection than that of the fundamental right to one's bodily integrity.

83. Plaintiff is of the view, thus, that strict scrutiny of the classification which a state makes in a matter impacting his/her bodily integrity, such as the Government Action/ Directives "is essential, lest unwittingly, or otherwise, invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws". *See Skinner*, 316 U.S. at 541.

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[15] American Sphinx, The Character of Thomas Jefferson, Joseph J. Ellis, Vintage Books, 1998, p. 10.

84. Under the Strict Scrutiny Standard, triggered by a government law or regulation impacting a fundamental right, the government must demonstrate that the law or regulation is necessary to achieve a "compelling state interest". The government must also demonstrate that the law is "narrowly tailored" to achieve the compelling purpose, and uses the "least restrictive means" to achieve the purpose.

85. Unvaccinated individuals such Plaintiff, who have contracted COVID-19 and have antibodies, must not be treated differently than vaccinated individuals, lest it violate the Equal Protection Clause, because the compelling government interest (to stop the spread of COVID) can be met by a more narrowly tailored, less restrictive means to achieve the same purpose (that is, treat natural immunity like vaccination).

86. The Defendants have cooperated, coordinated and conspired, each sharing a common purpose with one another, to deny the Plaintiff his/her rights under the Equal Protection Clause of the 14th Amendment, and thus the Government Defendant(s), the Employer Defendant and the Natural Person Defendants are jointly and severally liable to Plaintiff pursuant to 42 U.S.C. § 1983.

87. In their book, *The Miner's Canary: Enlisting Race, Resisting Power, Transforming Democracy*, the recently deceased Harvard Law Professor Lani Guinier and University of Texas Law Professor Gerald Torres "champion reform from below through 'public policy movements' - - reforms based on initiatives that are begun by minority groups but move beyond racial issues because they address the needs of other disadvantaged groups" poor white, felons, housewives arrested for traffic offenses, even citizens being taxed to build

new prison."[16] and, Plaintiff would argue, people in his/her position.

88. Thus, it is significant to the instant matter that, in a case dating back to the Civil Rights Era, *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970), the Supreme Court explained under what conditions both private actors and public actors might be liable under 42 U.S.C. § 1983 for a violation of the Equal Protection Clause of the Fourteenth Amendment. In that case, a white school teacher had been arrested for vagrancy by police upon leaving a restaurant where she had been refused service when she was in the company of her students, who were black. She filed a complaint under 42 U.S.C. § 1983 alleging that the refusal of service and her arrest was the result of a conspiracy between the restaurant and the police and violated the Equal Protection Clause of the Fourteenth Amendment to the Constitution

89. In an opinion delivered by Justice Harlan, the Supreme Court explained:

> *A. CONSPIRACIES BETWEEN PUBLIC OFFICIALS AND PRIVATE PERSONS -- GOVERNING PRINCIPLES*
>
> *The terms of § 1983 make plain two elements that are necessary for recovery. First, the plaintiff must prove that the defendant has deprived him of a right secured by the "Constitution and laws" of the United States. Second, the plaintiff must show that the defendant deprived him of this constitutional right "under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory." This second element requires that the plaintiff show that the defendant acted "under color of law."* [Footnote 4]
>
> As noted earlier, we read both counts of petitioner's complaint to allege discrimination based on race in violation of petitioner's equal protection rights. [Footnote 5] Few principles of law are more firmly stitched into our constitutional fabric than the proposition that a State must not discriminate against a person because of his race or the race of his companions, or in any way

[16] Books in Brief: 'The Miner's Canary', Allen D. Boyer, *The New York Times*, April 21, 2002 (Last retrieved January 10, 2022).

act to compel or encourage racial segregation. [Footnote 6] *Although this is a lawsuit against a private party, not the State or one of its officials, our cases make clear that petitioner will have made out a violation of her Fourteenth Amendment rights and will be entitled to relief under § 1983 if she can prove* that a Kress employee, in the course of employment, and a Hattiesburg policeman *somehow reached an understanding* to deny Miss Adickes service in the Kress store, or to cause her subsequent arrest because she was a white person in the company of Negroes.

The involvement of a state official in such a conspiracy plainly provides the state action essential to show a direct violation of petitioner's Fourteenth Amendment equal protection rights, whether or not the actions of the police were officially authorized, or lawful; Monroe v. Pape, 365 U. S. 167 (1961); see United States v. Classic, 313 U. S. 299, 313 U. S. 326 (1941); Screws v. United States, 325 U. S. 91, 325 U. S. 107-111 (1945); Williams v. United States, 341 U. S. 97, 341 U. S. 99-100 (1951). *Moreover, a private party involved in such a conspiracy, even though not an official of the State, can be liable under § 1983.*

"Private persons, jointly engaged with state officials in the prohibited action, are acting 'under color' of law for purposes of the statute. To act 'under color' of law does not require that the accused be an officer of the State. It is enough that he is a willful participant in joint activity with the State or its agents,"

United States v. Price, 383 U. S. 787, 383 U. S. 794 (1966). [Footnote 7]

Adickes v. S. H. Kress & Co., 398 U.S. 150-152.

B. STATE ACTION -- 14TH AMENDMENT VIOLATION

For petitioner to recover under the substantive count of her complaint, she must show a deprivation of a right guaranteed to her by the Equal Protection Clause of the Fourteenth Amendment. Since the "action inhibited by the first section of the Fourteenth Amendment is only such action as may fairly be said to be that of the States," Shelley v. Kramer, 334 U. S. 1, 334 U. S. 13 (1948), we must decide, for purposes of this case, the following "state action" issue: is there sufficient state action to prove a violation of petitioner's Fourteenth Amendment rights if she shows that Kress refused her service because of a state-enforced custom compelling segregation of the races in Hattiesburg restaurants?

In analyzing this problem, it is useful to state two polar propositions, each of which is easily identified and resolved. On the one hand, the Fourteenth Amendment plainly prohibits a State itself from discriminating because of race. On the other hand, § 1 of the Fourteenth Amendment does not forbid a private party, not acting against a backdrop of state compulsion or involvement, to discriminate on the basis of race in his personal affairs as an expression of his own personal predilections. As was said in Shelley v. Kraemer, supra, § 1 of "[t]hat Amendment erects no shield against merely private conduct, however discriminatory or wrongful." 334 U.S. at 334 U. S. 13.

At what point between these two extremes a State's involvement in the refusal becomes sufficient to make the private refusal to serve a violation of the Fourteenth Amendment is far from clear under our case law. *If a State had a law requiring a private person to refuse service because of race, it is clear beyond dispute that the law would violate the Fourteenth Amendment, and could be declared invalid and enjoined from enforcement. Nor can a State enforce such a law requiring discrimination through either convictions of proprietors who refuse to discriminate,* or trespass prosecutions of patrons who, after being denied service pursuant to such a law, refuse to honor a request to leave the premises. [Footnote 40]

The question most relevant for this case, however, is a slightly different one. *It is whether the decision of an owner of a restaurant to discriminate on the basis of race under the compulsion of state law offends the Fourteenth Amendment.* Although this Court has not explicitly decided the Fourteenth Amendment state action issue implicit in this question, underlying the Court's decisions in the sit-in cases is the notion that *a State is responsible for the discriminatory act of a private party when the State, by its law, has compelled the act. As the Court said in Peterson v. City of Greenville, 373 U. S. 244, 373 U. S. 248 (1963):*

"*When the State has commanded a particular result, it has saved to itself the power to determine that result, and thereby, 'to a significant extent' has 'become involved' in it.*"

Moreover, there is much support in lower court opinions for the conclusion that *discriminatory acts by private parties done under*

> *the compulsion of state law offend the Fourteenth Amendment*. In Baldwin v. Morgan, supra, the Fifth Circuit held that
>
> "*[t]he very act of posting and maintaining separate [waiting room] facilities when done by the [railroad] Terminal as commanded by these state orders is action by the state*."
>
> The Court then went on to say:
>
> "As we have pointed out above, the State may not use race or color as the basis for distinction. *It may not do so by direct action or through the medium of others who are under State compulsion to do so*."
>
> Id. at 755-756 (emphasis added). We think the same principle governs here.
>
> *For state action purposes, it makes no difference, of course, whether the racially discriminatory act by the private party is compelled by a statutory provision or by a custom having the force of law -- in either case, it is the State that has commanded the result by its law. Without deciding whether less substantial involvement of a State might satisfy the state action requirement of the Fourteenth Amendment, we conclude that petitioner would show an abridgment of her equal protection right if she proves that Kress refused her service because of a state-enforced custom of segregating the races in public restaurants*.
>
> *Adickes v. S. H. Kress & Co*., 398 U.S. 169-171.

90. That the Employer Defendant and the Natural Person Defendants are "jointly engaged with" the Government Defendant(s) "in the prohibited action" is clear from the facts set forth above and **[THE FOLLOWING BOLDED LANGUAGE IS ONLY APPLICABLE TO THE CMS MANDATES. IF THE GOVERNMENT ACTION/ DIRECTIVES/MANDATE WHICH YOU ARE SUBJECT TO ARE DIFFERENT, YOU WILL REQUIRE DIFFERENT PROOF OF YOUR COMPANY'S WORKING TOGETHER WITH THE GOVERNMENT THAT RISES TO THE LEVEL OF COORDINATION, CONSPIRACY, ETC., OR AT LEAST WOULD DEMONSTRATE IT "is a willful participant in joint activity with the State or its**

agents," TO GET YOU VACCINATED AGAINST YOUR WILL. YOU KNOW YOUR EMPLOYER AND THEIR ACTIVITIES BEST, AND, USING THE ITALICIZED LANGUAGE FROM *Adickes v. S. H. Kress & Co.*, 398 U.S. 169-171 SET FORTH IN THE ABOVE PARAGRAPH AS A GUIDE, YOU MUST LAY OUT THE FACTS THAT PROVE YOUR CASE, USING CONCRETE EXAMPLES FROM YOUR EXPERIENCE. IF THE CMS MANDATE APPLIES TO YOU, AND ONLY IF IT APPLIES TO YOU, MAY YOU USE THE FOLLOWING LANGUAGE. HOWEVER, EVEN IF SUCH IS THE CASE, YOU MUST DEVELOP THIS SECTION FURTHER, USING CONCRETE EXAMPLES FROM YOUR EXPERIENCE. THIS IS YOUR OPPORTUNITY TO TELL A FEDERAL JUDGE WHAT HAS BEEN DONE TO YOU, AND ONLY YOU CAN ENSURE THAT THIS PART, WHICH IS VERY IMPORTANT, IS DONE CORRECTLY, BECAUSE ONLY YOU ARE LIVING YOUR EXPERIENCE, DAY TO DAY.], moreover, by the Centers for Medicare & Medicaid Services (Center for Clinical Standards and Quality/Quality Safety, Safety & Oversight Group Memorandum, Ref: QSO-22-07-ALL, from Directors of Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG) to State Survey Agency Directors, dated December 28, 2021 ("QSO-22-07-ALL", attached hereto as Attachment E).

91. QSO-22-07-ALL specifies how each State Agency Director at the Government Defendant(s) is to work with entities in Employer Defendant's position, over a period of 30 to 90 days, to ensure that 100% of those in Plaintiff's position are vaccinated in accordance with the Government Action. In general, as long as the Employer Defendant and the Natural Person Defendants show steady efforts to comply with the

Government Defendant(s)'s denial of the Plaintiff's rights under the Equal Protection Clause of the Fourteenth Amendment, they will suffer no penalties. Thus, the Government Defendant(s) readily admits to its active involvement in the very operations of the Employer Defendant's business, via direct contact with and influence over, the Natural Person Defendants charged with executing such operations, to ensure that the Government Action/Directives are realized to their perfection (the ultimate vaccination of 100% of the employees of the Employer Defendant, other than those with a valid exception). Moreover, the Employer Defendant and the Natural Person Defendants are incentivized to coordinate, cooperate, and conspire with the Government Defendant(s) (and do so) to ensure that the Government Action/Directives are realized to their perfection (the ultimate vaccination of 100% of the employees of the Employer Defendant, other than those with a valid exception). The Employer Defendant and the Natural Person Defendants are literally paid by the Government Defendant(s) to do so, and they accept that payment in exchange for their thus rendered services to the Government Defendant(s).

92. That the Employer Defendant (and, thus, the remaining Defendants) are the willful participants in a joint activity is also suggested by the fact that, as pointed out several times during the January 7, 2022 oral arguments on the Government Action at the United States Supreme Court, there was no opposition to the Government Action submitted to the Court by anybody in the position of the Employer Defendant. They did not oppose the Government Action, because they approved of the Government Action.

93. The reason they might have approved (and conspired) are manifold, but one reason might be that the Employer Defendant and the Natural Person Defendants' economic and related interests, via for example, common shareholders, interlocking directorates and common sources of financing, are closely aligned with the large pharmaceutical companies who stand to benefit from the consumption of vaccines. Natural Person Defendants, of course, might consider future employment opportunities with large pharmaceutical companies and the Government Defendant(s). Interactions among all Defendants stemming from the real-world application of "Regulatory Capture" theory to the pharmaceutical/medical industry in which all Defendants operate must also be considered.

COUNT II: VIOLATION OF THE RIGHT TO REFUSE UNWANTED AND MEDICALLY UNNECESSARY CARE

94. Plaintiff realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

95. The Government Action/Directives require Plaintiff to take a vaccine without his/her consent **[YOU CANNOT INCLUDE THE FOLLOWING LANGUAGE IN BOLD AND CANNOT FILE THIS COMPLAINT IN ITS PRESENT FORM, UNLESS THIS IS TRUE, AND IF YOU DO, WITHOUT THIS BEING TRUE, YOU RISK COMMITTING PERJURY] —and against the expert medical advice of his/her doctor**—thereby depriving him/her of her ability to refuse unwanted medical care.

96. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]"

Washington v. Harper, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. *See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261, 278 (1990) ("'At common law, even the touching of one person by another without consent and without legal justification was a battery'"). *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984).); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

97. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." *Cruzan*, 497 U.S. at 278; *King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

98. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." *Washington v. Glucksberg,* 521 U.S. 702, 722 n.17 (1997).

99. The Court has explained that the right to refuse medical care derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco v. Quill*, 521 U.S. 793, 807 (1997).

100. Coercing employees to receive a vaccine (whether approved under merely under an Emergency Use Authorization or fully approved by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass

on to others because those employees already possess natural immunity to the virus, violates the liberty, equality and privacy interests that the Ninth and Fourteenth Amendments protect.

101."Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest." *Does v. Munoz*, 507 F.3d 961, 964 (2007).

102.Defendants cannot show that they have a compelling interest in coercing Plaintiff or others similarly situated into taking a COVID-19 vaccine, because the Defendants have no compelling interest in treating employees with natural immunity, such as Plaintiff, any differently from employees who obtained immunity from a vaccine.

103.Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Noorchashm Decl. ¶¶ 14-17; Joint Decl. at ¶¶ 15-24); Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination In Previously Infected Individuals*, MEDRXIV (June 5th, 2021), *available at* https://bit.ly/2TFBGcA (last visited Aug. 26, 2021); *see also* Yair Goldberg, et al., *Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three- Month Nationwide Experience from Israel*, MEDRXIV (Apr. 20, 2021), *available at* https://bit.ly/3zMV2fb (last visited Aug. 26, 2021); Michael Smerconish, *Should Covid Survivors and the Vaccinated Be Treated the Same?*: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), *available at* https://cnn.it/2WDurDn (last visited Aug. 26, 2021); Marty Makary,

The Power of Natural Immunity, WALL STREET JOURNAL (June 8, 2021), *available at* https://on.wsj.com/3yeu1Rx (last visited Aug. 26, 2021).

104.In recognition of the highly protective character of natural immunity, the European Union has recognized "a record of previous infection" as a substitute for any vaccine passport requirements. Noorchashm Decl. ¶ 38. Even France's controversial new restrictive mandate on the ability to participate in daily life focuses on a person's immunity rather than their vaccine status—treating natural immunity and vaccine immunity equally. *See, e.g.*, Clea Callcutt, *France Forced to Soften Rules After Coronavirus Green Pass Backlash*, POLITICO (July 20, 2021), *available at* https://politi.co/3f9AZzS (last visited Aug. 26, 2021).

105.Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Yet, documentation of recovery suffices as a substitute, although proof of vaccination does not. See Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States, CDC (July 6, 2021), available at https://bit.ly/3yfcJDM (last visited Aug. 26, 2021).

106.Recent data from Israel suggests that individuals who receive the BioNTech Vaccine can pass the virus onto others a mere few months after receiving it, casting doubt on any claim that the vaccine prevents spread of the virus, or at least any claim that it does so to a greater extent than natural immunity.

107. **There is no question that Plaintiff possesses natural immunity, given his/her recent antibodies screening tests and as confirmed by his/her doctor. [YOU CANNOT INCLUDE THIS BOLDED LANGUAGE IF THIS IS NOT THE CASE. IN FACT,**

YOU CANNOT USE THIS COMPLAINT IN ITS PRESENT FORM IF THAT SET FORTH IN THE BOLDED LANGUAGE IS NOT THE CASE, BUT MUST HAVE A LAWYER REVISE THE COMPLAINT TO ENSURE IT MEETS YOUR OBJECTIVES AND DOES NOT RUN AFOUL OF LAWS PENALIZING PERJURY.]

108.Given Plaintiff's naturally acquired immunity, Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) cannot establish that the Government Action/Directives (forcing Plaintiff either to be vaccinated **[IF A COVID TEST IS PART OF THE DIRECTIVE, INSERT "and/or regularly tested for COVID-19" AND IF THERE ARE OTHER REQUIREMENTS OF THE DIRECTIVE, INSERT THEM HERE]** or to suffer adverse professional consequences) is necessary to achieve a compelling state interest that overrides the Plaintiff's fundamental right to bodily integrity and other constitutional rights, and cannot establish that the Government Action/Directives in their present form are narrowly tailored to achieve any compelling purpose and use the least restrictive means to achieve the purpose.

109.Any interest that the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) may have in promoting immunity via the Government Action/Directives does not extend to those employees who already have natural immunity—particularly those who can demonstrate such immunity through antibody screenings.

110.This provides evidence that the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) is trying to exert control over individuals' personal health decisions via the Government Action/Directives, rather than attempting to promote a legitimate public health aim.

111.Any assertion by the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) that the vaccines are highly effective in preventing hospitalizations, severe disease and death from the delta variant of COVID-19 is also unavailing to an argument that the Government Action/Directives are truly directed towards protecting others, or are narrowly tailored to a compelling governmental interest, since natural immunity also prevents hospitalizations, severe disease and death.

112.Thus, the Government Action/Directives of the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) infringe on Plaintiff's bodily autonomy with no public health justification.

113.If vaccinated people can also transmit the disease, as it has become manifest, that only further undercuts any public health rationale for a vaccine mandate. It certainly drives home the arbitrary, nonsensical nature of the position of the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in

coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) that robust, naturally acquired immunity should not be recognized, while more limited immunity acquired through vaccination should be.

114.By the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) failing to tailor the Government Action/Directives to only those employees who lack immunity, the Government Action/ Directives force employees like Plaintiff (and those similarly situated), who have naturally acquired immunity, to choose between their health, their personal autonomy and their careers.

115.Plaintiff has suffered and will continue to suffer damage from the Government Defendant(s)'s (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff for the deprivation of her constitutional rights. He/she will suffer irreparable harm unless this Court enjoins the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) from enforcing their Government Action/Directives against employees with natural immunity.

116.Plaintiff is entitled to a judgment declaring that the Government Action/ Directives violate his/her constitutional rights to refuse medical treatment as well as his/her rights pursuant to the Equal Protection Clause of the Fourteenth Amendment to the United

States Constitution, and an injunction restraining the Government Defendant(s)'s (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) enforcement of the Government Action/Directives.

COUNT III: VIOLATION OF THE EUA STATUTE

117. The Government Action/Directives require Plaintiff and others similarly situated to receive a vaccine in order to continue working for Employer Defendant without regard to their natural immunity or the advice of their doctors.

118.The Government Action/Directives thus coerce Plaintiff and others like him/her into getting vaccines that FDA approved only for emergency use (since the only vaccine to have received a final approval, the Cominarty Vaccine, is not readily available in the United States).

119.The EUA statute mandates informed and voluntary consent. *See John Doe No. 1 v. Rumsfeld*, No. Civ. A. 03-707(EGS), 2005 WL 1124589, *1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA "on a *voluntary* basis"). *See also* 21 U.S.C. § 360bbb- 3(e)(1)(A)(ii).

120.It expressly states that recipients of products approved for use under it be informed of the "option to accept or refuse administration," of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id*.

121.Since the Government Action/Directives coerce Plaintiff by making enjoyment of his/her constitutionally and statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute.

See 21 U.S.C. § 360bbb-3.

122.The conflict between the Government Action/Directives and the EUA statute is particularly stark given that the statute's informed consent language requires that recipients be given the "option to refuse" the EUA product. That is at odds with the Government Action/Directives established by the Government Defendant(s) and the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), effectively forcing Plaintiff to sustain significant injury to her career if she determines to stand on the rights afforded her under the EUA statute and does not want to take the vaccine.

123.Put differently, the Government Action/Directives of the Government Defendant(s) and the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), frustrates the objectives of the EUA process.

A. The OLC Opinion Cannot Save the Government Action/Directives

124. Defendants may be expected to point to the fact that OLC made a memorandum available to the public on July 27, 2021 (dated July 6, 2021) opining that the EUA status of a medical product does not preclude vaccine mandates that might be imposed by either the public or private sectors. *See* "Memorandum Opinion for the Deputy Counsel to the President," *Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* (July 6, 2021) (OLC Op.) at 7-13, *available at* https://www.justice.gov/olc/file/1415446/download (last visited Aug.1, 2021).

125.Of course, the separation of powers dictates that this Court is not bound by the OLC Opinion—an advisory opinion written *by* the Executive Branch *for* the Executive Branch. *See Citizens for Responsibility & Ethics in Wash. v. Office of Admin.*, 249 F.R.D. 1 (D.C. Cir. 2008) ("OLC opinions are not binding on the courts[; though] they are binding on the executive branch until withdrawn by the Attorney General or overruled by the courts[.]"). (cleaned up)

126.The OLC Opinion is also premised on faulty reasoning. While recognizing that EUA products have "not yet been generally approved as safe and effective," and that recipients must be given "the option to accept or refuse administration of the product," the Opinion nevertheless maintains that the EUA vaccines can be mandated. OLC Op. at 3-4, 7.

127.According to OLC, the requirement that recipients be "informed" of their right to refuse the product does not mean that an administrator is precluded from mandating the vaccine. All that an administrator must do, in OLC's view, is tell the recipient they have the *option* to refuse the vaccine. *Id.* at 7-13. That facile interpretation sidesteps the fact that the Government Action/Directives employment consequences effectively coerce or at least unconstitutionally leverage the Employer Defendant community into taking the vaccine, rendering meaningless both the constitutional and statutory rights of informed consent. This approach should not past muster in this Court.

128.Recognizing the illogic of the Opinion and its inability to square its construction with the text of the EUA statute, OLC admits that its "reading ... does not fully explain why Congress created a scheme in which potential users of the product would be informed

that they have 'the option to accept or refuse' the product." *Id*. at 10. This understatement would be droll but for the serious rights at stake. In truth, Congress called for potential vaccine recipients to be informed precisely so that they could decide whether to refuse to receive an EUA product. OLC's obtuse reading of the statute blinks reality.

129.In other words, nothing in the OLC Opinion addresses the fact that if it were taken as a blanket authorization for any public or private actor to impose vaccine mandates, a vital portion of the EUA statute's text would be rendered superfluous. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.' ").

130.Yet, OLC turns around and claims that Congress would have explicitly stated if it intended to prohibit mandates for EUA products. *Id*. at 8-9. But Congress *did* say so. The plain language states that the recipient of an EUA vaccine must be informed "of the option to accept or refuse the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Especially when read against the backdrop of what the Constitution requires *and* against the common law rules from which the constitutional protections for informed consent arose, Congress's intent to protect informed consent is pellucid. And Congress "is understood to legislate against a background of common-law ... principles," *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991).

131.The EUA statute's prohibition on mandating EUA products is reinforced by a corresponding provision that allows the President, in writing, to waive the option of those in the U.S. military to accept or refuse an EUA product if national security so requires, 10 U.S.C. § 1107a(a)(1). That provision would be redundant if consent could be circumvented

merely by telling a vaccine recipient that he/she is free to refuse the vaccine but nonetheless must suffer various adverse employment consequences.

132.In fact, any sensible reading of that provision clarifies the view of Congress regarding the meaning of the EUA statute: " 10 U.S.C. § 1107a. Emergency Use Products (a) WAIVER BY THE PRESIDENT.-(1) In the case of the administration of a product authorized for emergency use under section 564[17] of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)1(ii)(III) of such Act and required under paragraph 1(A) or 2(A) of such section 564(e), *designed to ensure that individuals are informed of an option to accept or refuse administration of a product*, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security." (Emphasis added).

133.To circumvent the statutory text about the military waiver, OLC spins out a tortured argument under which the President's waiver would merely deprive military members of their rights to *know* that they can refuse the EUA product—rather than waiving their rights to actually refuse the product. OLC Op. at 14-15.

134.Unsurprisingly, OLC's strained reading runs counter to the Department of Defense's understanding of this statutory provision. As the OLC Opinion acknowledges, "DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section

[17] Note that Section 564 of the Federal Food, Drug, and Cosmetic Act is classified to section 360bbb-3 of Title 21, Food and Drugs.

1107a." *Id*. at 16 (citing DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008)).

135.OLC even acknowledges that its opinion is belied by the congressional conference report, which also contemplated that 10 U.S.C. § 1107a(a)(1) "would authorize the President to waive *the right of service members to refuse administration of a product* if the President determines, in writing, that affording service members the right to refuse a product is not feasible[.]" *Id*. (quoting H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.)).

136.Unlike OLC, this Court must not ignore the plain statutory prohibition on mandating EUA products. Though released to much fanfare in the media, the Court should discount the severely flawed OLC Opinion in its entirety, affording it no weight in this litigation.

B. The FDA's Approval of the Comirnaty Vaccine Does Not Save the Government Action/ Directives from Constituting A Violation of the EUA Statute

137.The other defense that we anticipate Defendants mounting is premised on the recent FDA approval of the Comirnaty Vaccine.

138.That the Comirnaty Vaccine has received full FDA approval does not foreclose the argument presented in this Count that the Government Action/Directives constitutes a violation of the EUA Statute, since this approval does not extend to the BioNTech Vaccine, which is actually available. Indeed, even Pfizer acknowledges that the two vaccines are "legally distinct." (Attachment C).

139.The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which

lack the force of law—do not warrant *Chevron*-style deference."); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as *de facto* law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety); *see also Maple Drive Farms Ltd. v. Vilsack*, 781 F.3d 837, 857 (6th Cir. 2015) (instructing USDA to carefully consider on remand whether its approach to the term "prior- converted wetlands" ran afoul of *Appalachian Power*).

140.The FDA cannot convert a legally distinct product under emergency use authorization only that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is not yet widely available. The FDA, via a mere guidance document, is improperly trying to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a transparent maneuver conducted to override federal statutory rights to informed medical consent.

141.Defendants cannot be permitted to rely on mere FDA-issued guidance documents, especially not where doing so would vitiate clear statutory rights.

142.Moreover, specifically referring to the Comirnaty Vaccine, Pfizer has admitted that there "is not sufficient approved vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA." (Attachment C).

143.The Comirnaty Vaccine, being the only FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population, per the manufacturer's own admission, and thus the Government Action/Directives, by forcing the Plaintiff to take a vaccine others than the Comirnaty Vaccine violates the EUA Statute.

C. The Nuremburg Code, and Related Sources of Law

144.Just as Congress prohibited the federal government from mandating EUA products, and thus the Government Action/Directives violate the EUA Statute, the Government Action/Directives violate the 1947 Nuremberg Code, a multilateral agreement between the United States, USSR, France, and the United Kingdom, governing human experimentation and inspired, of course, by events that took place during the Holocaust. The Nuremberg Code expressly states that "[t]he voluntary consent of the human subject is *absolutely essential*" and prohibits experimental treatments on anyone using "force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion." United States Holocaust Museum, *Nuremburg Code*, https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code (last visited Aug. 26, 2021) (emphasis added).

145.Title 45 of the Code of Federal Regulations part 46 is to similar effect, as is the Helsinki Declaration and the International Covenant on Civil and Political Rights adopted by the United Nations, to which the United States is a party. *See* International Covenant on Civil and Political Rights, pt III, art. 7, *available at* https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx (last visited Aug. 26, 2021); World Medical Association, *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, *available at* https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (last visited Aug. 26, 2021).

146.Defendants' Government Action/Directives are invalid pursuant to Article VI, Clause 2 of the United States Constitution, and must be enjoined and set aside.

ADDITIONAL LEGAL CLAIMS

147.Plaintiff has suffered and will continue to suffer damage from the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff for the deprivation of his/her constitutional and statutory rights. He/she will suffer irreparable harm unless this Court enjoins the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) from enforcing their Government Action/Directives.

148.42 U.S.C. § 1983 provides a civil right of action for deprivations of constitutional protections taken under color of law.

149.Plaintiff (and those similarly situated) is entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 because he/she is being deprived of "rights, privileges, or immunities secured by the Constitution and laws." Section 1983 thus supports both Plaintiff's constitutional and statutory causes of action against the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) because Section 1983 protects rights "secured by the Constitution *and* laws." 42 U.S.C. § 1983 (emphasis added).

150.In sum, Plaintiff is entitled to a judgment declaring that the Government Action/ Directives violate the EUA Statute and an injunction restraining the Government

Defendant(s)'s (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) enforcement of the Government Action/Directives.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court find the Government Defendant(s) and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), jointly and severally liable for having committed the violations alleged and described above, and issue in response the following:

A. A declaratory judgment that the Government Action/Directives established by the Government Defendant(s) and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), infringe upon Plaintiff's constitutional right to Equal Protection under the law guaranteed by the Fourteenth Amendment of the United States Constitution,

B. A declaratory judgment that the Government Action/Directives established by the Government Defendant(s) and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), infringe upon Plaintiff's constitutionally protected right to protect his/her bodily integrity and autonomy and to refuse unnecessary medical treatment.

C. A declaratory judgment that Government Action/Directives established by the Government Defendant(s) and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), violate the federal EUA Statute and Plaintiff's rights under the same.

D. Temporary, preliminary and permanent injunctive relief restraining and enjoining the Government Defendant(s) and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), their agents, servants, employees, attorneys, and all persons in active concert or participation with them (*see* Fed. R. Civ. P. 65(d)(2)), and each of them, from enforcing coercive or otherwise pressuring policies or conditions similar to those in the Government Action/Directives that act to compel or try to exert leverage on Plaintiff (and other similarly situated persons) with natural immunity to get a COVID-19 vaccine.

E. Make a finding that Plaintiff's constitutional rights were violated by the the Government Defendant(s) and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s), and award relief or damages accordingly.

F. Enter declaratory relief as requested above.

G. Enjoin the Government Defendant(s) (and, thus, the Employer Defendant and Natural Persons Defendants operating in coordination, cooperation and/or conspiracy, each sharing a common purpose, with the Government Defendant(s)) from mandating experimental vaccines.

H. Award damages and attorneys fees pursuant to 42 USC §1983 and 1988.

I. Declare that coercion and/or mandating an experimental injection constitutes a violation of customary international standards, and federal common law.

J. Grant such other and further relief as the Court deems just and proper in the circumstances.

JURY DEMAND

Plaintiff herein demands a trial by jury of any triable issues in the present matter.

Date: [Insert Date]

Respectfully submitted,

[INSERT YOUR NAME AND ADDRESS AND SIGN, BEFORE A NOTARY]

PLAINTIFF, proceeding *Pro Se*

ATTACHMENT A

Joint Declaration of Dr. Jayanta Bhattacharya and Dr. Martin Kulldoff

We, Drs. Jayanta ("Jay") Bhattacharya and Martin Kulldorff provide the following Joint Declaration and hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct:

Background

1. Dr. Jay Bhattacharya is a Professor of Medicine at Stanford University and a research associate at the National Bureau of Economic Research. He is also Director of Stanford's Center for Demography and Economics of Health and Aging. He holds an M.D. and Ph.D. from Stanford University. He has published 152 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. His research has been cited in the peer-reviewed scientific literature more than 11,000 times.

2. Dr. Martin Kulldorff is a Professor of Medicine at Harvard Medical School, and he is a biostatistician and epidemiologist at Brigham and Women's Hospital. He holds a Ph.D. from Cornell University. He is the author of 237 published articles in leading medical, epidemiological, statistics, and science journals, cited over 25,000 times in peer-reviewed scientific journals. Dr. Kulldorff is recognized internationally for his foundational research on the detection and monitoring of disease outbreaks and on the monitoring and evaluation of vaccine safety issues. His epidemiological methods are routinely used by the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA") and other public health agencies around the world.

3. Both of us have dedicated our professional careers to the analysis of public health data, including infectious disease epidemiology and policy, and the efficacy and safety of medical interventions.

4. We have both studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). We are intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

5. Our assessment of vaccine immunity is based on studies related to the efficacy and safety of the three vaccines that have received Emergency Use Authorization ("EUA") from the Food and Drug Administration (FDA) for use in the United States. These include two mRNA technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus vector vaccine technology (manufactured by Johnson & Johnson).

6. Neither of us has received any financial or other compensation to prepare this Declaration. Nor have we ever received any personal or research funding from any pharmaceutical company. In writing this, we are motivated solely by our commitment to public health.

7. Neither of us has an existing doctor-patient relationship with Jeanna Norris.

8. We have been asked to provide our opinion on several matters related to Michigan State University ("MSU" or "University") vaccine policy for faculty and staff (the "mandatory vaccination" directive), including the following:

a. Whether, based on the current medical and scientific knowledge, natural immunity is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;

b. Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity; and

c. An assessment of the comparative safety to recipients of administering vaccines to those who have natural immunity relative to immunologically naïve recipients with no prior history of COVID infection.

9. Our opinions are summarized in a recent article we published and which we reaffirm here: "[R]ecovered COVID patients have strong, long-lasting protection against severe disease if reinfected, and evidence about protective immunity after natural infection is stronger than the evidence from the vaccines. Hence, it makes no sense to require vaccines for recovered COVID patients. For them, it simply adds a risk, however small."[1]

Mortality Risk from COVID-19 Infection and Corresponding Marginal Benefit From Vaccination Varies By Orders of Magnitude Based on Age

10. The mortality risk posed by COVID infection is a basic parameter necessary to understand the public health benefits from vaccines. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or a positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts; these both miss infected people who are not identified by the public health authorities or do not volunteer for RT-PCR testing. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports or positive test counts are substantially biased upwards. According to a meta-analysis (published by the World Health Organization) by Dr. John Ioannidis of every seroprevalence study conducted with a supporting

[1] Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%.[2] A newly released meta-analysis by scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.[3]

11. The mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at higher risk of death if infected, while younger patients face a vanishingly small risk.[4] The same is true for hospitalization risk, which is similarly age-dependent. The best evidence on age-specific infection fatality rates comes again from seroprevalence studies.

12. The CDC's best estimate of the infection fatality ratio for people ages 0-19 years is 0.00002, meaning infected children have a 99.998% infection survivability rate.[5] The CDC's best estimate of the infection fatality rate for people ages 20-49 years is 0.0005, meaning that young adults have a 99.95% survivability rate. The CDC's best estimate of the infection fatality rate for people age 50-64 years is 0.006, meaning this age group has a 99.4% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 65+ years is .09, meaning seniors have a 91.0% survivability rate.

13. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the *Lancet*)[6] provides a detailed age breakdown of the infection survival rate in a preprint

[2] Ioannidis JPA, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, BULL WORLD HEALTH ORGAN (Jan 1, 2021).
[3] Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications*, MEDRXIV (Aug. 14, 2020), https://bit.ly/3gpIoIV.
[4] Kulldorff M., *COVID-19 Counter Measures Should Be Age-Specific*, LINKEDIN (Apr. 10, 2020), https://www.linkedin.com/pulse/covid-19-counter-measures-should-age-specific-martin-kulldorff/.
[5] Centers for Disease Control and Prevention, *COVID-19 Pandemic Planning Scenarios*, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.
[6] Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study*,THE LANCET (June 11, 2020), https://bit.ly/3l87S13.

companion paper[7]: 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65 years old.

14. In summary, the mortality risk posed by COVID infection in the young is vanishingly small, while the threat posed to the elderly is orders of magnitude higher. One direct corollary of this point is that the corresponding personal benefit from vaccination, at least as far as mortality risk is concerned, is orders of magnitude lower for the young relative to the elderly. Another corollary is that the community benefit from vaccines mandates is orders of magnitude lower for a university compared to say a nursing home, whee the average age is much higher.

Both Vaccine Immunity and Natural Immunity Provide Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected

15. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There has never been a reason to presume that vaccine immunity provides a higher level of protection than natural immunity, and there is now evidence that natual immunity is stronger than vaccine immunity. Since vaccines arrived one year after the disease, there is also stronger evidence for long lasting immunity from natural infection than from the vaccines.

16. Both types are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibodies level in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established

[7] Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland*, OSF PREPRINTS (June 15, 2020), https://osf.io/wdbpe/.

94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.[8,9] A Phase III trial showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.[10]

17. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells[11], bone marrow plasma cells[12], spike-specific neutralizing antibodies [13], and IgG+ memory B cells[14] following naturally acquired immunity.

[8] Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T., *COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, N ENGL J MED (Feb. 4, 2021).

[9] Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC, *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*, N ENGL J MED. (Dec. 31, 2020).

[10] Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, Goepfert PA, Truyers C, Fennema H, Spiessens B, Offergeld K, Scheper G, Taylor KL, Robb ML, Treanor J, Barouch DH, Stoddard J, Ryser MF, Marovich MA, Neuzil KM, Corey L, Cauwenberghs N, Tanner T, Hardt K, Ruiz-Guiñazú J, Le Gars M, Schuitemaker H, Van Hoof J, Struyf F, Douoguih M, *Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19*, N ENGL J MED (June 10, 2021), 2187-2201.

[11] Jennifer M. Dan, et al., *Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection*, SCIENCE (Feb. 5, 2021) (finding that memory T and B and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility for most individuals").

[12] Jackson S. Turner, et al., *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, NATURE (May 24, 2021) (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Ewen Callaway, *Had COVID? You'll probably make antibodies for a lifetime*, NATURE (May 26, 2021), https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

[13] Tyler J. Ripperger, et al., *Orthogonal SARS-Cov-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humor Immunity*, 53 IMMUNITY, Issue 5, pp. 925-933 E4 (Nov. 17, 2020) (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

[14] Kristen W. Cohen, et al., *Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells*, MEDRXIV (Apr. 27, 2021), https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v1 (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

18. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies show that natural immunity provides greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

19. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19[15] and show that the vast majority of reinfections are less severe than first-time infections.[16] For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided excellent protection in preventing COVID-19 infection, morbidity, and mortality.[17] Of the 187,549 unvaccinated persons with natural immunity in the study, only 894

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[15] Nabin K. Shrestha, et al., *Necessity of COVID-19 vaccination in previously infected individuals*, MEDRXIV (preprint), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3. ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study "and concluded that those with natural immunity are "unlikely to benefit from covid-19 vaccination"); Galit Perez, et al., *A 1 to 1000 SARS-CoV-2 reinfection proporation in members of a large healthcare provider in Israel: a preliminary report*, MEDRXIV (Mar. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1 (Israeli study finding that approximately 1/1000 of participants were reinfected); Roberto Bertollini, et al,. *Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar*, JAMA (June 9, 2021), https://jamanetwork.com/journals/jama/fullarticle/2781112?resultClick=1 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Stefan Pilz, et al., *SARS-CoV-2 re-infection risk in Austria*, EUR. J. CLIN. INVEST. (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988582/(previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Aodhan Sean Breathnach, et al., *Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies*, 82 J. OF INFECTION e11-e12 (2021) https://doi.org/10.1016/j.jinf.2021.05.024 (.0.86% of previously infected population in London became reinfected); Alison Tarke, *Negligible impact of SARS0CoV-2 variants on CD4 and CD8 T cell reactivity in COVID-19 exposed donors and vaccines*, BIORXIV (Mar. 1, 2021), https://www.biorxiv.org/content/10.1101/2021.02.27.433180v1 (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered Covid patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

[16] Laith J. Abu-Raddad, et al., *SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals followed for up to 35 weeks*, MEDRXIV (Feb. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.01.15.21249731v2 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Victoria Jane Hall, et al., *SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study*, 397 LANCET: 1459-69 (Apr. 9, 2021), https://pubmed.ncbi.nlm.nih.gov/33844963/ (finding "a 93% lower risk of COVID-19 symptomatic infection… [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Aidan T. Hanrah, et al., *Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection*, 82 JOURNAL OF INFECTION, Issue 4, E29-E30 (Apr. 1, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832116/ (Apr. 1, 2021) (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

[17] Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2*.

(0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age.

20. A more recent study from Israel directly compare natual immunity with vaccine immunity.[18] The study compares previously infected and recovered individuals who did not receive a vaccine after their recovery against individuals who received the Pfizer vaccine without having had the disease. The study considered four primary endpoints: a positive COVID test (a surrogate endpoint of limited value); symptomatic COVID-19 disease, hospitalization for COVID-19 disease, and COVID-19 associated mortality (all recorded in the months after recovery or vaccination). The study adjusts for age, demographic variables, patient comorbidities, and the timing of the disease/vaccine. The primary findings are that vaccinated individuals had 13.1 times higher risk of testing positive [95% CI: 8.08-21.1], 27 times higher risk of symptomatic disease [95% CI: 12.7-57.5], ~8.1 times higher risk of COVID-related hospitalization [95% CI: 1.01-64.55]. None of the patients in the study died due to COVID-related mortality. The vaccinated individuals were also at higher risk compared to those that had COVID disease before the vaccines became available. The authors concluded:

> This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity.

vaccine protection: A three-month nationwide experience from Israel, MEDRXIV (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

[18] Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. *medRxiv*. August 25, 2021. doi: https://doi.org/10.1101/2021.08.24.21262415.

21. Based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting.[19]

22. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 epidemic.[20] A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.[21]

23. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, researchers have argued that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.[22]

24. In short, there is no medical or scientific reason to believe that vaccine immunity is superior to or will prove longer-lasting than natural immunity, much less that all currently approved vaccines will be expected to prove more durable than natural immunity despite their different technological foundations and dosing protocols.

Vaccine Side Effects Do Occur, Including Rare But Deadly Side Effects

25. Though the COVID vaccines are safe by the standards of many other vaccines approved for use in the population, like all medical interventions, they have side effects. In

[19] Chris Baranjuk, *How long does covid-19 immunity last?* 373 BMJ (2021) (emphasis added).
[20] Nina Le Bert, *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control*, NATURE (Aug. 2020).
[21] Xiaocong Yu, et al., *Neutralizing antibodies derived form the B cells of 1918 influenze pandemic survivors*, NATURE (2008).
[22] Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses hove taught scientists*, 594 NATURE 164 (June 10, 2021), https://www.nature.com/articles/d41586-021-01505-x (study notes that "Six months is not much time to collect data on how durable vaccine responses will be…. In the meantime some researchers are looking to natural immunity as a guide.").

summarizing the evidence on vaccine side effects, the CDC lists both common side effects, at least one of which occurs in over half of all people who receive the vaccines, as well as deadly side effects that occur rarely in demographic subsets of the vaccinated population.

26. The common side effects include pain and swelling at the vaccination site and fatigue, headache, muscle pain, fever, and nausea for a limited time after vaccination.[23] Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur within 30 minutes after vaccination, which can typically be treated with an epinephrine injection if it occurs.[24] Finally, the CDC's vaccine safety committee has identified rare but deadly side effects, including a heightened risk of clotting abnormalities[25] in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis[26] in young people — but especially young men — after mRNA vaccination, and higher risk of Guillane-Barre Syndrome[27] after the J&J vaccine. There is still the possibility of severe side effects that have yet to be identified as the vaccines have been in use in human populations for less than a year. Active investigation to check for safety problems is still ongoing.

27. Though the CDC[28] still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts[29] have objected to overly rosy

[23] Centers for Disease Control, *Possible Side Effects After Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.
[24] Centers for Disease Control, *What to Do If You Have an Allergic Reaction after Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.
[25] Martin Kulldorff, *The Dangers of Pausing the J&J Vaccine*, THE HILL (April 17, 2021), https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine.
[26] Centers for Disease Control, *Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults* (May 28, 2021), https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.
[27] LaFranier and Weiland, *FDA Attaches Warning of Rare Nerve Syndrome to Johnson & Johnson Vaccine*, NEW YORK TIMES (July 12, 2021), https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html.
[28] Walensky, *CDC Director Statement on Pfizer's Use of COVID-19 Vaccine in Adolescents Age 12 and Older* (May 12, 2021), https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html.
[29] Pegden, *Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses* (June 24, 2021), https://medium.com/@wpegden?p=d7d6b3df7cfb.

assumptions made in the CDC analysis about vaccine side effects. They suggest that the recommendation is fragile to minor perturbation in their assumptions. The critical point for our analysis – undisputed in the scientific literature – is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known at this point in time.

28. While uncertain, some clinical evidence indicates that those who have recovered from COVID-19 could potentially have a *heightened* risk of adverse effects compared with those who have never had the virus.[30] [31] This may be because vaccine reactogenicity after the first dose is higher among those with prior natural immunity.[32]

Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

29. Since its spread through the human population, the SARS-CoV-2 virus – an RNA virus – has been mutating, including some forms that are likely more transmissible than the original wild-type virus that emerged from Wuhan, China, in 2019. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that a vaccine mandate is unwarranted.

[30] Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).

[31] Cristina Menni, *Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study*, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021) (finding that "Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 [i.e., AstraZeneca vaccine] and 2.9 times after the first dose of BNT162b2 [i.e., Pfizer/BioNTech vaccine]) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2).").

[32] Florian Krammer, et al., *Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a singe dose of SARS-CoV-2 mRNA vaccine*, MEDRXIV (Feb. 1, 2021), https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1 (concluding that "vaccine reactogenicity after the first dose is substantially more pronounced in individuals with pre-existing immunity." The authors note that "quantitative serological assays that measure antibodies to the spike protein could be used to screen individuals prior to vaccination," which would "limit the reactogenicity experienced by COVID-19 survivors.).

30. First, the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.[33,34,35] Although reinfection can occur, people who have been previously infected by the wild-type (non-variant) virus are unlikely to have a severe outcome (hospitalization or death) after exposure to a variant virus. A variant circulating in the population thus poses little additional risk of hospital overcrowding or excess mortality due to viral infection.

31. Second, theoretical work suggests that lockdowns place selective pressure that promotes the development and establishment of more deadly variants. This, in part, may explain why the most concerning variants have emerged in places like the U.K., South Africa, and California, where severe lockdowns have been imposed for extended periods.[36] While this hypothesis awaits a definitive empirical test, it is consistent with the *prima facie* evidence on mutant variants' development.

32. Third, the variants have been widely spreading in many countries these past months, even as cases have dropped. This is true, for instance, in Florida, where the U.K. variant B.1.1.7 was widespread this past winter[37], but cases fell sharply over the same period that the variant has been spreading. That variants with an infectivity advantage – but no more lethality –

[33] Alison Tarke, A., Sidney, J., Methot, N., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., da Silva Antunes, R., Frazier, A., Rawlings, S. A., Smith, D. M., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A., & Sette, A., *Negligible impact of SARS-CoV-2 variants on CD4 + and CD8 + T cell reactivity in COVID-19 exposed donors and vaccinees*, BIORXIV, 2021.02.27.433180 (2021), https://doi.org/10.1101/2021.02.27.433180.

[34] Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A., & Edwards, D. K., *mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants*, BIORXIV : THE PREPRINT SERVER FOR BIOLOGY, 2021.01.25.427948 (2021), https://doi.org/10.1101/2021.01.25.427948.

[35] Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T. C., & Tobian, A. A., *CD8+ T cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants*, MEDRXIV : THE PREPRINT SERVER FOR HEALTH SCIENCES, 2021.02.11.21251585 (2021), https://doi.org/10.1101/2021.02.11.21251585.

[36] Moran J., *Mutant variations and the danger of lockdowns*, THE CRITIC MAGAZINE (March 2, 2021), https://thecritic.co.uk/mutant-variations-and-the-danger-of-lockdowns/.

[37] US Centers for Disease Control, *US COVID-19 Cases Caused by Variants* (2021), https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html.

make up a larger fraction of a smaller number of cases is an interesting scientific observation but not crucial for public health policy.

33. Fourth, the dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still perhaps be infected but rarely have severe symptoms in response to infection. Throughout last year, a rise in cases was inevitably accompanied by an increase in deaths with a two-to-three-week lag. However, during this most recent wave, there has been little rise in daily deaths to accompany the rise in cases because of the deployment of the vaccine in the vulnerable older population in the United States. The same is true in Sweden and the U.K., where vaccines have been provided to the entirety of the vulnerable elderly population and more.[38] Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are now effectively decoupled.

The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID patients ("Long COVID") Does Not Alter The Conclusion that Vaccine Mandates Are Unwarranted

34. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify vaccine mandates and lockdown measures. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.[39] One cross-sectional study found that about 30% of recovered COVID patients reported at least one

[38]Jay Bhattacharya, Martin Kulldorff, and Sunetra Gupta, *Sweden's Lessons for the UK's Third Wave*, THE SPECTATOR (July 12, 2021), https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting.

[39] Nalbandian, A., Sehgal, K., Gupta, A. et al., *Post-acute COVID-19 syndrome*, NAT MED 27, 601–615 (2021), https://doi.org/10.1038/s41591-021-01283-z.

symptom months after recovery, with fatigue and anosmia (loss of sense of smell) by far the most common.[40] A separate study with a more convincing longitudinal methodology, by contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.[41] Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.[42] A study of children who recovered from COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.[43] Some analysts have noted the similarity between "long COVID" symptoms and other functional somatic syndromes that sometimes occur after other viral infections and other triggers (and sometimes with no identifiable etiology).[44]

35. To summarize, as with other viruses, long COVID symptoms occur in a minority of patients who recover from COVID and pose a real burden on patients who suffer from it. However, this fact does not alter the logic of our argument. On the countrary. After suffering through COVID, with or without long COVID, such individuals should not be forces to also endure common but mild vaccine adverse reactions or risk rare but serious adverse reactions. Moreover, the successful vaccine rollout in the United States – where every teenager and adult has free access to the vaccines – addresses the problem of long COVID, just as it addresses COVID-associated mortality.

CDC Recommendation for Vaccination of Recovered COVID Patients Applies With Equal Force to Previously Vaccinated

[40] Logue JK, Franko NM, McCulloch DJ, et al., *Sequelae in Adults at 6 Months After COVID-19 Infection*, JAMA NETW OPEN (2021);4(2):e210830, doi:10.1001/jamanetworkopen.2021.0830.
[41] Sudre, C.H., Murray, B., Varsavsky, T. et al., *Attributes and predictors of long COVID*, NAT MED 27, 626–631 (2021), https://doi.org/10.1038/s41591-021-01292-y.
[42] Arnold DT, Hamilton FW, Milne A, et al., *Patient outcomes after hospitalisation with COVID-19 and implications for follow-up: results from a prospective UK cohort*, THORAX, 76:399-401 (2021).
[43] Thomas Radtke, Agne Ulyte, Milo A Puhan, Susi Kriemler, *Long-term symptoms after SARS-CoV-2 infection in school children: population-based cohort with 6-months follow-up*, MEDRXIV (2021), https://doi.org/10.1101/2021.05.16.21257255.
[44] Ballering A, Olde Hartman T, Rosmalen J Long COVID-19, *persistent somatic symptoms and social stigmatization*, J EPIDEMIOL COMMUNITY HEALTH (2021).

36. Written before the Israel study, the CDC, in a frequently asked questions section of a website encouraging vaccination, provided the following advice to previously recovered patients in July 2021:[45]

> Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

37. The last sentence is true but irrelevant for people with natural immunity. The statement on CDC's website that "studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19," is incorrect. As one would expect, people with prior COVID-19 disease have increased levels of antibodies after receiving the vaccine, leading to fewer positive tests, just as if they are re-exposed to the disease. This does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths. In an update to the website[46] on August 19, 2021, the CDC links to a single study from Kentucky.[47] That study showed fewer positive tests among those who had both natural immunity and a vaccine, but the study did not evaluate the relevant outcomes of symptomatic disease, hospitalizations, deaths or transmission. Like the Kentucky study, the Israel study also found that those with both natural immunity and a vaccine were less likely to test positive compared with those with natural

[45] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (accessed July 30, 2021)
[46] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (accessed August 26, 2021)
[47] Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1081-1083. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e1

immunity but no vaccine. The Israel study also evaluated other outcomes, and did not find any statistically significant difference with respect to symptomatic disease, hospitalizations or deaths, all of which were very low in both groups (e.g. no deaths in either group).

38. The text of this advice by the CDC also does not address any of the scientific evidence we have provided in our declaration, herein, about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that we do not know how long natural immunity after recovery lasts, in terms of 5, 10, or 20 years from now, the immunological evidence to date suggests that protection against disease will last for years.[48]

39. That is because, with exceedingly few reinfections among millions of recovered COVID-19 patients, we know that there is excellent protection for at least 18 months, and that protection is not suddenly going to disappear after exactly 18 months.

40. Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID recovered patients from vaccination mandates, since the same is true to an even highe degree about vaccine mediated immunity. We do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

41. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine breakthrough infections itself recognizes.[49] On the same CDC FAQ webpage we cite above[50], the

[48] Patel N (2021) Covid-19 Immunity Likely Lasts for Years. MIT Technology Review. January 6, 2021. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/
[49] CDC COVID-19 Vaccine Breakthrough Case Investigations Team (2021) COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. May 28, 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm
[50] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

42. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who already has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the CDC's statement in the FAQ is non-responsive, and ignores the scientific evidence.

Conclusion

43. A fundamental ethical principle guiding the practice of medicine is that any medical intervention, whether surgical, pharmacological, or a vaccine, should be recommended and undertaken only if it is deemed medically necessary. Any medical procedure, including vaccination, involves risk. No medical procedure is 100% safe, especially those involving a new vaccine which by definition has not been studied for long-term adverse side effects. For this reason, it is a fundamental principle of medical ethics that the risks of the procedure be balanced against the potential benefits.

44. As we established earlier, based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable as that acquired through vaccination. In Jeanna Norris' case, there is no doubt that, based on recent measures of her antibody levels, she is protected by natural immunity (Dr. Bhattacharya has examined the results from Ms. Norris' laboratory tests). The results indicate the presence of both spike-protein and nucleocapsid protein antibodies; the latter is a reliable sign of previous natural infection (the former turns positive after either previous natural infection or vaccination). The existing clinical

literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date. From the point of view of Ms. Norris' personal health, there is no good reason that she should be vaccinated. At the very least, the decision should be left to Ms. Norris and her doctors without coercion applied by the University.

45. There is also no community health reason for the University to mandate vaccinations since she already has stonge immunity than those that ae vaccinated, and the vaccine is available to all teens and adults who want it. Indeed, based on our analysis of the existing medical and scientific literature, any policy mandating vaccinations that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.[51]

46. As we wrote in the *Wall Street Journal* this spring, "[t]he idea that everybody needs to be vaccinated is as scientifically baseless as the idea that nobody does. Covid vaccines are essential for older, high-risk people and their caretakers and advisable for many others. But those who've been infected are already immune . . . .If authorities mandate vaccination of those who don't need it, the public will start questioning vaccines in general . . . . Coercive vaccination policies would erode trust even further."[52]

47. We criticized those pushing for and implementing vaccine mandates as "undermining public trust in vaccines. In this sense, they are more dangerous than the small group of so-called anti-vaxxers have ever been."

[51] Jay Bhattacharya, Sunetra Gupta, and Martin Kulldorff, *The Beauty of Vaccines and Natural Immunity*, SMERCONISH NEWSLETTER (June 4, 2021), https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity.

[52] Martin Kulldorff and Jay Bhattacharya, *Vaccine Passports Prolong Lockdowns*, WALL STREET JOURNAL (Apr. 6, 2021), https://www.wsj.com/articles/vaccine-passports-prolong-lockdowns-11617726629.

48. It is unethical to coerce low-risk Americans to take the vaccine, such as low-risk students and those with natual immunity, while older high-risk individuals in Asia, Africa and Latin America are dying from COVID19 because there are not enough vaccines available in those countries.

49. Now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is even weaker than it was in the spring when we wrote that *Wall Street Journal* piece. There is no good public health case for MSU to require proof of vaccination for employees and students to participate in University activities that do not involve care for high-risk patients. And, since those recovered from COVID19 has better protection than vaccinated individuals, there are no public health reasons to impose different mask requirements for the two groups.

50. Since the successful vaccination campaign already protects the vulnerable population, even the unvaccinated who have not had COVID disease –pose a vanishingly small threat to the vaccinated o those with natual immunity. They are protected by an effective vaccine, that dramatically reduces the likelihood of hospitalization or death after infections to near zero, o by natural immunity.

51. With widespread vaccination of the vulnerable, asymptomatic people pose even less risk to the vulnerable than before the vaccine became available. At the same time, the requirement for a vaccine passport or other type of proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice that caution against warrantless discrimination against segments of the population (in this case, the unvaccinated).

52. We recently observed that "[u]niversities used to be bastions of enlightenment. Now many of them ignore basic benefit-risk analyses, a staple of the toolbox of scientists; they deny immunity from natural infection; they abandon the global international perspective for narrow nationalism; and they replace trust with coercion and authoritarianism. Mandating the COVID-19 vaccine thus threatens not only public health but also the future of science."[53]

53. Universities can be leaders in developing sensible policies grounded in sound scientific evidence and abide by the fundamental principles of medical ethics. Individuals who have recovered from COVID-19 should be exempt from any vaccine mandates and treated as in an identical position to those who have been vaccinated.

Respectfully submitted,

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Stanford University

Dr. Martin Kulldorff, Ph.D.
Professor of Medicine
Harvard University

[53] Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

ATTACHMENT B

Declaration of Dr. Hooman Noorchashm, MD, PhD

I, Hooman Noorchashm, provide the following Joint Declaration and hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct:

Background

1. I graduated from the Perelman School of Medicine at the University of Pennsylvania with a Doctorate degree in immunology and a Medical Doctorate in 2001/2002, under a "Medical Scientist Training Program" fellowship grant from the National Institutes of Health. I subsequently completed residencies in general surgery and cardiothoracic surgery from 2004-2013, first at the Hospital of the University of Pennsylvania and then at Harvard's Brigham and Women's Hospital. I also completed a post-doctoral research fellowship in Immunology and served as Principal Investigator on several Immunology research grants from the NIH. I have taught and practiced clinical medicine for nearly two decades. In addition to an academic career in medicine, I am an advocate for patient safety and medical ethics.

2. I have served on the clinical and research faculties at the University of Pennsylvania School of Medicine, Harvard Medical School Brigham and Women's Hospital, Thomas Jefferson University Hospital, and the Philadelphia VA Hospital. I have authored over 65 articles, abstracts, and reviews in peer-reviewed medical journals, including the New England Journal of Medicine, Journal of Immunology, Nature Medicine, American Journal of Transplantation, Critical Care Medicine, and Diabetes. I am currently a practicing physician with unrestricted medical licenses in the states of Pennsylvania and New Jersey. I have testified on numerous occasions before the Food and Drug Administration and state legislatures on issues related to medicine, immunology, patient safety, and patient's rights.

3. In 2013, my wife Dr. Amy Josephine Reed underwent a hysterectomy operation using a dangerous indiscriminate surgical procedure, which we later learned spread a misdiagnosed

uterine cancer and advanced it to stage 4 Leiomyosarcoma. She eventually died from complications related to indiscriminate, one-size-fits-all morcellation of her symptomatic uterine fibroid tumors.

4. Before her death, my wife and I began spreading awareness of this indiscriminate procedure's danger and advocating for patient safety and patient's rights. In recognition of those efforts, I received a Health Policy Heroes Award from the National Center for Health Research in 2015. This advocacy is fundamentally focused on the principles of ethical practice guided by the medical ethical ideas of "medical necessity" and "patient autonomy" – and a total rejection of non-personalized and algorithmic *"one-size-fits-all"* service line practices, wherein harm to minority subsets of patients is a near-certainty.

5. To continue the work that Dr. Amy Josephine Reed and I started, I founded the *American Patient Defense Union, Inc.* (APDU), an organization dedicated to advocating for patient rights and autonomy, preserving the integrity and sacred relationship between doctors and their patients, and protecting doctor and patient decisions about medical treatments from third-party influence.[1] This organization is involved with advocacy for, and defense of, individual patients or minority subsets of persons harmed by unsafe or unnecessary medical practices without adequate informed consent or inadequate evidence supporting their use.

[1] *See* Hooman Noorchashm, *Why Does Every American Need The American Patient Defense Union (APDU)?*, MEDIUM.COM (Oct. 17, 2017), https://noorchashm.medium.com/why-every-american-needs-the-american-patient-defense-union-apdu-2912e1fee5d4.

Jeanna Norris's Medical Condition

6. On August 20, 2021, Ms. Norris contacted me for a consultation on how to determine the status of her immunity to COVID-19. I agreed to review her case and provide my opinion.

7. During a phone call that same day, Ms. Norris informed me of the following relevant facts:

a. On November 19, 2020, she fell ill with a severe headache and a dry cough.

b. In the early morning hours of November 20, 2020, she was awakened by severe myalgias, arthralgia and a headache.

c. Ms. Norris undwerent a Rapid COVID Antigen test on November 21, 2020, which came back positive.

d. Her severe symptoms of body ache and headache lasted for 4 days and were not associated with any significant effects– these symptoms lingered for approximately 30 days.

e. Ms. Norris lost her sense of taste and smell on day 4-5 following onset of her symptoms. This sensory deficit lasted for approximately 30 days.

f. After an extensive discussion about her medical condition, I issued a prescription for full COVID-19 serological screening, which was conducted on August 20, 2021, at LabCorp. Ms. Norris underwent a blood draw that same day. I examined the results and, as expected, the test confirmed that Ms. Norris had previously recovered from SARS-CoV-2 and had both a positive IgG Spike Antibody assay and a positive SARS-CoV-2 Nucleocapsid result.

g. Ms. Norris' semiquantitative antibody reading measured 59.7 U/ml—approximately 70 times higher than the baseline level of <0.8 U/ml. This level is comparable to that I have seen empirically in many persons with acquired natural immunity to SAR-CoV-2 from a prior infection. In my opinion, Ms. Norris' spike antibody level is highly likely to be above the minimum necessary to provide adequate protection against re-infection from the SARS-CoV-2 virus.

Principles of Medical Ethics and Michigan State University's (MSU's) Vaccine Mandate

8. There are four basic principles governing medical ethics in the United States: (1) autonomy, (2) justice, (3) beneficence, and (4) non-maleficence.

9. A highly influential public health framework proposed by Childress, et al., lists five conditions that public health interventions must satisfy: (1) effectiveness, (2) proportionality, (3) necessity, (4) least infringement, and (5) public justification.[2]

10. The principle of necessity is reinforced by the principle of "least infringement," which requires that any intervention "seek to minimize the infringement of general moral considerations." In particular, "when a policy infringes autonomy, public health agents should seek the least restrictive alternative; when it infringes privacy, they should seek the least intrusive alternative."[3]

11. The principle of proportionality is also a defense against one-size-fits-all approaches that can cause harm in the context of medicine.

[2] James F. Childress, et al., *Public Health Ethics: Mapping the Terrain*, 30(2) J. LAW & MED. ETHICS 170 (2002).

[3] *Id.*

It is Medically Unnecessary for Ms. Norris to Undergo Vaccination Against SARS-CoV-2, and Forcing her to Do So Would Subject Her to an Elevated Risk of Adverse Side Effects

12. It is my opinion that undergoing a full course vaccination (two doses of an mRNA vaccination or one dose of the Johnson and Johnson [J&J] vaccine) is medically unnecessary and creates a risk of harm to Ms. Norris in light of her pre-established acquired immunity to SARS-CoV-2, while providing insignificant or no benefit to her or the MSU community.

13. A highly sensitive and specific antibody test has confirmed that Ms. Norris contracted and recovered from the SARS-CoV-2 virus. Her recent semi-quantitative antibodies screening test established that her level of immune protection remains high.

14. A series of epidemiological studies have demonstrated to a reasonable degree of medical certainty that natural immunity following infection and recovery from the SARS-CoV-2 virus provides robust and durable protection against reinfection, at levels equal to or better than the *most effective* vaccines currently available.[4]

15. For example, according to the Centers for Disease Control (CDC), in clinical trials the J&J vaccine provides an efficacy of only 66.3%—*far* below any measured efficacy of natural immunity to date.

16. Natural immunity protection to SARS-CoV-2 has already proven long-lasting and experience with prior coronaviruses strongly indicates that T-cell immunity provided by natural immunity could last years or even decades.

17. In my opinion, it is almost certainly true that natural infection provides broad-based protection against SARS-CoV-2 variants. Unlike vaccine-induced immunity, which is specialized

[4] Cites (Cleveland clinic, England, Israel, etc.); N. Kojima, et al., *Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees*, https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2 (July 8, 2021).

to target the Spike-protein of the original Wuhan variant of the SARS-CoV-2 virus, natural immunity recognizes the full complement of SARS-CoV-2 proteins, enabling it to provide protection against a greater array of variants. Emerging evidence is already confirming this immunological expectation.

18. Furthermore, based on my analysis of the clinical medical literature to date, undergoing a full course of vaccine treatment (two doses of mRNA or one dose of J&J vaccine) as required by MSU's vaccine mandate, in a setting of a prior infection and being immune, would expose Ms. Norris to an elevated risk of adverse effects, including serious ones, when compared with individuals who have never contracted COVID-19.

19. Any medical procedure carries the risk of adverse side effects. The SARS-CoV-2 vaccines are no exception. In many cases, the benefits of curing, mitigating, or preventing greater harm justifies undertaking a particular medical intervention notwithstanding any associated risk. But basic principles of medical ethics mandate that any potential benefits be weighed against the risks associated with the procedure. It is critical for any given medical treatment, including vaccination, to be delivered only in the setting of medical necessity in any given individual – and certainly if medical necessity is ruled out for any given medical treatment, forcing the treatment on any such person is unethical.

20. Because Ms. Norris has previously been infected with and recovered from SARS-CoV-2, in my opinion, a vaccination is unnecessary and could only subject her to the risk of harm with little to no tangible added benefit to her or the MSU community relative to "fully vaccinated" persons.

21. Additionally, it is becoming clear that undergoing vaccination in the setting of having had a prior infection subjects her to an elevated risk of adverse side effects compared to

those who have not previously been infected. Existing clinical reports indicate that individuals with a prior infection and natural immunity actually face an *elevated* risk of adverse effects from receiving the vaccine compared to those who have never contracted COVID-19.

22. According to a study in the medical journal *Life* (March 2021), "*our study links prior COVID-19 illness with an increased incidence of vaccination side effects* and demonstrates that mRNA vaccines cause milder, less frequent systemic side effects but more local reactions."[5] The elevated side effects identified in the article include events such as anaphylaxis, swelling, flu-like illness, breathlessness, fatigue, and others, some requiring hospitalization.

23. A study published in *The Lancet Infectious Diseases* (July 1, 2021) examined reports from 627,383 individuals using the COVID Symptom Study app. The authors reported a higher incidence of both systemic and local side effects from receiving the first vaccine dose for those who had previously been infected with COVID-19 compared to those who had not previously been infected.[6]

24. A study conducted at Mount Sinai Icahn School of Medicine also found among those receiving their first vaccine dose, "vaccine reactogenicity" was "substantially more pronounced in individuals with pre-existing immunity" than those who had not previously been infected and those with pre-existing immunity experienced "systemic side effects with a significantly higher frequency" than those who had not previously been infected.

[5] Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).
[6] Cristina Menni, *Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study*, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021).

25. In addition, there are numerous nonsystematic reports of individuals who have had unusually severe adverse reactions to vaccination shortly after recovering from COVID-19 infections.[7]

26. Notably many of these studies focused on the adverse effects of receiving just the *first* dose of a vaccine. They do not examine the frequency or severity of receiving a second dose of a vaccine. This uncertainty is especially important in light of the widespread recognition that those with natural immunity gain no significant benefit from receipt of a second vaccine dose (as is required by MSU's mandatory vaccination policy).

27. It is a fundamental principle of immunology that "vaccinating a person who is recently or concurrently infected can reactivate, or exacerbate, a harmful inflammatory response to the virus. This is NOT a theoretical concern."[8] This applies to SARS-CoV-2 just as it does to any virus.

28. To date, none of the vaccines in current application have been systematically or adequately tested for safety or efficacy in individuals who have previously been infected and recovered from SARS-CoV-2. In fact, Covid survivors *have overall been largely excluded* from Phase III vaccine clinical trials.[9] Thus, any determination with respect to the safety profile of the vaccines in this population, of which Ms. Norris is a member, can only be inferred from clinical studies in the time since the vaccines have been put into widespread application.

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[7] *See Multisystem Inflammatory Syndrome after SARS-CoV-2 Infection and COVID-19 Vaccination*, 27 (Number 7) EMERGING INFECTIOUS DISEASE (July 2021) (Centers for Disease Control and Prevention Dispatch); *see also* Hooman Noorchashm, *CDC Knows Vaccine Associated Critical Illness and Myocarditis are Linked to Prior COVID-19 Infections*, MEDIUM.COM (Jun 2, 2021), https://noorchashm.medium.com/cdc-knows-vaccine-associated-critical-illness-and-myocarditis-are-linked-to-prior-covid-19-62942c39c5ca.

[8] Homman Noorchashm, *The Recently Infected and Already Immune DO NOT Benefit from COVID-19 Vaccination*, MEDIUM.COM (Jun 1, 2021), https://noorchashm.medium.com/the-recently-infected-and-already-immune-do-not-benefit-from-covid-19-infection-7453886e8c89.

[9] *See* Fabio Angeli, *SARS-CoV-2 vaccines: Lights and shadows*, 88 EUROPEAN J. OF INTERNAL MEDICINE 1-8 (2021).

29. A recent study from the state of Kentucky suggested that COVID-recovered individuals who undergo added vaccination enjoy some marginal added benefit relative to COVID-recovered persons who are not vaccinated. However, this study did not compare the risk of subsequent infection in COVID-recovered, vaccinated persons versus those who are COVID-naïve and "fully vaccinated."

30. The preponderance of evidence from other studies indicates that COVID-recovered individuals, in fact, enjoy the same level of protection from subsequent infection, perhaps more, when compared to persons considered "fully vaccinated" using the adenoviral or mRNA vaccines. This latter comparison is the only relevant comparison that could have possibly justified any discriminatory practice against COVID-recovered, already immune people relative to "fully vaccinated" persons – IF there was any real difference between the two groups.

31. Additionally, the Kentucky study did not address or attempt to quantify the magnitude of risk and adverse effects in its comparison groups. Yet, other studies have demonstrated that in fact, the rate of adverse vaccination events is significantly higher in persons previously infected. Overall, it is my opinion that though the Kentucky study may make a case for COVID-recovered persons being offered a choice to be vaccinated if they choose to enjoy added protection, it is not ethical for MSU, or any other institution, to use the CDC's Kentucky study results to institute discriminatory practices in COVID-recovered, already immune persons versus "fully vaccinated" persons. It is my opinion that the Kentucky study does not compare the appropriate groups to justify forced vaccination of and discriminatory practices against COVID-recovered Americans.

32. In contrast to the determination that Ms. Norris has reached after consultation with me, about the details of her personal situation and medical history, MSU is inappropriately, and in

violation of the rules governing medical ethics, imposing a "one-size-fits-all" vaccine mandate on her and every member of the MSU community who is in an analogous situation to her.

33. MSU does not know the details of Ms. Norris' situation and evidence of her existing immunity levels or potential for adverse effects, such as the results of any quantitative antibodies screening test.

34. MSU's vaccine mandate is forcing Ms. Norris to choose between following ethically sound medical practice on one hand and being subject to MSU's burdensome and punitive discriminatory practices – which includes being forced to socially distance, remain socially isolated, or undergo frequent COVID-19 testing – on the other. No American should be put in such a position.

35. As with all patients, Ms. Norris and her consulting physicians should determine her future course of medical treatment. Thus, I will continue to monitor Ms. Norris's antibody levels as SARS-CoV-2 variants arise and/or her immune protection starts to wane. A this point in time, it is my opinion that neither Ms. Norris nor the MSU community are at any higher risk of being infected because of her autonomous choice to delay or forego a booster vaccination at this time.

MSU's Goals in Promoting Community Safety Can Be Accomplished More Effectively and with Less Harm Through Alternative, Less-Restrictive/Coercive Means

36. Protecting the MSU community from COVID-19 transmission can be achieved without exposing COVID-recovered and already immune members of the community to the risk of harm, in contrast to MSU's current indiscriminate vaccination plan.

37. The emerging consensus in the clinical literature on the protective benefits of acquired natural immunity compared to the elevated risks of indiscriminately vaccinating these individuals has led me to propose the personalized #ScreenB4Vaccine initiative for individual

American who correctly believe that medical necessity is the underpinning of safe medical practice.[10] #ScreenB4Vaccine contains two elements: (1) testing for the presence of natural immunity through widespread antibody testing, and (2) a test for presence of an active infection, before vaccination.

38. In fact, growing recognition of the highly protective character of acquired natural immunity in preventing reinfection, along with the elevated risk of vaccinating those who have natural immunity, has recently led the European Union to recognize "a record of previous infection" as a valid substitute for vaccination.[11]

39. Certainly, the Israeli Green Passport system allows for COVID-recovered persons with evidence of antibody immunity to be treated identically to those "fully vaccinated."

40. In short, just because an individual is vaccinated does not guarantee she is immune and just because she is not vaccinated does not mean she is not immune. "Immunity," as assessed by the presence of antibodies to SARS-CoV-2 Spike protein, is at the core of protection from SARS-CoV-2 infection – not vaccination, *per se*.

41. Instead of focusing its policy on blanket vaccination, therefore, MSU's policy should instead focus on *immunity*, regardless of how it is obtained.

Conclusion

42. I call on MSU to act responsibly and, based on the principles of sound medical ethics and immunology, to recognize the importance of acquired natural immunity in providing protection equal to or better than existing vaccines. Such a policy would also acknowledge, and

[10] *See* Hooman Noorchashm, *What is #ScreenB4Vaccine? And Why Is It Necessary for Keeping Every American Maximally Safe in the COVID-19 Pandemic?* MEDIUM.COM (May 7, 2021), https://noorchashm.medium.com/what-is-screenb4vaccine-80b639c4984e.

[11] *See* Julia Buckley, *EU Digital Covid Certificate: Everything you need to know*, CNN.COM (June 9, 2021), https://www.cnn.com/travel/article/eu-covid-certificate-travel-explainer/index.html.

therefore avoid, the elevated risk of side effects from vaccination among those who have already survived a SARS-CoV-2 infection and are recovered within the past year.

Respectfully submitted,

/s/ Hooman Noorchashm

Hooman Noorchashm MD, PhD.

ATTACHMENT C

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older and is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

A third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid

[1] 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.

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

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90ºC to -60ºC (-130ºF to -76ºF) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90ºC to -60ºC (-130ºF to -76ºF) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date		Updated Expiry Date
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

If not stored between -90ºC to -60ºC (-130ºF to -76ºF), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF).

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[2]

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) with other COVID-19 vaccines to complete the vaccination series.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Dose Preparation

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *(see Storage and Handling)*.

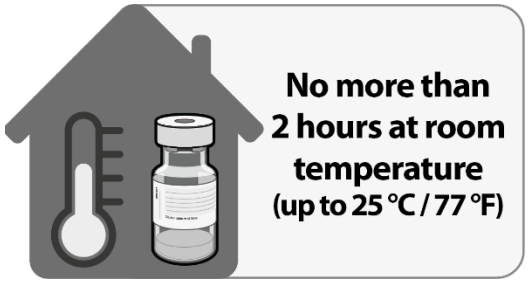
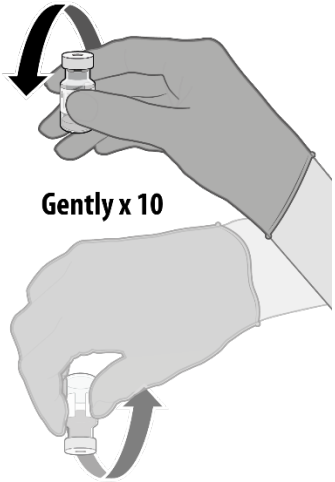
[2] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety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

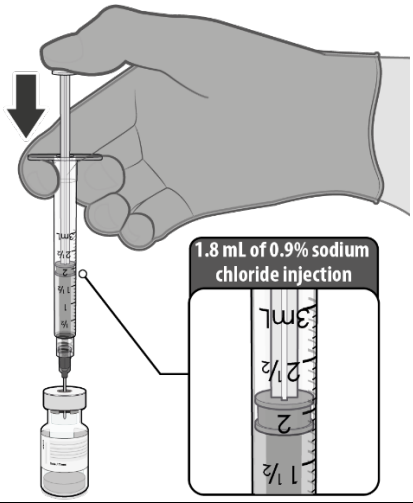
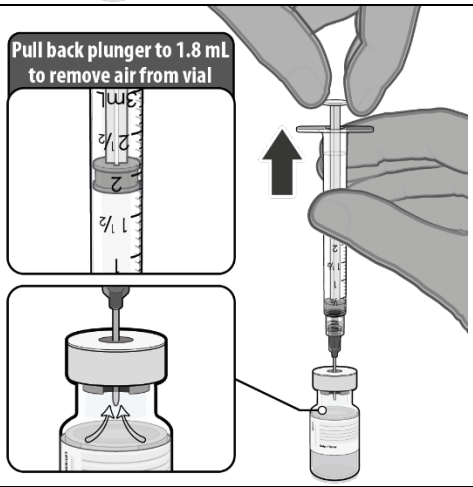
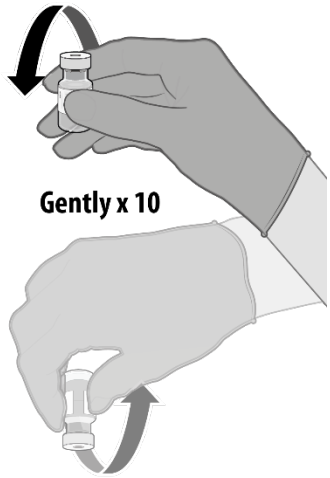
- Refer to thawing instructions in the panels below.

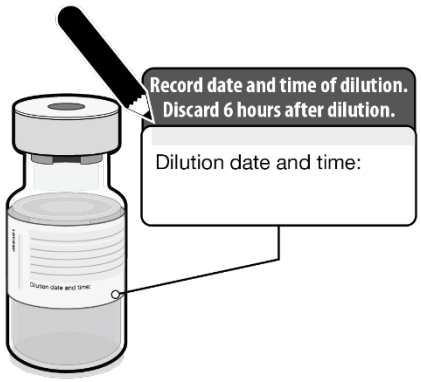
Dilution
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

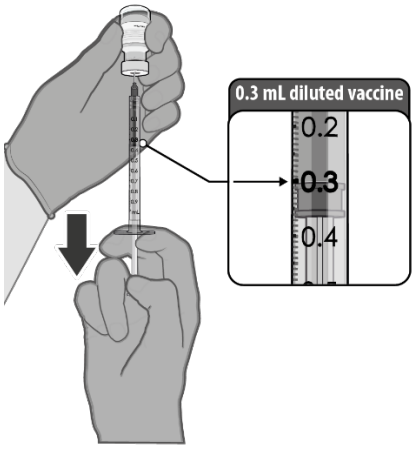
After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

- Refer to dilution and dose preparation instructions in the panels below.

<table>
<tr><th colspan="2">THAWING PRIOR TO DILUTION</th></tr>
<tr><td> 
</td><td>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.
○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
• Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.</td></tr>
<tr><td> 
</td><td>• Before dilution invert vaccine vial gently 10 times.
• Do not shake.
• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
• Do not use if liquid is discolored or if other particles are observed.</td></tr>
</table>

DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

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.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse Reactions in Clinical Trials
Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Adverse Reactions in Post Authorization Experience
Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, and pain in extremity (arm) have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Vaccine Information Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.

- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION[3]

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 12 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

[3] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

4. The vaccination provider is responsible for mandatory reporting of the following to the 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 (MIS) in adults and children, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for use in individuals 16 years of age and older. COMIRNATY (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years of age and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise. COMIRNATY (COVID-19 Vaccine, mRNA) has the same formulation as the Pfizer-BioNTech COVID-19 Vaccine. These vaccines can be used interchangeably to provide the COVID-19 vaccination series.[4]

There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients). For information regarding provider

[4] 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.

requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 12 years of age and older and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise. FDA-approved COMIRNATY is also authorized in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

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

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-11.4

Revised: 23 August 2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

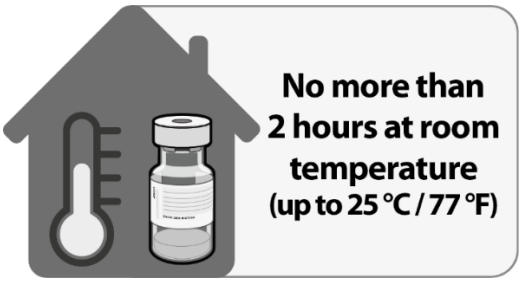
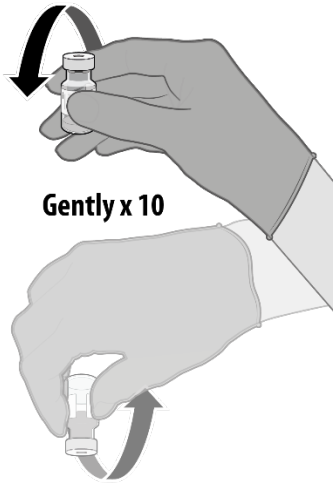
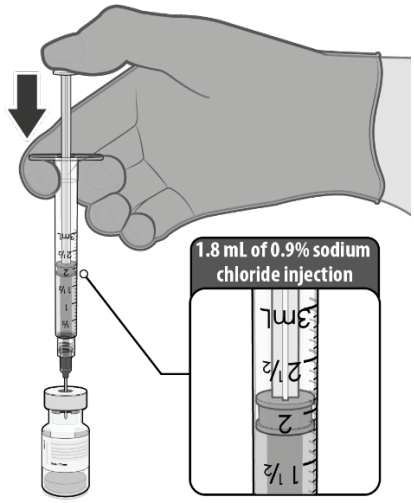
2.1 Preparation for Administration

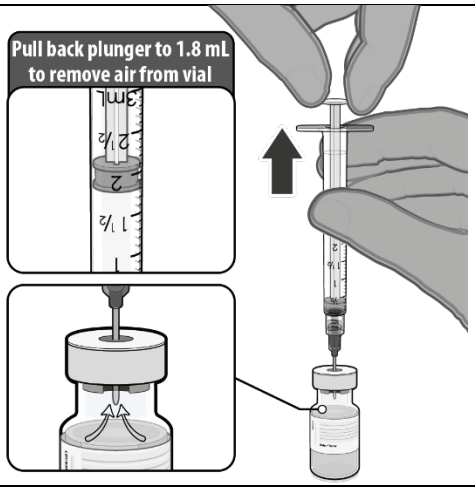
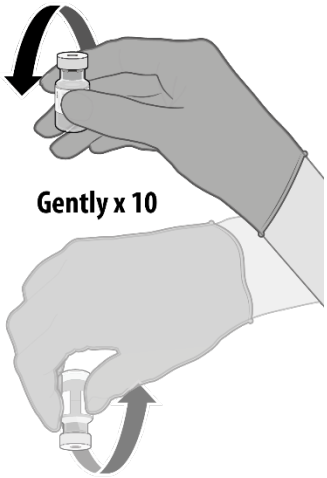
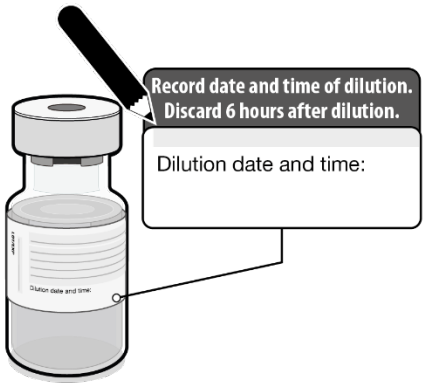
Prior to Dilution

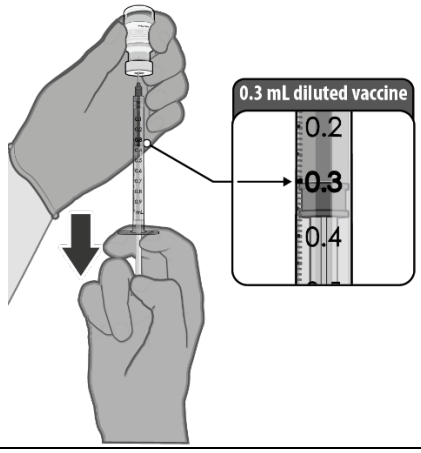
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month. o Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule for Individuals 12 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[5] There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) to complete the vaccination series.

[5] 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.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

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.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. [6] To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 12 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 46,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 adolescents are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively).

[6] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

In Study 2, all participants 12 to <16 years of age, and participants 16 years of age and older in the reactogenicity subset, were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination]. Tables 1 through 6 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine and placebo.

Participants 16 Years of Age and Older

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older had been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants 16 years and older enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Solicited Local and Systemic Adverse Reactions

Across both age groups, 18 through 55 years of age and 56 years and older, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	**Placebo Dose 1 N[a]=2298 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)**	**Placebo Dose 2 N[a]=2103 n[b] (%)**
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, in 99 individuals who had undergone various solid

organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously 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 in recipients who were followed for one month following post Dose 3.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7,960, placebo = 7,934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

In Study 2 in which 10,841 participants 16 through 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

The higher frequency of reported unsolicited non-serious adverse events among Pfizer-BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Adolescents 12 Through 15 Years of Age

In an analysis of Study 2, based on data up to the cutoff date of March 13, 2021, 2,260 adolescents (1,131 Pfizer-BioNTech COVID-19 Vaccine; 1,129 placebo) were 12 through 15 years of age. Of these, 1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) adolescents have been followed for at least 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine. The safety evaluation in Study 2 is ongoing.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among adolescents who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the adolescents who received the Pfizer-BioNTech COVID-19 Vaccine, 50.1% were male and 49.9% were female, 85.9% were White, 4.6% were Black or African American, 11.7% were Hispanic/Latino, 6.4% were Asian, and 0.4% were American Indian/Alaska Native.

Solicited Local and Systemic Adverse Reactions

The mean duration of pain at the injection site after Dose 1 was 2.4 days (range 1 to 10 days), for redness 2.4 days (range 1 to 16 days), and for swelling 1.9 days (range 1 to 5 days) for adolescents in the Pfizer-BioNTech COVID-19 Vaccine group.

Table 5: Study 2 – Frequency and Percentages of Adolescents With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	**Placebo Dose 1 N[a]=1127 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)**	**Placebo Dose 2 N[a]=1078 n[b] (%)**
Redness[c]				
Any (>2 cm)	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling[c]				
Any (>2 cm)	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Pain at the injection site[d]				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0 (0.0)	7 (0.6)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 6: Study 2 – Frequency and Percentages of Adolescents with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Fever				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
Headache[c]				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)
Chills[c]				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Vomiting[d]				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0 (0.0)	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhea[e]				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
New or worsened muscle pain[c]				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0 (0.0)	6 (0.5)	2 (0.2)
New or worsened joint pain[c]				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0 (0.0)	4 (0.4)	0 (0.0)
Use of antipyretic or pain medication[f]	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

In the following analyses of Study 2 in adolescents 12 through 15 years of age (1,131 of whom received Pfizer-BioNTech COVID-19 Vaccine and 1,129 of whom received placebo), 98.3% of study participants had at least 30 days of follow-up after Dose 2.

Serious Adverse Events

Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients. There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 5.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 5.8% of placebo recipients. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy plausibly related to the study intervention were imbalanced, with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (7) vs. the placebo group (1). There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

6.2 Post Authorization Experience

The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Gastrointestinal Disorders: diarrhea, vomiting
Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS[7]

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the 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 (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

[7] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12 through 18 years of age is based on safety and effectiveness data in this age group and in adults.

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 12 years of age.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical*

Trial Results and Supporting Data for EUA (18.1)]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

11.5 Use in Immunocompromised

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, safety and effectiveness of a third dose of the Pfizer-BioNTech COVID-19 vaccine have been evaluated in persons that received solid organ transplants. The administration of a third dose of vaccine appears to be only moderately effective in increasing potentially protective antibody titers. Patients should still be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

13 DESCRIPTION

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. Each 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, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants

with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion of Study 2, based on data accrued through November 14, 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 7 presents the specific demographic characteristics in the studied population.

Table 7: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	**Placebo (N=18,379) n (%)**
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years[b]	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[c]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[d]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. 100 participants 12 through 15 years of age with limited follow-up in the randomized population received at least one dose (49 in the vaccine group and 51 in the placebo group). Some of these participants were included in the efficacy evaluation

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)

depending on the population analyzed. They contributed to exposure information but with no confirmed COVID-19 cases, and did not affect efficacy conclusions.

c. Includes multiracial and not reported.

d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index ≥30 kg/m^2)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 8.

Table 8: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 through 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]

First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 through 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. No confirmed cases were identified in adolescents 12 through 15 years of age.
f. Credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

18.2 Efficacy in Adolescents 12 Through 15 Years of Age

A descriptive efficacy analysis of Study 2 has been performed in approximately 2,200 adolescents 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cutoff date of March 13, 2021.

The efficacy information in adolescents 12 through 15 years of age is presented in Table 9.

Table 9: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1005 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=978 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 through 15 years of age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)
First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1119 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=1110 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 through 15 years of age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

18.3 Immunogenicity in Adolescents 12 Through 15 Years of Age

In Study 2, an analysis of SARS-CoV-2 50% neutralizing titers 1 month after Dose 2 in a randomly selected subset of participants demonstrated non-inferior immune responses (within 1.5-fold) comparing adolescents 12 through 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2 (Table 10).

Table 10: Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Adolescents 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) –Participants Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine			
		12 Through 15 Years n[a]=190	16 Through 25 Years n[a]=170	12 Through 15 Years/ 16 Through 25 Years	
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Noninferiority Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1 month after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. Protocol-specified timing for blood sample collection.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12 through 15 years of age] – Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
e. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
f. SARS-CoV-2 50% neutralization titers (NT50) were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

18.4 Immunogenicity in Solid Organ Transplant Recipients

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, a single arm study has been conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously. 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. Among the 59 patients who had been seronegative before the third dose, 26 (44%) were seropositive at 4 weeks after the third dose. All 40 patients who had been seropositive before the third dose were still seropositive 4 weeks later. The prevalence of anti-SARS-CoV-2 antibodies was 68% (67 of 99 patients) 4 weeks after the third dose.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2). After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information

regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90ºC to -60ºC (-130ºF to -76ºF) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90ºC to -60ºC (-130ºF to -76ºF) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date		Updated Expiry Date
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

If not stored between -90ºC to -60ºC (-130ºF to -76ºF), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF).

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Vaccine Information Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1457-11.4

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U.S. FOOD & DRUG ADMINISTRATION

August 23, 2021

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 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 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).

[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 the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 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 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved 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 to update 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).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. 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.[8]

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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] 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.

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 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 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 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 or 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.

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 a two-dose regimen for individuals aged 12 through 15 years, or

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.

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:

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[9] alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[10]

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),[11] to emergency response stakeholders[12] as directed by the U.S.

[9] 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 that are approved to provide an additional dose to the immunocompromised population described in this EUA.

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

[11] "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.

[12] 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

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[13] and used only to prevent COVID-19 in individuals ages 12 and older; 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, or 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.

Product Description

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.

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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.

[13] 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).

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be administered at least 28 days following the second dose of the two dose regimen of this vaccine 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.

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, 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 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.[14]

[14] 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, 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), 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. This authorization thus remains in place with respect to that product for the previously-authorized indication and uses (i.e., for use to prevent COVID-19 in individuals 12 years of age and older with a two-dose regimen, and 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).

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, or 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. 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures