IN THE COURT OF APPEALS OF THE STATE OF OREGON

FREE OREGON, INC. and MANDATE FREE OREGON, INC., Oregon non-profit corporations; DOCTORS FOR FREEDOM, an unincorporated association; HEALTH FREEDOM DEFENSE FUND; and TAMARA DIMMICK; RASA SIDAGYTE; MICHELLE DAVIS; LISA NAVE; CHARLOTTE PERSINGER; CHRYSTAL GERVAIS; AARON HARRIS; ROY MCGRATH; GLENN CAMPBELL; JESSICA COX; BRITTANY WILSON; JOSHUA WILLIAMS; and MOLLY VALDEZ, individuals, Petitioners, v. OREGON HEALTH AUTHORITY, Respondent.	CA A176977

PETITIONERS' OPENING BRIEF

Petition for Judicial Review of Temporary Administrative Orders PH 39-2021 and PH 42-2021, and OAR 333-019-1010 and -1030

Continued…

TYLER D. SMITH #075287
YASHA RENNER #134681
Tyler Smith & Associates PC
181 N. Grant Street, Suite 212
Canby, OR 97013
Telephone: (503) 266-5590
Email:
tyler@ruralbusinessattorneys.com
yasha@ruralbusinessattorneys.com

Attorneys for Petitioners

ELLEN F. ROSENBLUM #753239
Attorney General
BENJAMIN GUTMAN #160599
Solicitor General
1162 Court St. NE
Salem, OR 97301-4096
Telephone: (503) 378-4402
Email:
benjamin.gutman@doj.state.or.us

Attorneys for Respondent

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STATEMENT OF THE CASE

1. Nature of the action and relief sought

Respondent Oregon Health Authority ("OHA") has adopted twin emergency public health orders requiring, with certain exceptions, some population sectors to be vaccinated against COVID-19. The vaccination orders for healthcare providers (codified at OAR 333-019-1010) and for educators (codified at OAR 333-019-1030) are collectively referred to herein as the "Rules." This is an action under ORS 183.400 for judicial review of the Rules. This Court is asked to invalidate the Rules, declaring them unlawful and without force.

2. Nature of the judgment

This case presents a challenge to the validity of administrative rules, rather than an appeal of a judgment.

3. Basis of appellate jurisdiction

This Court has jurisdiction under ORS 183.400(1) and Petitioners are persons with standing. *See* ORS 183.310(8); *Kellas v. Dep't of Corrections*, 341 Or 471, 145 P3d 139 (2006).

4. Effective date for appellate purposes

Neither ORS 183.400(1) nor the Oregon Rules of Appellate Procedure specify any time limitation to challenge the validity of an administrative rule. As amended,

the Rules were adopted August 25, 2021, and September 1, 2021, respectively. This petition for judicial review was timely filed on September 27, 2021.

5. Questions presented

(1) Whether the Rules are authorized by ORS 413.042, ORS 431A.010, ORS 431.110, and ORS 433.004.

(2) Whether the Rules are ultra vires under ORS 431.180.

(3) Whether the Rules are ultra vires under ORS 433.416.

(4) Whether the Rules are preempted by 21 USC § 360bbb-3.

(5) Whether the Rules violate the doctrine of separation of powers under the Oregon Constitution.

(6) Whether the Rules violate procedural due process rights under the United States Constitution.

(7) Whether the Rules violate the Contract Clause of the Oregon Constitution.

6. Summary of the arguments

The Rules are invalid under ORS 183.400(4) because they are not authorized by the agency's enabling statutes, but rather conflict with other applicable statutes regarding the same subject matter: ORS 431A.015, ORS 433.416, and ORS 433.267. Moreover, the Rules are in derogation of ORS 431.180(1) and thus exceed OHA's statutory authority.

In addition, the Rules violate the Supremacy Clause and Due Process Clause of the United States Constitution, as well as the Contract Clause and the separation of powers in Article III, section 1, of the Oregon Constitution.

7. Summary of the facts

Petitioners are domestic nonprofit corporations and various individuals, in their individual capacity or associated, who have been harmed by the Rules and are left without any other due process.

Petitioner Free Oregon, Inc. has more than 3,500 members who have been threatened with termination from employment because of the Rules and who have been deprived of their rights, under state and federal law, to freely choose their preferred medical treatments. *See* ER-1 to ER-3. Petitioner Mandate Free Oregon, Inc., has over 2,500 members similarly situated. *See* ER-18 to ER-22.

Other petitioners include one individual who suffered personal injury from a vaccine and, but for the Rules, would not have freely chosen to be vaccinated (*see* ER-22), as well as individuals with a constitutionally protected property interest in their public employment contracts (*see, e.g.*, ER-4 to ER-13).

FIRST ASSIGNMENT OF ERROR

A. Preservation of Error

This is a petition for judicial review under ORS 183.400 so preservation of error is not applicable here.

B. Standard of Review

This Court must declare the Rules invalid under ORS 183.400(4) only if they violate constitutional provisions, exceed OHA's statutory authority, or were adopted without compliance with applicable rulemaking procedures.

C. Arguments

(1) The Rules exceed OHA's statutory authority.

The Rules purport to be authorized by ORS 413.042, ORS 431A.010, ORS 431.110, and ORS 433.004. A careful review of those statutes shows they provide no such authorization.

ORS 413.042 provides general rulemaking authority but no authority to mandate vaccination or any other public health measure.

Next, ORS 431A.010(1) provides, in pertinent part, that OHA "shall have the power to enforce public health laws." Then follows a nonexclusive list of the agency's "enforcement powers." Notably, this section does not include any power to mandate vaccines or any other prophylaxis as a means of enforcing public health laws. Because this section only confers a general power to *enforce* (i.e., existing public health laws), logically, one must look elsewhere to determine the source and scope of OHA's rulemaking authority, as delegated by the legislature.

ORS 433.004 comes closer but is also inapposite. It provides that OHA "shall by rule" specify "reportable diseases" and establish who must report, and

how, as well as to "[p]rescribe measures and methods for investigating the source and controlling reportable diseases." ORS 433.004(1). A "reportable disease" is defined as a "disease or condition, the reporting of which enables a public health authority to take action to protect or to benefit the public health." ORS 431A.005(10); ORS 433.001(12). Thus, ORS 433.004 authorizes OHA to adopt rules that create a duty to report specified diseases that, upon reporting, triggers an investigation and prescribed public health measures. This is not, however, the type of rule at issue here. The Rules are not *reporting rules*, even if COVID-19 is a reportable disease (*cf.* OAR 333-018-0015), because there is no reporting requirement specified in the Rules and thus no follow-up investigation, source control, or other targeted public health measure. Accordingly, ORS 433.004 cannot be invoked to support the Rules.

Last but not least, ORS 431.110 specifies the general powers and duties of OHA. Since the foregoing sections do not provide the requisite authority, these emergency Rules must rise or fall on ORS 431.110. This section, however, is a rather modest grant of authority and it contains no express provision regarding vaccination. In the absence of clear legislative language, courts have declined to find authority to exercise powers not expressly granted. *See, e.g.*, *Gaynor v. Board of Parole & Post-Prison Supervision*, 165 Or App 609, 613, 996 P2d 1020 (2000) (agency without power to act outside its authority).

The only provision that could possibly authorize the Rules states that OHA has "full power in the control of all communicable diseases." ORS 431.110(7). But what does "full power" mean? Does it merely refer to the "enforcement powers" enumerated under ORS 431A.010, or does it confer additional (unwritten) powers? Clearly, it cannot mean that OHA may *overpower* the legislature by adopting rules that violate or supersede statute. In any case, if this subsection is to be invoked as delegating legislative power, then it contains no intelligible standard whatsoever and therefore violates the separation of powers in Article III, section 1, of the Oregon Constitution, as further explained in Part (3).

At a constitutional minimum, ORS 431.110(7) must be read in reference to OHA's enforcement powers, other relevant sections in ORS chapter 431, and elsewhere that set forth in express terms the manner in which Respondent may exercise its "control" power. By itself, however, ORS 431.110 does not authorize a public health order or administrative rule that requires individuals to be vaccinated, not even together with ORS 433.004 and ORS 431A.010. The statute is meant to emphasize the *fullness* of power vested in OHA regarding the means (control) and the subject (communicable diseases). For there are innumerable ways in which a communicable disease may be controlled, but not all such means are *ipso facto* lawful because of the power vested in OHA. As further explained in Part (1)(b), the word "control" discloses no standard, safeguard, or limitation under which

OHA may exercise its powers to the full. *Cf.* 71 Pa Const Stat § 532(a) (the Pennsylvania Department of Health "shall have the power, and its duty shall be" to "determine and employ the most efficient and practical means for the prevention and suppression of disease"), *cited in Corman et al. v. Acting Sec'y of Pa. Dep't of Health*, No 83 MAP 2021, 2021 Pa LEXIS 4348 (Pa Dec 10, 2021) (invalidating agency order requiring masking in schools as without statutory authority), *available at* https://cases.justia.com/pennsylvania/supreme-court/2021-83-map-2021-0.pdf.

In sum, the statutes cited in the Rules as purporting to authorize these twin orders all fall short of the legislative authority needed to justify an administrative rule imposing mandatory vaccinations.

(a) The Rules are ultra vires under ORS 431.180.

As a creature of statute, OHA has only those powers given it by the Oregon Legislative Assembly. *SAIF Corp. v. Shipley (In re Shipley)*, 326 Or 557, 561, 955 P2d 244 (1998) ("an agency has only those powers that the legislature grants and cannot exercise authority that it does not have"). OHA is vested with an important responsibility to promote the public health and control all communicable diseases. *See* ORS 431.110–431.120. Nevertheless, the legislature has expressly withdrawn certain subjects from the agency's purview, namely, an individual's private healthcare choices. ORS 431.180(1) provides, in pertinent part:

> Nothing in ORS 431.001 to 431.550 and 431.990 or any other public health law of this state shall be construed as authorizing the Oregon Health Authority or its representatives, or any local public health authority or its representatives, to interfere in any manner with an individual's right to select the physician, physician assistant, naturopathic physician or nurse practitioner of the individual's choice or the individual's choice of mode of treatment . . . .

Under ORS 431.180, OHA is powerless to "interfere in any manner with" personal healthcare choices, and not only the selection of one's provider but also, as applicable here, the "mode of treatment." Simply put, OHA cannot play doctor by prescribing the drugs and treatments it prefers against the private choices of individuals. But that is exactly what Respondent has done by adopting the Rules.

As amended over the years, ORS 431.180 represents a careful democratic judgment about the diverse character of the people of this state and, therefore, the *deference* owed by government to each individual on matters relating to his or her personal healthcare decisions. As such, the statute finely balances the interests of public health and of the individual. So while OHA has plenary authority over public health matters and the power to enforce public health laws, ORS 431.180 essentially stops all agency power at the point of interfering with individual healthcare choices.

In view of this express limitation, which has remained substantially unchanged since at least 1919 (notably, post *Jacobson*), the statutory text in context must be carefully analyzed. ORS 431.180(1) states that OHA may not

"interfere" with certain medical "choices," and that this interference may not be accomplished "in any manner." It would be difficult to write a limitation with wider scope than what the legislature has expressed in subsection (1). The word *interfere* is commonly defined as (i) "to enter into or take a part in the concerns of others"; or (ii) "to interpose in a way that hinders or impedes; come into collision or be in opposition." *Merriam-Webster*, https://www.merriam-webster.com/dictionary/interfere (last accessed Dec. 16, 2021).

According to this definition, the Rules are a hindrance and impediment to the freedom of choice provided under ORS 431.180(1), because some individuals who chose to be vaccinated *would not have done so* were it not for the mandate, such as Petitioner Molly Valdez who had a vaccine-related injury (*see* ER-22), while other Petitioners who have no intention of being vaccinated are forcefully *opposed* by an agency rule that prohibits their ability to return to work and earn a living (*see* ER-1, ER-18). True, Petitioners may still choose not to be vaccinated, but not without interference. For there to be an *interference*, it is not necessary that it actually result in prevention; one might reach the same decision in spite of another's interference. For example, a person seeking treatment at a clinic might be confronted at the door by a hostile bystander and yet enter, receiving the desired treatment notwithstanding. Healthcare providers, too, for example, may be more

(or less) inclined to openly discuss the risks and benefits of vaccination because of OHA's vaccination orders, and this too is a clear form of interference.

Without a doubt, the Rules *interfere* with (i.e., hinder, impede, oppose, and collide with) personal healthcare choices. At bottom, Petitioners wish to exercise personal responsibility for their own health care, without interference by unelected bureaucrats who, with all due respect, are not authorized by statute to interfere with that choice, and certainly not to impose their choice on others. As required by ORS 431.180, the difference between *public* health, which is the special competence of OHA, and the universe of *private* healthcare decisions must be strictly observed. With the latter, individuals are informed by the doctor-patient relationship, which in turn is subject to rules of medical ethics. Above all, the informed, voluntary consent of the patient, a fundamental ethical norm raised to the level of positive law, is essential. *See* ORS 677.097 (codifying the procedure to obtain informed consent). Consequently, no healthcare provider in this state may legally vaccinate a person without informed consent. Thus, within the sphere of the private individual, the legislative policy of this state, as expressed in ORS 431.180 and ORS 677.097, is undeniably in favor of personal liberty under the legal protection of informed consent. *See Mayor v. Dowsett*, 240 Or 196, 232, 400 P2d 234 (1965) ("It may be stated as a general rule that a physician who performs an operation or administers treatment to which his patient has not expressly or impliedly consented is guilty of

a technical battery."); *accord Washington v. Glucksberg*, 521 US 702, 725, 117 S Ct 2258 (1997) (observing "the common-law rule that forced medication [is] a battery"). And yet the very thing that healthcare providers are forbidden to do by law, OHA contends it is free to do without public comment, supervening every individual choice and the doctor-patient relationship in violation of ORS 431.180. As discussed in Part 2, this important statutory limitation on OHA's authority actually corresponds with a federally-enlarged right to informed consent under Section 564 of the Food, Drug, and Cosmetic Act (FD&C Act) (codified at 21 USC § 360bbb-3).

To the extent that the administration of a vaccine constitutes a mode of treatment, Respondent appears to concede the point. Instead, Respondent argues, unconvincingly, that no interference is taking place: "The rules merely require individuals to be vaccinated as a condition of working in certain settings . . . ." *Respondent's Response to Emergency Motion for Stay* at 13 (hereinafter "*Response*"). That is certainly true: restricting Petitioners' access to employment on condition of vaccination, as a means of coercing vaccine uptake, is the very definition of interference. The fact that OHA's interference is conditional with respect to persons and settings changes only the subject and direction of the interference; the law, however, prohibits OHA from interfering "in any manner." ORS 431.180(1).

Therefore, insofar as OHA is empowered under ORS 431.110 to "control" all communicable diseases, it may only do so according to its express enforcement powers (*see* ORS 431A.010) and any other authorized public health measures—sanitation, inspection, isolation and quarantine, testing, etc. *See* ORS 431A.005(9). As explained above, the Rules do not enforce any existing public health laws, but rather purport to create new legal requirements.

Although "treatment" is included in the definition of a "public health measure," that option appears to be available only under the limited conditions specified in ORS 431A.015. In response to a public health threat, the Public Health Director may require "a person" (i.e., a specific individual) to obtain treatment, but the statute also provides exemptions for medical, religious, and conscientious objections. ORS 431A.015(2)(d). So in that scenario, there is no conflict with ORS 431.180. At any rate, the Rules do not purport to be authorized by ORS 431A.015, which prescribes adequate safeguards to individuals who would be affected by administrative action. *See Warren v. Marion County*, 222 Or 307, 314, 353 P2d 257 (1960) (holding that statute authorizing the adoption of local building codes was not unlawful delegation of legislative power because, in addition to incorporating building standards, it also required a procedure to appeal contested cases). Had ORS 431A.015 been implemented, OHA could not have adopted the sweeping mandates it did. Given that no other statute expressly authorizes medical

treatments on individuals as a means of controlling a "disease outbreak, epidemic or other condition of public health importance," ORS 431A.015 is arguably the only one under which OHA may require emergency vaccinations, suggesting that the agency has implemented the wrong statute. *See* ORS 431A.015(4).

Indeed, rather than operating within the statutory framework and public health standards (and safeguards) already furnished by the Oregon legislature in the event of an epidemic, Respondent points to the "full power" clause in ORS 431.110 as a complete justification for its actions. This section, however, is not a *standard to be implemented*, nor is it a blank check to do any act or impose any restriction in the name of "public health." *See Warren*, 222 Or at 314 (opining that "we have learned that it is of little or no significance in the administration of a delegated power that the statute which generated it stated the permissible limits of its exercise in terms of such abstractions as . . . 'for the public health, safety, and morals' and similar phrases accepted as satisfying the standards requirement"). The Rules at issue here, adopted on little more than abstract legal phrases, are in direct conflict with ORS 431A.015. "It is elementary that, when an administrative rule cannot be reconciled with a statute, it is the statute that controls." *Smith v. Dep't of Corrections*, 276 Or App 862, 864, 369 P3d 1213 (2016) (quoting *State v. Newell*, 238 Or App 385, 392 (2010)). As the Oregon Supreme Court explained in *Smith*, "a rule is deemed to exceed its statutory authority not only if it exceeds the express

or implied authority of the statutes that the rule purports to implement, but also if the rule 'contravene[s] some other applicable statute.'" *Id.* (quoting *Planned Parenthood Assn. v. Dep't of Human Res.*, 297 Or 562, 565, 687 P2d 785 (1984) (alteration in original)).

Furthermore, to the extent that the Rules purport to exclude unvaccinated individuals from school facilities, the Rules are totally preempted by state law on required immunizations and disease control, *viz.*, ORS 433.235 to ORS 433.284. *See* Part 3 (separation of powers).

To avoid the conclusion that the Rules violate ORS 431.180(1), Respondent contends they are "sanitary" requirements under the limited exception provided in subsection (2).

What, therefore, is a sanitary requirement?

Respondent offers no explanation of its own or cites to any legal authority on the subject, yet is certain that mandatory vaccinations are such a requirement. Under Respondent's sanitation rationale, OHA could mandate the use of any drug from Tylenol to ivermectin if the agency believed it was necessary to control the spread of an infectious disease. It should be obvious that such medical mandates do not qualify as sanitary requirements.

On the contrary, the term "sanitation" is generally defined as the "use of measures designed to promote health and prevent disease; the development and

establishment of conditions in the environment favorable to health." *Illustrated Stedman's Medical Dictionary* 1253 (24th ed 1982); *id.* (defining "sanitary" as "[h]ealthful; conducive to health; usually in reference to a clean environment"); *Black's Law Dictionary* 933 (6th ed 1991) (defining "sanitation" as "[d]evising and applying of measures for preserving and promoting public health; removal or neutralization of elements injurious to health; practical application of sanitary science"). These definitions better accord with the historical meaning of the term and thus the one intended in ORS 431.180. *See, e.g.*, *Jacobson v. Massachusetts*, 197 US 11, 25 S Ct 358 (1905) (syllabus) ("Smallpox has ceased to be the scourge which it once was, and there is a growing tendency to resort to *sanitation and isolation rather than vaccination*.") (emphasis added). Notice the quotation just cited, in which the terms "sanitation" and "isolation" are categorically distinguished from "vaccination." This quotation comes from the 1905 syllabus of the Supreme Court's opinion in *Jacobson* and essentially restates the arguments of counsel in that case. This ought to be sufficient to refute Respondent's bare assertion, though additional examples of a sanitary law can be furnished from the Oregon case law. *See, e.g.*, *Sunshine Dairy v. Peterson*, 183 Or 305, 321–22, 193 P2d 543 (1948) ("Sanitary or other considerations may require that the use of various types of container should be regulated . . . ."); *Van Winkle v. Fred Meyer, Inc.*, 151 Or 455, 471, 49 P2d 1140 (1935) (stating that the "legislature, under the

police power, may pass any reasonable sanitary law to protect the public from the sale of impure or deleterious food products"); *Portland v. Traynor*, 94 Or 418, 426, 183 P 933 (1919) (environmental regulations such as "plumbing, water supply, ventilation and cleanliness" (quoting city ordinance imposing sanitation requirements for licensed food and soft drink establishments)); *Smith v. Silverton*, 71 Or 379, 142 P 609 (1914) (sanitary laws relating to water quality and pollution).

From the preceding authorities it should be evident that the Rules do not qualify as sanitary laws under any reasonable definition of the term. Nevertheless, Respondent proffers an alternative definition that is practically unlimited in scope. *See Response* at 13–14. Respondent's interpretation evinces an extreme view of OHA's authority that would give it authority to mandate drugs upon the entire population, so long as such drugs are "designed to secure or preserve health." *Id.* (quoting *Webster's New International Dictionary* 1878 (1909)). Respondent's interpretation, even if plausible, would lead to absurd results and should not be countenanced by this Court. *See Lozano v. Schlesinger*, 191 Or App 400, 406, 84 P3d 816 (2004) (explaining "the maxim of statutory construction that courts will attempt to avoid absurd results" in construing two plausible statutory interpretations).

(b) The Rules are ultra vires under ORS 433.416.

It has been argued elsewhere that ORS 433.416 "specifically contemplates" an agency rule that requires vaccination as a condition of work. *See* App-4. This interpretation is wrong because it neglects important factual and legal matters. As disclosed by the working drafts of Senate Bill 741 (1989),[1] the main purpose of the statute is to require worker notifications in the event of an actual exposure to an infectious disease, and to provide immunizations at no cost. Further, Respondent OHA is charged with implementing ORS 433.416 by the adoption of rules. *See* ORS 433.423. Here, the Rules were not adopted pursuant to ORS 433.423, which, unlike the authorities cited in the Rules, expressly covers the subject matter (i.e., healthcare workers at risk of exposure). Once again, it appears that OHA has purposely implemented the wrong statute, for had it done so, OHA could have only recommended vaccination—otherwise the statute would be self defeating. Hence, the conclusion above evades the legislative intent of the worker-immunization exemption. Basically, the fallacious argument is that ORS 433.416 prohibits vaccination as a condition of employment, *including by rules adopted by OHA under this section*, unless OHA requires vaccination as a condition of employment. The exception swallows the rule under this construction, erasing subsection (3) altogether.

[1] Available at http://records.sos.state.or.us/ORSOSWebDrawer/RecordView/7901751.

In Petitioners' view, the phrase "otherwise required" is not as broad as that; rather, it means that vaccination may be required *otherwise than* as a condition of work. The "unless" clause grammatically refers to the subject of the preceding clause: "A worker shall not be required as a condition of work to be immunized under this section," that is, when a healthcare worker is "at risk of contracting an infections disease in the course of employment." ORS 433.416(1). As applicable, Petitioners are healthcare workers "at risk of contracting" COVID-19 in the course of employment, and so this statute is squarely on point, and yet the Rules require vaccination as a condition of work.

(2) The Rules are preempted by federal law and FDA regulations.

(a) The Rules violate and conflict with the federal law on emergency use authorizations (EUA)

The Supremacy Clause of the United States Constitution, Article VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. *Gibbons v. Ogden*, 9 Wheat 1, 211 (1824) (Marshall, C.J.). In the absence of express preemptive language in a federal statue or regulation, courts have recognized the doctrine of conflict preemption. To the extent that state law actually conflicts with federal law, the former must yield to the latter. As explained by the United States Supreme Court, "[s]uch a conflict arises when 'compliance with both federal and state regulation is a physical impossibility' or when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of

Congress[.]'" *Hillsborough County v. Automated Medical Labs.*, 471 US 707, 105 S Ct 2371 (1985) (citations omitted).

As discussed in Part (2)(b), state vaccine mandates are precluded by federal law when the product is subject to EUA. The prior-consent requirement under 21 USC § 360bbb-3 is a *condition* of authorization that cannot be infringed without disqualifying the product from the exception as a whole.

By attempting to mandate an unlicensed vaccine that is the subject of strict federal regulation under EUA, Respondent has unlawfully conditioned—and therefore infringed—the exercise of the federal right to refuse an EUA vaccine. So even assuming the argument—viz., that prior informed consent is only required at the doctor-patient level—that right would be a nullity since it cannot be exercised without adverse employment consequences. The Rules must be preempted because they stand as an obstacle to the extraordinary objectives of Congress in providing a regulatory shortcut for the interstate distribution of unlicensed experimental drugs. Otherwise, OHA could, in principle, circumvent any other condition of authorization, such as eligibility requirements, thereby substituting its own judgment for that of Congress and the FDA. *See* 21 USC § 360bbb-3(e)(1)(A) (providing for conditions "appropriate to protect the public health").

"Federal regulations have no less pre-emptive effect than federal statutes." *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 US 141, 153–54 102 S Ct 3014

(1982); *see, e.g.*, *Dusek v. Pfizer Inc.*, Civ A No 02-3559, 2004 US Dist LEXIS 28056, 2004 WL 2191804, at (SD Tex Feb 20 2004) ("State requirements actually conflicting with a *standard implemented by the FDA* are preempted, whether an express preemption clause exists in the FDCA or not.") (emphasis added).

Here, the Rules conflict with federal regulations because they purport to supersede (or allow third parties to violate) the conditions required for EUA. The prior-consent requirement under 21 USC § 360bbb-3(e) is a precise "standard" implemented by the FDA when the agency fashions the totality of the EUA for a particular medical product. As such, FDA's implementation of federal law preempts any conflicting agency standard implemented under state law—and this is true even if Respondent is not directly subject to 21 USC § 360bbb-3. *See id*; *de la Cuesta*, 458 US at 154 ("A pre-emptive regulation's force does not depend on express congressional authorization to displace state law[.]").

The Public Health Service Act of 1944 (PHS Act), 78 Pub L 410, 58 Stat 682 (codified as amended at 42 USC ch 6A), under which biological products are licensed and regulated, generally poses no preemption issues with respect to state laws imposing additional or stricter requirements that do not conflict with the federal regulatory scheme. *See Hillsborough Cnty.*, 471 US 707 (holding that local government standards for collecting blood plasma were not preempted by FDA regulations). In addition, state tort laws are generally not preempted. *See, e.g.*,

Hurley v. Lederle Labs., 863 F2d 1173 (5th Cir 1988) (holding that state law claim alleging vaccine-related injury to child was not preempted by PHS Act); *Jones v. Lederle Labs.*, 695 F Supp 700 (EDNY 1988) (state law claim alleging defecting design of pertussis vaccine).

Here, the Rules do not impose stricter consent requirements but, rather, ignore what is minimally required by the EUA/FDA, creating an irreconcilable conflict between the two. Save for medical and religious exceptions, the Rules require individual compliance under penalty of law. *See* OAR 333-019-1010(4) (imposing on individual persons a legal duty to provide "proof of vaccination"); OAR 333-019-1030(4), (8) (same). Thus, a person who exercises the federal right to refuse an EUA vaccine is *ipso facto* noncompliant with the Rules. The Rules erase a substantial right provided by federal law by imposing a *duty* on the same subject, namely, the right to refuse an EUA vaccine without exception.

(b) The scope of informed consent required by federal law for EUA biological products under 21 USC § 360bbb-3 includes the right to refuse without penalty.

Under the federal law of EUA, individuals who are eligible to be vaccinated must be "informed . . . 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 USC § 360bbb-3(e).

It is beyond question that this provision of the EUA law creates a prior-consent requirement under federal law; the only issue, which has not been well settled, is the scope and application of the requirement. *Compare Doe v. Rumsfeld*, 297 F Supp 2d 119 (D DC 2003), *Doe v. Austin*, No. 3:21-cv-1211-AW-HTC, ___ F Supp 3d ___, 2021 US Dist LEXIS 236327 (ND Fla Nov 12, 2021), *and Navy Seal 1 v. Biden*, No. 8:21-cv-2429-SDM-TGW, 2021 US Dist LEXIS 224656 (MD Fl Nov 22, 2021), *with Klaasen v. Trustees of Ind. Univ.*, No. 1:21-CV-238 DRL, ___ F Supp 3d ___, 2021 US Dist LEXIS 133300 (ND Ind July 18, 2021), *aff'd*, 7 4th 592 (7th Cir 2021), *Valdez v. Grisham*, No. 21-cv-783 MV/JHR, ___ F Supp 3d ___, 2021 US Dist LEXIS 173680 (DNM Sept 13, 2021), *and Rhoades v. Savannah River Nuclear Sols., LLC*, No. 1:21-cv-03391-JMC, 2021 US Dist LEXIS 231844 (D SC Dec 3, 2021).

Therefore, it must be asked why the Congress of the United States created a *federal* requirement for obtaining informed consent when state laws on the subject are ubiquitous and already sufficient for that purpose. *See, e.g.*, ORS 677.097. The best answer is the one presupposed by the federal district court in *Doe v. Rumsfeld*. In that case, the court held that unlicensed investigational drugs (including *a fortiori* those under EUA) could not be mandated by the Department of Defense (DOD) as a matter of law, *that is, from the top down*, via military order, and not just between the doctor and patient. *See Rumsfeld*, 297 F Supp 2d at 134–35; *see*

also Petitioners' Reply in Support of Emergency Stay Motion at 18–20 (quoting legislative history).

If *Rumsfeld* was correctly decided, the unstated premise is that the coercive effect of DOD's vaccine mandate, like OHA's, vitiates consent as a matter of law, analogous to, for example, a prior restraint on free speech. In prior-restraint cases, the speaker is not forcibly silenced, as one might be forcibly vaccinated. Rather, it is the force of law that silences, or hopes to silence. As the right to free speech is protected from prior restraints, so too the federally-enlarged right to informed consent under EUA, includes a right intended by Congress to shield individuals from legal mandates and allow them to refuse administration of an experimental drug with impunity. Unlike vaccines that are fully tested and licensed by the FDA, biological products under the protective cloak of EUA are, in fact, experimental in their stage of development. *See* 21 USC § 360bbb-3(c), (k); *Rumsfeld*, 297 F Supp 2d at 122, 134. *See generally Abdullah v. Pfizer Inc.*, 562 F3d 163 (2nd Cir 2009).

Consequently, the individual's right to informed consent under federal law cannot be exercised vicariously, nor can the corresponding duty to personally ascertain the quality of consent be delegated to another. *Cf.* ORS 436.225 (requisite consent for sterilization may not be given by a natural parent, legal guardian, or conservator of a minor child or protected person). The primary purpose of the federal law of EUA is to allow experimental drugs and medical products to be

introduced into interstate commerce in a declared emergency. 21 USC § 360bbb-3(b). Without enlarging the scope of informed consent (i.e., to mean a nondelegable voluntary consent), as Congress certainly intended, there is no practical difference between an approved medical product, which is licensed for use in interstate commerce, and an experimental product, otherwise considered to be a clinical investigation subject to strict regulation. 21 USC § 360bbb-3(k).

The holding in *Rumsfeld* is only justified by the court's implicit rationale, from which the rule of law is inferred, that voluntary informed consent without any form of coercion is required under federal law. In *Rumsfeld*, the plaintiffs were ordered to submit to vaccination; like the Petitioners, they could have refused and suffered the consequences, a superficial observation which has insulated the issue from judicial scrutiny in some jurisdictions. *See, e.g.*, *Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 US Dist LEXIS 110382 (SD Tex June 12, 2021). The court in *Rumsfeld*, however, would not have been persuaded by that kind of rhetoric when legal sanctions are used to obtain compliance. *Rumsfeld*, 297 F Supp 2d at 135 (holding that "requiring a person to submit to an inoculation *without informed consent* or a presidential waiver is an irreparable harm for which there is no monetary relief") (emphasis added).

The solitary exception to the *Rumsfeld* rule is a presidential waiver in cases involving members of the armed forces and threats to national security. 10 USC §

1107(f) (investigational new drugs); 10 USC § 1107a (EUA). And that is why even now, the only vaccines required by the DOD are those licensed by the FDA, as opposed to EUA biologicals. Thus, the court in *Doe v. Austin* denied the servicemembers' motion for a preliminary injunction—not because vaccines under EUA can be mandated—but rather because the "DOD acknowledge[d] that the President has not executed a waiver under this section [10 USC § 1107a] . . . so as things now stand, the DOD cannot mandate vaccines that only have an EUA." *Austin*, 2021 US Dist LEXIS 236327 at *13–14. Of course, the same rule applies to Respondent OHA, which has mandated unlicensed vaccines that only have an EUA or face legal consequences—here, the deprivation of gainful employment.

Therefore, to the extent that the Rules purport to mandate any vaccine other than Comirnaty, they violate both the informed-consent requirement under federal law—a "statutory right to refuse" according to the court's opinion in *Austin*—and ORS 431.180, which incorporates that right and further guarantees that OHA will not interfere with the freedom of choice under Oregon law.

(c) OHA is a "person" who carries out EUA activity

While 21 USC § 360bbb-3 does not create a private right of action, OHA is nonetheless directly subject to the prior-consent requirement. The statute expressly applies to "a person who carries out an activity for which an authorization under this section is issued." 21 USC § 360bbb-3(*l*). The phrase "an activity" cannot be

confined solely to the end users, since it is obvious that drug manufacturers are also persons who carry out EUA activity. As for Respondent, OHA is deemed an "emergency stakeholder" as defined in the FDA's letters of authorization and thus carries out EUA activity no less than the vaccination providers. *See* ER-72 n12; *Petitioners' Emergency Motion to Stay Enforcement of Rule Pending Review* at 17–20 (hereinafter *Petitioners' Motion to Stay*). Consequently, Respondent must confine its activity to the scope and conditions of authorization.

A few courts have concluded that the prior-consent requirement under 21 USC § 360bbb-3(e) only applies to the person actually administering the vaccine (i.e., the healthcare provider). *See, e.g.*, *Bridges*, 2021 US Dist LEXIS 110382, at *7. These decisions are at odds with weightier precedents. If true, that argument would have been dispositive in *Doe v. Austin*, since the DOD's vaccine mandate, like OHA's and every other, must be mediated through a qualified provider who performs the actual injection. In every instance, the person ordered or required to be vaccinated may refuse the vaccine, and yet the DOD has twice acknowledged that it cannot mandate an EUA vaccine. *Austin*, 2021 US Dist LEXIS 236327, at * 13–14; *Navy Seal 1 v. Biden*, No. 8:21-cv-2429-SDM-TGW, 2021 US Dist LEXIS 224656, at *7 (MD Fl Nov 22, 2021).

In *Klaassen*, a case involving a university mandate, the court's opinion contains no analysis of this issue because the "students admit[ted] that the

informed consent requirement under the EUA statute only applies to medical providers." *Klaasen*, 2021 US Dist LEXIS at *64–65. The court's dictum was then quoted as controlling authority in *Valdez v. Grisham*, 2021 US Dist LEXIS at *13–14, a case against the New Mexico Department of Health, and again in *Rhoades v. Savannah River Nuclear Sols., LLC*, No. 1:21-cv-03391-JMC, 2021 US Dist LEXIS 231844 (D SC Dec 3, 2021), a case against a private entity. Besides these cases, Petitioners are not aware of any case that has closely analyzed the issue or expressly holds that states need not comply with federal EUA laws.

Klaasen and *Valdez* cannot be reconciled with the plain text of 21 USC § 360bbb-3(*l*) or the holdings in *Rumsfeld* and more recently in *Austin*. As these courts both presupposed, it is not a valid argument that a state or federal actor may simply disclaim responsibility (or aver compliance) by circumscribing the legal analysis to the lowest possible level of human interaction—that is, by positing that one can still decline to be vaccinated although the government has attached grave economic consequences to the free exercise of a personal liberty and fundamental right. *Cruzan v. Director, Mo. Dep't of Health*, 497 US 261, 278, 110 S Ct 2841 (1990) ("The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions."). On the contrary, the element of coercion, which so undermines the federal right to informed consent, must be tested at the font of its power (i.e.,

the mandate, order, directive, etc.). *Cf. Pitre v. Cain*, 562 US 992, 131 S Ct 8 (2010) (Sotomayor, J., dissenting from denial of cert.) (opining that a prisoner's "right to refuse HIV medication . . . would not permit respondents to punish [plaintiff], or to attempt to coerce him to take medication") (quotation marks omitted).

Further, as strongly suggested in *Austin*, 2021 US Dist LEXIS 236327 at *15, a correct analysis must first recall the doctrine of federal supremacy and the *default rule* lest it be forgotten in the details of the exception. And the rule is simply this: "No person shall introduce or deliver for introduction into interstate commerce" any new drug or biological product unless licensed by the FDA as provided under federal law. 42 USC § 262(a) (biological products); 21 USC § 355(a) (new drugs). Consequently, states are ordinarily precluded from mandating unlicensed biological products as a matter of federal supremacy.

EUA, on the other hand, is an *exception* to the rule. *See* 21 USC § 360bbb-3 (authorizing the introduction into interstate commerce drugs, devices, or biological products for use in an actual or potential emergency "subject to the provisions of this section"). The terms and conditions provided under federal law and further specified by the FDA in connection with a particular EUA *constitute the exception as a whole*. *See* 21 USC § 360bbb-3(k)–(*l*). Because the terms and conditions of EUA are "baked into" the exception, any activity that is not strictly confined to

EUA activity, but rather exceeds it, remains proscribed by 42 USC § 262(a). Without EUA, an unlicensed biological product is simply unavailable—it does not legally exist. And therefore, it should go without saying that no public (or private entity) can mandate that which does not legally exist, since the very subject matter of the intended mandate is not licensed for distribution to the American public. If the DOD cannot legally mandate vaccines under EUA, neither can Respondent.

(d) The curious case of Comirnaty

The only COVID vaccine not subject to the federal law of prior informed consent is Pfizer's Comirnaty. As discussed above, the district court in *Doe v. Austin* understood the difference between an EUA product, which could not be mandated, and a licensed product. As conceded by the DOD, vials labeled "Comirnaty" are generally unavailable in the U.S. market.[2] In fact, the DOD admitted that it was administering "vaccines from EUA-labeled vials." *Austin*, 2021 US Dist LEXIS 236327 at *14. And like Respondent's arguments in this case, *see Response* at 16 & n 2, the defendants in *Austin* believed "that is fine because the contents of EUA-labeled vials are chemically identical to the contents

[2] According to the Centers for Disease Control and Prevention, "COMIRNATY products are not orderable at this time." CDC, *COVID-19 Vaccine Related Codes*, https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html. "At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution." *Id.*

of vials labeled 'Comirnaty' (if there are any such vials)." *Austin*, 2021 US Dist LEXIS 236327 at *15 ("DOD argues that once the FDA licensed Comirnaty, all EUA-labeled vials essentially became Comirnaty, even if not so labeled"). The court was not convinced by this interpretation. "For starters," the court explained, "FDA licensure does not retroactively apply to vials shipped before BLA approval." *Austin*, 2021 US Dist LEXIS 236327 at *15 (citing 21 USC § 355(a)). Consequently, all such vials shipped before August 23, 2021, if any remain in the state's inventory, are permanently under EUA and cannot be mandated by the Rules. For vials shipped after the date of approval, the court explained that "the [legal] distinction is more than mere labeling: to be BLA compliant, the drug must be produced at approved facilities . . . and there is no indication that all EUA-labeled vials are from BLA-approved facilities." *Austin*, 2021 US Dist LEXIS 236327 at *16 (noting that "DOD concedes that some of its current vials are not BLA-compliant, and that there is no policy to ensure that servicemembers get only BLA-compliant vaccines"). The court's opinion accords with the FDA's letters of authorization, which clarify in a footnote that while the licensed vaccine has the same formulation as the EUA-authorized vaccine, the "products are legally distinct." ER-69 n8; *see Petitioners' Motion to Stay* at 36–39. The only reason the *Austin* court denied the plaintiffs' motion was because the DOD could affirm that it was, in fact, administering "BLA-compliant" vaccine albeit EUA-labeled.

Unlike the DOD's vaccine mandate, the Rules adopted by OHA make no distinction between licensed and unlicensed vaccines (the rules only refer to doses). Thus, as applied to the single-dose vaccine (viz., Janssen), the Rules are facially unlawful. And as for the two-dose vaccines (viz., Moderna and Pfizer), the Rules are fatally overly broad because they conflict with, and are preempted by, the prior-consent requirement under 21 USC § 360bbb-3. At a minimum, only FDA-licensed vaccine can be mandated by OHA—assuming it has the statutory authority to do so—and this requirement must be expressed in writing in any future rules so that only licensed or BLA-compliant vaccine may be administered.

(3) The Rules violate the principle of separation of powers.

The Rules adopted by OHA are unconstitutional because they conflict with and abrogate statutes. As an agency, OHA does not have legislative authority.

Until very recently, there were no "vaccine mandates" in the State of Oregon with the exception of childhood vaccines for "restrictable diseases" as a condition to attend school in grades K-12. As a rule, adults were free to work, even in healthcare, without any required vaccinations. *See* ORS 433.416. Unlike OHA's vaccine mandates, however, mandatory school-vaccination laws were enacted by the Oregon legislature. *See* ORS 433.235–433.284. And unlike OHA's vaccine mandates, the legislature expressly authorized OHA to adopt rules to implement the state's public policy, giving the agency clear standards to follow. *See* ORS

433.273; OAR ch 333, div 50. Further, unless actually sick (or suspected to be), no child could be excluded from school or loaded with special burdens because he or she declined to be vaccinated. *See* ORS 433.255–433.260; ORS 433.267 (providing medical, religious, and philosophical exemptions).

Respondent, on the other hand, has done something truly unprecedented and without any express statutory authority. Besides OHA's school-immunization rules (OAR ch 333, div 50), there were no other agency rules mandating vaccines until 2021. In light of the only existing public policy on mandatory vaccination, it should be evident that OHA has adopted Rules that are far more restrictive, and far more injurious to civil liberties, than the comparable statutes enacted by the Oregon legislature. In particular, OAR 333-019-1030 requires *exclusion* of unvaccinated teachers and other employees who do not have a documented medical or religious exception. State statute, on the other hand, only permits this outcome under strict conditions: "Except in strict conformity with the rules of the Oregon Health Authority, no child *or employee* shall be permitted to be in any school or children's facility when" the employee "has any restrictable disease" or "comes from any house in which exists any restrictable disease." ORS 433.255(1)–(2) (emphasis added).

Under ORS 433.267, the proper authority who may require the exclusion of employees is not OHA, but rather the "administrator"—that is, the "principal or

other person having general control and supervision of a school or children's facility." ORS 433.235(1). The administrator's power to exclude can only be exercised if the employee was, in fact, "exposed" to a restrictable disease or if the administrator "has reason to suspect" that he or she was exposed. ORS 433.267(1). Further, it is not absolutely necessary to exclude even exposed employees, as may be determined by the local health officer. *See* OAR 333-019-0010(5)–(6). And that is the sum total of the legislature's vaccine mandate as pertaining to the exclusion of school employees, a public policy which OHA is charged with implementing. *See* ORS 433.273. OHA's attempt to abrogate existing state statute via temporary rulemaking is unconstitutional.

Of course, COVID-19 is a restrictable disease. *See* OAR 333-050-0010(26); OAR 333-019-0010(1)(c)(B). The Rules, however, cannot be reconciled with the statutory framework, which, first of all, does not require adults or employees to be vaccinated against any "restrictable disease" as a condition of working in schools (or in healthcare settings). As applied to children, the statutes provide generous exemptions, including what could be called a "personal" exemption to decline vaccination without any stated reason. ORS 433.267(1)(c).

Moreover, the Rules cannot be reconciled with the statutory "exposure" requirement, even under OHA's new definition of exposure. *See* OAR 333-019-0010(1)(b). In an apparent attempt to harmonize the COVID vaccine mandate for

schools with the statutory scheme, OHA has unconstitutionally enlarged the legislative standard of "exposure" by creating a new "susceptibility" standard, which incorporates the Rules by a tacit reference under the guise of "evidence of immunity." *See* OAR 333-019-0010(1)(a)(E). All this, however, is mere word play. As defined in the rule, the term "susceptible" is simply a container for the term "evidence of immunity," which is defined as follows:

> "(i) Having received a complete series of COVID-19 vaccine as recommended by the Centers for Disease Control and Prevention;
> (ii) Having received a dose of COVID-19 vaccine after having documented SARS-CoV-2 infection; or
> (iii) Having had laboratory-confirmed SARS-CoV-2 infection within the preceding 90 days."

OAR 333-019-0010(1)(a)(E).

Thus, with the mere stroke of a pen, the legislative "exposure" standard is partly converted into one of the vaccine mandates at issue here. Being *exposed* to something is not the same as being *susceptible* to exposure, nor even reasonably related concepts, and in no way is it the same as being vaccinated; they are objectively different facts, the truth of which cannot be assailed without doing violence to the state's public policy allowing children to attend school without the recommended vaccinations—and no special reason or justification need be given. *See* ORS 433.267. As noted above, the mere fact that a child is unvaccinated is not synonymous with the requisite "exposure" defined under Oregon law. So too with school employees.

Because the Oregon legislature has not authorized OHA to categorically exclude school employees on the basis of their vaccination status, OAR 333-019-1030 is clearly unconstitutional, as it exceeds the agency's statutory authority to implement. *Cf. Let Them Choose v. San Diego Unified School District*, No. 37-2021-43172-CU-WM-CTL (Superior Ct Ca Dec 20, 2021) (invalidating vaccine mandate adopted by school district without a "personal belief exemption" because preempted by statutory scheme requiring vaccination in schools), *available at* App-8 to -11.

Clearly, Respondent has many legitimate powers related to public health and to control disease, but there is no legislative authority, delegated or otherwise, that comes close to authorizing OHA's sweeping vaccine mandates, neither the school mandate nor the healthcare-setting mandate. Respondent is charged with enforcing the state's public health laws and policies, not to write them. Indeed, the Rules constitute *legislative fiat* and must be declared unconstitutional.

Based on prior case law, vaccine mandates may come within the state's police power but, for that very reason, are the prerogative of legislative authority. *See, e.g.*, *Jacobson v. Massachusetts*, 197 US 11, 25, 25 S Ct 358 (1905) ("the police power of a State must be held to embrace, at least, such reasonable regulations *established directly by legislative enactment* as will protect the public health") (emphasis added). Without an explicit legislative mandate, as there is with

compulsory vaccinations to attend school, Respondent OHA simply cannot mandate vaccines (even licensed vaccines) under the conditions prescribed in the Rules, and as a matter of historical fact has not done so until now.

(4) The Rules violate procedural due process requirements

The Fourteenth Amendment to the U.S. Constitution provides that no state shall "deprive any person of life, liberty, or property, without due process of law." US Const, Amend IV, § 1. "Before the state deprives someone of a protected property interest, 'the right to some kind of prior hearing is paramount.'" *Blantz v. Cal. Dep't of Corr. & Rehab.*, 727 F3d 917, 922 (9th Cir 2013) (quoting *Bd. of Regents of State Colleges v. Roth*, 408 US 564, 569–70, 92 S Ct 2701 (1972)).

"State law defines the interest, but federal constitutional law determines whether an underlying property interest rises to the level of a legitimate claim of entitlement protected by the Due Process Clause." *Maddox v. Clackamas Cnty. School Dist.*, 293 Or 27, 37, 643 P2d 1253 (1982) (quotation marks omitted) (quoting *Memphis Light, Gas & Water Div. v. Craft*, 436 US 1, 9, 98 S Ct 1554 (1978)).

Here, the property interest implicated by the Rules and claimed by a number of Petitioners is that of continuing employment, specifically in the fields of health care, public education, and law enforcement. To claim a protected property interest, a merely "unilateral expectation" of continued employment is insufficient;

rather, the person must demonstrate a legitimate claim of entitlement. *Blantz*, 727 F3d at 922. "Governmental deprivation of such a property interest must be accompanied by at least minimal procedural protections including some form of notice of the contemplated action and some sort of opportunity to be heard if that action is contested." *Tupper v. Fairview Hospital & Training Ctr.*, 276 Or 657, 662, 556 P2d 1340 (1976).

It is well established that government employees have a protected property interest in continued employment "if the terms of the employment make it clear that the employee can be fired only for cause." *Blantz*, 727 F3d at 922. Thus, for example, the Oregon Supreme Court held in *Maddox* that an elementary school teacher had a property interest in a probationary employment contract for a one-year term because the contract was subject to a "good faith" standard for termination under state law. *Maddox*, 293 Or at 36 (noting that the "United States Supreme Court cases which have found a property right in public employment have involved individuals who could be dismissed only for 'cause.'") (citing cases).

Here, the Rules mandate a predetermined outcome without any right to a hearing, neither pre-deprivation nor post-deprivation. Petitioner Jessica Cox, for example, who has been placed on unpaid leave since the compliance deadline of October 18, 2021, has a two-year employment contract with her public employer,

an education service district. *See* ER-10. Like the teacher in *Maddox*, Petitioner Cox has a protected property interest in continued employment under the terms of her employment contract and under state law. *See* ORS 342.865; ORS 342.835. Respondent, a state actor, has deprived Petitioner Cox of that property interest via the Rules and without any opportunity to be heard.

In addition, Petitioners consist of a number of other individuals with a protected property interest in public employment, including two public school teachers with collective-bargaining agreements (*e.g.*, ER-4), not to mention numerous other unionized government employees (*e.g.*, ER-1, ER-18).

Respondent admits that "as a practical matter, most workers in covered positions who refuse vaccines will ultimately not be able to continue in their jobs." *Response* at 18. On the contrary, the statute compels both public and private employers to terminate or at least suspend ("may not employ") Petitioners and others like them. Given that Respondent knew that, by adopting the Rules, some employees would be deprived of their jobs, and also knew that it was likely that constitutionally protected property interests were at stake, the Rules are facially unconstitutional. Apparently, the considerations provided under ORS 183.335(5) were completely ignored by OHA, knowing that a mandatory-vaccination rule would have the effect of violating federal due process rights with respect to "the interest of the parties concerned." The fact that OHA can engage in emergency

rulemaking does not nullify federal due process requirements where, as here, there is a reasonably foreseeable deprivation of protected property interests.

(5) The Rules violate the Contract Clause of the Oregon Constitution

Article I, section 21, of Oregon Constitution provides in part: "No . . . law impairing the obligation of contracts shall ever be passed . . . ." This constitutional prohibition applies to contracts made by the state and its subdivisions as well as to contracts between private parties. *Eckles v. State of Oregon*, 306 Or 380, 390, 760 P2d 846 (1988), *appeal dismissed*, 490 US 1032 (1989).

Further, this Court has observed that the "parties to an at-will employment relationship have no less of an interest in the integrity and security of their contract than do any other contracting parties." *Porter v. Oba, Inc.*, 180 Or App 207, 213–14, 42 P3d 931 (2002) (quoting *Lewis v. Oregon Beauty Supply Co.*, 302 Or 616, 620–21, 733 P2d 430 (1987)). Likewise, the United States Supreme Court recognized in *Truax v. Raich*, 239 US 33, 36 S Ct 7 (1915):

> The fact that the employment is at the will of the parties, respectively, does not make it one at the will of others. The employe [sic] has a manifest interest in the freedom of the employer to exercise his judgment without illegal interference or compulsion and, by the weight of authority, the unjustified interference of third persons is actionable although the employment is at will.

Id. at 38 (citing cases).

To establish a constitutional violation, it must be shown, first, that a contract exists and, second, that some law impairs the obligations arising from that contract.

"General principles of contract law normally govern both inquiries, even where the state is alleged to be a party to the contract at issue." *Hughes v. State*, 314 Or 1, 13–14, 838 P2d 1018 (1992).

Here, Petitioners each have a contract of employment with their respective employers; some are at will, some are for a fixed term, and some are subject to collective-bargaining agreements. All of them, however, have been impaired by the Rules to the extent that Petitioners have already been or will be dismissed, demoted, suspended, placed on unpaid leave, or otherwise deprived of gainful employment or other forms of employee compensation. *See Home Bldg. & Loan Ass'n v. Blaisdell*, 290 US 398, 431, 54 S Ct 231 (1934) (noting that "impairment . . . has been predicated of laws which without destroying contracts derogate from substantial contractual rights").

Incredibly, Respondent contends that the Rules do not impair the obligations of employment contracts because neither rule expressly tells employers *you must fire unvaccinated employees*. In Respondent's view, the Rules "merely prohibit employers from *allowing* unvaccinated workers who in the course of their jobs have direct or indirect contact with students, patients, or infectious material to work in a healthcare setting or school." *Response* at 17 (emphasis added). This is a specious argument devoid of any sense of *juris prudence*, for "[t]he purpose of an act must be found in its natural operation and effect." *Truax*, 239 US at 40.

Here, Respondent has already admitted that the Rules *practically* require some employers to terminate unvaccinated employees without a medical or religious exception. *Response* at 17–18 ("The consequence of refusal [to be vaccinated] is that they cannot work in healthcare settings or schools."). OHA's attempt to wash its hands on the basis of clever legal drafting, while ignoring the reality that employment contracts are, in fact, impaired by the Rules, is not an argument in its favor.

Nevertheless, Respondent argues that the Rules "do not purport to authorize employers to do anything that would violate their employment contracts with employees." *Response* at 19. If that assertion were true, then employers subject to the Rules remain contractually obligated to continue paying wages to unvaccinated employees who are temporarily stayed from working in certain settings until February 22, 2022. For just as an employer has an obligation to pay wages, the employee has a corresponding obligation to render services. *See Moro v. State*, 357 Or 167, 196, 351 P3d 1 (2015) ("In the employment context, an employer frequently offers a promise of compensation in exchange for an employee's service."). Thus, Respondent's contention seems to be that it can constitutionally impair the latter, but not the former; that OHA may break an employee's promise to work, but it may not require employers to keep their promises to pay wages

while a handful of employees are temporarily kept from working in certain settings.

Despite OHA's assurances to the contrary, many employers are reading the Rules as forcing them to terminate unvaccinated employees without exception, a more than plausible interpretation. *See* OAR 333-019-1010(3)(b) (stating that employers "may not employ" unvaccinated employees); OAR 333-019-1030(3)(b), (7)(b) (same). Respondent made no attempt to explain the meaning of the words "may not employ" in its own Rules, or amend them to better reflect OHA's official gloss in the form of nonbinding FAQs. Instead, Respondent asserts that the Rules superimpose a condition of employment on existing contracts. *See Response* at 13 (stating that the Rules "require individuals to be vaccinated as a condition of working in certain settings").

Even if the Rules can be construed in a way that does not directly require employers to terminate existing employment contracts, that cannot be the only kind of impairment entitled to protection under the Contract Clause. Any state action that alters, suspends, or terminates an employer's preexisting *duty* to pay wages are likewise protected. For instance, Petitioner Cox, who has an approved religious exception to the Rules, has been placed on unpaid leave by her public employer. She is now essentially unemployed, and there are many other Petitioners like her, who have been informed by their employers that they will no longer be gainfully

employed because of the Rules. Therefore, at a minimum, the Rules must be interpreted to only apply to future employees.

DATED: January 20, 2022.

Tyler Smith & Associates, P.C.

/s/Tyler Smith

Tyler D. Smith, OSB# 075287
Yasha Renner, OSB# 134681
181 N. Grant St., Suite 212
Canby, OR 97013
Phone: (503) 266-5590
Tyler@RuralBusinessAttorneys.com
Of Attorneys for Petitioners

George R. Wentz, Jr. (Louisiana Bar# 2180)*
Davillier Law Group, LLC
935 Gravier Street, Suite 1702
New Orleans, LA 70112
Phone: (504) 582-6998
gwentz@davillierlawgroup.com
**Admitted pro hac vice*

COMBINED CERTIFICATE OF COMPLIANCE WITH BRIEF LENGTH AND TYPE SIZE REQUIREMENTS, AND CERTIFICATES OF FILING AND SERVICE

I certify that this brief complies with the word-count limitation in ORAP 5.05, which word count is 9,938 words, and that the size of the type in this brief is not smaller than 14 point for both the text of the brief and footnotes.

I certify that on January 20, 2022, I filed this brief with the Appellate Court Administrator, and that service of a copy of this brief will be accomplished on the following participant(s) in this case, who is a registered user of the appellate courts' eFiling system, by the appellate courts' eFiling system at the participant's email address as recorded this date in the appellate eFiling system:

Benjamin Gutman
Solicitor General
1162 Court Street NE
Salem, Oregon 97301-4096
Benjamin.Gutman@doj.state.or.us

I certify that on January 20, 2022, I served a copy of this brief by first-class mail on the Attorney General of the State of Oregon, Office of the Solicitor General, 400 Justice Building, 1162 Court Street NE, Salem, OR 97301-4096.

DATED this 20th day of January, 2022.

Tyler Smith & Associates, P.C.

/s/Tyler Smith

Tyler D. Smith, OSB# 075287
181 N. Grant St., Suite 212
Canby, OR 97013
Phone: (503) 266-5590
Tyler@RuralBusinessAttorneys.com
Of Attorneys for Petitioners

APPENDIX

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IN THE COURT OF APPEALS OF THE STATE OF OREGON

OREGON HEALTHCARE WORKERS FOR MEDICAL FREEDOM
and MANDATE FREE OREGON,
Petitioners,

v.

OREGON HEALTH AUTHORITY,
Respondent.

Court of Appeals No. A176900

ORDER DENYING MOTION TO STAY

In this judicial review proceeding pursuant to ORS 183.400, petitioners move for a stay of enforcement of the Oregon Health Authority Administrative Order PH 42-2021 and OAR 333-019-1010 (the "Healthcare Vaccine Mandate"). Respondent Oregon Health Authority (OHA) opposes the requested stay. As explained below, the motion is denied.

OAR 333-019-1010 requires that "healthcare providers" and "healthcare staff" must show proof of vaccination or provide documentation of a medical or religious exemption by October 18, 2021, or they may not "work, learn, study, assist, observe, or volunteer in a healthcare setting." Petitioners are "non-profit member benefit corporation[s]" whose "members face termination on October 18, 2021, if they are not fully vaccinated."

The court has authority to stay enforcement of an administrative rule pending completion of judicial review under ORS 183.400. *Northwest Title Loans, LLC v. Division of Finance*, 180 Or App 1, 10, 42 P3d 313 (2002).[1] In determining whether to grant a stay pending completion of rule-challenge proceedings, the court considers the

[1] Although *Northwest Title Loans* was vacated as moot, the court continues to refer to portions of that decision that remain persuasive. *Lovelace v. Board of Parole and Post-Prison Supervision*, 183 Or App 283 n 3, 51 P3d 1269 (2002).

likelihood that petitioner will prevail on judicial review,[2] the likelihood of irreparable harm to the petitioners in the absence of an immediate stay, and the likelihood of harm to the public if a stay is granted. *See id.* at 13 & n 7 (stating that a stay will not be granted in the absence of a showing that failure to grant a stay will result in irreparable harm; suggesting that, in evaluating whether a stay should be granted in a judicial review proceeding under ORS 183.400, the court could require a petitioner to meet requirements analogous to those imposed in ORS 183.482). Petitioners assert that the relevant factors support their request for a stay. OHA, for its part, argues that the likelihood of harm to the public weighs decisively against a stay, that petitioners have no likelihood of success on the merits, and that petitioners do not face irreparable harm that would justify a stay. Petitioners reply, in part, that, in their view, the public will suffer irreparable harm if a stay is not granted.

The court determines that petitioners have little-to-no likelihood of success on the merits of their judicial review. As to that factor, petitioners argue that the Healthcare Vaccine Mandate (1) exceeds OHA's statutory authority, (2) violates the separation of powers doctrine of the Oregon Constitution, (3) was adopted without compliance with the temporary rule making process, and (4) violates healthcare workers' constitutional rights. In considering whether a stay should be granted, the court has evaluated all of the merits arguments set forth in the motion. The court will address some of those arguments in more detail below. Suffice it to say, however, that, although not all of petitioners' "merits" argument will be specifically discussed in this order, the court determines that none of them are sufficient to show a likelihood of success on judicial review.

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[2] In their motion, petitioners argue that they can establish a colorable claim of error. *See* ORS 183.482 (on judicial review of agency order in contested case proceeding, a stay will be granted on a showing of irreparable injury to the petitioner and a colorable claim of error in the order, unless substantial public harm will result if the order is stayed). However, in considering whether a stay should be granted in a rule-challenge proceeding under ORS 183.400, the court evaluates whether petitioners have a reasonable likelihood of success on appeal. *Northwest Title Loans*, 180 Or App at 21-22 ("A 'colorable' claim of error has been described as something less than a showing that the petitioner is reasonably likely to prevail on appeal, and as a seemingly valid, genuine, or plausible [claim] of error or substantial and nonfrivolous claim of error. A validly promulgated agency rule has the force of law and its enforcement should not be enjoined based on a merely plausible or nonfrivolous claim." (Brewer, J., concurring; internal citations omitted; brackets in original)).

With respect to petitioners' argument that OHA exceeded its rulemaking authority in issuing and adopting the Healthcare Vaccine Mandate, in order "[t]o determine whether a challenged rule exceeds the agency's statutory authority, [the court] may consider only 'the wording of the rule itself (read in context) and the statutory provisions authorizing the rule.'" *Assn. of Acupuncture v. Bd of Chiropractic Examiners*, 260 Or App 676, 678, 320 P3d 575 (2014) (quoting *Wolf v. Oregon Lottery Commission*, 344 Or 345, 355, 182 P3d 180 (2008)). OHA points to the following four statutes as providing authority for the mandate: ORS 413.042, ORS 431A.010, ORS 431.110, and ORS 433.004. Petitioners argue that those statutes do not confer the requisite rulemaking authority on OHA. However, when taken together and "read in context," it is clear that those statutes do, in fact, authorize OHA to issue and adopt the Healthcare Vaccine Mandate.

ORS 413.042 provides, "In accordance with applicable provisions of ORS chapter 183, the Director of the [OHA] may adopt rules necessary for the administration of the laws that the [OHA] is charged with administering." ORS 431A.010 provides that OHA "and local public health administrators shall have the power to enforce public health laws," including, among other powers, as noted in ORS 431A.010(1)(c), the power to "[i]ssue administrative orders to enforce compliance with public health laws." ORS 431.110(7) provides that OHA shall "[h]ave full power in the control of all communicable diseases." Finally, 433.004(1)(d) provides that OHA "shall by rule * * * [p]rescribe measures and methods for * * * controlling reportable diseases."

As applied to this case, first, COVID-19 is a communicable disease of which OHA has "full power in the control." *See* ORS 431.110(7). Pursuant to ORS 433.004(1)(d), OHA must, by rule, "prescribe measures and methods" for controlling reportable diseases; COVID-19 is a reportable disease. Pursuant to ORS 413.042, OHA may adopt a rule necessary for the administration of the laws that it is charged with administering; ORS 433.004(1)(d) is a law that OHA is charged with administering. By adopting OAR 333-019-1010, OHA exercised the authority given to it by ORS 413.042 in order to administer ORS 433.004(1)(d). OHA then issued an administrative order to ensure compliance with OAR 333-019-1010 pursuant to ORS 431A.010. Although petitioners may disagree with OHA about the Healthcare Vaccine Mandate being *necessary* in order to administer ORS 433.004(1)(d), that does not mean that OHA has exceeded its rulemaking authority in issuing and adopting the mandate. Petitioners have not demonstrated a likelihood of success in prevailing on their argument that OHA has exceeded its statutory authority in issuing and adopting the mandate.

Petitioners' further argue that the mandate "invades on the Legislature's powers as it attempts to overrule the Legislature." That argument is grounded on ORS 433.416, which provides that an employer of a "health care worker at risk of contracting an infectious disease in the course of employment shall provide to the worker preventive immunization [at no cost to the worker] * * * if available and * * * medically appropriate." ORS 433.416(1). Further, ORS 433.416(3) provides that a "worker shall not be required as a condition of work to be immunized under this section, unless such immunization is otherwise required by federal or state law, rule or regulation." Petitioners emphasize that the "Oregon Legislature has enacted no law authorizing vaccinations of workers," and argue that the mandate "directly contradicts the legislature's intent as expressed in ORS 433.416. However, in making that argument petitioners ignore the import of the statute's express text, which makes clear that immunizations *may* be a condition of work if required by, among other things, state rules or regulations. In other words, the statute specifically contemplates that an agency rule might, in some circumstances, require a health care worker to be immunized against an infectious disease. Thus, petitioners have little-to-no likelihood of success in arguing that the Healthcare Vaccine Mandate violates the separation of powers doctrine of the Oregon Constitution.

Petitioners' assert that OHA failed to follow the temporary rulemaking requirements set forth in ORS 183.335. An agency may adopt a temporary rule if it, among other things, prepares a "statement of its findings that its failure to act promptly will result in serious prejudice to the public interest or the interest of the parties concerned and the specific reasons for its findings of prejudice." ORS 183.335(5)(a). OHA prepared such a statement, which provides as follows:

> "The [OHA] finds that failure to act promptly will result in serious prejudice to the public interest, the [OHA], and healthcare personnel and patients seeking and relying on health care. This rule needs to be adopted promptly so that the state can continue to prevent and slow the spread of COVID-19, for the reasons specified above [in the statement regarding the need for the rule]. Requiring vaccination of healthcare personnel in healthcare settings is crucial to the effort in controlling COVID-19."

Petitioners assert that the statement is "superficial at best and fails to list 'the specific reasons for its findings of prejudice.'" The Supreme Court, however, has explained that, "[a]lthough not every prejudice will be sufficiently serious or require sufficiently prompt action to justify bypassing the public participation required by the permanent rulemaking

process, the standard that the legislature adopted is [relatively] flexible and permissive." *Friends of the Columbia Gorge v. Energy Facility Siting Council*, 366 Or 78, 92, 456 P3d 635 (2020). Here, petitioners have little likelihood of success on their argument that the justification of temporary filing, which also references OHA's determination of the need for the rule, fails to meet the requirements of ORS 183.335(5)(a).

Petitioners further argue that the rule violates "the privileges and immunities granted to [them] under the Oregon Constitution." *See* Or Const, Art 1, § 20 ("No law shall be passed granting to any citizen or class of citizens privileges, or immunities, which, upon the same terms shall not equally belong to other citizens."). However, only laws that disparately treat a "true class" may violate the Privileges and Immunities Clause of Article I, section 20. *See Tanner v. OHSU*, 157 Or App 502, 520, 971 P2d 435 (1998) ("In attempting to describe precisely what is meant by a 'true class,' the cases draw a distinction between classes that are created by the challenged law or government action itself and classes that are defined in terms of characteristics that are shared apart from the challenged law of action."). Further, even where a rule creates disparately treated true classes, depending "on what type of true class is involved, the legislation or governmental action may be upheld in spite of the disparity." *Id.* at 521. Disparate treatment of "nonsuspect true class[es]" may "be justified on a 'rational basis' examination." *Id.* at 523. As the state correctly points out, the class ("healthcare workers") that petitioners' assert is subject to disparate treatment under the rule does not appear to be a true class, as that term has been defined, and, thus, it appears that the Privileges and Immunities Clause may not even be implicated by the mandate. In any event, however, even if a true class, healthcare workers are clearly *not* a suspect class (unlike classes based on characteristics like race, gender, alienage, and religious affiliation) and, thus, the rule would only have to survive rational basis review. *See id.* Petitioners have little-to-no likelihood of success in persuading the court on judicial review that the rule has no rational basis.

Likewise, petitioners are unlikely to succeed in their constitutional argument that the Healthcare Vaccine Mandate violates their religious freedom. The rule itself expressly provides for religious exemptions from the vaccination requirement. *See* OAR 333-019-1010(2)(g) ("'Religious exception' means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination."); OAR 333-019-1010(4)(b)(B) ("A religious exception must be corroborated by a document * * * signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the

individual."). Petitioners have little likelihood of success in arguing that, despite the specific provision of religious exceptions to the vaccine requirement, the Healthcare Vaccine Mandate violates healthcare workers' religious freedom.

The same is true of petitioners' remaining arguments. Simply put, petitioners have demonstrated little-to-no likelihood of success in any of the arguments they seek to raise on judicial review.

The likelihood of success factor, together with the risk of harm to the public if a stay is granted, dispositively weighs against granting a stay in this case. Even assuming that petitioners have made a sufficient showing of irreparable harm to their members that will result from the denial of a stay, the court agrees with the state that granting a stay would be harmful to the public interest. As all involved are aware, this case arises during the COVID-19 pandemic; COVID-19 is a disease that has caused hundreds of thousands of deaths in this country. As the rule itself states, healthcare workers generally have contact with many patients, including those who are "more likely than the general public to have conditions that put them at risk for complications due to COVID-19." According to OHA, requiring healthcare workers to be vaccinated is an effective way to increase vaccination rates and, thereby, to help control COVID-19, protect patients, and protect the state's healthcare workforce. *See* OAR 333-019-1010(1). As the Supreme Court discussed more than a year ago in *Elkhorn Baptist Church v. Brown*, 366 Or 506, 509, 466 P3d 30 (2020):

> "There have been and will continue to be debates about how best to respond to the threat posed by the coronavirus. Those debates include debates about what balance government should strike between protecting lives and protecting liberties. To the extent that those debates concern policy choices, they are properly for policymakers. That is, those difficult choices must be made by the people's representatives in the legislative and executive branches of government."

Here, the rules are directly aimed at protecting the public and, although petitioners disagree with the way that is being done, the executive branch is "uniquely situated, and duty bound, to protect the public in emergency situations and to determine, in such emergencies, where the public interest lies." *Id.* at 546 (Garrett, J, concurring). The court determines that the agency has properly made that determination here and that the risk of harm to the public if a stay is granted is significant.

In sum, in light of petitioners' lack of a reasonable likelihood of success on judicial review and the likelihood of harm to the public if a stay is granted, petitioners' motion for a stay of enforcement of the Healthcare Vaccine Mandate pending completion of the rule-challenge proceeding is denied.

THERESA M. KIDD
APPELLATE COMMISSIONER
10/5/2021 8:44 AM

c: Daniel E Thenell
Kirsten L Curtis
Chelsea P Pyasetskyy
Benjamin Gutman

ej

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN DIEGO

LET THEM CHOOSE, an initiative of LET THEM BREATHE, a California nonprofit public benefit corporation;

Plaintiffs,

vs

SAN DIEGO UNIFIED SCHOOL DISTRICT; and DOES 1 -50,

Defendants.

Case Number: 37-2021-43172-CU-WM-CTL
(consolidated with 37-2021-49949 *S.V. v. SDUSD*)

Hearing Date: December 20 2021

TENTATIVE RULING

In September 2021, Respondent San Diego Unified School District's (SDUSD) Board of Education voted to approve a "Vaccination Roadmap" (the Roadmap). The Roadmap requires all students eligible for a fully FDA approved COVID-19 vaccine to receive the vaccine in order to attend school in-person and participate in extra-curricular activities. Currently, only those students aged 16 and older fall within the mandate and must receive both doses of the vaccine by December 20, 2021. Students who do not comply will be placed into an independent study program beginning with the new semester. Petitioners Let Them Choose, an initiative of Let Them Breathe, and S.V., individually and on behalf of J.D. (collectively, Petitioners) seek a writ of mandate restraining SDUSD from implementing the Roadmap.

SDUSD "may initiate and carry on any program, activity, or may otherwise act in any manner which is not in conflict with or inconsistent with, or preempted by, any law and which is not in conflict with the purposes for which school districts are established." (Educ. Code, § 35160, emphasis added; see *Hartzell v. Connell* (1984) 35 Cal.3d 899, 915–916.) Petitioners contend that the Roadmap field is preempted by Education Code section 120325 et seq. and directly conflicts

with both California Code of Regulations, title 17, section 6025 and provisions of Education Code section 51745 et seq.

"Under the normal rules of preemption, a local ordinance that conflicts with state law is preempted by the state law and void. . . . Pursuant to preemption law, a conflict exists if the local legislation duplicates, contradicts, or enters an area fully occupied by general law, either expressly or by legislative implication." (*Haytasingh v. City of San Diego* (2021) 286 Cal.Rptr.3d 364, 392; see generally *O'Connell v. City of Stockton* (2007) 41 Cal.4th 1061; *American Financial Services Assn. v. City of Oakland* (2005) 34 Cal.4th 1239.)

More than a century ago, the Legislature began regulating the field of school vaccination requirements. In 1890, the California Supreme Court upheld a "Vaccination Act" that required schools to exclude children who had not been vaccinated against smallpox. (*Abeel v. Clark* (1890) 84 Cal. 226, 227–228, 230.) The Court stated that vaccination, "being the most effective method known of preventing the spread of the disease referred to, it was for the legislature to determine whether the scholars of the public schools should be subjected to it." (*Id.* at p. 230, emphasis added.) The Legislature subsequently put control of smallpox under the direction of the State Department of Public Health (DPH) and provided that "no rule or regulation on the subject of vaccination shall be adopted by school or local health authorities." (Educ. Code, § 49405, emphasis added; see also Health & Saf. Code § 131052, subd. (3).)

Between 1961 and 2010, the Legislature imposed a total of 10 vaccine requirements for school children—diphtheria, hepatitis B, haemophilus influenza type b, measles, mumps, pertussis, poliomyelitis, rubella, tetanus, and varicella. (Health & Saf. Code, §§ 120325, subd. (a)(1)–(10), 120335, subd. (b)(1)–(10); see Assem. Com. on Health, Analysis of Sen. Bill No. 277 (2015–2016 Reg. Sess.) as amended May 7, 2015, p. 4.) "Each of the 10 diseases was added to the California code through legislative action, after careful consideration of the public health risks of these diseases, cost to the state and health system, communicability, and rates of transmission." (*Love v. State Department of Education* (2018) 29 Cal.App.5th 980, 987, emphasis added.) A detailed statutory and regulatory scheme has been established to implement the school vaccine mandates. (See Health & Saf. Code, § 120325 et seq.; Cal. Code Regs., tit. 17, § 6000 et seq.) The scheme included exemptions for both medical reasons and personal beliefs. (See Health & Saf. Code, § 120370; former Health & Saf. Code, § 120365.)

In 2015, in response to decreasing vaccination rates and a rise in measles, the Legislature removed the "personal beliefs" exemption to these 10 school vaccination requirements. (Sen. Bill No. 277 (2015–2016) §§ 1, 4; see generally *Love*, *supra*, 29 Cal.App.5th 980; *Brown v. Smith* (2018) 24 Cal.App.5th 1135.) In doing so, the Legislature considered whether "the issue of public health could be addressed by mandating vaccines on a community by community or school district [by] school district basis," but concluded that "a statewide approach is the correct approach." (Sen. Com. on Judiciary, Analysis of Sen. Bill No. 277 (2015–2016) as amended Apr. 22, 2015, p. 18.) "To provide a statewide standard, allows for a consistent policy that can be publicized in a uniform manner, so districts and educational efforts may be enacted with best practices for each district. . . . Further in consultation with various health officers, they believe a statewide policy provides them the tools to protect all children equally from an outbreak." (*Ibid.*)

Recognizing the need for additional vaccine mandates that may arise in the future, the Legislature added a "number 11" mandating that school children be vaccinated against "[a]ny other disease

deemed appropriate by the [State Department of Public Health], taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians." (Health & Saf. Code, §§ 120325, subd. (a)(11), 120335, subd. (b)(11); see also *id.* at § 131051, subd. (a)(3)(J).) However, because the addition of a new mandate via this "catch all" provision "disrupts the careful balancing of the various rights involved" in the legislative process, the Legislature decided to maintain the "personal beliefs" exemption for new vaccination requirements added by the DPH. (*Id.* at § 120338; Sen. Com. on Judiciary, Analysis of Sen. Bill No. 277 (2015–2016) as amended Apr. 22, 2015, pp. 17–18.)

The DPH is charged with adopting and enforcing regulations to carry out the vaccination requirements. (Health & Saf. Code, § 120330; see Cal. Code Regs., tit. 17, § 6000 et seq.) The DPH has not added COVID-19 as a required vaccine under the "catch all" provision, which would need to include a personal belief exemption. (Cal. Code Regs., tit. 17, § 6025; see Health & Saf. Code, § 120338.) Rather, DPH regulations state that a school "shall unconditionally admit or allow continued attendance" to any student who has either received each of 10 enumerated vaccines or obtained an exemption. (*Ibid.*, emphasis added; see also *Puerta v. Torres* (2011) 195 Cal.App.4th 1267, 1272 ["The term 'shall' is mandatory"].)

Vaccination requirements do not apply to students who are enrolled in an independent study program and not receiving classroom-based instruction. (Health & Saf. Code, § 120335, subd. (f).) However, the decision to participate in independent study must be voluntary. (See Educ. Code, §§ 51747, subds. (f), (g)(8), 51749.5, subd. (a)(9), (12), 51749.6, subd. (a)(6); Cal. Code Regs., tit. 5, § 11700, subd. (d).) Thus, if students have received all 10 vaccinations, a school district cannot force or coerce them into non-classroom-based independent study.

In light of the above, it is clear that SDUSD's Roadmap attempts to impose an additional requirement in a field that the Legislature fully occupies through Health and Safety Code section 120325 et seq. The Legislature intended a statewide standard for school vaccination requirements and established a detailed scheme. The Legislature expressly contemplated the addition of new vaccine mandates without further legislative action, but assigned that responsibility to the DPH, taking into account recommendations from other relevant agencies and organizations and mandating that those new mandates include a personal belief exemption. The statutory scheme leaves no room for each of the over 1,000 individual school districts to impose a patchwork of additional vaccine mandates, including those like the Roadmap that lack a personal belief exemption and therefore are even stricter than what the DPH could itself impose upon learned consideration.

SDUSD is correct that certain statutes contemplate school districts administering vaccines in cooperation with local health officers to help prevent and control communicable diseases in school age children, including "diseases that represent a current or potential outbreak as declared by a federal, state, or local public health officer," provided the district has received parental consent. (See Educ. Code, § 49403; see also Health & Saf. Code, §§ 120375, subd. (d), 120380.) However, the Roadmap was not enacted to cooperate with the local health officer, and more to the point, those statutes do not detract from the Legislature's intent to occupy the field of mandating a specific vaccine for school age children.

SDUSD's Roadmap also attempts to impose an additional requirement that directly conflicts with California Code of Regulations, title 17, section 6025 and the above referenced provisions of Education Code section 51745 et seq. SDUSD is required to admit students and allow their continued in-person attendance as long as they have received the 10 enumerated vaccines. SDUSD's attempt to impose an additional vaccine mandate and force students (both new and current) who defy it into non-classroom-based independent study directly conflicts with state law.

The sole function of this Court is to determine whether the Roadmap is preempted by state law. SDUSD's Roadmap appears to be necessary and rational, and the district's desire to protect its students from COVID-19 is commendable. Unfortunately, the field of school vaccine mandates has been fully occupied by the State, and the Roadmap directly conflicts with state law. The addition of a COVID-19 vaccine mandate without a personal belief exemption must be imposed by the Legislature. Accordingly, this Court is compelled to **GRANT** the petitions for writ of mandate.

EXCERPT OF RECORD

Index

Note: *The foregoing declarations were filed as attachments to Petitioners Emergency Motion to Stay Enforcement of Rule Pending Review*

IN THE COURT OF APPEALS OF THE
STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC. DOCTORS FOR FREEDOM, et al, Petitioners, v. STATE OF OREGON, acting by and through the OREGON HEALTH AUTHORITY; KATE BROWN, in her official capacity as Governor of Oregon Chief Executive of the Oregon Health Authority, Respondents.	Oregon Health Authority, Public Health Division No. _____ CA A _____ **DECLARATION OF BEN EDTL IN SUPPORT OF PETITION FOR JUDICIAL REVIEW**

1.

My name is Ben Edtl, I am over 18 years of age. I am the Founder and Executive Director of Free Oregon, Inc. a petitioner in this case, and a resident of Washington County, Oregon and a citizen of the United States. I am fully competent to make this Declaration and I have personal knowledge of the facts stated in this declaration. To the best of my knowledge, all the facts stated in this declaration are true and accurate.

2.

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

Free Oregon, Inc. is a non-profit corporation, registered in the State of Oregon. Free Oregon has more than 3,500 members, and growing by about 1000 per week including petitioners Chrystal Gervais, Charlotte Persinger, Lisa Nave, Rasa Sidagyte, Aaron Harris, Glenn Campbell, Jessica Cox, and Brittany Wilson. Our mission is to preserve civil rights and civil liberties for residents of the State of Oregon, including our members who are firefighters, paramedics, EMTs, police, doctors, nurses, heath care workers, state executive branch employees, correctional institution members and more. Our members have contacted me directly about the vaccine mandates being challenged in this case via OAR 333-019-1010 and OAR 333-019-1030. We have members like Charlotte Persinger who will be terminated from their employment, despite the fact that they have an employment agreement under which they would otherwise have continued employment or a right to continued employment. Neither the governor, nor OHA is bargaining with our members nor giving them special extensions. Our members do not want to be forced to become vaccinated, some have already had COVID-19, some are allergic to vaccines, some have other treatments and remedies that have worked for themselves or their families, and some have seen illness and injury in direct connection with receipt of the vaccine. Many of our members have applied for exceptions and been turned down and some have been accepted, with many more uncertain of their fate. Many of our members have been denied exceptions that

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

appear to violate Title VII of the Civil Rights act and we have told them they will have to sue. Some of our members are being threatened with termination even though they appear to not be covered by the mandate. If this mandate is not stayed our observation is that tens of thousands of people will have their rights violated, be terminated and have their lives destroyed.

3.

Our members demand that Oregon follow federal law and Oregon law and make the vaccine treatment for prevention of COVID-19 optional. Our organization would have participated and informed the Oregon Health Authority of the travesty that would befall our members and this state if they would have simply followed normal law and discussed mandates via permanent rulemaking or legislation.

4.

I hereby Declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

DATED this 24th day of September, 2021.

By _____
BEN EDTL, Founder and Officer Free Oregon

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

IN THE COURT OF APPEALS OF THE
STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC. DOCTORS FOR FREEDOM, et al, Petitioners, v. STATE OF OREGON, acting by and through the OREGON HEALTH AUTHORITY; KATE BROWN, in her official capacity as Governor of Oregon Chief Executive of the Oregon Health Authority, Respondents.	Oregon Health Authority, Public Health Division No. _____ CA A _____ **DECLARATION OF BRITTANY WILSON IN SUPPORT OF PETITION FOR JUDICIAL REVIEW**

1.

My name is BRITTANY WILSON, I am over 18 years of age. I am a petitioner in this case, and a resident of Clark County, Washington, and a citizen of the United States. I currently work in Multnomah County. I am fully competent to make this Declaration and I have personal knowledge of the facts stated in this declaration. To the best of my knowledge, all the facts stated in this declaration are true and accurate.

2.

TYLER SMITH & ASSOCIATES, P.C
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

I am currently employed as a special education teacher for Portland Public School located at Boise-Eliot-Humboldt Elementary School, who is my employer. I have worked for this employer for five years.

3.

On August 18, 2021, my employer notified me that I had to get vaccinated pursuant to the Oregon Administrative Rule or else I would be fired and lose by job. A true and accurate copy of that letter is attached as Exhibit 1.

4.

I have an employment agreement and contract with my employer that does not allow my employer to terminate me because I have not taken any of the treatments that the Oregon Health Authority are calling vaccines. OAR 333-019-1010 substantially interferes with my contract with my employer in that it will terminate that contract and leave me without employment.

5.

I have not been informed by my employer nor any medical provider that the vaccines are only approved for Emergency Use Authorization and that they are optional. I have not been given the option to decline vaccination. All of the providers that I am aware of in the state of Oregon are in violation of their CDC

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

vaccination provider agreement by complying with OHA's directive that I get vaccinated, or the state will take my job away by forcing my employer to terminate me. I have been told that I must get vaccinated and provide proof of vaccination or an exception or I will be fired.

6.

Other treatments are available for me to fight against the Covid virus, and I choose to select the treatment that is best for me to avoid Covid or fight Covid if I become infected. I assert my rights under ORS 431.180 to select my own medical provider and my own medical treatments. Obtaining a vaccine, mRNA treatment or other injection of unknown foreign objects into my body is a permanent treatment and will last beyond the expiration of this administrative rule on January 31, 2022. Thus, this rule is permanent in nature as it relates to me.

7.

If a preliminary injunction or stay is not granted, I will lose my job. If I lose my job, I will:

a. lose my source of income;

b. be unable to provide for myself because all of my family and friends live in Indiana;

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503-266-5590; Fax 503-212-6392

c. be unable to continue making payments on my car and will be unable to make my rent payments; and

d. be unable to financially support and feed my dog.

8.

I am currently a contributing member of the Free Oregon non-profit organization and the Mandate Free Oregon non-profit organization.

9.

I hereby Declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

DATED this 24th day of September, 2021.

By _____
Brittany Wilson

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

Cole Parkinson

From: Brittany Wilson <bwilson@pps.net>
Sent: Friday, September 24, 2021 11:58 AM
To: Cole Parkinson
Subject: Fwd: Urgent - Employee Vaccination Requirement Form and Details

Follow Up Flag: Follow up
Flag Status: Flagged

See below.

Brittany Wilson
MSEd Special Education
Communication Behavior Teacher
Boise-Eliot/ Humboldt School
Portland Public Schools
(503) 916-6171

Check out my Donor's Choose page to support my classroom!
https://www.donorschoose.org/mswilsonsautismclass

---------- Forwarded message ---------
From: **PPS Communications** <vaccine@pps.net>
Date: Mon, Aug 23, 2021 at 4:08 PM
Subject: Urgent - Employee Vaccination Requirement Form and Details
To: Brittany Wilson <bwilson@pps.net>

Dear Colleagues,

On August 18, I shared with you that all PPS employees will be required to submit proof of full vaccination by August 31, unless they have an approved exception. PPS employees who do not provide proof of vaccination by August 31 will be required to be tested regularly, or until proof of vaccination is submitted.

Every employee must complete the COVID-19 Vaccination Requirement Form regardless of vaccination status. Through this form you will upload documentation of your proof of vaccination, request a medical exception or deferral, request a non-medical religious exception, or sign up for regular testing. Details regarding exceptions and testing are available via the survey.

Click this personalized link to complete the COVID Vaccination Requirement Form. Do not share this link with anyone else; each employee will receive a personal link to the form. The form can be easily completed via a mobile phone or computer.

Proof of Vaccination
Vaccination records must include the name of the person vaccinated, type of vaccine provided, date or dates given, and the name/location of the health care provider or site where the vaccine was administered.

Acceptable forms of documentation include:

- a copy of your COVID-19 Vaccination Record Card (issued by the Department of Health and Human Services Centers for Disease Control & Prevention or WHO Yellow Card); OR
- a photo, or scanned copy of your Vaccination Record Card as a separate document; OR
- documentation of your COVID-19 vaccination from a health care provider.

Thank you for your commitment and dedication toward protecting our students, staff and community and towards our path to ending this pandemic.

To learn about PPS' efforts to create access to and promote the COVID-19 vaccine, visit PPS.net/COVID-19Vaccination.

If you have questions, please visit the employee vaccination website to review our FAQs or reach out to our email address vaccine@pps.net for staff vaccine questions.

Sharon Reese
Chief of Human Resources

Opt out

IN THE COURT OF APPEALS OF THE
STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC. DOCTORS FOR FREEDOM, et al, Petitioners, v. STATE OF OREGON, acting by and through the OREGON HEALTH AUTHORITY; KATE BROWN, in her official capacity as Governor of Oregon Chief Executive of the Oregon Health Authority, Respondents.	Oregon Health Authority, Public Health Division No. _____ CA A _____ **DECLARATION OF JESSICA COX IN SUPPORT OF PETITION FOR JUDICIAL REVIEW**

1.

My name is JESSICA COX, I am over 18 years of age. I am a petitioner in this case, and a resident of Washington County, Oregon, and a citizen of the United States. I am fully competent to make this Declaration and I have personal knowledge of the facts stated in this declaration. To the best of my knowledge, all the facts stated in this declaration are true and accurate.

2.

TYLER SMITH & ASSOCIATES, P C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

I am currently employed as a licensed special education teacher and a licensed autism specialist for Northwest Regional Educational District who is my employer. I have worked for this employer for three and a half years.

3.

On August 6, 2021, my employer notified me that I had to get vaccinated pursuant to the Oregon Administrative Rule or else I would be fired and lose by job. A true and accurate copy of that letter is attached as Exhibit 1.

4.

I have an employment agreement and contract with my employer that does not allow my employer to terminate me because I have not taken any of the treatments that the Oregon Health Authority are calling vaccines. OAR 333-019-1010 substantially interferes with my contract with my employer in that it will terminate that contract and leave me without employment.

5.

I have not been informed by my employer nor any medical provider that the vaccines are only approved for Emergency Use Authorization and that they are optional. I have not been given the option to decline vaccination. All the providers that I am aware of in the state of Oregon are in violation of their CDC

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503-266-5590; Fax 503-212-6392

vaccination provider agreement by complying with OHA's directive that I get vaccinated, or the state will take my job away by forcing my employer to terminate me. I have been told that I must get vaccinated and provide proof of vaccination or an exception or I will be fired.

6.

Other treatments are available for me to fight against the Covid virus, and I choose to select the treatment that is best for me to avoid Covid or fight Covid if I become infected. I assert my rights under ORS 431.180 to select my own medical provider and my own medical treatments. Obtaining a vaccine, mRNA treatment or other injection of unknown foreign objects into my body is a permanent treatment and will last beyond the expiration of this administrative rule on January 31, 2022. Thus, this rule is permanent in nature as it relates to me.

7.

If a preliminary injunction or stay is not granted, I will lose my job. If I lose my job, I will:

a. lose my source of income;

b. be unable to provide for my two children;

c. be unable to care for my four dogs, one of which requires severe medical attention; and

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181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

d. be unable to make payments on my house, my cars, and my credit cards.

8.

I am currently a contributing member of the Free Oregon non-profit organization.

9.

I hereby Declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

DATED this 27th day of September, 2021.

By _____
Jessica Cox

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

Cole Parkinson

From: Jessica Cox <jessicamcox321@gmail.com>
Sent: Saturday, September 25, 2021 8:21 AM
To: Cole Parkinson
Subject: Re: Declaration

If you need this in a different format let me know. I'm assuming since it was in our webpage the link is shareable. But if not I can download as a PDF and send it to you that way.

Jessica

On Fri, Sep 24, 2021 at 3:38 PM Jessica Cox <jessicamcox321@gmail.com> wrote:
Hi Cole,

Here are the Emails that I have received from HR:

Email from HR: 9/7/2021

Debbie Simons
to bcc: me

Hello,
You are receiving this communication because NWRESD has not received your vaccination information or the information we have received is that you are not yet fully vaccinated. **In order to be fully vaccinated, staff must have the second dose of a two-dose vaccine or the only dose of a single-dose vaccine no later than October 4, 2021.**
We are following up for two reasons. 1) To verify that you were able to successfully sign up for weekly testing; and 2) To provide information on expectations as we approach the Oct. 18 deadline when testing will no longer be an alternative option to proof of vaccination. Below is some information for you to consider as the October 18 deadline approaches.
Just like districts and other agencies have to follow all kinds of rules/laws/regulations like concussion protocols, ensuring licensed staff have licenses, reporting child abuse, etc., NWRESD must comply with these requirements. **Staff who do not provide proof of fully vaccinated status by October 18, 2021 or obtain an approved medical or religious exception will have their employment terminated.**
The specific language in the OAR states, "After October 18, 2021, teachers, school staff and volunteers may not teach, work, learn, study, assist, observe, or volunteer at a school unless they are fully vaccinated or have provided documentation of a medical or religious exception. **A school may not employ, contract with, or accept the volunteer services of teachers, school staff or volunteers who are teaching, working, learning, studying, assisting, observing, or volunteering at a school unless the teachers or school staff are fully vaccinated against COVID-19 or have a documented medical or religious exception."**
One or more of the scenarios below may apply to you:
I still need to sign up for weekly testing:
The enrollment process into this program is a 2-step process.

1. You will fill out the OHA Staff Screening Enrollment form.

2. Once you do this you will be sent an email on how to sign up for a LabDash account. Asking for insurance information is a standard piece of setting up a LabDash account. You can put in "no insurance" or if you want to put in your insurance, that is fine too. As long as you did step 1, the billing of insurance will be by-passed.

I have had my first shot; however am not fully vaccinated but will be by October 18:

1. In order to be fully vaccinated, staff must have completed the vaccination process **no later than October 4, 2021** in order to reach fully vaccinated status before the October 18th deadline.
2. Upload your completed vaccination card **no later than** October 5, 2021. Directions for uploading your vaccination card are here.

I am not vaccinated, however plan to be by October 18, here are your options:

1. Complete the vaccination process **no later than October 4, 2021** in order to reach fully vaccinated status before the October 18th deadline.
2. Upload your completed vaccination card **no later than** October 5, 2021. Directions for uploading your vaccination card are here.

I am not fully vaccinated and will be applying for a medical or religious exception:

1. If applying for a medical exception, please have your medical provider complete the medical exception request form, and submit it to Human Resources for approval **no later than September 25, 2021** to allow time for the information to be reviewed, and either approved or additional information requested.
2. If applying for a religious exception, please complete the religious exception request form **no later than September 25, 2021** to allow time for the information to be reviewed, and either approved or additional information requested.
3. **Please provide the information completely as there is no guarantee of approval.** Incomplete information, or information that is not truthful will affect the likelihood of your situation being approved.

I have COVID and am unable to be fully vaccinated by October 18, 2021, but I intend to be:

1. Contact Human Resources no later than Friday, September 15, 2021 to discuss your circumstances.

I am not fully vaccinated and do not intend to be:

1. You may work until Monday, October 18, 2021.
2. You can resign effective Tuesday, October 19, 2021.
3. Staff who do not provide proof of fully vaccinated status by October 18, 2021 or obtain an accepted medical or religious exception will no longer be employed.

The following links are provided for your information:
Link to OAR requiring vaccinations
School Vaccine FAQ

I know that this is a lot of information and complex requirements. If I can answer any questions for you, please do not hesitate to let me know. Have a wonderful week!

Debbie Simons
Chief Human Resources Officer

Northwest Regional ESD
5825 NE Ray Circle
Hillsboro, OR 97124
(503)614-1407

From HR: 9/15/2021
Debbie Simons Wed
to bcc: me

Hello,

EXHIBIT 1 - PAGE 2

Below is an email I sent last week clarifying your vaccination status as deadlines are approaching. **Staff who do not provide proof of fully vaccinated status by October 18, 2021 or obtain an approved medical or religious exception will have their employment terminated.**

As of today, Human Resources has not heard from you; and while you still have time to respond, time is running out to have a plan if you have not yet started the vaccination process. Please respond to the survey link below to give us an idea of where you are so that we can plan accordingly and prepare to set aside time to meet with you.

Vaccination Status Plan Survey

If you are planning on applying for an exception, please know that those are subject to approval and in most cases will require additional requirements on your part. If you are in a role that works directly with students, it may be necessary to change your assignment from working with students to other work if it is available.

Also, until you meet the requirement of being fully vaccinated, it is necessary for you to test weekly. We know that there have been a few glitches this week as the testing program gets up to speed. That being said, the expectation is:

1. You sign up as noted in the email below
2. You test weekly
3. Your sample must be yours (i.e. another person cannot test for you)
4. If you test positive you are to notify your supervisor immediately, generally within 24-36 hours(There is no requirement to report negative results at this time).
5. You understand that failing to meet this testing requirement or providing untruthful information will result in disciplinary action; up to and including dismissal.

We appreciate you responding as the deadline to apply for any sort of exception is next Friday by the end of the business day, and the last day to receive your second dose of the vaccine if you are in the process is October 4. All completed vaccination cards are due no later than October 5.

If you have any questions, please do not hesitate to let me know.

Debbie Simons
Chief Human Resources Officer

Northwest Regional ESD
5825 NE Ray Circle
Hillsboro, OR 97124
(503)614-1407

On Tue, Sep 7, 2021 at 3:23 PM Debbie Simons <dsimons@nwresd.k12.or.us> wrote:

Hello,

You are receiving this communication because NWRESD has not received your vaccination information or the information we have received is that you are not yet fully vaccinated. **In order to be fully vaccinated, staff must have the second dose of a two-dose vaccine or the only dose of a single-dose vaccine no later than October 4, 2021.**

We are following up for two reasons. 1) To verify that you were able to successfully sign up for weekly testing; and 2) To provide information on expectations as we approach the Oct. 18 deadline when testing will no longer be an alternative option to proof of vaccination. Below is some information for you to consider as the October 18 deadline approaches.

Just like districts and other agencies have to follow all kinds of rules/laws/regulations like concussion protocols, ensuring licensed staff have licenses, reporting child abuse, etc., NWRESD must comply with these requirements. **Staff who do not provide proof of fully vaccinated status by October 18, 2021 or obtain an approved medical or religious exception will have their employment terminated.**

The specific language in the OAR states, "After October 18, 2021, teachers, school staff and volunteers may not teach, work, learn, study, assist, observe, or volunteer at a school unless they are fully vaccinated or have provided documentation of a medical or religious exception. **A school may not employ, contract with, or accept the volunteer services of teachers, school staff or volunteers who are teaching, working, learning, studying, assisting, observing, or volunteering at a school unless the teachers or school staff are fully vaccinated against COVID-19 or have a documented medical or religious exception."**

One or more of the scenarios below may apply to you:

I still need to sign up for weekly testing:

The enrollment process into this program is a 2-step process.

1. You will fill out the OHA Staff Screening Enrollment form.
2. Once you do this you will be sent an email on how to sign up for a LabDash account. Asking for insurance information is a standard piece of setting up a LabDash account. You can put in "no insurance" or if you want to put in your insurance, that is fine too. As long as you did step 1, the billing of insurance will be by-passed.

I have had my first shot; however am not fully vaccinated but will be by October 18:

1. In order to be fully vaccinated, staff must have completed the vaccination process **no later than October 4, 2021** in order to reach fully vaccinated status before the October 18th deadline.
2. Upload your completed vaccination card **no later than** October 5, 2021. Directions for uploading your vaccination card are here.

I am not vaccinated, however plan to be by October 18, here are your options:

1. Complete the vaccination process **no later than October 4, 2021** in order to reach fully vaccinated status before the October 18th deadline.
2. Upload your completed vaccination card **no later than** October 5, 2021. Directions for uploading your vaccination card are here.

I am not fully vaccinated and will be applying for a medical or religious exception:

1. If applying for a medical exception, please have your medical provider complete the medical exception request form, and submit it to Human Resources for approval **no later than September 25, 2021** to allow time for the information to be reviewed, and either approved or additional information requested.
2. If applying for a religious exception, please complete the religious exception request form **no later than September 25, 2021** to allow time for the information to be reviewed, and either approved or additional information requested.
3. **Please provide the information completely as there is no guarantee of approval.** Incomplete information, or information that is not truthful will affect the likelihood of your situation being approved.

I have COVID and am unable to be fully vaccinated by October 18, 2021, but I intend to be:

1. Contact Human Resources no later than Friday, September 15, 2021 to discuss your circumstances.

I am not fully vaccinated and do not intend to be:

1. You may work until Monday, October 18, 2021.
2. You can resign effective Tuesday, October 19, 2021.
3. Staff who do not provide proof of fully vaccinated status by October 18, 2021 or obtain an accepted medical or religious exception will no longer be employed.

The following links are provided for your information:
Link to OAR requiring vaccinations
School Vaccine FAQ

I know that this is a lot of information and complex requirements. If I can answer any questions for you, please do not hesitate to let me know. Have a wonderful week!

IN THE COURT OF APPEALS OF THE
STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC. DOCTORS FOR FREEDOM, et al, Petitioners, v. STATE OF OREGON, acting by and through the OREGON HEALTH AUTHORITY; KATE BROWN, in her official capacity as Governor of Oregon Chief Executive of the Oregon Health Authority, Respondents.	Oregon Health Authority, Public Health Division No. _____ CA A _____ **DECLARATION OF KRISTINA FISH IN SUPPORT OF PETITION FOR JUDICIAL REVIEW**

1.

My name is Kristina Fish, I am over 18 years of age. I am the Founder and an officer of Mandate Free Oregon, Inc. I am a resident of Clackamas County, Oregon and a citizen of the United States. I am fully competent to make this Declaration and I have personal knowledge of the facts stated in this declaration. To the best of my knowledge, all the facts stated in this declaration are true and accurate.

2.

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

Mandate Free Oregon, Inc. is a non-profit membership corporation, registered in the State of Oregon. Mandate Free Oregon's sole purpose was formed to aid, assist and advocate for firefighters, paramedics, EMTs, police and other first respondents and others covered by the healthcare industry vaccine mandate known as OAR 333-019-1010. Mandate Free Oregon has more than 2,526 members as of last count. The lives of the firefighters, EMTs and paramedics who will lose their jobs because they are not willing to undergo this mandated treatment. The fire services industry will be devastated if this mandate is not stayed and so many departments lose so many employees all at once. Firefighters across this state have become members because they are not willing to be forcefully compelled to get vaccinated or be retaliated against, punished by government mandate and lose their career.

Firefighters, police, health care workers and other first responders have been on the front lines serving the public throughout this pandemic and those who have wanted to be vaccinated have had that opportunity and obtained the vaccine. Many of us have not wanted to be vaccinated and will not take the vaccine. We are well aware of the risks of COVID-19, the capacities of the hospitals, the various treatments available, the statistics on who is most in danger of having a severe case and who is at little risk of having a severe case. We are the on the ground experts on the risks, yet others want to make these choices of treatments for us. We have

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members who will be terminated from their employment, despite the fact that they have collective bargaining agreements and other employment agreements under which they would otherwise have continued employment or a right to continued employment.

Some of our members have other treatments and remedies that have worked for themselves or their families, and some have seen illness and injury in direct connection with receipt of the vaccine. Many of our members have applied for exceptions and been turned down and some have been accepted, with many more uncertain of their fate. Many of our members have been denied exceptions in ways and for reasons that appear to violate Title VII of the Civil Rights act and their only other recourse – after the fact - will be to sue. Some of our members are being threatened with termination even though they appear to not even be covered by the mandate. Police, fire, and healthcare industries all have some employees who are not in direct contact with the public or are not in "healthcare settings" where they are near the direct provisioning of care to patients. If this mandate is not stayed our observation is that tens of thousands of people will have their rights violated, be terminated and have their lives destroyed.

3.

Our members demand that Oregon follow federal law and Oregon law and make the vaccine treatment for prevention of COVID-19 optional. Our

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organization would have participated and informed the Oregon Health Authority of the travesty that would befall our members and this state if they would have simply followed normal law and discussed mandates via permanent rulemaking or legislation.

4.

Our members include firefighters, EMTs, paramedics, nurses, police, and many more like Michelle Davis, Brittany Wilson, myself, all of the other officers, directors and volunteers for Mandate Free Oregon and are facing this same dire false choice.

5.

I hereby Declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

DATED this 27th day of September, 2021.

By _____
Kristina Fish, Founder and Officer
Mandate Free Oregon, Inc.

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

IN THE COURT OF APPEALS OF THE
STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC. DOCTORS FOR FREEDOM, et al, Petitioners, v. STATE OF OREGON, acting by and through the OREGON HEALTH AUTHORITY; KATE BROWN, in her official capacity as Governor of Oregon Chief Executive of the Oregon Health Authority, Respondents.	Oregon Health Authority, Public Health Division No. _____ CA A _____ **DECLARATION OF MOLLY VALDEZ IN SUPPORT OF PETITION FOR JUDICIAL REVIEW**

1.

My name is MOLLY VALDEZ, I am over 18 years of age. I am a petitioner in this case, and a resident of Washington County, Oregon and a citizen of the United States. I am fully competent to make this Declaration and I have personal knowledge of the facts stated in this declaration. To the best of my knowledge, all the facts stated in this declaration are true and accurate.

///

///

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

2.

I am currently employed as an ophthalmologist technician for Oregon Eye Specialist who is my employer. I have worked for this employer for six months.

3.

On August 06, 2021, my employer notified me that I had to get vaccinated pursuant to the Oregon Administrative Rule or else I would be forced to voluntarily resign and lose by job. A true and accurate copy of that letter is attached as Exhibit 1.

4.

I have an employment agreement and contract with my employer that does not allow my employer to terminate me because I have not taken any of the treatments that the Oregon Health Authority are calling vaccines. OAR 333-019-1010 substantially interferes with my contract with my employer in that it will terminate that contract and leave me without employment.

5.

I have not been informed by my employer nor any medical provider that the vaccines are only approved for Emergency Use Authorization and that they are optional. I have not been given the option to decline vaccination. All the

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providers that I am aware of in the state of Oregon are in violation of their CDC vaccination provider agreement by complying with OHA's directive that I get vaccinated, or the state will take my job away by forcing my employer to terminate me. I have been told that I must get vaccinated and provide proof of vaccination or an exception or I will be fired.

6.

I contracted COVID in April. After which, my employer required me to get the vaccination. I received a medical exemption from my doctor, who specifically told me that I should not get the vaccine because it would negatively affect me. I turned in the medical exemption, which was promptly denied. I was then forced to get the Johnson & Johnson vaccine. Soon after getting the vaccine, I felt my left foot and leg start to tingle. Additionally, I had paralysis on the left side of my face. I promptly went to the emergency room, where they told me I only had a migraine. The next morning, the right side of my face and body started to tingle. While the symptoms to my face have subsided, the issues involving my body have not. I was required to purchase a cane so I could walk. I again, went back to the emergency room. As a result of the negative effects, I must see a physical therapist to gain my strength. In total, I was hospitalized for two days. Of the various doctors I saw, I was told that I suffered nerve damage. To this day, I still require a walker to move and have periods where my body will go completely numb.

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7.

Other treatments are available for me to fight against the Covid virus, and I choose to select the treatment that is best for me to avoid Covid or fight Covid if I become infected. I assert my rights under ORS 431.180 to select my own medical provider and my own medical treatments. Obtaining a vaccine, mRNA treatment or other injection of unknown foreign objects into my body is a permanent treatment and will last beyond the expiration of this administrative rule on January 31, 2022. Thus, this rule is permanent in nature as it relates to me.

8.

If a preliminary injunction or stay is not granted, I will lose my job. If I lose my job, I will:

a. lose my source of income;

b. be unable to provide for my three animals;

c. be unable to sustain my medical bills; and

d. be unable to make payments on my car.

///

///

///

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

9.

I hereby Declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

DATED this 27th day of September, 2021.

By: _____
Molly Valdez

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

September 10, 2021

Oregon Eye Specialists, P.C. Vaccine Exception Policy

Overview: Oregon Eye Specialists, P.C. (OES) is committed above all else to a safe and healthy environment for all patients and staff. OES requires that all staff be vaccinated against coronavirus disease (COVID-19), to limit the contraction and spread of the virus to our patients and other staff members, as well as their family and friends. OES is deeply committed to transparent policies and actions that will allow us to achieve this safe environment, while considering the importance of individual well-being, and religious and spiritual beliefs.

Purpose: The purpose of this policy is to provide an administrative and logistical protocol for those employees who choose not to receive COVID-19 vaccination(s).

Scope: This affects all clinical environments where OES is operating and the administrative headquarters at 6420 SW Macadam.

Policy: All employees of OES must be fully vaccinated against COVID-19 to retain their current position, if the position includes any patient contact or any contact with other staff members, in or outside of the clinical and administrative setting. This stance is strongly supported by Oregon law [1] and the guidance of multiple organizations, including the Centers for Disease Control and Prevention.

In concordance with the Centers for Disease Control and Prevention recommendations [2], the only recognized medical exemption for COVID-19 vaccination is a prior allergic reaction specifically to the COVID-19 vaccine, not simply a belief or feeling that the vaccine could create medical problems in the present or future.

Religious exemptions will be evaluated on an individual basis with the consideration of published positions of major faith leaders [see Appendices 1-4]. Personal beliefs will be weighed with the potential risks of COVID-19 to patients and other staff members.

All medical or religious exemption requests will be sent to the individual's clinic manager or supervisor at the latest by **September 10th, 2021.** These exemption requests will be reviewed by the Vaccine Exemption Subcommittee.

If a COVID-19 vaccine exemption is granted by the subcommittee, the unvaccinated individual will be unable to work in any clinical or administrative environment in which direct contact with patients or contact among staff members occurs. If a position is available to work 100% remotely for an unvaccinated individual, it will likely include a revision of job responsibility and compensation.

Additionally, for unvaccinated individuals who have not been granted an exemption on medical or religious grounds, there will be no additional pay protection in place for any COVID-related absences due to exposure or infection over and above the current accrued sick leave provided by Oregon law.

If a medical or religious exemption is submitted, but not approved by the Vaccine Exemption Subcommittee, the individual employee faces the choice of vaccinating or voluntarily resigning. A vaccine declination form will be available on September 13th, 2021, to employees who have not been granted an exemption or have not submitted their vaccine cards. The deadline to complete the declination form will be September 17th, 2021, at 5:00PM. If an employee does not complete the declination form by the deadline or attests that they have no intention of becoming vaccinated, Oregon Eye Specialists will consider them to have voluntarily resigned no later than September 24th, 2021.

Any employee who is granted a vaccine exemption may be required to be tested weekly for COVID-19.

Vaccines are recorded by the immunization registry for the state the vaccine was administered. OES may require employees to obtain proof and validity of vaccination status from the registry. Any employees who are found to have provided fraudulent evidence of vaccination will be immediately terminated.

Above all else, OES prides itself on being an organization that provides excellent patient care and keeps all patients, staff and their family members and friends safe and healthy.

References

1. Oregon Secretary of State, Oregon Health Authority; ***line item 5*** — 333-019-1010 COVID-19 Vaccination Requirement for Healthcare Providers and Healthcare Staff in Healthcare Settings: https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=280799.

2. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications.

Appendix A: Catholic Faith Vaccine Position
Appendix B: Christian Faith Vaccine Position
Appendix C: Jewish Faith Vaccine Position
Appendix D: Muslim Faith Vaccine Position

IN THE COURT OF APPEALS OF THE
STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC., Oregon non-profit corporations, and **DOCTORS FOR FREEDOM,** an unincorporated association, **HEALTH FREEDOM DEFENSE FUND, and TAMARA DIMMICK, RASA SIDAGYTE, MICHELLE DAVIS, LISA NAVE, CHARLOTTE PERSINGER, CHRYSTAL GERVAIS, AARON HARRIS, ROY McGRATH, GLENN CAMPBELL, JESSICA COX, BRITTANY WILSON, JOSHUA WILLIAMS,** and **MOLLY VALDEZ** individuals,

Petitioners,

v.

STATE OF OREGON, acting by and through the **OREGON HEALTH AUTHORITY; KATE BROWN,** in her official capacity as Governor of Oregon and as Chief Executive of the Oregon Health Authority; **PATRICK ALLEN,** in his official capacity as Director of the Oregon Health Authority,

Respondents.

Oregon Health Authority, Public Health Division

No. _____

CA A _____

DECLARATION OF YASHA RENNER IN SUPPORT OF PETITIONERS' EMERGENCY STAY MOTION

1. The undersigned declarant is an attorney for the Petitioners and a member in good standing of the Oregon State Bar. This declaration is based upon

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

personal knowledge and is made in support of the Petitioners' emergency stay motion. I am over the age of 18 and competent to testify to the matters herein.

2. Attached as Exhibit 1 is a true and accurate copy of the Oregon Health Authority (OHA) Temporary Administrative Order PH 42-2021 (OAR 333-019-1010).

3. Attached as Exhibit 2 is a true and accurate copy of the OHA Temporary Administrative Order PH 39-2021 (OAR 333-019-1030).

4. Attached as Exhibit 3 is a true and accurate copy of the combined factsheet for recipients and caregivers about COMIRNATY and Pfizer EUA vaccine.

5. Attached as Exhibit 4 is a true and accurate copy of the factsheet for recipients and caregivers about the Janssen EUA vaccine.

6. Attached as Exhibit 5 is a true and accurate copy of the factsheet for recipients and caregivers about the Moderna EUA vaccine.

7. Attached as Exhibit 6 is a true and accurate copy of the FDA's reissued letter of authorization for the Pfizer EUA vaccine.

8. Attached as Exhibit 7 is a true and accurate copy of the FDA's reissued letter of authorization for the Janssen EUA vaccine.

9. Attached as Exhibit 8 is a true and accurate copy of the FDA's reissued letter of authorization for the Moderna EUA vaccine.

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

10. Attached as Exhibit 9 is a true and accurate copy of the FDA's letter approving the biologics license for the COMIRNATY vaccine.

11. Attached as Exhibit 10 is a true and accurate copy of the FDA-approved draft package insert for the COMIRNATY vaccine.

12. Attached as Exhibit 11 is a true and accurate copy of an uncompleted form of the CDC COVID-19 Vaccination Program Provider Agreement.

13. Attached as Exhibit 12 is a true and accurate copy of the combined factsheet for providers about COMIRNATY and Pfizer EUA vaccine.

14. Attached as Exhibit 13 is a true and accurate copy of the factsheet for providers about the Moderna EUA vaccine.

15. Attached as Exhibit 14 is a true and accurate copy of the factsheet for providers about the Janssen EUA vaccine.

I hereby declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

DATED this 27th day of September, 2021.

By ***s/ Yasha Renner***
Yasha Renner, OSB#134681

TYLER SMITH & ASSOCIATES, P.C.
181 N. Grant St. STE 212, Canby, Oregon 97013
503-266-5590; Fax 503-212-6392

OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

PH 42-2021
CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
09/01/2021 12:01 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Vaccination Requirements to Control COVID-19 for Healthcare Providers and Healthcare Staff

EFFECTIVE DATE: 09/01/2021 THROUGH 01/31/2022

AGENCY APPROVED DATE: 09/01/2021

CONTACT: COVID Response and Recovery Unit
503-945-5488
COVID.19@dhsoha.state.or.us

800 NE Oregon St.
Portland,OR 97232

Filed By:
Brittany Hall
Rules Coordinator

NEED FOR THE RULE(S):

It is vital to this state that health care providers and health care staff be vaccinated against COVID-19 in order to protect themselves, their patients and statewide hospital capacity. COVID-19 infection is caused by a virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This virus undergoes frequent mutations as it replicates, which over time has resulted in variants that are more transmissible, cause more severe disease or have other features of public health concern such as decreased vaccine effectiveness. In August of 2021, the B.1.617.2 (Delta) variant accounted for more than 98% of the COVID-19 infections in Oregon.

The Delta variant is approximately 2-3-fold more transmissible than early wild-type COVID-19 variants. People infected with the Delta variant have higher viral loads and a shorter incubation period. There is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may transmit this variant effectively. Being vaccinated, is therefore critical to prevent spread of Delta. Health care providers have contact with multiple patients over the course of a typical day, including providers who provide care for people in their homes. Individuals cared for by health care providers are more likely than the general public to have conditions that put them at risk for complications of COVID-19. The Delta variant is causing a surge in unvaccinated cases and vaccine breakthrough cases. This rule is necessary to help control COVID-19, protect patients, and to protect the state's healthcare workforce.

This filing replaces Temporary Administrative Order PH 38-2021 filed and effective on August 25, 2021.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and healthcare personnel and patients seeking and relying on health care. This rule needs to be adopted promptly so that the state can continue to prevent and slow the spread of COVID-19, for the reasons specified above. Requiring

vaccination for healthcare personnel in healthcare settings is crucial to the effort in controlling COVID-19.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Oregon Health Care Workforce COVID-19 Vaccine Uptake (https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonHealthCareWorkforceCOVID-19VaccineUptake/Dash-Overview)

Long-Term Care Facilities COVID-19 Vaccination Data (July 26, 2021) (https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/LTCFCOVID-19VaccinationData/WeeklyTrend)

OHA COVID-19 Breakthrough Report (August 19, 2021) (https://www.oregon.gov/oha/covid19/Documents/DataReports/Breakthrough-Case-Report.pdf)

OHA Dashboard: Hospital Capacity and Usage in Oregon (reported by HOSCAP), August 20, 2021. Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19Update/HospitalCapacity.

OHA Dashboard: Oregon's Hospitalization Trend by Severity (August 20, 2021). Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19HospitalCapacity/HospitalizationbySeverity.

OHA Dashboard: Oregon's COVID-19 Disease Spread (August 22, 2021). Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19PublicHealthIndicators/DiseaseSpread.

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

Christie A, Brooks JT, Hicks LA, et al. Guidance for Implementing COVID-19 Prevention Strategies in the Context of Varying Community Transmission Levels and Vaccination Coverage. MMWR Morb Mortal Wkly Rep 2021;70:1044–1047. DOI: http://dx.doi.org/10.15585/mmwr.mm7030e2

COVID, C., Team, V.B.C.I., COVID, C., Team, V.B.C.I., COVID, C., Team, V.B.C.I., Birhane, M., Bressler, S., Chang, G., Clark, T. and Dorough, L., 2021. COVID-19 Vaccine Breakthrough Infections Reported to CDC—United States, January 1–April 30, 2021. Morbidity and Mortality Weekly Report, 70(21), p.792. available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm

Herlihy R, Bamberg W, Burakoff A, et al. Rapid Increase in Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — Mesa County, Colorado, April–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1084-1087. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e2

Lee JT, Althomsons SP, Wu H, et al. Disparities in COVID-19 Vaccination Coverage Among Health Care Personnel Working in Long-Term Care Facilities, by Job Category, National Healthcare Safety Network — United States, March 2021. MMWR Morb Mortal Wkly Rep 2021;70:1036–1039. DOI: http://dx.doi.org/10.15585/mmwr.mm7030a2

Li, B., Deng, A., Li, K., Hu, Y., Li, Z., Xiong, Q., Liu, Z., Guo, Q., Zou, L., Zhang, H. and Zhang, M., 2021. Viral infection and Transmission in a large well-traced outbreak caused by the Delta SARS-CoV-2 variant available at https://www.medrxiv.org/content/10.1101/2021.07.07.21260122v1.

Moline HL, Whitaker M, Deng L, et al. Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged 65 Years — COVID-NET, 13 States, February–April 2021. MMWR Morb Mortal Wkly Rep 2021;70:1088-1093. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e3

Nanduri S, Pilishvili T, Derado G, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e3

Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e1

ADOPT: 333-019-1010

SUSPEND: Temporary 333-019-1010 from PH 38-2021

RULE TITLE: COVID-19 Vaccination Requirement for Healthcare Providers and Healthcare Staff in Healthcare Settings

RULE SUMMARY: OAR 333-019-1010 helps to prevent and slow the spread of COVID-19 by requiring health care personnel and healthcare staff who work in healthcare settings to be vaccinated against COVID-19 or request a medical or religious exception.

Healthcare personnel includes individuals, paid and unpaid working, learning, studying, assisting, observing or volunteering in a healthcare setting providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials, and includes but is not limited to any individual licensed by a health regulatory board as that is defined in ORS 676.160, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, student and

volunteer personnel.

Healthcare setting includes any place where health care, including physical or behavioral health care is delivered and includes, but is not limited to any health care facility or agency licensed under ORS chapter 441 or 443, such as hospitals, ambulatory surgical centers, birthing centers, special inpatient care facilities, long-term acute care facilities, inpatient rehabilitation facilities, inpatient hospice facilities, nursing facilities, assisted living facilities, residential facilities, residential behavioral health facilities, adult foster homes, group homes, pharmacies, hospice, vehicles or temporary sites where health care is delivered (for example, mobile clinics, ambulances), and outpatient facilities, such as dialysis centers, health care provider offices, behavioral health care offices, urgent care centers, counseling offices, offices that provide complementary and alternative medicine such as acupuncture, homeopathy, naturopathy, chiropractic and osteopathic medicine, and other specialty centers.

However, healthcare setting does not include:

- Any setting described in paragraph (2)(e)(A) of the rule where the responsible party is a part of state government as that is defined in ORS 174.111.
- An individual's private home if the home is not otherwise licensed, registered or certified as a facility or home listed in paragraph (2)(e)(A) of the rule.

Medical exception means that an individual has a physical or mental impairment that prevents the individual from receiving a COVID-19 vaccination.

Religious exception means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination.

After October 18, 2021:

- A health care provider or healthcare staff person may not work, learn, study, assist, observe, or volunteer in a healthcare setting unless they are fully vaccinated or have provided documentation of a medical or religious exception.
- An employer of healthcare providers or healthcare staff, a contractor, or a responsible party may not employ, contract with, or accept the volunteer services of healthcare providers or healthcare staff persons who are working, learning, studying, assisting, observing or volunteering at a healthcare setting unless the healthcare providers or healthcare staff persons are fully vaccinated against COVID-19 or have a documented medical or religious exception.

On or before October 18, 2021, healthcare providers and healthcare staff must provide their employer, contractor or responsible party with either:

- Proof of vaccination showing they are fully vaccinated; or
- Documentation of a medical or religious exception.

A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, on a form prescribed by the Oregon Health Authority (OHA) or a similar form that contains all of the information required in the OHA form, certifying that the individual has a physical or mental impairment that limits

the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.

A religious exception must be corroborated by a document, on a form prescribed by the Oregon Health Authority (OHA) or a similar form that contains all of the information required in the OHA form, signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the individual.

Employers of healthcare providers or healthcare staff, contractors and responsible parties who grant an exception to the vaccination requirement must take reasonable steps to ensure that unvaccinated healthcare providers and healthcare staff are protected from contracting and spreading COVID-19.

On or before October 18, 2021, all employers of healthcare providers or healthcare staff, contractors, and responsible parties must have documentation that all healthcare providers and healthcare staff are in compliance with the rule.

The rule permits employers of healthcare providers or healthcare staff, contractors and responsible parties to:
• Have more restrictive or additional requirements, including but not limited to requiring healthcare providers and healthcare staff to have documentation of an additional or booster dose of a COVID-19 vaccine if that is recommended by the U.S. Centers for Disease Control and Prevention.
• Impose the vaccination requirements at an earlier date.

The vaccination documentation and documentation of medical and religious exceptions described in the rule must be:
• Maintained in accordance with applicable federal and state laws;
• Maintained for at least two years; and
• Provided to the Oregon Health Authority upon request.

Employers of healthcare providers or healthcare staff, contractors and responsible parties who violate any provision of this rule are subject to civil penalties of $500 per day per violation.

RULE TEXT:
(1) It is vital to this state that healthcare providers and healthcare staff be vaccinated against COVID-19. COVID-19 undergoes frequent mutations as it replicates, which over time has resulted in variants that are more transmissible or cause more severe disease. As of the time this rule was adopted, Delta was the variant making up more than 98 percent of sequenced specimens in Oregon. The Delta variant is approximately two to three times more infectious than early wild-type COVID-19 variants. There is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may transmit this variant effectively. Being vaccinated, is therefore critical to prevent spread of Delta. Healthcare providers and healthcare staff have contact with multiple patients over the course of a typical day and week, including providers that provide care for people in their homes. Individuals cared for in these settings are more likely than the general public to have conditions

that put them at risk for complications due to COVID-19. COVID-19 variants are running through the state's unvaccinated population and causing an increase in breakthrough cases for those who are fully vaccinated. This rule is necessary to help control COVID-19, protect patients, and to protect the state's healthcare workforce.

(2) For purposes of this rule, the following definitions apply:

(a) "Contractor" means a person who has healthcare providers or healthcare staff on contract to provide services in healthcare settings in Oregon.

(b) "COVID-19" means a disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

(c) "Fully vaccinated" means having received both doses of a two-dose COVID-19 vaccine or one dose of a single-dose COVID-19 vaccine and at least 14 days have passed since the individual's final dose of COVID-19 vaccine.

(d) "Healthcare providers and healthcare staff":

(A) Means individuals, paid and unpaid, working, learning, studying, assisting, observing or volunteering in a healthcare setting providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials, and includes but is not limited to any individual licensed by a health regulatory board as that is defined in ORS 676.160, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, student and volunteer personnel.

(B) Does not mean parents, family members, guardians or foster parents residing in the home and providing care to a child or foster child in the home.

(e) "Healthcare setting":

(A) Means any place where health care, including physical or behavioral health care is delivered and includes, but is not limited to any health care facility or agency licensed under ORS chapter 441 or 443, such as hospitals, ambulatory surgical centers, birthing centers, special inpatient care facilities, long-term acute care facilities, inpatient rehabilitation facilities, inpatient hospice facilities, nursing facilities, assisted living facilities, residential facilities, residential behavioral health facilities, adult foster homes, group homes, pharmacies, hospice, vehicles or temporary sites where health care is delivered (for example, mobile clinics, ambulances), and outpatient facilities, such as dialysis centers, health care provider offices, behavioral health care offices, urgent care centers, counseling offices, offices that provide complementary and alternative medicine such as acupuncture, homeopathy, naturopathy, chiropractic and osteopathic medicine, and other specialty centers.

(B) Does not include any setting described in paragraph (A) of this subsection where the responsible party is a part of state government as that is defined in ORS 174.111.

(C) Does not include a person's private home if the home is not otherwise licensed, registered or certified as a facility or home listed in paragraph (A) of this subsection.

(f) "Medical exception" means that an individual has a physical or mental impairment that prevents the individual from receiving a COVID-19 vaccination.

(g) "Religious exception" means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination.

(h) "Proof of vaccination" means documentation provided by a tribal, federal, state or local government, or a health care provider, that includes an individual's name, date of birth, type of COVID-19 vaccination given, date or dates given, depending on whether it is a one-dose or two-dose vaccine, and the name/location of the health care provider or site where the vaccine was administered. Documentation may include but is not limited to a COVID-19 vaccination record card or a copy or digital picture of the vaccination record card, or a print-out from the Oregon Health Authority's immunization registry.

(i) "Responsible party" means a person or persons who have control or responsibility for the activities of healthcare providers or healthcare staff in a healthcare setting.

(3) After October 18, 2021:

(a) A health care provider or healthcare staff person may not work, learn, study, assist, observe, or volunteer in a healthcare setting unless they are fully vaccinated or have provided documentation of a medical or religious exception.

(b) An employer of healthcare providers or healthcare staff, a contractor, or a responsible party may not employ,

contract with, or accept the volunteer services of healthcare providers or healthcare staff persons who are working, learning, studying, assisting, observing or volunteering at a healthcare setting unless the healthcare providers or healthcare staff persons are fully vaccinated against COVID-19 or have a documented medical or religious exception.

(4) On or before October 18, 2021, healthcare providers and healthcare staff must provide their employer, contractor or responsible party with either:

(a) Proof of vaccination showing they are fully vaccinated; or

(b) Documentation of a medical or religious exception.

(A) A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, on a form prescribed by the Oregon Health Authority (OHA) or a similar form that contains all of the information required in the OHA form, certifying that the individual has a physical or mental impairment that limits the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.

(B) A religious exception must be corroborated by a document, on a form prescribed by the Oregon Health Authority (OHA) or a similar form that contains all of the information required in the OHA form, signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the individual.

(5) Employers of healthcare providers or healthcare staff, contractors and responsible parties who grant an exception to the vaccination requirement under section (4) of this rule must take reasonable steps to ensure that unvaccinated healthcare providers and healthcare staff are protected from contracting and spreading COVID-19.

(6) On or before October 18, 2021, all employers of healthcare providers or healthcare staff, contractors, and responsible parties must have documentation that all healthcare providers and healthcare staff are in compliance with section (4) of this rule.

(7) Nothing in this rule is intended to prohibit employers of healthcare providers or healthcare staff, contractors and responsible parties from:

(a) Complying with the Americans with Disabilities Act and Title VII of the Civil Rights Act, and state law equivalents, for individuals unable to be vaccinated due to a medical condition or a sincerely held religious belief.

(b) Having more restrictive or additional requirements, including but not limited to requiring healthcare providers and healthcare staff to have documentation of an additional or booster dose of a COVID-19 vaccine if that is recommended by the U.S. Centers for Disease Control and Prevention.

(c) Imposing these requirements at an earlier date.

(8) The vaccination documentation and documentation of medical and religious exceptions described in section (4) of this rule must be:

(a) Maintained in accordance with applicable federal and state laws;

(b) Maintained for at least two years; and

(c) Provided to the Oregon Health Authority upon request.

(9) Employers of healthcare providers or healthcare staff, contractors and responsible parties who violate any provision of this rule are subject to civil penalties of $500 per day per violation.

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.010, ORS 431.110, ORS 433.004

STATUTES/OTHER IMPLEMENTED: ORS 431A.010, ORS 431.110, ORS 433.004

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SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

PH 39-2021
CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
08/25/2021 10:11 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Vaccination Requirements to Control COVID-19 for Schools and School-based Programs

EFFECTIVE DATE: 08/25/2021 THROUGH 02/20/2022

AGENCY APPROVED DATE: 08/25/2021

CONTACT: COVID Response and Recovery Unit
503-945-5488
COVID.19@dhsoha.state.or.us

800 NE Oregon St.
Portland,OR 97232

Filed By:
Brittany Hall
Rules Coordinator

NEED FOR THE RULE(S):

It is vital to this state that teachers, school staff, volunteers, and school-based program staff and volunteers be vaccinated against COVID-19 in order to protect themselves, children and students, particularly those who are too young to get vaccinated, against COVID-19, hospitalization and death. COVID-19 infection is caused by a virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This virus undergoes frequent mutations as it replicates, which over time has resulted in variants that are more transmissible, cause more severe disease or have other features of public health concern such as decreased vaccine effectiveness. In August of 2021, the B.1.617.2 (Delta) variant accounted for more than 98% of the COVID-19 infections in Oregon.

The Delta variant is approximately 2-3-fold more transmissible than early wild-type COVID-19 variants. People infected with the Delta variant have higher viral loads and a shorter incubation period. There is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may transmit this variant effectively. Being vaccinated, is therefore critical to prevent spread of Delta. The Delta variant is causing a surge in unvaccinated cases and vaccine breakthrough cases and Oregon's health care system is overwhelmed as a result. This rule is necessary to help control COVID-19, and to protect children, teachers, school staff, volunteers, and school-based program staff and volunteers.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and those working, attending and volunteering in schools and school-based programs. COVID-19 case numbers are higher than they have ever been, hospitalization of COVID-19 patients is on a steep rise, and Oregon's health care system is overwhelmed and at or over capacity. This rule needs to be adopted promptly so that the state can continue to prevent and slow the spread of COVID-19, for the reasons specified above. Requiring vaccination for those working and volunteering in schools and school-based programs is crucial to the effort in controlling COVID-19, and to ensure that students can stay in school and receive in-person instruction.

OHA Dashboard: Pediatric COVID-19 Cases (August 18, 2021). Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19PediatricReport/Demographics.

OHA Dashboard: Hospital Capacity and Usage in Oregon (reported by HOSCAP), August 20, 2021. Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19Update/HospitalCapacity.

OHA Dashboard: Oregon's Hospitalization Trend by Severity (August 20, 2021). Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19HospitalCapacity/HospitalizationbySeverity.

OHA Dashboard: Oregon's COVID-19 Disease Spread (August 22, 2021). Available at https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonCOVID-19PublicHealthIndicators/DiseaseSpread.

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

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Herlihy R, Bamberg W, Burakoff A, et al. Rapid Increase in Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — Mesa County, Colorado, April–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1084-1087. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e2

Hershow RB, Wu K, Lewis NM, et al. Low SARS-CoV-2 Transmission in Elementary Schools — Salt Lake County, Utah, December 3, 2020–January 31, 2021. MMWR Morb Mortal Wkly Rep 2021;70:442–448. DOI: http://dx.doi.org/10.15585/mmwr.mm7012e3

Li, B., Deng, A., Li, K., Hu, Y., Li, Z., Xiong, Q., Liu, Z., Guo, Q., Zou, L., Zhang, H. and Zhang, M., 2021. Viral infection and Transmission in a large well-traced outbreak caused by the Delta SARS-CoV-2 variant available at https://www.medrxiv.org/content/10.1101/2021.07.07.21260122v1.

Moline HL, Whitaker M, Deng L, et al. Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults

Aged 65 Years — COVID-NET, 13 States, February–April 2021. MMWR Morb Mortal Wkly Rep 2021;70:1088-1093. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e3

Nanduri S, Pilishvili T, Derado G, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e3

Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e1

Rubin D, Eisen M, Collins S, Pennington JW, Wang X, Coffin S. SARS-CoV-2 Infection in Public School District Employees Following a District-Wide Vaccination Program — Philadelphia County, Pennsylvania, March 21–April 23, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1040–1043. DOI: http://dx.doi.org/10.15585/mmwr.mm7030e1

Ryan S. McGee, Julian R. Homburger, Hannah E. Williams, Carl T. Bergstrom, Alicia Y. Zhou. Model-driven mitigation measures for reopening schools during the COVID-19 pandemic. DOI: https://doi.org/10.1101/2021.01.22.21250282

Volpp KG, Kraut BH, Ghosh S, Neatherlin J. Minimal SARS-CoV-2 Transmission After Implementation of a Comprehensive Mitigation Strategy at a School — New Jersey, August 20–November 27, 2020. MMWR Morb Mortal Wkly Rep 2021;70:377–381. DOI: http://dx.doi.org/10.15585/mmwr.mm7011a2

ADOPT: 333-019-1030

RULE TITLE: COVID-19 Vaccination Requirements for Teachers and School Staff

RULE SUMMARY: OAR 333-019-1030 helps to prevent and slow the spread of COVID-19 by requiring teachers, school staff, volunteers, and school-based program staff and volunteers who work in schools to be vaccinated against COVID-19 or request a medical or religious exception.

Teachers, school staff and volunteers:
(A) Means anyone age 16 and older:
(i) Who is employed at a school or anyone who is not employed but is otherwise engaged to provide goods or services to or at a school through any formal or informal agreement, whether compensated or uncompensated, and includes but is not limited to teachers, administrative staff, cleaning staff, coaches, school bus drivers, family volunteers and substitute teachers; and
(ii) Providing goods or services at or for a school that includes direct or indirect contact with students.
(B) Does not mean short-term visitors, individuals making deliveries, or school board members unless they are also volunteering in a school.

School-based program staff and volunteers:
(A) Means anyone age 16 and older:
(i) Who is employed by a school-based program or who is not employed but is otherwise engaged to provide goods or services to a school-based program through any formal or informal agreement, whether compensated or uncompensated, and includes but is not limited to teachers, administrative staff, child care staff, cleaning staff, coaches, school-based program drivers, family volunteers; and
(ii) Providing goods or services at or for a school-based program that includes direct or indirect contact with children or students.
(B) Does not mean short-term visitors or individuals making deliveries.

School means a public, private, parochial, charter or alternative educational program offering kindergarten through grade 12 or any part thereof. School does not mean stand-alone preschool program that goes up through kindergarten.

School-based program means a program serving children or students that takes place at or in school facilities.

Medical exception means that an individual has a physical or mental impairment that prevents the individual from receiving a COVID-19 vaccination.

Religious exception means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination.

After October 18, 2021:
• School staff and volunteers and school-based program staff and volunteers may not teach, work, provide care, learn, study, assist, observe, or volunteer at or for a school or school-based program unless they are fully vaccinated or have provided documentation of a medical or religious exception.
• Schools and school-based programs may not employ, contract with, or accept the volunteer services of teachers, school staff and volunteers, or school-based program staff and volunteers unless they are fully vaccinated against COVID-19 or have a documented medical or religious exception.

On or before October 18, 2021, teachers, school staff and volunteers, and school-based program staff and volunteers must provide the school or school-based program with either:
• Proof of vaccination showing they are fully vaccinated; or
• Documentation of a medical or religious exception.

A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, certifying that the individual has a physical or mental impairment that limits the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.

A religious exception must be corroborated by a document, on a form prescribed by the Oregon Health Authority, signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the individual.

Schools and school-based programs who grant an exception to the vaccination requirement must take reasonable steps to ensure that unvaccinated teachers, school staff and volunteers, and school-based program staff and volunteers are protected from contracting and spreading COVID-19.

On or before October 18, 2021, schools must have documentation that all teachers, school staff and volunteers are in compliance with this rule.

A school may request that a school-based program operating at that school, attest to whether it is, or is not, in compliance with this rule. If a school-based program receives such a request from a school, it must respond.

A school-based program may request that a school at which they intend to operate, attest to whether it is, or is not, in compliance with this rule. If a school receives such a request from a school-based program, it must respond.

The rule permits schools and school-based programs to:
• Have more restrictive or additional requirements, including but not limited to requiring teachers, school staff and volunteers, and school-based program staff and volunteers to have documentation of an additional or booster dose of a COVID-19 vaccine if that is recommended by the U.S. Centers for Disease Control and Prevention.
• Impose the vaccination requirements at an earlier date.

The vaccination documentation and documentation of medical and religious exceptions described in the rule must be:
• Maintained in accordance with applicable federal and state laws;
• Maintained for at least two years; and
• Provided to the Oregon Health Authority upon request.

Schools and school-based programs that violate any provision of this rule are subject to civil penalties of $500 per day per violation.

RULE TEXT:
(1) Children are required to attend school, which is a congregate setting where COVID-19 can spread easily if precautions are not taken. COVID-19 undergoes frequent mutations as it replicates, which over time has resulted in variants that are more transmissible or cause more severe disease. As of the time this rule was adopted, Delta was the variant making up more than 98 percent of sequenced specimens in Oregon. The Delta variant is approximately two to three times more infectious than early wild-type COVID-19 variants. There is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine

breakthrough cases may transmit this variant effectively. Being vaccinated, is therefore critical to prevent spread of Delta. COVID-19 variants are running through the state's unvaccinated population and causing an increase in breakthrough cases for those who are fully vaccinated. This rule is necessary to help control COVID-19, and to protect students, teachers, school staff, and volunteers.

(2) For purposes of this rule, the following definitions apply:

(a) "COVID-19" means a disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

(b) "Fully vaccinated" means having received both doses of a two-dose COVID-19 vaccine or one dose of a single-dose COVID-19 vaccine and at least 14 days have passed since the individual's final dose of COVID-19 vaccine.

(c) "Medical exception" means that an individual has a physical or mental impairment that prevents the individual from receiving a COVID-19 vaccination.

(d) "Religious exception" means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination.

(e) "Proof of vaccination" means documentation provided by a tribal, federal, state or local government, or a health care provider, that includes an individual's name, date of birth, type of COVID-19 vaccination given, date or dates given, depending on whether it is a one-dose or two-dose vaccine, and the name/location of the health care provider or site where the vaccine was administered. Documentation may include but is not limited to a COVID-19 vaccination record card or a copy or digital picture of the vaccination record card, or a print-out from the Oregon Health Authority's immunization registry.

(f) "School":

(A) Means a public, private, parochial, charter or alternative educational program offering kindergarten through grade 12 or any part thereof.

(B) Does not mean stand-alone preschool program that goes up through kindergarten.

(g) "School-based program" means a program serving children or students that takes place at or in school facilities.

(h) "School-based program staff and volunteers":

(A) Means anyone age 16 and older:

(i) Who is employed by a school-based program or who is not employed but is otherwise engaged to provide goods or services to a school-based program through any formal or informal agreement, whether compensated or uncompensated, and includes but is not limited to teachers, administrative staff, child care staff, cleaning staff, coaches, school-based program drivers, family volunteers; and

(ii) Providing goods or services at or for a school-based program that includes direct or indirect contact with children or students.

(B) Does not mean short-term visitors or individuals making deliveries.

(i) "Teachers, school staff and volunteers":

(A) Means anyone age 16 and older:

(i) Who is employed at a school or anyone who is not employed but is otherwise engaged to provide goods or services to or at a school through any formal or informal agreement, whether compensated or uncompensated, and includes but is not limited to teachers, administrative staff, cleaning staff, coaches, school bus drivers, family volunteers and substitute teachers; and

(ii) Providing goods or services at or for a school that includes direct or indirect contact with students.

(B) Does not mean short-term visitors, individuals making deliveries, or school board members unless they are also volunteering in a school.

(3) After October 18, 2021:

(a) Teachers, school staff and volunteers may not teach, work, learn, study, assist, observe, or volunteer at a school unless they are fully vaccinated or have provided documentation of a medical or religious exception.

(b) A school may not employ, contract with, or accept the volunteer services of teachers, school staff or volunteers who are teaching, working, learning, studying, assisting, observing, or volunteering at a school unless the teachers or school staff are fully vaccinated against COVID-19 or have a documented medical or religious exception.

(4) On or before October 18, 2021, teachers, school staff and volunteers must provide their school, employer or contractor with either:

(a) Proof of vaccination showing they are fully vaccinated; or

(b) Documentation of a medical or religious exception.

(A) A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, on a form prescribed by the Oregon Health Authority, certifying that the individual has a physical or mental impairment that limits the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.

(B) A religious exception must be corroborated by a document, on a form prescribed by the Oregon Health Authority, signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the individual.

(5) Schools that grant an exception to the vaccination requirement under section (4) of this rule must take reasonable steps to ensure that unvaccinated teachers, school staff and volunteers are protected from contracting and spreading COVID-19.

(6) On or before October 18, 2021, schools must have documentation that all teachers, school staff and volunteers are in compliance with section (4) of this rule.

(7) After October 18, 2021:

(a) School-based program staff and volunteers may not teach, work, provide care, learn, study, assist, observe, or volunteer for a school-based program unless they are fully vaccinated or have provided documentation of a medical or religious exception.

(b) A school-based program may not employ, contract with, or accept the volunteer services of school-based program staff or volunteers who are teaching, working, providing care, learning, studying, assisting, observing, or volunteering at a school-based program unless the staff or volunteers are fully vaccinated against COVID-19 or have a documented medical or religious exception.

(8) On or before October 18, 2021, school-based program staff and volunteers must provide their school-based program with either:

(a) Proof of vaccination showing they are fully vaccinated; or

(b) Documentation of a medical or religious exception.

(A) A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, on a form prescribed by the Authority, certifying that the individual has a physical or mental impairment that limits the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.

(B) A religious exception must be corroborated by a document, on a form prescribed by the Oregon Health Authority, signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the individual.

(9) School-based programs that grant an exception to the vaccination requirement under section (8) of this rule must take reasonable steps to ensure that unvaccinated school-based program staff and volunteers are protected from contracting and spreading COVID-19.

(10) On or before October 18, 2021, school-based programs must have documentation that all school-based program staff and volunteers are in compliance with section (8) of this rule.

(11) A school may request that a school-based program operating at that school, attest to whether it is, or is not, in compliance with this rule. If a school-based program receives such a request from a school, it must respond.

(12) A school-based program may request that a school at which they intend to operate, attest to whether it is, or is not, in compliance with this rule. If a school receives such a request from a school-based program, it must respond.

(13) Nothing in this rule is intended to prohibit schools or school-based programs from:

(a) Complying with the Americans with Disabilities Act and Title VII of the Civil Rights Act, and state law equivalents, for individuals unable to be vaccinated due to a medical condition or a sincerely held religious belief.

(b) Having more restrictive or additional requirements, including but not limited to requiring teachers, school staff and volunteers, and school-based program staff and volunteers to have documentation of an additional or booster dose of a COVID-19 vaccine if that is recommended by the U.S. Centers for Disease Control and Prevention.

(c) Imposing these requirements at an earlier date.

(d) Allowing a school district or other governing body to collect the documentation required under sections (4), (6), (8) and (10) of this rule.

(14) The vaccination documentation and documentation of medical and religious exceptions must be:

(a) Maintained in accordance with applicable federal and state laws;

(b) Maintained for at least two years; and

(c) Provided to the Oregon Health Authority upon request.

(15) Schools and school-based programs that violate any provision of this rule are subject to civil penalties of $500 per day per violation.

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.010, ORS 431.110, ORS 433.004

STATUTES/OTHER IMPLEMENTED: ORS 431A.010, ORS 431.110, ORS 433.004

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

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

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 prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- **a two-dose primary series in individuals 12 through 15 years;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- **a two-dose primary series in individuals 12 years of age and older;**
- **a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**

[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.

- **18 through 64 years of age at high risk of severe COVID-19**
- **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. 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.

WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

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

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever

[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.

- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?
You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE VACCINE?
The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HAS THE VACCINE BEEN USED BEFORE?
Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020.

WHAT ARE THE BENEFITS OF THE VACCINE?
The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea

- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

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

You may also be given an option to enroll 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 on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE VACCINE GIVE ME COVID-19?
No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

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

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. 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).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
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.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

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.

Manufactured by
Pfizer Inc., New York, NY 10017

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

LAB-1451-9.3

Revised: 22 September 2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 08/2021

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common 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.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,
- have ever fainted in association with an injection.

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.
- Swollen lymph nodes.
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).
- Diarrhea, vomiting.

Severe Allergic Reactions

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,

- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

You may also be given an option to enroll 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 live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. 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, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

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 TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must

be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Aug/27/2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 02/2021

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, 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.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine at least 1 month after the second dose.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?
In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna COVID-19 Vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll 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 on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?
- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. 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, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
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 TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 04/2021

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]

[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.

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

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,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

June 10, 2021

Janssen Biotech, Inc.
Attention: Ms. Ruta Walawalkar
920 Route 202
Raritan, NJ 08869

Dear Ms. Walawalkar:

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, subject to terms of any authorization issued under that section.[2]

On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older pursuant to Section 564 of the Act.

On June 10, 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 February 27, 2021 letter in its entirety with revisions incorporated to clarify terms and conditions that relate to export of Janssen COVID-19 Vaccine from the United States.

The Janssen COVID-19 Vaccine is for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a recombinant, replication-incompetent human adenovirus serotype 26 (Ad26) vector, encoding the SARS-CoV-2 viral spike (S) glycoprotein, stabilized in its pre-fusion form. It is an investigational vaccine not licensed for any indication.

[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).

FDA reviewed safety and efficacy data from an ongoing phase 3 trial which has enrolled 43,783 participants randomized 1:1 to receive Janssen COVID-19 Vaccine or saline control. The trial has enrolled participants 18 years of age and older. FDA's review has considered the safety and effectiveness data as they relate to the request for emergency use authorization. FDA's review of the available safety data from 43,783 participants 18 years of age and older, who were followed for a median duration of eight weeks after receiving the vaccine or placebo, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the efficacy data from 39,321 participants 18 years of age and older who were SARS-CoV-2 seronegative or who had an unknown serostatus at baseline show that the vaccine was 66.9% effective (95% confidence interval (CI): 59.0, 73.4) and 66.1% effective (95% CI: 55.0, 74.8) in preventing moderate to severe/critical COVID-19 occurring at least 14 days and at least 28 days after vaccination, respectively. Based on these data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on February 26, 2021, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

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

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

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Janssen 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 the Janssen COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

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

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

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:

- Janssen Biotech, Inc. will supply the Janssen COVID-19 Vaccine, either directly or through authorized distributor(s)[4] to emergency response stakeholders[5] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Janssen COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[6] and used only to prevent COVID-19 in individuals ages 18 and older; and
- The Janssen COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

The Janssen COVID-19 Vaccine is supplied as a suspension in multi-dose vials. The Janssen COVID-19 Vaccine does not contain a preservative.

[4] "Authorized Distributor(s)" are identified by Janssen Biotech, 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 Janssen COVID-19 Vaccine.

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

[6] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. 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).

Each 0.5 mL dose of the Janssen COVID-19 Vaccine is formulated to contain $5x10^{10}$ virus particles of the Ad26 vector encoding the S glycoprotein of SARS-CoV-2. Each dose of the Janssen COVID-19 Vaccine also includes the following inactive ingredients 2.19 mg sodium chloride, 0.14 mg citric acid monohydrate, 2.02 mg trisodium citrate dihydrate, 0.16 mg polysorbate-80, 25.5 mg 2-hydroxypropyl-B-cyclodextrin, 2.04 mg ethanol. Each dose may also contain residual amounts of host cell proteins (≤0.15 mcg) and/or host cell DNA (≤3 ng).

The dosing regimen is a single dose of 0.5 mL

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

The Janssen COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Janssen 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.

The Janssen 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 the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the Janssen 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 the Janssen 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 the Janssen 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 the Janssen 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), the Janssen COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 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:

Janssen Biotech, Inc. and Authorized Distributor(s)

A. Janssen Biotech, Inc. and authorized distributor(s) will ensure that the authorized Janssen 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. Janssen Biotech, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Janssen Biotech, 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 the authorized Janssen COVID-19 Vaccine. Janssen Biotech, 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. Janssen Biotech, 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. Janssen Biotech, Inc. may request changes to this authorization, including to the authorized Fact Sheets for the Janssen COVID-19 Vaccine. Any request for changes to this EUA must be submitted to the Office of Vaccines Research and Review

(OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[7]

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

G. Janssen Biotech, Inc. must submit to Investigational New Drug application (IND) number 22657 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 the Agency.

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

J. Janssen Biotech, 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.

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

K. Janssen Biotech, Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due June 1, 2021.

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

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

N. Janssen Biotech, Inc. will conduct post-authorization observational studies to evaluate the association between Janssen 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 Janssen COVID-19 Vaccine under this EUA in the general U.S. population (18 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. Janssen Biotech, Inc. will provide protocols and status update reports to the IND 22657 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

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

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

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

Vaccination Providers

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

S. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination.

T. Vaccination providers administering the Janssen COVID-19 Vaccine must report the following information associated with the administration of the Janssen COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse event
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem Inflammatory Syndrome in 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 "Janssen 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 Janssen Biotech, Inc. by contacting 1-800-565-4008 or by providing a copy of the VAERS form to Janssen Biotech, Inc.; Fax: 215-293-9955, or by email JNJvaccineAE@its.jnj.com.

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 Janssen 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 Janssen 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 18 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 product 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.

IV. Duration of Authorization

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

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

August 12, 2021

ModernaTX, Inc.
Attention: Ms. Carlota Vinals
200 Technology Square
Cambridge, MA 02139

Dear Ms. Vinals:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes 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 (the FD&C Act or the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older, pursuant to Section 564 of the Act. FDA reissued the letter of authorization twice: February 25, 2021[3] and July 7, 2021.[4]

On August 12, 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 again is reissuing the letter in its entirety with revisions incorporated to authorize for emergency use a third dose of the Moderna COVID-19 vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[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 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 ModernaTX, Inc.

[4] In the July 7, 2021 revision, , FDA clarified terms and conditions that relate to export of Moderna COVID-19 Vaccine from the United States.

Moderna COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

FDA reviewed safety and efficacy data from an ongoing phase 3 trial in approximately 30,000 participants randomized 1:1 to receive Moderna COVID-19 Vaccine or saline control. The trial has enrolled participants 18 years of age and older.

FDA's review of the available safety data from 30,351 participants 18 years of age and older, who were followed for a median of 7 weeks after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. Review of additional safety data from these participants with a median of 9 weeks of follow-up after receipt of the second dose did not change FDA's assessment of safety of the vaccine.

FDA's analysis of the efficacy data from 28,207 participants 18 years of age and older without evidence of SARS-CoV-2 infection prior to dose 1 confirms the vaccine was 94.1% effective (95% confidence interval (CI) 89.3, 96.8) in preventing COVID-19 occurring at least 14 days after the second dose (with 11 COVID-19 cases in the vaccine group compared to 185 COVID-19 cases in the placebo group). In this final scheduled analysis participants had been followed for a median of 9 weeks following the second dose. This result is consistent with that obtained from an interim analysis of efficacy conducted after these participants had been followed for a median of 7 weeks after the second dose (vaccine efficacy 94.5%, 95% CI: 86.5, 97.8).

Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on December 17, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the August 12, 2021 authorization of a third dose of the Moderna COVID-19 vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 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 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 the Moderna COVID-19 vaccine was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals for comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to

indicate this antibody titer was possibly protective. Secondary outcome was based on a virus neutralization assay 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 SARS-CoV-2 antibodiesindicative 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. A supportive secondary study describes 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 a similar mRNA COVID-19 vaccine, Pfizer-BioNTech COVID-19, was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of SARS-CoV-2 antibodies meeting the pre-identified 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 had an increase in antibody titers that the investigators considered significant. 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. Despite the moderate enhancement in antibody titers, the totality of data (including the supportive paper by Kamar et al. and demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Moderna COVID-19 vaccine may be effective in this population, and that the known and potential benefit of a third dose of Moderna COVID-19 vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 18 years of age who have received two doses of the Moderna 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 Moderna COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Moderna 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 Moderna 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 Moderna COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.[5]

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:

- ModernaTX, Inc. will supply Moderna COVID-19 Vaccine either directly or through authorized distributor(s)[6] to emergency response stakeholders[7] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Moderna COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[8] and used only to prevent COVID-19 in individuals ages 18 and older; and

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

[6] "Authorized Distributor(s)" are identified by ModernaTX, 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 Moderna COVID-19 Vaccine.

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

[8] 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 Moderna COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

The Moderna COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials.. The Moderna COVID-19 Vaccine does not contain a preservative.

Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains 100 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Moderna COVID-19 Vaccine also includes the following ingredients: lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The dosing regimen is two doses of 0.5 mL each, one month 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 18 years of age or older who have undergone solid organ transplantation, or individuals 18 and older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The manufacture of the authorized Moderna COVID-19 Vaccine is limited to those facilities identified and agreed upon in the ModernaTX, Inc. request for authorization.

The Moderna COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Moderna 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.

The Moderna 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 the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Moderna 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 Moderna 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 Moderna 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 Moderna 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), Moderna COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 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:

ModernaTX, Inc. and Authorized Distributor(s)

A. ModernaTX, Inc. and authorized distributor(s) will ensure that the authorized Moderna 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. ModernaTX, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. ModernaTX, 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 Moderna COVID-19 Vaccine. ModernaTX, 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. ModernaTX, 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. ModernaTX, Inc. may request changes to this authorization, including to the authorized Fact Sheets for Moderna COVID-19 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[9].

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

G. ModernaTX, Inc. must submit to Investigational New Drug application (IND) number 19745 periodic safety reports at monthly intervals, in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE), 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).

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

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

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

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

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

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

N. ModernaTX, Inc. will conduct post-authorization observational studies to evaluate the association between Moderna 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 Moderna COVID-19 Vaccine under this EUA in the general U.S. population (18 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. ModernaTX, Inc. will provide protocols and status update reports to the IND 19745 with agreed-upon study designs and milestone dates.

O. ModernaTX, Inc., working with its contract research organization, will continue to monitor the performance of its clinical investigators in ongoing clinical studies of its vaccine and will report to FDA promptly any significant deviations from the protocols.

Emergency Response Stakeholders

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

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

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

Vaccination Providers

S. 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.

T. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

U. Vaccination providers administering Moderna COVID-19 Vaccine must report the following information associated with the administration of Moderna COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in 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 " Moderna 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 ModernaTX, Inc., by contacting 1-866-663-3762, by providing a copy of the VAERS form to ModernaTX, Inc., Fax: 1-866-599-1342 or by email; ModernaPV@modernatx.com.

V. 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.

W. 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.

X. 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

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna 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.

Z. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna 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 18 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

AA. If the product is exported from the United States, conditions C, D, and P through Z 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.

IV. Duration of Authorization

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

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at (b) (4)

The final formulated product will be manufactured, filled, labeled and packaged at Pfizer (b) (4)

. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at (b) (4)

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90°C to -60°C (-130°F to -76°F). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at (b) (4) , the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer (b) (4) , it is defined as the date of the (b) (4)

Following the final sterile filtration, (b) (4) , no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

   Final Protocol Submission: February 8, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.
Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June 30, 2022

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

    Final Protocol Submission: March 22, 2021

    Study Completion: December 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use COMIRNATY safely and effectively. See full prescribing information for COMIRNATY.

COMIRNATY® (COVID-19 Vaccine, mRNA) suspension for injection, for intramuscular use
Initial U.S. Approval: 2021

---------- INDICATIONS AND USAGE----------
COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
- For intramuscular injection only. (2.2)
- COMIRNATY is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart. (2.3)

---------- DOSAGE FORMS AND STRENGTHS----------
Suspension for injection. After preparation, a single dose is 0.3 mL. (3)

---------- CONTRAINDICATIONS ----------
Known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. (5.2)
- Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY. Procedures should be in place to avoid injury from fainting. (5.4)

---------- ADVERSE REACTIONS ----------
- In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%). (6.1)
- In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache, (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 8/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

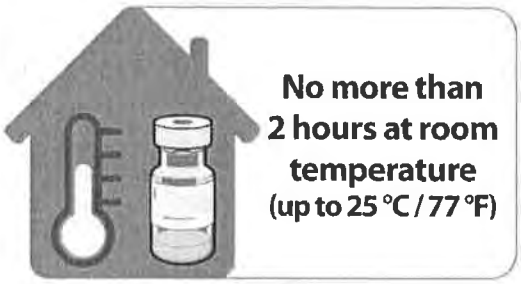
Prior to Dilution

- COMIRNATY 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 [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *[see How Supplied/Storage and Handling (16)]*.
- Refer to thawing instructions in the panels below.

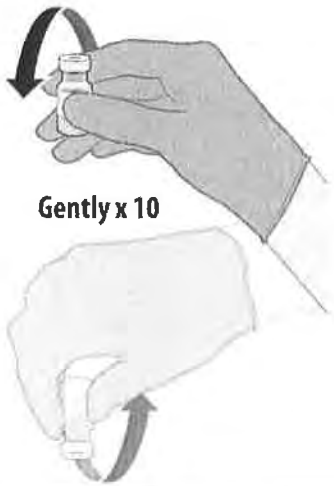
Dilution

- Dilute the vial contents using 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP to form COMIRNATY. Do not add more than 1.8 mL of diluent.
- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Vials of sterile 0.9% Sodium Chloride Injection, USP are provided but shipped separately. Use the provided diluent or another sterile 0.9% Sodium Chloride Injection, USP as the diluent.
    - Provided diluent vials are single-use only; discard after 1.8 mL is withdrawn.
    - If another sterile 0.9% Sodium Chloride Injection, USP is used as the diluent, discard after 1.8 mL is withdrawn.
    - Do not dilute more than 1 vial of COMIRNATY using the same diluent vial.
- After dilution, 1 vial of COMIRNATY contains 6 doses of 0.3 mL each.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION

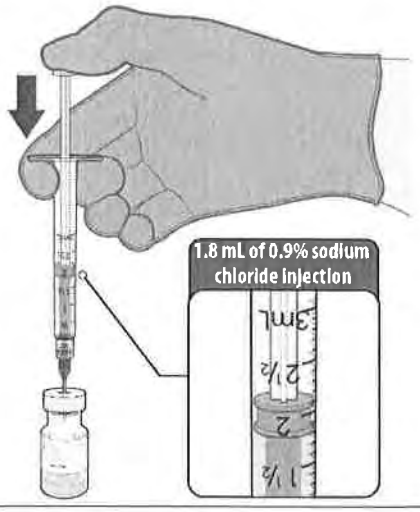


- Thaw vial(s) of COMIRNATY before dilution either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

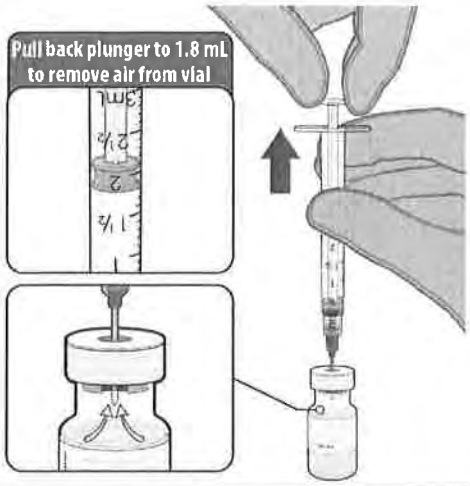
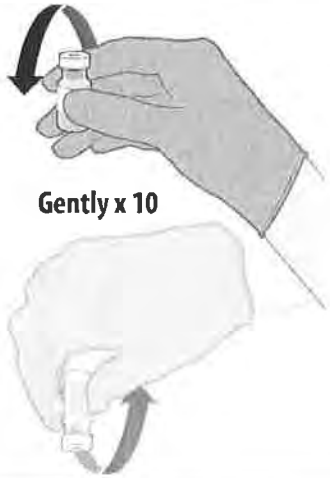
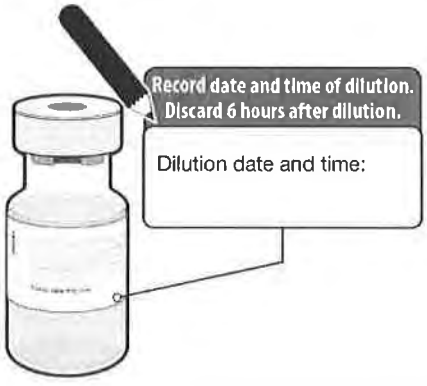


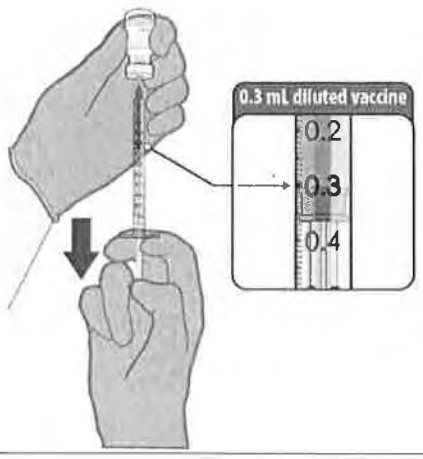
- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vaccine vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

DILUTION



- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent.
- Withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Add 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vaccine vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing COMIRNATY 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 COMIRNATY 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 COMIRNATY	
	• Withdraw 0.3 mL of COMIRNATY 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 a single vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

After dilution, vials of COMIRNATY contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 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.

2.2 Administration Information

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The vaccine will be an off-white suspension. Do not administer if vaccine is discolored or contains particulate matter.

Administer a single 0.3 mL dose of COMIRNATY intramuscularly.

2.3 Vaccination Schedule

COMIRNATY is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the vaccination series. Individuals who have received 1 dose of COMIRNATY should receive a second dose of COMIRNATY to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

COMIRNATY is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer COMIRNATY to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the COMIRNATY *[see Description (11)]*.

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 COMIRNATY.

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, including COMIRNATY. 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 COMIRNATY.

5.5 Limitation of Effectiveness

COMIRNATY may not protect all vaccine recipients.

6 ADVERSE REACTIONS

In clinical studies, the most commonly reported (≥10%) adverse reactions in participants 16 through 55 years of age following any dose were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies, the most commonly reported (≥10%) adverse reactions in participants 56 years of age and older following any dose were pain at the injection site (78.2%), fatigue (56.9%), headache, (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

6.1 Clinical Trials Experience

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

The safety of COMIRNATY was evaluated in participants 16 years of age and older in 2 clinical studies conducted in Germany (Study 1), United States, Argentina, Brazil, Turkey, South Africa, and Germany (Study 2). Study BNT162-01 (Study 1) was a Phase 2-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age. Study C4591001 (Study 2) is a Phase 1/2/3 multicenter, multinational, randomized, saline placebo-controlled, double-blinded (Phase 2/3), dose-finding, vaccine candidate-selection and efficacy study that has enrolled approximately 44,047 participants (22,026 COMIRNATY; 22,021 placebo) 16 years of age or older (including 378 and 376 participants 16 through 17 years of age in the vaccine and placebo groups, respectively). Upon issuance of the Emergency Use Authorization (December 11, 2020) for COMIRNATY, participants were unblinded to offer placebo participants COMIRNATY. Participants were unblinded in a phased manner over a period of months to offer placebo participants COMIRNATY. Study 2 also included 200 participants with confirmed stable human immunodeficiency virus (HIV) infection; HIV-positive participants are included in safety population disposition but are summarized separately in safety analyses. Confirmed stable HIV infection was defined as documented viral load <50 copies/mL and CD4 count >200 cells/mm^3 within 6 months before enrollment, and on stable antiretroviral therapy for at least 6 months.

At the time of the analysis of the ongoing Study 2 with a data cut-off of March 13, 2021, there were 25,651 (58.2%) participants (13,031 COMIRNATY and 12,620 placebo) 16 years of age and older followed for ≥4 months after the second dose.

Participants 16 years 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].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received COMIRNATY and those who received placebo. Overall, among the total participants who received either COMIRNATY or placebo, 50.9% were male, 49.1% were female, 79.3% were 16 through 64 years of age, 20.7% were 65 years of age and older, 82.0% were White, 9.6% were Black or African American, 25.9% were Hispanic/Latino, 4.3% were Asian, and 1.0% were American Indian or Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days following each dose of COMIRNATY and placebo in the subset of participants 16 through 55 years of age included in the safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of COMIRNATY and placebo for participants 56 years of age and older.

In participants 16 through 55 years of age after receiving Dose 2, the mean duration of pain at the injection site was 2.5 days (range 1 to 70 days), for redness 2.2 days (range 1 to 9 days), and for swelling 2.1 days (range 1 to 8 days) for participants in the COMIRNATY group. In participants 56 years of age and older after receiving Dose 2, the mean duration of pain at the injection site was 2.4 days (range 1 to 36 days), for redness 3.0 days (range 1 to 34 days), and for swelling 2.6 days (range 1 to 34 days) for participants in the COMIRNATY group.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 16 Through 55 Years of Age – Reactogenicity Subset of the Safety Population*

	COMIRNATY Dose 1 N[a]=2899 n[b] (%)	Placebo Dose 1 N[a]=2908 n[b] (%)	COMIRNATY Dose 2 N[a]=2682 n[b] (%)	Placebo Dose 2 N[a]=2684 n[b] (%)
Redness[c]				
Any (>2.0 cm)	156 (5.4)	28 (1.0)	151 (5.6)	18 (0.7)
Mild	113 (3.9)	19 (0.7)	90 (3.4)	12 (0.4)
Moderate	36 (1.2)	6 (0.2)	50 (1.9)	6 (0.2)
Severe	7 (0.2)	3 (0.1)	11 (0.4)	0
Swelling[c]				
Any (>2.0 cm)	184 (6.3)	16 (0.6)	183 (6.8)	5 (0.2)
Mild	124 (4.3)	6 (0.2)	110 (4.1)	3 (0.1)
Moderate	54 (1.9)	8 (0.3)	66 (2.5)	2 (0.1)
Severe	6 (0.2)	2 (0.1)	7 (0.3)	0
Pain at the injection site[d]				
Any	2426 (83.7)	414 (14.2)	2101 (78.3)	312 (11.6)
Mild	1464 (50.5)	391 (13.4)	1274 (47.5)	284 (10.6)
Moderate	923 (31.8)	20 (0.7)	788 (29.4)	28 (1.0)
Severe	39 (1.3)	3 (0.1)	39 (1.5)	0

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
No Grade 4 solicited local reactions were reported in participants 16 through 55 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, this information was included in the column header.

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.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 16 Through 55 Years of Age – Reactogenicity Subset of the Safety Population*

	COMIRNATY Dose 1 N[a]=2899 n[b] (%)	Placebo Dose 1 N[a]=2908 n[b] (%)	COMIRNATY Dose 2 N[a]=2682 n[b] (%)	Placebo Dose 2 N[a]=2684 n[b] (%)
Fever				
≥38.0°C	119 (4.1)	25 (0.9)	440 (16.4)	11 (0.4)
≥38.0°C to 38.4°C	86 (3.0)	16 (0.6)	254 (9.5)	5 (0.2)
>38.4°C to 38.9°C	25 (0.9)	5 (0.2)	146 (5.4)	4 (0.1)
>38.9°C to 40.0°C	8 (0.3)	4 (0.1)	39 (1.5)	2 (0.1)
>40.0°C	0	0	1 (0.0)	0
Fatigue[c]				
Any	1431 (49.4)	960 (33.0)	1649 (61.5)	614 (22.9)
Mild	760 (26.2)	570 (19.6)	558 (20.8)	317 (11.8)
Moderate	630 (21.7)	372 (12.8)	949 (35.4)	283 (10.5)
Severe	41 (1.4)	18 (0.6)	142 (5.3)	14 (0.5)

	COMIRNATY Dose 1 N[a]=2899 n[b] (%)	Placebo Dose 1 N[a]=2908 n[b] (%)	COMIRNATY Dose 2 N[a]=2682 n[b] (%)	Placebo Dose 2 N[a]=2684 n[b] (%)
Headache[c]				
Any	1262 (43.5)	975 (33.5)	1448 (54.0)	652 (24.3)
Mild	785 (27.1)	633 (21.8)	699 (26.1)	404 (15.1)
Moderate	444 (15.3)	318 (10.9)	658 (24.5)	230 (8.6)
Severe	33 (1.1)	24 (0.8)	91 (3.4)	18 (0.7)
Chills[c]				
Any	479 (16.5)	199 (6.8)	1015 (37.8)	114 (4.2)
Mild	338 (11.7)	148 (5.1)	477 (17.8)	89 (3.3)
Moderate	126 (4.3)	49 (1.7)	469 (17.5)	23 (0.9)
Severe	15 (0.5)	2 (0.1)	69 (2.6)	2 (0.1)
Vomiting[d]				
Any	34 (1.2)	36 (1.2)	58 (2.2)	30 (1.1)
Mild	29 (1.0)	30 (1.0)	42 (1.6)	20 (0.7)
Moderate	5 (0.2)	5 (0.2)	12 (0.4)	10 (0.4)
Severe	0	1 (0.0)	4 (0.1)	0
Diarrhea[e]				
Any	309 (10.7)	323 (11.1)	269 (10.0)	205 (7.6)
Mild	251 (8.7)	264 (9.1)	219 (8.2)	169 (6.3)
Moderate	55 (1.9)	58 (2.0)	44 (1.6)	35 (1.3)
Severe	3 (0.1)	1 (0.0)	6 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	664 (22.9)	329 (11.3)	1055 (39.3)	237 (8.8)
Mild	353 (12.2)	231 (7.9)	441 (16.4)	150 (5.6)
Moderate	296 (10.2)	96 (3.3)	552 (20.6)	84 (3.1)
Severe	15 (0.5)	2 (0.1)	62 (2.3)	3 (0.1)
New or worsened joint pain[c]				
Any	342 (11.8)	168 (5.8)	638 (23.8)	147 (5.5)
Mild	200 (6.9)	112 (3.9)	291 (10.9)	82 (3.1)
Moderate	137 (4.7)	55 (1.9)	320 (11.9)	61 (2.3)
Severe	5 (0.2)	1 (0.0)	27 (1.0)	4 (0.1)
Use of antipyretic or pain medication[f]	805 (27.8)	398 (13.7)	1213 (45.2)	320 (11.9)

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

No Grade 4 solicited systemic reactions were reported in participants 16 through 55 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction or use of antipyretic or pain medication was the same, therefore, this information was included in the column header.

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.

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*

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)
Redness[c]				
Any (>2.0 cm)	106 (5.3)	20 (1.0)	133 (7.2)	14 (0.8)
Mild	71 (3.5)	13 (0.7)	65 (3.5)	10 (0.5)
Moderate	30 (1.5)	5 (0.3)	58 (3.1)	3 (0.2)
Severe	5 (0.2)	2 (0.1)	10 (0.5)	1 (0.1)
Swelling[c]				
Any (>2.0 cm)	141 (7.0)	23 (1.2)	145 (7.8)	13 (0.7)
Mild	87 (4.3)	11 (0.6)	80 (4.3)	5 (0.3)
Moderate	52 (2.6)	12 (0.6)	61 (3.3)	7 (0.4)
Severe	2 (0.1)	0	4 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2.0 cm)	1408 (70.1)	185 (9.3)	1230 (66.1)	143 (7.8)
Mild	1108 (55.2)	177 (8.9)	873 (46.9)	138 (7.5)
Moderate	296 (14.7)	8 (0.4)	347 (18.7)	5 (0.3)
Severe	4 (0.2)	0	10 (0.5)	0

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
No Grade 4 solicited local reactions were reported in participants 56 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, the information was included in the column header.

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.

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*

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)
Fever				
≥38.0°C	26 (1.3)	8 (0.4)	219 (11.8)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.1)	3 (0.2)	158 (8.5)	2 (0.1)
>38.4°C to 38.9°C	2 (0.1)	3 (0.2)	54 (2.9)	1 (0.1)
>38.9°C to 40.0°C	1 (0.0)	2 (0.1)	7 (0.4)	1 (0.1)
>40.0°C	0	0	0	0

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)
Fatigue[c]				
Any	677 (33.7)	447 (22.5)	949 (51.0)	306 (16.7)
Mild	415 (20.7)	281 (14.1)	391 (21.0)	183 (10.0)
Moderate	259 (12.9)	163 (8.2)	497 (26.7)	121 (6.6)
Severe	3 (0.1)	3 (0.2)	60 (3.2)	2 (0.1)
Grade 4	0	0	1 (0.1)	0
Headache[c]				
Any	503 (25.0)	363 (18.3)	733 (39.4)	259 (14.1)
Mild	381 (19.0)	267 (13.4)	464 (24.9)	189 (10.3)
Moderate	120 (6.0)	93 (4.7)	256 (13.8)	65 (3.5)
Severe	2 (0.1)	3 (0.2)	13 (0.7)	5 (0.3)
Chills[c]				
Any	130 (6.5)	69 (3.5)	435 (23.4)	57 (3.1)
Mild	102 (5.1)	49 (2.5)	229 (12.3)	45 (2.5)
Moderate	28 (1.4)	19 (1.0)	185 (9.9)	12 (0.7)
Severe	0	1 (0.1)	21 (1.1)	0
Vomiting[d]				
Any	10 (0.5)	9 (0.5)	13 (0.7)	5 (0.3)
Mild	9 (0.4)	9 (0.5)	10 (0.5)	5 (0.3)
Moderate	1 (0.0)	0	1 (0.1)	0
Severe	0	0	2 (0.1)	0
Diarrhea[e]				
Any	168 (8.4)	130 (6.5)	152 (8.2)	102 (5.6)
Mild	137 (6.8)	109 (5.5)	125 (6.7)	76 (4.1)
Moderate	27 (1.3)	20 (1.0)	25 (1.3)	22 (1.2)
Severe	4 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	274 (13.6)	165 (8.3)	537 (28.9)	99 (5.4)
Mild	183 (9.1)	111 (5.6)	229 (12.3)	65 (3.5)
Moderate	90 (4.5)	51 (2.6)	288 (15.5)	33 (1.8)
Severe	1 (0.0)	3 (0.2)	20 (1.1)	1 (0.1)
New or worsened joint pain[c]				
Any	175 (8.7)	124 (6.2)	353 (19.0)	72 (3.9)
Mild	119 (5.9)	78 (3.9)	183 (9.8)	44 (2.4)
Moderate	53 (2.6)	45 (2.3)	161 (8.7)	27 (1.5)
Severe	3 (0.1)	1 (0.1)	9 (0.5)	1 (0.1)
Use of antipyretic or pain medication[f]	382 (19.0)	224 (11.3)	688 (37.0)	170 (9.3)

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

The only Grade 4 solicited systemic reaction reported in participants 56 years of age and older was fatigue.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. N for each reaction or use of antipyretic or pain medication was the same, therefore was included in the column header.

b. n = Number of participants with the specified reaction.

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity; Grade 4 reactions were defined in the clinical study protocol as emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration; Grade 4 emergency visit or hospitalization for severe vomiting.
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; Grade 4: emergency room or hospitalization for severe diarrhea.
f. Severity was not collected for use of antipyretic or pain medication.

In participants with chronic, stable HIV infection the frequencies of solicited local and systemic adverse reactions were similar to or lower than those observed for all participants 16 years of age and older.

Unsolicited Adverse Events

Overall, 11,253 (51.1%) participants in the COMIRNATY group and 11,316 (51.4%) participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 in the blinded placebo-controlled follow-up period with an additional 1,778 (8.1%) and 1,304 (5.9%) with ≥6 months of blinded follow-up time in the COMIRNATY and placebo groups, respectively.

A total of 12,006 (54.5%) participants originally randomized to COMIRNATY had ≥6 months total (blinded and unblinded) follow-up after Dose 2.

In an analysis of all unsolicited adverse events reported following any dose, through 1 month after Dose 2, in participants 16 years of age and older (N=43,847; 21,926 COMIRNATY group vs. 21,921 placebo group), those assessed as adverse reactions not already captured by solicited local and systemic reactions were nausea (274 vs. 87), malaise (130 vs. 22), lymphadenopathy (83 vs. 7), asthenia (76 vs. 25), decreased appetite (39 vs. 9), hyperhidrosis (31 vs. 9), lethargy (25 vs. 6), and night sweats (17 vs. 3).

In analyses of all unsolicited adverse events in Study 2 from Dose 1 up to the participant unblinding date, 58.2% of study participants had at least 4 months of follow-up after Dose 2. Among participants 16 through 55 years of age who received at least one dose of study vaccine, 12,995 of whom received COMIRNATY and 13,026 of whom received placebo, unsolicited adverse events were reported by 4,396 (33.8%) participants in the COMIRNATY group and 2,136 (16.4%) participants in the placebo group. In a similar analysis in participants 56 years of age and older that included 8,931 COMIRNATY recipients and 8,895 placebo recipients, unsolicited adverse events were reported by 2,551 (28.6%) participants in the COMIRNATY group and 1,432 (16.1%) participants in the placebo group. Among participants with confirmed stable HIV infection that included 100 COMIRNATY recipients and 100 placebo recipients, unsolicited adverse events were reported by 29 (29%) participants in the COMIRNATY group and 15 (15%) participants in the placebo group. The higher frequency of reported unsolicited adverse events among COMIRNATY recipients compared to placebo recipients was primarily attributed to events that are consistent with adverse reactions solicited among participants in the reactogenicity subset (Table 3 and Table 4).

Throughout the placebo-controlled safety follow-up period, Bell's palsy (facial paralysis) was reported by 4 participants in the COMIRNATY group and 2 participants in the placebo 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. In the placebo group the onset of facial paralysis was Day 32 and Day 102. Currently available information is insufficient to determine a causal relationship with the vaccine. In the analysis of blinded, placebo-controlled follow-up, 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 COMIRNATY. In the analysis of unblinded follow-up, there were no notable patterns of specific categories of non-serious adverse events that would suggest a causal relationship to COMIRNATY.

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 (COMIRNATY =12,995; placebo = 13,026), serious adverse events from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 103 (0.8%) COMIRNATY recipients and 117 (0.9%) placebo recipients. In a similar analysis, in participants 56 years of age and older (COMIRNATY = 8,931; placebo = 8,895), serious adverse events were reported by 165 (1.8%) COMIRNATY recipients and 151 (1.7%) placebo recipients who received at least 1 dose of COMIRNATY or placebo, respectively. In these analyses, 58.2% of study participants had at least 4 months of follow-up after Dose 2. Among participants with confirmed stable HIV infection serious adverse events from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 2 (2%) COMIRNATY recipients and 2 (2%) placebo recipients.

In the analysis of blinded, placebo-controlled follow-up, there were no notable patterns between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to COMIRNATY. In the analysis of unblinded follow-up, there were no notable patterns of specific categories of serious adverse events that would suggest a causal relationship to COMIRNATY.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postmarketing use of COMIRNATY, including under Emergency Use Authorization. Because these reactions are reported voluntarily from a population of uncertain size, 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 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COMIRNATY during pregnancy. Women who are vaccinated with COMIRNATY during pregnancy are encouraged to enroll in the registry by visiting https://mothertobaby.org/ongoing-study/covid19-vaccines/.

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 COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

A developmental toxicity study has been performed in female rats administered the equivalent of a single human dose of COMIRNATY on 4 occasions; twice prior to mating and twice during gestation. These studies revealed no evidence of harm to the fetus due to the vaccine *(see Animal Data)*.

Data

Animal Data

In a 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 COMIRNATY was administered to female rats by the intramuscular route on 4 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.

8.2 Lactation

Risk Summary

It is not known whether COMIRNATY is excreted in human milk. Data are not available to assess the effects of COMIRNATY on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for COMIRNATY and any potential adverse effects on the breastfed child from COMIRNATY or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of COMIRNATY in individuals 16 through 17 years of age is based on safety and effectiveness data in this age group and in adults *[see Adverse Reactions (6) and Clinical Studies (14.1)]*.

The safety and effectiveness of COMIRNATY in individuals younger than 16 years of age have not been established.

8.5 Geriatric Use

Of the total number of COMIRNATY recipients in Study 2 as of March 13, 2021 (N = 22,026), 20.7% (n = 4,552) were 65 years of age and older and 4.2% (n = 925) were 75 years of age and older *[see Clinical Studies (14.1)]*. No overall differences in safety or effectiveness were observed between these recipients and younger recipients.

11 DESCRIPTION

COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use. COMIRNATY 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 COMIRNATY contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the COMIRNATY 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.

COMIRNATY does not contain preservative.

The vial stoppers are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA 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.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. In a developmental toxicity study in rats with COMIRNATY there were no vaccine-related effects on female fertility *[see Use in Specific Populations (8.1)]*.

14 CLINICAL STUDIES

Efficacy in Participants 16 Years of Age and Older

Study 2 is an ongoing, multicenter, multinational, 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 HIV, hepatitis C virus (HCV), or hepatitis B virus (HBV).

In Study 2, based on data accrued through March 13, 2021, approximately 44,000 participants 16 years of age and older were randomized equally and received 2 doses of COMIRNATY or placebo. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

Overall, among the total participants who received COMIRNATY or placebo, 51.4% or 50.3% were male and 48.6% or 49.7% were female, 79.1% or 79.2% were 16 through 64 years of age, 20.9% or 20.8% were 65 years of age and older, 81.9% or 82.1% were White, 9.5% or 9.6% were Black or African American, 1.0% or 0.9% were American Indian or Alaska Native, 4.4% or 4.3% were Asian, 0.3% or 0.2% Native Hawaiian or other Pacific Islander, 25.6% or 25.4% were Hispanic/Latino, 73.9% or 74.1% were non-Hispanic/Latino, 0.5% or 0.5% did not report ethnicity, 46.0% or 45.7% had comorbidities [participants who have 1 or more

comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or body mass index (BMI) ≥30 kg/m^2], respectively. The mean age at vaccination was 49.8 or 49.7 years and median age was 51.0 or 51.0 in participants who received COMIRNATY or placebo, respectively.

Efficacy Against COVID-19

The population for the analysis of the protocol pre-specified primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COMIRNATY 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. The population in the protocol pre-specified 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.

For participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2, vaccine efficacy against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0% (95% credible interval: 90.3, 97.6), which met the pre-specified success criterion. The case split was 8 COVID-19 cases in the COMIRNATY group compared to 162 COVID-19 cases in the placebo group.

The population for the updated vaccine efficacy analysis included participants 16 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 during blinded placebo-controlled follow-up through March 13, 2021, representing up to 6 months of follow-up after Dose 2. There were 12,796 (60.8%) participants in the COMIRNATY group and 12,449 (58.7%) in the placebo group followed for ≥4 months after Dose 2 in the blinded placebo-controlled follow-up period.

SARS-CoV-2 variants of concern identified from COVID-19 cases in this study include B.1.1.7 (Alpha) and B.1.351 (Beta). Representation of identified variants among cases in vaccine versus placebo recipients did not suggest decreased vaccine effectiveness against these variants.

The updated vaccine efficacy information is presented in Table 5.

Table 5: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants 16 Years of Age and Older Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**COMIRNATY N[a]=19,993 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,118 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
All participants[f]	77 6.092 (19,711)	833 5.857 (19,741)	91.1 (88.8, 93.1)
16 through 64 years	70 4.859 (15,519)	709 4.654 (15,515)	90.5 (87.9, 92.7)
65 years and older	7 1.233 (4192)	124 1.202 (4226)	94.5 (88.3, 97.8)

First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection			
Subgroup	COMIRNATY N[a]=21,047 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=21,210 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
All participants	81 6.340 (20,533)	854 6.110 (20,595)	90.9 (88.5, 92.8)
16 through 64 years	74 5.073 (16,218)	726 4.879 (16,269)	90.2 (87.5, 92.4)
65 years and older	7 1.267 (4315)	128 1.232 (4326)	94.7 (88.7, 97.9)

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. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Subgroup analyses of vaccine efficacy (although limited by small numbers of cases in some subgroups) did not suggest meaningful differences in efficacy across genders, ethnic groups, geographies, or for participants with obesity or medical comorbidities associated with high risk of severe COVID-19.

Efficacy Against Severe COVID-19

Efficacy analyses of secondary efficacy endpoints supported benefit of COMIRNATY in preventing severe COVID-19. Vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 6) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the COMIRNATY and placebo groups.

Table 6: Vaccine Efficacy – First Severe COVID-19 Occurrence in Participants 16 Years of Age and Older With or Without* Prior SARS-CoV-2 Infection Based on Protocol† or Centers for Disease Control and Prevention (CDC)‡ Definition From 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up

Vaccine Efficacy – First Severe COVID-19 Occurrence			
	COMIRNATY Cases n1[a] Surveillance Time[b] (n2[c])	Placebo Cases n1[a] Surveillance Time[b] (n2[c])	Vaccine Efficacy % (95% CI[d])
7 days after Dose 2[d]	1 6.353 (20,540)	21 6.237 (20,629)	95.3 (70.9, 99.9)
Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC Definition			
	COMIRNATY Cases n1[a] Surveillance Time[b] (n2[c])	Placebo Cases n1[a] Surveillance Time[b] (n2[c])	Vaccine Efficacy % (95% CI[d])
7 days after Dose 2[d]	0 6.345 (20,513)	31 6.225 (20,593)	100 (87.6, 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.

† Severe illness from COVID-19 is defined in the protocol as confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥125 beats per minute, saturation of oxygen ≤93% on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen <300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];
- Evidence of shock (systolic blood pressure <90 mm Hg, diastolic blood pressure <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an Intensive Care Unit;
- Death.

‡ Severe illness from COVID-19 as defined by CDC is confirmed COVID-19 and presence of at least 1 of the following:

- Hospitalization;
- Admission to the Intensive Care Unit;
- Intubation or mechanical ventilation;
- Death.

a. n1 = Number of participants meeting the endpoint definition.
b. 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.
c. n2 = Number of participants at risk for the endpoint.
d. Two-side confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

16 HOW SUPPLIED/STORAGE AND HANDLING

COMIRNATY Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 0069-1000-03) or 195 multiple dose vials (NDC 0069-1000-02). A 0.9% Sodium Chloride Injection, USP diluent is provided but shipped separately, and should be stored at controlled room temperature 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. The provided 0.9% Sodium Chloride Injection, USP diluent will be supplied either as cartons of 10 mL single-use vials manufactured by

Hospira, Inc (NDC 0409-4888-10), or 2 mL single-use vials manufactured by Fresenius Kabi USA, LLC (NDC 63323-186-02).

After dilution, 1 vial contains 6 doses of 0.3 mL.

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 COMIRNATY 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 -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. Alternatively, 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 1 time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F). 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 COMIRNATY 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 -90°C to -60°C (-130°F to -76°F). 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 1 time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F).

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] 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 25°C (77°F)] 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 1 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.

17 PATIENT COUNSELING INFORMATION

Inform vaccine recipient of the potential benefits and risks of vaccination with COMIRNATY.

Inform vaccine recipient of the importance of completing the two dose vaccination series.

There is a pregnancy exposure registry for COMIRNATY. Encourage individuals exposed to COMIRNATY around the time of conception or during pregnancy to register by visiting https://mothertobaby.org/ongoing-study/covid19-vaccines/.

Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 and www.vaers.hhs.gov.

This product's labeling may have been updated. For the most recent prescribing information, please visit https://dailymed.nlm.nih.gov/dailymed/.

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

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1448-1.0

US Govt. License No. 2229

Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* (Section A). *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination Location covered under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

ORGANIZATION IDENTIFICATION		
Organization's legal name:		
Number of affiliated vaccination locations covered by this agreement: _____		
Organization telephone number:	Email *(must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)*:	
Organization address:		
RESPONSIBLE OFFICERS		
For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.		
Chief Medical Officer (or Equivalent) Information		
Last name	First name	Middle initial
Title	Licensure (state and number)	
Telephone number:	Email:	
Address:		
Chief Executive Officer (or Chief Fiduciary) Information		
Last name	First name	Middle initial
Telephone number:	Email:	
Address:		

AGREEMENT REQUIREMENTS	
I understand this is an agreement between Organization and CDC. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:	
1.	Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).[1]
2.	Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website.[2] Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.[2] Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3.	Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
4.	Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.
5.	Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6.	Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.[3]
7.	Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following: a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit[4], which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit[4]; c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies through footnoted weblinks. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

[2] https://www.cdc.gov/vaccines/programs/iis/index.html

[3] https://www.cdc.gov/vaccines/pandemic-guidance/index.html

[4] https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

	d) Organization must monitor and comply with COVID-19 Vaccine expiration dates; and e) Organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8.	Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.
9.	Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.[5]
10.	Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).[6]
11.	Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.
12.	a) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine. b) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 Vaccine-administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if Organization fails to comply with these requirements with respect to the administered COVID-19 Vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.[7]

[5] The disposal process for remaining unused COVID-19 Vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

[6] https://vaers.hhs.gov/reportevent.html

[7] *See* Pub. L. No. 109-148, Public Health Service Act §§ 319F-3 and 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

Chief Medical Officer (or Equivalent)		
Last name	First name	Middle initial
Signature:		Date:
Chief Executive Officer (or Chief Fiduciary)		
Last name	First name	Middle initial
Signature:		Date:

For official use only:

VTrckS ID for this Organization, if applicable: _____

Vaccines for Children (VFC) PIN, if applicable: _____ *Other PIN (e.g., state, 317):* _____

IIS ID, if applicable: _____

Unique COVID-19 Organization ID (Section A):* _____

**The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A"). This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). These unique identifiers are required even if there is only one location associated with an organization.*

Section B. CDC COVID-19 Vaccination Program Provider Profile Information

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

ORGANIZATION IDENTIFICATION FOR INDIVIDUAL LOCATIONS	
Organization location name:	Will another Organization location order COVID-19 vaccine for this site? ☐ Yes; provide Organization name: _____ ☐ No

CONTACT INFORMATION FOR LOCATION'S PRIMARY COVID-19 VACCINE COORDINATOR		
Last name:	First name:	Middle initial:
Telephone:	Email:	

CONTACT INFORMATION FOR LOCATION'S BACK-UP COVID-19 VACCINE COORDINATOR		
Last name:	First name:	Middle initial:
Telephone:	Email:	

ORGANIZATION LOCATION ADDRESS FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS			
Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:		Fax:	

ORGANIZATION ADDRESS OF LOCATION WHERE COVID-19 VACCINE WILL BE ADMINISTERED (IF DIFFERENT FROM RECEIVING LOCATION)			
Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:		Fax:	

DAYS AND TIMES VACCINE COORDINATORS ARE AVAILABLE FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS				
Monday	Tuesday	Wednesday	Thursday	Friday
AM:	AM:	AM:	AM:	AM:
PM:	PM:	PM:	PM:	PM:

For official use only:

VTrckS ID for this location, if applicable: _____ *Vaccines for Children (VFC) PIN, if applicable:* _____

IIS ID, if applicable: _____ *Unique COVID-19 Organization ID (from Section A):* _____ *Unique Location ID**:* _____

***The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number will include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A), has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3.*

COVID-19 VACCINATION PROVIDER TYPE FOR THIS LOCATION (SELECT ONE)

- ☐ Commercial vaccination service provider
- ☐ Corrections/detention health services
- ☐ Health center – community (non-Federally Qualified Health Center/non-Rural Health Clinic)
- ☐ Health center – migrant or refugee
- ☐ Health center – occupational
- ☐ Health center – STD/HIV clinic
- ☐ Health center – student
- ☐ Home health care provider
- ☐ Hospital
- ☐ Indian Health Service
- ☐ Tribal health
- ☐ Medical practice – family medicine
- ☐ Medical practice – pediatrics
- ☐ Medical practice – internal medicine
- ☐ Medical practice – OB/GYN
- ☐ Medical practice – other specialty
- ☐ Pharmacy – chain
- ☐ Pharmacy – independent
- ☐ Public health provider – public health clinic
- ☐ Public health provider – Federally Qualified Health Center
- ☐ Public health provider – Rural Health Clinic
- ☐ Long-term care – nursing home, skilled nursing facility, federally certified
- ☐ Long-term care – nursing home, skilled nursing facility, non-federally certified
- ☐ Long-term care – assisted living
- ☐ Long-term care – intellectual or developmental disability
- ☐ Long-term care – combination (e.g., assisted living and nursing home in same facility)
- ☐ Urgent care
- ☐ Other (Specify: _____)

SETTING(S) WHERE THIS LOCATION WILL ADMINISTER COVID-19 VACCINE (SELECT ALL THAT APPLY)

- ☐ Childcare or daycare facility
- ☐ College, technical school, or university
- ☐ Community center
- ☐ Correctional/detention facility
- ☐ Health care provider office, health center, medical practice, or outpatient clinic
- ☐ Hospital (i.e., inpatient facility)
- ☐ In-home
- ☐ Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)
- ☐ Pharmacy
- ☐ Public health clinic (e.g., local health department)
- ☐ School (K – grade 12)
- ☐ Shelter
- ☐ Temporary or off-site vaccination clinic – point of dispensing (POD)
- ☐ Temporary location – mobile clinic
- ☐ Urgent care facility
- ☐ Workplace
- ☐ Other (Specify: _____)

APPROXIMATE NUMBER OF PATIENTS/CLIENTS ROUTINELY SERVED BY THIS LOCATION

Number of children 18 years of age and younger: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of adults 19 – 64 years of age: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of adults 65 years of age and older: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of unique patients/clients seen per week, on average: _____
☐ Unknown
☐ Not applicable (e.g., for commercial vaccination service providers)

INFLUENZA VACCINATION CAPACITY FOR THIS LOCATION

Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season:
_____ *(Enter "0" if no influenza vaccine doses were administered by this location in 2019-20)*
☐ Unknown

POPULATION(S) SERVED BY THIS LOCATION (SELECT ALL THAT APPLY)

- ☐ General pediatric population
- ☐ General adult population
- ☐ Adults 65 years of age and older
- ☐ Long term care facility residents (nursing home, assisted living, or independent living facility)
- ☐ Health care workers
- ☐ Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services)
- ☐ Military – active duty/reserves
- ☐ Military – veteran
- ☐ People experiencing homelessness
- ☐ Pregnant women
- ☐ Racial and ethnic minority groups
- ☐ Tribal communities
- ☐ People who are incarcerated/detained
- ☐ People living in rural communities
- ☐ People who are under-insured or uninsured
- ☐ People with disabilities
- ☐ People with underlying medical conditions* that are risk factors for severe COVID-19 illness
- ☐ Other people at higher-risk for COVID-19 (Specify: _____)

DOES YOUR ORGANIZATION CURRENTLY REPORT VACCINE ADMINISTRATION DATA TO THE STATE, LOCAL, OR TERRITORIAL IMMUNIZATION INFORMATION SYSTEM (IIS)?

- ☐ Yes [List IIS Identifier: _____]
- ☐ No
- ☐ Not applicable

If "No," please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:

If "Not applicable," please explain:

ESTIMATED NUMBER OF 10-DOSE MULTIDOSE VIALS (MDVs) YOUR LOCATION IS ABLE TO STORE DURING PEAK VACCINATION PERIODS (E.G., DURING BACK-TO-SCHOOL OR INFLUENZA VACCINE SEASON) AT THE FOLLOWING TEMPERATURES:

Refrigerated (2°C to 8°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs
Frozen (-15° to -25°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs
Ultra-frozen (-60° to -80°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs

STORAGE UNIT DETAILS FOR THIS LOCATION

List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:

1. *Example: CDC & Co/Red series two-door/refrigerator*
2.
3.
4.
5.

I attest that each unit listed will maintain the appropriate temperature range indicated above: (*please sign and date*)

_____

Medical/pharmacy director or location's vaccine coordinator signature

_____

Date

* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html

PROVIDERS PRACTICING AT THIS FACILITY *(additional spaces for providers at end of form)*		
Instructions: *List below all licensed healthcare providers at this location who have prescribing authority (i.e., MD, DO, NP, PA, RPh).*		
Provider Name	**Title**	**License No.**

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 -90°C to -60°C (-130°F to -76°F) 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 -90°C to -60°C (-130°F to -76°F) 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 [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *(see Storage and Handling)*.

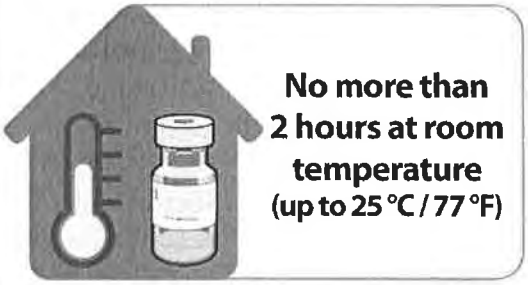
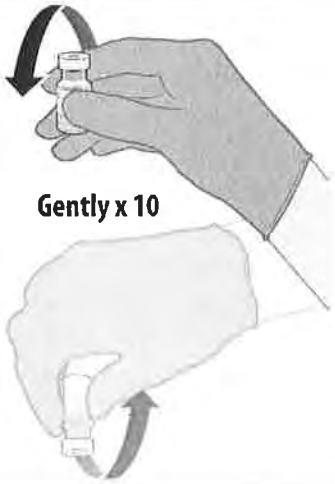
[2] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety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

- Refer to thawing instructions in the panels below.

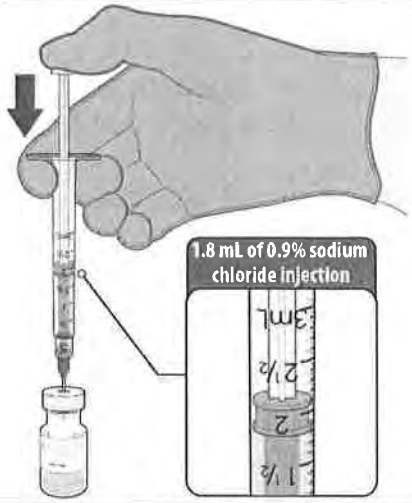
Dilution
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic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

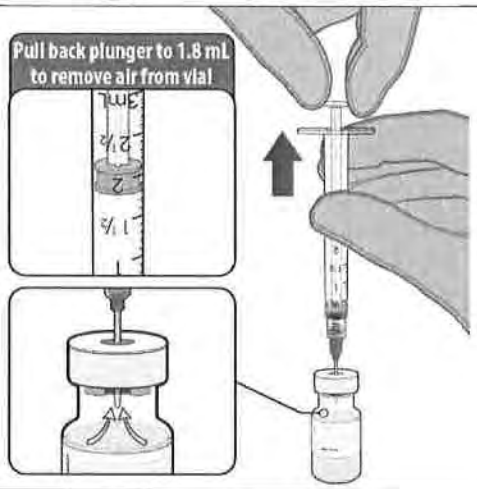
- Refer to dilution and dose preparation instructions in the panels below.

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 [2°C to 8°C (35°F to 46°F)]. 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 25°C (77°F)] 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.

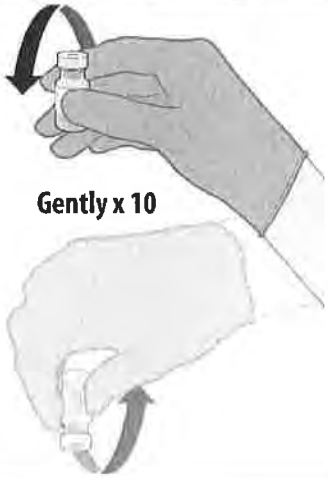
DILUTION



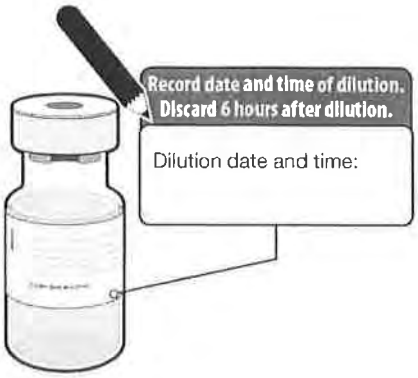
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, 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.

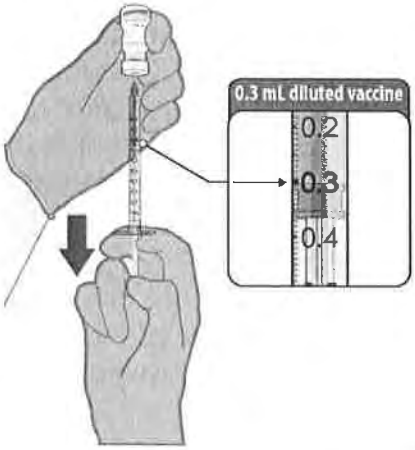


- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.



- 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 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

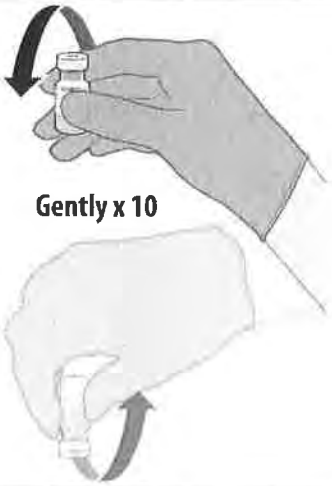
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature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

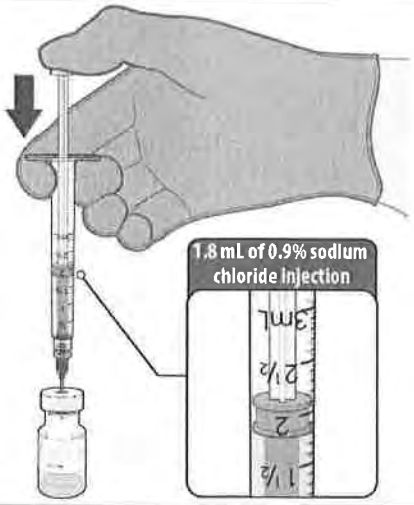
THAWING PRIOR TO DILUTION

- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. 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 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

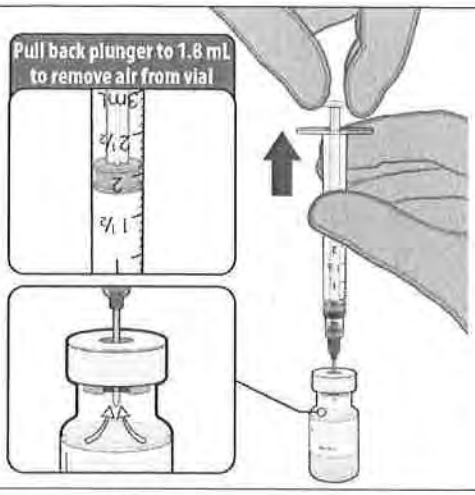
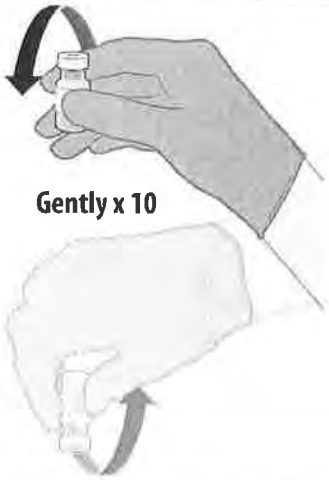


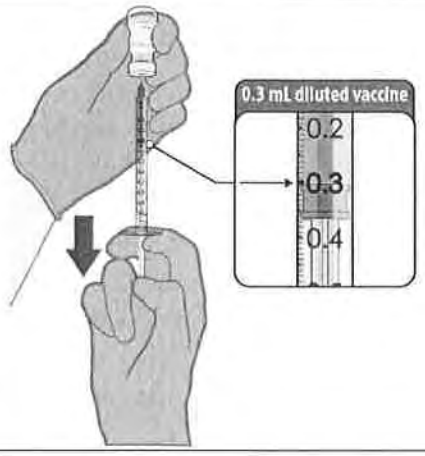
- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

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 -90°C to -60°C (-130°F to -76°F) 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 -90°C to -60°C (-130°F to -76°F) 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 -90°C to -60°C (-130°F to -76°F), 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 -90°C to -60°C (-130°F to -76°F). 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 -90°C to -60°C (-130°F to -76°F). 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 -90°C to -60°C (-130°F to -76°F).

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] 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 25°C (77°F)] 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.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1457-11.4

Revised: 23 August 2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA 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, **MODERNA COVID-19 VACCINE**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

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 cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

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.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna 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 and 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
The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50° to -15°C (-58° to 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2° to 8°C (35° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 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

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range: 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
    - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
    - Each dose must contain 0.5 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
    - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

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

WARNINGS

Management of Acute Allergic Reactions
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna 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 18 through 24 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. 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 Moderna COVID-19 Vaccine.

Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS
Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. *(See Full EUA Prescribing Information)*

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

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

USE WITH OTHER VACCINES
There is no information on the co-administration of the Moderna 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 "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna 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 evaluating the use of the Moderna 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 Moderna 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 MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION
In order to mitigate the risks of using this unapproved product under EUA and to optimize the

potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

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

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
   - 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 "Moderna 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 cases of COVID-19 that result in hospitalization or death following administration of the Moderna 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 MODERNATX, 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 ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

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

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. 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, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider 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 TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department 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, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information.*

This EUA for the Moderna COVID-19 Vaccine 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.

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 vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

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

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna 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 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range: 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
    - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
    - Each dose must contain 0.5 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
    - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 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

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

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

Monitor Moderna 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 18 through 24 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. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.5 Limitations of Vaccine Effectiveness
The Moderna 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 Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination 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 vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3[f]	219 (1.9)	553 (5.0)	162 (1.4)	129 (1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting, Grade 3[g]	4 (0.1)	10 (0.3)	4 (0.1)	3 (<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[g] Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[h] Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported

by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy 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 adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

In 60 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years) 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.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or 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 Moderna COVID-19 Vaccine.

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Moderna 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
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

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

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna 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 adults
- Cases of COVID-19 that results 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.

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 Moderna 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 Moderna 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 "Moderna 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 ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

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

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. 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 Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. 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 Moderna COVID-19 Vaccine on the breastfed

infant or on milk production/excretion.

11.3 Pediatric Use
Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use
Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants *[*see *Overall Safety Summary (6.1)]*.

11.5 Use in Immunocompromised

Safety and effectiveness of a third dose of the Moderna COVID-19 Vaccine have been tested in persons that received solid organ transplants. The administration of third vaccine doses appears to be only moderately effective in increasing antibody titers, so patients should 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

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA 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

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38°C), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one

NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per- Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room

air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

A separate randomized-controlled study has been 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 previously (range 1.99-6.75 years). A third dose of the Moderna COVID-19 Vaccine was administered to 60 individuals approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison. Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 Vaccine group and 10/57 (17.5%) of the placebo group.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials are supplied as follows:

NDC 80777-273-99	Carton of 10 multiple-dose vials, each vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL)
NDC 80777-273-98	Carton of 10 multiple-dose vials, each vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL)

During storage, minimize exposure to room light.

Store frozen between -50° to -15°C (-58° to 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2°C to 8°C (35°F to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the 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, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN 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, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

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 cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection administered as a **single dose** (0.5 mL).

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.janssencovid19vaccine.com.

For information on clinical trials that are testing the use of the Janssen 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

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.

Storage and Handling

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Revised: Aug/27/2021

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

Dosing and Schedule

The Janssen COVID-19 Vaccine is administered intramuscularly as a **single dose** (0.5 mL).

There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

Dose Preparation

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake**.
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Revised: Aug/27/2021

Administer the Janssen COVID-19 Vaccine intramuscularly.

CONTRAINDICATION

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

WARNINGS

Management of Acute Allergic Reactions

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

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

Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. The reporting rate of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. In individuals with suspected thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (*https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia*). *(see Full EUA Prescribing Information)*.

Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

Altered Immunocompetence

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

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Limitations of Vaccine Effectiveness

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following administration of the Janssen COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Adverse Reactions Identified during Post Authorization Use

Severe allergic reactions (including anaphylaxis), thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials.

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

USE WITH OTHER VACCINES

There is no information on the co-administration of the Janssen 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 "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.janssencovid19vaccine.com to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Janssen 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 Janssen COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the name of the vaccine ("Janssen COVID-19 Vaccine") and date of administration to document vaccination.

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 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 JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

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

1. The Janssen COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

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

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
    - 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 "Janssen 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 cases of COVID-19 that result in hospitalization or death following administration of the Janssen 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 JANSSEN BIOTECH, 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 Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

ADDITIONAL INFORMATION

For general questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit www.janssencovid19vaccine.com or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

AVAILABLE ALTERNATIVES

Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

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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, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider 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 TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) 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, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on Janssen Biotech, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the Full EUA Prescribing Information.

This EUA for the Janssen COVID-19 Vaccine 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, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

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

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION JANSSEN COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION: CONTENTS*

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

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Janssen 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 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake**.
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

2.2 Administration

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 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 Janssen COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Janssen COVID-19 Vaccine is administered intramuscularly as a **single dose** (0.5 mL).

There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

3 DOSAGE FORMS AND STRENGTHS

Janssen COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen 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 the Janssen COVID-19 Vaccine.

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

5.2 Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination *[see Overall Safety Summary (6.2)]*. The reporting rate of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. Specific risk factors for thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

Healthcare professionals should be alert to the signs and symptoms of thrombosis with thrombocytopenia in individuals who receive the Janssen COVID-19 Vaccine. In individuals with suspected thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (*https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia*).

Recipients of Janssen COVID-19 Vaccine should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain,

neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination.

5.3 Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

5.4 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.5 Altered Immunocompetence

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

5.6 Limitations of Vaccine Effectiveness

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

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 hospitalized or fatal cases of COVID-19 following vaccination with the Janssen COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Janssen Biotech, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS or Janssen Biotech, Inc.

Adverse Reactions in Clinical Trials

In study COV3001, the most common local solicited adverse reaction (≥10%) reported was injection site pain (48.6%). The most common systemic adverse reactions (≥10%) were headache (38.9%), fatigue (38.2%), myalgia (33.2%), and nausea (14.2%) (see Tables 1 to 4).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Janssen COVID-19 vaccine.

Adverse Reactions Identified during Post Authorization Use

Severe allergic reactions (including anaphylaxis), thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination 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 the Janssen COVID-19 Vaccine has been assessed in an ongoing Phase 3 Study (COV3001). A total of 43,783 individuals were enrolled in this study, of whom 21,895 adults aged 18 years and older received the Janssen COVID-19 Vaccine [Full Analysis Set (FAS)]. This study is being conducted in the United States (n=19,302), Brazil (n=7,278), South Africa (n=6,576), Colombia (n=4,248), Argentina (n=2,996), Peru (n=1,771), Chile (n=1,133), Mexico (n=479). In this study, 45.0% were female, 54.9% were male, 58.7% were White, 19.4% were Black or African American, 45.3% were Hispanic or Latino, 3.3% were Asian, 9.5% were American Indian/Alaska Native and 0.2% were Native Hawaiian or other Pacific Islander, 5.6% were from multiple racial groups and 1.4% were unknown races (see Table 5). The median age of individuals was 52.0 years (range: 18-100). There were 4,217 (9.6%) individuals who were SARS-CoV-2 seropositive at baseline and who were included in the study. In the United States, 838 of 19,302 (4.3%) individuals were SARS-CoV-2 seropositive. Demographic characteristics were similar among individuals who received the Janssen COVID-19 Vaccine and those who received saline placebo.

The safety subset includes 6,736 individuals (3,356 from the Janssen COVID-19 Vaccine group, 3,380 from the placebo group). The demographic profile in the safety subset was similar in terms of age and gender compared to the FAS. A larger percentage of individuals in the safety subset were White (83.4%) compared to the FAS (58.7%). Geographically, the safety subset was limited to individuals from the United States (51.4%), Brazil (38.5%) and South Africa (10.2%). Fewer individuals in the safety subset compared to the FAS were SARS-CoV-2 seropositive at baseline, 4.5% vs. 9.6%, and had at least one comorbidity 34.1% vs 40.8%.

Safety monitoring in the clinical study consisted of monitoring for: (1) solicited local and systemic reactions occurring in the 7 days following vaccination in a subset of individuals (safety subset), (2) unsolicited adverse events (AEs) occurring in the 28 days following vaccination in the safety subset, (3) medically-attended AEs (MAAEs) occurring in the 6 months following vaccination in the entire study population (FAS), (4) serious AEs (SAEs) and AEs leading to study discontinuation for the duration of the study in the entire study population.

Solicited adverse reactions

Shown below are the frequencies of solicited local adverse reactions (Tables 1 and 2) and systemic adverse reactions (Tables 3 and 4) reported in adults by age group in the ongoing Phase 3 clinical trial (COV3001) in the 7 days following vaccination.

Table 1: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n(%)	Placebo N=2,049 n(%)
Injection Site Pain		
Any	1,193 (58.6)	357 (17.4)
Grade 3[a]	8 (0.4)	0
Injection Site Erythema		
Any (≥25 mm)	184 (9.0)	89 (4.3)
Grade 3[b]	6 (0.3)	2 (0.1)
Injection Site Swelling		
Any (≥25 mm)	142 (7.0)	32 (1.6)
Grade 3[b]	5 (0.2)	2 (0.1)

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

[b] Grade 3 injection site swelling and erythema: Defined as >100 mm.

Table 2: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older

Adverse Reactions	Janssen COVID-19 Vaccine N=1,320 n(%)	Placebo N=1,331 n(%)
Injection Site Pain		
Any	439 (33.3)	207 (15.6)
Grade 3[a]	3 (0.2)	2 (0.2)
Injection Site Erythema		
Any (≥25 mm)	61 (4.6)	42 (3.2)
Grade 3[b]	1 (0.1)	0
Injection Site Swelling		
Any (≥25 mm)	36 (2.7)	21 (1.6)
Grade 3[b]	2 (0.2)	0

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

[b] Grade 3 injection site swelling and erythema: Defined as >100 mm.

Table 3: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n(%)	Placebo N=2,049 n(%)
Headache		
Any	905 (44.4)	508 (24.8)
Grade 3[a]	18 (0.9)	5 (0.2)
Fatigue		
Any	891 (43.8)	451 (22.0)
Grade 3[b]	25 (1.2)	4 (0.2)
Myalgia		
Any	796 (39.1)	248 (12.1)
Grade 3[b]	29 (1.4)	1 (<0.1)
Nausea		
Any	315 (15.5)	183 (8.9)
Grade 3[b]	3 (0.1)	3 (0.1)
Fever[c]		
Any	261 (12.8)	14 (0.7)
Grade 3	7 (0.3)	0
Use of antipyretic or pain medication	538 (26.4)	123 (6.0)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

Table 4: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older

Adverse Reactions	Janssen COVID-19 Vaccine N=1,320 n(%)	Placebo N=1,331 n(%)
Headache		
Any	401 (30.4)	294 (22.1)
Grade 3[a]	5 (0.4)	4 (0.3)
Fatigue		
Any	392 (29.7)	277 (20.8)
Grade 3[b]	10 (0.8)	5 (0.4)
Myalgia		
Any	317 (24.0)	182 (13.7)
Grade 3[b]	3 (0.2)	5 (0.4)
Nausea		
Any	162 (12.3)	144 (10.8)
Grade 3[b]	3 (0.2)	3 (0.2)
Fever[c]		
Any	41 (3.1)	6 (0.5)
Grade 3	1 (0.1)	0
Use of antipyretic or pain medication	130 (9.8)	68 (5.1)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

Solicited local and systemic adverse reactions reported following administration of the Janssen COVID-19 Vaccine had a median duration of 1 to 2 days.

Unsolicited adverse events

Individuals within the safety subset in study COV3001 (N=6,736) were monitored for unsolicited adverse events (AEs) for 28 days following vaccination with 99.9% (N= 6,730) of individuals completing the full 28 days of follow-up. The proportion of individuals who reported one or more unsolicited AEs was similar among those in the Janssen COVID-19 Vaccine group (13.1%) and those in the placebo group (12.0%).

Serious Adverse Events (SAEs) and other events of interest

In study COV3001, up to a cut-off date of January 22, 2021, 54.6% of individuals had follow-up duration of 8 weeks. The median follow-up duration for all individuals was 58 days. SAEs, excluding those related to confirmed COVID-19, were reported by 0.4% (n=83) of individuals who received the Janssen COVID-19 Vaccine (N= 21,895) and 0.4% (n=96) of individuals who received placebo (N= 21,888).

Additional adverse events of interest, including but not limited to allergic, neurologic, inflammatory, vascular, and autoimmune disorders, were analyzed among all adverse events collected through protocol-specified safety monitoring procedures as well as unsolicited reporting.

Urticaria (all non-serious) was reported in five vaccinated individuals and 1 individual who received placebo in the 7 days following vaccination. In addition, an SAE of hypersensitivity, not classified as anaphylaxis, was reported in 1 vaccinated individual with urticaria beginning two days following vaccination and angioedema of the lips with no respiratory distress beginning four days following vaccination. The event was likely related to the vaccine.

An SAE of severe pain in the injected arm, not responsive to analgesics, with immediate onset at time of vaccination, and that was ongoing 74 days following vaccination was reported in an individual who received the Janssen COVID-19 Vaccine. An SAE of severe generalized weakness, fever, and headache, with onset on the day following vaccination and resolution three days following vaccination was reported in an individual who received the Janssen COVID-19 Vaccine. Both SAEs are likely related to the vaccine.

Numerical imbalances, with more events in vaccine than placebo recipients, were observed for the following serious and other adverse events of interest in individuals receiving the vaccine or placebo, respectively:

- Thromboembolic events:
    - Deep vein thrombosis: 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events (1 serious; 2 within 28 days of vaccination).
    - Pulmonary embolism: 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event (serious and within 28 days of vaccination).
    - Transverse sinus thrombosis with thrombocytopenia: 1 event (serious, with onset of symptoms 8 days post- vaccination) vs. 0.

- Seizures: 4 events (1 serious; 4 within 28 days of vaccination) vs. 1 event (0 serious and 0 within 28 days following vaccination).

- Tinnitus: 6 events (0 serious; 6 within 28 days of vaccination, including 3 within 2 days of vaccination) vs. 0.

For these events, a causal relationship with the Janssen COVID-19 vaccine could not be determined based on study COV3001. The assessment of causality was confounded by the presence of underlying medical conditions that may have predisposed individuals to these events. However, taking into consideration post-authorization experience, a causal relationship with Janssen COVID-19 Vaccine is plausible for thrombosis with thrombocytopenia *[see Warnings and Precautions (5.2) and Overall Safety Summary (6.2)]*.

There were no additional notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and cardiovascular events) that would suggest a causal relationship to the Janssen COVID-19 Vaccine.

6.2 Post Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Janssen 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.

Blood and Lymphatic System Disorders: Thrombosis with thrombocytopenia, Lymphadenopathy.

Ear and labyrinth disorders: Tinnitus.

Gastrointestinal disorders: Diarrhea, Vomiting.

Immune System Disorders: Allergic reactions, including anaphylaxis.

Nervous System Disorders: Guillain-Barré syndrome, Syncope, Paresthesia, Hypoesthesia.

Vascular Disorders: Capillary leak syndrome, Thrombosis with thrombocytopenia.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

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 Janssen COVID-19 Vaccine administration 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,

- 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.

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 Janssen 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 Janssen 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 "Janssen 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 Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

10 DRUG INTERACTIONS

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

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 Vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com.

Risk Summary

All Pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. 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 Janssen COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive developmental toxicity study female rabbits were administered 1 mL of the Janssen COVID-19 Vaccine (a single human dose is 0.5 mL) by intramuscular injection 7 days prior to mating and on Gestation Days 6 and 20 (i.e., one vaccination during early and late gestation, respectively). No vaccine related adverse effects on female fertility, embryo-fetal or postnatal development up to Postnatal Day 28 were observed.

11.2 Lactation

Risk Summary

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

11.3 Pediatric Use

Emergency Use Authorization of the Janssen COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Janssen COVID-19 Vaccine included individuals 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)]*. Of the 21,895 individuals who received a single-dose of the Janssen COVID-19 Vaccine in COV3001, 19.5% (n=4,259) were 65 years of age and older and 3.7% (n=809) were 75 years of age and older. No overall differences in safety or efficacy were observed between individuals 65 years of age and older and younger individuals.

13 DESCRIPTION

The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. It contains no visible particulates. The vaccine consists of a replication-incompetent recombinant adenovirus type 26 (Ad26) vector expressing the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein in a stabilized conformation.

The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6 TetR cells, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.

Each 0.5 mL dose of Janssen COVID-19 Vaccine is formulated to contain 5×10^{10} virus particles (VP) and the following inactive ingredients: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl-β-cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg). Each dose may also contain residual amounts of host cell proteins (≤0.15 mcg) and/or host cell DNA (≤3 ng).

Janssen COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The Janssen COVID-19 Vaccine is composed of a recombinant, replication-incompetent human adenovirus type 26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

An ongoing, multicenter, randomized, double-blind, placebo-controlled Phase 3 Study (COV3001) (NCT04505722) is being conducted in the United States, South Africa, Brazil, Chile, Argentina, Colombia, Peru and Mexico to assess the efficacy, safety, and immunogenicity of a single-dose of the Janssen COVID-19 Vaccine for the prevention of COVID-19 in adults aged 18 years and older. Randomization was stratified by age (18-59 years, 60 years and older) and presence or absence of comorbidities associated with an increased risk of progression to severe COVID-19. The study allowed for the inclusion of individuals with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy during the 3 months preceding vaccination, as well as individuals with stable human immunodeficiency virus (HIV) infection.

A total of 44,325 individuals were randomized equally to receive Janssen COVID-19 Vaccine or saline placebo. Individuals are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The primary efficacy analysis population of 39,321 individuals (19,630 in the Janssen COVID-19 Vaccine group and 19,691 in the placebo group) included 38,059 SARSCoV-2 seronegative individuals at baseline and 1,262 individuals with an unknown serostatus. Demographic and baseline characteristics were similar among individuals who received the Janssen COVID-19 Vaccine and those who received placebo (see Table 5).

Table 5: Summary of Demographics and Baseline Characteristics - Primary Efficacy Analysis Population

	Janssen COVID-19 Vaccine (N=19,630) n (%)	Placebo (N=19,691) n (%)
Sex		
Male	10,924 (55.6)	10,910 (55.4)
Female	8,702 (44.3)	8,777 (44.6)
Age (years)		
Mean (SD)	51.1 (15.0)	51.2 (15.0)
Median	52.0	53.0
Min, max	(18; 100)	(18; 94)
Age group		
≥18 to 59 years of age	12,830 (65.4)	12,881 (65.4)
≥60 years of age	6,800 (34.6)	6,810 (34.6)
≥65 years of age	3,984 (20.3)	4,018 (20.4)
≥75 years of age	755 (3.8)	693 (3.5)
Race[a]		
White	12,200 (62.1)	12,216 (62.0)
Black or African American	3,374 (17.2)	3,390 (17.2)
Asian	720 (3.7)	663 (3.4)
American Indian/Alaska Native[b]	1,643 (8.4)	1,628 (8.3)
Native Hawaiian or other Pacific Islander	54 (0.3)	45 (0.2)
Multiple	1,036 (5.3)	1,087 (5.5)
Unknown	262 (1.3)	272 (1.4)
Not reported	341 (1.7)	390 (2.0)
Ethnicity		
Hispanic or Latino	8,793 (44.8)	8,936 (45.4)
Not Hispanic or Latino	10,344 (52.7)	10,259 (52.1)
Unknown	173 (0.9)	162 (0.8)
Not reported	319 (1.6)	333 (1.7)
Region		
Northern America (United States)	9,185 (46.8)	9,171 (46.6)
Latin America	7,967 (40.6)	8,014 (40.7)
Southern Africa (South Africa)	2,478 (12.6)	2,506 (12.7)
Comorbidities[c]		
Yes	7,830 (39.9)	7,867 (40.0)
No	11,800 (60.1)	11,824 (60.0)

[a] Some individuals could be classified in more than one category.

[b] Including 175 individuals in the United States, which represents 1% of the population recruited in the United States.

[c] Number of individuals who have 1 or more comorbidities at baseline that increase the risk of progression to severe/critical COVID-19: Obesity defined as BMI ≥30 kg/m^2 (27.5%), hypertension (10.3%), type 2 diabetes (7.2%), stable/well-controlled HIV infection (2.5%), serious heart conditions (2.4%), asthma (1.3%), and in ≤1% of individuals: cancer, cerebrovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, cystic fibrosis, immunocompromised state (weakened immune system) from blood or organ transplant, liver disease, neurologic conditions, pulmonary fibrosis, sickle cell disease, thalassemia and type 1 diabetes, regardless of age.

Efficacy Against COVID-19

The co-primary endpoints evaluated the first occurrence of moderate to severe/critical COVID-19 with onset of symptoms at least 14 days and at least 28 days after vaccination. Moderate to severe/critical COVID-19 was molecularly confirmed by a central laboratory based on a positive SARS-CoV-2 viral RNA result using a polymerase chain reaction (PCR)-based test.

- Moderate COVID-19 was defined based on the following criteria: the individual must have experienced any one of the following new or worsening signs or symptoms: respiratory rate

≥20 breaths/minute, abnormal saturation of oxygen (SpO2) but still >93% on room air at sea level, clinical or radiologic evidence of pneumonia, radiologic evidence of deep vein thrombosis (DVT), shortness of breath or difficulty breathing OR any two of the following new or worsening signs or symptoms: fever (≥38.0°C or ≥100.4°F), heart rate ≥90 beats/minute, shaking chills or rigors, sore throat, cough, malaise, headache, muscle pain (myalgia), gastrointestinal symptoms, new or changing olfactory or taste disorders, red or bruised appearing feet or toes.

- Severe/critical COVID-19 was defined based on the following criteria: the individual must have experienced any one of the following at any time during the course of observation: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/minute, oxygen saturation (SpO2) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO2/FiO2) <300 mmHg), respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]), evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors), significant acute renal, hepatic, or neurologic dysfunction, admission to intensive care unit (ICU), death.

Final determination of severe/critical COVID-19 cases were made by an independent adjudication committee.

The median length of follow up for efficacy for individuals in the study was 8 weeks post-vaccination. Vaccine efficacy for the co-primary endpoints against moderate to severe/critical COVID-19 in individuals who were seronegative or who had an unknown serostatus at baseline was 66.9% (95% CI: 59.0; 73.4) at least 14 days after vaccination and 66.1% (95% CI: 55.0; 74.8) at least 28 days after vaccination (see Table 6).

Table 6: **Analyses of Vaccine Efficacy Against Centrally Confirmed Moderate to Severe/Critical COVID-19 – With Onset at Least 14 Days and at Least 28 Days Post-Vaccination - Primary Efficacy Analysis Population**

	Janssen COVID-19 Vaccine N=19,630		Placebo N=19,691		
Subgroup	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	% Vaccine Efficacy (95% CI)
14 days post-vaccination					
All subjects[a]	116	3116.6	348	3096.1	66.9 (59.0; 73.4)
18 to 59 years of age	95	2106.8	260	2095.0	63.7 (53.9; 71.6)
60 years and older	21	1009.8	88	1001.2	76.3 (61.6; 86.0)
28 days post-vaccination					
All subjects[a]	66	3102.0	193	3070.7	66.1 (55.0; 74.8)[b]
18 to 59 years of age	52	2097.6	152	2077.0	66.1 (53.3; 75.8)
60 years and older	14	1004.4	41	993.6	66.2 (36.7; 83.0)

[a] Co-primary endpoint.

[b] The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

Vaccine efficacy against severe/critical COVID-19 at least 14 days after vaccination was 76.7% (95% CI: 54.6; 89.1) and 85.4% (95% CI: 54.2; 96.9) at least 28 days after vaccination (see Table 7).

Table 7: **Analyses of Vaccine Efficacy: Secondary Endpoints of Centrally Confirmed Severe/Critical COVID-19 – in Adults 18 Years of Age and Older With Onset at Least 14 Days and at Least 28 Days Post-Vaccination – Primary Efficacy Analysis Population**

	Janssen COVID-19 Vaccine N=19,630		Placebo N=19,691		
Subgroup	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	% Vaccine Efficacy (95% CI)
14 days post-vaccination					
Severe/critical	14	3125.1	60	3122.0	76.7 (54.6; 89.1)[a]
28 days post-vaccination					
Severe/critical	5	3106.2	34	3082.6	85.4 (54.2; 96.9)[a]

[a] The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

Among all COVID-19 cases with onset at least 14 days post vaccination, including cases diagnosed by a positive PCR from a local laboratory and still awaiting confirmation at the central laboratory, there were 2 COVID-19 related hospitalizations in the vaccine group (with none after 28 days) and 29 in the placebo group (with 16 after 28 days).

As of the primary analysis cut-off date of January 22, 2021, there were no COVID-19-related deaths reported in Janssen COVID-19 Vaccine recipients compared to 5 COVID-19-related deaths reported in placebo recipients, who were SARS-CoV-2 PCR negative at baseline.

Janssen COVID-19 Vaccine Efficacy in Countries With Different Circulating SARS-CoV-2 Variants.

Exploratory subgroup analyses of vaccine efficacy against moderate to severe/critical COVID-19 and severe/critical COVID-19 for Brazil, South Africa, and the United States were conducted (see Table 8). For the subgroup analyses, all COVID-19 cases accrued up to the primary efficacy analysis data cutoff date, including cases confirmed by the central laboratory and cases with documented positive SARS-CoV-2 PCR from a local laboratory which are still awaiting confirmation by the central laboratory, were included. The concordance rate observed up to the data cut-off date between the PCR results from the local laboratory and the central laboratory was 90.3%.

Table 8: Summary of Vaccine Efficacy against Moderate to Severe/Critical and Severe/Critical COVID-19 for Countries With >100 Reported Moderate to Severe/Critical Cases

		Severity	
	Onset	Moderate to Severe/Critical Point estimate (95% CI)	Severe/Critical Point estimate (95% CI)
US	at least **14 days** after vaccination	74.4% (65.0; 81.6)	78.0% (33.1; 94.6)
	at least **28 days** after vaccination	72.0% (58.2;81.7)	85.9% (-9.4; 99.7)
Brazil	at least **14 days** after vaccination	66.2% (51.0; 77.1)	81.9% (17.0; 98.1)
	at least **28 days** after vaccination	68.1% (48.8; 80.7)	87.6% (7.8; 99.7)
South Africa	at least **14 days** after vaccination	52.0% (30.3; 67.4)	73.1% (40.0; 89.4)
	at least **28 days** after vaccination	64.0% (41.2; 78.7)	81.7% (46.2; 95.4)

Strain sequencing was conducted on available samples with sufficient viral load from centrally confirmed COVID-19 cases (one sequence per case). As of February 12, 2021, samples from 71.7% of central laboratory confirmed primary analysis cases had been sequenced [United States (73.5%), South Africa (66.9%) and Brazil (69.3%)]. In the United States, 96.4% of strains were identified as the Wuhan-H1 variant D614G; in South Africa, 94.5% of strains were identified as the 20H/501Y.V2 variant (B.1.351 lineage); in Brazil, 69.4% of strains were identified to be a variant of the P.2 lineage and 30.6% of strains were identified as the Wuhan-H1 variant D614G. As of February 12, 2021, SARS-CoV-2 variants from the B1.1.7 or P.1 lineages were not found in any of the sequenced samples.

19 HOW SUPPLIED/STORAGE AND HANDLING

Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials (NDC 59676-580-15). A maximum of 5 doses can be withdrawn from the multi-dose vial.

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the 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 or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit www.janssencovid19vaccine.com or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.janssencovid19vaccine.com.

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Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

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