IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

JEANNA NORRIS, on behalf of herself and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	
SAMUEL L. STANLEY, JR. in his official capacity as President of Michigan State University; DIANNE BYRUM, in her official capacity as Chair of the Board of Trustees, DAN KELLY, in his official capacity as Vice Chair of the Board of Trustees; and RENEE JEFFERSON, PAT O'KEEFE, BRIANNA T. SCOTT, KELLY TEBAY, and REMA VASSAR, in their official capacities as Members of the Board of Trustees of Michigan State University, and JOHN and JANE DOES 1-10,	)	**CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** JURY TRIAL DEMANDED
Defendants.	)	

Plaintiff and those similarly situated, by and through their attorneys at the New Civil Liberties Alliance ("NCLA"), hereby complains and alleges the following:

INTRODUCTORY STATEMENT

a. By the spring of 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, had spread across the globe. Since then, and because of the federal government's "Operation Warp Speed," three separate coronavirus vaccines have been developed and approved more swiftly than any other vaccines in our nation's history. The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-

BioNTech COVID-19 Vaccine ("BioNTech Vaccine") on December 11, 2020.[1] Just one week later, FDA issued a second EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine").[2] FDA issued its most recent EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine") on February 27, 2021 (the only EUA for a single-shot vaccine).[3]

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

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

d. Michigan State University ("MSU") announced "COVID directives" for the Fall 2021 semester by email and on its website on July 30, and then provided an expanded version via its website on August 5, 2021. The directives include a "Mandatory COVID-19 Vaccine" ("the Directive").

e. According to the Directive, all faculty, staff, and students must either be fully vaccinated or have received one of a two-dose series by August 31, 2021, unless they obtain a religious or medical exemption, both of which are limited in nature and application. The Directive specifically excludes natural immunity as a basis for a medical exemption. Even employees who work remotely are subject to the Directive.

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

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

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

f. MSU's Directive recognizes all vaccines currently approved by the World Health Organization ("WHO"), including the Janssen Vaccine and others which the FDA has not approved, such as the Sinovac and Sinopharm Vaccines.

g. Those who do not comply with the Directive face potential disciplinary action, including termination of employment.

h. Plaintiff has already contracted and fully recovered from COVID-19. As a result, she has naturally acquired immunity, confirmed unequivocally by two recent SARS-CoV-2 antibody tests. Her immunologist, Dr. Hooman Noorchashm, has advised her that it is *medically unnecessary* to undergo a vaccination procedure at this point (which fact also renders the procedure and any attendant risks medically unethical).

i. Yet, if Plaintiff follows her doctor's advice and elects not to take the vaccine, she faces adverse disciplinary consequences. In short, the Directive is unmistakably coercive and cannot reasonably be considered anything other than an unlawful mandate. Furthermore, it represents an unconstitutional condition being applied to Plaintiff's constitutional and statutory rights to bodily integrity and informed consent, respectively.

j. Plaintiff brings this action on behalf of a class of similarly situated individuals – employees of MSU who have naturally acquired immunity to COVID-19 and for whom the Directive represents a violation of their constitutional rights to bodily autonomy and to decline medical treatment.

k. Given the her naturally acquired immunity, MSU cannot establish a compelling governmental interest in overriding the personal autonomy and constitutional rights of Plaintiff and those who are similarly situated by forcing them either to be vaccinated or to suffer adverse professional consequences.

l. Naturally acquired immunity is at least as robust and durable as that attained through the most effective vaccines, and it is significantly more protective than some of the inferior vaccines that MSU accepts. Studies further indicate that naturally acquired immunity is significantly longer lasting than that acquired through the best vaccines. As a result, MSU's Directive is designed to nullify informed consent and infringes upon Plaintiff's rights, and the rights of those who are similarly situated, under the Ninth and Fourteenth Amendments to the United States Constitution.

m. For similar reasons, the Directive constitutes an unconstitutional condition, because it is poorly calibrated to protect the public health, yet it imposes disproportionate risks on some of its targets. That renders the Directive an unlawful condition insufficiently germane to its purported purpose. Furthermore, the disciplinary action that MSU is using to leverage ostensibly voluntary compliance with its Directive is not proportional to MSU's purported public health aims.

n. Even beyond its constitutional defects, MSU's unlawful Directive is irreconcilable with and frustrates the objectives of the statute governing administration of medical products authorized for emergency use only. Pursuant to the Supremacy Clause of the United States Constitution, federal law overrides conflicting state law and action by agents of the State of Michigan. Accordingly, the Directive is preempted by the EUA statute and must be enjoined.

o. In a highly publicized opinion recently made public, the U.S. Department of Justice's Office of Legal Counsel ("OLC") argues that public and private entities can lawfully mandate that their employees receive one of the EUA vaccines.[4] The opinion is silent on preemption, however, and thus cannot be read to prevent the EUA statute from having its ordinary

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

preemptive effect. This is especially true in light of the fact that Congress never assigned any role to OLC to administer the EUA statute. The OLC Opinion, as explained in detail in Count III below, is also deeply flawed on multiple additional legal grounds.

p. Regardless of whether Pfizer recently received full FDA approval for the Comirnaty Vaccine, the remaining vaccines "approved" for use by MSU have not. As Pfizer itself acknowledges, the Comirnaty Vaccine is not widely available in the United States. And despite its attempts to create equivalence between its BioNTech and Comirnaty Vaccines, the two are legally distinguishable. Thus, even after the Comirnaty Vaccine's approval, the Directive still essentially forces individuals, including Plaintiff and those who are similarly situated, to take one of the EUA vaccines (or, worse yet, one of the domestically unapproved World Health Organization ["WHO"] vaccines).

q. In sum, the Directive violates *both* the constitutional *and* federal statutory rights of Plaintiff and those who are similarly situated because it undermines their bodily integrity and autonomy and conditions their employment on their willingness to take a medically unnecessary vaccine. Forcing Plaintiff and others to take this vaccine will provide no discernible, let alone compelling, benefit either to Plaintiff or to the MSU community. Although obtaining the vaccine could raise Plaintiff's antibody levels even higher, her levels are already high enough to be equivalent to most vaccinated people, so any augmented benefit is negligible. The unconstitutional conditions doctrine exists precisely to prevent government actors from clothing unconstitutional objectives and policies in the garb of supposed voluntarism when those actors fully intend and expect that the pressure they are exerting will lead to the targets of such disguised regulation succumbing to the government's will. Plaintiff invokes this Court's Article III and inherent powers to insulate her from this pressure and to vindicate her constitutional and statutory rights.

PARTIES

1. Plaintiff Jeanna Norris (37 years old) is a supervisory Administrative Associate and Fiscal Officer at MSU. She resides in Portland, Michigan, which is located in the Western District of Michigan, Southern Division.

2. Defendant Samuel L. Stanley is President of MSU, a public research institution located in East Lansing, Michigan. He is sued in his official capacity.

3. Defendant Dianne Byrum is Chair of the Board of Trustees at MSU.[5] She is sued in her official capacity.

4. Defendant Dan Kelly is Vice Chair of the Board of Trustees. He is sued in his official capacity.

5. Defendants Renee Jefferson, Pat O'Keefe, Brianna T. Scott, Kelly Tebay and Rema Vassar are Members of the Board of Trustees. They are sued in their official capacities.

6. John and Jane Does 1-10 are as-yet-unidentified MSU officials involved in setting the policy embodied in the Directive.

7. MSU, for whom the Defendants are agents, is principally located in the Western District of Michigan.

STATUTORY AND NONSTATUTORY JURISDICTION AND VENUE

8. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3)-(4) (equitable relief), and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. That is because the claims here arise under the Constitution and statutes of the United States and because Plaintiff seeks prospective redress against state actors in their

[5] The Board of Trustees "have general supervision over the university and its funds." "Board of Trustees," *Michigan State University*, *available at* https://trustees.msu.edu (last visited Aug. 27, 2021).

official capacity to end the deprivation, under state law, of her rights, privileges, and immunities secured by federal law.

9. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391. Plaintiff Norris resides in this judicial district, a substantial part of the events, actions, or omissions giving rise to the claim occurred in this judicial district, and MSU is located in this judicial district.

10. The Western District of Michigan is comprised of both a Southern and a Northern Division. MSU is located in the Southern Division. *See* Civ. L. R. 3.2.

11. This Court's equitable powers permit it to issue nonstatutory injunctions to protect Plaintiff against wayward state actors engaged in unlawful conduct. *See Trump v. Vance*, 140 S. Ct. 2412, 2428-29 (2020) ("*Ex parte Young*, 209 U.S. 123, 155–156 (1908) (holding that federal courts may enjoin state officials to conform their conduct to federal law).").[6] The only limitation is that a defendant subject to such an injunction must possess a connection to the establishment and enforcement of MSU's vaccine mandate. Defendants in this action have the requisite connection. *See, e.g.*, *Russell v. Lundergan-Grimes*, 784 F.3d 1037 (6th Cir. 2015) (finding that, in action brought by business owners alleging that electioneering statute violated their First Amendment rights, Attorney General could be sued under *Ex parte Young*, since he fielded and investigated complaints of impermissible electioneering and threatened criminal sanctions). *See generally Free Enter. Fund v. PCAOB*, 561 U.S. 477, 491 n.2 (2010) (collecting cases in the vein of *Bell v. Hood*, 327 U.S. 678, 684 (1946) ("[I]t is established practice for this Court to sustain the *jurisdiction* of federal courts to issue injunctions to protect rights safeguarded by the Constitution")

[6] *See* Erwin Chemerinsky, FEDERAL JURISDICTION, 8th ed. (2021) (*Ex parte Young* "has been heralded as 'one of the three most important decisions the Supreme Court of the United States has ever handed down.'"), *quoting Allied Artists Pictures Corp. v. Rhodes*, 473 F. Supp. 560, 564 (E.D. Ohio 1979) (citations omitted).

(emphasis added)); *Schuette v. Coalition to Defend Affirmative Action, Integration, and Immigrant Rights*, 572 U.S. 291 (2014) (Board of Trustees was initially named defendant in Equal Protection claim against Michigan State University).

12. In addition, this Court may issue declaratory relief pursuant to 28 U.S.C. § 2201. "Further necessary or proper relief based on a declaratory judgment may [also] be granted …," including via injunction. *See Powell v. McCormack*, 395 U.S. 486, 499 (1969) ("A declaratory judgment can then be used as a predicate to further relief, including an injunction. 28 U.S.C. § 2202 ….").

STATEMENT OF FACTS

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

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

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

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

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

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

18. This past winter, FDA approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3.

a. FDA issued an EUA for the BioNTech Vaccine on December 11, 2020.

b. Just one week later, FDA issued an EUA for the Moderna Vaccine.

c. FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.

d. The Comirnaty Vaccine received full FDA approval on August 23, 2021.

e. In a footnote to its "Fact Sheet for Health Care Providers," FDA states that Comirnaty "has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are *legally distinct* with certain differences that do not impact safety or effectiveness." (emphasis added). FDA, "Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers)," (Aug. 23, 2021) (Attachment C) (relating to both the BioNTech Vaccine and Comirnaty Vaccine).

f. The Comirnaty Vaccine is *not* widely available due to limited supply, as Pfizer also notes that "there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA." (Attachment C). *See also* FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Aug. 25, 2021).

19. The EUA status of the vaccines that are available at present in the United States means that FDA has not yet fully approved them but permits their conditional use nonetheless due to exigent circumstances.

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

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

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

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

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

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

26. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current

COVID-19 pandemic." FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), *available at* bit.ly/3x8wImn (last visited August 26, 2021).

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

28. The EUA statute states that individuals to whom the product is administered must be informed: (1) that the Secretary has authorized emergency use of the product; (2) of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown; and (3) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

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

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

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

32. The heightened risk of adverse effects results from "preexisting immunity to SARS-Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Angeli *et al.*, *SARS-CoV-2 Vaccines: Lights and Shadows*, 88 EUR. J. INTERNAL MED. 1, 8 (2021).

II. PRIOR INFECTION LEADS TO NATURALLY-ACQUIRED IMMUNITY TO COVID-19 AT LEAST AS ROBUST AS VACCINE-ACQUIRED IMMUNITY

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

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

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

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

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

38. Recent Israeli data found that those who had received the BioNTech Vaccine were 6.72 times *more likely* to suffer a subsequent infection than those with natural immunity. David Rosenberg, *Natural Infection vs Vaccination: Which Gives More Protection*?

ISRAELNATIONALNEWS.COM (Jul. 13, 2021), *available at* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited Aug. 26, 2021).

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

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

41. A CDC/IDSA clinician call on July 29, 2021, summarized the current state of the knowledge regarding the comparative efficacy of natural and vaccine immunity. The presentation reviewed three studies that directly compared the efficacy of prior infection versus mRNA vaccine treatment and concluded "the protective effect of prior infection was similar to 2 doses of a COVID-19 vaccine."

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

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

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

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

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

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

48. In fact, vaccine immunity only targets the spike-protein of the original Wuhan variant, whereas natural immunity recognizes the full complement of SARS-CoV-2 proteins and thus provides protection against a greater array of variants. Noorchashm Decl. ¶ 17.

49. While the CDC and the media have touted a study from Kentucky as proof that those with naturally acquired immunity should get vaccinated, that conclusion is unwarranted. As

Drs. Bhattacharya and Kulldorff explain, although individuals with naturally acquired immunity who received a vaccine showed increased antibody levels, "[t]his does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths." Joint Decl. ¶ 37.

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

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

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

53. The Chinese Sinovac Vaccine has been approved by WHO (making it adequate to satisfy MSU's policy), which itself determined that this vaccine prevented *symptomatic* disease in just 51% of those who received it. *See WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WHO.INT (June 1, 2021), *available at* bit.ly/3yitIW7 (last visited Aug. 26, 2021).

54. Other clinical studies have found that the Sinovac Vaccine offers even lower levels of protection against infection. For instance, a study of Brazilian healthcare workers determined a mere 50.39% efficacy in preventing infection. *See* Elizabeth de Faria et al., *Performance of*

Vaccination with Coronavac[7] *in a Cohort of Healthcare Workers (HCW)—Preliminary Report*, MEDRXIV (Apr. 15, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.04.12.21255308v1 (last visited Aug. 26, 2021).

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

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

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

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

58. Early data also suggests that naturally acquired immunity may provide greater protection against both the Delta and Gamma variants than that achieved through vaccination. A recent analysis of an outbreak among a small group of mine workers in French Guiana found that 60% of fully vaccinated miners suffered breakthrough infections compared to *zero* among those with natural immunity. Nicolas Vignier, et al., *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinate Gold Miners, French Guiana, 2021*, 27(10) EMERG. INFECT. DIS. (Oct. 2021), *available at* https://wwwnc.cdc.gov/eid/article/27/10/21-1427_article (last visited Aug. 26, 2021).

59. In this vein, the CDC recently reported that "new scientific data" indicated that vaccinated people who experienced breakthrough infections carried similar viral loads to the unvaccinated (but not naturally immune), leading the CDC to infer that vaccinated people transmit the virus at concerning levels. *See CDC Reversal on Indoor Masking Prompts Experts to Ask, "Where's the Data?"*, WASHINGTON POST (July 28, 2021), *available at* wapo.st/2THpmIQ (last visited Aug. 26, 2021). For example, 74% of cases in a Cape Cod outbreak occurred in vaccinated

individuals, again demonstrating that the vaccines are inferior to natural immunity when it comes to preventing infection. *See* Molly Walker, *CDC Alarmed: 74% of Cases in Cape Cod Cluster Were Among the Vaxxed*, MEDPAGE TODAY (July 30, 2021), *available at* bit.ly/2V6X3UP (last visited Aug. 26, 2021).

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

61. As Drs. Bhattacharya and Kulldorff have explained, there is no legitimate public-health rationale for MSU to require proof of vaccination to participate in activities that do not involve care for high-risk individuals:

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

Joint Decl. ¶¶ 50-51.

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

62. Though the COVID-19 vaccines appear to be relatively safe at a population level, like all medical interventions, they carry a risk of side effects. Those side effects include common,

temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and nausea. More rarely, they can cause serious side effects that result in hospitalization or death. Joint Decl. ¶¶ 25-26.

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

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

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

65. Jeanna Norris, age 37, is a supervisory Administrative Associate and Fiscal Officer at MSU. She has been employed at MSU for eight years. Jeanna Norris Declaration ("Norris Decl.") ¶ 1 (Attachment D).

66. Her duties and responsibilities entail approving expenditures, ensuring compliance with financial policy, developing financial reports and budgets, and approving personnel actions. Norris Decl. ¶ 2.

67. Since March of 2020, Ms. Norris has been working remotely. MSU currently has no timetable for her to return to work in person. Norris Decl. ¶ 4.

68. Ms. Norris is the stepmother of her husband's five children, who range in age from 14 to 22. She is the primary breadwinner for the family. Norris Decl. ¶ 3.

69. On November 19, 2020, Ms. Norris became ill with a severe headache and dry cough. The following day she developed body aches and pains that reminded her of the flu. Norris Decl. ¶ 5.

70. Ms. Norris received a positive COVID-19 Rapid test on November 21, 2020 at Ouch Urgent Care in Clinton County, Michigan. Norris Decl. ¶ 6.

71. After approximately four days, Ms. Norris's symptoms began to abate and her health condition improved, but her sense of taste and smell disappeared for a full month. Norris Decl. ¶ 7.

72. Plaintiff received a positive COVID-19 antibody test on August 17, 2021 at Sparrow Health System, and a second positive COVID-19 antibody test on August 21, 2021 at LabCorp. Norris Decl. ¶ 8; Noorchashm Decl. ¶ 7(f); Joint Decl. 44.

73. The test results confirmed that Plaintiff contracted and recovered from the SARS-CoV-2 virus. Her recent semi-quantitative antibodies screening test established that her level of immune protection remains high. Noorchashm Decl. ¶ 13. Indeed, her "spike antibody level is highly likely to be above the minimum necessary to provide adequate protection against re-infection from the SARS-CoV-2 virus." Noorchashm Decl. ¶ 7(g).

74. Having consulted with Plaintiff and reviewed her lab results, Dr. Noorchashm concluded that undergoing a full vaccination course would be medically unnecessary, create a risk of harm to her, and provide insignificant or no benefit either to her or the MSU community. Noorchashm Decl. ¶ 12.

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

76. Accordingly, mandating that Plaintiff receive a COVID-19 vaccine violates the rules of medical ethics. Noorchashm Decl. ¶¶ 8-35.

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

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

79. MSU's Directive applies equally to employees working on or off campus and thus Ms. Norris's ability to function as class representative is not diminished as to class members working on campus, many of whom may, from time to time, also work from home. *See also infra* at ¶¶ 92-99.

V. BACKGROUND AND MSU'S IMPOSITION OF A BLANKET VACCINE REQUIREMENT AS PART OF ITS REOPENING POLICY

80. MSU is a public research university located in East Lansing, Michigan, in Ingham County, in the Western District of Michigan.

81. MSU announced its "COVID Directives" for the Fall 2021 semester via email and on its website on July 30, 2021 and, and provided a more detailed version on its website on August 5, 2021. (Attachments E-G). MSU's Directives include a vaccine mandate.

82. The Directive requires all faculty, staff, and students to be fully vaccinated or to obtain an approved exemption for the Fall 2021 semester. (Attachments E-G).

83. By August 31, 2021, all faculty, staff, and students must have completed a full COVID-19 vaccination course or received at least one dose of a two-dose series. Employees and students also are required to report their vaccine status using an online form. (Attachments E-G).

84. Those who have not completed a full vaccine course (but only a partial one) by August 31, 2021 are subject to various restrictions pursuant to the "Early Detection Policy," including testing and quarantining requirements. (Attachment F).

85. MSU accepts all FDA-authorized as well as all WHO-approved vaccines. (Attachments E-G).

86. In order to obtain a medical exemption, an individual must demonstrate:

a. A documented anaphylactic allergic reaction or other severe adverse reaction to any COVID-19 vaccine;

b. A documented allergy to a component of a COVID-19 vaccine;

c. Another documented medical condition that constitutes a disability under the Americans with Disabilities Act; or

d. A limited-term inability to receive a vaccine such as pregnancy or breastfeeding. (Attachment H).

87. In its "FAQs" Section pertaining to the Directive, MSU states that the rationale for its policy is that, *inter alia*, "new studies demonstrate[] both unvaccinated and vaccinated individuals can transmit the disease to those who cannot currently be vaccinated, including children less than 12 years old and immunocompromised individuals" and "new data reveal[s] the Delta variant can create breakthrough infections in vaccinated individuals." (Attachment G).

88. Employees who do not comply with the vaccine requirements are subject to disciplinary action, including termination from the university. (Attachment G).

89. One of the questions posed in the FAQ section is "I have had COVID-19 in the past and have laboratory evidence of antibodies. Do I need to be vaccinated?" The answer is "Even those who have contracted COVID-19 previously are required to receive a vaccine, which provides

additional protection." (Attachment G). Hence, there is no doubt that MSU does not recognize natural immunity as a basis for getting a medical exemption.

90. In response to the question, "[w]hy should I get a vaccine if the delta variant breaks through the current vaccines," the webpage states that: "[t]he current vaccines remain highly effective in preventing hospitalizations, severe disease and death from the delta variant of COVID-19." (Attachment G).

91. Even employees who have arranged to work remotely during the Fall semester must either be vaccinated or obtain a religious or medical exemption. (Attachment G).

92. Plaintiff, and others similarly situated, require a temporary restraining order ("TRO") and/or preliminary injunctive relief on a tight timeline because MSU did not announce the Directive until a mere month before the August 31, 2021 deadline it set for employees to receive the vaccine. (Attachments F-H). Indeed, the email version contained insufficient data from which Plaintiff and others similarly situated could conclude whether or not they were subject to the mandate. Thus, they were only provided with the final version three weeks before the deadline to receive the vaccine.

93. Potential litigation by those not wishing to be vaccinated was a prospect that was or should have been reasonably foreseeable to the Defendants and other agents of MSU.

VI. PLAINTIFF HAS EXPERIENCED, AND WILL CONTINUE TO EXPERIENCE, CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF MSU'S VACCINE POLICY

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

95. By threatening adverse professional and personal consequences, MSU's Directive not only directly and palpably harms Plaintiff's bodily autonomy and dignity, but it forces her to

endure the stress and anxiety of choosing between her employment—upon which her family relies—and her health.

96. The risk-avoidance benefits that the Directive provides, compared to the restrictions and intrusive options offered to Plaintiff, are disproportionate. Similarly, given that naturally acquired immunity confers equal or greater protection than that provided by the vaccines (especially with respect to some of the WHO-approved vaccines that MSU considers adequate to fulfill the Directive's requirements), the Directive is arbitrary and irrational. There is no indication that the Directive is tailored to account for its impact on those who have acquired natural immunity. In fact, official MSU explanations of the Directive specifically refuse to recognize those with natural immunity as posing different issues and requiring different treatment as compared to unvaccinated individuals who lack natural immunity.

CLASS ACTION ALLEGATIONS

97. ***Class Definition.*** Plaintiff brings this action on behalf of herself and all others similarly situated ("the Class"), pursuant to Federal Rule of Civil Procedure 23. The Class is defined as follows:

> (i) All MSU employees employed by the University (ii) on or after August 31, 2021 (the deadline for those employees to become vaccinated against COVID-19), including employees newly hired, whether or not they work on campus, at home, or both (iii) who have naturally acquired immunity demonstrable by antibody testing and where (iv) application of the Directive will invade their rights of bodily integrity, coerce or significantly burden their choices, or deny their rights of informed consent.

98. For purposes of this Complaint, references to Plaintiff, because this suit is being brought as a class action, should be construed as applying to class members even where not explicitly so stated.

99. ***Numerosity.*** The exact size of the class is unknown. However, by the end of March 2020, 23% of New Yorkers had COVID-19 antibodies and by February of 2021, 45% of Los Angeles residents did. *See* Marty Makary, *The Power of Natural Immunity*, THE WALL STREET JOURNAL (June 8, 2015), *available at* https://www.wsj.com/articles/the-power-of-natural-immunity-11623171303 (last visited August 26, 20210). MSU has around 7,365 staff members and 5,703 faculty, meaning that the size of the class is likely large. Hence, the numerosity requirement in Fed. R. Civ. P. 23(a)(1) is met here.

100. ***Commonality.*** There are multiple questions of law and fact common to the class, including but not limited to:

a. Whether MSU's Directive constitutes an unconstitutional infringement on Plaintiffs' rights to bodily autonomy and to decline medical treatment under the Ninth and Fourteenth Amendments to the United States Constitution;

b. Whether MSU's Directive creates an unconstitutional condition on the exercise of Plaintiffs' constitutionally protected rights; and

c. Whether MSU's Directive violates Plaintiffs' federal statutory rights under the Emergency Use Authorization (EUA) statute.

As a result, the commonality requirement of Fed. R. Civ. P. 23(a)(2) is met here.

101. ***Typicality.*** Plaintiff's claims are typical of the Class, as she has naturally acquired immunity to COVID-19, as verified by two recent antibodies tests, she is an employee of MSU, and she objects to the Directive on the grounds that it violates her constitutional and statutory rights as described above. As a result, the typicality requirement of Fed. R. Civ. P. 23(a)(3) is met here.

102. ***Adequacy of Representation.*** Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff's interests are aligned with, and not antagonistic to, those of the other members of the Class. Additionally, Plaintiff is seeking identical declaratory and injunctive relief that would benefit all putative class members. Plaintiff has also retained counsel competent and experienced in the prosecution of class-action litigation to represent herself and the Class. As a result, the adequacy-of-representation requirement of Fed. R. Civ. P. 23(a)(4) is met here.

103. ***Fed. R. Civ. P. 23(b)(2) Class Type.*** Certification for injunctive and declaratory relief is appropriate under Rule 23(b)(2) because Defendants have both acted (principally by mandating that MSU employees receive the vaccines) and refused to act (via their refusal to recognize natural immunity) on grounds that generally apply to the whole class. This also makes temporary, preliminary, and permanent injunctive relief appropriate "respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

104. ***Class Action Superiority & Efficiency.*** Additionally, though it is not necessary to plead as part of a Rule 23(b)(2) class action, class-wide treatment of the common issues presented by this suit against MSU in a single forum represents a superior means of determining Defendants' liability to each Class Member than potentially hundreds or thousands of individual lawsuits. As a result, class-wide adjudication of Defendants' liability followed by the grant of undifferentiated declaratory and injunctive relief is the most efficient means of adjudication.

CLAIMS FOR RELIEF

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

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

106. MSU's Directive requires Plaintiff to take a vaccine without her consent—and against the expert medical advice of her immunologist—thereby depriving her of her ability to refuse unwanted medical care.

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

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

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

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

111. Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others because those employees already possess natural immunities to the virus, violates the liberty and privacy interests that the Ninth and Fourteenth Amendments protect.

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

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

114. The blithe statement on MSU's FAQ page to the effect that vaccinating a naturally immune individual provides "additional protection"—without citation to *any* scientific data—cannot overcome the vast amount of scientific literature that Plaintiff has provided to establish otherwise. And, as Drs. Bhattacharya, Kulldorff, and Noorchashm attest, the study from Kentucky

that the CDC has touted as substantiating MSU's proposition has been both wrongly interpreted and incorrectly portrayed by the media. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31.

115. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Noorchashm Decl. ¶¶ 14-17; Joint Decl. at ¶¶ 15-24); Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination In Previously Infected Individuals*, MEDRXIV (June 5th, 2021), *available at* https://bit.ly/2TFBGcA (last visited Aug. 26, 2021); *see also* Yair Goldberg, et al., *Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience from Israel*, MEDRXIV (Apr. 20, 2021), *available at* https://bit.ly/3zMV2fb (last visited Aug. 26, 2021); Michael Smerconish, *Should Covid Survivors and the Vaccinated Be Treated the Same?*: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), *available at* https://cnn.it/2WDurDn (last visited Aug. 26, 2021); Marty Makary, *The Power of Natural Immunity*, WALL STREET JOURNAL (June 8, 2021), *available at* https://on.wsj.com/3yeu1Rx (last visited Aug. 26, 2021).

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

117. Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Yet,

documentation of recovery suffices as a substitute, although proof of vaccination does not. *See Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States*, CDC (July 6, 2021), *available at* https://bit.ly/3yfcJDM (last visited Aug. 26, 2021).

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

119. The State of Michigan's public policy has also traditionally reflected that it lacks any interest in vaccinating persons for a disease to which they carry antibodies. For instance, the law mandating vaccination of school children *explicitly exempts* from the requirements those who can demonstrate existing immunity through serological testing that measures protective antibodies. MICH. ADMIN. CODE r. 325.176 (2021).

120. MSU simply has no compelling interest in departing from the State's typical public policy in this case. There is no question that Plaintiff possesses natural immunity, given her recent antibodies screening tests and as confirmed both by her immunologist and Dr. Bhattacharya. Joint Decl. ¶ 44; Noorchashm Decl. ¶¶ 7(f), (g), 13.

121. In addition to MSU's lack of a valid governmental interest in requiring that already immune employees get vaccinated, Defendants cannot show that the Directive is narrowly tailored to a compelling governmental interest.

122. Any interest that MSU may have in promoting immunity on campus does not extend to those employees who already have natural immunity—particularly those who can demonstrate such immunity through antibody screenings.

123. This provides evidence that MSU is trying to exert control over individuals' personal health decisions, rather than attempting to promote a legitimate public health aim.

124. Indeed, MSU's Directive—likely inadvertently—acknowledges that it lacks a valid public health basis for its vaccine policy. In explicating the reasoning underlying the Directive on its "FAQ" page, MSU states that the vaccines are "highly effective in preventing hospitalizations, severe disease and death from the delta variant of COVID-19." (Attachment G).

125. In other words, MSU does not even pretend that the mandate is truly about protecting others, since natural immunity also prevents hospitalizations, severe disease and death. Thus, the Directive infringes on Plaintiff's bodily autonomy with no public health justification.

126. Another ground MSU provides for its Directive is that "new studies demonstrate[] both unvaccinated and vaccinated individuals can transmit the disease to those who cannot currently be vaccinated, including children less than 12 years old and immunocompromised individuals" and that "new data reveal[s] the Delta variant can create breakthrough infections in vaccinated individuals." (Attachment G).

127. However, if vaccinated people can also transmit the disease, as MSU concedes, that only further undercuts any public health rationale for a vaccine mandate. It certainly drives home the arbitrary, nonsensical nature of the position that robust, naturally acquired immunity should not be recognized, while more limited immunity acquired through vaccination should be.

128. Nor does MSU provide any sound reasoning for the claim that its Directive will protect those who cannot be vaccinated.

a. *First*, college campuses are rarely frequented by individuals under 12 years of age.

b. *Second*, MSU has not provided any information about or otherwise provided any assurance that it has analyzed the number of immunocompromised people living and working on campus, rendering this justification flimsy.

c. *Finally*, as MSU acknowledges, vaccinated individuals can also spread COVID-19. It is thus unclear just how a vaccine mandate will protect immunocompromised individuals. Presumably, anyone who cannot receive the vaccine and is at risk from severe illness already takes measures to protect him or herself, most likely by working or attending school remotely.

129. In sum, MSU's justifications for its Directive are not only speculative, but logically incoherent.

130. Another reason the Directive lacks any constitutional validity is that many of the vaccines that MSU accepts, such as the Janssen, Sinovac, and Sinopharm vaccines are much less effective in preventing infection, compared to natural immunity. That renders Plaintiff significantly less likely to contract or spread the virus than her colleagues who have been immunized with these inferior vaccines. Yet she is subject to termination while her similarly situated colleagues, who have received these subpar vaccines, are not.

131. By failing to tailor its Directive to only those employees who lack immunity, MSU forces employees like Plaintiff (and those similarly situated), who have naturally acquired immunity, to choose between their health, their personal autonomy and their careers.

132. Plaintiff has suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff for the deprivation of her constitutional rights. She will suffer irreparable harm unless this Court enjoins Defendants from enforcing their Directive against employees with natural immunity.

133. Plaintiff is entitled to a judgment declaring that the Directive violates her constitutional rights to refuse medical treatment, an injunction restraining Defendants' enforcement of the Directive.

COUNT II: VIOLATION OF THE UNCONSTITUTIONAL CONDITIONS DOCTRINE AND THE FOURTEENTH AMENDMENT'S RIGHT TO DUE PROCESS

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

135. Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, MSU cannot impair Plaintiff's right to refuse medical care through subtle forms of coercion any more than it could through an explicit mandate. *See, e.g., Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"); *Memorial Hosp. v. Maricopa Cty.*, 415 U.S. 250 (1974) (finding that state residency requirement impinged on the constitutionally guaranteed right to interstate travel, while lacking a compelling state interest, and thus was unconstitutional).

136. The Due Process Clause of the Fourteenth Amendment provides: "nor shall any state deprive any person of life, liberty, or property, without due process of law … ." U.S. Const., amend. XIV, sec. 1.

137. Plaintiff possesses both a liberty interest in her bodily integrity and a property interest in her career and a statutory interest in informed consent.

138. It is less appreciated in legal circles that unconstitutional conditions claims do not need to establish that a challenged government policy amounts to coercion. Instead, it is sufficient

that the state policy burdens a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right.

139. In other words, the presence of some remaining voluntarism after new conditions are imposed on the exercise of a constitutional right does not stand as a barrier to establishing a successful unconstitutional conditions claim. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder.

140. For example, in *Speiser v. Randall*, 357 U.S. 513 (1958), the Court invalidated a loyalty oath imposed as a condition for veterans to obtain a state property tax exemption, even though (a) California citizens were not required to own real property, of course; (b) California veterans could freely opt not to seek the exemption and simply pay the unadorned tax; and (c) California was not even obligated to provide veterans with the exemption but rather the exemption was a mere privilege.

141. The *Speiser* Court deemed the oath condition unconstitutional in part because the burden to establish qualification for the exemption was placed on applicants. *See id.* at 522. The question the Supreme Court saw itself deciding was "whether this allocation of the burden of proof, on an issue concerning freedom of speech, falls short of the requirements of due process." *Id.* at 523.

142. The Court addressed this question by stating the guiding principle that

> Where one party has at stake an interest of transcending value—as a criminal defendant his liberty—this margin of error is reduced as to him by the process of placing on the other party the burden of producing a sufficiency of proof in the first instance …. [But] Due process commands that no man shall lose his liberty unless the

> Government has borne the burden of producing the evidence and convincing the factfinder of his guilt.

Id. at 525-26.

143. Here, the analogue of the criminal defendant rights of "transcending value" referenced in *Speiser* are the liberty rights of all persons to be free of unconsented-to bodily intrusions and medical interventions. This means that unconstitutional conditions doctrine and due process rights *combine* to invalidate the Directive. That result occurs because MSU has not and cannot show that the school's forcing Plaintiff and those similarly situated to take the vaccine reduces any risk that they will become infected with and spread the virus to MSU students and personnel. *See also Lawrence v. Texas*, 539 U.S. 558, 562 (2003) (The Due Process Clause protects "liberty of the person both in its spatial and in its more transcendent dimensions").

144. Similar to the California law in *Speiser* "creat[ing] the danger that … legitimate utterance will be penalized," 357 U.S. at 526, the process MSU has established in relation to taking COVID-19 vaccines poses dangers to Plaintiff's health (and thus to her liberty interests) as well as threatening her with penalties if she does not comply.

145. Indeed, more so than in *Speiser*, the factual issues involved in this case are complex. "How can a claimant … possibly sustain the burden of proving the negative of these complex factual elements? In practical operation, therefore, this procedural device must necessarily produce a result which the State could not command directly." *Id.* There is perhaps no better encapsulation than the preceding sentence by the Supreme Court of how unconstitutional conditions doctrine and Due Process can and do intersect and reinforce one another. *See also id.* at 529 ("The State clearly has no such compelling interest at stake as to justify a short-cut procedure which must inevitably result in suppressing protected speech."). MSU similarly possesses no compelling interest that could justify its defective Directive that will inevitably result

in at least some unwarranted medical intrusions into the bodies of members of the MSU community.

146. For these reasons, MSU cannot by means of its Directive effectively flip the burden of proof and require Plaintiff and others similarly situated to prove that it is safe for them to perform their respective jobs while unvaccinated. And setting up such a process, which is what MSU's directive does, thereby represents a concurrent *procedural* due process of law violation *and* an unconstitutional condition burdening her liberty interests to be free of unwanted medical interventions.

147. *Speiser* also rests on the mismatch between the loyalty oath California required and the grant of a property tax exemption to veterans. "[T]he State is powerless to erase the service which the veteran has rendered his country; though he be denied a tax exemption, he remains a veteran." *Id.* at 528.

148. In this situation, there is an equally jarring logical incongruity. MSU's Directive is terse. It offers no justifications for why the penalties and other restrictions it establishes are appropriate and tailored to members of the University community who have acquired robust natural immunity. And the rationales it does offer are not logically coherent. Whatever MSU is trying to decree through its unconstitutional-conditions sleight of hand, Plaintiff remains a community member with natural immunity as a matter of pre-Directive fact (just as the *Speiser* veterans remained veterans as a matter of pre-tax-law fact), and the existence of such immunity fully serves the supposed purposes of the public-health protection that MSU says that it is pursuing.

149. The proportionality of the Directive is also deficient because it does not seek to assess the current antibody levels of its targets, something that it is now feasible for medical science to test.[8]

150. The Directive is not a mere initial presumption that vaccination is superior to natural immunity (a contention that would have to be borne out by the science in any event or else MSU had no business adopting its Directive) that Plaintiff can try to overcome.

151. The Directive is, in essence, *a conclusive presumption* (and a procedural due process of law violation) that vaccination is required (even as to vaccines of far-lesser efficacy), unless the risks of the vaccine to a particular recipient warrant a special exception.

152. But Plaintiff and others with natural immunity possess equal or higher levels of antibodies than those who took one or more of the various inferior vaccines that MSU accepts and equivalent levels to those who took the mRNA vaccines approved by the FDA.

153. MSU has deemed all vaccines to be equally protective in the fictitious presumption it has established. There is no scientific basis for the suppositions that MSU has built into its Directive.

154. For the foregoing reasons, the *de facto* presumptions the Directive establishes become another part of MSU's procedural due process of law violations that run afoul of unconstitutional conditions doctrine. In short, by allocating burden of proof responsibility to those with natural immunity like Plaintiff, coupled with MSU stacking the process deck with

[8] Such antibody testing was not possible more than a century ago when *Jacobson v. Massachusetts* was decided, as diagnostic antibody testing was not invented until the 1970's. 197 U.S. 11 (1905) (upholding a city regulation fining individuals $5 if they refused to take Smallpox vaccine). *See The History of ELISA from Creation to COVID-19 Research*, MOLECULAR DEVICES, *available at* https://www.moleculardevices.com/lab-notes/microplate-readers/the-history-of-elisa (last visited Aug. 1, 2021).

presumptions that Plaintiff has shown are scientifically unwarranted, MSU contravenes the Due Process Clause. *See Perry v. Sinderman*, 408 U.S. 592, 597 (1972) (holding that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"); *Wieman v. Updegraff*, 344 U.S. 183, 192 (1952) ("We need not pause to consider whether an abstract right to public employment exists. It is sufficient to say that constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory").

COUNT III: VIOLATION OF THE SUPREMACY CLAUSE

155. Plaintiff realleges and incorporates by reference all the foregoing allegations as though fully set forth herein.

A. The EUA Statute Preempts MSU's Directive

156. Defendants' Directive requires Plaintiff and others similarly situated to receive a vaccine in order to continue working for MSU without regard to their natural immunity or the advice of their doctors.

157. Plaintiff and others must also divulge personal medical information by uploading it into an online form and are threatened with disciplinary action if they decline to comply with these arbitrary mandates.

158. The Directive thus coerces or, at the very least, unduly pressures, Plaintiff and others like her into getting vaccines that FDA approved only for emergency use.

159. The United States Constitution and federal laws are the "Supreme Law of the Land" and supersede the constitutions and laws of any state. U.S. Const. art. VI, cl. 2.

160. "State law is pre-empted to the extent that it actually conflicts with federal law." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (internal citations and quotation marks omitted).

161. Federal law need not contain an express statement of intent to preempt state law for a court to find any conflicting state action invalid under the Supremacy Clause. *See Geier v. American Honda*, 520 U.S. 861, 867-68 (2000).

162. Rather, federal law preempts any state law that creates "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399-400 (2012).

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

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

165. Since MSU's Directive (a state program) coerces Plaintiff by making enjoyment of her constitutionally and statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute. *See* 21 U.S.C. § 360bbb-3.

166. The conflict between the Directive and the EUA statute is particularly stark given that the statute's informed consent language requires that recipients be given the "option to refuse"

the EUA product. That is at odds with the Directive effectively forcing Plaintiff to sustain significant injury to her career if she does not want to take the vaccine.

167. Put differently, the Directive frustrates the objectives of the EUA process. *See Geier*, 520 U.S. at 873 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

B. The OLC Opinion Cannot Save MSU's Directive from Preemption

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

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

170. Relatedly, the Justice Department until only recently took a very different approach. *See* Attorney General Memorandum, *Balancing Public Safety with the Preservation of Civil Rights* (Apr. 27, 2020), *available at* https://www.justice.gov/opa/page/file/1271456/download (last visited Aug. 26, 2021, 2021) ("If a state or local ordinance crosses the line from an appropriate exercise of authority to stop the spread of COVID-19 into an overbearing infringement of constitutional and statutory protections, the Department of Justice may have an obligation to

address that overreach in federal court."). *See also* Kevin Liptak, CNN, *Biden Jumps Into Vaccine Mandate Debate as VA Requires Health Workers to Get Vaccinated* (July 26, 2021) ("The [new OLC] opinion marks a reversal from the previous administration. Last year, Attorney General William Barr used the Justice Department's legal power to try to fight certain Covid restrictions, including joining some businesses that sought to overturn state mask mandates."), *available at* cnn.it/37bwAbl (last visited Aug. 26, 2021).

171. Moreover, the OLC Opinion is entirely silent on the issue of preemption. As such, it cannot be read even as offering a potentially persuasive legal view on whether the MSU Policy is preempted by the EUA statute or not. In light of what this Count pleads, the OLC opinion is a legal *non sequitur*.

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

173. According to OLC, the requirement that recipients be "informed" of their right to refuse the product does not mean that an administrator is precluded from mandating the vaccine. All that an administrator must do, in OLC's view, is tell the recipient they have the *option* to refuse the vaccine. *Id.* at 7-13.[9] That facile interpretation sidesteps the fact that the Directive's (or other similar policies') employment consequences effectively coerce or at least unconstitutionally

[9] The OLC opinion is as irrelevant to the constitutional questions in this case posed by Counts I and II as it is to the preemption questions in Count III. For it was no answer in *Speiser* to the due process and unconstitutional conditions problems created by California's property tax exemption and oath system for the courts to breathe a sigh of relief when the state's tax authorities could simply tell veterans applying for the tax exemption that they could just go away and forgo the tax exemption. The Constitution and the text of congressional statutes cannot be so easily dodged.

leverage the MSU community into taking the vaccine, reducing to nothingness both the constitutional and statutory rights of informed consent. This approach of stating the obvious but ignoring competing arguments is likely why the Opinion remained mum on the doctrine of preemption.

174. Recognizing the illogic of the Opinion and its inability to square its construction with the text of the EUA statute, OLC admits that its "reading … does not fully explain why Congress created a scheme in which potential users of the product would be informed that they have 'the option to accept or refuse' the product." *Id.* at 10. This understatement would be droll but for the serious rights at stake, especially given that the elephant in the room—which the OLC Opinion ignores—is the Supremacy Clause and the preemption doctrine that Clause powers. In truth, Congress called for potential vaccine recipients to be informed precisely so that they could decide whether to refuse to receive an EUA product. OLC's obtuse reading of the statute blinks reality.

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

176. Yet, OLC turns around and claims that Congress would have explicitly stated if it intended to prohibit mandates for EUA products. *Id.* at 8-9. But Congress *did* say so. The plain language states that the recipient of an EUA vaccine must be informed "of the option to accept or refuse the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Especially when read against the backdrop

of what the Constitution requires *and* against the common law rules from which the constitutional protections for informed consent arose, Congress's intent to protect informed consent is pellucid. And Congress "is understood to legislate against a background of common-law … principles," *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991).

177. The EUA statute's prohibition on mandating EUA products is reinforced by a corresponding provision that allows the President, in writing, to waive the option of those in the U.S. military to accept or refuse an EUA product if national security so requires. 10 U.S.C. § 1107a(a)(1). That provision would be redundant if consent could be circumvented merely by telling a vaccine recipient that he or she is free to refuse the vaccine but nonetheless must suffer various adverse employment consequences violating the unconstitutional conditions doctrine.

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

179. Unsurprisingly, OLC's strained reading runs counter to the Department of Defense's understanding of this statutory provision. As the OLC Opinion acknowledges, "DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a." *Id.* at 16 (citing DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008)).

180. OLC even acknowledges that its opinion is belied by the congressional conference report, which also contemplated that 10 U.S.C. § 1107a(a)(1) "would authorize the President to waive *the right of service members to refuse administration of a product* if the President

determines, in writing, that affording service members the right to refuse a product is not feasible[.]" *Id.* (quoting H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.)).

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

C. The FDA's Approval of the Comirnaty Vaccine Does Not Save MSU's Directive from Preemption

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

183. That the Comirnaty Vaccine has received full FDA approval does not foreclose the preemption argument presented in this Count, since this approval does not extend to the BioNTech Vaccine, which is actually available. Indeed, even Pfizer acknowledges that the two vaccines are "legally distinct." (Attachment C).

184. The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference."); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as *de facto* law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety); *see also Maple Drive Farms Ltd. v. Vilsack*, 781 F.3d 837, 857 (6th Cir. 2015) (instructing USDA to carefully consider on remand whether its approach to the term "prior-converted wetlands" ran afoul of *Appalachian Power*).

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

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

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

188. Since the Comirnaty Vaccine, being the only FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population, per the manufacturer's own admission, the EUA statute's sphere of preemption continues to apply to override MSU's Directive. Worse yet, no publicly released documents from MSU indicate that MSU has even considered the issue of federal preemption and whether the full approval granted to the unavailable Comirnaty Vaccine has any significance to the rights of Plaintiff and the Class.

189. Furthermore, the Directive accepts many vaccines that have not received full FDA approval.

D. The Supremacy Clause, the Nuremburg Code, and Related Sources of Law

190. Just as Congress prohibited the federal government from mandating EUA products, the state governments cannot do so, for the Supremacy Clause dictates that the EUA statute must prevail over conflicting state law or policy.

191. Defendants' Directive is thus preempted by federal law. *See* U.S. Const. art. VI, cl. 2; *see also Kindred Nursing Ctrs. Ltd P'ship v. Clark*, 137 S. Ct. 1421 (2017) (holding that Federal Arbitration Act preempted incompatible state rule); *Hughes v. Talen Energy Marketing, LLC*, 136 S. Ct. 1288, 1297 (2016) ("federal law preempts contrary state law," so "where, under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" the state law cannot survive).

192. For similar reasons, the Directive violates the 1947 Nuremberg Code, a multilateral agreement between the United States, USSR, France, and the United Kingdom, governing human experimentation and inspired, of course, by events that took place during the Holocaust. The Nuremberg Code expressly states that "[t]he voluntary consent of the human subject is *absolutely essential*" and prohibits experimental treatments on anyone using "force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion." United States Holocaust Museum, *Nuremburg Code*, https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code (last visited Aug. 26, 2021) (emphasis added).

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

194. Defendants' Directive is invalid pursuant to Article VI, Cl. 2 of the United States Constitution, and must be enjoined and set aside.

ADDITIONAL LEGAL CLAIMS

195. Plaintiff has suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff or class members for the deprivation of their constitutional and statutory rights. They will suffer irreparable harm unless this Court enjoins Defendants from enforcing their Directive.

196. 42 U.S.C. § 1983 provides a civil right of action for deprivations of constitutional protections taken under color of law.

197. Plaintiff (and those similarly situated) is entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 because she is being deprived of "rights, privileges, or immunities secured by the Constitution and laws." Section 1983 thus supports both Plaintiff's constitutional and statutory causes of action against MSU defendants because Section 1983 protects rights "secured by the Constitution *and* laws." 42 U.S.C. § 1983 (emphasis added).

198. Likewise, Plaintiff is entitled to injunctive relief pursuant to *Ex parte Young*'s nonstatutory equitable right of action. *See Verizon Md., Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 648 (2002) ("We conclude that 28 U.S.C. § 1331 provides a basis for jurisdiction over Verizon's claim that the Commission's order requiring reciprocal compensation for ISP-bound calls is pre-empted by federal law. We also conclude that the doctrine of *Ex parte Young* permits Verizon's suit to go forward against the state commissioners in their official capacities.").

199. In sum, Plaintiff is entitled to a judgment declaring that the Directive violates the Supremacy Clause and an injunction restraining Defendants' enforcement of the Directive, since it is preempted by federal law.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court find the Defendants have committed the violations alleged and described above, and issue in response the following:

A. A declaratory judgment that MSU's Directive infringes upon Plaintiff's constitutionally protected right to protect her bodily integrity and autonomy and to refuse unnecessary medical treatment.

B. A declaratory judgment that MSU's Directive represents an unconstitutional condition, especially in light of a set of explicit and implicit procedures that violate the Due Process Clause of the Fourteenth Amendment.

C. A declaratory judgment that MSU's Directive is preempted under the Supremacy Clause because the Policy, a state program, conflicts with the federal EUA Statute; AND

D. Temporary, preliminary and permanent injunctive relief restraining and enjoining Defendants, their agents, servants, employees, attorneys, and all persons in active concert or participation with them (*see* Fed. R. Civ. P. 65(d)(2)), and each of them, from enforcing coercive or otherwise pressuring policies or conditions similar to those in the Directive that act to compel or try to exert leverage on MSU employees with natural immunity to get a COVID-19 vaccine.

JURY DEMAND

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

August 27, 2021

Respectfully submitted,

/s/ Harriet Hageman

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ATTACHMENT A

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

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

Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

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

ATTACHMENT B

Declaration of Dr. Hooman Noorchashm, MD, PhD

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

Background

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

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

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

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

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

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

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

Jeanna Norris's Medical Condition

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[3] *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

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

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

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

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

Respectfully submitted,

/s/ Hooman Noorchashm

Hooman Noorchashm MD, PhD.

ATTACHMENT C

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

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

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

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

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

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

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

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

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

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

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

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

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

DESCRIPTION OF COVID-19

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

DOSAGE AND ADMINISTRATION

Storage and Handling

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

Do not refreeze thawed vials.

Frozen Vials Prior to Use

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

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

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

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

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

Transportation of Frozen Vials

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

Thawed Vials Before Dilution

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

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

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

Transportation of Thawed Vials

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

Vials After Dilution

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

Dosing and Schedule

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

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

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

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

Dose Preparation

Prior to Dilution

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

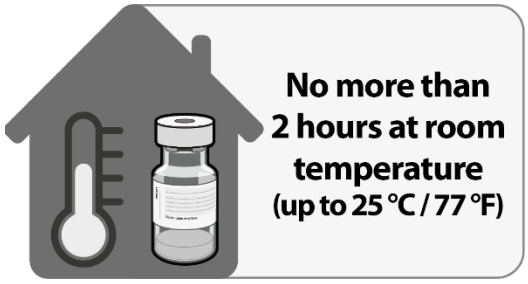
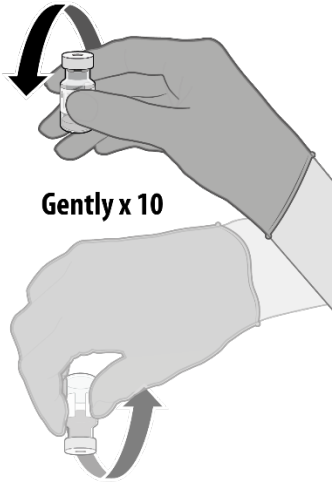
[2] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety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

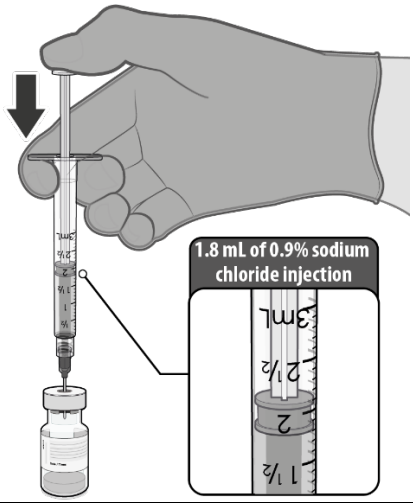
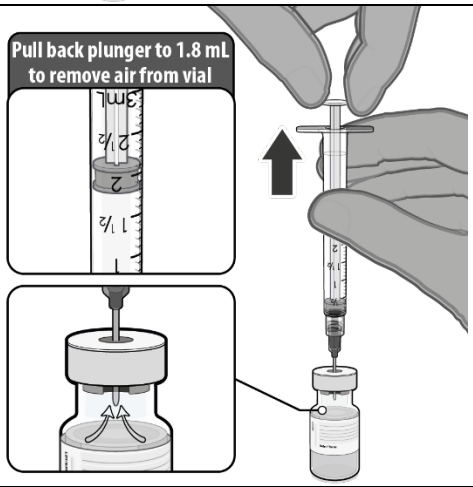
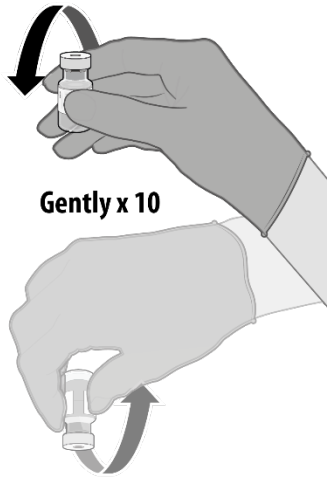
- Refer to thawing instructions in the panels below.

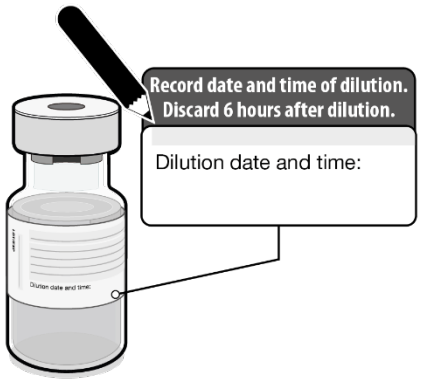
Dilution
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic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

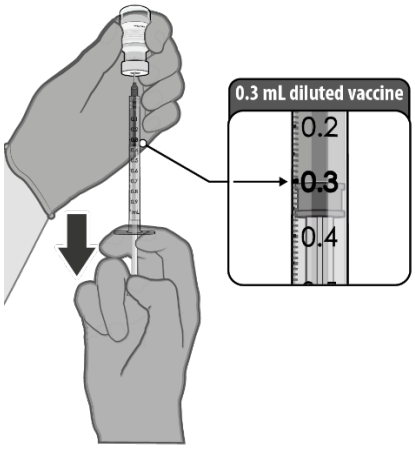
After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

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

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

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

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

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

Administration

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

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

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

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

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

Contraindications

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

Warnings

Management of Acute Allergic Reactions

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

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

Myocarditis and Pericarditis

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

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

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

Limitation of Effectiveness

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

Adverse Reactions

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

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

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

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

Use with Other Vaccines

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

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

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

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

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

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

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

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

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

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

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

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

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

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

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
    - cases of COVID-19 that result in hospitalization or death.

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

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

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

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

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

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

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

ADDITIONAL INFORMATION

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

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

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

AVAILABLE ALTERNATIVES

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

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

FEDERAL COVID-19 VACCINATION PROGRAM

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

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

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

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

AUTHORITY FOR ISSUANCE OF THE EUA

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

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

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

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

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

The Countermeasures Injury Compensation Program

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

Manufactured by
Pfizer Inc., New York, NY 10017

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

LAB-1450-11.4

Revised: 23 August 2021

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

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

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

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

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

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

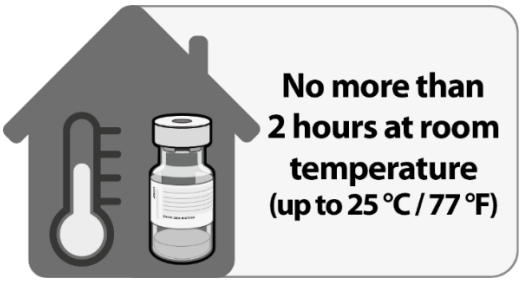
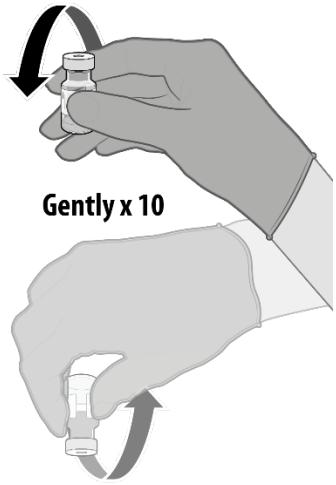
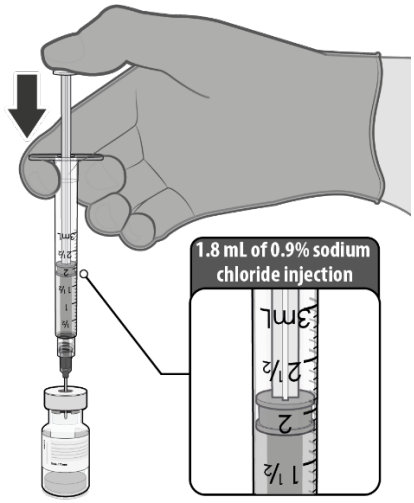
2.1 Preparation for Administration

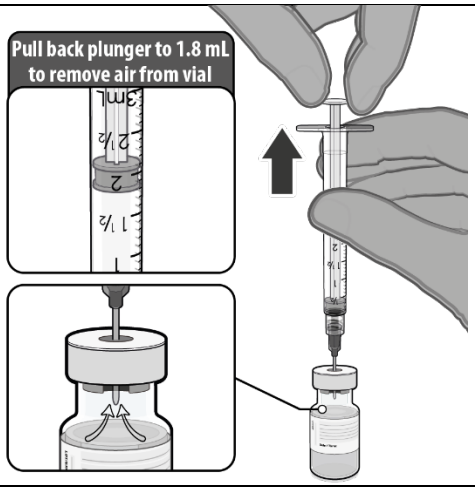
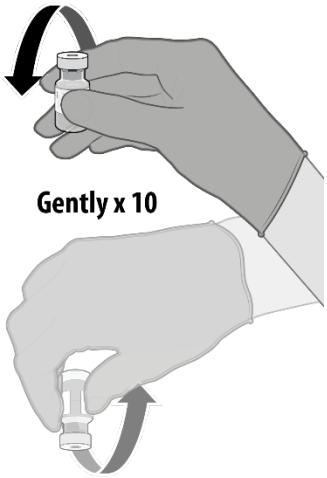
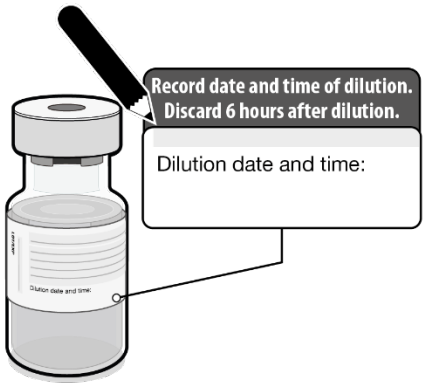
Prior to Dilution

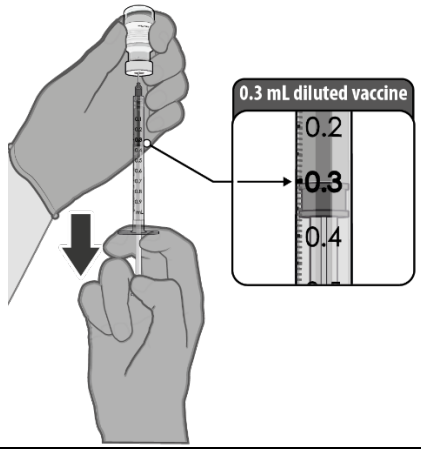
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature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

Dilution

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

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

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

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

2.2 Administration Information

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

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

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

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

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

2.3 Vaccination Schedule for Individuals 12 Years of Age and Older

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

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

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

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

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

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

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

5.2 Myocarditis and Pericarditis

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

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

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

5.5 Limitation of Effectiveness

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

6 OVERALL SAFETY SUMMARY

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

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

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

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

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

6.1 Clinical Trials Experience

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

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

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

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

Participants 16 Years of Age and Older

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

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

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

Solicited Local and Systemic Adverse Reactions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported in recipients who were followed for one month following post Dose 3.

Unsolicited Adverse Events

Serious Adverse Events

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

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

Non-Serious Adverse Events

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

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

Adolescents 12 Through 15 Years of Age

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

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

Solicited Local and Systemic Adverse Reactions

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

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

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

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

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

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

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

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

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

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

Unsolicited Adverse Events

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

Serious Adverse Events

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

Non-Serious Adverse Events

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

6.2 Post Authorization Experience

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

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

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

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

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

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

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

Instructions for Reporting to VAERS

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

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

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

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

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

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

Other Reporting Instructions

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

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

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

10 DRUG INTERACTIONS

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

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

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

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

11.2 Lactation

Risk Summary

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

11.3 Pediatric Use

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

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

11.4 Geriatric Use

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

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

11.5 Use in Immunocompromised

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

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

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

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

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

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

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

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

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

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

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

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

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

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

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

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

c. Includes multiracial and not reported.

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

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

The vaccine efficacy information is presented in Table 8.

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

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

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

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

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

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

18.2 Efficacy in Adolescents 12 Through 15 Years of Age

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

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

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

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

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

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

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

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

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

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

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

18.3 Immunogenicity in Adolescents 12 Through 15 Years of Age

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

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

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

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

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

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

18.4 Immunogenicity in Solid Organ Transplant Recipients

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

19 HOW SUPPLIED/STORAGE AND HANDLING

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

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

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

Do not refreeze thawed vials.

Frozen Vials Prior to Use

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

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

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

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

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

Transportation of Frozen Vials

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

Thawed Vials Before Dilution

Thawed Under Refrigeration

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

Thawed at Room Temperature

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

Vials must reach room temperature before dilution.

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

Transportation of Thawed Vials

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

Vials After Dilution

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

20 PATIENT COUNSELING INFORMATION

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

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

21 CONTACT INFORMATION

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

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

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

Manufactured by
Pfizer Inc., New York, NY 10017

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

LAB-1457-11.4

Revised: 23 August 2021

U.S. FOOD & DRUG ADMINISTRATION

August 23, 2021

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

Dear Ms. Harkins:

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

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

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

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

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

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

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7]

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[8]

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

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

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

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

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

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

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

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide a two-dose regimen for individuals aged 12 through 15 years, or

to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

I. Criteria for Issuance of Authorization

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

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

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

C. There is no adequate, approved, and available[9] alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[10]

II. Scope of Authorization

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

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[11] to emergency response stakeholders[12] as directed by the U.S.

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

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

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

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

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[13] and used only to prevent COVID-19 in individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Product Description

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

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

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official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

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

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be administered at least 28 days following the second dose of the two dose regimen of this vaccine to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

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

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

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

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

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

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

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

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

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

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

III. Conditions of Authorization

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

Pfizer Inc. and Authorized Distributor(s)

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

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

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

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

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[14]

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

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

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

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

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

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

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

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

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

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

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

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

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

Emergency Response Stakeholders

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

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

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

Vaccination Providers

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

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

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

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

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

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

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

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

Conditions Related to Printed Matter, Advertising, and Promotion

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

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

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

Condition Related to Export

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

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 vaccine that was manufactured and labeled in accordance with this emergency use authorization. This authorization thus remains in place with respect to that product for the previously-authorized indication and uses (i.e., for use to prevent COVID-19 in individuals 12 years of age and older with a two-dose regimen, and to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise).

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

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

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

ATTACHMENT D

Declaration of Jeanna Norris

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct:

1. I am a 37-year-old supervisory Administrative Associate and Fiscal Officer at MSU ("MSU"), a public research university in East Lansing, Michigan, where I have been employed for eight (8) years.

2. My duties entail authorizing expenditures, ensuring compliance with financial policy, developing financial reports and budgets, and approving personnel actions.

3. I am stepmother to my husband's five (5) children, who range in age from 14 to 22 years old. I am the family's primary breadwinner.

4. Since March of 2020, I have worked remotely, and there is currently no plan for me to return to in-person work.

5. On November 19, 2020, I became sick, manifesting symptoms consistent with a COVID-19 infection, including a severe headache and dry cough. The following day I developed flu-like aches and pains.

6. On November 21, 2020, I received a positive COVID-19 Rapid test at Ouch Urgent Care clinic in St. Johns, Clinton County, Michigan.

7. After about four (4) days, I began to improve, but I lost my sense of taste and smell for a full month and have not entirely regained it.

8. I received positive COVID-19 antibody test results on August 17, 2021, from Sparrow Health System and again on August 21, 2021 from LabCorp.

9. I consulted with Dr. Hooman Noorchashm on August 21, 2021 and August 26, 2021 about receiving a vaccine in light of my natural immunity. Dr. Noorchashm advised me that immunization was medically unnecessary.

10. According to MSU, if I remain unvaccinated by the August 31 deadline, I face the threat of disciplinary action, including termination of my employment.

11. I was notified of the vaccine requirement via email for the first time on July 30, 2021. The email did not contain significant detail about the vaccine mandate, only announcing that all students and employees must be immunized by August 31, 2021 unless they receive a religious or medical exemption.

12. On August 5, 2021, the University posted a more detailed Directive on its website, including that medical and religious exemptions could be granted, and applying the Directive to employees who have recovered from COVID-19 infections and all employees regardless of whether they work on campus. On August 17, 2021 the University released the forms for religious and medical exemptions which detailed the qualifying medical circumstances (natural immunity does not qualify).

13. I contacted the New Civil Liberties Alliance ("NCLA") on August 12, 2021, in an attempt to secure representation to challenge MSU's Directive as it applied to me.

14. NCLA agreed to represent me on August 26, 2021, and I signed an engagement letter on that date.

15. MSU's mandate that I receive the vaccine as a condition for performing my duties has caused me significant distress and anguish. The University is forcing me to choose between performing my professional duties to the best of my ability and protecting my personal health. The University is also forcing me to choose between protecting my constitutional right to bodily

autonomy, privacy and protection and keeping my job, which is the lifeblood of my family's livelihood. I believe I will suffer irreparable injury (injury that money will not be able to make up for) to the extent my request for a temporary restraining order and/or preliminary injunction is not granted.

16. Moreover, by forcing me to ignore my own medical concerns and my immunologist's medical advice, MSU's mandate has caused my family members significant anxiety.

17. The heightened fears that MSU is unnecessarily inflicting on my family members and myself by coercing me to undergo an unnecessary and potentially risky medication procedure has adversely impacted my mental health and will continue to do so while the University's coercive Directive remains in place or operative in some fashion against me.

Executed on:

Jeanna Norris

Jeanna Norris

08/26/2021

Date

ATTACHMENT E

MSU Faculty, Staff and Students,

Since I arrived at MSU and throughout the pandemic, I have continued to place the health and safety of our students, faculty and staff at the forefront of all decisions. My priority has been to protect our campus and surrounding communities as we respond to the COVID-19 pandemic, using data and science-based information to inform every decision.

I have been a constant advocate for the COVID-19 vaccine as the best defense against the spread of the disease and the clearest path to the resumption of our on-campus living and learning. I am encouraged that the response to the vaccine has been largely positive, and members of our community are making the choice to protect themselves and others.

However, the yesterday's CDC data is concerning and significantly shifts the landscape. Across the country and here in Michigan, we are seeing a rise in cases and are finding the delta variant is more contagious. The new CDC data suggests that even vaccinated individuals can in some cases spread the virus.

These recent developments and my commitment to keeping students, staff and faculty safe have led me to update our requirements, including those for the fall semester. Today, I am announcing two key actions:

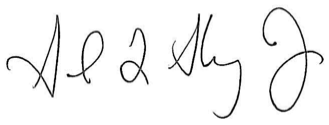
1. All individuals are required to wear masks indoors beginning Aug. 1 in all campus buildings and other MSU facilities in East Lansing and throughout the state. This requirement will be in place for at least the first weeks of the fall semester.
2. All students, faculty and staff are required to be fully vaccinated against COVID-19 with an FDA-authorized or WHO-approved vaccine by Aug. 31. Limited exemptions for medical or religious reasons will be provided.

More details about these new requirements will be shared in the coming days.

For those who have not received a COVID-19 vaccination yet, it's time to do so. You can receive one through the MSU Health Care Pharmacy or find a vaccination provider near you by visiting vaccines.gov. Students, faculty or staff who have not completed their vaccine regimen and those exempt from the vaccine for health or religious reasons will be required to take part in MSU's Early Detection Program or other measures that help keep them safe.

We are all in this battle against COVID-19 and its variants together and I firmly believe the actions we are taking today are necessary measures. As we have throughout the pandemic, we will continue to monitor the situation and will adjust as needed. I appreciate the commitment of our students, faculty, staff and others to protect our Spartan Community.

Sincerely,



Samuel L. Stanley Jr., M.D. (he/him)
President

ATTACHMENT F

COVID directives

Updated Aug. 5, 2021

To slow the spread of COVID-19, Michigan State University is directing everyone to take personal responsibility to protect their own health and safety, as well as the health and safety of MSU faculty, staff, students, visitors and loved ones.

Face Coverings

Individuals with COVID-19 are highly infectious for up to two days before the onset of symptoms. Thus, face coverings are a crucial public health measure and help protect others by reducing exposure to droplets if someone is unknowingly infected with COVID-19. Wearing a face covering, whether you feel ill or have been diagnosed with COVID-19, is critical to maintaining everyone's health and safety.

Starting Aug. 1, 2021 and lasting until at least Sept. 15, 2021, face coverings must be worn by everyone indoors (including all faculty, staff, students, vendors and visitors) while you are on property owned or governed by MSU or while participating in MSU-related or MSU-sponsored activities. If you have a medical condition that may prevent you from safely wearing a face covering, you should contact MSU's Resource Center for Persons with Disabilities to begin the accommodation process.

Exceptions to the requirement for face coverings will be limited. For example, if you are indoors on property owned or governed by MSU, exceptions are limited to when:

1. you are in your own place of residence (*g.*, residence hall room or apartment);
2. you are in a private, single-occupancy office or lab space with a closed door and can reasonably expect other individuals not to enter (but if you leave your private, single-occupancy office or lab space and proceed into a common area or hallway – even if there are no other individuals present – you must wear a face covering);
3. you are eating or drinking;
4. you are receiving a medical or personal care service for which removal of the face covering is necessary; **or**
5. you are younger than 2 years old.

If you are working, an exception may be allowed in the following situations:

1. you are working in a setting where a face covering may increase the risk of a hazard (for example, the face covering could become wet, the face covering could get caught in machinery, or the face covering could become contaminated with chemicals used in the work environment);
2. you can maintain physical distance (at least six feet of separation) from others; **and**
3. you have previously consulted with your supervisor to determine the appropriate face covering for your setting.

Face coverings are not required **outdoors** while you are on property owned or governed by MSU.

Face coverings should:

1. be non-medical grade to maintain supplies for health care use,
2. fit snugly against the side of your face,
3. cover your nose and mouth,
4. be secured with ties or ear loops, **and**
5. allow for breathing without restriction.

Cloth face coverings should only be worn for one day at a time, and they must be properly hand washed or laundered with soap/detergent before subsequent use. Face coverings may vary (for example, disposable non-medical masks are acceptable).

In addition to wearing face coverings, whether you are on- or off-campus, you also must adhere to the guidelines and recommendations from the Centers for Disease Control and Prevention (CDC), as well as federal and state government authorities, in order to protect your own health and the health of the entire MSU community.

Mandatory COVID-19 Vaccine

For the fall 2021 semester and potentially beyond, all faculty, staff, and students are required to be fully vaccinated or have an approved exemption. **On or before Aug. 31, 2021**, all MSU faculty, staff, and students must have completed or received at least one dose of a two-dose series of the COVID-19 vaccination and report their vaccine information using the Vaccine Form (https://covidresponse.msu.edu/vaccine/survey). Persons who received one dose of a two-dose series are expected to complete their vaccination series according to the recommended schedule and must report when they have done so via the Vaccine Form (https://covidresponse.msu.edu/vaccine/survey). Further, persons who are not fully vaccinated by Aug. 31, 2021 are required to participate in the Early Detection Program (https://earlydetection.msu.edu) until they are fully vaccinated and follow the Face Coverings directive.

Arriving from an international location. Faculty, staff, and students arriving from an international location may not be able to be vaccinated before arriving on campus and meet the Aug. 31, 2021 deadline. These persons should so indicate on the Vaccine form

(hhttps://covidresponse.msu.edu/vaccine/survey) and plan to receive a COVID-19 vaccine upon their arrival in the United States. Persons who are not fully vaccinated by Aug. 31, 2021 are required to participate in the Early Detection Program (https://earlydetection.msu.edu) until they are fully vaccinated and follow the Face Coverings directive.

Authorized and approved vaccines. FDA-authorized and WHO-approved vaccines will meet MSU's vaccine requirement.

Exemption process. In the interest of the health and safety of the entire MSU community, exemptions to the vaccine requirement will be limited. The exemptions are:

1. *Religious exemptions*. Persons requesting an exemption due to a sincerely held religious belief that precludes them from receiving the COVID-19 vaccine may submit a request for a religious exemption. A religious exemption is not the same as a philosophical, moral, or conscientious exemption.
2. *Medical exemptions*. Persons requesting an exemption due to a medical condition that precludes them from receiving the COVID-19 vaccine may submit a request for a medical exemption. Documentation from a medical provider is required. The exemption will be provided only for CDC-recognized contraindications and for individuals with disabilities under the ADA.

Faculty, staff, and students can request an exemption for religious or medical reasons using the respective online forms (covid19-vaccine/exemptions.html). Requests for exemptions will be reviewed by the Review Committee, or other designated MSU personnel, and the Review Committee will inform the person whether their request for an exemption is approved or denied.

For the fall 2021 semester and potentially beyond, faculty, staff, and students with approved exemptions for religious or medical reasons will be required to wear face coverings while indoors in public spaces, participate in the Early Detection Program (https://earlydetection.msu.edu), and quarantine if exposed to someone who has tested positive for COVID-19.

Additionally, students who are only taking online courses and will not be on property owned or governed by MSU for any reason during the fall 2021 semester will be exempt from MSU's Mandatory COVID-19 Vaccine Directive. These students can request an exemption for the fall 2021 semester by using this online form (covid19-vaccine/exemptions.html).

Personal Hygiene

Practice good personal hygiene, including washing hands frequently with soap and water for at least 20 seconds, especially after going to the bathroom, blowing your nose, coughing and before eating. If soap and water is not available, use hand sanitizer with at least 60% alcohol. Avoid touching your eyes, nose or mouth with unwashed hands. Clean and disinfect frequently

touched objects, such as doorknobs, tables, light switches, phones, keyboards and faucets. Clean your personal spaces and workspaces regularly with soap followed by using an approved household disinfectant.

Self-Monitoring

Symptoms may appear 2-14 days after exposure to the virus. Using whichever tools and processes are made available by the university, pay attention for the appearance of possible flu-like symptoms, including:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

This list may not include all possible symptoms. Public health officials, including the CDC, will continue to update the list as they learn more about COVID-19. If you begin exhibiting symptoms, stay home and contact the Olin Health Center's 24-hour nurse line at (517) 353-5557 or your personal health care provider.

Exposure to COVID-19

The best way to prevent illness is to avoid being exposed to the virus. If you believe you have been exposed to someone with COVID-19, you should self-quarantine and monitor your symptoms. If feeling ill, students should contact MSU's COVID-19 hotline at 855-958-2678 or contact their health care provider. Faculty and staff should contact their primary care physician.

MSU will test any faculty, staff, or student who becomes symptomatic after returning to campus. You may also get tested through the State of Michigan Coronavirus Testing Hotline. Call (888) 535-6136 from 8 a.m. to 5 p.m., Monday through Friday, and press 1 to be connected to an operator who can help you find a nearby location and schedule an appointment. Or, visit Michigan.gov/CoronavirusTest to find locations near you. There are many locations where you can get tested at no cost.

Adherence to Public Health Guidance and Cooperation with Public Health Authorities

For the protection of the entire community, MSU expects all faculty, staff, and students to follow all applicable state and public health guidance and cooperate with public health authorities, including, but not limited to, participating in contact tracing efforts.

Adherence to Signage and Instructions

To protect yourself and others, faculty, staff, and students must (a) look for instructional signs posted by MSU or public health authorities, (b) observe instructions from MSU or public health authorities that are emailed to your "msu.edu" account, and (c) follow those instructions.

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ATTACHMENT G

FAQs

On July 30, 2021, Michigan State University made the decision to require students, faculty and staff to be vaccinated against COVID-19 by Aug. 31 (either fully or with at least one dose of a two-dose vaccine), with limited medical and religious exemptions (../covid19-vaccine/index.html). Additionally, all individuals are now required to wear a mask indoors on any MSU property.

These decisions were made after careful consideration of the scientific data on the delta variant, which is driving the rising number of COVID-19 cases (and in some areas hospitalizations) across the state and country. The latest CDC data show the variant is more infectious and, in some cases, can be transmitted by vaccinated individuals. Our goal with this requirement is simple: Protect students, faculty and staff, as well as our surrounding communities. Health and safety remain our top priority, and this is the best path to the fall we all seek – living and learning on campus.

Below are answers to questions about these new requirements (../directives.html) as well as general FAQs.

COVID-19 vaccine mandate

How do I get the COVID-19 vaccine? +

What is considered fully vaccinated? What about booster shots? +

Why did MSU institute a vaccine mandate? +

How will I provide proof that I have been vaccinated? +

Can I change my form if I make an error or need to add my second dose? +

How do I request an exemption from the vaccine mandate? +

Who will have access to the verification and exemption information submitted by students, faculty and staff? +

What are the consequences for not complying with the vaccine or mask requirement? +

If I qualify for a medical or religious exemption, will I be required to participate in the Early Detection Program? +

If I've started the vaccination process but am not fully vaccinated by Aug. 31, do I need to enroll in the Early Detection Program? +

I have had COVID-19 in the past and have laboratory evidence of antibodies. Do I need to be vaccinated? -

Even those who contracted COVID-19 previously are required to receive a vaccine, which provides additional protection.

Will MSU recognize international vaccines? +

If I received my first dose somewhere other than campus), can I receive my second dose on campus? +

Will guests and volunteers at the Spartan Stadium, MSU Pavilion, museums, or other public venues on campus need to be vaccinated? +

Do people with adjunct appointments only (such as unpaid or volunteer appointments; clinical faculty) need to be vaccinated? +

Can outside entities hosting events at MSU require masks or ask about vaccination status? +

How can MSU legally mandate a vaccine? +

Why should I get a vaccine if the delta variant breaks through with the current vaccines? +

Will emeriti working in MSU buildings on campus need to be vaccinated? Are they considered faculty and academic staff under the vaccine mandate? +

Will there be an app or some other technology that people will show as they enter buildings to prove that they have been vaccinated or that they have an exemption and accommodations? +

Who will need to determine whether faculty, staff and students in offices are vaccinated? Who will that fall to? +

What happens if it is learned – through some established process or accidentally – that an employee or student has attested to being vaccinated when in fact the person was not actually vaccinated? +

If students arrive to campus the day before their first dose, can I still move in? +

Can students have visitors who are unvaccinated? +

Vaccine exemptions

How do I apply for a medical exemption? +

If I applied for an exemption do I still need to fill out the attestation form? +

How do I attach the form to the email? +

What is the turnaround time for getting a response? +

Is there be an appeal process if denied? +

Who is on the exemption review committee? +

Where do my form and documentation go? +

Is the information I submit in my exemption request confidential? +

Can I apply for both a religious and medical exemption? +

I would prefer to send the form to a mail-in address, rather than attaching it to an email. Can I do that? +

I received my vaccine in another country and the vaccine was not FDA-authorized or WHO-approved. My doctor says that getting another vaccine at this point may not be safe. What should I do? +

Face coverings

Do students need to wear masks in their residence hall rooms? +

Do visitors to rooms in the residence halls need to wear a mask? +

Do employees need to wear masks in MSU vehicles? +

How about wearing masks in the dining halls? +

How do students and employees get access to personal accommodations, such as clear face coverings? +

Do I need to wear a mask to ride the CATA bus? +

Do I need to wear a mask while working out on campus? +

Are family members or significant others required to wear a mask in my dorm room with me? +

What are the rules for masks at Spartan Stadium and other athletic venues? +

Students

Can a student be enrolled and attend classes after Aug. 31, 2021, if they have not yet received the second of a two-dose COVID-19 vaccine at least two weeks prior to Aug. 31? +

Can a student remain enrolled at MSU without being vaccinated if they take only online courses? +

Can I choose to be unvaccinated and just participate in the Early Detection Program? +

If a student is not comfortable attending their in-person classes until they are fully vaccinated, what should they do? +

What if a student enrolled in an in-person course requests to be remote/online because of their circumstances (e.g., health, international)? +

Is MSU providing space for quarantining/isolating students, or do they need to have their own action plan? +

Do students need to inform a faculty member, academic adviser, or residence hall adviser of their vaccination status? +

Can students still participate in in-person activities and classes if they are not fully vaccinated but are participating in the Early Detection Program? +

If I have friends visiting me in my residence hall room or apartment, or have family helping me move onto campus, do they need to be vaccinated? +

Can I receive a full tuition refund if I withdraw from the university? +

Can I receive a full refund if I cancel my housing contract at this time? +

Will there be restrictions on how many people can be in a dorm room? +

Are visitors allowed to stay the night in the residence halls? +

Faculty and staff

Do employees need to inform their supervisor of their vaccination status? +

Can I choose to be unvaccinated and just participate in the Early Detection Program? +

Can an employee remain employed at MSU without being vaccinated if they are working remotely? +

Should units who are still working remotely continue to do so with cases on the rise? What is the updated return-to-campus plan? +

I am represented by a labor organization. What role does that play in connection with this policy? +

Will all courses need to have a remote/Zoom option to accommodate unvaccinated students? +

What are the expectations for instructors when determining whether to accommodate requests for remote learning from students who are concerned about COVID? +

How do I respond if a student refuses to wear a mask? +

Will we need to have a mask on while teaching? +

Will face shields substitute for a mask? +

Will faculty be informed about the vaccination status of everyone in their class (vaccinated or have an appropriate exemption)? +

Does the campus mask requirement apply to individuals when they are alone in private offices? +

Do contractors and vendors need to be vaccinated to work on campus? +

If a person is on FMLA or another leave, must they get vaccinated by Aug. 31 or would it be before they return to work? +

General

What do I do if I am feeling ill or test positive for COVID-19? +

Will we practice physical distancing? +

How are buildings being prepared as more faculty, staff and students return to campus? +

What is the COVID-19 Early Detection Program? +

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ATTACHMENT H

MICHIGAN STATE UNIVERSITY

Covid-19 Vaccine Medical Exemption Request

Mandatory COVID-Vaccine Policy

Michigan State University requires all faculty, students, and staff to be fully vaccinated against COVID-19. Universal vaccination of students, faculty and staff against COVID-19 will significantly reduce the risk of transmission of COVID-19 on campus and in the surrounding communities and is the clearest path to the resumption of full on-campus living and learning. This form should be used by faculty, students, and staff needing an exemption from the mandatory vaccine requirement due to a medical condition that prevents them from getting the COVID-19 vaccine. This form also applies to students and employees seeking a deferment for medical, pregnancy, or breastfeeding related reasons. Exemption requests for any of these reasons must be submitted **on or before Aug. 31, 2021**. While waiting for an exemption decision, students and employees must wear a face covering on campus, participate in the Early Detection Program, and quarantine if exposed to COVID-19.

If approved, the employee or student acknowledges they will comply with the Directives for unvaccinated individuals with exemptions, including wearing a face covering indoors, participating in the Early Detection Program and quarantining if exposed to COVID-19.

Section I: To be completed by employee or student and parent or guardian (if student is under 18)

Last Name _____First Name_____ Middle Initial ____
Email _____ Date of Birth _____ MSU ID # (APID or ZPID) _____

The undersigned understands the content of the Medical Exemption Request and the University's COVID-19 Vaccination Directives, has had the opportunity to ask questions about it, and verifies the truth and accuracy of the statements in this Medical Exemption Request.

Upon expiration of the deferment, or if earlier, upon cessation of the medical condition or contraindication, the undersigned agrees to receive the COVID-19 vaccination and submit proof of vaccination status.

If student is less than 18 years old the request must be signed by both the student and the parent or guardian.

Employee Signature: _____ Date: _____

Student Signature: _____ Date: _____
If student is under 18,
Signature of parent or guardian: _____ Date: _____

Section II: Medical Exemption Request (to be completed by medical provider)

MICHIGAN STATE UNIVERSITY

Medical Provider Certification of Contraindication: I certify that my patient (named above) should not be vaccinated against COVID-19 because they have one of the following contraindications as set forth by the CDC. [Complete the appropriate section and sign the bottom of the form].

☐ Documented anaphylactic allergic reaction or other severe adverse reaction to any COVID-19 vaccine – e.g., cardiovascular changes, respiratory distress, or history of treatment with epinephrine or other emergency medical attention to control symptoms. Generally does not include gastro-intestinal symptoms as the sole presentation of allergy. Describe the specific reaction:

_____

_____

_____

☐ Documented allergy to a component of the COVID-19 vaccine – does not include sore arm, local reaction or subsequent respiratory tract infection. Describe the specific reaction:

_____

_____

_____

Medical Provider Certification of Medical Exemption: I certify that the patient identified above cannot safely receive the COVID-19 vaccination due to:

☐ Other documented medical condition. Note that the medical condition must constitute a disability under the Americans with Disabilities Act. Explain in detail the medical condition and the reasons why you believe the patient should not receive the COVID-19 vaccine:

_____

_____

_____

Medical Provider Certification of Deferment: I certify that the patient named above is requesting a deferment of the COVID-19 vaccine due to:

☐ A limited term inability to receive the COVID-19 vaccination (such as due to receipt of Monoclonal antibody or convalescent plasma for the treatment of COVID-19 in the last 90 days, pregnancy, or breastfeeding).

Important Note: Guidance from the CDC currently states that pregnant and breastfeeding people can get the COVID-19 vaccine. The CDC also notes that pregnant and recently pregnant people are more likely to get severe illness and/or suffer preterm birth with COVID-19 compared with non-pregnant people. Those who are pregnant, or breastfeeding can receive a COVID-19 vaccine and getting the COVID-19 vaccine during pregnancy can protect from severe illness and pre-term birth from COVID-19.

Expiration of deferment: _____

Signature of Healthcare Provider: _____ License #_____

Name (print): _____ Address/Clinic Stamp: _____ Phone: _____

Please submit this form to medicalexemption@msu.edu.