Nos. 21A244 and 21A247

IN THE

Supreme Court of the United States

IN RE: MCP NO. 165, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, INTERIM FINAL RULE: COVID-19 VACCINATION AND TESTING; EMERGENCY TEMPORARY STANDARD 86 FED. REG. 61402, ISSUED ON NOVEMBER 4, 2021

(*Caption continued on inside cover*)

ON EMERGENCY APPLICATIONS FOR STAY OF AGENCY STANDARD PENDING THE DISPOSITION BY THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT OF A PETITION FOR REVIEW AND ANY FURTHER PROCEEDINGS IN THIS COURT OR, ALTERNATIVELY, PETITION FOR A WRIT OF CERTIORARI BEFORE JUDGMENT AND STAY PENDING RESOLUTION

MOTION OF DEFENDING THE REPUBLIC, INC. FOR LEAVE TO FILE ATTACHED *AMICUS* BRIEF IN SUPPORT OF EMERGENCY APPLICATIONS FOR A STAY OR INJUNCTION PENDING CERTIORARI AND FOR LEAVE TO FILE WITHOUT 10 DAYS NOTICE

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December 29th, 2021

NATIONAL FEDERATION OF INDEPENDENT BUSINESS, ET AL.,

Applicants,

—v.—

DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL.,

Respondents.

STATE OF OHIO, ET AL.,

Applicants,

—v.—

DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL.,

Respondents.

Amicus Defending The Republic, Inc. ("DTR") requests leave to file the attached *amicus curiae* brief in support of the Emergency Applications, filed on December 17–18, 2021, seeking a stay or injunction pending certiorari to review the Sixth Circuit's decision granting a motion to dissolve a stay of the Occupational Safety and Health Administration (OSHA) Emergency Testing Standard on COVID-19 vaccination and testing. The Fifth Circuit entered a stay before the matter was transferred to the Sixth Circuit. *Amicus* further moves for leave to file the attached brief without 10 days advance notice to the parties. See Sup. Ct. R. 37.2(a).

By email on December 24, 2021, *amicus* provided notice to the parties in 21A244 and 21A247 of its intent to file an *amicus* brief in support of the emergency applications. Counsel for the petitioners-applicants the National Federation of Independent Businesses in 21A244 stated that he does not oppose the filing. Counsel for the State petitioners in 21A247 stated that he consents to the filing. Counsel for the respondent U.S. Department of Labor takes no position. Respondent's briefs are due December 30. Replies are due January 3. Oral argument is set for January 7.

Amicus DTR is a nonprofit organization that is dedicated to defending the Constitution, the rule of law, and protecting individual rights of Americans including medical freedom and religious liberty. DTR represents over thirty military service members in litigation involving the violation of their religious freedoms and their other constitutional and statutory rights to refuse mandatory vaccination with experimental COVID-19 treatments. DTR also expects to file suit soon to challenge the federal contractor vaccine mandate on behalf of individual federal

contractors on similar grounds that have led multiple federal district courts to impose a nation-wide injunction and stay.

The COVID-19 vaccine mandate at issue in this case is contrary to the mission and values of DTR. It will subject tens of millions of Americans to an unprecedented federal seizure of power, threatening this nation's Constitutional system of federalism. It contradicts and violates existing laws and individual rights to make health care decisions, and it violates this Court's long-standing recognitions of rights to privacy.

In consideration of these interests, DTR seeks to inform the Court that the Pfizer COVID-19 vaccine mandated by the OSHA ETS and described as being the one approved by the FDA, i.e., Comirnaty, is not currently available to anyone in the United States. The United States finally and reluctantly conceded this in a lawsuit DTR brought in Florida. There is no supply of Comirnaty. The only vaccines in production and available are the vaccines approved under the FDA's Emergency Use Authorization ("EUA"). DTR files this brief to explain why the OSHA COVID-19 vaccine mandate before the Court is an illegal federal mandate to compel Americans to take an experimental vaccine.

No counsel for any party authored the proposed brief in whole or in part, and no person or entity, other than the *amicus curiae* or its undersigned counsel, contributed money intended to fund preparing or submitting this brief.

CONCLUSION

Because no party has opposed the instant filing, *amicus* requests that the Court grant leave to file the attached *amicus* brief without 10 days advance notice to the parties.

Respectfully submitted,

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[PROPOSED] BRIEF OF *AMICI CURIAE* DEFENDING THE REPUBLIC, INC. IN SUPPORT OF EMERGENCY APPLICATIONS FOR A STAY OR INJUNCTION PENDING CERTIORARI

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CORPORATE DISCLOSURE STATEMENT

Defending the Republic ("DTR") is a 501(c)(4) not-for-profit corporation organized under the laws of Texas. It has no corporate parents or affiliates, nor has it issued shares or securities.

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STATEMENT OF INTEREST[1]

DTR is dedicated to defending the Constitution, the rule of law, and protecting individual rights of Americans including medical freedom and religious liberty. Currently, DTR represents over thirty military service members in litigation challenging the Department of Defense ("DOD") vaccine mandate because it violates service members' constitutional rights, religious freedoms, and their right to refuse COVID-19 vaccines issued under an Emergency Use Authorization ("EUA"). DTR will also be filing suits challenging federal vaccine mandates for federal contractors and federal employees in the near future.

The Occupational Safety and Health Administration ("OSHA") COVID-19 Emergency Temporary Standard ("ETS") at issue here[2] is contrary to the mission and values of DTR. It represents an unprecedented federal usurpation of power, threatening this nation's Constitutional system of federalism and violating individual rights. Further, it is part of a larger wrongful system of federal mandates that violate the rights of hundreds of millions of American men, women, and children against being required to take an experimental medical treatment as a condition for employment, education, worship, or the exercise of other constitutional rights.

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[1] In accordance with Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part, and that no counsel or party, other than amicus curiae or undersigned counsel, made a monetary contribution intended to fund the preparation or submission of this brief

[2] OSHA, *COVID-19 Vaccination and Testing: Emergency Temporary Standard*, 86 Fed. Reg. 61,402 (Nov. 5, 2021) ("OSHA Mandate" or "OSHA ETS").

In consideration of these interests, DTR provides the Court crucial information not addressed by others.[3] The government has conceded that the only COVID-19 vaccine approved by the Food and Drug Administration ("FDA")—Pfizer-BioNTech's Comirnaty—is not available in the United States. The only vaccines available are experimental products. DTR files this brief to explain why the COVID-19 vaccine mandate before the Court is really an unlawful federal mandate to take an experimental vaccine.

SUMMARY OF THE ARGUMENT

A critical issue that has not been addressed in the Applicants' briefs, the OSHA Mandate, or the opinions by the Fifth or Sixth Circuit Courts of Appeals, is that OSHA and other federal agencies are mandating the administration of an experimental product that has not been approved by the FDA.[4] In fact, none of the approved "vaccine" is available in the United States.

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[3] DTR supports Applicants' arguments that the OSHA Mandate exceeds OSHA's authority for the reasons set forth in their briefs and will not repeat those arguments here. DTR's arguments are solely focused on bringing to the Court's attention the unavailability of FDA-licensed vaccine (*i.e.*, Comirnaty), and the implications a vaccine mandate may have for any federal or state vaccine mandates.

[4] The experimental status of the available COVID-19 vaccines undermines the Sixth Circuit's decision because the court was not informed that Comirnaty is unavailable. This was critical to its reasoning which held that "OSHA acted within its discretion in making the practical decision to wait for [FDA] approval before issuing the ETS," and found that such approval "support[ed] OSHA's conclusion that the current situation is an emergency, and one that can be ameliorated by FDA action." *In re MCP No. 165*, --- F.4th --- (2021), 2021 WL 5989357, at *9 (6th

DTR urges the Court to grant Applicants' request to find that the OSHA Mandate exceeds the agency's authority. But first, it is imperative to explain why the OSHA Mandate is properly understood as an experimental vaccine mandate. Currently, the only COVID-19 "vaccine"[5] that has been approved by the

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Cir. Dec. 17, 2021) (internal citations omitted throughout) ("*MCP*").

[5] Here and in the proceedings where DTR represents service members challenging DOD mandates, see *John Doe #1 v. Austin*, No. 3:21-cv-1211 (N.D. Fla.) (subsequently captioned *Coker v. Austin*) and *Crosby v. Austin*, 8:21-cv-2730 (M.D. Fla.), DTR's clients and expert witnesses dispute the FDA's characterization of COVID-19 treatments as "vaccines." Instead,the new products should be classified as one treatment among many other alternatives. Unlike traditional vaccines, the COVID-19 "vaccines" have a short and rapidly waning efficacy, cannot prevent infection or transmission, require booster shots, and utilize an entirely novel mechanism of action (mRNA) and delivery (nanolipids). DTR's position is proved by the CDC itself, which changed its own definition of "vaccine" and "vaccination" within a week after the FDA's August 23, 2021, approval of Comirnaty to reflect the fact that, unlike traditional vaccines, these COVID-19 treatments provide "protection" rather than "immunity." *Compare* CDC, *Vaccines and Immunizations: Definition of Terms*, available at: http://web.archive.org/web/20120710132002/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Dec. 28, 2021) (defining "vaccine" as "[a] product that produces immunity therefore protecting the body from the disease.") *with* CDC, *Vaccines and Immunizations: Definition of Terms* (Aug. 26, 2021), available at: http://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Dec. 27, 2021) (defining "vaccine as "[a] product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease."). For the avoidance of confusion, however, DTR will refer to these treatments as "vaccines." These products also have produced adverse events including deaths, heart attacks, strokes, and severe neurological problems. See CDC, *Selected Adverse Events Reported After*

FDA is Pfizer-BioNTech's Comirnaty, which is not available in the United States. The only COVID-19 products that are available are not FDA approved and instead are subject to an EUA.

As explained below, the distinction between an EUA and an FDA-approved product matters. *See infra* Section III. In particular, the FDA's grant of EUA requires little, if any, demonstration that the EUA product is safe and effective. Nor does the EUA include FDA review or approval of manufacturing processes, facilities, storage, distribution, or quality control procedures. This is why the FDA has acknowledged the products are "legally distinct."[6]

The unavailability of Comirnaty raises a second question that also has not been asked, much less addressed, by OSHA or in the judicial decisions under review. Federal laws and applicable FDA regulations expressly provide a "right to refuse" experimental or EUA products. See 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Yet, the OSHA Mandate unlawfully overrides or circumvents those laws.

These rights to informed consent and to refuse experimental drugs—embodied not only in federal law, like 21 U.S.C. § 360bbb-3, but also international law and conventions like the Nuremburg Code—should foreclose such a wide-ranging mandate. DTR urges this Court to consider the enormous wrongful consequences of imposing an illegal mandate requiring

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COVID-19 Vaccination, available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (last visited Dec. 28, 2021).

[6] *See* FDA, Pfizer-BioNTech EUA Letter at 2 n.8 (Aug. 23, 2021) ("FDA BioNTech EUA Expansion Letter"), available at: https://www.fda.gov/media/150386/download (last visited Dec. 27, 2021).

nearly the entire United States adult workforce to take an experimental and irreversible medical treatment.

The immeasurable ramifications of endorsing a near-universal federal mandate justify granting a stay to give more time for deeper consideration by this Court, the political branches, public health experts, and the citizens of the United States to consider the legal arguments and scientific evidence on the safety and efficacy of the newly manufactured "vaccines," the rapidly proliferating range of therapies, and alternative federal, state, and local public health measures. Surely a stay to allow this Court to hear the arguments presented by all Parties and *Amici* is appropriate given the momentous consequences for tens of millions of Americans who face the loss of their rights to work, education, travel, worship and other fundamental constitutional rights unless they submit to an unproven, experimental medical treatment with an unprecendented history of adverse effects including deaths.

ARGUMENT

I. The Development of COVID-19 Vaccines

The pharmaceutical industry undoubtedly moved quickly to develop vaccines in response to the COVID-19 pandemic. This was done in conjunction with the United States government's Operation Warp Speed, that awarded billions to these companies to spur the development and distribution of the vaccines.[7] To clear the way for expedited development, the Secretary of

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[7] Congressional Research Service, *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*, (Mar. 1, 2021), available at: https://crsreports.congress.gov/product/pdf/IN/IN11560 (last visited Dec. 27, 2021).

Health and Human Services ("HHS") issued notice, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, that COVID-19 had a "significant potential to affect national security or the health and security of United States Citizens" and that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic." 85 Fed. Reg. 18,250 (April 1, 2020).

The currently available COVID-19 "vaccines" are the results of these efforts. The Pfizer-BioNTech vaccine received its EUA on December 11, 2021.[8] This was followed by EUAs for the Moderna and Johnson and Johnson Vaccines ("Moderna Vaccine" and "Janssen Vaccine") on December 18, 2021 and February 27, 2021, respectively.[9] These EUAs were granted after limited testing. For example, the Pfizer-BioNTech Vaccine's EUA was issued based on an "entire enrolled study population [that] had a median follow-up of less than 2 months."[10] Typically, vaccines

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[8] FDA, *FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020), available at: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (last visited Dec. 27, 2021).

[9] Carl Zimmer, *et al., Coronavirus Vaccine Tracker*, THE NEW YORK TIMES (last updated Dec. 22, 2021) ("NY Times COVID Tracker") available at: https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html (last visited Dec. 27, 2021).

[10] *See* FDA, *Emergency Use Authorization for an Unapproved Product: Review Memorandum (Pfizer-BioNTech COVID-19 Vaccine / BNT162b2)* at 17 (Nov. 20, 2020) ("FDA Pfizer-BioNTech EUA Review Memo"), available at: https://www.fda.gov/media/144416/download (last visited Dec. 27, 2021).

"require years of research and testing before reaching the clinic."[11]

II. The FDA-Approved Comirnaty is Unavailable to the American Public

On August 23, 2021, the FDA approved the Pfizer-BioNTech mRNA vaccine under the marketed name Comirnaty.[12] Soon thereafter, on September 9, 2021, President Biden announced that he would "protect vaccinated workers from unvaccinated co-workers" by having the Department of Labor issue "an emergency rule to require all employers with 100 or more employees . . . to ensure their workforces are fully vaccinated or show a negative test at least once a week."[13]

With these marching orders, the Secretary of Labor, through OSHA, issued the OSHA ETS, which mandated that private businesses with 100 or more employees "develop, implement, and enforce a mandatory COVID-19 vaccination policy, with an exception for employers that instead adopt a policy

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[11] NY Times COVID Tracker. *See also* Gail A. Van Norman, MD, *Drugs, Devices and the FDA: Part 1: An Overview of Approval Processes for Drugs*, JACC: Basic to Translational Science, Apr. 2016;1(3): 170-79 (explaining that it typically takes 10 years or more for initial review and clinical trials to FDA approval). FDA approval of Comirnaty took approximately three months from May 18 to August 23, 2021.

[12] FDA, *FDA Approves First COVID-19 Vaccine*, FDA Press Release (Aug. 23, 2021), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Dec. 27, 2021).

[13] White House, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021), available at: https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ (last visited Dec. 27, 2021).

requiring employees to either get vaccinated or elect to undergo regular COVID-19 testing and wear a face covering at work in lieu of vaccination." OSHA ETS, 86 Fed. Reg. at 61,402. Americans subject to this ETS are in compliance if they receive the recommended minimum doses of COVID-19 vaccines that are "[a]pproved or authorized for emergency use by the FDA." *Id*. at 61,479.

Notwithstanding the jurisdictional issues underlying the OSHA Mandate, there is a significant problem concerning how Americans are forced to comply with the mandate. Specifically, the only FDA-approved vaccine – Comirnaty – is not available to the American public. According to the CDC, "COMIRNATY products are not orderable at this time."[14] As of December 16, 2021, "there is not sufficient approved vaccine [i.e., Comirnaty] available for the population for whom it is authorized." *See supra*, FDA Pfizer-BioNTech Expansion Letter, note 6 at 5 n.9. In fact, it appears that Comirnaty is not available at all in the United States. Pfizer and the National Institutes of Health confirmed that Comirnaty would be unavailable for months after its approval.[15]

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[14] CDC, *COVID-19 Vaccine Codes*, available at: https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html (last visited Dec. 28, 2021).

[15] On September 13, 2021, the National Institutes of Health ("NIH") posted an announcement by Pfizer that Pfizer "does not plan to produce any product with these new [Comirnaty] NDCs and labels over the next few months while the EUA authorized product is still available and being made available for U.S. distribution." *See* NIH-Pfizer Announcement of Comirnaty Unavailability (Sept. 13, 2021), available at: https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html (last visited Dec. 27, 2021). *See also* FDA, Summary Basis of Regulatory

The Department of Justice ("DOJ") finally conceded the unavailability of Comirnaty through defense counsel for DOD in *Austin*, where DTR represents service members challenging the DOD Mandate. While DOD initially claimed that the DOD in fact possessed Comirnaty and was administering it to service members, in oral argument, DOJ defense counsel acknowledged that not only did it not have Comirnaty and did not know when it would it get it, but also "could not say even whether vaccines labeled 'Comirnaty' exist at all." *Doe v. Austin*, 2021 WL 5816632, at *5 (N.D. Fla. Nov. 12, 2021) (citations omitted).[16]

DOD is the largest purchasing organization in the United States, and given its priority for national security matters, it would necessarily go to the front of

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Action – Comirnaty at 5 (Nov. 8, 2021) ("November 8 Comirnaty SBRA") ("In the U.S., there are no licensed vaccines or anti-viral drugs for the prevention of COVID-19."), available at: https://www.fda.gov/media/151733/download (last visited Dec. 27, 2021).

[16] The government's fallback position was that, while DOD does not have Comirnaty, it is instead administering EUA-labeled vials that the DOD claims are chemically identical to, and manufactured in accordance with, the requirements of the FDA license, which the government refers to as "BLA-compliant" vaccines. *See Austin*, 2021 WL 5816632, at *5. The government's position is incorrect for the reasons set forth below. *See infra* Section III. In any case, there is no discussion or mention of "BLA-compliant" vaccines in the OSHA ETS, nor does OSHA claim that there are sufficient BLA-compliant vials currently available to implement the OSHA Mandate. Accordingly, OSHA may not rely on "BLA-compliant" vaccines to defend its mandate because courts may not uphold agency actions based on reasons that the agency never gave. *See, e.g.*, *SEC v. Chenery*, 318 U.S. 80, 87 (1943). Nor is there any showing that the "vaccines" are identical. They are not by definition. If they were, they could be labeled Comirnaty.

the line for any purchasing COVID-19 vaccines. Yet DOD does not have Comirnaty and to this day the DOD cannot say when it will get Comirnaty. If the DOD cannot obtain Comirnaty, then how can average Americans who are subject to the OSHA Mandate? And perhaps more importantly, how can employees be fired for the failure of their employers to obtain a vaccine that even the DOD cannot procure?

The unavailability of Comirnaty is important. First, while OSHA purports to give employers the option of requiring vaccination or allowing testing and masks, it does not hide its real intent to force employees to choose vaccination to keep their jobs. If an employee opts out of their employer's mandatory vaccination policy, OSHA believes its ETS and the costs it imposes on that employee – which includes paying for regular testing – "creates a financial incentive for those employees to become fully vaccinated and avoid that cost." OSHA Mandate, 86 Fed. Reg. at 61,532.

As Judge Larsen observed in his dissenting opinion on the emergency motion to dissolve the stay of the OSHA Mandate, the Mandate's main purpose is to compel vaccination:

> Here, employers, not employees, control any non-vaccine option in the first instance; and OSHA has been candid that it has stacked the deck in favor of vaccination … OSHA has alerted us to no prior attempt on its part to mandate a solution that extends beyond the workplace walls— much less a permanent and physically intrusive one, promulgated on an emergency basis, without any chance for public participation. But that it is what OSHA has done here. A vaccine may not be taken off

> when the workday ends; and its effects, unlike this rule, will not expire in six months.[17]

Second, and in consideration of OSHA's coercive policy, workers will only be able to comply with the OSHA Mandate if they receive a vaccine under an EUA.[18] This is especially important because EUA vaccines bypass the FDA and PHS Act's requirements for safety and efficacy.

III. Important Differences Between EUA and FDA-Approved Vaccines

There are significant differences between the FDA's approval standards and the EUA standards. EUA vaccines require little to no proof of safety or efficacy. FDA vaccine approvals do.

The FDA may grant an EUA where: (1) the HHS Secretary has declared a public health emergency that justifies the use of an EUA, *see* 21 U.S.C. § 360bbb-3(b)(1); and (2) the FDA finds that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating" the disease in question. 21 U.S.C. § 360bbb-3(c)(3).

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[17] *MCP*, 2021 WL 5989357, at *27 (Larsen, C.J., dissenting) (citations omitted).

[18] The Sixth Circuit majority's comparison of the current OSHA Mandate to the 1991 OSHA standard requiring employers to make the Hepatitis B vaccine available to certain employees, 29 C.F.R. § 1910.1030(f), is inapposite for two reasons. First, OSHA only required employers to make it available to employees. Second, by that time the Hepatitis B vaccine had long been approved by the FDA and its side effects were within the range of tolerable adverse incidents. *See* CDC, *Epidemiology and Prevention of Vaccine-Preventable Diseases*, available at: https://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html (last visited Dec. 27, 2021) (noting that the Hepatitis B vaccine "was first licensed for use in the United States in 1981").

The differences between licensed vaccines and those subject to an EUA render them "legally distinct." *See supra*, FDA Pfizer-BioNTech EUA Expansion Letter, note 6 at 2 n.8. First, the requirements for efficacy are much lower for EUA products than for licensed products. EUAs require only a showing that, based on scientific evidence "if available," "it is reasonable to believe," the product "may be effective" in treating or preventing the disease. 21 U.S.C. §360bbb-3(c)(2)(A).

By plan, those vaccines that are subject to the OSHA Mandate have relatively little data to support their authorization. The Pfizer-BioNTech Vaccine was granted its EUA after approximately 2 months of follow-up testing. See supra, FDA Pfizer-BioNTech EUA Review Memo, note 10 at 17. The Moderna Vaccine received its EUA after providing its studies to the FDA "with a median of 7 weeks of follow-up after the second dose."[19] And for the Janssen Vaccine, which also received an EUA, "the median follow-up duration for participants in the efficacy and safety analysis populations was 8 weeks after vaccination."[20]

Second, the safety requirements are minimal, requiring only that the FDA conclude that the "known and potential benefits … outweigh the known and potential risks" of the product, considering the risks of

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[19] *See* FDA, Emergency Use Authorization for an Unapproved Product: Review Memorandum (Moderna COVID-19 Vaccine) at 6-7 (Dec. 18, 2020) ("FDA Moderna EUA Review Memo"), available at: https://www.fda.gov/media/144673/download (last visited Dec. 27, 2021).

[20] *See* Emergency Use Authorization for an Unapproved Production Review Memorandum (Janssen COVID-19 Vaccine) at 18 (Feb. 27, 2021) ("FDA Janssen EUA Review Memo"), available at: https://www.fda.gov/media/146338/download (last visited Dec. 27, 2021).

the disease. 21 U.S.C. §360bbb-3(c)(2)(B). There is no requirement that the FDA know the potential risks of the product.

In comparison, vaccines that go through traditional FDA review typically take 10 years or more to reach approval.[21] And the approval process compiles more information on the risks of the vaccine, gathered through lab testing and clinical trials, "to assess the safety and effectiveness of each vaccine."[22]

A. The Right to Refuse an EUA Vaccine

The FDA's grant of an EUA is subject to informed consent requirements to "ensure that individuals to whom the product is administered are informed" that they have "the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

For the three COVID-19 vaccines, FDA implemented the "option to accept or refuse" condition described in Section 564(e)(1)(A)(ii)(III) in each letter granting the EUA by requiring that FDA's "Fact Sheet for Recipients and Caregivers" be made available to every potential vaccine recipient. These include the statement that the recipient "has the option to accept

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[21] *See supra* Norman, note 11. *See also* HHS, *Vaccine Safety* (the process to test a vaccine in labs – before there is a decision to test it on people – "can take several years."), available at: https://www.hhs.gov/immunization/basics/safety/index.html (last visited Dec. 27, 2021).

[22] FDA, *Ensuring the Safety of Vaccines in the United States*, last updated July 2011, available at: https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf (last visited Dec. 27, 2021).

or refuse" the vaccine.[23] Moreover, the EUA label itself must expressly state that the recipient has a "right to refuse" administration of the EUA product. Accordingly, the OSHA Mandate contradicts established federal law and will require any covered employer, including state agencies, to violate an express requirement of federal law and the express terms of the FDA labeling and packaging requirements.

B. OSHA Cannot Override Informed Consent Rights

The norm of informed consent has been "firmly embedded" in U.S. law and FDA regulations for nearly 60 years. *Adullahi v. Pfizer, Inc.*, 562 F.3d 163, 182 (2d Cir. 2009). Congress first enacted this requirement in 1962 drawing on the Nuremberg Code and the Helsinki Declaration, "which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation." *Adullahi*, 562 F.3d at 182. Informed consent requirements are a cornerstone of FDA rules governing human medical experimentation. *See, e.g.*, 21 C.F.R. §§ 50.20, 50.23-.25, 50.27, 312.20, 312.120 (2008); 45 C.F.R. §§ 46.111, 46.116-117.

In any case, OSHA has not even acknowledged workers' informed consent rights, much less explained how its mandate can override these rights or force private and public sector employers into violating these rights. Accordingly, the OSHA Mandate cannot stand.

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[23] *See, e.g.*, Fact Sheet for Healthcare Providers Administering Vaccine (Moderna COVID-19 Vaccine) (Revised Dec. 9, 2021), available at: https://www.fda.gov/media/144637/download (last visited Dec. 27, 2021).

A helpful analogy when considering forced vaccination is to compare the present case to the DOD's much narrower Anthrax Vaccination Immunization Program. Courts enjoined that program, as it sought to impose a vaccine mandate on service members using experimental, unapproved anthrax mandates, which were expressly barred by statute. *See* 10 U.S.C. §§ 1107 and 1107a. Even in those cases, courts recognized the limitations of DOD power over military service members, observing "the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Doe No. 1 v. Rumsfeld*, 297 F.Supp.2d 119, 135 (D.D.C. 2003) (granting injunctive relief against DOD for mandating an EUA anthrax vaccine).[24] Certainly, OSHA has even less authority over American workers.

IV. EUA and FDA Licensed Products do not have the "Same Formulation" and are not "Interchangeable"

Notwithstanding any potential assertions to the contrary, the EUA and licensed versions of Pfizer-BioNTech do not have the "same formulation" as revealed by a simple inspection of the Pfizer Vaccine EUA letters and the Summary Basis for Regulatory Action (SBRA) for Comirnaty. Thus, they cannot be treated as "interchangeable," because there is no legal basis to administer an EUA product as if it were the FDA-licensed product. By definition, they are different.

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[24] *See also John Doe #1 v Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) (enjoining mandate of anthrax vaccine as investigational new drug under 10 U.S.C. § 1107), *modified* 2005 WL 774857 (D.D.C. 2005) (expanding injunction against mandated EUA anthrax vaccine under 10 U.S.C. § 1107a).

There is no evidence in the public record for finding that the EUA Pfizer-BioNTech vaccine and FDA-licensed Comirnaty have the "same formulation." There is, however, ample evidence for finding that they do not. The most detailed information on Comirnaty's composition, manufacturing process, manufacturing locations and other matters approved by the FDA is included in the FDA Comirnaty SBRA, nearly all of which is redacted,[25] while most of this information was never made available in the Pfizer-BioNTech EUA applications or authorizations. To the extent such information is available, it reveals differences in the composition of the EUA and the licensed product.[26] There is also no dispute that the FDA EUA does not address manufacturing processes or locations, which are addressed in the Comirnaty license. *See* August 23 Comirnaty SBRA at 12-13.

For the same reasons, the public record does not support any argument that the two admittedly "legally distinct" products are "interchangeable." "Interchangeable" and "interchangeability" are

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[25] *See* FDA, Summary Basis for Regulatory Action (Pfizer Vaccine), Nov. 8, 2011, available at: fda.gov/media/151733/download (last visited Dec. 27, 2021).

[26] *See Doe v. Austin*, 2021 WL 5816632, at *3 n.5. *Compare Summary Basis of Regulatory Action*, BLA 125742/0 at 9 (Aug. 23, 2021) ("August 23 Comirnaty SBRA") (listing 11 components, including .450 ml per vial of a redacted excipient) (this document has been scrubbed from the FDA website, but was filed as an exhibit in the *Doe v. Austin* and *Crosby v. Austin* proceedings and can be filed with the Court if the *amicus* motion is granted), *with* FDA BioNTech EUA Expansion Letter, *supra*, note 6 at 7 (listing 10 components, all of which also appear on the Comirnaty SBRA) and November 8 Comirnaty SBRA at 7-8 (listing 11 components, but removing .450 ml per vial of redacted excipient and replacing with unspecified amount of water as 11th component).

specifically defined terms in Section 351 of the Public Health Service Act ("PHS Act"), 42 U.S.C. § 262, in relation to a "reference product," which is a biological product licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a). For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product; in this case, the FDA-licensed Comirnaty Vaccine. But the "interchangeable" product, the EUA BioNTech Vaccine, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k), and there is no indication that any such application was ever filed by BioNTech, much less reviewed or approved by the FDA.

Any "interchangeability" determination would therefore reverse the temporal order of the COVID-19 licensed product and the interchangeable product. The reference product under 42 U.S.C. § 262(a) is the first licensed product, and therefore the basis for determining the interchangeability of the later product (*i.e.*, the generic or EUA product). Here, however, the EUA Pfizer-BioNTech Vaccine is the earlier product, while the licensed Comirnaty is the latter product; the earlier EUA product cannot rely on the FDA's safety and efficacy determinations for Comirnaty. Thus, an "interchangeability" determination would be a transparent attempt to retroactively license the earlier EUA Pfizer-BioNTech Vaccine, solely for the purpose of enabling the unlawful vaccine mandate.

Moreover, "FDA licensure does not retroactively apply to vials shipped before [FDA] approval." *Austin*, 2021 WL 5816632, at *6. Any EUA-labeled vaccines manufactured before licensure and "vaccines produced after August 23 in unapproved facilities—remain 'product[s] authorized for emergency use,'" *i.e.*, EUA

rather than licensed products. *Id*. In any case, such a post hoc interchangeability determination should not even be considered by the Court. "An agency must defend its actions based on the reasons it gave when it acted." *DHS v. Regents of the Univ. of Cal.*, 140 S.Ct. 1891, 1909 (2020).

CONCLUSION

This Court should stay the OSHA Mandate because the unavailability of Comirnaty precludes compliance. Congress has not clearly granted the agency the power to require private employers to mandate that their employees take an experimental vaccine.[27] Congress has not granted OSHA the authority to require State agencies to impose and police a mandate which cannot be satisfied through distribution of FDA-approved vaccines. No American can be compelled to suffer an injection of an experimental product.

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[27] See *Alabama Assn. of Realtors v. Department of Health and Human Services*, 594 U.S. __, 2021 U.S. LEXIS 3679, at *8 (Aug. 26, 2021) (per curiam) (Congress must "speak clearly when authorizing an agency to exercise vast powers of economic and political significance.")

Respectfully submitted,

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