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ISSUE BRIEF

Are COVID-19 Vaccine Mandates Requiring an Employee or Student to Receive an Unlicensed Emergency Use Product Legal?

This Issue Brief discusses whether mandates requiring an employee or student to receive an unlicensed, investigational Emergency Use Authorized product, such as the COVID-19 vaccine, is legal. This Issue Brief is provided for informational and educational purposes and does not constitute legal advice, nor does it establish an attorney/client relationship with anyone. For the reasons set forth below, mandating an unlicensed emergency use product is unprecedented, illegal, and unethical.

THE FDA HAS NOT LICENSED THE INVESTIGATIONAL EUA PRODUCT

The U.S. Food and Drug Administration ["**FDA**"] is the governmental agency responsible for regulating biological products (or biologics), such as vaccines. The FDA has not approved or licensed any COVID-19 vaccine. On the contrary, the FDA *authorizes* the use of only three investigational COVID-19 vaccines. These vaccines are currently in use under an emergency use authorization ["**EUA**"] and their use is governed by 21 U.S.C. § 360bbb–3. "The issuance of an EUA is different than an FDA approval (licensure) of a vaccine, in that a vaccine available under an EUA is not approved."[1]

In evaluating a product for an EUA, the FDA uses a lower evidentiary standard than it does when reviewing a product for full FDA licensure. An EUA only requires that the product "may be effective" in diagnosing, treating, or preventing a disease, and the FDA does not evaluate its "effectiveness" in doing so.[2] The FDA granted EUAs for the Pfizer/BioNTech,[3] Moderna,[4] and Janssen[5] vaccines; however, the clinical trials the FDA will rely upon to ultimately decide whether to license these vaccines as safe and effective are ongoing.[6] These ongoing clinical trials

[1] https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine

[2] https://www.fda.gov/media/97321/download (stating that "the 'may be effective' standard for EUAs provides for a lower level of evidence than the 'effectiveness' standard that FDA uses for product approvals." *See also*, https://www.fda.gov/media/144638/download ("Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product."); https://www.fda.gov/media/144414/download ("Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product"); and https://www.fda.gov/media/146305/download ("Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product).

[3] https://www.fda.gov/media/144412/download

[4] https://www.fda.gov/media/144636/download

[5] https://www.fda.gov/media/146303/download

[6] https://media.tghn.org/medialibrary/2020/11/C4591001_Clinical_Protocol_Nov2020_Pfizer_BioNTech.pdf

will collect data that the FDA will scrutinize to determine if these vaccines meet the safety and efficacy criteria necessary for a biologics license. Thus, it is currently unknown if these investigational, unlicensed vaccines will ever receive full FDA licensure.

Requiring an employee or student to take an investigational, unlicensed biologic is unprecedented. Unlike the investigational and unlicensed COVID-19 vaccines, all other vaccine mandates apply to vaccines that the FDA has fully licensed. The FDA has not licensed the COVID-19 vaccines but has authorized the vaccines using a lower safety and efficacy standard pursuant to temporary EUAs. Because the safety and efficacy of these investigational and unlicensed vaccines are not sufficiently established, 21 U.S.C. § 360bbb–3 requires that individuals have "the option to accept or refuse administration of the product . . . . "

FEDERAL STATUTORY AUTHORITY

An unlicensed, investigational EUA product mandate for an employee or student is **unprecedented**. The body of case law that governs vaccine mandates does not apply to unlicensed, investigational EUA products because these cases exclusively involve vaccines that have obtained full FDA licensure.

Moreover, a COVID-19 mandate that requires an individual to receive an investigational and unlicensed EUA product implicates 21 U.S.C. § 360bbb–3 [the "**EUA Statute**"]. The EUA statute requires that all individuals are entitled to informed consent, to the extent practicable given the applicable circumstances, regarding investigational and unlicensed EUA products. Specifically, section (e)(1)(A)(i) and (ii) states as follows:

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

> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. [7]

While it is clear that all individuals are entitled to informed consent regarding unlicensed EUA projects, to the extent practicable given the applicable circumstances, no court has interpreted this provision, including the term "consequences." This term is essential in the context of EUA product mandates. Does the term encompass health-related consequences of forgoing the investigational product? Or, does the term encompass any consequence of refusing the investigational product, such as loss of employment, unrestricted travel, public access, scholarship, student housing, etc.? If the answer is the latter, the law could be construed as providing an opportunity for mandating unlicensed EUA products. Thus, the legality of a COVID-19 mandate may pivot on how the term "consequences" is defined.[8] Because the law does not define this term, statutory interpretation principles require using the word's ordinary meaning within the statute's context.

This section of the EUA Statute details "conditions of authorization" for EUA products that the Secretary of Health and Human Services finds necessary or appropriate to protect public health. Subsections (i) and (ii) require that the Secretary create "appropriate conditions designed to ensure" that both healthcare professionals administering the EUA product and its recipients are adequately informed about the unlicensed EUA product; it focuses strictly on promoting informed medical consent for the product's administrators and recipients. For example, the "informed consent" provisions of subsection (ii) require that the recipient receive information about the unlicensed product, including its risks and benefits, known alternatives, and the option to refuse. Thus, sections (i) and (ii) only concern informed medical consent related to the unlicensed EUA product. The term "consequences" found in subsection (ii) is limited to the informed medical consent consequences of declining the unlicensed EUA product.[9] If this is true, the EUA Statute does not create the legal authority to mandate an unlicensed EUA product, including the COVID-19 vaccines.

This outcome makes good sense. If the term "consequences" found in subsection (ii)(III) is defined to include *any* consequence of declining unlicensed EUA products, then the EUA Statute requires every administrator of these products to inform every recipient of *all* consequences of refusing the product.[10] Depending on the facts and circumstances for each individual, it could include even those impermissible consequences of declining the unlicensed EUA product, such as loss of

[7] Emphasis added. Statute available at https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapV-partE-sec360bbb-3.pdf
[8] https://www.healthaffairs.org/do/10.1377/hblog20210212.410237/full/
[9] *See*, https://www.healthaffairs.org/do/10.1377/hblog20210212.410237/full/ (reaching a similar conclusion).
[10] *Id*.

employment, public access, unrestricted travel, scholarship, student housing, etc. It is unlikely that Congress would impose such a vast informed consent requirement upon healthcare workers who are administering unlicensed products available under an EUA.

Additionally, the FDA did not include the term "consequences" in any of its implementing documents. For example, the statutorily required "conditions of authorization" for the unlicensed EUA products are executed via the FDA's EUA letters. The FDA has issued an EUA letter for each COVID-19 vaccine that it has authorized for emergency use. As a condition of authorization, these letters require that fact sheets are provided to healthcare workers who administer the unlicensed EUA products and also to each recipient/caregiver of the product. While these required fact sheets cite the aforementioned informed medical consent provisions found in the statute, not one of the three fact sheets for "Recipients and Caregivers" mentions the "consequences" of declining the investigational EUA product.[11] Likewise, none of the "Fact Sheet for Healthcare Providers Administering Vaccine" documents (i.e., authorized labeling) issued for each authorized vaccine mention "consequences" for individuals who decline the unlicensed and investigational EUA product. For example, the Moderna document states that:

> [a]s the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) **prior to** the individual receiving each dose of the Moderna COVID-19 Vaccine, including:
>
> - FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
> - **The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine**.
> - The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
> - Information about available alternative vaccines and the risks and benefits of those alternatives.[12]

Thus, if the term "consequences" found at 360bbb-3 (e)(1)(A)(ii)(III) had meaning distinct from the rest of the section and was intended to grant public and private entities legal authority to mandate unlicensed EUA products, it is unlikely that the FDA's "authorizing conditions" found the in EUA letters and required fact sheets would have eliminated the language. Conversely, assuming the term "consequences" grants public and private entities the legal authority to mandate unlicensed EUA products, the Secretary omitted this language from the required "authorizing conditions" found in the EUA letters and its required fact sheets, which would indicate that it abrogated said authority.

[11] https://www.fda.gov/media/144638/download (Moderna)
[12] https://www.fda.gov/media/144637/download Emphasis added.

Moreover, 10 U.S. Code § 1107a adds clarity to the EUA Statute because it provides a specific exception to EUA products and allows the President to waive the statutory requirement of choice; however, this exception applies only to people in the armed forces and only in specific circumstances. The language of 10 U.S. Code § 1107a indicates that the EUA Statute requires choice and is "designed to ensure that individuals are informed of an option to accept or refuse administration of a product." This statute sets forth the only exception to the choice requirement for EUA products.[13]

Furthermore, the Congressional Record does not provide evidence that governmental or private entities have the legal authority to mandate unlicensed EUA products, including the investigational and unlicensed COVID-19 vaccines.[14] Finally, as two legal scholars astutely noted,

> if segment two of Section 360bbb-3(e)(1)(A)(ii)(III) opens the door to mandates, it would render meaningless the option stated in segment one. Under canons of statutory interpretation, one segment of statute should not be interpreted to obstruct another. Rather, provisions should be interpreted in a way that makes them compatible, not contradictory."[15]

For the preceding reasons, the term "consequences" found in the EUA Statute is limited to the informed medical consent consequences of forgoing an investigational and unlicensed EUA product. The EUA Statute signals that an individual is entitled to a choice regarding the administration of EUA products. Thus, the EUA Statute does not grant an employer or academic institution the authority to mandate or otherwise require an individual to receive the investigational and unlicensed COVID-19 vaccine. In fact, the EUA Statute forbids such a mandate.[16]

FEDERAL LAW EXCLUSIVELY GOVERNS EUA PRODUCTS

The doctrine of federal preemption invalidates and voids a COVID-19 mandate. The FDA anticipated that conflicts between federal and state law would arise regarding unlicensed EUA products. It has determined that the terms and conditions of an EUA product preempt state or local law imposing different or additional requirements on the medical product for which the EUA was issued.[17] The FDA further warns that:

> [i]n an emergency, it is critical that the conditions that are part of the EUA [] those that FDA has determined to be necessary or appropriate to protect the public health—be strictly followed, **and that no additional conditions be imposed.** To the extent there may be circumstances in which FDA would like people carrying out activities under an EUA to also comply with requirements contained in preempted state law, FDA anticipates

[13] 10 U.S.C. §1107a (available at https://www.law.cornell.edu/uscode/text/10/1107a)
[14] https://www.congress.gov/crec/2004/07/14/CREC-2004-07-14-pt1-PgH5721-3.pdf
[15] https://www.healthaffairs.org/do/10.1377/hblog20210212.410237/full/
[16] See also, *Doe v Rumsfeld*, 341 F Supp.2d 1 (DDC 2004) (holding that Congress has prohibited the administration of investigational drugs to service members without their consent).
[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#footnote2

incorporating such requirements into the terms and conditions of the EUA.[18]

The EUA letters dictating the conditions of authorization of the unlicensed EUA vaccines strictly prohibit any inconsistency with the authorized labeling of the vaccines (i.e., the fact sheet) and command that all printed matter, advertising, and promotional material relating to the use of the vaccines be consistent with the fact sheets, the terms outlined in the EUA letters, and federal statute.[19] The EUA letters also explicitly state that "[t]he emergency use of [the] COVID-19 Vaccine under this EUA must be consistent with, and **may not exceed** [] the Scope of Authorization" (the section of the EUA that requires the fact sheets).[20] A COVID-19 mandate is inconsistent with and may exceed the choice provision found in each of these federal materials.

Federal law may preempt a COVID-19 mandate because, for those who object to taking the investigational and unlicensed EUA product, compliance with both the EUA Statute and the vaccine mandate is impossible. Also, a COVID-19 mandate may pose a clear obstacle to the purpose of the EUA Statute that grants an individual the right to forgo an investigational and unlicensed EUA product. A COVID-19 mandate also imposes impermissible "additional conditions" not found within the EUA letters. Finally, the FDA exclusively occupies the field of biologics and how unlicensed and investigational biologics are governed and administered. A COVID-19 mandate possibly disregards the requirements found in the EUA Statute, the EUA letters, and the authorized labeling that an individual has the right to accept or refuse administration of the investigational and unlicensed vaccines.

Therefore, the EUA Statute and the doctrine of federal preemption may prevent any employer or academic institution from requiring that an individual receive an unlicensed EUA product. This prohibition may also include requiring individuals to receive the unlicensed and investigational EUA COVID-19 vaccines on penalty of losing employment, housing, the right to attend class in-person, scholarship, or under threat of other punitive action. [21]

THE FDA AND CDC HAVE DETERMINED THAT UNLICENSED EUA PRODUCTS ARE EXEMPT FROM MANDATES

The FDA, the governmental organization that regulates biologics and authorized the use of the investigational and unlicensed COVID-19 vaccines, has determined that EUA products cannot be mandated. As indicated previously, pursuant to the EUA Statute, the letters authorizing the unlicensed COVID-19 vaccines for emergency use set forth the terms and conditions of the products' authorization. Each of these authorizing letters requires that FDA-approved fact sheets are provided to vaccination providers and recipients. These fact sheets make clear that getting the vaccine is optional. For example, the Moderna fact sheet for recipients states that "[i]t is your choice to receive

[18] *Id*. (also stating that "the PREP Act, which expressly provides immunity from tort liability [] preempts state laws that are different from, or in conflict with, any requirement applicable to a covered countermeasure under the PREP Act and relating to, among other things, any matter applicable because of a requirement of the FD&C Act. This includes actions taken to meet the terms of an EUA . . . . ." Emphasis added.

[19] https://www.fda.gov/media/144636/download (Section III.D.)

[20] https://www.fda.gov/media/144636/download (Moderna). Emphasis added.

[21] *See generally*, *Lorillard Tobacco Co. v Reilly*, 533 US 525, 570-71 (2001) (overturning a state public health law because it was already the subject of a comprehensive federal scheme to manage public health).

or not receive the COVID-19 Vaccine." [22]

Likewise, the Centers for Disease Control and Prevention ["**CDC**"] has clearly stated that unlicensed EUA products cannot be mandated. In August 2020, at an Advisory Committee on Immunization Practices ["**ACIP**"] meeting, the committee's executive secretary and Chief Medical Officer of the National Center for Immunizations and Respiratory Diseases, Dr. Amanda Cohn "reminded everyone that under an EUA, vaccines are not allowed to be mandatory. Therefore, early in the vaccination phase individuals will have to be consented [*sic*] and cannot be mandated to be vaccinated."[23]

Accordingly, the two governmental agencies that exclusively govern biologics and disease control have indicated that investigational, unlicensed EUA products, such as the COVID-19 vaccines, cannot be mandated.

THE LONG-TERM SAFETY OF THE UNLICENSED AND INVESTIGATIONAL EUA VACCINES IS UNKNOWN

The EUA authorization process is not the same as the FDA approval process. Under an EUA, the FDA makes a product available to the public based on the best available evidence without waiting for all the evidence needed for FDA approval.[24] In evaluating a product for an EUA, the FDA uses a lower evidentiary standard than it does when reviewing a product for FDA licensure. While the FDA granted EUAs for the Pfizer/BioNTech, Moderna, and Janssen vaccines, these products' long-term safety and efficacy are not established. The FDA will rely upon the clinical trials to ultimately decide whether to license these vaccines as safe and effective; however, these ongoing trials are not likely to conclude until 2022-2023.

Therefore, data on the long-term safety and efficacy of the investigational, unlicensed EUA products do not exist. For example, the FDA authorized the emergency use of the Moderna vaccine on December 18, 2020. The fact sheet for healthcare providers (i.e., authorized labeling) for this product warns that "additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine."[25] Indeed, on April 1, 2021, the FDA amended Moderna's EUA letter and authorized labeling to include that "[s]evere allergic reactions, including anaphylaxis, have been reported following the administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials."[26] Before April 1, 2020, individuals who received this investigational, unlicensed EUA product were deprived of knowledge of its risk of severe allergic reaction. Likewise, the FDA authorized the Janssen vaccine on February 27, 2021. Forty-five days later, on April 13, 2021, the unlicensed, investigational EUA product was "paused" by the FDA and CDC due to severe adverse reactions.[27] Again, the individuals that received this unlicensed, investigational EUA product before April 13, 2021, were deprived of information

[22] https://www.fda.gov/media/144638/download
[23] https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf
[24] https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19#:~:text=The%20EUA%20process%20is%20different,to%20evaluate%20the%20available%20data
[25] https://www.fda.gov/media/144637/download
[26] https://www.fda.gov/media/147284/download
[27] https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine. ACIP voted to resume the use of the Janssen vaccine on 4/23/2021.

regarding these later identified severe adverse reactions.

Therefore, the FDA has made it clear that more adverse events are likely to be uncovered as more individuals take the investigational, unlicensed EUA product. In fact, the FDA routinely utilizes the Vaccine Adverse Event Reporting System ["**VAERS**"] to "identify safety issues that may only be detected following vaccination of a much larger and more diverse population."[28] As of the date of this Issue Brief, 95,532 adverse events have been reported to VAERS following COVID-19 vaccination, including 3,053 deaths, 1,899 life-threatening events, 6,260 hospitalizations, 12,330 emergency room visits, and 1,217 events associated with a permanent disability.[29]

It is unlikely that an employer or academic institution has the authority to deprive an individual of the right to decline an investigational and unlicensed EUA product because all severe reactions, including death, associated with the administration of the product may not be apparent until pharmacovigilance and surveillance data is scrutinized and the ongoing clinical trials have concluded.

A EUA PRODUCT MANDATE AND CONSTITUTIONAL RIGHTS

A COVID-19 mandate requiring an injection of an unlicensed and investigational EUA product may violate the affected individual's constitutional rights, including but not limited to the due process right to life and liberty under the 14th Amendment. Other rights may include an invasion of the zone of privacy and right to bodily integrity, which courts have held to emanate from various Bill of Rights amendments such as the first, fourth, fifth, and ninth amendments. The body of existing case law involving vaccine mandates is not applicable because (1) these cases exclusively involve vaccines that have received full FDA licensure, and (2) unlike these cases, a COVID-19 mandate requires injection of an unlicensed, investigational EUA product.

Furthermore, a governmental entity's interest in manding the investigational and unlicensed EUA products is not compelling, legitimate, or rationally-based; the vaccines only provide a limited benefit to the individual and do not convey a proven benefit to others. SARS-CoV-2 is the virus that causes the COVID-19 disease. The FDA has not authorized the vaccines to prevent transmission of the SARS-CoV-2 virus from the vaccinated individual to others. The investigational vaccines are only authorized to prevent COVID-19 disease in the recipient. The FDA explicitly states concerning all investigational COVID-19 vaccines that "data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person."[30] Moreover, the Review Memorandum for each authorized vaccine states that "[d]ata are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination" and that "[a]dditional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection."[31]

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[28] https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview
[29] https://wonder.cdc.gov/controller/saved/D8/D151F261
[30] *See* https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; and https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.
[31] Emphasis added. https://www.fda.gov/media/146338/download (Janssen);

CONCLUSION

Based on the above analysis, the federal law, EUA letters, authorized labeling, FDA, and CDC requires elevated deference to meaningful choice in the context of the COVID-19 vaccines because the EUA products are unlicensed and investigational. This elevated "choice" requirement does not exist in the presence of a mandate, coercion, or threatened punitive action.

Though the intention of a COVID-19 mandate is laudable, it is not legal. Requiring an individual to take an investigational, unlicensed biologic is unprecedented and is not supported by law, case law, or federal directives. Offering exemptions to a COVID-19 mandate does not cure the illegality of such a mandate. Receipt of an unlicensed and investigational EUA COVID-19 vaccine should remain a personal choice for the individual. If employers and educational institutions continue to mandate these unlicensed, investigational products, they will likely be forced to defend the mandate in court. Ultimately, the courts will decide if COVID-19 vaccine mandates are legal and enforceable.

https://www.fda.gov/media/144416/download (Pfizer); and https://www.fda.gov/media/144673/download (Moderna).