IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSE and AMY MILLER, Plaintiffs, v. FOOD and DRUG ADMINISTRATION, and JANET WOODCOCK, Acting Commissioner of Food and Drug Administration, Defendants.	)	**Case No. 1:21-cv-00200** **Date:** _____ **Time:** _____ **Dept:** _____

PLAINTIFFS' MOTION TO STAY THE FOOD and DRUG ADMINISTRATION'S BIOLOGIC LICENSE FOR THE PFIZER COMIRNATY COVID-19 VACCINE [5 U.S.C. §705]

[*Ex Parte* Application and Declaration of Robert E. Barnes, Esq. filed concurrently]

TO THE HONORABLE JUDGE OF THE COURT:

COME NOW Plaintiffs Children's Health Defense and Amy Miller to ask this Court to grant a motion to stay the U.S. Food and Drug Administration's ("FDA") licensure of the Pfizer Comirnaty vaccine while the emergency use authorization ("EUA") for the Pfizer-BioNTech COVID-19 mRNA vaccine remains in force for the same target population for the medical indication, i.e., prevention of COVID-19 in those 16 years of age and up.

WHEREFORE, in light of the foregoing reasons, Plaintiffs respectfully request this Court grant a stay of the FDA's biologic license for the Pfizer Comirnaty vaccine while any EUA still exists for this same indication pending judicial review of Plaintiffs' complaint.

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Dated: September 9, 2021

Respectfully submitted,

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FOR THE EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSE, and AMY MILLER,	)
Plaintiffs,	)
v.	)
FOOD and DRUG ADMINISTRATION, and JANET WOODCOCK, Acting Commissioner	)
Defendants.	)

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO STAY THE FOOD and DRUG ADMINISTRATION'S BIOLOGIC LICENSE FOR THE PFIZER COMIRNATY COVID-19 VACCINE

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INTRODUCTION

This case arises out of a May 16, 2021 Citizen Petition from Children's Health Defense (CHD) to the Food and Drug Administration (FDA). CHD raised basic questions before FDA licensure of any COVID-19 vaccine. Instead of adequately addressing CHD's concerns, the FDA issued a license for the Pfizer Comirnaty vaccine on August 23, 2021, the same day it finally responded to CHD. Using an opaque licensing process that excluded even the FDA's own vaccine advisory committee as well as the public, Defendants chose to mislead the American people by licensing the largely unavailable Pfizer Comirnaty vaccine while retaining existing Pfizer Emergency Use Authorization (EUA) vaccines for the same indication on the market, in violation of federal law.

The law requires FDA to make a simple choice: license a COVID-19 vaccine and revoke the existing EUA for the same vaccine and indication, or delay licensure until the product is actually available. Important consequences flow from FDA licensure: a fully licensed vaccine has the FDA's imprimatur of "safety and efficacy," including assurances of good manufacturing and marketing practices, which make the vaccine more readily subject to mandate, while typically removing the blanket liability protection that EUA vaccines enjoy. By contrast to licensed vaccines, EUA products only "may be effective" under federal law, are exempt from certain manufacturing and marketing standards, enjoy blanket liability protection, and cannot be mandated under the plain language of federal law.

Instead of an honest approach, the FDA chose a bait-and-switch fraud on one of the most important issues of the day. The FDA told the world it had licensed the Pfizer COVID-19 vaccine, but, the vaccine it licensed – Pfizer's Comirnaty vaccine -- is largely unavailable. Many employers, including the military, have mandated individuals to take this "fully FDA-licensed"

Comirnaty vaccine. But the FDA "licensed" a vaccine that is not the one being mandated. The FDA is unlawfully extending the EUA for the Pfizer-BioNTech vaccine for the same 16 and up target group under the guise that the vaccine being offered is "fully FDA approved."

Pfizer's Comirnaty mRNA vaccine received full FDA approval with fine print and footnotes admitting that the supply is insufficient. Specifically, footnote 9 of the FDA approval letter states: "there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA." Concurrently, the FDA granted an updated EUA to the widely distributed and "interchangeable" Pfizer-BioNTech mRNA vaccine, noting there was a "significant amount" available.

Since the FDA violated federal law when it again granted the EUA for the Pfizer-BioNTech product for those aged 16 and up for first and second doses, this Court should stay FDA's biologic license for the Pfizer Comirnaty vaccine until Pfizer can make sufficient doses available of the licensed product. The FDA's bait-and-switch operation is illegal and should be stopped.

FACTS

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.[1] Suffice it to say, FDA approval for a typical vaccine is often lengthy and complex. Generally, it takes five to ten years, at minimum, to develop a vaccine, from inception to administration to the public.[2] Several years are dedicated to

[1] *See*, CDC, *Vaccine Testing and the Approval Process* (May 1, 2014), available at https://bit.ly/3rGkG2s (last visited August 26, 2021).
[2] *Vaccine Research and Development,* Johns Hopkins University, available at https://coronavirus.jhu.edu/vaccines/timeline.

performing adequate tests and clinical trials to ensure the safety and efficacy of a vaccine prior to FDA licensure.

In contrast to this six-step approval process, Congress vested the Health and Human Services Secretary ("Secretary") with the power to "authorize the introduction into interstate commerce, during the effective period of a declaration of emergency…a drug, device, or biological product intended for use in an actual or potential emergency. . ." 21 U.S.C. § 360bbb-3(a)(1) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"). Under this statute, the FDA may grant emergency use authorization for a vaccine not yet approved or licensed for use under the typical regulatory regime. When there are no FDA-licensed, available alternatives, and other important criteria are met, FDA can make vaccines available under an emergency access mechanism called "Emergency Use Authorization" (EUA).[3]

EUAs allow the FDA to make a product available to the public quickly based on the best available data, without waiting for all the evidence needed for licensure.[4] The important distinction is between "authorization" for an EUA vaccine and "licensure" for an "approved vaccine." While in other legal contexts, "authorized," "approved," and "licensed" may be used synonymously, that is not the case here. There is a world of difference between what the FDA "authorizes," which "may be effective," and what the FDA "licenses," where the FDA has vetted the manufacturers' clinical trial data and has determined that the vaccine IS "safe and effective."[5]

EUAs are used in times of emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current

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[3] *See generally*, FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), available at bit.ly/3x8wImn (last visited August 26, 2021).
[4] See, *FDA, Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), available at bit.ly/3x8wImn (last visited August 29, 2021).
[5] 21 U.S.C. § 360bbb-3.

COVID-19 pandemic."[6] Thus, the goal of the EUA process is to cut the red tape, providing a stopgap measure until a product, drug, vaccine, or device receives full FDA licensure.

Criteria for Emergency Use Authorization

First, when issuing an EUA under Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, the Secretary ("Secretary") of Health and Human Services (HHS) must first declare that circumstances exist to justify the emergency use of experimental products.[7] On or about February 4, 2020, the Secretary determined COVID-19 presented a public health emergency.[8] Furthermore, on or about March 27, 2020, the Secretary determined that circumstances existed to justify the authorization of emergency use of drugs and biological products.[9]

Second, after the Secretary declares that circumstances exist to justify the emergency use of experimental products, the Secretary must then make several additional determinations before any product, device, vaccine or drug can be authorized for emergency use.

21 U.S.C. § 360bbb-3(c)(1)-(3) lays out three additional criteria required to grant emergency use authorization for a product. At issue here is the third criterion, which requires the Secretary to conclude "*that there is no adequate, approved, and available alternative* to the product for diagnosing, preventing, or treating such disease or condition..."[10]

The Defendants' Bait and Switch

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[6] FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), available at bit.ly/3x8wImn (last visited August 26, 2021).
[7] 21 U.S.C. § 360bbb-3; 85 FR 18250; *See also*, CDC, *Fact Sheet for Patients, Centers for Disease Control and Prevention*, (July 21, 2021), available at https://www.fda.gov/media/144414/download (last visited Sept. 4, 2021).
[8] 85 FR 18250, available at https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06905.pdf (last visited Sept. 4, 2021).
[9] *Id*.
[10] 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

The definition of an unlawful bait-and-switch scheme is an insincere offer to sell one item to induce a buyer to purchase another.[11] That is precisely what the FDA has done, although admittedly in a novel context.

The Pfizer-BioNTech COVID-19 vaccine was first authorized for emergency use by the FDA on December 11, 2020, pursuant to 21 U.S.C. § 360bbb, for individuals 16 years of age and older, and later for individuals 12-15 years of age, and later still as a third dose for highly immunocompromised individuals.

The FDA subsequently reauthorized Pfizer-BioNTech COVID-19 vaccine for emergency use on August 23, 2021.[12] The letter of authorization from August 23, 2021 reads in part:[13]

> "[F]DA 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 a section outlining the criteria of re-issuance from the August 23, 2021 letter, the Secretary contorts 21 U.S.C. § 360bbb-3(c)(3) to mean something it does not. Buried in the fine print of a footnote, the Secretary writes: "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."[14]

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[11] David Adam Friedman, Explaining "Bait-and-Switch" Regulation, 4 Wm. & Mary Bus. L. Rev. 575 (2013), https://scholarship.law.wm.edu/wmblr/vol4/iss2/6.
[12] FDA, *Pfizer-BioNTech COVID-19 Vaccine EUA LOA Reissued*, (Aug. 23, 2021) available at https://www.fda.gov/media/150386/download last visited on (Aug. 28, 2021).
[13] *Id*.
[14] *See* Ftn. 9 (emphasis added).

The same day the FDA reauthorized the EUA for the Pfizer-BioNTech COVID-19 vaccine, the agency also granted the biologic license application (BLA) for the Pfizer Comirnaty vaccine to prevent COVID-19 in individuals 16 years of age and older for first and second doses.[15]

The fact sheet provided by the FDA on August 23, 2021 for healthcare providers administering the EUA-Pfizer-BioNTech vaccine reads:[16]

> 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.* (emphasis added).

But, in the fine print of footnote 1 on the fact sheet for healthcare providers, the FDA admits that the two vaccines are "*legally distinct"* from one another.[17] Similarly, the FDA acknowledges the EUA Pfizer-BioNTech vaccine is "[l]egally distinct" from the FDA-approved Comirnaty vaccine in the agency's approval letter to Pfizer dated August 23, 2021.[18] In sum, on the same day the FDA granted *full approval and licensure* to the Pfizer Comirnaty vaccine, it also reissued an EUA for the Pfizer-BioNTech COVID-19 vaccine for the same indication, i.e. for prevention of COVID-19 in individuals 16 and up. In doing so, FDA violated federal law, 21 U.S.C. § 360bbb-3(c)(3), by authorizing continuing use of the Pfizer-BioNTech COVID-19 vaccine when an identical vaccine, Pfizer's Comirnaty vaccine, was fully licensed. FDA is

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[15] FDA, *FDA Approval Letter to Pfizer,* (August 23, 2021) available at https://www.fda.gov/media/150386/download (last visited Sept. 4, 2021).
[16] FDA, *Fact Sheet for Healthcare Provider Administering Vaccine (Vaccination Providers)*, (Aug. 23, 2021) available at https://www.fda.gov/media/144413/download (last visited Aug. 26, 2021).
[17] https://www.fda.gov/media/144413/download
[18] FDA, *Pfizer-BioNTech COVID-19 Vaccine EUA LOA Reissued*, (Aug. 23, 2021) available at https://www.fda.gov/media/150386/download (last visited on Aug. 28, 2021).

mangling federal law to suggest that insufficient supply to distribute to the population in its entirety is the basis for concurrent licensure and EUA – the FDA has made a bridge too far.

Either Pfizer's vaccine for people 16 and up is licensed or it's EUA – it can't be both simultaneously under federal law. Either it's available or it's not available – it can't be "approved" and "not approved" and "available" and "not available" all at the same time -- which is what the FDA has green-lighted, enabling Pfizer's bait-and-switch that the vaccines are all "interchangeable" and thus "approved and licensed."

Liability Shield

All EUA COVID-19 vaccines enjoy an extraordinary liability shield under the 2005 Public Readiness and Emergency Preparedness Act ("PREP Act"). Vaccine manufacturers, distributors, providers, and government planners are immune from any realistic liability. The only way an injured party can sue is if he or she can prove willful misconduct by clear and convincing evidence after having exhausted all administrative remedies, from which there would otherwise be no right of judicial appeal.[19]

No such lawsuit for willful misconduct against an EUA product manufacturer or purveyor has ever succeeded. Courts characterize PREP Act immunity as "sweeping."[20] It applies to all types of legal claims under state and federal law. *Id*. In short, the COVID-19 EUA vaccines enjoy an almost unimaginable liability shield under the PREP Act.

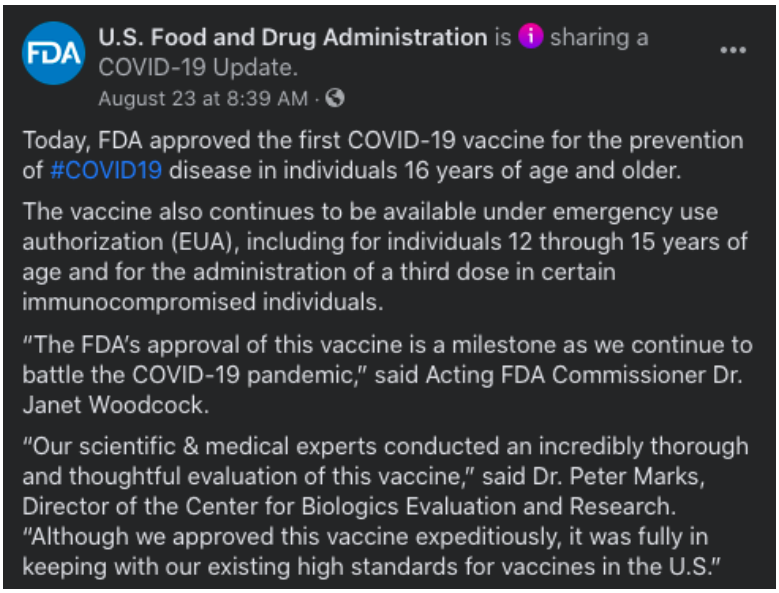
[19] 42 U.S.C.S. § 247d-6d (LexisNexis 2021)

[20] *See*, Congressional Research Service, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures*, (March 19, 2021) available at https://crsreports.congress.gov/product/pdf/LSB/LSB10443#:~:text=To%20encourage%20the%20expeditious%20development,to%20the%20administration%20of%20medical (last visited Aug. 26, 2021).

On March 10, 2020, the Secretary invoked the PREP Act and determined that COVID-19 constitutes a public health emergency.[21] As a result, Pfizer, Moderna, and Johnson & Johnson, the leading COVID-19 vaccine manufacturers in the United States, enjoy blanket liability protection from liability for severe adverse effects and harms, including permanent disabilities and death, resulting from COVID-19 EUA vaccines.

Defendants willfully failed to follow the statutory scheme outlined in 21 U.S.C. § 360bbb-3(c) when the FDA reauthorized the Pfizer-BioNTech COVID-19 vaccine for emergency use while misleading the public into believing that a fully licensed vaccine, the Comirnaty vaccine, was widely available in the U.S. The FDA Acting Commissioner Woodcock, the FDA and other U.S. government officials willfully misled the American public, including members of the military, by conflating the two vaccines and falsely claiming that the Pfizer COVID-19 vaccine currently available, i.e. the Pfizer-BioNTech vaccine, is fully FDA-approved (see examples below).[22]

[21] *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures.*
[22] U.S. Food and Drug Administration, (@FDA) *FDA Approves First COVID Vaccine*, (Aug. 23, 2021) available at https://www.facebook.com/FDA/posts/10159678210002299 (last visited Sept. 5, 2021).



Note that the FDA's Facebook post fails to note that the Pfizer EUA vaccine is available for those 16 and up, the same indication as the Comirnaty vaccine. The post just notes the different, appropriate EUA indications -- for individuals 12 through 15 years and for booster shots. FDA deceptively neglected to note the Comirnaty vaccine for precisely the same indication as exists for the Pfizer-BioNTech vaccine, i.e. administration in those 16 and up. This Facebook post exemplifies FDA's marketing a licensed product to push the EUA version.

COVID-19 Vaccination Mandates Following FDA "Licensure"

After the misleading advertisements and press statements by Defendants on and after August 23, 2021, the military and others have mandated vaccination with the "FDA approved vaccine." As a result, vast numbers of Americans, including hundreds of thousands of military service members, are currently being misled into receiving the Pfizer-BioNTech COVID-19 EUA vaccine while believing they are receiving the fully licensed, FDA-approved Comirnaty vaccine. If injured by the Pfizer-BioNTech COVID-19 vaccines, individuals are unlikely to ever be made whole financially, let alone physically. Without a stay, Plaintiffs and those similarly situated will be harmed by the FDA's unlawful bait-and-switch.

LEGAL STANDARD

When deciding whether to grant a stay, courts typically consider four factors:[23] whether Plaintiffs have shown:

(1) the likelihood of success on the merits,

(2) the likelihood of irreparable harm to them in the absence of a stay,

(3) that the balance of equities weighs in plaintiffs' favor, and

(4) that a stay is in the public interest.

While authority is split regarding how to weigh certain factors or whether to use a sliding scale, in either case the "third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party."[24]

The Administrative Procedures Act's (APA) stay provision allows courts to grant a stay on the proceedings in cases properly arising out of the APA. 5 U.S.C. § 705 provides that:

> When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to *prevent irreparable injury*, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, *may issue all necessary and appropriate process* to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings. (emphasis added).

The APA defines agency action as a "rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[25]

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[23] *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 25 (2008).
[24] *Nken v. Holder,* 556 U.S. 410, 420 (2009); See, e.g., *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 51 (2008) (Ginsburg, J., dissenting); Eric J. Murdock & Andrew J. Turner, *How "Extraordinary" Is Injunctive Relief in Environmental Litigation?* A Practitioner's Perspective, 42 ENVTL. L. REP. NEWS & ANALYSIS 10464 (2012).
[25] 5 U.S.C. § 551(13).

In *Sampson v. Murray*, 415 U.S. 61 (1974), the Supreme Court relied on the APA's legislative history to observe that § 705 was intended to codify the existing power of federal courts to issue a stay.[26] While both stays and preliminary injunctions are temporary remedies, stays are different from preliminary injunctions in one important way: preliminary injunctions act on the person while stays act on the proceeding.[27]

Under APA § 705, the Court is obliged, in the interest of justice and to prevent irreparable injury, to stay the biologic license that the FDA unlawfully granted to Pfizer's Comirnaty vaccine while it simultaneously authorized Pfizer to retain an EUA for the identical product with the same indication.

ARGUMENT AND AUTHORITIES

1. Petition to Review FDA's Grant of a Biologic License to Pfizer's Comirnaty Vaccine is Likely to Succeed on the Merits

"The first factor, a strong showing of a likelihood of success on the merits, requires more than a mere possibility that relief will be granted."[28]

The FDA's Licensure of Pfizer's Comirnaty Vaccine is Arbitrary and Capricious under APA 5 U.S.C. § 706(2)(A)

The Administrative Procedures Act (APA) protects the public from arbitrary and capricious executive branch action by imposing the rule of reason and the rule of law through judicial oversight. An agency is "required to engage in reasoned decision making."[29] This requires that the agency "articulate a satisfactory explanation for its action."[30] This process

[26] *Id*. at 68 n.15 (citing S. REP. NO. 752, at 230 (1945)) (citing S. REP. NO. 752, at 230 (1945)).
[27] *Nken v. Holder*, 556 U.S. 418, 432–33. (2009).
[28] *Id.* at 420.
[29] *Michigan v. EPA*, 576 U.S. 743, 750 (2015).
[30] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

requires Defendants to articulate clear rationales for decisions, especially when their actions are bound to lead to medical mandates with severe consequences for millions of people.[31]

Defendants' action to license Pfizer's Comirnaty vaccine has misled the public to believe that the vaccine being mandated is fully FDA-approved when in fact it is actually Pfizer's EUA product. The FDA unlawfully, arbitrarily and capriciously allowed Pfizer to represent its Comirnaty vaccine as licensed and available while selling off its inventory of EUA vaccines with blanket liability protection. Pfizer represents that its Comirnaty vaccine also has blanket liability protection under the PREP Act. Defendants' actions are arbitrary and capricious.

Plaintiffs have made a strong showing of the likelihood of success on the merits.

2. **Plaintiffs Will Suffer Irreparable Harm Absent a Stay**

The FDA grant of a biologic license for Pfizer's Comirnaty vaccine, while reissuing the EUA for the Pfizer-BioNTech vaccine, has created the false impression that the vaccines being administered routinely are fully FDA-licensed. While the FDA license approved [Pfizer] to manufacture COVID-19 vaccine[32] for distribution to individuals 16 and older, the FDA simultaneously renewed the EUA for the Pfizer-BioNTech COVID-19 vaccine for its previously authorized indication and use, in addition to new indications. The renewed Letter of Authorization for the EUA stated that "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 at the time of reissuance of this EUA."[33] Therefore, most Pfizer vaccines on the market are unlicensed and actually EUA.

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[31] *Burlington Truck Lines v. United States*, 371 U.S. 156, 158 (1962).
[32] BLA Approval Letter, https://www.fda.gov/media/151710/download, p. 1.
[33] Letter of EUA Authorization (Reissued), https://www.fda.gov/media/150386/download, p. 5.

The plain text of 21 U.S.C. § 360bbb-3(c)(3) is clear: the Secretary must conclude "*that there is no adequate, approved, and available alternative to the product* for diagnosing, preventing, or treating such disease or condition...." (emphasis added). The law states three criteria: (1) adequate, (2) approved, and (3) available for the alternative that must exist to enable an EUA. These are concurrent conditions, not disjunctive conditions. These are "and" factors, not "or" factors. The licensed product must be adequate, approved, AND available as the alternative to the EUA. If the licensed product does not constitute that alternative – if it is not adequate, approved, and available, then it should not preempt the EUA product. The EUA should continue until such time as the licensed product is adequate, approved, and available. The distinction between a licensed product and an EUA product should be a bright line – not the blur that the FDA has made of it.

The FDA's cynical wordplay regarding a COVID vaccine license set off a firestorm, misleading institutions, including the U.S. military, to coerce unlicensed, experimental mRNA vaccines on service members and employees. The FDA has allowed Pfizer, federal agencies, and states to falsely boast of "safety and efficacy," to Plaintiffs' detriment. In mandating COVID-19 vaccines for all enlisted service members, the military has relied on FDA's assurance of licensure.

On August 24, 2021, Secretary of Defense Austin issued guidance for mandatory COVID-19 vaccination and "direct[ed] the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated

against COVID-19."[34] The memorandum went on to state that "mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA)."[35] Secretaries of the Military Departments were ordered to implement "ambitious timelines" for enforcement.[36]

Under the Department of Defense's own guidance, however, it cannot mandate COVID-19 vaccines while the available product is unlicensed. Yet the military services have already attempted to force servicemembers to receive EUA vaccines in lieu of licensed ones. If Plaintiffs were to receive a vaccine now, they would almost certainly receive an EUA product, to which they have a legal right to refuse.

Under federal law, individuals to whom an EUA product is administered must be informed "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) Federal precedent establishes that military service members have an absolute right to refuse EUA vaccines without punishment.[37] Plaintiff Children's Health Defense is bringing this suit on behalf of its members, including military members, who may suffer irreparable harm if they are subject to vaccine mandates resulting from deceitful, factual misrepresentations.

The unwanted effects of an experimental mRNA COVID-19 vaccine are irreversible in some individuals; there is significant potential for harm if individuals are forced to receive a

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[34]https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF
[35] *Id.*
[36] *Id.*
[37] *Doe #1 v. Rumsfeld*, 297 F.Supp.2d 119 (2003). ("...the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Id*. at 135)

vaccine with virtually no liability when they mistakenly believe that they are receiving an FDA-licensed product for which there is some legal recourse. At this time, even though the available vaccines are overwhelmingly EUA, individuals are being told that they will suffer significant harm to their careers, education, and civil liberties if they refuse. Military members have been threatened with severe consequences for refusal. See Declaration of Pam Long, Exh. 01.

FDA's deceitful actions risk irreparable injury to millions of Americans, duped into believing they are receiving a vaccine with certain legal protections when in fact they have no real legal protection because of Defendants' bait-and-switch.

3. The Issuance of a Stay Will Not Substantially Injure Others and Furthers the Public Interest

"The third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party."[38] Here, the FDA, acting in its capacity as a federal agency within the Department of Health and Human Services, has executed government action. Therefore, courts merge consideration of agency harm into the public interest analysis.

Generally, when looking at the effect an action may have on the public interest, courts consider not only the law but also ethics. According to the American Medical Association, under the Code of Medical Ethics, it is a patient's right to be able to give informed consent to her physician when considering medical care or treatment.[39] Informed consent fosters trust and support in the doctor-patient relationship. It is in the public interest that those seeking vaccines receive accurate, truthful, complete information, and that they give informed consent or informed refusal. To be able to give informed consent, the patient must be able to understand: (1) the

[38] *Nken v. Holder* at 420 (2009).
[39] *Code of Medical Ethics Opinion 2.1.1*, ama-assn.org (September 5, 2021) https://www.ama-assn.org/delivering-care/ethics/informed-consent

relevant medical information and the implications of treatment alternatives for an independent, voluntary decision; (2) the burdens, risks, and expected benefits of all options, including alternative treatments; and (3) the documentation the healthcare workers provide. The first requirement is most relevant here.

The FDA's action of misleading Plaintiffs has created the illusion that a licensed COVID-19 vaccine exists that they can receive. The reality is that the FDA is purposefully conflating the two Pfizer vaccines in the examples shown above.[40] The FDA has permitted Pfizer to claim to the world that some of its EUA vaccines are considered "BLA-approved." See below and Exh. 02.

August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

COMIRNATY®
(COVID-19 Vaccine, mRNA)

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

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

Pfizer

2021TA035 v1.0

[40] U.S. Food and Drug Administration, (@FDA) *FDA Approves First COVID Vaccine*, (Aug. 23, 2021) available at https://www.facebook.com/FDA/posts/10159678210002299 (last visited Sept. 5, 2021).

The Pfizer vaccines are either EUA or they are licensed; the FDA has unlawfully permitted Pfizer to completely blur this line and to literally call EUA vaccines licensed vaccines.

Millions of Americans, including soldiers, now face vaccine mandates based on this FDA deception. Deceiving people about a product that carries risks that include injury and death is unconscionable. Undoubtedly such deception erodes public confidence in public health generally.

The public is served by protecting the right to informed consent, especially to emergency use products, as the law is absolute in its requirement that EUA products only exist when "*there is no adequate, approved, and available alternative* to the product for diagnosing, preventing, or treating such disease or condition..." 21 U.S.C. § 360bbb-3(c)(3) (emphasis added). [41]

By granting a stay on the FDA's biologic license to Pfizer for the Comirnaty vaccine until it is actually available, the Court would end the FDA's bait-and-switch and require that it follow the law. Such a stay would mean that Defendants have to be honest with the American public. Particularly in the midst of a pandemic, the American people deserve no less.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' Motion for Stay and direct the FDA to suspend its license for Pfizer's Comirnaty vaccine while any Emergency Use Authorization still exists for the same product for the same indication, pending judicial review of Plaintiffs' complaint.

Dated: September 9, 2021

Respectfully submitted,

__/s/ Derek Jordan_____

[41] 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

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Counsel for Plaintiffs CHILDREN'S HEALTH DEFENSE and AMY MILLER

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSEE and AMY MILLER,	)
Plaintiffs,	)
v.	)
FOOD & DRUG ADMINISTRATION, and JANET WOODCOCK, Acting Commissioner of Food and Drug Administration,	)
Defendants.	)

PLAINTIFFS' MOTION FOR STAY OF THE FOOD & DRUG ADMINISTRATION'S BIOLOGIC LICENSE FOR PFIZER'S COMIRNATY COVID-19 VACCINE

Declaration of Pam Long
In Support of Children's Health Defense and Amy Miller

I, Pam Long, declare:

1. I am over 18 years of age and am competent to testify in this matter.
2. All of the statements made in this declaration are true to the best of my own personal knowledge.
3. I am Pam Long, and I make this declaration in support of Children's Health Defense's and Amy Miller's motion for stay of the FDA biologic license for Pfizer's Comirnaty COVID-19 vaccine. I am a graduate of the U.S. Military Academy at West Point and a former Army officer. I was commissioned in 1997 and served as a Medical Service Corps officer up to the rank of Captain. I served among Army medics as a Commander of HHD, 36th Medical Evacuation Battalion. I currently live in Colorado as a veteran and civilian.
4. I am the military health writer for the Children's Health Defense online newspaper *The Defender*. I have an active network of 18,000 people on social media who have shared concerns about the military vaccine mandate of the Emergency Use Authorized (EUA) COVID vaccines.
5. I verify all messages to me about vaccine coercion in the military with two other sources who also lead health organizations with over 20,000 supporters each. All of the following reports have been verified as happening to more than one person, at more than one duty location. I also communicate directly with spouses of active duty personnel and parents of cadets.
6. Vaccine coercion to take EUA vaccines, being called licensed vaccines, is happening across all branches, all ranks, both active and reserve units, and at military academies. Some of these policies have been documented in written memoranda by the chain of command.
7. **Basic needs.** Unvaccinated Service Members (SM) have been denied access to dining facilities and gyms. This includes reports from deployed soldiers in Baghdad who are denied access to all Morale, Welfare, and Recreation (MWR) facilities including the Post Exchange, without access to other venues to purchase toiletries, and forced to conduct Physical Training in 100+ degree heat outside while wearing a mask.
8. **Promotion.** Unvaccinated SM have been removed from leadership positions, denied Temporary Duty Station (TDY) and Permanent Change of Station (PCS) travel, denied schools for promotion, and told they are flagged as non-deployable. A non-deployable status for 12 months can result in separation.
9. **Leave.** Unvaccinated SM have been ordered to forfeit their two-week leave with families prior to deployment to live in quarantine facilities, even with negative Polymerase Chain Reaction (PCR) tests.

10. **Solitary Confinement of Sailors.** Unvaccinated SM on ships have been denied common port calls to leave the ship for up to the duration of the 8-12 month deployment and some SM have been placed in solitary confinement with meals brought to their confined space.
11. **Physical and Emotional Coercion.** SM report being ordered to stand in the sun at attention for hours until they consent to the vaccine. SM report a requirement to write a 1500 word essay explaining their refusal to be approved by the chain of command before they can leave for a long weekend.
12. **Pregnancy.** Pregnant and breastfeeding SM have been told they are required to take the experimental drug or face punishment or separation, while exemptions for pregnant SM are common with other vaccines. Similar coercion has been applied to SM in childbearing years expressing concerns about unknown fertility risk and developmental harm to a future child at conception.
13. **Cadets.** USMA required the unvaccinated cadets to wear masks at graduation in May 2021. USMA relocated all unvaccinated cadets for summer training out of barracks with their platoons with latrines and fans to live in a co-ed tent exceeding capacity with a portable latrine nearby. USMA segregated all unvaccinated athletes from eating and traveling with their teams and then removed unvaccinated athletes from collegiate sports teams.
14. **Junior Enlisted.** One unvaccinated SM reported that he was ordered to say into a recorded phone conversation with the installation commander that he was not being coerced to take the vaccine, promised he would be approved for a school if he took the vaccine, and when he complied and took the vaccine, he was denied approval for the school.
15. **Junior Officers.** After the FDA announcement of Comirnaty licensure and the Secretary of Defense's announcement of a mandate, a junior officer was ordered to a clinic to get the vaccine. He verified with the medical staff that the vial offered to him was Pfizer BioNTech, not Comirnaty, and that he was fully within his rights to decline a voluntary EUA drug. He left the clinic unvaccinated.
16. **Senior Officers.** I personally know an officer in the rank of lieutenant colonel who is promotable to brigadier general with 20+ years of service who will retire rather than advance if the vaccine is mandated.

17. **Pilots.** Unvaccinated pilots report being administratively grounded and sent home from training, even with a demonstrated higher risk of blood clots associated with the experimental COVID vaccines.
18. **Families.** Families of unvaccinated SM and cadets have been denied attendance at graduations and special events. Some events require the civilian family members to also be vaccinated to attend.
19. **Civilian Spouses and Children.** SM report their orders for Permanent Change of Station (PCS) now include a mandate for the SM, spouse, and children to be vaccinated to move to a new location.
20. **Religious Accommodations.** SM report chain of command unwilling to process Religious Accommodation paperwork to exempt from COVID vaccine with objectional ingredients and threatening to separate SM as alleged "religious extremists."

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct. I executed this declaration on September 7, 2021.

Pam Long

EXHIBIT 2

August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

COMIRNATY®
(COVID-19 Vaccine, mRNA)

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

Manufactured by
Pfizer Inc.
New York, NY 10017

US License No. 2229

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

Pfizer

2021TA035 v1.0

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSE, et al, Plaintiffs, v. FOOD & DRUG ADMINISTRATION, et al. Defendants.	Case No.: 1:21-cv-00200 **CERTIFICATE OF SERVICE**

IT IS HEREBY CERTIFIED THAT:

I, Robert Holzinger, am a citizen of the United States and am at least 18 years of age. My business address is 700 South Flower Street, Suite 1000, Los Angeles, California 90017.

I am not a party to the above titled action. I have caused service of "**Plaintiffs' Motion To Stay The Food and Drug Administration's Biologic License For the Pfizer Comirnaty COVID-19 Vaccine [5 U.S.C. § 705]**" on the following party(ies) by filing with the Clerk of the Court using the CM/ECF system, and that a courtesy copy was forwarded by mail to the following defendant parties:

Food & Drug Administration
c/o U.S. Attorney's Office
1110 Market Street, Suite 515
Chattanooga, TN 37402

Food & Drug Administration
c/o U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Janet Woodcock,
acting commissioner of Food & Drugs
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

I declare under penalty of perjury that the foregoing is true and correct. Executed on September 9, 2021.

/s/ Robert Holzinger