

Testimony of Meryl Nass, MD before the Health and Human Services Committee  
January 11, 2022

Honorable Chairpersons, Members and Senators,

I write in support of LD 867. There are many reasons why preventing COVID vaccine mandates until adequate, sufficient safety studies have been performed is the right decision for this committee and legislature.

**1. COVID vaccines are experimental**

Let me say, first, that no matter what claims have been made regarding these vaccines, they are not "safe and effective." "Safe and effective" is an FDA 'term of art'<sup>1</sup> that may only be applied to licensed drugs and vaccines. All currently available COVID vaccines in the United States are unlicensed and experimental, a.k.a. investigational.

Medicines and vaccines are *either* licensed products or experimental products. There is no gray area between them in US law. Whether or not research is explicitly conducted, the use of experimental products (including those issued under an Emergency Use Authorization) falls under the Nuremberg Code and under US law regulating experimental drugs. As former FDA Commissioner Stephen Hahn himself noted, "*EUA products are still considered investigational.*"<sup>2</sup>

According to 21CFR Subchapter D Part 312:<sup>3</sup> "*an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.*" Vaccines are considered a subset of drugs by FDA.<sup>4</sup> And the use of unlicensed, Emergency Use Authorized vaccines is thus, by definition, experimental.

US law requires that humans receiving experimental products must provide written informed consent.<sup>5</sup> However, when the PREP Act creating Emergency Use Authorizations (EUAs) was written, this requirement was loosened slightly for emergencies in which EUA products would be used. The required disclosures when using EUAs were specified below. **Please note the option to accept or refuse.**

**21 U.S. Code § 360bbb-3 - Authorization for medical products for use in emergencies<sup>6</sup>**

**(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—**

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<sup>1</sup> <https://www.fda.gov/science-research/risk-communication/fdas-risk-communication-research-agenda>

<sup>2</sup> <https://www.usatoday.com/story/news/2020/11/24/fda-commissioner-stephen-hahn-timing-safety-covid-19-vaccine/6393865002/>

<sup>3</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.3#:~:text=Clinical%20investigation%20means%20any%20experiment,the%20course%20of%20medical%20practice.>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7152379/>

<sup>5</sup> <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#sp45.1.46.a>

<sup>6</sup> <https://www.law.cornell.edu/uscode/text/21/360bbb-3>

- (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.**

All Moderna, Janssen (Johnson and Johnson) and all childhood Pfizer-BioNTech vaccines are being used under EUAs. And while the adult Pfizer-BioNTech vaccine is supposed to be licensed with brand name *Comirnaty*, in fact the Pfizer vaccines being used in the US today are EUA products as well.

## **2. While FDA licensed Comirnaty, the only approved COVID vaccine, only Emergency Use Authorized (experimental) vaccines are being used**

Despite claims to the contrary, the only vaccine currently available in the US is the Pfizer-BioNTech, not the licensed and branded *Comirnaty*. The Pfizer-BioNTech vaccine is authorized under an Emergency Use Authorization, which provides a broad liability shield to the manufacturer, distributor, administrator, program planner, and virtually anyone else involved in the vaccination process. The branded product, on the other hand, is subject to ordinary liability claims at the present time.

Exactly three weeks after FDA issued *Comirnaty* a license, the National Library of Medicine, part of the NIH, posted information that Pfizer was not planning to make *Comirnaty* available in the US while the EUA vaccine was still available:<sup>7</sup>

*"SEPTEMBER 13, 2021*

*Pfizer received FDA BLA license for its COVID-19 vaccine*

*Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older ([COMIRNATY](#)). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename.*

*At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels."*

FDA extended the vaccine's EUA authorization on the same day it licensed the vaccine.

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<sup>7</sup> <https://dailymed.nlm.nih.gov/dailymed/dailymed-announcements-details.cfm?date=2021-09-13>

FDA appears to have been acceding to the White House demand that the vaccine be licensed, in order for it to be mandated for large sectors of the US population. Under an EUA, which specifies that potential recipients have the right to refuse,<sup>8</sup> mandates cannot be imposed. So a license was issued, allowing the administration to inform the public that the vaccine was fully approved and licensed. But in fact, the public was unable to access the licensed vaccine.

Why was this convoluted regulatory process performed? While under EUA, Pfizer has an almost bulletproof liability shield. According to the Congressional Research Service (CRS) on September 23, 2021,<sup>9</sup> "*courts have characterized PREP Act immunity as 'sweeping.'*" The CRS explains, "*the PREP Act immunizes a covered person from legal liability for all claims for loss relation to the administration or use of a covered countermeasure.*"

### **3. FDA instructed Pfizer-BioNTech that FDA's Congressionally-mandated databases are inadequate to assess the danger of myocarditis (and other potential COVID vaccine side effects) and therefore Pfizer-BioNTech must perform studies to evaluate these risks over the next six years**

On the day FDA issued a license for *Comirnaty*, August 23, 2021, FDA instructed Pfizer-BioNTech that it did NOT have sufficient information on serious potential risks of the product, and required Pfizer and BioNTech, the manufacturers, to conduct a series of studies to assess these potential risks.<sup>10</sup> These studies were to be performed on **both** products: the licensed *Comirnaty* and the EUA Pfizer-BioNTech vaccine. Note that they include the requirement for a safety study in pregnancy, which will not be completed until December 31, 2025.

I have reproduced part of what FDA wrote about these required safety studies below, directly from pages 6-11 of the FDA approval letter sent to BioNTech, linked below.

FDA's admission that it cannot assess these safety risks, and that up to 6 years will be taken to study them, provides us with additional *de facto* evidence that the Pfizer vaccines cannot be termed safe, as many of the fundamental safety studies are only now getting started.

<https://www.fda.gov/media/151710/download>

"POSTMARKETING REQUIREMENTS UNDER SECTION 505(o) Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

**We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known**

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<sup>8</sup> <https://www.law.cornell.edu/uscode/text/21/360bbb-3>

<sup>9</sup> <https://crsreports.congress.gov/product/pdf/LSB/LSB10443>

<sup>10</sup> <https://www.fda.gov/media/151710/download>

**serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.**

Furthermore, **the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.**

Therefore, based on appropriate scientific data, we have determined that **you are required to conduct the following studies:**

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the **Pfizer-BioNTech COVID-19 mRNA Vaccine** in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY. We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule: Final Protocol Submission: August 31, 2021 Monitoring Report Submission: October 31, 2022 Interim Report Submission: October 31, 2023 Study Completion: June 30, 2025 **Final Report Submission: October 31, 2025**

5. Study C4591021, entitled “Post **Conditional Approval [EUA] Active Surveillance Study Among Individuals in Europe** Receiving the **Pfizer-BioNTech** Coronavirus Page 7 – STN BL 125742/0 – Elisa Harkins Disease 2019 (COVID-19) Vaccine,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY. We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule: Final Protocol Submission: August 11, 2021 Progress Report Submission: September 30, 2021 Interim Report 1 Submission: March 31, 2022 Interim Report 2 Submission: September 30, 2022 Interim Report 3 Submission: March 31, 2023 Interim Report 4 Submission: September 30, 2023 Interim Report 5 Submission: March 31, 2024 Study Completion: March 31, 2024 **Final Report Submission: September 30, 2024**

6. Study C4591021 sub-study to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY. We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule: Final Protocol Submission: January 31, 2022 Study Completion: March 31, 2024 Final Report Submission: September 30, 2024 7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network). We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule: Final Protocol Submission: November 30, 2021 Study Completion: December 31, 2026 Page 8 – STN BL 125742/0 – Elisa Harkins **Final Report Submission: May 31, 2027**

8. Study C4591007 sub-study to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age. We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the

following schedule: Final Protocol Submission: September 30, 2021 Study Completion: November 30, 2023 **Final Report Submission: May 31, 2024**

9. Study C4591031 sub-study to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age. We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule: Final Protocol Submission: November 30, 2021 Study Completion: June 30, 2022.

**Final Report Submission: December 31, 2022 ...**

10. Study C4591022, entitled “**Pfizer-BioNTech COVID-19 Vaccine [the EUA vaccine] Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.**”

Final Protocol Submission: July 1, 2021 Study Completion: June 30, 2025

**Final Report Submission: December 31, 2025**

#### **4. The World Health Organization does not recommend COVID vaccines for normal children**

The WHO website "WHO SHOULD GET VACCINATED"<sup>11</sup> states the following:

*Children and adolescents tend to have milder disease compared to adults, so unless they are part of a group at higher risk of severe COVID-19, it is less urgent to vaccinate them than older people, those with chronic health conditions and health workers.*

*More evidence is needed on the use of the different COVID-19 vaccines in children to be able to make general recommendations on vaccinating children against COVID-19.*

*WHO's Strategic Advisory Group of Experts (SAGE) has concluded that the Pfizer/BionTech vaccine is suitable for use by people aged 12 years and above. Children aged between 12 and 15 who are at high risk may be offered this vaccine alongside other priority groups for vaccination. Vaccine trials for children are ongoing and WHO will update its recommendations when the evidence or epidemiological situation warrants a change in policy.*

If the World Health Organization believes there is insufficient evidence to support general vaccination of normal children, why would this committee and the Maine Legislature think otherwise?

To sum up:

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<sup>11</sup> <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice>

- All available COVID vaccines are experimental products
- They must legally provide recipients the right to refuse.
- Mandates negate the right of refusal.
- Basic safety questions regarding the vaccines have not been resolved, and some will not be answered until 2027.
- The WHO does not recommend broad COVID vaccinations for children
- Parents should be permitted to make individualized decisions regarding their children's risks and benefits from COVID vaccines.
- Unfortunately, no one can make a fully informed decision about COVID vaccines until the public has access to complete information on safety and efficacy, which are not now available.

Thank you very much for your attention.

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