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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE ACTION REGARDING COVID-19 VACCINE LICENSURE	Docket No. _____

CITIZEN PETITION

On behalf of Children's Health Defense, the undersigned submit this petition under 21 C.F.R. § 10.20, § 10.30, § 50.23, § 600 – 680, § 601.2, 21 U.S.C. § 352, and § 553(e) of the Administrative Procedure Act.

We ask the Commissioner of the Food and Drug Administration (FDA) to deem Moderna's SPIKEVAX and all its currently marketed Biologics License Application ("BLA") versions (including MNEXSPIKE) and Pfizer/BioNTech's Comirnaty, and all its BLA versions, misbranded; and, that he initiates corrective actions at the agency's disposal, including revoking the BLA for these vaccines due to a lack of compliance with FDA regulations for the reasons set forth herein.

Under U.S. law, particularly the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (PHSA) (for biologics), a "misbranded" drug or biologic is one that is labeled, promoted, or packaged in a false, misleading, or noncompliant way, meaning it fails to meet FDA labeling or disclosure requirements. That is the case here.

Misbranding is a legal designation, not just a descriptive one, that constitutes a violation of federal law (*21 U.S.C. § 352*) that can trigger seizure, injunction, criminal penalties, and/or license revocation.

Vaccines can reach the arms of Americans under investigational or non-investigational pathways that are separate and distinct: (a) the non-investigational Emergency Use Authorization (EUA) pathway (meaning a product that is not part of a clinical investigation under an Investigational New Drug (IND) application and exemption); or, (b) the investigational Biologics License Application (BLA) pathway, or its sub-category; an investigational Expanded Access Use (EAU) pathway that is part of the clinical investigation pathway.

The key distinction between the investigational and non-investigational pathway is the differing legal requirements that are associated with the approval and labeling of the biologic product. Among its many requirements, clinical investigations (aka "clinical trials"), for purposes of the BLA, require oversight of an Institutional Review Board (IRB)[1] and strict adherence to all other clinical trial requirements, as well as strict and enforceable compliance with the current Good Manufacturing and Good Laboratory Practices (cGxP).

Importantly, a product that had previously obtained full BLA licensure can be labeled EUA during a declared public health emergency for more rapid access or unapproved indications and thus can exist in two versions – BLA-labeled and EUA-labeled. However, a product that never received BLA licensure and only reached the market through the non-investigational EUA pathway cannot be granted BLA without first demonstrating full compliance with the investigational BLA standards. COVID-19 mRNA vaccines have not demonstrated full compliance.

During the tumultuous time of Operation Warp Speed, the FDA granted COVID-19 mRNA vaccines EUA status in December 2020, by correctly (under EUA standards) waiving the legal requirements of IRB oversight, clinical trials,[2] and current Good Manufacturing and Laboratory Practices (cGxP) compliance that are strictly required for the IND and BLA pathways.

However, the FDA allowed Pfizer to follow the non-investigational EUA pathway even when it unlawfully granted Pfizer's Comirnaty COVID-19 vaccine BLA licensure on August 23, 2021, while leaving its "interchangeable" EUA Pfizer-BioNTech version on the market. Then, on January 31, 2022, the agency granted full BLA approval to Moderna's SPIKEVAX COVID-19 vaccine even though it continuously followed a non-investigational EUA pathway.

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[1] Public Law 93-348 The National Research Act issued 45 CFR § 46: Protection of Human Subjects. The National Research Act is overseen by the Office of Human Research Protections. The Act also formalized a regulated IRB process through local institutional review boards, also overseen by the Office of Human Research Protections.

[2] In addition, neither the expanded use access (EAU), nor emergency use authorization (EUA) pathways constitute a *clinical trial*/*clinical investigation* under 21 CFR § 312.3(b) and 21 U.S.C. § 360bbb-3(k), respectively.

Now that there are no EUA COVID-19 vaccines[3] in the United States, all currently available vaccines are BLA-labeled, albeit improperly. According to the FDA, the Pfizer-BioNTech vaccine that initially reached the market as an EUA countermeasure "is marketed" under the Comirnaty label.[4] According to Moderna, its COVID-19 vaccine that initially reached the market as an EUA countermeasure was then and is marketed as SPIKEVAX (COVID-19 Vaccine, mRNA).[5]

EUA vaccines cannot be merely marketed under a BLA label, however. There are licensing standards that need to be met but are not. There is no evidence that the current mRNA COVID-19 vaccine licensures comply with the legal standards of BLA labeling. In fact, it is quite the contrary.

The most egregious of the FDA's violations is that the only human clinical studies for COVID-19 vaccines were conducted under an EUA pathway that lacked IRB oversight and were not legally compliant clinical investigations. In addition, ample evidence points to the FDA's continual waiver of most (if not all) normally applicable BLA standards, such as cGMP/cGLP compliance in R&D and manufacture of these products.

COVID-19 vaccines that the FDA authorized for market under an EUA pathway in December 2020 *jumped tracks* without satisfying requisite standards to become BLA-labeled (Pfizer, August 23, 2021, and Moderna, January 31, 2022). By law, manufacturing practices and the data collected while under an EUA status can never satisfy regulatory and statutory BLA standards, as legal investigational pathway standards are explicitly made inapplicable to the non-investigational uses of products (under EUA). In a court declaration,[6] Peter Marks, then head of the FDA's Center for Biologics Evaluation and Research (CBER), correctly stated that, "products approved under BLAs are required to have the labeling that was approved as part of BLA." These COVID-19 vaccines were manufactured under EUA standards, without clinical trials, and without continuous compliance with BLA labeling standards. They cannot remain in

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[3] Federal Register, *Revocation of Emergency Use of Three Biological Products; Availability* (October 2, 2025) https://www.federalregister.gov/documents/2025/10/02/2025-19272/revocation-of-emergency-use-of-three-biological-products-availability

[4] FDA, *FDA Approves First COVID-19 Vaccine* (August 23, 2021) https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

[5] FDA, *FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)* (p. 17 *14)(June 17, 2022) https://www.fda.gov/media/157232/download

[6] *Declaration of Peter Marks, N.D. Fla. Case Number 3:21-cv-0121* p. 6 ¶11 (October 21, 2021) https://www.docdroid.net/xQZCCkd/declaration-of-marks-pdf

interstate commerce because they are, in fact, misbranded products. By law, their licenses must be revoked.

In 2025, both Comirnaty and SPIKEVAX labels have been substantially revised with indication and usage restrictions,[7] and additional warnings for myocarditis/pericarditis.[8] These actions were warranted; however, they do not rectify the underlying mislabeling violations described herein. This Petition is not arguing about the safety or efficacy of marketed COVID-19 mRNA vaccines, but rather violations of BLA labeling standards under the law.

The burden is on the FDA to prove that all BLA standards were satisfied when it fully licensed Pfizer's and Moderna's vaccines, which it cannot do.

Therefore, based on the foregoing, the undersigned ask the FDA to revoke all mRNA COVID-19 vaccine licensure based on the FDA's continuing lack of adherence to proper BLA standards.

I. ACTIONS REQUESTED

1. Petitioners ask the FDA to revoke all BLA's for every mRNA COVID-19 vaccine for all demographic groups because manufacturers do not and have never met BLA standards. Further, in granting licensure, FDA failed to enforce these standards.

2. Petitioners ask the FDA to find Comirnaty (all versions) and SPIKEVAX (including MNEXSPIKE) mislabeled/misbranded.

3. Petitioners ask the FDA to find Comirnaty (all versions) and SPIKEVAX (including MNEXSPIKE) adulterated or potentially adulterated.

4. Petitioners ask the FDA to properly designate every mRNA COVID-19 vaccine as an Emergency Use Authorization biologic as long as the HHS Secretary's Declaration of Emergency is in effect. 21 U.S. Code § 360bbb-3(c)).

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[7] FDA, *FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants (August 22, 2024)* https://www.fda.gov/news-events/press-announcements/fda-approves-and-authorizes-updated-mrna-covid-19-vaccines-better-protect-against-currently

[8] FDA, *FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination* (June 25, 2025) https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and

II. STATEMENT OF GROUNDS

A. All available COVID-19 mRNA vaccines fail to meet BLA licensure standards

New biological products that have never been approved for market before (such as mRNA vaccines prior to 2020) must follow these mutually exclusive regulatory pathways to reach the U.S. market:

Feature	**IND/BLA Pathway**	**EUA Pathway**
Legal Authority	21 U.S.C. § 355 / 42 U.S.C. § 262	21 U.S.C. § 360bbb-3
Status	Investigational medicine	Non-investigational use
Purpose	Research & full licensure	Emergency distribution
IRB Oversight	**Required** (21 CFR 56)	**Not required**
Informed Consent	**Required** (21 CFR 50)	**Not required**
cGxP compliance	**Required**	**Not required**

Each regulatory pathway is briefly discussed below.

1. Emergency Use Authorization (EUA)

According to the FDA, under section 564 of the (FD&C Act), when the HHS Secretary declares that emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by Chemical,

Biological, Radiological and Nuclear ("CBRN") threat agents when certain criteria are met, such as instances when there are no adequate, approved, and available alternatives.

During an emergency, 21 USC 360bbb-3a(c) authorizes the HHS Secretary to deviate "from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation." Further, a countermeasure, "shall not be deemed adulterated or misbranded under this chapter because … the Secretary has authorized deviations from current good manufacturing practices."

Unlike standard research under 21 CFR Parts 50 and 56, EUA use is not a "clinical investigation" and therefore does not require IRB approval or informed consent under those parts. There are alternative disclosure obligations:

> 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) requires that recipients be informed of:
>
> 1. The option to accept or refuse administration of the product,
> 2. The consequences, if any, of refusing, and
> 3. The alternatives to the product that are available and of their benefits and risks.

What is sometimes referred to as the EUA Fact Sheet requirement replaces traditional "informed consent" under human-subjects research rules.[9]

Additionally, EUA products are deployed on the market based on only a "may be effective"[10] opinion of the HHS Secretary and are not subject to formal product recall procedures, applicable to regular pharmaceutical products.

Therefore, licensure requirements of 21 C.F.R. Part 610 (General Biological Products Standards) are, in effect, waived by 21 USC 360bbb–3(a)(2)(A), and when products are brought to the market under EUA regulations, with its lax FDA enforcement, manufacturers are on an honor system to self-monitor.

2. Biologics License Application (BLA)

According to the FDA, the Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR

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[9] FDA, *GUIDANCE DOCUMENT Emergency Use Authorization of Medical Products and Related Authorities* (p. 15) (January 2017) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#:~:text=b.%20Information%20for,preparation%20

[10] 21 U.S. Code § 360bbb-3(c) - *Authorization for medical products for use in emergencies, criteria for issuance of authorization.*

601.2). The BLA is regulated under 21 CFR 600 – 680. A BLA is submitted by any legal person or entity who is engaged in manufacturing or an applicant for a license who takes responsibility for compliance with product and establishment standards. Form 356h specifies the requirements for a BLA, which the FDA must formally review before granting the licensure, and to which the manufacturer is bound to comply continuously, including:

- Applicant information
- Product/Manufacturing information
- Pre-clinical studies
- Clinical studies
- Labeling

Thus, the FDA can only license biologics that meet (purity, potency, safety, efficacy, manufacturing compliance, labeling disclosure/marketing compliance, and other applicable legal standards) requirements.

Importantly, BLA licensure is not a one-time event; it requires ongoing, strictly enforceable compliance with applicable statutes while the product remains in interstate commerce.

For purposes of this Petition, the manufacturing compliance (cGMP), preclinical studies compliance (cGLP), and clinical investigation compliance are briefly outlined below. Compliance with these requirements ensures accurate and truthful disclosure in the labeling of BLA biological products. Absent adherence to such procedures, biologics are mislabeled and misbranded and are therefore subject to recall and BLA licensure revocation.

a. Manufacturing compliance requirements for BLA (cGMP):

cGMP requirements for biologics, purity/potency/safety are described in 21 CFR 600–610, which establish the general FDA standards for biological products, including vaccines licensed under the Public Health Service Act (42 U.S.C. § 262). 21 CFR Part 610 describes General Biological Product Standards, i.e., core technical standards for vaccines and similar biologics.

In principle, to initially receive and continue to maintain a biologics license, a manufacturer must continuously demonstrate, for the specific product, its end-to-end production and supply chain:

1. **Safety** – product causes no undue harm when used as intended. (§610.11 Safety). This part requires testing in animals or other validated models.
2. **Purity** – free from contamination or unintended substances. (§610.12 Purity). Product must be free from extraneous materials (cell debris, endotoxins, residual DNA, etc.).
3. **Sterility** (§610.10)**:** Each lot must be free of contaminating microorganisms.

4. **Potency** – proven biological activity consistent with intended therapeutic or immunologic effect. (§610.17–§610.18 Potency & Stability). Potency must be demonstrated using validated biological or immunological assays.
5. **Identity and Constituents** (§610.13–§610.15). Validated tests must confirm correct identity and permissible additives.
6. **Expiration Dating:** Manufacturers must establish expiration dating based on real-time stability data.
7. **Consistency** – validated manufacturing process ensures reproducibility of quality.
8. **Compliance with cGMP** – per 21 CFR Parts 210 & 211**,** adapted for biologics.

To comply with the above-mentioned requirements for purposes of BLA licensure,[11] manufacturers must:

- establish, validate, and consistently apply controlled production methods that
- ensure each lot of a biologic product is safe, pure, potent, and stable, as verified through documented testing, records, and continuous FDA oversight.

Establishing a manufacturing process that is compliant with the legal requirements of the BLA is complex. It typically takes many years to license an entirely new product or technology platform, numerous compliance requirements are specified in the law, and several overarching principles must be continuously upheld:

1. A validated and BLA-compliant manufacturing process[12] must be fully representative of the final/current commercial lot production process. Due to uncertainties inherent in the design of new innovative biological products, the manufacturing for novel technologically advanced platforms typically requires many changes and iterations as the

[11] Regulatory Bases: The requirements to show *controlled, reproducible production* come primarily from:

21 CFR Parts 600 & 610 — General biologics standards (licensing, testing, lot control).
21 CFR Parts 210 & 211 — Current Good Manufacturing Practice (cGMP).
11.1 FDA, Guidance for Industry *Process Validation: General Principles and Practices* (January 2011). https://www.fda.gov/media/71021/download
11.2 FDA, *Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)* (January 2023), https://www.fda.gov/media/113760/download
11.3 FDA, *Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry* (October 2023), https://www.fda.gov/media/139638/download

[12] FDA, *Guidance for Industry, Process Validation: General Principles and Practices* (January 2011). https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf

production is scaled from pilot/research scale to commercial scale. Thus, to obtain a BLA, the manufacturers are required to fully validate and demonstrate compliance with the law for the final commercial scale process.

2. The BLA manufacturing process must be fully representative of the product lots used in clinical trials and preclinical studies upon which the labeling – including claims of safety and efficacy – is established.

3. Throughout pivotal clinical trials and post BLA, each production lot must demonstrate lot-to-lot consistency[13] and pass identity, purity, safety, sterility, potency, and stability tests (§§ 610.10–610.13) in order to meet the labeling specifications preapproved in the Biologics License Application (BLA). If variability arises, the manufacturer must investigate and demonstrate that it does not compromise quality.

Manufacturing process validation is a vast area of law and regulation, which generally includes:

- Design qualification (DQ) – define process and critical quality attributes.
- Installation/operational qualification (IQ/OQ) – verify equipment and system performance.
- Performance qualification (PQ) – produce several consecutive lots that meet all release criteria under routine conditions. These lots are often called Process Performance Qualification (PPQ) lots.[14]

For continued BLA licensure, the above-mentioned requirements are fully enforceable by the FDA. The FDA must withdraw licensure for any of the listed category violations. While manufacturers may volunteer to adhere to these standards under EUA, none of the above-mentioned categories are strictly required or enforced by the FDA under EUA.

b. Pre-clinical compliance requirements for BLA (Good Laboratory Practices, cGLP):

Regulatory Basis for cGLP Requirements is the 21 CFR Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies and associated FDA Guidance for Industry documents.[15] To meet BLA licensure standards, the manufacturers must demonstrate that the data used to support

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[13] 21 CFR 610.1 & 610.12–610.20
[14] Ibid. Footnote 12
[15] **15.1** FDA, *Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers in Preventive Vaccine Clinical Trials* (2007) https://www.fda.gov/media/73679/download;
15.2 FDA, *Guidance for Industry Preclinical Assessment of Investigational Cellular and Gene Therapy Products* (November 2013) https://www.fda.gov/media/87564/download

human clinical trials are representative of the final biological product as dispensed to the consumer, and are reliable, traceable, and scientifically valid. FDA explicitly states that GLP applies when nonclinical safety studies are intended to support research or marketing applications for biologics, drugs, or medical devices (§58.1(a)).

In the context of vaccines, this includes:

- **Toxicology studies** (single and repeat-dose toxicity, and reproductive toxicity)
- **Local tolerance studies** (e.g., intramuscular or subcutaneous injection sites)
- **Biodistribution studies** (required for novel platforms like mRNA or viral vectors)
- **Immunopathology** or **adjuvant safety** studies
- **Safety pharmacology** if system effects are relevant (required for novel platforms and when biodistribution shows systemic exposure)

Exploratory or proof-of-concept immunogenicity studies, or early mechanism-of-action studies, are not required to be GLP and can be conducted under research-quality conditions. However, any pivotal safety studies cited in a BLA must comply with GLP. In its Guidance for Industry documents, the FDA requires that, if a study cannot fully comply with GLP (e.g., species model constraints), deviations must be scientifically justified, documented, and disclosed to FDA.[16]

c. BLA-compliance requirements for human subjects in investigational clinical trials

When a sponsor submits a biologics license application under Public Health Service Act § 351(a) (42 U.S.C. § 262), part of the "safe, pure, and potent" demonstration relies on legally defined clinical investigations in humans.

FDA regulations make clear that:

- Humans may not be enrolled in research unless informed consent has been obtained (21 CFR 50.20).
- An IRB must review and approve human-subject research (21 CFR 56.109(a)).
- Documentation of consent and IRB decisions must be maintained (§ 50.27 and § 56.109(c)).

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[16] **16.1** FDA, *Guidance for Industry S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals* (July 1997) (page 3, section III.A ("General Principles")); https://www.fda.gov/media/72028/download; and
16.2 FDA, *Guidance for Industry Preclinical Assessment of Investigational Cellular and Gene Therapy Products* (November 2013) https://www.fda.gov/media/87564/download

Thus, IRB oversight and informed consent are strict prerequisites for data from human clinical trials to be acceptable to FDA for biologics licensing (BLA).

Clinical trials, defined per 21 CFR Part 312 as "clinical investigation" studies, must follow a set of laws and regulations,[17] which are intended to protect the rights, safety, and welfare of human subjects participating in human trials, ensure the quality, validity, and integrity of the clinical trial data, and promote the availability of new medical products to the public. These laws and regulations define the roles and responsibilities of entities, such as sponsors, clinical investigators, and institutional review boards. In addition, various guidance documents[18] and standard operating procedures[19] are available to clarify policies and procedures for the IND process.

d. BLA Requirements for Representative Commercial Process/Product

Crucially, the initial and ongoing compliance with BLA requires that data used to support licensure come from processes representative of the final commercial manufacturing process. This is because in biologics manufacture, the process is the product. Discussing the cGMP on its website,[20] the FDA states that:

> A consumer usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work. While CGMP requires testing, testing alone is not adequate to ensure quality. In most instances testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used for patients rather than destroyed by testing.

Clearly, "testing alone" is not sufficient to ensure ongoing BLA compliance. Testing of one or many doses of one or many batches of a product that does not accurately represent the actual product injected into a consumer cannot and will not meet the BLA standards established by the FDA.

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[17] FDA, *Regulations: Good Clinical Practice and Clinical Trials* (January 21, 2021) https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials

[18] Ibid.

[19] FDA, *Biologics Procedures (SOPPs)* (October 31, 2025) https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-procedures-sopps

[20] FDA, *Facts About the Current Good Manufacturing Practice (CGMP)* (November 21, 2025) https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp

The FDA explicitly requires that manufacturing and testing used to support licensure (including preclinical and clinical material) be representative of the final commercial process:

- Same or scaled-equivalent facilities, equipment, and controls.
- Same cell substrate or vector system, purification steps, and formulation.
- Same process control strategy and release specifications.

In the context of cGLP, preclinical studies must reflect the intended clinical/commercial material, meaning that the test article(s) used in preclinical studies should be representative of the material intended for clinical use, manufactured using comparable processes and controls to those planned for clinical and commercial production, while significant manufacturing changes after preclinical testing may necessitate additional bridging studies to demonstrate comparability.[21]

The FDA cites specific regulations for process validation and reporting (e.g., 21 CFR 211.22, 211.100, 211.110(a), and 211.165) when explaining why manufacturing changes late in development can require additional qualification or bridging studies.[22]

In the context of cGMP, Clinical and PPQ Manufacturing must reflect the final commercial process. This means that the process must be defined, controlled, and validated to yield consistent product quality, which inherently requires it to represent what will be commercially manufactured.

FD&C Act § 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), and 21 CFR 210/211 and 21 CFR 601.20 collectively require that the actual facilities and equipment used to manufacture the licensed biologic operate in a state of cGMP control and validated performance.

In addition, FDA Guidance "Process Validation: General Principles and Practices"[23] defines manufacturing Process Qualification as:

> During the process qualification (PQ) stage of process validation, the process design is evaluated to determine if it is capable of reproducible commercial manufacture.

PPQ (Process Performance Qualification) lots, i.e. the manufacturing validation lots submitted for the BLA, must be made using the same process, materials, and controls as final commercial production. If these criteria are not met, the process is not considered validated for licensure.

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[21] "FDA, *Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products Draft Guidance for Industry* (July 2023) https://www.fda.gov/media/170198/download
[22] Ibid.
[23] FDA, *Guidance for Industry Process Validation: General Principles and Practices* (January 2011), (p. 13 of 22) https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf

FDA Guidance "CMC Information for Human Gene Therapy INDs" (2023)[24] specifies that the manufacturing process and analytical methods used for clinical production should be representative of those intended for commercial manufacturing; that significant changes during development should be assessed for impact on product comparability, and that demonstration of process control and reproducibility should be based on production-scale runs that reflect the final process design.

Finally, BLA Review Standard (21 CFR §601.2(a)) states that:

> To obtain a biologics license under section 351 of the Public Health Service Act for any biological product … [the application shall include] sample(s) representative of the product for introduction or delivery for introduction into interstate commerce

This means that the FDA requires evidence that the *exact* process proposed for commercial use can reproducibly make a product meeting all standards – one cannot obtain a BLA license for a product on the basis of a research-grade or pilot-scale process.

e. When Manufacturing Process Is Not Representative

If preclinical or clinical material differs substantially from the final process:

- Bridging studies must be performed to compare the new and old lots (analytical comparability + potentially new animal or clinical data).
- FDA may reject PPQ data if the validation lots are not representative of commercial manufacturing.
- The BLA may be Refuse To File (RTF) until comparability or validation is demonstrated.

f. When a drug or biologic is considered misbranded

Examples of misbranding relevant to this Petition include:

1. False or Misleading Labeling (21 U.S.C. § 352(a)(1)) categorizes a product as misbranded; "If its labeling is false or misleading in any particular." Specific examples include claims of safety or effectiveness which are not supported by data, or omission of material facts, such as risks and limitations of use.

2. Failure to Comply With cGMP

[24] FDA, *Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs) Guidance for Industry* (January 2020) https://www.fda.gov/media/113760/download

If a product's labeling implies that it was manufactured under approved standards but cGMP (21 CFR Parts 210–211 for drugs; 600–680 for biologics) was not followed, the product may be considered adulterated and misbranded.

To rectify misbranding, the FDA has numerous enforcement mechanisms, including:

- FDA can issue a Warning Letter or request voluntary recall.
- Products may be detained or seized under 21 U.S.C. § 334.
- Manufacturers may lose licensure under PHSA § 351(d) for biologics.

B. The FDA failed to follow its own regulatory guidelines when it illegally granted BLAs to COVID-19 mRNA vaccines

The FDA granted the BLAs to Pfizer and Moderna without following the BLA requirements specified in the FDA's own regulations and the law. Substantial evidence points to several such glaring violations that are also contrary to historically established regulatory practice.

1. Evidence that Comirnaty and SPIKEVAX labels are non-compliant with legal standards for cGMP (noncompliant clinical data (Section 14 of BLA label))

In late November 2020, records for Pfizer's COVID-19 vaccine regulatory review were publicly released by a data leak from the European Medicines Agency.[25] The authenticity of the documents was confirmed by the British Medical Journal.[26] The EMA did not deny the authenticity of the documents. The documents also contain some of the FDA reviewers' correspondence with Pfizer. In addition to the manufacturing documentation, the EMA files also contain 14 screenshots of emails dating from mid to late November 2020.[27] The email exchanges are between the EMA staff and senior executives at the agency and their correspondence with the FDA and MHRA (the UK regulator). These emails demonstrate that the EMA reviewers were under massive political pressure to overlook all regulatory deficiencies. It is also evident that the EMA and FDA leadership at the time were concerned primarily with coordinating the launch dates, and the "authorization" of these shots was a foregone conclusion.

Emails leaked from EMA also demonstrate that the EU regulators were primarily concerned with the dates of product launch prior to reviewing the necessary regulatory data package. The process was highly political and not scientific. As stated above, the EMA staff reviewers

[25] European Medicines Agency leaked files
[26] British Medical Journal, *The EMA covid-19 data leak, and what it tells us about mRNA instability* (March 10, 2021)
https://www.bmj.com/content/372/bmj.n627
[27] European Medicines Agency leaked emails

objected to the data, but the high-ranking officials appeared to have ignored and overruled their concerns.

The regulatory review and approval standards in the United States and the European Union are substantially the same due to the International Conference on Harmonization (ICH) and Mutual Recognition Agreements. The documents show that the first regulatory review of Pfizer's manufacturing process, a so-called "rolling review", began on or around November 26, 2020. During this review, the Biologics Working Party (BWP) at the European Medicines Agency identified three Quality Major Objections (MOs)[28] during the assessment of Pfizer's CMC documentation. There were severe and unresolvable – given the unrealistic timeline – issues with the quality of the product the EMA staff were pressured to ok. The manufacturing process was woefully out of cGMP compliance. Specifically, major objections included:

> **MO1:** lack of cGMP compliance and inability to establish it prior to launch;
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> **MO2:** lack of mRNA integrity and large amounts of mRNA fragments, and incomparability of the commercial process (PPQ batches) with the process that was used to make the doses for the pivotal clinical trial that had just wrapped up the data collection;
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> **MO3:** many significant gaps in manufacturing documentation making it impossible to determine if the product could be made as described. The manufacturing process compliance with cGMP (BLA or CMA standards) could not be verified at all.

Additionally, 100+ objections and observations were issued by the reviewers flagging a variety of serious concerns with the manufacturing process quality and data completeness.

The EMA regulatory review of Pfizer CMC documentation revealed that the Phase 3 data could not satisfy the BLA standards. The two main reasons for this failure were:

- The manufacturing process used to produce the Phase 3 clinical trial drug product (aka Process 1) was found non-representative of the commercial scale manufacturing process being presented to the regulatory review (Process 2); and
- The scaled Process 2 was found non-compliant with cGMP requirements due to numerous identified deficiencies and large gaps - missing or pending normally required information. This made it impossible for the regulators to evaluate Pfizer's process for cGMP compliance prior to commercial distribution of the product.

Each one of these reasons by itself precludes the possibility of Pfizer's Phase 3 clinical trial data, from late fall of 2020, being acceptable for BLA labeling in August of 2021.

[28] Ibid.

The magnitude and severity of the cGMP non-compliance issues identified by the European regulators at that time preclude the possibility that the data from the Phase 3 COVID-19 vaccine clinical trials could satisfy the accurate BLA labeling at a later date.

The pivotal trials for COVID-19 vaccines had completed primary Phase 3 data collection in late fall of 2020. Specifically, for Pfizer, the data lock for the primary efficacy endpoints was on November 14, 2020,[29] and for Moderna - on or before November 16, 2020.[30] Both dates are prior to the dates of the EMA/FDA CMC regulatory review for Pfizer, which happened around November 26, 2020. At that time, Moderna's CMC documentation was not available for review at all. While for both vaccines, final trial completion dates are listed in 2022-2023, both trials broke the blinding and removed the placebo control groups by injecting the participants with the COVID-19 vaccines starting around December 2020. This, too, is a serious violation of the BLA standards, but is acceptable for EUA. Some special-population post-market studies were performed in 2021-2022 (e.g., in children and some immunocompromised populations, updated product versions); however, none were BLA-compliant.

The FDA cannot claim that objections and observations of the European regulators are not relevant. Unlike the FDA, the EMA used an investigational regulatory pathway (Conditional Marketing Authorization, CMA[31]) for initially deploying COVID-19 vaccines in the EU. The CMA standards are substantially similar to the BLA standards in the United States, as they apply to the products legally deemed investigational. In fact, until COVID-19 vaccines, the CMA pathway had never been utilized for approving any product for a very broad indication and mass deployment. CMA requires the same cGMP compliance as any commercially approved investigational drug or biologic, while allowing for some regulatory commitments post-market. Therefore, the major objections of the EMA reviewers are highly relevant as evidence of major deficiencies with respect to the BLA-readiness of Pfizer's manufacturing process at the time of the primary data completion of its pivotal Phase 3 trial.

The FDA cannot claim that these manufacturing compliance violations have been resolved between 2020 and 2025, for the following reasons:

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[29] FDA, *Pfizer-BioNTech Covid-19 vaccine (BNT162, PF-07302048) Vaccines and Related Biological Products Advisory Committee Briefing Document: 10 December 2020*, p.8; https://www.fda.gov/media/144246/download

[30] Businesswire, *Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization* (November 30, 2020) https://www.businesswire.com/news/home/20201130005506/en/Moderna-Announces-Primary-Efficacy-Analysis-in-Phase-3-COVE-Study-for-Its-COVID-19-Vaccine-Candidate-and-Filing-Today-with-U.S.-FDA-for-Emergency-Use-Authorization

[31] NIH, National Library of Medicine Pub Med Central, *The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines* (January 13, 2021) https://pmc.ncbi.nlm.nih.gov/articles/PMC7833511/

> Even if the FDA can demonstrate that Pfizer's Comirnaty manufacturing process is cGMP compliant today, the manufacturing process today is NOT the same process that was used to manufacture the Phase 3 trial material. Therefore, the data from the Phase 3 trial do not represent the product that is being shipped today, and the product should be deemed mislabeled.
>
> Even if the FDA has discretion to use the so-called "real world" observational data as supporting evidence for various regulatory decisions, these "real-world" data alone, regardless of how voluminous, are not a valid substitute for legally prescribed evidentiary data package collected in cGMP compliant manner, as required for BLA labeling.

Effect: the data from Phase 3 trials, which are included in several sections of Comirnaty and SPIKEVAX BLA labels (Sections 6, 8, 14), cannot be deemed representative of the commercially shipped SPIKEVAX and Comirnaty vials. This means that vials being distributed in interstate commerce today are mislabeled for purposes of BLA.

2. **Evidence that Preclinical and Toxicology sections of Comirnaty, SPIKEVAX, and MNEXSPIKE labels do not comply with BLA standards (cGLP)**

In June 2020, the FDA published "Development and Licensure of Vaccines to Prevent COVID-19." This guidance document is final, was implemented without prior public participation, and is intended to remain in effect for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and currently extended to December 31, 2029. Regarding the nonclinical assessments for COVID-19 vaccines (2020) the FDA guidance[32] states that:

> For a COVID-19 vaccine candidate consisting of a novel product type and for which no prior nonclinical and clinical data are available, nonclinical safety studies will be required prior to proceeding to FIH [first-in-human] clinical trials 21 CFR 312.23(a)(8). (P.6)
>
> When needed to support proceeding to FIH clinical trials, nonclinical safety assessments including toxicity and local tolerance studies must be conducted under conditions consistent with regulations prescribing good laboratory practices for conducting nonclinical [*sic*] laboratory studies (GLP) (21 CFR Part 58). Such studies should be completed and analysed [*sic*] prior to initiation of FIH clinical trials. When toxicology studies do not adequately characterize risk, additional safety testing should be conducted as appropriate. (P.7)

[32] FDA, *Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry* (October 2023) https://www.fda.gov/media/139638/download

The agency also states that where the guidance says "should," those sentences describe nonbinding recommendations, while where it says "must" and cites the applicable law, it describes enforceable items.

There were no nonclinical or clinical data available for mRNA-1273 (later SPIKEVAX) or BNT162b2 (later Comirnaty) before 2020. Both products formulated in lipid nanoparticles constitute entirely novel biologic products and active substances, requiring strict adherence to BLA standards if the product is to be labeled as such.

Review of Moderna's FOIA Productions of SPIKEVAX Nonclinical Summaries[33] and Comirnaty Nonclinical Summaries[34] revealed severe non-compliance with BLA standards and the FDA's own Guidance for mRNA vaccines.

a. The BLA requirement for completion of nonclinical safety studies prior to the start of the first-in-human trials was not met by either Pfizer or Moderna products.

Specifically, Moderna initiated human clinical studies on March 16, 2020.[35] For the biodistribution component of the non-clinical assessment, Moderna submitted a non-GLP study for another unapproved product, mRNA-1647 (a construct of 6 different mRNAs which had been in development for an experimental cytomegalovirus vaccine), completed in male animals only, in 2017. Since this study was non-GLP and did not include SPIKEVAX formulation (mRNA 1273), the biodistribution for SPIKEVAX has not been studied under BLA standards at all. For other components of Moderna's non-clinical package, studies that utilized mRNA-1273 or its components were all initiated after March 16, 2020, and key data were still indicated as pending or incomplete when the FOIA production was obtained in 2022.[36]

Pfizer initiated human clinical studies in April 2020, and its pivotal Phase 3 trial on July 27, 2020. As evidenced in the Nonclinical Summaries FOIA production, Combined Fertility and Developmental Study (DART) for Comirnaty was completed on October 12, 2020, and the biodistribution study was completed on September 24, 2020. The 17-Day Intramuscular Toxicity Study of BNT162B2 (V9) in Wistar Han Rats (Study 20GR142) is noted in conflicting terms in

[33] Moderna Nonclinical Summaries Responsive records 4.pdf (February 28, 2022)
[34] HHS, *Re: FDA FOIA Request 2021-4379; Judicial Watch, Inc. v. U.S. Department of Health and Human Services, 21-cv-2418* (April 13, 2022) https://www.judicialwatch.org/wp-content/uploads/2022/08/JW-v-HHS-Biodistribution-Prod-4-02418.pdf
[35] *Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (March 16, 2020) https://s29.q4cdn.com/435878511/files/doc_news/2020/03/16/moderna-announces-first-participant-dosed-nih-led-phase-1-study.pdf
[36] Ibid. Footnote 34 p. 349, 353, 354, 355.

the documentation. In one summary table, this study is listed as "Completed." However, other sections state that this study was "Ongoing" at the time of the review, noting that the remaining endpoints (serology and microscopic pathology from the dosing phase, plus all recovery phase endpoints) were pending submission. No specific experimental completion date or final report date is provided for Study 20GR142 in the available document production.[37]

b. The GLP requirements for BLA were not met.

The nonclinical summaries (Module 2.4 and associated sections) for the Pfizer/BioNTech vaccine candidate BNT162b2 detail a total of 17 individual studies or definitive reports across the domains of Pharmacology, Pharmacokinetics/ADME, and Toxicology. While some GLP-compliant studies were included in the package, the whole nonclinical package cannot be deemed GLP-compliant, as several key required studies were non-GLP. Specifically, the only two GLP studies that evaluated the final BLA product candidate were the intramuscular Repeat-Dose Toxicity Study 20GR142 and the Reproductive Toxicity study (DART 20256434**,** Sponsor Reference No. RN9391R58). Another Repeat-Dose Toxicity Study (Study 38166) is listed as GLP; however, it was conducted with the vaccine candidate that was not the final BLA licensed vaccine product, but another version. Single Dose Pharmacokinetics (PK) and Excretion Study (PF-07302048) evaluated the novel lipid excipients (ALC-0315 and ALC-0159) and is listed as non-GLP. Since these lipids have never been used in any approved biologic product, it is a violation of the BLA standards. Finally, the critical component of the toxicology assessment, the biodistribution study, "Tissue Distribution Study (Radiolabeled Lipid/mRNA), study number 185350, was not conducted under GLP conditions. The final report explicitly states that GLP regulations are not applicable to studies of this nature; therefore, no claim of GLP compliance is made. This is acceptable for the EUA regulatory pathway; however, it violates the regulatory standards for BLA products.[38]

The nonclinical summaries for Moderna's SPIKEVAX contain several versions of the same documentation package. They appear to contain information derived from 9 individual studies or types across the domains of Pharmacology, Pharmacokinetics, and Toxicology. In addition, several tests for individual components of the lipid nanoparticle technology are included. The only GLP-compliant study of mRNA-1273 (SPIKEVAX) in the entire package is the

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[37] **37.1** MDPI, *Toxicological Assessments of a Pandemic COVID-19 Vaccine—Demonstrating the Suitability of a Platform Approach for mRNA Vaccines* Giovanelli M. (February 11, 2023) https://www.mdpi.com/2076-393X/11/2/417
37.2 Pfizer Inc.,17-Day Intramuscular Toxicity Study of BNT162B2 (V9)17-DAY *INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY STUDYID: 20GR142* (January 19, 2021) https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/030123/125742_S1_M4_20gr142_nsdrg.pdf

[38] Ibid. Footnote 33

Developmental & Reproductive Toxicity (DART). This is the only study that satisfies both the BLA requirement for GLP and for representative product testing. All primary pharmacology studies for SPIKEVAX were non-GLP. All other studies in the submission do not meet the GLP requirements. In many instances, GLP studies of irrelevant products (not SPIKEVAX) are included. These may satisfy the EUA standards but do not meet the BLA standards because the tested materials are not representative of the commercial product.[39]

The nonclinical studies for Moderna's MNEXSPIKE[40] contain only one GLP-compliant study with representative product "Combined Perinatal/Postnatal Developmental & Reproductive Toxicity Study." The study was conducted in females only, and no male reproductive toxicity was assessed. This violation of BLA standard is further discussed in section (f) below. The remainder of nonclinical studies for MNEXSPIKE were non-GLP compliant. The "Non-GLP Repeat Dose Toxicity and Immunogenicity Study," (*see* p. 9) in addition to being non-GLP, was conducted with non-representative products (mRNAs-1284 and -1285). However, MNEXSPIKE is mRNA-1283. The "Nonclinical Pharmacology Studies Supporting mRNA-1283"[41] were all non-GLP compliant.

On or around November 28, 2025, an internal memo[42] from Vinayak Kashyap Prasad M.D., M.P.H., director of the FDA's CBER, leaked to the press, opened with:

> I am writing to report that OBPV [Office of Biostatistics and Pharmacovigilance] career staff have found that at least 10 children have died after and because of receiving COVID-19 vaccination. These deaths are related to vaccination (likely/probable/possible attribution made by staff). That number is certainly an underestimate due to underreporting, and inherent bias in attribution.

This statistic is based on an initial analysis of 96 deaths in children who received COVID-19 vaccines. Director Prasad also wrote:

> This is a profound revelation. For the first time, the US FDA will acknowledge that COVID-19 vaccines have killed American children.

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[39] Moderna mRNA-1273 (SPIKEVAX) Nonclinical Program
[40] FDA, *Summary Basis for Regulatory Action MNEXSPIKE p. 15 (May 30, 2025)* https://www.fda.gov/media/187164/download?attachment
[41] Ibid. Table 6, p. 16-17
[42] Vinay Prasad MD MPH, *Subject: Deaths in children due to COVID-19 vaccines and CBER's path forward* (November 2025)

c. Safety Pharmacology assessments were not performed for Pfizer and Moderna mRNA COVID-19 Vaccines

Safety pharmacology was omitted entirely for both products, with Pfizer citing WHO guidelines for vaccines from 2005 as justification.

Per **ICH S6(R1)** – *Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals,* dedicated "safety pharmacology studies" are not routinely required for vaccines, unless the vaccine contains a novel active substance, new excipient, or delivery system with potential systemic pharmacologic activity. Otherwise, repeat-dose toxicity and local tolerance studies (often in one relevant animal species) are considered sufficient. However, vaccine preclinical safety evaluation must still demonstrate absence of undue toxicity or adverse physiological effects — and this is part of the nonclinical section of the Biologics License Application (BLA) under 21 CFR 601.2 and 21 CFR 600.3(p).

In other words, if a vaccine's components (e.g., adjuvants, delivery platforms, genetic vectors) could interact with physiological systems (CNS, cardiovascular, respiratory, etc.), then focused safety pharmacology is warranted. Biodistribution studies are conducted in part to determine the systemic exposure effects. For both Pfizer and Moderna's products, the biodistribution studies have demonstrated distribution and accumulation of the product in major organ systems, including the heart and cardiovascular system. This and the fact that the products were extremely novel active substances means that, for purposes of BLA licensing, they required at least some dedicated safety pharmacology assessments before initiating human trials.

Further evidence that this should have been done before granting the BLA license is the fact that four years afterwards, on April 17, 2025, the FDA found that children and young adults were put at undue risk for serious and often permanent heart damage by these vaccines and required Pfizer and Moderna to update the label with a warning for myocarditis.[43] In the meantime, these products were mandated for college students for whom they were advertised as "safe" via inaccurate BLA labeling.

d. Moderna's SPIKEVAX biodistribution was studied in male animals only, while SPIKEVAX and MNEXSPIKE are BLA-labeled for both sexes

Moderna's only biodistribution study is officially titled "A Single Dose Intramuscular Injection Tissue Distribution Study of mRNA-1647 in Male Sprague-Dawley Rats." Thus, it fails BLA

[43] **43.1** FDA, *Safety Labeling Change Notification Letter - COVID-19 Vaccine, mRNA (COMIRNATY)* (April 17, 2025) https://www.fda.gov/media/186581/download?attachment
43.2 FDA, *Safety Labeling Change Notification Letter - COVID-19 Vaccine, mRNA (SPIKEVAX)* (April 17, 2025) https://www.fda.gov/media/186580/download?attachment

licensing standards on three counts: it was not studying the representative product, it was non-GLP, and it was not studying it for the intended clinical population.[44]

For a biologic (including vaccines) intended for use in both sexes, biodistribution studies limited to males are not considered sufficient to fully characterize risk – unless the sponsor provides a scientifically justified rationale that female testing is not relevant or feasible. FDA and ICH guidance explicitly expect that both sexes are evaluated when the product is intended for both. Per 21 CFR 312.23(a)(8), nonclinical studies must include *"*adequate information about pharmacological and toxicological studies of the drug in animals… sufficient to support a conclusion that it is reasonably safe to begin human trials.*"* This means that the studies must reflect the intended clinical population (i.e. both sexes in this case).

While in some cases, the biodistribution in one of the sexes can be omitted, the sponsor must provide a robust scientific justification (e.g., "no target expression or receptor distribution differences between sexes in preclinical data"). This justification must be included in the BLA nonclinical summary.

There was no justification provided by Moderna for excluding female animals from the biodistribution study, and none exists. Pfizer's study was conducted in both male and female rats and demonstrated distribution and accumulation of the LNPs in the ovaries, indicating potentially serious reproductive toxicity risk. The risk was later confirmed by scientific peer-reviewed studies.[45]

e. Statistically significant increase in fetal abnormalities was found in Moderna's DART study

In a FOIA production,[46] the full report for the study was not included and indicated it is still pending as of 2022. Safety assessments in the study appear to be very limited, however, the following findings were described in the summary.

In the rat pups, the following skeletal malformations were observed:

> In the F1 generation [rat pups], there were no mRNA-1273-related effects or changes in the following parameters: mortality, body weight, clinical observations, macroscopic observations, gross pathology, external or visceral malformations or variations, skeletal malformations, and mean number of ossification sites per fetus per litter.

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[44] Ibid. Footnote 34 p. 3-671
[45] MDPI, *Impact of mRNA and Inactivated COVID-19 Vaccines on Ovarian Reserve* (March 21, 2025)
https://www.mdpi.com/2076-393X/13/4/345
[46] Ibid. Footnote 34 p. 692

> mRNA-1273-related variations in skeletal examination included statistically significant increases in the number of F1 rats with 1 or more wavy ribs and 1 or more rib nodules. Wavy ribs appeared in 6 fetuses and 4 litters with a fetal prevalence of 4.03% and a litter prevalence of 18.2%. Rib nodules appeared in 5 of those 6 fetuses.

Statistically significant increases of skeletal abnormalities constitute a serious signal of risk, requiring additional studies for exclusion/characterization of this risk. To date, the BLA label for SPIKEVAX, Section 8.1 states: *"*Available data from published observational studies following use of mRNA COVID-19 vaccines during pregnancy do not show a risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.*"* Observational studies are considered low-quality scientific evidence that do not meet BLA standards.

When issuing the BLA license, the FDA obligated Moderna to complete several post-market studies, including two studies focusing on use in pregnancy:

Study mRNA-1273-P902: As per the FDA Approval Letter[47] for SPIKEVAX (Jan 31 2022) – this study is described as: *"Moderna mRNA-1273 Observational Pregnancy Outcome Study."* The
milestone dates for this study were listed as Final Protocol Submission: July 31 2022; Study Completion Date: September 30 2023; Final Report Submission: June 30 2024.

Study mRNA-1273-P905: The FDA Approval Letter lists this as: *"*Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries.*"* The milestone dates: Final Protocol Submission: November 4 2021, (completed); Study Completion Date: March 31 2023; Final Report Submission: December 31 2023.

Extensive searches conducted by the authors of this Petition could *not* locate an FDA document or Moderna public disclosure stating that the final report has been submitted or accepted by the FDA.

Non-completed post-market commitments constitute a serious violation of the BLA standard.

It is possible that Moderna completed these studies and the FDA has received the final reports; however, they are not reflected in the BLA label for SPIKEVAX. This too violates the BLA licensing standards for this product.

[47] FDA, *BLA Approval SPIKEVAX* (January 31, 2022)
https://www.fda.gov/media/155815/download

f. Reproductive toxicity in males was not assessed for either Pfizer's Comirnaty (all versions) or Moderna's SPIKEVAX and MNEXSPIKE

For both Pfizer and Moderna, the biodistribution studies demonstrated distribution and accumulation of LNPs in testes, yet no assessments of male fertility were performed. The reproductive toxicity studies (DART) for Comirnaty, SPIKEVAX, and MNEXSPIKE[48] did not vaccinate the male animals prior to mating. This constitutes a major data gap, as the BLA product labels advertise this product as intended for men and women of reproductive age.

For biologics, including vaccines, evaluation of male reproductive organ toxicity is a standard component of the nonclinical safety package supporting a BLA, especially when the product is intended for use in men and women of reproductive potential.

Both the FDA and ICH guidance specify that if the biologic shows tissue distribution to reproductive organs, then specific fertility studies in male animals may be required, assessing sperm count, motility, morphology, mating success and fertility index, testicular weight, and histology. These are typically separate studies or add-ons to repeat-dose toxicity studies.

ICH S6(R1), §5.2.3: *"When reproductive organs are affected in toxicity studies, or there is a plausible mechanism for such an effect, further specific fertility studies should be considered."*

For gene- or mRNA-based biologics, the FDA Guidance (2020): Nonclinical Biodistribution for Gene Therapy Products states that *"Sponsors should evaluate distribution to gonadal tissues and consider potential effects on germline transmission."*

3. Human studies of all Pfizer and Moderna COVID-19 mRNA vaccines utilized non-validated clinical assays for primary efficacy endpoints

Both Pfizer's and Moderna's pivotal studies in humans utilize unvalidated assays for primary efficacy endpoints. Specifically, "Summary Basis for Regulatory Action" document for MNEXSPIKE shows that "RT-qPCR Assay by [redacted] for the Quantification of SARS-CoV-2 RNA [...] is an FDA Emergency Use Authorized In Vitro Diagnostic test for the qualitative detection of SARS CoV-2 nucleic acid in nasal and nasopharyngeal swabs from infected people."[49] For Comirnaty, "Summary Basis for Regulatory Action" document states that "Two clinical diagnostic assays (Cepheid Xpert Xpress RT-PCR assay for the detection of SARS-CoV-2 in clinical specimens and Roche Elecsys Anti-SARS-CoV-2 assay for the

[48] Moderna, *MNEXSPIKE package insert*, "Animal Data" p. 20 of 34 (August 2025) https://www.fda.gov/media/186738/download

[49] FDA, *Summary Basis for Regulatory Action* (MNEXSPIKE) (Section 6 p. 17 of 34) (May 30, 2025) https://www.fda.gov/media/187164/download?attachment

evaluation of serostatus to SARS-CoV-2) were used to assess clinical endpoints. Both assays have received FDA authorization under EUA."[50]

FDA's own nonclinical/clinical assay-validation guidances[51] highlight the need that before a BLA (or pivotal trial), all assays should be "fully validated and demonstrated to be suitable for their intended purpose." Unvalidated (or partially validated/qualified) assays can be scientifically useful, especially in hypothesis-generating or mechanistic studies – but they are not suitable for primary endpoint for approval-level claims, efficacy demonstrations, or lot release for biologics.

Use of unvalidated assays for primary endpoints is unacceptable for BLA licensing due to potentially unreliable/non-reproducible results, uncertain clinical meaning, and false-positive and false-negative results can be deemed to be valid findings.

According to the relevant statutes and the FDA's own regulatory guidance,[52] the FDA may refuse to accept study results as "adequate and well controlled," which are required for approval. 21 CFR standards for clinical trials and for biologics manufacturing expect reliable, validated measurements. Specifically, the statute establishing the legal standard of "adequate and well-controlled investigations" (21 U.S.C. § 355 (FD&C Act) – New drugs) states that "As used in this subsection . . . the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, … on the basis of which it could fairly and responsibly be concluded … that the drug will have the effect it purports or is represented to have …."

FDA may refuse to approve an NDA if there is a "lack of substantial evidence consisting of adequate and well-controlled investigations … that the drug product will have the effect it purports …." (*See 21 CFR § 314.125, and 21 CFR § 601.2*)

4. Currently available BLA mRNA vaccines are EUA vaccines in disguise

As discussed above, non-investigational EUA countermeasures, including vaccines are not required to adhere to BLA standards, including, but not limited to: § 610.1 Tests prior to release of each lot or product; § 610.10 Potency; § 610.11 General safety; § 610.12 Sterility; § 610.13 Purity; § 610.14 Identity; § 610.9 Equivalent methods and processes; Product recall 42 U.S.C. § 262(d)(1), and Misbranding 21 U.S.C. § 352.

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[50] FDA, *Summary Basis for Regulatory Action* (November 8, 2021) (Comirnaty p. 9) https://www.fda.gov/media/151733/download?attachment

[51] FDA, *FDA CBER OTP Town Hall: Cell Therapy CMC Readiness for Late-Stage INDs* (September 5, 2024) https://www.fda.gov/media/183285/download

[52] FDA, *Bioanaytical Method Validation Guidance for Industry* (May 2018) https://www.fda.gov/files/drugs/published/Bioanalytical-Method-Validation-Guidance-for-Industry.pdf

a. FDA Did not Follow BLA Regulatory Standards

Under 42 U.S.C. § 262 – Regulation of biological products law, FDA can (only) license biologics that meet (purity, potency, safety, efficacy, manufacturing compliance and labeling disclosure/marketing compliance, and other applicable legal standards) requirements (ex. mfr, ingredients, disclosure, advertising, warnings, etc.) for investigational products, as discussed in this Petition. Products that reach consumers as EUA countermeasures under a declared emergency cannot satisfy BLA labeling standards retroactively, no matter how widely they have been distributed for emergency use. Full BLA licensing requires end-to-end, start-to-finish compliance with BLA standards. The BLA law is clear.

Therefore, the FDA must withdraw licensure for lack of purity, potency, safety, efficacy, manufacturing compliance and labeling disclosure/marketing compliance, and other applicable legal standards violations**.**

In addition, manufacturers' liability typically induces the manufacturer to remedy issues even without FDA enforcement actions. The fact that the HHS and the United States Government shield manufacturers under the ongoing PREP Act declaration for COVID-19 emergency countermeasures adds to the unenforceability of expected consumer protections. Nondisclosure to the public of the numerous BLA violations and non-enforcement of the pharmaceutical law discussed in this Petition compound the injuries and harm attributable to the COVID-19 mRNA shots.

b. By law, vaccines that were developed and produced under EUA standards cannot retroactively satisfy BLA standards

The Northern District Court in Florida held: "FDA licensure does not retroactively apply to vials shipped before BLA approval." "[V]accines produced after August 23[, 2021] in unapproved facilities – remain product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." The District Court continued, "Indeed, the Summary Basis for Regulatory Action lists a redacted excipient for BLA-approved Comirnaty that does not appear on the ingredient list in the EUA letter." The Court cited the Supreme Court's holding in *Generix*; "two products with the same active ingredients were nonetheless not the same 'drug' under the FDCA where the district court had found that their different excipients created a reasonable possibility that the unlicensed drug was 'less safe and effective' than the licensed one." *Doe v. Austin*, 572 F. Supp. 3d 1224 (November 7, 2022)

The N.D. Fla., Court also found, "A fully approved FDA-compliant vaccine is not the same as its EUA version. There are restrictions on the manner and location of FDA-approved vaccines, for example, that do not apply to EUA products, which have more relaxed manufacturing

specifications. See, e.g., 21 C.F.R. §§ 600.11, 600.20-.21." *Coker v. Austin*, 2022 U.S. Dist. LEXIS 240820, *13 (Nov. 8, 2022).

c. Clinical trials were not conducted to satisfy BLA requirements

According to the CDC:[53]

> Before vaccines are made available to people in real-world settings, FDA assesses the findings from clinical trials. Initially, they determined that COVID-19 vaccines met FDA's safety and effectiveness standards and granted those vaccines Emergency Use Authorizations (EUAs). The EUAs allowed the vaccines to be quickly distributed for use while maintaining the same high safety standards required for all vaccines. Learn more in this video about EUAs.
>
> FDA has granted full approval for some COVID-19 vaccines. Before granting approval, FDA reviewed evidence that built on the data and information submitted to support the EUA. This included:
>
> - preclinical and clinical trial data and information,
> - details of the manufacturing process,
> - vaccine testing results to ensure vaccine quality, and
> - inspections of the sites where the vaccine is made.

According to the FDA:

> The EUA authority is separate and distinct from use of a medical product under an investigational application
>
> ….with regard to pre-EUA activities, an EUA is not a substitute for sponsor efforts to develop the product toward approval, including conducting clinical trials designed to determine whether the product is safe and effective for its intended use. When appropriate, FDA encourages sponsors to design and propose appropriately controlled clinical trials that could be conducted during the emergency response either to run in parallel with an EUA or instead of an EUA.
>
> The EUA authority is separate and distinct from use of a medical product under an investigational application (i.e., Investigational New Drug Application (IND).[54]

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[53] CDC, *COVID-19 Vaccine Basics - Authorization or Approval* (September 3, 2024) https://www.cdc.gov/covid/vaccines/how-they-work.html#:~:text=Before%20vaccines%20are,vaccine%20is%20made

[54] FDA, *Emergency Use Authorization of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders* (January 2017) (*see p. 30 Footnote 35*)

During a Vaccines and Related Biological Products Advisory Committee ("VRBPAC") meeting, the transcript[55] reveals testimony that informed consent was explicitly waived/abandoned by Operation Warp Speed in October 2020. Without IRB and informed consent enforcement, and in accordance with the EUA pathway, Pfizer and Moderna Phase 3 "studies" completed by December 2020 were not legal investigational clinical trials.

Testimony by Marion Gruber, Ph.D., formerly of the FDA, explained: "Use of an investigational COVID-19 vaccine under an EUA is not subject to informed consent requirements." "Under EUA, it is your choice to receive or not receive the vaccine."[56] This was admitted in 2021 during the time when only EUA versions of the product were being shipped in the United States.

Doran Fink (Operation Warp Speed ("OWS")) also testified that the COVID-19 vaccines were not going to utilize the investigational regulatory pathways. Specifically, responding to the question whether OWS considered using the Expanded Access Use (EAU) pathway, Fink replied: "So among many other things, those regulations require use of an institutional review board and also obtaining informed consent from recipients of the investigational vaccine according to regulations for clinical investigations -- research use of investigational vaccines. And so operationally speaking, an expanded access protocol would add some complexity, and that is why Emergency Use Authorization is being considered primarily as the mechanism for addressing the public health emergency that has been declared."[57] OWS was not going to use an investigational pathway and instead would utilize the non-investigational EUA pathway, citing the desire of OWS not to be bound by the requirements of the IRB and informed consent.

21 U.S. Code § 360bbb-3(k) Relation to other provisions, confirms:

> If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 355(i), 360b(j), or 360j(g) of this title or any other provision of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262].

Thus, the clinical trials for COVID-19 vaccines were not subject to IRB review and did not undergo clinical trials sufficient to satisfy the statutory BLA requirements.

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

[55] FDA, *FOOD AND DRUG ADMINISTRATION (FDA) Center for Biologics Evaluation and Research (CBER) 161st Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting transcript* (October 22, 2020) https://www.fda.gov/media/143982/download,

[56] Ibid. at p. 36

[57] Ibid. at p. 203-204

C. Conclusion to Statement of Grounds

The FDA's mission is "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products…."[58] President Roosevelt's signing of the FD&C Act closed many safety and efficacy loopholes and improved the landscape of consumer protection forever.[59]

After the devastation of Thalidomide, President John F. Kennedy signed into law landmark legislation that established the scientific framework used today by the FDA that "required drug manufacturers to prove scientifically that a medication was not only safe, but effective."[60] The 1962 Kefauver-Harris amendment set in motion regulatory standards for biologics licensure that require proven efficacy "to ensure that consumers will not be the victims of unsafe and ineffective medications."

The FDA published proposed procedures for the review of safety, effectiveness, and labeling of biological products in the Federal Register on August 18, 1972. The preamble stated, "The importance to the American public of safe and effective vaccines…and other biological products cannot be understated."[61] These historic advances require reflection.

Biologics, as with all drugs and devices, must have adequate directions for use and be proven safe and effective before FDA approval and licensure. The FDA erred with the anthrax vaccine, and it took a Citizen Petition[62] and a federal court decision to make it comply with the FD&C Act.[63] At other times, the FDA has upheld its mission to make tough regulatory rulings, as the Supreme Court has acknowledged.[64] With this Petition, we look forward to the FDA's appropriate, tough regulatory action to remove COVID-19 mRNA vaccine licensure due to FDA's failure to follow federal law and its own regulatory guidance for BLA products.

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[58] FDA, *What We Do* (November 21, 2023) https://www.fda.gov/about-fda/what-we-do#mission
[59] FDA, *80 Years of the Federal Food, Drug, and Cosmetic Act* (Nov. 7, 2018), https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act
[60] FDA, *Kefauver-Harris Amendments Revolutionized Drug Development* (Oct. 9, 2012), https://www.gvsu.edu/cms4/asset/F51281F0-00AF-E25A-5BF632E8D4A243C7/kefauver-harris_amendments.fda.thalidomide.pdf
[61] HHS, FDA, *Biological Products March 1936-March 1978*, (August 18, 1972) Preamble, p. 56, 37 Fed. Reg. 16679
[62] **62.1** *Dingle/Rempfer Citizen Petition 01P-0471/CP1* (October 12, 2001) https://img1.wsimg.com/blobby/go/4fa7f468-a250-4088-926e-3c56a998df1f/downloads/citizen%20petition%20ava%20rempfer%20dingle.pdf?ver=1620969217312,
62.2 HHS, Response (August 8, 2002) https://downloads.regulations.gov/FDA-2001-P-0119-0003/attachment_1.pdf.
[63] *Doe # 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 Order
[64] U.S. Reports: *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609 (1972), https://tile.loc.gov/storage- services/service/ll/usrep/usrep412/usrep412609/usrep412609.pdf.

We ask the FDA to be ever cognizant of its longstanding, statutory mission and duty to protect the public health and to ensure that the American public receives only safe and effective vaccines. Most Americans are not aware of the strict compliance requirements for licensed (BLA) COVID-19 vaccines and the numerous violations of the BLA standards that are currently allowed for the marketed COVID-19 vaccines, as described in this Petition. They do not know that the FDA has fully approved these vaccines as safe and effective under the FD&C Act when they do not meet licensed (BLA) standards. Americans are unaware that the FDA, even though it is responsible for protecting public health, has failed to enforce the law. Reversing these licensures or granting EUA status is imperative.

Acting on this Citizen Petition will enhance the FDA's credibility with the public. Given the obvious safety, effectiveness, labeling, and branding concerns over mRNA COVID-19 vaccines detailed above, along with anticipated comments on this docket, we respectfully appeal to the FDA to implement the actions requested in this Citizen Petition.

III. ENVIRONMENTAL IMPACT

The undersigned hereby state that the relief requested in this Petition will have no environmental impact, and therefore an environmental assessment is not required under 21 C.F.R. §§ 25.30 and 25.31.

IV. ECONOMIC IMPACT

Economic impact information will be submitted upon request of the Acting Commissioner.

V. CERTIFICATION

The undersigned certify that, to their best knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data and/or information known to the Petitioners that are unfavorable to the Petition. Further, the undersigned certify that they have taken reasonable steps to ensure that any representative data and or information which are unfavorable to this petition were disclosed to them.

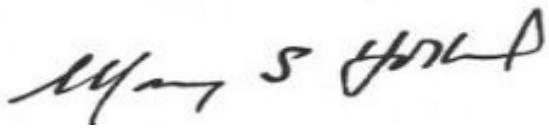
They further certify that the information upon which they have based this action requested herein first became known to the parties on or about the following date: December 2020.

The undersigned do not expect to receive payments, including cash and other forms of consideration, to file this information or its contents.

We verify under penalty of perjury that the foregoing is true and correct as of the date of this submission of this petition.

December 8, 2025

Sincerely,



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