# The Fallacy of Interchangeability

Rogue political and corporate actors promoted that an EUA drug, sharing formulation with a licensed product, can be mandated. The fallacy of mandating an EUA COVID-19 vaccine as a licensed drug constitutes a felony. (U.S. Code Title 21)

The FDA statement relating to Pfizer's licensed and EUA COVID-19 drugs added to misperception:

> "The licensed vaccine has the same formulation as the EUA vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness." — FDA (August 23, 2021 letter to Pfizer) (emphasis added)

Peter Marks, M.D., Ph.D., is the Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration. Dr. Marks provided a declaration in COKER v. AUSTIN (3:21-cv-01211) clarifying the intent of FDA's statement:

> "FDA provided this information [interchangeability] in the authorization letter to make clear that pharmacies and other healthcare practitioners could provide the vaccination series to recipients using Pfizer-BioNTech, Comirnaty, or both (e.g., first dose of Pfizer-BioNTech followed by second dose of Comirnaty, or vice versa), since the formulation was the same and both products are made by the same manufacturer under current good manufacturing practice requirements. FDA included the interchangeability information in the authorization letter to avoid the unnecessary operational complications that may have resulted if pharmacies or other healthcare practitioners had believed that individuals who had received Pfizer-BioNTech for the first dose were not authorized to receive Comirnaty for the second dose, or vice versa. While FDA determined Comirnaty and the

> Pfizer-BioNTech Covid- 19 vaccine are medically interchangeable, there are legal distinctions between BLA-approved and EUA-authorized products." (emphasis added)

LEGAL DISTINCTIONS

Drugs and biologics are assigned to a class, category, classification, or schedule by the FDA before access protocols are granted for regulatory enforcement purposes (e.g., COMIRNATY belongs to a class of drugs called Vaccines). Drugs approved and licensed by the FDA for general commercial marketing must also be approved for indications and usage. Indications mean the medical condition (purpose) for which the drug is promoted, and under what conditions (e.g., age, gender, etc.)

Pfizer's COMIRNATY's drug insert sheet states that its indication is "a vaccine approved for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older." (emphasis added)

Pfizer has two different statements for the Pfizer-BioNTech COVID-19 Vaccine (EUA) listed in their EUA drug insert sheets:

> 1) "Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients," or
> 2) "The duration of protection against COVID-19 is currently unknown."

The FDA classifies an EUA drug or biologic as experimental (21 CFR 312.3) with no legal intent (indication). Notice above how COMIRNATY "prevents" and BioNTech's level of protection "is currently unknown."

Once a drug has been approved for indication, the manufacturer may not promote that drug outside of that indication. For example, Pfizer was previously fined over $2B and convicted of a felony for promoting four drugs outside of their approved indication.

> "Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called 'off-label' uses – i.e., any use not specified in an application and approved by FDA." (Justice Department Announces Largest Health Care Fraud Settlement in Its History, 2009)

With FDA approval, Pfizer is essentially doing the same thing today by referencing the approved indication of licensed COMIRNATY within the EUA fact sheet. The insert sheet infers that the COMIRNATY indication applies to its EUA product. The fact that Pfizer has not once shipped its licensed product for general commercial marketing demonstrates that the reference was premeditatively misleading. Formerly, the FDA prosecuted pharmaceutical companies for engaging in similar misinformation schemes. Never should two legally distinct drugs with significant consequences to the end-user share the same drug insert sheet.

Furthermore, authorized "emergency stakeholders" for the EUA product and healthcare practitioners have engaged in unlawful activity by promoting the EUA vaccines as being 'safe and effective.'

> "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug…its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation…" (21 CFR 312.7)

During the pandemic, the "sponsor" is the United States Government, and the "person" acting on behalf of a sponsor include State Governors, military commanders, healthcare workers, and other emergency stakeholders.

When the FDA approves (licenses) or authorizes (under EUA) a drug, it is assigned a label for regulatory enforcement purposes. Attached to that label is a substantial set of laws having significant consequences for the manufacturer, distributor, administrator, recipient, and courts involved in

regulating its legal environment. Laws associated with a licensed drug are uniquely different from those associated with an experimental drug having no legal indication.

For example, a drug under 21 U.S.C. §360bbb-3 (EUA laws) protection requires individuals to volunteer for biomedical research and forfeit certain litigation rights when participating. Should a doctor administer the Pfizer BioNTech COVID-19 EUA drug to an individual, they must do so according to the Scope of Authorization outlined in the drug's EUA letter. The doctor is under no such obligation when administering COMIRNATY.

Case in point: same formulation; different classifications, labels, and laws.

All EUA COVID-19 vaccines are classified by the FDA as Investigational New Drugs (IND) and must adhere to IND laws. Such laws require authorities to establish a legally approved environment, ensuring individuals are not under "sanctions," "coercion," and or "undue influence" before offering the opportunity to participate in the EUA process. This legal requirement is directly attributed to the fact that the drug has no legal indication and is only used for experimental clinical research. Furthermore, Congress prohibits authorities from acting in a fiat manner, using laws interchangeably to fit their unjust political whims. Therefore, by what authority does a Governor, mayor, or CEO mandate what Congress deems unlawful?

In a court of law, only labels, classifications, and associated laws are relevant, not shared formulation. If a person attempted to sue Pfizer utilizing laws associated with COMIRNATY but received their EUA drug, the judge would not allow it. Instead, the judge would rule that the laws associated with the EUA drug must be utilized since that is what the plaintiff received. Just because an EUA drug shares formulation with a licensed drug and may be utilized interchangeably for medical purposes does not grant authorities the power to use laws associated with those two drugs interchangeably.

Claims of interchangeability are nonsensical and designed to confuse the judiciary about the rights of American citizens. Judges need only ask which laws are associated with the drug's label. If the drug is under an EUA,

defendants must comply with those laws. Lawyers who argue patently untrue claims in a court of law should be disbarred for life.

The shared formulation is irrelevant for purposes of governance and mandates. For example, Pfizer's COMIRNATY was under an EUA simultaneously with BioNTech COVID-19 Vaccine. COMIRNATY had to come under an EUA because it was being utilized for an indication (age of recipient) not approved by the FDA, demonstrating that its formulation was not part of the regulatory environment. The label is the law, not the formulation.

Authorities may not mandate the use of an unlicensed product. To do so constitutes a felony because they are introducing an EUA product into interstate commerce "as if" it is a licensed product in defiance of federal law.

> "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." — 21 U.S.C. §355(a)

No EUA drug, biologic, or device fulfills 21 U.S.C. §355(a) legal requirements. Governors, mayors, school boards, and employers violated federal law when mandating EUA COVID-19 vaccines because they treated BioNTech COVID-19 Vaccine as if it was approved and licensed by the FDA for general commercial marketing despite the FDA informing them otherwise. All committed criminal fraud by claiming non-existent statute to perpetuate their unlawful behavior on an unaware population.

Lastly, there does not exist a statute declaring that if a drug is under EUA expanded access protocols and shares formulation with a licensed drug, then the right of individuals to refuse that drug is forfeited. Therefore, employers violated significant federal law when requiring clinical research drug participation as a condition of employment.

This letter describes in part what the FDA meant by stating "the products are legally distinct."

**“Individuals have the explicit right to refuse a COVID-19 EUA vaccine without incurring a penalty or losing a benefit to which they are otherwise entitled. This statement is irrefutable by statute.” - Brian Ward**

Discover the truth about the above statement by reading, ‘The Legal Right To Refuse’ at CovidPenalty.Com

Over 1000+ hours of research into understanding clinical research laws and their application during a pandemic has been invested by Mr. Brian Ward. He is available for expert consultation, testimony, and legislative efforts.

Signed//
Brian Ward
February 08, 2023