[Non]Regulatory and [Il]Legal Framework Behind “Covid Countermeasures”

November 15, 2023

Sasha Latypova, sashalatypova.substack.com

Summary

- Covid-19 injections marketed as "vaccines" reached commercial market as "EUA countermeasures under Public Health Emergency".
- Based on EUA status, they cannot be used as investigational products (21USC 360bbb), no IRB, no informed consent rules apply, and not subject to the US FDA evidentiary standards for safety and efficacy. Only “maybe effective” criterion and declarations of “circumstances that justify” apply.
- Despite being described as “investigational products” (e.g. in Pfizer’s SEC reports), they cannot meet the standards for properly regulated pharmaceuticals or biomedical research products.
- Absence of true and enforceable consumer safeguards in relation to these products makes them potential poisons with no lawful mechanisms to rectify the harm while they remain in circulation.

Legal Structure for Deployment of EUA Countermeasures

"Public Health Emergency" declaration, no review or stopping criteria

EUA Countermeasures funded by US DOD under Defense Production Act and Other Transaction Authority

Ex-US: Liability of manufacturers is likely removed via predatory contracts which must be disclosed

FDA's Normal Regulatory Pathways for Market Approval

FDA Approved Marketed Drug:

- Labeling
- Marketing/Advertisement
- Packaging
- Distribution
- Traceability
- cGMP compliance
- Recalls & other enforcement

Investigational Drug (under IND exemption):

- Clinical trial program
- Investigational human subject safety
- cGMP compliance
- Evidentiary data for safety and efficacy review
- Risk/benefit assessment
- Labeling claims

"Expanded Access Use" Product (21CFR 312.300):

- Has "emergency use" language
- Sometimes referred to as "EAU" or "EUA"
- ONLY if no alternatives exist
- NO ability to mandate use
- Temporary authorization (typically 1 year)
- Requires compliance with investigational drug use regulations, requires IRB and informed consent
- EAU and full approval cannot co-exist for same product

HHS-Declared Emergency!

"EUA Countermeasure under PHE" § 564 of FD&C Act

Investigational New Drug regulations do not apply!

No IRB, no informed consent required

"Maybe effective" opinion of HHS is the only applicable criterion for commercial deployment

Clinical trial data is not required = when fraud is proven it's not material for FDA's decision!

Co-exists with declared "fully FDA approved" versions.

FDA “Emergency” Guidance for Covid-19 Vaccines States:

- FDA Guidance = Non-binding recommendations to pharmaceutical manufacturers
- “General Considerations:
  - COVID-19 vaccines licensed in the United States must meet the statutory and regulatory requirements for vaccine development and approval, including for quality, development, manufacture, and control (section 351(a) of the Public Health Service Act (PHS Act), (42 U.S.C. 262)).
  - The vaccine product must be adequately characterized and its manufacture in compliance with applicable standards including current good manufacturing practice (cGMP) (section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) and 21 CFR Parts 210, 211, and 610). It is critical that vaccine production processes for each vaccine are well defined and appropriately controlled to ensure consistency in manufacturing”.

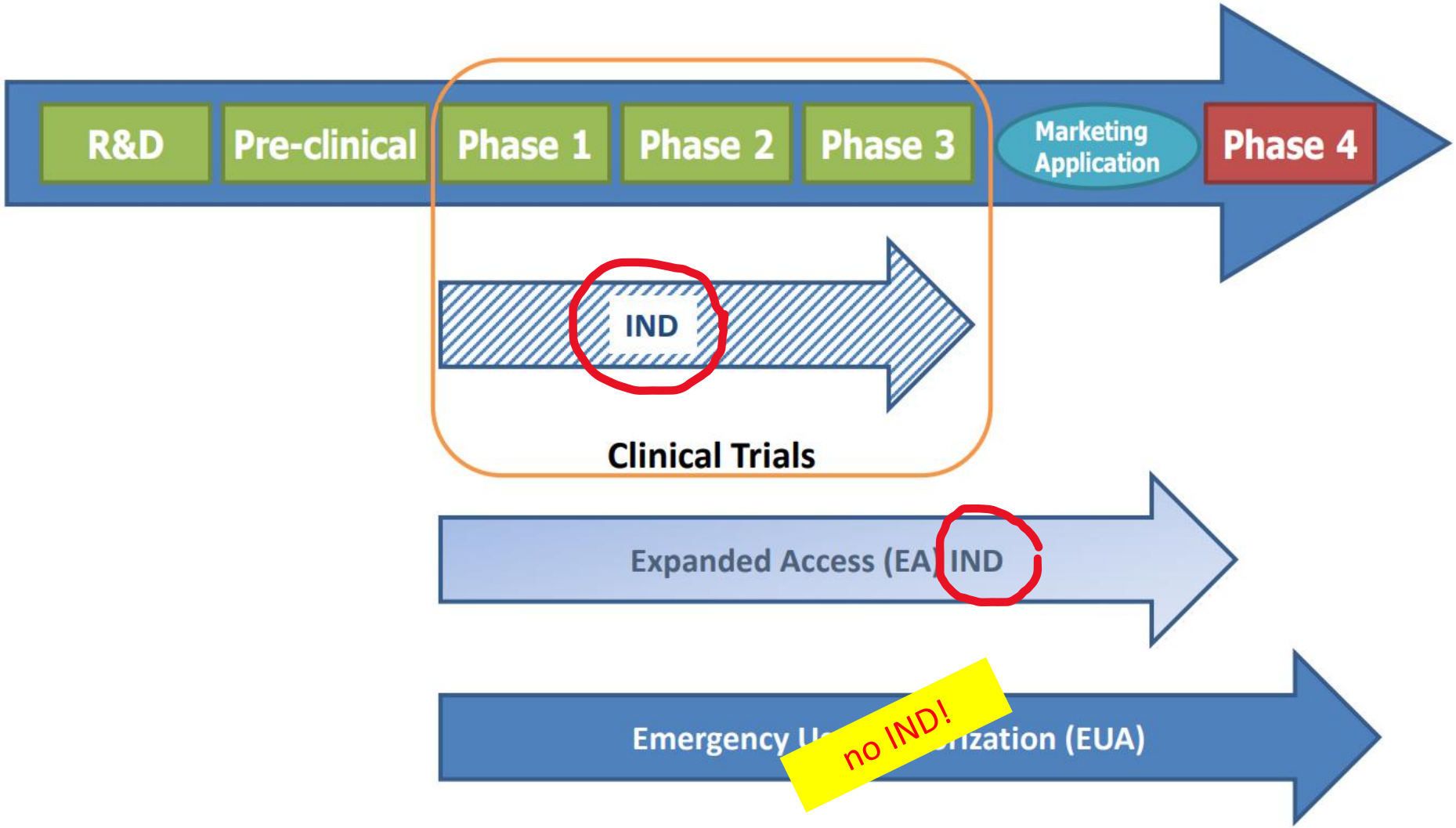
…But EUA Countermeasures are Not Investigational!

- 21 USC 360bbb-3(k): 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].
- *Clinical investigation* means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

If a product cannot be investigational, there is no process for assembling the regulatory evidence of safety, efficacy and manufacturing control for purposes of compliance with Section 351(a) of the Public Health Service Act (PHS Act), (42 U.S.C. 262) and cGMP (section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) and 21 CFR Parts 210, 211, and 610).

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312

Regulatory Mechanisms to Enable Access to Investigational Products



www.fda.gov/medicalcountermeasures

https://public4.pagefreezer.com/browse/FDA/15-09-2022T08:43/https://www.fda.gov//media/154536/download

Legal/Regulatory Mechanisms for Emergency Use of MCMs

- **Expanded Access (EA) to Investigational Drugs and Devices**
  - FD&C Act § 561
  - Investigational New Drug Application (IND) (21 CFR Parts 312.300-320)
  - Investigational Device Exemption (IDE) (21 CFR Part 812)

- **Emergency Use Authorization (EUA)**
  - FD&C Act § 564

- **Other Emergency Use Authorities**
  - FD&C Act §§ 564A, 505-1, and 564B
  - Only applicable to FDA-approved MCMs

https://public4.pagefreezer.com/browse/FDA/15-09-2022T08:43/https://www.fda.gov//media/154536/download

Why are legal/regulatory mechanisms for emergency use of MCMs needed?

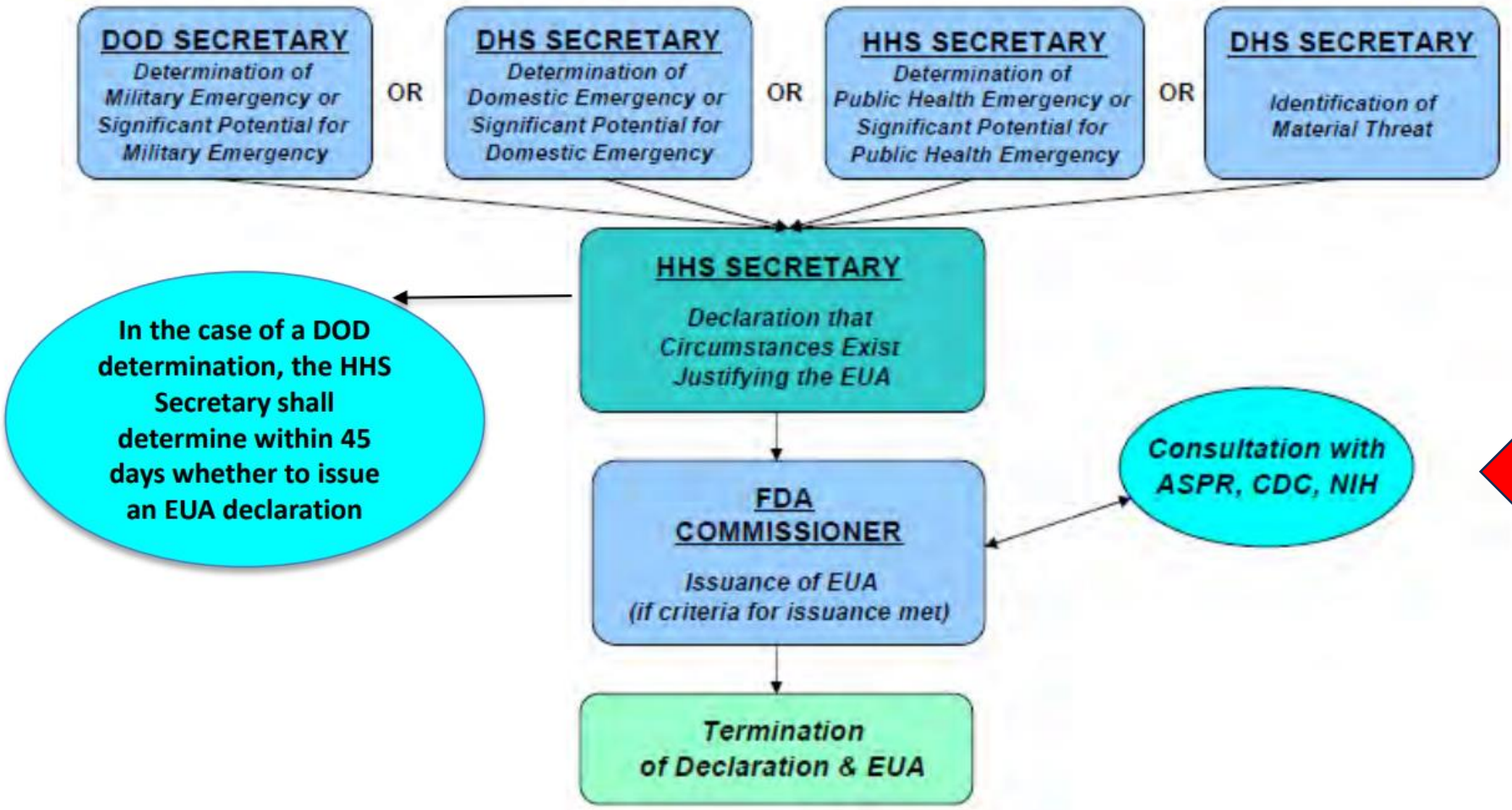
They knew they needed to violate the law to put mRNA on the market!

Without these mechanisms, certain preparedness and response activities could otherwise violate provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act:

- Some MCMs needed for a response might not be approved, licensed, or cleared by FDA
- Some MCMs needed for a response might be approved by FDA, but not for the emergency use (e.g., for a new indication)
- Some might be approved for the emergency use, but mass dispensed without individual prescriptions, with special instructions, or beyond expiry their dates
- Also, to ensure any available HHS Public Readiness and Emergency Preparedness (PREP) Act protections apply

https://public4.pagefreezer.com/browse/FDA/15-09-2022T08:43/https://www.fda.gov//media/154536/download

Summary of Process for EUA Issuance



No clinical trial data is needed for EUA issuance!

https://public4.pagefreezer.com/browse/FDA/15-09-2022T08:43/https://www.fda.gov//media/154536/download

(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION

The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes—

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, in trials, if available, it is reasonable to believe that—

(A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product a this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;

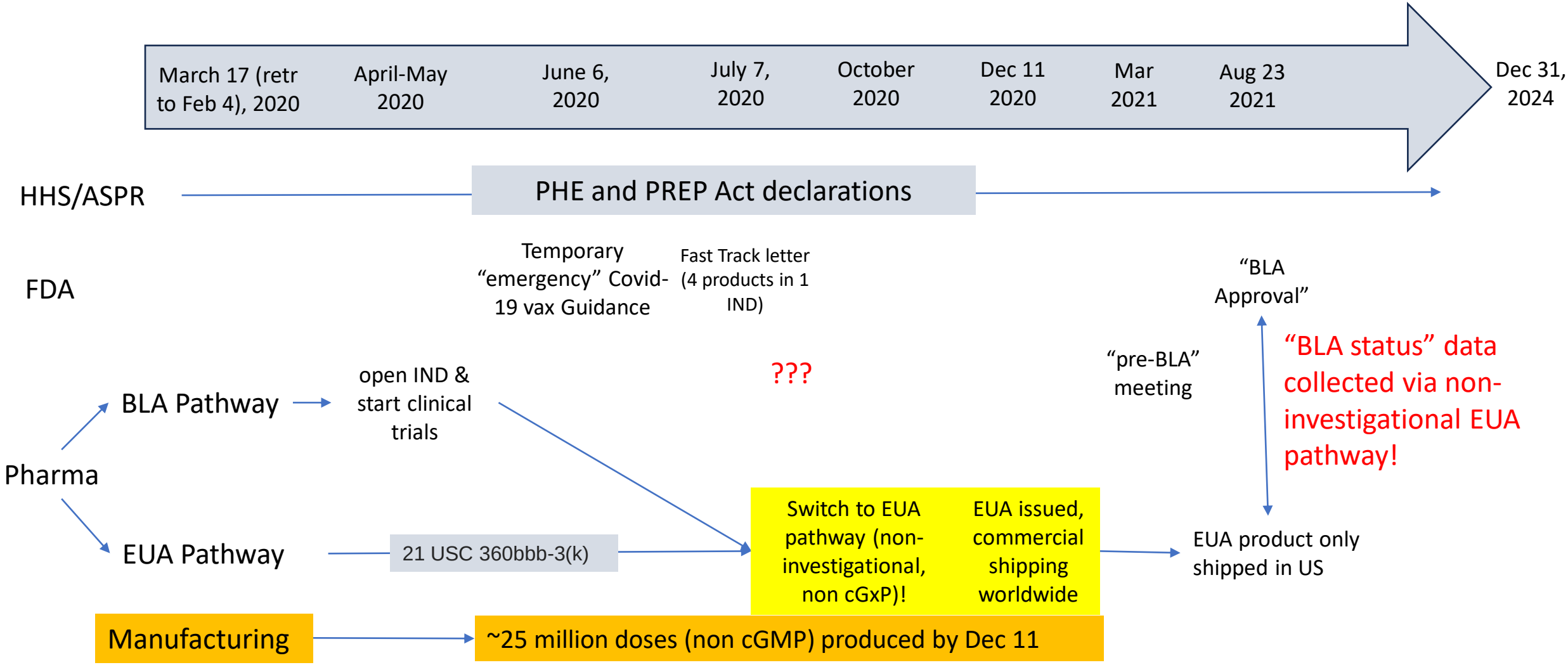
(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and

(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

Countermeasures deployed at sole discretion of the HHS Sec during HHS-declared PHE:

"May be effective" criterion, no data needed, no Congressional or judicial review allowed, no stopping criteria!

Timeline of Covid-19 shots (Pfizer)



Comirnaty – Summary Basis for Regulatory Action (https://www.fda.gov/media/151733/download)

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.

"Expanded Access Use" vs. Non-investigational EUA Pathway

- P201/408 of transcript:

- *"DR. KURILLA: And then for Doran [FINK], did you consider at all the possibility of an expanded access protocol for those specific groups that you would issue the indication for the EUA instead of an EUA?*
- *P203 Dr. FINK: Yeah. So to answer your question about an expanded access protocol, that is another regulatory mechanism for providing access to investigational vaccine. I think if we were to consider an expanded access protocol of the same size and scope as what is being considered for an Emergency Use Authorization, then the benefit/risk considerations and the data to inform those benefit/risk considerations and allow that type of use would be highly similar. The differences between expanded access use and Emergency Use Authorization are that expanded access use is done -- or is carried out under FDA's investigational new drug regulations. 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."*

Both Clinical Trials Cited as Basis for BLA are Conducted Using EUA Non-Investigational Pathway

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

August 23, 2021

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

With respect to whether or not the typical cGMP regulations in manufacturing apply to COVID shots:

- https://uscode.house.gov/view.xhtml?req=(title:21%20section:360bbb-3a%20edition:prelim)

(c) Current good manufacturing practice

(1) In general

The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including requirements under section 351 or 360j(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 360j(f)(2) of this title.

(2) Effect

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and **shall not be deemed adulterated or misbranded** under this chapter because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

=**There are no required standards for quality-control in manufacturing; no inspections of manufacturing procedures; no prohibition on wide variability among lots; no prohibition on adulteration; and no required compliance with Current Good Manufacturing Practices. EUA products, even though unregulated and non-standardized, "shall not be deemed adulterated or misbranded." 21 USC 360bbb-3a(c). 2013.**

"Vaccine BLA Approval" is based on non-investigational use of a drug – a deception

- Vaccines ordered as "prototypes" and "demonstrations" (i.e. fakes) in DOD contracts
- Clinical trials were not ordered by DOD/HHS - not legally possible for EUA countermeasures under PHE
- cGxP compliance is not possible to enforce due to the EUA countermeasure status and PREP Act
- This means people in Costa Rica were deceived into an illegal medical experiment with no informed consent

No Clear Mechanism to Take Dangerous Adulterated EUA Countermeasure Off Market

FDA Responds After Being Urged to Recall Pfizer's Vaccine Over DNA Fragments, October 31, 2023 The Epoch Times

The U.S. Food and Drug Administration (FDA) is refusing to recall Pfizer's COVID-19 vaccine, promoting the view that the inclusion of a previously-undisclosed DNA sequence that leaves behind fragments is not of concern.

The FDA is not required to take Pfizer's COVID-19 vaccine, or other COVID-19 shots, off the market, an agency spokeswoman told The Epoch Times via email.

"With over a billion doses of the mRNA vaccines administered, no safety concerns related to the sequence of, or amount of, residual DNA have been identified. With regard to the FDA-approved mRNA vaccines, available scientific evidence supports the conclusion that they are safe and effective," the spokeswoman added.

Pharmaceutical regulations (IND, evidentiary standards of safety/efficacy and risk benefit assessments) DO NOT APPLY to EUA Countermeasures. No criteria for product recalls or FDA enforcement apply.
"Billions of doses given" is not a safety standard. Billions of cigarettes and illicit drug doses have been consumed, too.

https://www.theepochtimes.com/article/fda-responds-after-being-urged-to-recall-pfizers-vaccine-over-dna-fragments-5519632

Absence of true and enforceable consumer safeguards in relation to these products makes them potential poisons with no lawful mechanisms to rectify the harm while they remain in circulation.