Memo Re EUA Countermeasures for doctors, pharmacists, employers, schools, sheriffs, county commissioners and state lawmakers

Purpose: To clarify the legal status of EUA Medical Countermeasures (MCMs)

Summary: The process through which the EUA products enter interstate commerce and claims about their safety, efficacy or contents are based solely on the HHS Secretary opinion, which requires no supporting scientific evidence.

Misrepresentation of safety, efficacy and/or contents of EUA products is allowed by federal law.

Thus, claims provided by federal health authorities and/or manufacturers cannot be considered reliable sources of information.

1. Pursuant to Section 564 of the FD&C Act, as amended by PAHPRA, 2013, and the Supremacy Clause of the United States Constitution (Article VI, Clause 2), EUA MCMs have potentially been exempted from testing using Good Laboratory Practices, Good Clinical Practice, including informed consent, and from being assessed to determine if Risk Evaluation and Mitigation Strategies (REMS) are necessary.

2. Safety regulations governing the manufacture, shipment, holding, dispensing, administration and labeling do not necessarily apply to MCMs, rather, they are subject to an opinion by FDA and HHS officials without proper Congressional or judicial review for the duration of HHS-declared emergency. The declaration of emergency is likewise without properly defined stopping criteria, nor Congressional or judicial review.

3. Under federal law, FDA must approve any new drug product prior to a manufacturer introducing it into interstate commerce.[1] This process requires manufacturer to open an Investigational New Drug application and obtain an exemption from the FDA for its use in regulated investigational clinical research (trials). This normal regulated process is therefore referred to as an "investigational" regulatory pathway. It requires a manufacturer to conduct regulated clinical research (trials) under the IND, obtaining Institutional Review Board's (IRB) approval for clinical trial protocols, independent safety monitoring oversight, and properly executed informed consent from clinical trial volunteers. In addition, manufacture of the drugs and biologics subject to the investigational status is regulated by the current Good Manufacturing practices (cGMP)[2]

4. EUA Medical Countermeasures are a radically different, defined in law as ***non-investigational*** drugs, biologics and devices deployed under FDA's authorization power known as the "Emergency Use Authorization" (EUA) process[3].

[1] See, e.g., 21 U.S.C. § 355 (drugs); 42 U.S.C. § 262 (biologics).
[2] CFR Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799, and 800-1299.
[3] Section 564 FD&C Act. Note that the EUA pathway should not be confused with the "Expanded Access Use" regulatory pathway which is often colloquially referred to as an "emergency use". The expanded access is an investigational pathway and is regulated in the same manner as all normal drug approvals. (21 CFR 312.310-320)

5. The EUA process is used only when the United States Secretary of Health and Human Services declares an emergency.[4]

6. By law, the EUA process is non-investigational[5]: while the manufacturers may choose and FDA may ask to undertake some of the activities typically expected from an investigational clinical trial and manufacturing validation process, none of the typical regulatory standards are applicable in an enforceable way.

7. FDA has the discretion to issue an EUA if the applicant shows that its product **"may be effective"** in treating the relevant disease or condition[6]. It is important to emphasize that **no other criteria for approval apply in an enforceable way**.

8. FDA will approve EUA products on incomplete information so long as the applicant shows that the "known and potential benefit of the product" merely "outweigh[s] the known and potential risks"[7] and considers it unlikely that "comprehensive effectiveness data" will be available before an EUA grant. In contrast, for an investigational drug (under normal regulatory approval process) the FDA "shall" deny approval if the applicant "do[es] not show that such drug is safe."[8]

9. Therefore, the EUA status of an MCM precludes collection of investigational (subject to IRB and informed consent) clinical trial data and thus precludes reliable, valid scientific knowledge of risks and benefits associated with the EUA Countermeasure.

10. The EUA process precludes meaningful informed consent from the recipients of the product: while Congress mandated that FDA directly inform health care professionals and product recipients of any "significant known and potential benefits and risks,"[9] formal regulated clinical trials are neither required nor possible for a non-investigational EUA product. Thus, there is no reliable and scientifically valid information on risks and benefits of an EUA, especially for extremely novel technologies such as mRNA shots.

11. Furthermore, there are no required standards for quality-control in manufacturing; no inspections of manufacturing procedures; no lot-release testing and no prohibition on wide variability among lots; no prohibition on adulteration; and no required compliance with Current Good Manufacturing Practices (cGMP). EUA products, even though unregulated and non-standardized, "shall not be deemed adulterated or misbranded."[10]

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[4] 21 U.S.C. § 360bbb-3(a)(1), (b).
[5] 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].
[6] 21 U.S.C. § 360bbb-3(c)(2)(A)
[7] 21 U.S.C. § 360bbb3(c)(2)(B)
[8] 21 U.S.C. § 355(d)(2); See also 42 U.S.C. § 262(a)(2)(RB) (biologic approved only if it actually "is . . . safe").
[9] 21 U.S.C. § 360bbb-3(e)(1)(A)(II)
[10] 21 USC 360bbb-3a(c).

In summary, the process through which the EUA products enter interstate commerce and claims about their safety, efficacy or contents are based solely on the HHS Secretary opinion, which requires no supporting scientific evidence.

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Thus, claims provided by the federal health authorities or manufacturers cannot be considered reliable sources of information.

Additional References**:**

January 2017 Emergency Use Authorization of Medical Products and Related Authorities, Guidance for Industry and Other Stakeholders, Procedural OMB Control No. 0910- 0595 Expiration Date 09/30/2025[11], particularly pages 15, 22-25, 27, 28, 33, and 39-41.

April 2019 Risk Evaluation and Mitigation Strategies (REMS): FDA's Application of Statutory Factors in Determining When a REMS Is Necessary, Guidance for Industry, April 2019 [12]

PowerPoint briefings on Section 564 of the FD&C Act [13]

- August 25-27, 2020 - FDA-CDC Joint Learning Session, Regulatory Updates on Use of Medical Countermeasures Preparedness Summit.[14] (FDA-Office of Counterterrorism and Emerging Threats Regulatory Counsel Elizabeth Sadove.
- Feb. 10, 2021 PHEP Connects Webinar; Emergency Response Authorities and Access to Medical Countermeasures (FDA-OCET Regulatory Counsel, Brooke Courtney)
- March 1, 2021 - American Bar Association Health Law Section Overview of FDA's Emergency Use Authorization (EUA) Authority & COVID-19 Response (FDA-OCET Regulatory Counsel Brooke Courtney)
- March 18, 2021 - Council of State and Territorial Epidemiologists, Public Health Law Webinar; Overview of FDA's Emergency Use Authorization (EUA) Authority: Implications for COVID-19 Vaccination [15] (FDA-OCET Regulatory Counsel Brooke Courtney)
- April 2021 - 2021 Preparedness Summit, Tri-Agency Task Force for Emergency Diagnostics Session, Overview from FDA[16] (FDA-OCET Regulatory Counsel Jennifer Ross)

[11] www.fda.gov/media/97321/download
[12] https://www.fda.gov/media/100307/download
[13] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-legal-and-policy-presentations-publications-and-qas
[14] https://public4.pagefreezer.com/browse/FDA/15-09-2022T08:43/https://www.fda.gov//media/154536/download
[15] https://www.fda.gov/media/154527/download?attachment
[16] https://www.fda.gov/media/154310/download?attachment

- May 15, 2021 - Pennsylvania Society for Post-Acute and Long-Term Care Medicine, Spring Symposium, FDA's EUAs and Other Related Authorities [17] (FDA-OCET Regulatory Counsel Jennifer Ross)
- Nov. 21, 2021 - BARDA (Biomedical Advanced Research and Development Authority) Industry Day. FDA's EUAs and Other Related Authorities [18] (FDA-OCET)

Key Enabling Statutes

Six primary enabling statutes include:

- Title 21 – Federal Food and Drugs Act, at §360bbb et seq, "Expanded access to unapproved therapies and diagnostics," as established in 1997;
- Title 42 – Public Health Service Act, at §247d et seq, "Public health emergencies," as established in 1983;
- Title 42 – Public Health Service Act, at §300hh et seq, "National All-Hazards Preparedness for Public Health Emergencies," as established in 2002;
- Title 42 – Public Health Service Act, at §300aa-1 et seq, "Vaccines," as established in 1986;
- Title 10 – Armed Forces Act, at §4021 et seq, "Research projects: transactions other than contracts and grants," as established for DoD use for "prototype" contracting in 2015;
- Title 50, Chapter 32, §1511 et seq, "Chemical and Biological Warfare," as established in 1969.

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[17] https://www.fda.gov/media/154313/download?attachment
[18] https://www.fda.gov/media/154532/download?attachment