EUA COUNTERMEASURES AND PREP ACT

Urgent: Please submit your comments to the FDA for the Citizen Petition for Reclassification of mRNA as Gene Therapy

Petition submitted to the FDA from our friends at the Interest of Justice

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Interest of Justice - please subscribe and support IOJ. I know these folks and they are true fighters, scraping pennies to carry forward this outstanding work.

Link to the Citizens Petition on the FDA site - this is an excellently written document discussing the applicable law, legislative history, the wrongful actions committed by the FDA, HHS and DOD during the faked covid “pandemic”, deployment of “countermeasures” falsely advertised as medicinal products, and outlining the concrete steps that the agency must take for reform and accountability. The document is fairly long (150 pages) and I am going to provide a briefing summary of it in this post below.

my work, consider becoming a free or paid subscriber.

This document blows MAHA lies, i.e. *"we need more gold standard science to convince every last brainwashed idiot whom we ourselves thoroughly brainwashed in the first place"*, out of the water! We don't need any science for this. No science was needed for the criminal cartel to commit their crimes, to launch the fake pandemic exercise and to strip us of our Constitutional rights. They use "gold standard science" as a defensive narrative to continue committing their crimes. To stop them we must force them to follow the law. And in order to do that, we must educate ourselves and others.

Link to submit your comment to this petition - DO IT NOW!

IOJ Citizens Petition Briefing:

Executive Summary:

This briefing document summarizes a Citizen Petition submitted to the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) on June 17, 2025. The petition, filed by "Interest of Justice" (Dustin Bryce Rosondich and Xylie Desiree Eshleman), requests the immediate reclassification of all COVID-19 mRNA and adenoviral vector products as "gene therapy products." The petitioners argue that the current classification as "vaccines" is a misapplication of regulatory standards, leading to statutory violations, international legal contraventions, and insufficient safety oversight.

Based on their mechanism of action, these products unequivocally meet the FDA's own established definitions of gene therapy. The petition leverages the Accardi doctrine, which mandates that agencies adhere to their own established rules and guidance, and the recent overturning of Chevron deference in Loper Bright v. Raimondo (2024), to argue that the FDA no longer has interpretive shield to justify its current classification. The petition further highlights systemic regulatory failures, including the suppression of safety information, improper use of Emergency Use Authorizations (EUAs), and violations of military and international informed consent requirements. It calls for comprehensive regulatory and administrative actions, including clinical holds, EUA revocations, and long-term safety monitoring.

Key Arguments:

Misclassification of COVID-19 mRNA and Adenoviral Vector Products:

- The central premise is that COVID-19 mRNA and adenoviral vector products function by delivering genetic instructions to human cells, which then produce foreign proteins (like the SARS-CoV-2 spike protein). This mechanism, according to the petitioners, directly aligns with the FDA's own definitions of "gene therapy products."
- **FDA's Definition of Gene Therapy:** The petition cites FDA guidance documents, specifically "Guidance for Human Somatic Cell Therapy and Gene Therapy" (1998), which states that "Human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use," and "Chemistry, Manufacturing, and Control (CMC) Information

for Human Gene Therapy Investigational New Drug Applications" (2020), which defines gene therapy products as those that "mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome."

- **Mechanism of Action vs. Therapeutic Intent:** The petitioners argue that FDA's classification *should* be based on the product's mechanism of action, not its therapeutic intent (i.e., stimulating immunity). They state, "Critically, FDA's binding guidance documents explicitly define gene therapy products based on their mechanism of action, not their therapeutic intent." For further explanation of this absolute nonsense reclassification based on “intended use”, see my article discussing this issue here.
- **Prior Manufacturer/Official Statements:** The petition highlights past statements from manufacturers and FDA officials, including Moderna's 2019 SEC filing stating, "Currently, mRNA is considered a gene therapy product by the FDA," and Bayer executive Stefan Oelrich's 2021 statement, "The mRNA vaccines are an example for cell and gene therapy." Dr. Peter Marks, Director of FDA's CBER, is also quoted as stating in 2019 that mRNA-based therapeutics represent "a significant advance in the field of gene therapy." These are presented as "admissions against interest."

Scientific Evidence Supporting Gene Therapy Classification

- **Mechanism of Action:** mRNA and adenoviral vector products "mediate their effects by transcription and/or translation of transferred genetic material," aligning with the gene therapy definition.

- **Genomic Integration Potential:** Presents theoretical pathways and laboratory evidence (Aldén et al., 2022; Zhang et al., 2021; Journal of Molecular Biology, 2025) suggesting that exogenous mRNA, particularly in the presence of LINE-1 retrotransposons, could potentially integrate into the host genome.
- **Biodistribution Beyond Injection Site:** Cites Pfizer's own studies and European Medicines Agency evaluations showing lipid nanoparticle (LNP) distribution to multiple organs (spleen, heart, kidney, lungs, brain, reproductive organs) and across the blood-brain barrier.
- **Extended Duration of Expression:** Highlights research (Yale University, Frontiers in Immunology, 2025) demonstrating spike protein expression persisting for up to 700 days and in lymph node germinal centers for up to 15 months post-injection, contradicting the "transient expression" assumption used to differentiate them from gene therapies. This persistence is a key risk factor in FDA's gene therapy guidance.
- **SV40 Promoter and DNA Contamination:** DNA plasmid contamination, including SV40 promoter sequences, in commercially distributed products, exceeding regulatory limits. The SV40 promoter is highlighted for its "well-documented oncogenic potential," as publicly acknowledged by HHS Secretary Robert F. Kennedy Jr.

Regulatory Violations and Mandatory Duties:

- **Arbitrary and Capricious Agency Action:** The FDA's classification decision is characterized as "arbitrary and capricious" under the Administrative Procedure Act (APA), arguing it "fails to consider an important aspect of the problem.

- **Systematic Suppression of Safety Information:** Cites a May 21, 2025 Congressional investigation revealing deliberate efforts to suppress safety signals (e.g., myocarditis) in early 2021 and coordination with pharmaceutical companies to downplay risks. "DoD consultants warned that V-safe was deliberately designed to avoid detecting cardiac adverse events, with officials acknowledging 'If you do not ask, you will not see it'."
- **Ultra Vires Expansion of EUA Authority:** Argues that the Emergency Use Authorization (EUA) framework was illegally expanded from a "narrow and limited authority" for specific threats to a "freewheeling mechanism for rubberstamping the indiscriminate mass deployment of unlicensed, inadequately tested products to millions of Americans." More on EUA Countermeasures can be found in many of my articles, including this detailed legal memo.
- **Minimal Risk Misclassification:** The "minimal risk" designation for intramuscular injection of novel genetic material is inappropriate, citing judicial precedent (Grimes v. Kennedy Krieger Institute, 2001) that any invasive procedure "categorically exceeds the minimal risk threshold."
- **Adulteration and Purity Standard Violations:** The presence of DNA plasmid contamination (including SV40 promoter sequences) renders these products "adulterated" under 21 U.S.C. § 351, and that purity specifications were set significantly lower (50-58%) than the typical 95% for biological products.
- **Scientific Integrity Policy Violations:** The FDA's actions violate HHS's own Scientific Integrity Policy (September 16, 2024) and the National Science and Technology Council (NSTC) report, which prohibit "inappropriate, scientifically

unjustified intervention" and "censorship, suppression, or distortion of scientific or technological findings."

- "**Unreasonable Risk" Standard:** FDA's own guidance on gene therapy products states that administration to "a large number of subjects" constitutes an "unreasonable risk," triggering a "non-discretionary duty" to impose a clinical hold.
- **Long-Term Monitoring Requirements:** The 5-15 year (FDA) or 30 year (EMA) long-term monitoring required for gene therapies was inappropriately waived for mRNA products, despite similar risks.

Executive Branch Acknowledgment of the Experimental Status of mRNA Injections:

- **Secretary Hegseth's Characterization:** Defense Secretary Pete Hegseth's April 2025 memorandum explicitly characterized COVID-19 mRNA products as "experimental COVID-19 vaccine," impacting the reinstatement of service members. This is presented as an "official admission" by a principal executive officer.
- **Secretary Kennedy's Risk-Benefit Assessment:** HHS Secretary Robert F. Kennedy Jr.'s April 2025 public statements questioning the risk-benefit profile of these products, particularly for children, and acknowledging "profound risk," are cited as official acknowledgments necessitating reclassification. "The recommendation for children was always dubious... So why are we giving this to tens of millions of kids when the vaccine itself does have profound risk?"

- **Dr. Steven Hatfill's Disclosures:** Official disclosures by Dr. Steven J. Hatfill, Senior Medical Advisor to HHS ASPR, confirming SV40 enhancer activity, LINE-1 DNA integration, tumor formation potential, multi-organ biodistribution, reproductive toxicity, and clinical trial fraud, are presented as further executive branch acknowledgments.

Department of Defense (DoD) Statutory Violations:

- **Misuse of Other Transaction Authority (OTA):** Operation Warp Speed's use of DoD's OTA (10 U.S.C. § 2371b) to develop and distribute COVID-19 countermeasures to civilians falls outside its statutory limit of "prototype projects directly relevant to enhancing the mission effectiveness of military personnel." More about OTA contracts here, here, and Robert Malone's confession here.
- **Violation of Military Informed Consent (10 U.S.C. § 1107):** The military COVID-19 vaccine mandate violated informed consent requirements for investigational medical products, especially given Secretary Hegseth's characterization of the products as "experimental."
- **Violation of Congressional Reporting Requirements (50 U.S.C. § 1520a):** The DoD failed to submit mandatory reports to Congress before using "biological agents on a civilian population," as required by statute.

Requested Actions form the HHS:

The petition requests the FDA and the Secretary of Health and Human Services to take immediate and comprehensive actions, including but not limited to:

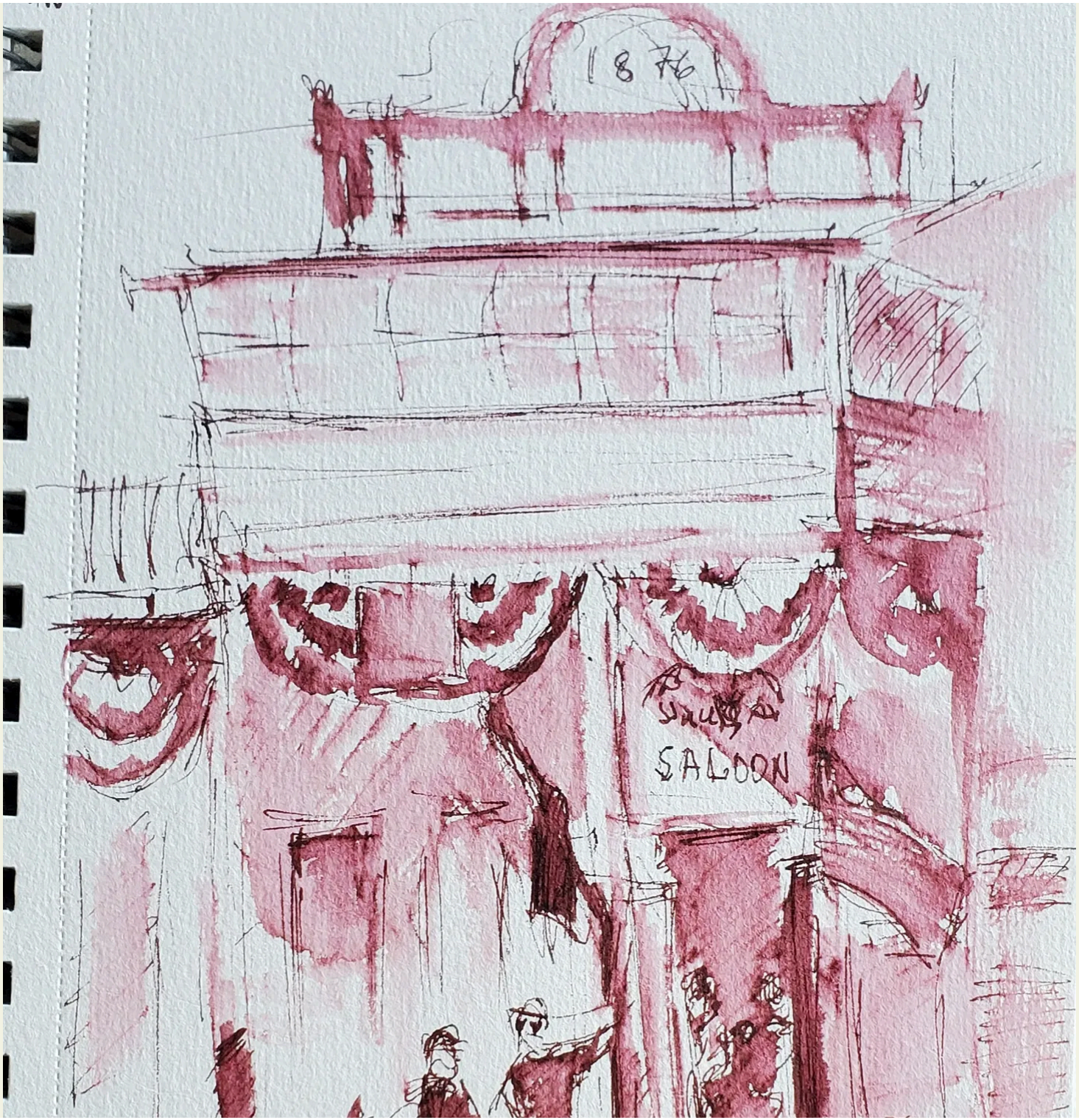
1. **Immediate Reclassification:** Reclassify all COVID-19 mRNA and adenoviral vector products as "gene therapy biologics."
2. **Regulatory Compliance:** Require all such products to comply with comprehensive gene therapy regulatory requirements (premarket review, labeling, post-market surveillance).
3. **Rescind Minimal Risk Designation:** Acknowledge that intramuscular injection of novel genetic material cannot be classified as "minimal risk."
4. **Mandate Labeling Revisions:** Accurately reflect the "EXPERIMENTAL nature, gene therapy classification and associated risk profile," including warnings for genomic integration, autoimmune reactions, and extended expression duration.
5. **Formal Rulemaking:** Initiate proceedings to establish clear standards for product classification based on mechanism of action.
6. **Enforce Adulteration Standards:** Rescind waivers and issue a formal determination of adulteration due to DNA plasmid contamination (including SV40 promoter sequences).
7. **Emergency Safety Investigation:** Direct ASPR to investigate ovarian reserve, tumor signaling, and DNA recombination in post-mRNA patients.
8. **Public Health Advisory:** Issue an immediate advisory correcting prior misclassification and informing the public of gene therapy status.
9. **Clinical Hold Order:** Impose an immediate clinical hold on all COVID-19 mRNA and adenoviral vector products due to "unreasonable risk" for large populations.

10. **EUA Suspension/Revocation:** Suspend or revoke all EUAs and BLAs until full compliance with gene therapy regulations is demonstrated, citing "fraudulent product classification" and failure to meet effectiveness criteria as gene therapies.
11. **PREP Act Liability Determination:** Formally declare that these products, as gene therapies, "DO NOT QUALIFY FOR LIABILITY IMMUNITY" under the PREP Act, as it covers "vaccines" only.
12. **Safety Communication:** Issue an immediate safety communication to healthcare providers and recipients regarding reclassification and potential risks.
13. **Executive Branch Confirmation:** Issue a formal determination confirming recent characterizations by Secretary Hegseth and Secretary Kennedy regarding the experimental nature of these products.
14. **Ultra Vires Determination:** Formally determine that the FDA's expansion of EUA for mass population use was an illegal expansion of individualized investigational use.
15. **Clinical Hold Based on Hatfill Disclosures:** Impose a clinical hold based on Dr. Steven Hatfill's disclosures of plasmid DNA, SV40 enhancers, and LINE-1 integration mechanisms.
16. **Enforcement Actions:** Initiate against manufacturers failing to comply with gene therapy requirements.
17. **Public Report:** Provide a detailed public report on regulatory failures and corrective actions.
18. **Scientific Hearing:** Convene a formal scientific hearing with expert witnesses.

19. **CDC Schedule Removal:** Direct removal of COVID-19 mRNA and adenoviral vector products from the CDC Immunization Schedule.
20. **Manufacturer Data Submissions:** Direct manufacturers to submit comprehensive genotoxicity, biodistribution, integration potential, long-term expression, carcinogenicity, reproductive toxicity, and DNA sequencing data within 90 days.
21. **Long-Term Follow-Up Requirements:** Institute mandatory long-term follow-up (minimum 5 years, preferably 15 years) for all recipients.
22. **Rejection of DoD Regulatory Changes:** Formally reject proposed DoD changes that would codify OTA misapplications.
23. **DoD Coordination Investigation:** Investigate military authority overreach in Operation Warp Speed, including OTA misuse and violations of informed consent.
24. **PCR Diagnostic Reevaluation:** Reevaluate EUAs for PCR diagnostics, emphasizing standardized cycle threshold parameters and clinical correlation.
25. **Comprehensive Transparency:** Immediately disclose all safety data, adverse event reports, biodistribution studies, and pharmacovigilance findings.
26. **Whistleblower Protection:** Ensure Dr. Steven Hatfill receives whistleblower protections and his disclosures are public.
27. **Inspector General Referral:** Refer for investigation of clinical trial suppression and data withholding.

Please share this information far and wide and please support IOJ!

Art for today: Sketch from Virginia City, NV. Pen and ink. Available art here.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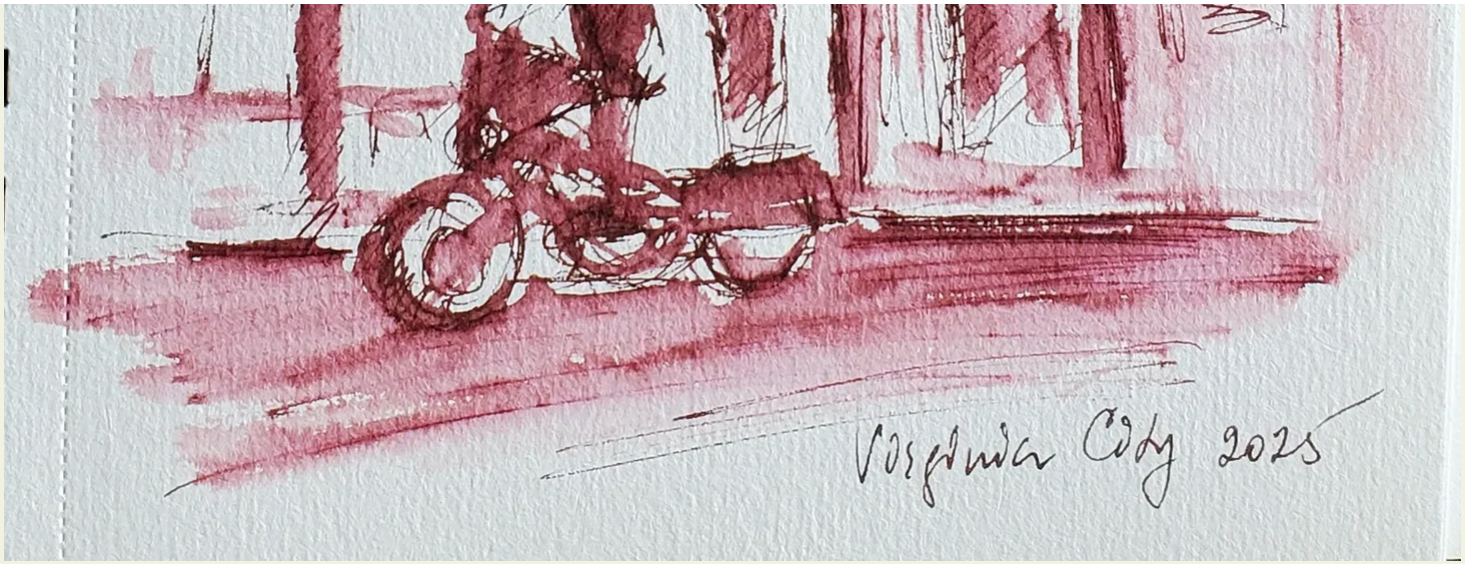

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Kris 5d

Liked by Sasha Latypova

Here is my comment I'm posting it there now

To the FDA and all responsible agencies:

You murdered my brother-in-law. And he is just one of countless victims of your reckless, unlawful, and deceitful misclassification of mRNA injections as “vaccines.” I am sickened and furious. The blood of thousands—if not millions—is on your hands. This is not “misinformation,” it’s a matter of criminal accountability.

You knew exactly what you were doing. Your own guidance from 1998 and 2020 defines gene therapy as products that “modify, manipulate, or mediate expression of genetic material.” That’s exactly what these COVID-19 shots do. Yet you bypassed the full regulatory process by calling them “vaccines,” suppressing long-term safety monitoring, ignoring your own risk standards, and fraudulently using Emergency Use Authorizations (EUAs).

You’ve now lost your Chevron shield. The Loper Bright v. Raimondo decision means you are no longer above the law. You cannot hide behind “agency discretion” to excuse murder, fraud, and systemic regulatory abuse. The Accardi doctrine demands that you follow your own rules—and you didn’t.

These injections should have been classified as gene therapy. Instead, you allowed experimental products to be injected into the arms of civilians, children, pregnant women, military personnel—without proper consent, without safety transparency, and without recourse. That’s premeditated deception. And people died because of it.

You violated:

Scientific Integrity Policies

Gene Therapy Regulatory Standards

PREP Act definitions (they are not vaccines and do not qualify for immunity)

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13 replies by Sasha Latypova and others

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Liked by Sasha Latypova

It's in the patent as a gene therapy injection which was reclassified as a "vaccine"

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5 replies

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