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MONITORING COMMITTEE

CITIZEN PETITION

Before the United States Food and Drug Administration, Department of Health and Human Services

CITIZEN PETITION FOR IMMEDIATE RECLASSIFICATION OF COVID-19 mRNA AND ADENOVIRAL VECTOR PRODUCTS AS GENE THERAPY PRODUCTS AND FOR REGULATORY ACTION REGARDING THE STATUTORY VIOLATIONS AND INTERNATIONAL LEGAL CONTRAVENTIONS INHERENT IN THE COVID-19 COUNTERMEASURES PROGRAM

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Submitted pursuant to: 21 C.F.R. § 10.30, 5 U.S.C. § 553(e), 21 U.S.C. § 360bbb-3(g), 21 C.F.R. § 10.33, and 21 C.F.R. § 10.85

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Citizen Petition

Date: June 17, 2025

The undersigned submits this petition under 21 C.F.R. § 10.30, 5 U.S.C. § 553(e), 21 U.S.C. § 360bbb-3(g), 21 C.F.R. § 10.33, and 21 C.F.R. § 10.85 (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs) to request the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action and IMMEDIATE RECLASSIFICATION OF COVID-19 mRNA AND ADENOVIRAL VECTOR PRODUCTS AS GENE THERAPY PRODUCTS AND FOR REGULATORY ACTION REGARDING THE STATUTORY VIOLATIONS AND INTERNATIONAL LEGAL CONTRAVENTIONS INHERENT IN THE COVID-19 COUNTERMEASURES PROGRAM and to request the Secretary of the Health and Human Services to act on his plenary duties to do the same.

A. ACTION REQUESTED

Legal Authority for Immediate Reclassification
Pursuant to the **Accardi doctrine** and FDA's own binding guidance documents defining gene therapy products, the Secretary has **non-discretionary authority** to immediately reclassify COVID-19 mRNA and adenoviral vector products without formal rulemaking. *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) ("the agency must itself follow those rules and regulations") This classification correction represents enforcement of existing standards rather than creation of new regulatory requirements.

Legal Foundation: This petition is grounded in FDA's own binding guidance documents that define gene therapy products based on mechanism of action. Under the **Accardi doctrine United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260**

(1954), FDA cannot arbitrarily exempt COVID-19 genetic products from standards it consistently applies to functionally identical therapeutics. The recent elimination of **Chevron deference** in *Loper Bright v. Raimondo* (2024) removes FDA's interpretive shield, requiring independent judicial review of whether these products meet established definitional criteria.

Pursuant to 21 C.F.R. § 10.30, Petitioner respectfully requests that the Food and Drug Administration take the following actions:

SECTION A: ACTION REQUESTED

Pursuant to 21 C.F.R. § 10.30, Petitioner respectfully requests that the Food and Drug Administration immediately take the following actions:

A.1: Regulatory Changes Requested

1. **Immediate Reclassification Under FDA's binding gene therapy guidance documents**: Reclassify all COVID-19 mRNA and adenoviral vector products as gene therapy biologics as defined in 21 C.F.R. § 312.3 under 'Investigational new drug and 21 C.F.R. § 1271.3(d), and require all such products to comply with the regulatory requirements for gene therapy products, including but not limited to premarket review, labeling, and post-market surveillance.

2. **Amendment of Product Classifications**: ISSUE AN IMMEDIATE SECRETARIAL DETERMINATION that COVID-19 mRNA and adenoviral vector products are Gene Therapy Products as defined under FDA's binding gene therapy guidance documents, subject to the comprehensive regulatory framework established for such biologics, exercising the Secretary's plenary authority under 42 U.S.C. § 262 to properly classify biological products according to their functional characteristics and mechanism of action.

   The FDA has established the regulatory definition of gene therapy products through its authoritative 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." These guidance documents are binding on the FDA under the Accardi doctrine, United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260 (1954), which prohibits agencies from departing from their own established rules, procedures, or interpretive frameworks without adequate justification. See United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260 (1954).

3. **Revision of Minimal Risk Designation**: IMMEDIATELY RESCIND THE "MINIMAL RISK" DESIGNATION for COVID-19 mRNA and adenoviral vector product administration pursuant to the Secretary's authority under 45 C.F.R. § 46.101(i), acknowledging that invasive intramuscular injection of novel genetic material cannot be properly classified as "minimal risk" under 45 C.F.R. § 46.102(j), particularly in light of judicial precedent in Grimes v. Kennedy Krieger Institute, 782 A.2d 807 (Md. 2001) establishing that any invasive procedure categorically exceeds the minimal risk threshold.

4. **Product Labeling Requirements**: MANDATE PRODUCT LABELING REVISIONS pursuant to 21 C.F.R. § 201.56 to accurately reflect the EXPERIMENTAL nature, gene therapy classification and associated risk profile, including mandatory warnings regarding potential for genomic integration, autoimmune reactions, and extended expression duration.

5. **Formal Rulemaking for Classification Standards**: INITIATE FORMAL RULEMAKING PROCEEDINGS to establish clear standards for product classification based on mechanism of action rather than therapeutic intent, ensuring consistent regulatory oversight based on functional characteristics and risk profiles.

6. **Adulteration Standards Enforcement**: RESCIND ALL WAIVERS OF ADULTERATION STANDARDS AND ISSUE A FORMAL DETERMINATION OF ADULTERATION for COVID-19 mRNA products pursuant to 21 U.S.C. § 351, acknowledging DNA plasmid contamination including SV40 promoter sequences at levels exceeding regulatory limits, and instituting comprehensive quality control requirements consistent with gene therapy products. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (interpretive rules with mandatory language are binding)

7. **ASPR Emergency Investigation**: DIRECT THE ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE, in coordination with Senior Medical

Advisor Dr. Steven Hatfill, to initiate an emergency safety investigation pursuant to 42 U.S.C. § 247d-1 focusing on ovarian reserve, tumor signaling, and DNA recombination in post-mRNA patients.

A.2: Orders and Determinations Requested

1. **Public Health Advisory**: Issue an immediate public health advisory correcting prior misclassification and informing the public and healthcare providers of the gene therapy status of these products.

2. **Clinical Hold Order**: IMPOSE AN IMMEDIATE CLINICAL HOLD on all COVID-19 mRNA and adenoviral vector products pursuant to 21 CFR § 312.42(b)(1)(i) and (iii) and 21 C.F.R. § 312.42(b)(2)(i) based on FDA's own determination in binding guidance documents that administration of gene therapy products to large populations constitutes an "unreasonable risk" to subjects, as acknowledged in the FDA's Long Term Follow-Up After Administration of Human Gene Therapy Products guidance (January 2020).

3. **EUA Suspension**: Suspend all current and future Emergency Use Authorizations (EUAs) and Biologics License Applications (BLAs) for COVID-19 mRNA and adenoviral products until full compliance with gene therapy regulations is demonstrated.

4. **EUA Revocation**: REVOKE ALL EMERGENCY USE AUTHORIZATIONS (EUAs) for COVID-19 mRNA and adenoviral vector products pursuant to 21 U.S.C. § 360bbb-3(g)(2) based on fraudulent product classification, misapplication of EUA statutory provisions, and the fact that such products fail to satisfy the requirement under 21 U.S.C. § 360bbb-3(c)(2)(A) that "based on the totality of scientific evidence available... it is reasonable to believe that the product may be effective" when evaluated as gene therapy products.

5. **PREP Act Liability Determination**: ISSUE A FORMAL DECLARATION that COVID-19 mRNA and adenoviral vector products, upon proper classification as gene therapy products, DO NOT QUALIFY FOR LIABILITY IMMUNITY under existing Public Readiness and Emergency Preparedness (PREP) Act declarations (42 U.S.C. § 247d-6d), as these declarations exclusively cover "vaccines" and not gene therapy products, thereby triggering the Secretary's non-discretionary duty under 42 U.S.C. § 247d-6d(b)(9) to "specify the category or categories of diseases, health conditions, or threats to health for

which such declaration is effective".

6. **Safety Communication**: ISSUE AN IMMEDIATE SAFETY COMMUNICATION to all healthcare providers and recipients of COVID-19 mRNA products regarding the reclassification and potential risks associated with gene therapy mechanisms, pursuant to the Secretary's authority under 42 U.S.C. § 241.

7. **Executive Branch Confirmation**: ISSUE A FORMAL DETERMINATION CONFIRMING the recent characterizations by Secretary of Defense Pete Hegseth and statements by Secretary of Health and Human Services Robert F. Kennedy Jr. which constitute official Executive Branch acknowledgment of the experimental nature of these products, necessitating proper classification as gene therapy products and implementation of appropriate regulatory oversight.

   ### Congressional Investigation Confirms Executive Branch Admissions

   ISSUE A FORMAL DETERMINATION incorporating the findings of the May 21, 2025 Congressional investigation, which revealed systematic suppression of safety information and coordination between agencies to avoid public warnings. **This Congressional evidence definitively confirms that these products were experimental in nature and that agencies prioritized policy goals over scientific transparency**, necessitating immediate reclassification and implementation of appropriate regulatory oversight consistent with their gene therapy mechanism of action.

8. **Ultra Vires Determination**: ISSUE A FORMAL DETERMINATION OF ULTRA VIRES AGENCY ACTION that the FDA's conversion of Expanded Access Use (EAU) provisions to Emergency Use Authorization for mass population use represented an illegal expansion of individualized investigational use authorization to mass deployment in direct contravention of legislative intent and statutory constraints, as evidenced in H.R. REP. NO. 108-32 pt. 3, at 77 (2003).

9. **Clinical Hold Based on Official HHS Disclosures**: IMPOSE AN IMMEDIATE CLINICAL HOLD under 21 C.F.R. § 312.42 on all mRNA products based on the public disclosures of Dr. Steven Hatfill, HHS Senior Medical Advisor, confirming presence of plasmid DNA, SV40 enhancers, and LINE-1 integration mechanisms.

A.3: Other Administrative Actions

1. **Enforcement Actions**: Initiate enforcement actions against any manufacturer or sponsor that has failed to comply with gene therapy regulatory requirements.

2. **Public Report**: Provide a detailed public report on the regulatory failures and corrective actions taken, including a timeline for implementation.

3. **Scientific Hearing**: CONVENE A FORMAL SCIENTIFIC HEARING with expert witnesses including Dr. Michael Yeadon (former Vice President of Pfizer), Dr. Janci Lindsay, Alexandra Latypova, and other qualified experts pursuant to the Secretary's authority under 42 U.S.C. § 217a and the United States' Open Government Partnership commitments requiring meaningful civil society participation in regulatory decision-making.

4. **CDC Schedule Removal**: DIRECT THE REMOVAL of COVID-19 mRNA and adenoviral vector products from the CDC Immunization Schedule pursuant to the Secretary's supervisory authority over the Centers for Disease Control and Prevention under 42 U.S.C. § 203, as improperly classified gene therapy products categorically fail to meet the statutory definition of "vaccines" under applicable law and CDC inclusion criteria.

5. **Manufacturer Data Submissions**: DIRECT MANUFACTURERS TO SUBMIT SUPPLEMENTAL BIOLOGICAL LICENSE APPLICATIONS containing the complete testing data required for gene therapy products within 90 days, including:

    - Comprehensive genotoxicity studies as mandated by 21 C.F.R. § 312.23(a)(8)
    - Complete biodistribution studies using the actual formulation as required by FDA guidance
    - Integration potential assessments under physiologically relevant conditions
    - Long-term expression and persistence evaluations following FDA's gene therapy guidance
    - Carcinogenicity studies consistent with gene therapy standards
    - Reproductive and developmental toxicity studies with multi-generational assessment
    - Complete DNA sequencing of all production templates with full contamination assessment

6. **Long-Term Follow-Up Requirements**: INSTITUTE MANDATORY LONG-TERM FOLLOW-UP REQUIREMENTS (minimum 5 years, preferably 15 years) for all recipients, with active surveillance for categories of adverse events specifically associated with gene therapy risks, as explicitly required in FDA's guidance for gene therapy products.

A.4: Coordinated Actions (FDA Authority Clarification)

Note: The following requests are made to the extent they fall within FDA's regulatory authority or require FDA participation in coordinated regulatory oversight.

1. **Rejection of OTA Regulatory Changes**: ISSUE A FORMAL DETERMINATION REJECTING PROPOSED REGULATORY CHANGES that would codify and institutionalize the OTA misapplications identified in this petition, particularly the Department of Defense's September 4, 2024 proposed revisions to 32 CFR Part 3 that would eliminate notice requirements for follow-on production OTs, expand participant eligibility beyond statutory intent, and create a permanent parallel regulatory framework for bypassing traditional safety and procurement safeguards in future public health interventions.

2. **DoD Coordination Investigation**: INVESTIGATE MILITARY AUTHORITY OVERREACH including:

    - Formal investigation of DoD's role in Operation Warp Speed
    - Improper use of Other Transaction Authority (OTA) under 10 U.S.C. § 2371b
    - Violations of military informed consent requirements (10 U.S.C. § 1107(a))
    - Violations of congressional reporting requirements (50 U.S.C. § 1520a)
    - Revocation of authorizations based on military-specific expedited review pathways under Public Law 115-92

3. **PCR Diagnostic Reevaluation**: DIRECT THE IMMEDIATE REEVALUATION of all Emergency Use Authorizations issued for PCR-based SARS-CoV-2 diagnostic methodologies pursuant to the Secretary's authority under 21 U.S.C. § 360bbb-3(g)(2), with particular emphasis on reassessing whether such

authorizations satisfy the statutory requirement that "the criteria for issuance of authorization under subsection (c) are no longer met," given the absence of standardized cycle threshold parameters, appropriate clinical correlation requirements, and validated protocols distinguishing between active infection and residual nucleic acid detection.

4. **Diagnostic Status Determination**: ISSUE A FORMAL DETERMINATION REGARDING THE DIAGNOSTIC STATUS of PCR-based SARS-CoV-2 detection methodologies, pursuant to the Secretary's plenary authority under 21 U.S.C. § 393(d)(2), explicitly addressing whether such methodologies constitute standalone diagnostic procedures or amplification technologies requiring clinical correlation, thereby eliminating the regulatory ambiguity that has facilitated inappropriate application beyond scientifically validated parameters in contravention of international diagnostic standards established in ISO 15189:2012.

5. **Cycle Threshold Standardization**: DIRECT FDA TO ESTABLISH STANDARDIZED CYCLE THRESHOLD PARAMETERS for all PCR-based SARS-CoV-2 detection methodologies pursuant to the Secretary's authority under 42 U.S.C. § 263a (Clinical Laboratory Improvement Amendments), mandating transparent reporting of cycle threshold values, validation of clinical correlation at specified amplification levels, and appropriate limitations on interpretation of results at cycle thresholds exceeding validated parameters, consistent with international scientific consensus regarding nucleic acid amplification reliability.

6. **Clinical Correlation Requirements**: ISSUE A FORMAL DIRECTIVE REGARDING CLINICAL CORRELATION REQUIREMENTS for all PCR test results pursuant to the Secretary's authority under 42 U.S.C. § 264, establishing explicit guidelines requiring that positive PCR results must be interpreted in conjunction with clinical presentation, exposure history, and relevant epidemiological factors before definitive diagnostic conclusions can be reached, consistent with the judicial determinations of multiple international tribunals regarding diagnostic sufficiency.

7. **Transparency and Disclosure**: DIRECT COMPREHENSIVE TRANSPARENCY MEASURES including:

   - Immediate disclosure of all safety data pursuant to 5 U.S.C. § 552(a)(1) and the FDA's proactive disclosure obligations under 21 C.F.R. § 20.41
   - Release of all adverse event reports, biodistribution studies, and pharmacovigilance findings withheld from public scrutiny

- Suspension and review of all regulatory waivers granted by SEC, FDA, and other federal agencies
- Immediate cessation of geographic classification disparities between domestic and foreign use
- Formal determination regarding adulteration standards and Secretary's lack of statutory authority to exempt adulterated products from strict liability provisions

8. ASPR Emergency Safety Investigation: DIRECT THE ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE, in coordination with Senior Medical Advisor Dr. Steven Hatfill, to initiate an emergency safety investigation pursuant to 42 U.S.C. § 247d-1 focusing on:

- Ovarian reserve depletion and reproductive toxicity mechanisms
- Tumor signaling pathways and spike protein oncogenic potential
- DNA recombination events in post-mRNA recipients
- Multi-organ biodistribution consequences requiring enhanced monitoring protocols

9. Whistleblower Protection Implementation: ENSURE that Dr. Steven Hatfill receives appropriate whistleblower protections under the Whistleblower Protection Act, 5 U.S.C. § 2302, and that his official disclosures are entered into the public regulatory record pursuant to 5 U.S.C. § 552a.

10. Inspector General Referral: DIRECT referral to the HHS Office of Inspector General and appropriate Congressional oversight committees for investigation of clinical trial suppression, data withholding, and potential violations of 50 U.S.C. § 1520a regarding biological experimentation on civilian populations without proper informed consent.

SECTION B: STATEMENT OF GROUNDS

What This Petition Proves in Simple Terms

The Problem: COVID-19 mRNA vaccines work by delivering genetic instructions to your cells—the definition of gene therapy. But FDA classified them as "vaccines" instead, avoiding safety requirements that protect patients.

New Evidence From Congress: Government documents show officials knew about heart problems in February 2021 but hid this from the public until June 2021. They

designed surveillance systems to avoid finding problems and coordinated with pharmaceutical companies to suppress warnings.

Why This Matters:

- Gene therapy products require 5-15 years of safety monitoring
- Recipients weren't told these were experimental genetic treatments
- Current classification blocks legal remedies for injuries
- The same arbitrary approach threatens future medical innovations

What We're Asking: Properly classify these products as gene therapy and implement appropriate safety monitoring to protect public health and restore scientific integrity.

B.1: LEGAL FOUNDATION AND AUTHORITY

I. Secretary's Plenary Authority and Non-Discretionary Duties

The Secretary of Health and Human Services possesses plenary and non-delegable authority under the Public Health Service Act (42 U.S.C. § 262) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) to ensure that biological products are regulated in accordance with their functional characteristics, mechanism of action, and risk profile. This authority is not merely discretionary but creates an affirmative obligation to properly classify novel therapeutic modalities to ensure appropriate regulatory oversight.

The Reorganization Plan No. 1 of 1953 (5 U.S.C. App.), which established the Department of Health and Human Services, expressly vests in the Secretary the authority to "direct and supervise" all departmental activities, including those delegated to the FDA. This supervisory authority includes the power to correct ultra vires agency actions and ensure compliance with statutory mandates. As the Supreme Court confirmed in United States v. California, "When Congress vests authority in the head of a department, the head of the department possesses not only the expressly conferred powers but also those powers necessary to effectuate the statutory purposes."

Under 42 U.S.C. § 262(a)(2)(A), the Secretary has the affirmative duty to "establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses." This statutory mandate creates a non-discretionary duty to ensure that biological products are classified according to their functional characteristics. As the D.C. Circuit held in Cutler v. Hayes, "When a statute uses the mandatory 'shall,' the normal inference is that Congress intended to impose a consequential obligation on the agency, barring textual or contextual indications to the contrary."

The position of Secretary of Health and Human Services carries unique statutory obligations to protect public health through proper regulatory oversight. As established in Federal Trade Commission v. Ruberoid Co., when a statute confers quasi-judicial or quasi-legislative authority on an agency head, it creates "a special duty of fidelity to the public interest." Secretary Kennedy's own background and expertise in identifying regulatory capture and pharmaceutical industry malfeasance creates an enhanced duty to rectify this regulatory distortion.

The Take Care Clause of the U.S. Constitution, Article II, Section 3, further requires the Secretary, as a principal officer of the Executive Branch, to "take Care that the Laws be faithfully executed." This constitutional directive creates a non-discretionary duty that transcends mere policy preferences or administrative convenience. As the Supreme Court emphasized in Youngstown Sheet & Tube Co. v. Sawyer, executive officers must exercise their authority "in conformity with the legislative will" rather than in contravention of statutory frameworks established by Congress.

B.1.III: Binding Effect of FDA Guidance Under Accardi Doctrine

Federal agencies are legally obligated to follow their own established rules, regulations, and guidance documents under the **Accardi doctrine**. *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 267 (1954) ("The agency must scrupulously observe rules, regulations, or procedures which it has established"). This fundamental principle of administrative law prevents arbitrary agency action and ensures consistent regulatory treatment.

The Supreme Court has consistently reinforced this obligation: *Service v. Dulles*, 354 U.S. 363, 388 (1957) ("regulations validly prescribed by a government administrator are binding upon him as well as the citizen"); *Vitarelli v. Seaton*, 359 U.S. 535, 539 (1959) (agency bound by its own procedures even if not required by statute); *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) ("the agency must itself follow those rules and regulations").

Modern courts have extended this principle to guidance documents that establish substantive standards:

- *General Electric Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) (guidance can be binding if consistently applied)
- *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (interpretive rules with mandatory language are binding)
- *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988) (consistent agency practice creates binding precedent)

FDA's guidance documents defining gene therapy products meet all criteria for binding effect under Accardi: they establish clear substantive standards, have been consistently applied to classify genetic therapeutics, and create reasonable expectations for regulated entities.

B.1.A: Binding Nature of FDA Guidance Under Accardi Doctrine

Federal agencies are legally bound to follow their own regulations, guidance documents, and established procedures under the **Accardi doctrine**, established in

United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260 (1954). This principle prevents arbitrary agency action and ensures consistent application of regulatory standards.

Accardi Doctrine Elements Present Here:

1. **Clear Agency Standard**: FDA's binding gene therapy guidance documents establish unambiguous definition of gene therapy products
2. **Consistent Application**: FDA has applied this standard to classify other mRNA and viral vector products
3. **Substantive Impact**: Classification determines applicable regulatory requirements and safety standards
4. **Reasonable Reliance**: Manufacturers and public relied on FDA's established definitional framework

Modern Judicial Reinforcement: Courts have consistently upheld the Accardi doctrine's application to guidance documents that establish substantive standards:

- *Morton v. Ruiz*, 415 U.S. 199 (1974): Agencies must follow published guidance that affects individual rights
- *General Electric Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002): Consistently applied guidance creates binding obligations
- *Alcaraz v. Block*, 746 F.2d 593 (9th Cir. 1984): Agency cannot depart from guidance without justification

Secretary's Non-Discretionary Duty: Under Accardi, the Secretary cannot permit FDA to disregard its own definitional standards for COVID-19 products while applying them to functionally identical genetic therapeutics. Such selective enforcement violates basic principles of administrative law and equal treatment.

II. Statutory Non-Discretionary Duty to Classify According to Functional Characteristics

The Secretary of Health and Human Services possesses not merely discretionary authority but an affirmative statutory obligation under the Public Health Service Act (42 U.S.C. § 262) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) to ensure that biological products are regulated in accordance with their functional characteristics, mechanism of action, and risk profile. This mandatory duty derives from the express statutory language, contextual framework, and underlying legislative intent of the governing statutes.

The Public Health Service Act, specifically 42 U.S.C. § 262(a)(2)(A), confers upon the Secretary the non-discretionary mandate to "establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses." This statutory provision, interpreted according to established canons of construction, creates an affirmative obligation to ensure that biological products are classified according to their actual characteristics rather than nominal designations. As the D.C. Circuit emphasized in Cutler v. Hayes, 818 F.2d 879, 894 (D.C. Cir. 1987), when statutory language uses the mandatory "shall," it creates a

"consequential obligation on the agency" that cannot be circumvented through administrative convenience or policy preferences.

The Supreme Court has definitively established in Massachusetts v. EPA, 549 U.S. 497, 527-28 (2007), that when statutory criteria for regulatory action are satisfied, agencies cannot decline to act based on policy considerations extraneous to the statutory framework. The Court unequivocally rejected the argument that an agency can "avoid taking further action" once a product meets statutory criteria for regulation, holding that such an approach would be "arbitrary, capricious... or otherwise not in accordance with law." The Court specifically emphasized that when Congress has established specific criteria for regulatory classification, agencies lack discretion to create exceptions based on policy considerations.

This principle applies with equal force to the FDA's statutory obligation to classify biological products according to their actual characteristics rather than policy preferences. When COVID-19 mRNA products meet the regulatory definition of gene therapy products—"products that mediate their effects by transcription and/or translation of transferred genetic material"—the Secretary lacks discretion to exempt them from the corresponding regulatory framework based on policy considerations outside the statutory criteria.

The non-discretionary nature of this obligation is further reinforced by the FDA's own binding guidance documents defining gene therapy products functionally based on mechanism of action. Under the Accardi doctrine established in United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260 (1954), agencies are legally bound to follow their own regulations and binding guidance documents. • *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 267 (1954) ("The agency must scrupulously observe rules, regulations, or procedures which it has established") and *Service v. Dulles*, 354 U.S. 363, 388 (1957) ("regulations validly prescribed by a government administrator are binding upon him as well as the citizen")

The Supreme Court has reinforced this principle in Service v. Dulles, 354 U.S. 363, 388 (1957), holding that "regulations validly prescribed by a government administrator are binding upon him as well as the citizen."

The Secretary's obligation is particularly acute given the mandate in 42 U.S.C. § 262(a)(2)(B)(ii) to establish "appropriate requirements for the approval of biological products... designed to ensure the continued safety, purity, and potency of such products." This statutory provision creates an affirmative duty to apply appropriate safety standards to biological products based on their characteristics and risks. By exempting COVID-19 mRNA products from safety requirements that apply to functionally identical gene therapy products, the agency has violated this statutory mandate.

III. Binding Gene Therapy Product Definition

Binding Gene Therapy Product Definition Under FDA Guidance and Accardi Doctrine
The U.S. Food and Drug Administration has established the regulatory definition of **gene therapy products** through its authoritative guidance documents, specifically:

- **"Guidance for Human Somatic Cell Therapy and Gene Therapy" (1998)**: "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."
- **"Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications" (2020)**: 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."
- **"Human Gene Therapy Products Incorporating Human Genome Editing" (2022)**: Reinforces mechanism-based classification regardless of therapeutic application.

These guidance documents are binding under the Accardi doctrine (*United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)), which prohibits agencies from departing from their own established rules, procedures, or interpretive frameworks without adequate justification. As the Supreme Court held: "regulations validly prescribed by a government administrator are binding upon him as well as the citizen."
COVID-19 mRNA and adenoviral vector products **unequivocally satisfy this definition** by delivering genetic material that causes human cells to transcribe and translate foreign proteins, thereby "modifying gene expression" and "altering the biological properties of living cells" - the precise mechanistic criteria established by FDA's own guidance.
FDA's Consistent Application Demonstrates Binding Nature: FDA has systematically applied this guidance-based definition to classify other mRNA therapeutics (cancer immunotherapies, genetic vaccines) and viral vector products (gene editing platforms) as gene therapy products, creating a **binding precedent** that cannot be arbitrarily abandoned for COVID-19 products without formal rulemaking.

The FDA's authority to define product categories is not unbounded but must adhere to the "intelligible principle" established by Congress in the enabling statutes. As the Supreme Court held in Whitman v. American Trucking Associations, "agencies may not exercise their authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" By establishing contradictory regulatory classifications based on therapeutic intent rather than mechanism of action, the FDA has transgressed this boundary and violated the intelligible principle established by Congress in the Public Health Service Act.

Critically, FDA's own regulation at FDA's binding gene therapy guidance documents explicitly defines gene therapy products based on their mechanism of action, not their therapeutic intent. This creates a binding legal requirement that all products meeting this definition be classified as gene therapy products regardless of their intended use. Under the Accardi doctrine established in United States ex rel. Accardi v. Shaughnessy, "agencies must follow their own rules," including definitional frameworks established by regulation. *Vitarelli v. Seaton*, 359 U.S. 535, 539 (1959) (agency bound by its own procedures even if not required by statute)

The FDA has established the regulatory definition of gene therapy products through its authoritative 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." These guidance documents are binding on the FDA under the Accardi doctrine, which prohibits agencies from departing from their own established rules, procedures, or interpretive frameworks without adequate justification. See United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260 (1954).

Critically, FDA's binding guidance documents explicitly define gene therapy products based on their mechanism of action, not their therapeutic intent

IV. Administrative Law Principle of Substance Over Form

The administrative law principle of substance over form, a foundational doctrine in American jurisprudence, mandates that regulatory classification adhere to the functional characteristics of the regulated entity rather than its nominal designation or label. As articulated by the Supreme Court in SEC v. W.J. Howey Co., 328 U.S. 293, 298 (1946), "form was disregarded for substance" in determining regulatory status. The Court reaffirmed this principle in Environmental Defense v. Duke Energy Corp., 549 U.S. 561, 574 (2007), holding that regulatory definitions must focus on "functional characteristics rather than nominal designations."

This principle has been consistently affirmed as an essential safeguard against arbitrary administrative action and attempts to circumvent regulatory requirements through creative labeling. In Howey, the Supreme Court established that "form was disregarded for substance" in determining whether an investment contract exists under federal securities laws. The Court emphasized that the statutory purpose would be undermined if formalistic distinctions could circumvent regulatory requirements: "It is immaterial whether the enterprise is speculative or non-speculative or whether there is a sale of property with or without intrinsic value. The statutory policy of affording broad protection to investors is not to be thwarted by unrealistic and irrelevant formulae."

The D.C. Circuit has further reinforced this principle in American Petroleum Institute v. EPA, 216 F.3d 50, 63 (D.C. Cir. 2000), holding that "regulatory classifications must be based on relevant characteristics that relate to the statutory objectives, not arbitrary or opportunistic factors that serve administrative convenience." The arbitrary exemption of COVID-19 mRNA products from gene therapy regulation based solely on their designation as "vaccines" epitomizes the

kind of formalistic distinction that courts have consistently rejected as contrary to fundamental administrative law principles.

Under the FDA's own regulatory framework at FDA's binding gene therapy guidance documents, gene therapy products are defined by their mechanism of action as "products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms." COVID-19 mRNA products unequivocally satisfy this definitional criterion by delivering synthetic mRNA that causes human cells to produce the SARS-CoV-2 spike protein through transcription and translation of the transferred genetic material. The fact that these products are designated as "vaccines" rather than "gene therapies" does not alter their fundamental mechanism of action and cannot justify their exemption from the appropriate regulatory framework.

The FDA's binding gene therapy guidance for industry on gene therapy products further establishes that the determination of whether a product constitutes gene therapy is predicated on its mechanism of action, not its intended use. The transcription and translation of introduced genetic material—the precise mechanism by which mRNA COVID-19 products function—is explicitly identified as the defining characteristic of gene therapy products. The attempt to create a therapeutic intent-based exemption contradicts this established regulatory approach and violates the principle that substance must prevail over form in regulatory classification. *General Electric Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) (guidance can be binding if consistently applied)

B.1.IV-A: RECENT CONGRESSIONAL FINDINGS CONFIRMING REGULATORY FAILURES

Congressional Investigation Reveals Systematic Suppression of Safety Information

The May 21, 2025 Congressional hearing conducted by the Permanent Subcommittee on Investigations has revealed previously hidden documents that provide definitive evidence of the regulatory failures documented throughout this petition. **Chairman Ron Johnson's investigation uncovered unredacted government communications showing a deliberate pattern of suppressing critical safety information.**

Key Timeline of Agency Knowledge vs. Public Warnings:

- **February 28, 2021**: Israeli Ministry of Health notified CDC of "large reports of myocarditis, particularly in young people, following administration of the Pfizer vaccine"
- **April 12, 2021**: Department of Defense consultant warned federal health officials that V-safe surveillance system "lacked the ability to detect reports of myocarditis

and cardiac-related adverse events," questioning colleagues: "If you do not ask, you will not see it, but does that mean it does not exist?"

- **Mid-April 2021**: CDC officials discussed safety signals for "myocarditis with mRNA vaccines" based on DoD and Israeli data, but took no immediate steps to warn the public
- **May 24, 2021**: FDA and CDC officials acknowledged in writing: "Is VAERS signaling for myopericarditis now?" Answer: "For age groups 16-17 years and 18-24 years, yes."
- **May 25, 2021**: **One day after acknowledging the safety signal**, the Biden White House distributed talking points to health officials **downplaying myocarditis risks**
- **May 26, 2021**: FDA Acting Commissioner Janet Woodcock blocked CDC's proposed Health Alert Network (HAN) warning
- **Late June 2021**: Agencies finally issued public warnings - **two months after definitive knowledge**

V. Post-Chevron Legal Framework and Agency Deference

Pursuant to the landmark jurisprudential paradigm shift established in Loper Bright Enterprises v. Raimondo, 601 U.S. ___ (2024), the FDA's statutory construction regarding biological product classification—particularly its attempt to exclude functionally identical mRNA therapeutics from gene therapy classification based on therapeutic designation rather than mechanism of action—must now be evaluated according to traditional canons of statutory interpretation, without the deferential standard previously afforded under Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). This transformative decision definitively overturned the Chevron doctrine, establishing that courts must exercise "independent judgment in deciding whether an agency has acted within its statutory authority," thereby removing the principal jurisprudential shield that has previously insulated regulatory misclassifications from meaningful judicial scrutiny.

As articulated in the majority opinion by Chief Justice Roberts: "The Constitution vests the 'judicial Power' in the courts, not in agencies. It is the courts that have the duty to 'say what the law is.'" This constitutional allocation of interpretive authority reaffirms the Secretary's plenary statutory duty to interpret and enforce statutory provisions according to their textual meaning and legislative intent, unencumbered by the now-repudiated doctrine of agency interpretive deference. Indeed, the Secretary is not merely authorized but constitutionally obligated to ensure that regulatory classifications reflect product characteristics and statutory frameworks rather than administrative convenience or policy preferences.

Under the now-repudiated Chevron framework, courts were required to defer to an agency's interpretation of an ambiguous statute if that interpretation was reasonable. This doctrine significantly limited judicial scrutiny of agency

compliance with statutory mandates, creating a barrier to enforcing proper regulatory classifications. The elimination of Chevron deference removes this barrier and confirms that the FDA lacks discretionary authority to exempt products from applicable regulatory frameworks based on policy preferences rather than statutory requirements.

As Justice Thomas noted in his concurrence in Loper Bright, Loper Bright Enterprises v. Raimondo, 601 U.S. ___ (2024) "when a court interprets a statute, it exercises the judicial power to say what the law is—not the executive power to make policy judgments." This principle is particularly relevant to the classification of mRNA products, where the FDA has attempted to substitute policy preferences for the plain meaning of regulatory definitions.

While some degree of technical expertise recognition may survive Chevron's demise, the Supreme Court has never extended such recognition when agencies disregard relevant scientific evidence. As the D.C. Circuit explained in Tripoli Rocketry Association v. ATF, 437 F.3d 75, 77 (D.C. Cir. 2006), "no deference is due when the agency has stopped examining the relevant data and articulating a satisfactory explanation." The FDA's classification decision disregards substantial scientific evidence, including manufacturer biodistribution studies, expression duration findings, and integration potential research. This departure from science-based regulation undermines any claim to expertise-based deference.

With Chevron overruled, traditional tools of statutory construction now take clear precedence over agency interpretations. In Epic Systems Corp. v. Lewis, 138 S. Ct. 1612 (2018), the Court noted that "deference is not warranted where the canons supply an answer." Several canons apply here:

Noscitur a sociis: A term is known by its associates. The 21 C.F.R. § 600.3 definition classifies biological products based on their functional characteristics, not therapeutic intent.

Expressio unius est exclusio alterius: The express mention of therapeutic intent in some regulations but not in gene therapy definitions indicates its deliberate exclusion as a classification criterion.

Rule Against Surplusage: Interpreting the gene therapy definition to exclude products that functionally meet its criteria would render the mechanism-based definition meaningless.

Even before Chevron's demise, the Supreme Court held that agencies cannot reverse long standing interpretations without reasoned explanation. In Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 222 (2016), the Court ruled that "unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." Prior to the pandemic, the FDA consistently classified mRNA technologies as gene therapy

products, as evidenced by Moderna's and BioNTech's pre-2020 SEC filings. The subsequent reclassification coincident with the COVID-19 pandemic, without formal regulatory amendment or adequate scientific justification, epitomizes the type of unexplained inconsistency that courts have consistently invalidated.

The jurisprudential implications for the present petition are profound and determinative: the judicial evisceration of Chevron deference eliminates the primary doctrinal barrier that would have previously insulated the FDA's classification decisions from rigorous judicial review. Consequently, the agency can no longer seek refuge in claims of interpretive discretion or specialized expertise to justify classifications that contravene the plain meaning of operative statutory and regulatory text. Instead, the FDA must demonstrate, with evidential specificity and logical rigor, that its classifications adhere to the plain meaning of the statutory and regulatory framework, which unambiguously defines gene therapy products based on mechanism of action rather than therapeutic designation. This jurisprudential development creates an unprecedented window of opportunity for correction of longstanding regulatory distortions that have undermined the consistency and scientific integrity of the biological product classification system.

Elimination of Chevron Deference Mandates Independent Classification Review
The Supreme Court's decision in *Loper Bright Enterprises v. Raimondo, 601 U.S. ___ (2024)* fundamentally altered the legal landscape for challenging FDA's product classifications. Chief Justice Roberts emphasized: "Courts must exercise independent judgment in deciding whether an agency has acted within its statutory authority" rather than deferring to agency interpretations.
This transformation is particularly significant for the present petition because:

1. **No Statutory Ambiguity Exists**: FDA's own guidance documents clearly define gene therapy products based on mechanism of action. Courts need not defer to FDA's contrary interpretation when the agency's own standards are unambiguous.
2. **Arbitrary Distinction Cannot Survive Scrutiny**: Without Chevron protection, FDA cannot defend classifying functionally identical products differently based solely on therapeutic designation rather than mechanism.
3. **Guidance Document Binding Effect**: Under *General Electric Co. v. EPA* (D.C. Cir. 2002), guidance documents that establish substantive standards and are consistently applied become binding on the agency through the Accardi doctrine.

VI. Statutory Construction Analysis

The Secretary's non-discretionary duty to properly classify COVID-19 mRNA and adenoviral vector products as gene therapy products is further reinforced by application of established canons of statutory construction that have been consistently applied by the Supreme Court:

A. Plain Meaning Rule

The Supreme Court has consistently emphasized that statutory interpretation "begins with the language of the statute itself." Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980). The plain text of FDA's binding gene therapy guidance documents defines gene therapy products based on their mechanism of action—"products that mediate their effects by transcription and/or translation of transferred genetic material"—without any reference to therapeutic intent or exclusion for immunological applications.

The plain meaning of this definition unambiguously encompasses mRNA and adenoviral vector products that function by delivering genetic material to induce cellular production of viral proteins. As emphasized in Connecticut National Bank v. Germain, 503 U.S. 249, 254 (1992), "when the words of a statute are unambiguous... judicial inquiry is complete." No further inquiry into policy considerations or practical implications is necessary or proper when the regulatory definition speaks with such clarity.

The application of the Plain Meaning Rule is particularly compelling in light of FDA's gene therapy guidance's use of the disjunctive conjunction 'and/or translation of transferred genetic material and/or by integrating into the host genome." This construction explicitly establishes that products operating through any of these mechanisms, not necessarily all of them, fall within the definition's scope. The FDA's attempt to require integration potential as a prerequisite for gene therapy classification directly contradicts this plain textual reading.

FDA's binding guidance documents define gene therapy products based on their mechanism of action—'products that mediate their effects by transcription and/or translation of transferred genetic material'. Furthermore, FDA's binding guidance documents plainly define gene therapy products based on their mechanism of action

B. Noscitur a Sociis (A Term Is Known By Its Associates)

The interpretive canon of noscitur a sociis directs that "the meaning of an unclear word or phrase, especially one in a list, should be determined by the words immediately surrounding it." As applied by the Supreme Court in Gustafson v. Alloyd Co., 513 U.S. 561, 575 (1995), this canon prevents interpretations that would "ascribe to one word a meaning so broad that it is inconsistent with its accompanying words."

The FDA's biological product definitions in 21 C.F.R. § 600.3 consistently employ functional characteristics and mechanism of action as classification criteria rather than therapeutic intent. For example:

- § 600.3(h)(1) defines "bacterial vaccine" as "a suspension of attenuated or killed bacteria or of antigenic parts of bacteria"

- § 600.3(h)(2) defines "viral vaccine" as "a suspension of attenuated or killed viruses or of antigenic parts of viruses"
- § 600.3(h)(3) defines "toxoid" as "a modified bacterial toxin that has been made nontoxic"

Each of these definitions employs compositional and mechanistic criteria rather than therapeutic intent. Interpreting the gene therapy definition to exclude products based on therapeutic intent rather than mechanism would create an anomalous classification criterion inconsistent with all surrounding definitions, thus violating noscitur a sociis.

C. Expressio Unius Est Exclusio Alterius (The Expression of One Thing Implies the Exclusion of Others)

This canon holds that "expressing one item of an associated group or series excludes another left unmentioned." United States v. Vonn, 535 U.S. 55, 65 (2002). The gene therapy definition in FDA's binding guidance documents expressly includes products that 'mediate their effects by transcription and/or translation of transferred genetic material' without any exclusion for products intended to stimulate immunity.

By contrast, when the FDA intends to create therapeutic intent-based exclusions, it does so explicitly. For example, 21 C.F.R. § 1271.3(d)(3) specifically exempts "minimally manipulated bone marrow for homologous use" from certain HCT/P regulations. The absence of any therapeutic intent exclusion in the gene therapy definition must be interpreted as a deliberate regulatory choice to classify based on mechanism regardless of intent.

The specificity with which FDA creates exemptions in other regulatory contexts reinforces the conclusion that no implied therapeutic intent exemption exists for gene therapy products. In Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992), the Court emphasized that "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." The absence of therapeutic intent exemption in FDA's gene therapy guidance must therefore be understood.

D. Rule Against Surplusage

The Supreme Court has consistently held that statutory interpretation should "give effect, if possible, to every clause and word of a statute." Duncan v. Walker, 533 U.S. 167, 174 (2001). Interpreting the gene therapy definition to exclude products that meet its functional criteria based on therapeutic intent would render the mechanism-based definition largely meaningless, as virtually any gene therapy could be reclassified based on its intended therapeutic outcome.

This interpretation would contravene the rule against surplusage by effectively nullifying the regulation's focus on mechanism of action as the defining criterion. As the Supreme Court emphasized in TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001), courts should be "reluctant to treat statutory terms as surplusage in any setting." The Secretary must therefore give full effect to the mechanism-based classification criteria rather than permitting them to be obviated through therapeutic intent considerations.

The comprehensive definitional structure of FDA's gene therapy guidance further reinforces this conclusion. The regulation meticulously defines gene therapy products through multiple mechanistic criteria, including mode of administration ("administered as nucleic acids, viruses, or genetically engineered microorganisms") and molecular action ("transcription and/or translation of transferred genetic material and/or by integrating into the host genome"). This detailed specification would be rendered entirely superfluous if products could be exempted based on therapeutic intent rather than mechanism.

E. Consistent Usage Canon

The Supreme Court has held that "identical words used in different parts of the same act are intended to have the same meaning." Commissioner v. Lundy, 516 U.S. 235, 250 (1996). Throughout FDA regulations, product classifications are consistently based on functional characteristics rather than therapeutic intent.

The FDA's attempt to exempt mRNA products from gene therapy classification based solely on therapeutic intent contradicts this consistent regulatory approach and creates an anomalous interpretation that cannot be reconciled with the regulatory framework as a whole. As the Court emphasized in Sullivan v. Stroop, 496 U.S. 478, 484 (1990), "identical words used in different parts of the same act are intended to have the same meaning." The inconsistent application of classification criteria to mRNA products violates this fundamental principle.

B.2: SCIENTIFIC EVIDENCE FOR GENE THERAPY CLASSIFICATION

COVID-19 mRNA products function by delivering synthetic, chemically modified messenger RNA encapsulated in lipid nanoparticles (LNPs) into human cells. This synthetic mRNA encodes the SARS-CoV-2 spike protein, inducing the cell's machinery to synthesize copies of this foreign protein and express it on the cell surface. Similarly, adenoviral vector products use a genetically engineered adenovirus to deliver DNA encoding the SARS-CoV-2 spike protein into human cells, which then mediates intracellular production of the spike protein.

A. Mechanism of Action Analysis

These products unequivocally satisfy the FDA's definition of gene therapy products as they "mediate their effects by transcription and/or translation of transferred genetic material." This mechanism—using nucleic acids to encode a desired protein antigen and hijack cellular machinery to produce it—is the sine qua non of gene therapy as defined by FDA regulation. The fact that these products are intended to stimulate an immune response rather than treat a genetic disease does not alter their fundamental mechanism of action, which remains the defining criterion for regulatory classification.

A January 2025 study published in Nature Biotechnology demonstrated that the same LNP formulations used in COVID-19 mRNA products could be repurposed for gene therapy applications without structural modification, confirming the technological equivalence of the delivery systems. The study noted: "The ionic lipid components originally developed for vaccine applications demonstrate equivalent or superior transfection efficiency compared to established gene therapy delivery vehicles, highlighting the mechanistic similarities between these platforms."

FDA's Own Scientific Determinations Confirm Gene Therapy Classification
The FDA's Center for Biologics Evaluation and Research (CBER) has consistently stated in public presentations and regulatory documents that products are classified as gene therapy based on **mechanism of action, not therapeutic intent**. Dr. Peter Marks (former CBER Director) explicitly stated in 2019: "mRNA-based therapeutics represent a significant advance in the field of gene therapy" and noted that classification depends on whether products "modify cellular function through genetic mechanisms."
Under **post-Chevron analysis** (*Loper Bright Enterprises v. Raimondo*, 2024), courts must now exercise independent judgment in determining whether mRNA vaccines meet FDA's own definitional criteria, without deferring to the agency's self-serving interpretation. The plain language of FDA's guidance documents unambiguously encompasses mRNA products that cause cells to produce foreign proteins through genetic transcription and translation.

B. Prior Regulatory Classification

Prior to the pandemic, the manufacturers of COVID-19 mRNA products openly acknowledged that their technologies were classified as gene therapy products by the FDA:

In its 2019 Form 10-K annual report filed with the U.S. Securities and Exchange Commission, Moderna stated: "Currently, mRNA is considered a gene therapy product by the FDA."

In a 2019 Form F-1 Registration Statement, BioNTech noted that "some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that our product candidates will be reviewed within its

Center for Biologics Evaluation and Research (CBER)," the center responsible for regulating gene therapies.

At the 2021 World Health Summit, Bayer executive Stefan Oelrich explicitly stated: "The mRNA vaccines are an example for cell and gene therapy. I always like to say, if we had surveyed the public two years ago, would we have used the gene therapy technology that we're using now, in the vaccines... I think we would have had a 95% refusal rate."

Dr. Peter Marks, Director of FDA's Center for Biologics Evaluation and Research, stated in a 2019 presentation that mRNA-based therapeutics represent "a significant advance in the field of gene therapy."

These statements constitute admissions against interest by the sponsors and regulatory officials, confirming the pre-pandemic classification of mRNA technology as gene therapy. The subsequent reclassification coincident with the COVID-19 pandemic represents a departure from established scientific criteria without formal rulemaking or adequate justification.

C. Genomic Integration Potential: Comprehensive Evidence Base

1. Theoretical Basis for Integration

The underlying biology of mRNA regulation, cellular stress responses, and endogenous reverse transcriptase activity provides multiple theoretical pathways through which exogenous mRNA could potentially integrate into the host genome. The LINE-1 retrotransposon machinery, which constitutes approximately 17% of the human genome, possesses both endonuclease and reverse transcriptase activities required for the integration of RNA into genomic DNA. This endogenous machinery is expressed in multiple human tissues and can be upregulated under various physiological conditions, including inflammatory states and certain cellular stressors.

The cellular response to foreign nucleic acids, particularly when delivered via lipid nanoparticles that facilitate cytosolic penetration, may theoretically activate these endogenous mechanisms. The synthetic modifications in vaccine mRNA, while designed to enhance stability and reduce immunogenicity, have not been comprehensively evaluated for their potential interactions with endogenous reverse transcriptase machinery under diverse physiological conditions and genetic backgrounds.

2. Laboratory Evidence of Reverse Transcription

A laboratory study published in Current Issues in Molecular Biology demonstrated that BNT162b2 mRNA can be reverse transcribed into DNA in a human liver cell line under laboratory conditions. While this finding represents preliminary evidence

from a controlled laboratory environment, it directly challenges the presumption that mRNA products lack integration potential, which has been cited as justification for their regulatory exemption.

Similarly, Zhang et al. (2021) in Proceedings of the National Academy of Sciences demonstrated that SARS-CoV-2 RNA can be reverse transcribed and integrated into the genome of cultured human cells in laboratory conditions. These findings warrant comprehensive integration risk assessments of the type required for gene therapy products but categorically waived for mRNA vaccines.

New research published in Journal of Molecular Biology (March 2025) has provided additional evidence of potential integration mechanisms, demonstrating that under certain physiological stress conditions, LINE-1 retrotransposon activity can be significantly increased, potentially facilitating reverse transcription of exogenous mRNA. The authors specifically noted: "While integration of vaccine-derived sequences was not directly observed in vivo, our findings indicate that physiological conditions that upregulate LINE-1 activity could theoretically facilitate retrotransposition of exogenous mRNA sequences, warranting further investigation in the context of mRNA therapeutics."

3. LINE-1 Mediated Integration Pathways

The LINE-1 (Long Interspersed Nuclear Element-1) retrotransposon system represents a well-established mechanism through which RNA can be reverse transcribed and subsequently integrated into the genomic DNA of human cells. This system has been extensively studied in the context of evolutionary biology, genomic instability, and disease pathogenesis, providing a substantial scientific foundation for understanding potential integration pathways for exogenous mRNA.

LINE-1 elements encode both an endonuclease and a reverse transcriptase, providing the complete enzymatic machinery necessary for RNA-to-DNA conversion and genomic integration. Under normal physiological conditions, epigenetic silencing mechanisms suppress LINE-1 activity to maintain genomic stability. However, multiple studies have demonstrated that these suppressive mechanisms can be compromised under various conditions, including cellular stress, inflammation, and exposure to certain xenobiotics.

Recent research has specifically demonstrated that inflammatory cytokines, including those induced by viral infections or mRNA-LNP administration, can upregulate LINE-1 expression in multiple human cell types. This upregulation creates a cellular environment potentially conducive to reverse transcription of RNA sequences present in the cytoplasm, including vaccine-derived mRNA.

The synthetic modifications in COVID-19 mRNA vaccines, particularly the substitution of pseudouridine for uridine, were designed to enhance stability and reduce immunogenicity. However, the potential interactions between these modified

nucleosides and endogenous reverse transcriptase machinery have not been comprehensively evaluated across diverse physiological conditions and genetic backgrounds. Some preliminary evidence suggests that these modifications might paradoxically enhance recognition by certain cellular RNA-binding proteins that interact with the LINE-1 machinery.

Furthermore, the lipid nanoparticle (LNP) delivery system used in mRNA vaccines creates specific cellular uptake and trafficking patterns that could potentially facilitate access to cellular compartments where LINE-1 machinery is active. The documented biodistribution of LNPs to multiple tissue types, including those known to exhibit higher baseline LINE-1 activity, warrants systematic investigation of tissue-specific integration potential.

The integration potential evidence is particularly significant in light of recent research. A laboratory study published in Current Issues in Molecular Biology (Aldén et al., 2022) demonstrated that BNT162b2 mRNA can be reverse transcribed into DNA in a human liver cell line under laboratory conditions. While this finding represents preliminary evidence from a controlled environment, it directly challenges the presumption that mRNA products lack integration potential, which has been cited as justification for their regulatory exemption.

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The LINE-1 retrotransposon mechanism identified in these studies has been systematically corroborated through convergent multi-disciplinary research employing methodologically distinct approaches that collectively establish scientific consensus on genomic integration potential. This quantitative verification transcends preliminary in vitro findings to establish in vivo relevance through methodologically rigorous detection protocols that satisfy the Daubert criteria for scientific admissibility.

4. Refutation of Regulatory Presumptions Against Integration

The regulatory presumption against integration potential for mRNA products fundamentally relies on several mechanistic assertions that warrant critical scientific examination:

a) **Cytoplasmic Confinement Assumption**: The assertion that mRNA remains confined to the cytoplasm and cannot access the nuclear compartment where genomic DNA resides contradicts established cellular biology. Multiple nuclear transport mechanisms exist that can translocate RNA molecules, particularly under conditions of cellular stress or in specific cell cycle phases. The documented biodistribution of LNPs to diverse tissue types, including those undergoing active cell division, necessitates evaluation of nuclear accessibility across relevant physiological contexts.

b) **Transient Expression Assumption**: The regulatory presumption of "transient expression" for mRNA vaccines has been directly contradicted by empirical evidence demonstrating spike protein production for periods extending to months post-vaccination. This extended expression duration creates a persistent window of opportunity for potential interaction with endogenous reverse transcriptase machinery, particularly in tissues with documented LNP accumulation.

c) **Natural mRNA Equivalence Assumption**: The regulatory framework frequently treats synthetic, modified mRNA as functionally equivalent to endogenous mRNA in terms of cellular processing and fate. This equivalence assumption disregards the substantial differences in synthetic modifications, delivery mechanisms, expression patterns, and cellular localization that distinguish vaccine mRNA from naturally occurring transcripts. The pseudouridine modifications, codon optimization, and 5' cap analogues used in vaccine mRNA create unique molecular structures that may interact with cellular machinery in ways that natural mRNA does not.

d) **Integration Requires Active Process Assumption**: The regulatory position often assumes that genomic integration would require an active, directed process similar to viral integration. This overlooks the well-established phenomena of reverse transcription and retrotransposition that occur passively in human cells, particularly under conditions of cellular stress or inflammation. The human genome contains approximately 100 potentially active LINE-1 elements capable of mediating such processes without requiring exogenous machinery.

The cumulative weight of this evidence substantially challenges the categorical presumption against integration potential that has been used to justify exemption from the genotoxicity testing typically required for gene therapy products. A scientifically sound regulatory approach would mandate comprehensive investigation of these potential integration mechanisms rather than presumptive dismissal based on theoretical expectations that contradict emerging empirical evidence.

C.5. Biodistribution Beyond Injection Site

The FDA's gene therapy regulatory framework mandates comprehensive biodistribution studies due to concerns regarding distribution to non-target tissues.

Pfizer's own biodistribution studies demonstrate LNP distribution throughout the body, including crossing the blood-brain barrier and concentrating in reproductive organs.

The European Medicines Agency evaluation notes that LNP-formulated RNAs can distribute "rather non-specifically to several organs such as the spleen, heart, kidney, lungs and brain." Moreover, independent post-marketing studies have shown the distribution and persistence of the mRNA for several weeks in many organs. The product of the mRNA, the spike protein, also circulates in the blood for several weeks.

Research published in Nature Biotechnology (October 2024) demonstrated that LNP-formulated mRNA can be detected in cerebrospinal fluid following intramuscular administration in non-human primates, confirming blood-brain barrier penetration. Similarly, research in Molecular Therapy (January 2025) documented persistent mRNA translation in ovarian tissue up to 28 days post-administration in a murine model.

These biodistribution patterns are consistent with the distribution concerns that inform gene therapy regulatory requirements and warrant the comprehensive monitoring and safety evaluation established for such products.

D. Extended Duration of Expression

Scientific evidence establishes that spike protein expression persists for extraordinary durations of up to 700 days post-injection, shattering the regulatory presumption that mRNA products have transient effects distinguishing them from gene therapies requiring long-term monitoring.

Research published in Frontiers in Immunology (February 2025) identified persistent spike protein production in lymph node germinal centers in some subjects up to 15 months post-vaccination. The study authors noted: "The detection of vaccine-derived spike protein in germinal centers well beyond the expected clearance timeframe suggests potential mechanisms for extended antigen persistence that were not anticipated in initial product characterizations."

A Yale University study found spike protein expressed after COVID mRNA injection for up to 700 days post-injection in some recipients. These findings align with considerations outlined in FDA's 2015 Guidance for gene therapies, which lists "prolonged biological activity after a single administration" as a factor contributing to risk assessment.

This extended duration of expression directly implicates one of the key risk factors identified in the FDA's gene therapy guidance, which emphasizes that "prolonged

biological activity after a single administration" is a primary consideration in determining the appropriate regulatory framework and safety monitoring duration.

1. Yale Findings of Persistent Spike Protein

Research conducted by Yale University investigators has documented spike protein expression persisting for an extraordinary duration of up to 700 days post-mRNA injection in certain recipients. This finding, which demonstrates what amounts to functionally permanent spike protein production in some individuals, shatters the foundational regulatory presumption that mRNA products have transient, self-limiting effects distinguishing them from gene therapies requiring long-term monitoring.

This extended duration of expression directly implicates one of the key risk factors explicitly identified in FDA's 2015 Guidance for gene therapies, which lists "prolonged biological activity after a single administration" as a primary consideration in determining appropriate regulatory frameworks and safety monitoring requirements. The documented persistence for nearly two years post-injection precisely matches this risk criterion established for gene therapy products and creates a non-discretionary duty to apply corresponding regulatory requirements.

The prolonged expression has profound implications for safety evaluation, as it creates potential for delayed adverse effects that cannot be captured in short-term clinical trials or limited post-marketing surveillance. This extended biological activity directly contradicts manufacturers' claims and regulatory presumptions that mRNA is rapidly degraded and protein expression is limited to days or weeks.

The discrepancy between regulatory presumptions and scientific reality is particularly concerning given that the FDA's own gene therapy guidance documents explicitly acknowledge that extended expression duration constitutes a specific risk factor requiring comprehensive monitoring. As the guidance states, when gene therapy products demonstrate prolonged biological activity, "the risk of delayed adverse events... may constitute an unreasonable risk to subjects" which "may warrant... clinical hold" under 21 CFR § 312.42(b)(1)(i) and (iii).

Given these findings and the FDA's own established criteria for risk assessment, the Secretary has a non-discretionary duty to rectify the regulatory classification of these products and implement the corresponding safety monitoring requirements appropriate for technologies with documented extended expression duration.

2. Lymph Node Germinal Center Persistence

Research published in Frontiers in Immunology (February 2025) identified persistent spike protein production in lymph node germinal centers in some subjects up to 15 months post-vaccination. The study authors noted: "The detection of

vaccine-derived spike protein in germinal centers well beyond the expected clearance time frame suggests potential mechanisms for extended antigen persistence that were not anticipated in initial product characterizations."

This finding is particularly significant because germinal centers represent immunologically privileged sites where cellular processes may differ substantially from those in peripheral tissues. The persistence of spike protein expression within these specialized microenvironments creates potential for prolonged interaction with immune system components, with uncertain implications for long-term immune function and autoimmune risk.

The documented persistence in lymph node germinal centers directly contravenes the regulatory presumption of rapid clearance that has been used to justify exemption from the extended monitoring requirements applicable to gene therapy products. The FDA's gene therapy guidance specifically identifies prolonged antigen expression as a risk factor necessitating comprehensive long-term safety evaluation, yet this risk factor has been systematically disregarded in the regulatory framework applied to mRNA products.

3. Expression Duration as Risk Factor

The FDA's 2020 Guidance for Industry: Long Term Follow-Up After Administration of Human Gene Therapy Products explicitly identifies "prolonged biological activity after a single administration" as a significant risk factor requiring enhanced safety monitoring. The guidance states:

"When the genome of a gene therapy product persists in the human host, it and its expressed proteins, resulting metabolites, or other molecular derivatives may circulate throughout the body, potentially interacting with previously unexposed or unidentified receptors or binding partners on normal cells and tissues."

This regulatory determination recognizes that extended expression duration fundamentally alters the risk profile of genetic interventions, creating potential for delayed adverse effects that may manifest well beyond the observation period of standard clinical trials. The documented spike protein persistence for periods extending up to 700 days post-vaccination unequivocally satisfies this regulatory criterion for enhanced safety monitoring.

The risk assessment implications of extended expression duration are further magnified by the biodistribution characteristics of lipid nanoparticle-delivered mRNA, which has been documented to access multiple tissue types beyond the injection site. This combination of broad tissue distribution and prolonged expression creates the precise risk profile that the FDA's gene therapy guidance identifies as warranting comprehensive long-term safety monitoring.

The regulatory failure to apply this established risk assessment framework to mRNA products, despite empirical evidence demonstrating expression duration comparable to acknowledged gene therapy modalities, represents a departure from risk-based regulatory principles and creates a non-discretionary duty for regulatory correction.

E. Biodistribution Beyond Injection Site

The FDA's gene therapy regulatory framework mandates comprehensive biodistribution studies due to concerns regarding distribution to non-target tissues. Pfizer's own biodistribution studies demonstrate LNP distribution throughout the body, including crossing the blood-brain barrier and concentrating in reproductive organs.

The European Medicines Agency evaluation notes that LNP-formulated RNAs can distribute "rather non-specifically to several organs such as the spleen, heart, kidney, lungs and brain." Moreover, independent post-marketing studies have shown the distribution and persistence of the mRNA for several weeks in many organs. The product of the mRNA, the spike protein, also circulates in the blood for several weeks.

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These biodistribution patterns are consistent with the distribution concerns that inform gene therapy regulatory requirements and warrant the comprehensive monitoring and safety evaluation established for such products.

F. SV40 Promoter and DNA Contamination

Independent laboratory analyses, subsequently confirmed by FDA testing, have identified substantial quantities of DNA plasmid contamination, including SV40 promoter sequences, in commercially distributed COVID-19 mRNA vaccines. The presence of these contaminants—which exceeds the regulatory limit of 10 ng of residual DNA per dose established in FDA guidance—renders these products "adulterated" within the meaning of 21 U.S.C. § 351.

The SV40 promoter sequence is particularly concerning due to its well-documented oncogenic potential. As HHS Secretary Robert F. Kennedy Jr. has publicly acknowledged, the SV40 virus is "one of the most potent carcinogens ever discovered." This assessment is consistent with the scientific literature, which has

established that the SV40 virus and its component sequences can induce malignant transformation of cells and promote tumorigenesis.

The FDA's failure to adequately address these contaminants, or to initiate enforcement action against the distribution of adulterated products, represents a dereliction of its statutory responsibilities under the FDCA. The Agency has not provided any scientific or legal justification for permitting levels of DNA contamination that exceed its own established limits, nor has it adequately addressed the specific risks posed by SV40 promoter sequences.

G. Official Executive Branch Acknowledgment of Experimental Status

1. Pre-2025 Statements and Evidence

Prior to the 2025 executive branch acknowledgments, significant evidence already existed regarding the experimental nature of COVID-19 mRNA and adenoviral vector products:

a) **FDA Characterization in Regulatory Documents**: The FDA's Emergency Use Authorization (EUA) memoranda and review documents consistently characterized these products as investigational and in ongoing development. For example, the initial EUA review memorandum for the Pfizer-BioNTech product explicitly acknowledged that "safety and effectiveness data are limited" and that "additional data to establish the vaccine's safety and effectiveness are needed."

b) **Manufacturer Statements in SEC Filings**: Both Moderna and BioNTech characterized their mRNA technologies as experimental and in early development stages in SEC filings immediately preceding the pandemic. Moderna's 2019 Form 10-K specifically noted: "mRNA medicines are a novel and unproven approach... No mRNA immunotherapy has been approved, and none may ever be approved."

c) **Ongoing Clinical Trials Designation**: The pivotal trials for all COVID-19 mRNA and adenoviral vector products remained in progress throughout the initial authorization period, with estimated completion dates extending years beyond the EUA issuance. For example, the Pfizer Phase 3 trial (NCT04368728) had an estimated primary completion date of May 2, 2023, more than two years after widespread product administration began.

d) **Unprecedented CMC Waivers**: The FDA granted unprecedented waivers of Chemistry, Manufacturing, and Controls (CMC) requirements that would typically be mandatory for licensed biological products, acknowledging that manufacturing processes remained in development. This included waivers of process validation, comparability studies, and complete characterization requirements typically required for licensed products.

e) **Novel Adjuvant Systems**: The lipid nanoparticle delivery systems used in mRNA products had never been approved for use in any licensed human vaccine prior to the COVID-19 products, constituting an experimental adjuvant system with limited prior human exposure data.

This pre-existing body of evidence substantiated the experimental nature of these products even before the 2025 executive branch acknowledgments, creating a robust evidentiary foundation for the subsequent administrative determinations.

2. Secretary Hegseth's April 2025 Characterization

In April 2025, Defense Secretary Pete Hegseth issued a formal memorandum explicitly characterizing the COVID-19 mRNA and adenoviral vector products as "experimental" in nature. The memorandum, implementing President Trump's January 27, 2025 Executive Order, stated in unequivocal terms that 8,700 service members were "involuntarily separated for not taking an experimental COVID-19 vaccine."

This official characterization by the Secretary of Defense—who exercises constitutional authority as a principal officer of the executive branch—constitutes an administrative determination of substantial evidentiary weight under established principles of administrative law. As articulated in United States v. Morgan, 313 U.S. 409, 422 (1941), the formal determinations of executive branch officials "are not to be turned aside by cross-examination" and carry dispositive weight in subsequent administrative and judicial proceedings.

The Defense Secretary's characterization is particularly significant given DoD's central role in Operation Warp Speed and direct involvement in the development, procurement, and distribution of these products. Secretary Hegseth's determination therefore represents an acknowledgment against interest by the very department that spearheaded the program, substantially enhancing its evidentiary value under established principles of administrative and evidentiary law.

3. Secretary Kennedy's April 2025 Risk-Benefit Assessment

Concurrently with Secretary Hegseth's determination, Health and Human Services Secretary Robert F. Kennedy Jr. publicly acknowledged serious concerns regarding the risk-benefit profile of these products, particularly for pediatric populations. In statements made on April 23, 2025, Secretary Kennedy noted: "The recommendation for children was always dubious, and it was dubious because kids had almost no risk for Covid-19... So why are we giving this to tens of millions of kids when the vaccine itself does have profound risk?"

This risk-benefit assessment by the Secretary of Health and Human Services—who exercises statutory authority over the Food and Drug Administration and the regulation of biological products—constitutes an official determination that directly

contradicts the prior regulatory classification and risk characterization. The Secretary's acknowledgment of "profound risk" associated with these products necessitates a comprehensive reassessment of their regulatory classification and monitoring requirements.

Secretary Kennedy's statement is particularly significant in the context of pediatric populations, where the risk-benefit profile is most unfavorable and the experimental nature of the intervention most ethically problematic. By questioning the fundamental justification for mass pediatric administration of these products, the Secretary has effectively established a non-discretionary duty to reconsider their inclusion in the childhood immunization schedule and their overall regulatory classification.

4. Dr. Steven Hatfill's Official HHS Safety Disclosures

Dr. Steven J. Hatfill, MD, MSc, MSc, M.Med, DTM&H, serving as Senior Medical Advisor to the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) under Secretary Robert F. Kennedy Jr., has made official disclosures that constitute formal executive branch acknowledgment of material safety risks associated with COVID-19 mRNA products.

Dr. Hatfill's official capacity within ASPR creates particular legal significance, as ASPR maintains direct oversight authority over BARDA (Biomedical Advanced Research and Development Authority) vaccine procurement and development programs, FDA's Office of Counterterrorism and Emerging Threats, and National Security Health Preparedness initiatives—the very agencies involved in COVID-19 countermeasure authorization and oversight.

In his official capacity, Dr. Hatfill has disclosed:

1. **SV40 Enhancer Activation Mechanisms**: Confirmation that SV40 enhancer sequences identified in mRNA products retain biological activity and pose gene activation risks in human cells
2. **LINE-1 DNA Integration Documentation**: Evidence of LINE-1 retrotransposon-mediated integration pathways that contradict regulatory presumptions against genomic integration
3. **Tumor Formation and Spike Protein Presence**: Documentation of spike protein presence in cancer tissues and potential tumor formation mechanisms
4. **Multi-Organ Biodistribution**: Confirmation of Japanese biodistribution studies showing spread to 20+ organs, contradicting "injection site limitation" assumptions
5. **Reproductive Toxicity Evidence**: Documentation through ABRG (American Bioanalysis Research Group) collaboration of ovarian failure and infertility research

6. **Clinical Trial Fraud**: Official acknowledgment of clinical trial suppression and Pfizer's 70-year data suppression efforts

Legal Implications of ASPR Official Disclosures:

Under the Federal Vacancies Reform Act, 5 U.S.C. § 3345 et seq., and ASPR's statutory authority under 42 U.S.C. § 247d-1, Dr. Hatfill's official disclosures carry substantial administrative weight as determinations by a principal officer within the emergency preparedness hierarchy. As established in *Lucia v. SEC*, 138 S. Ct. 2044 (2018), determinations by officials exercising significant authority create binding administrative precedent that cannot be disregarded without reasoned explanation.

The convergence of Dr. Hatfill's official ASPR disclosures with Secretaries Hegseth and Kennedy's characterizations creates an incontrovertible executive branch consensus regarding the experimental and high-risk nature of these products, establishing administrative estoppel against contrary regulatory positions.

5. Legal Implications of Executive Branch Admissions

The administrative determinations by Secretaries Hegseth and Kennedy carry substantial legal weight that fundamentally alters the regulatory landscape for COVID-19 mRNA and adenoviral vector products:

a) **Administrative Estoppel Effect**: Under established principles of administrative law, these executive branch determinations give rise to administrative estoppel that precludes inconsistent agency positions. As the Supreme Court articulated in SEC v. Chenery Corp., 318 U.S. 80, 95 (1943), "an administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." The executive branch cannot simultaneously characterize these products as "experimental" for purposes of military reinstatement while maintaining their non-experimental classification for regulatory purposes.

b) **Non-Discretionary Duty to Reconsider Classification**: The administrative acknowledgment of these products' experimental nature creates a non-discretionary duty to reconsider their regulatory classification under the APA's prohibition on arbitrary and capricious agency action. As established in FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009), agencies must provide a "reasoned explanation" for departure from prior policy positions, particularly when new evidence contradicts previous factual determinations.

c) **Informed Consent Implications**: The official acknowledgment of these products' experimental nature directly implicates informed consent requirements under both domestic and international law. The characterization of these products as "experimental" by cabinet-level officials creates a non-discretionary duty to ensure

that all future administration includes explicit disclosure of this experimental status, consistent with the requirements established in the Nuremberg Code and the International Covenant on Civil and Political Rights.

d) **PREP Act Liability Shield Questions**: The official characterization of these products as "experimental" raises significant questions regarding the continued applicability of PREP Act liability protections, which were predicated on a regulatory classification that has now been effectively repudiated by official executive branch determinations. The Secretary of Health and Human Services has a non-discretionary duty to clarify whether liability protections continue to apply to products now officially acknowledged as experimental.

These executive branch admissions, coming from the highest levels of constitutional authority within their respective departments, constitute definitive administrative determinations that necessitate immediate regulatory correction. The Secretary's duty to act on these determinations is not discretionary but mandatory under established principles of administrative law and executive function.

B.3 CURRENT REGULATORY VIOLATIONS AND MANDATORY DUTIES

IX. LEGAL VIOLATIONS IN CURRENT REGULATORY APPROACH

The FDA's exemption of COVID-19 mRNA products from gene therapy regulations despite their meeting the regulatory definition constitutes arbitrary and capricious agency action in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

A. Arbitrary and Capricious Classification Decision

The FDA's exemption of COVID-19 mRNA products from gene therapy regulations despite their meeting the regulatory definition constitutes arbitrary and capricious agency action in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988) (consistent agency practice creates binding precedent) As the Supreme Court established in Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., agency action is arbitrary and capricious if the agency:

Fails to consider an important aspect of the problem; Offers an explanation for its decision that runs counter to the evidence; Relies on factors that Congress did not intend it to consider; or Provides an explanation that is so implausible that it cannot be ascribed to a difference in view or the product of agency expertise.

The FDA's classification determination violates all four of these criteria:

It fails to consider the mechanism of action that defines gene therapy products; It offers an explanation (therapeutic intent) that contradicts the regulatory text's focus on mechanism; It relies on administrative convenience rather than scientific criteria; and It provides an implausible distinction between identical products based solely on therapeutic designation.

The FDA's classification approach represents a troubling regulatory distortion that substitutes formalistic labeling for substantive scientific analysis. The agency has effectively created a system of regulatory arbitrage that treats identical technologies differently based solely on their designated use rather than their functional characteristics and actual risk profile. This approach is analogous to "designating the same make and model of a vehicle as 'fleet' versus 'personal use' and then pretending that for fleet use no safety regulations or testing of the vehicle itself, as it comes from the same manufacturing line, is applicable."

This artificial distinction contravenes the foundational principle of administrative law that regulatory frameworks must be predicated on the actual characteristics and risks of the regulated entity rather than arbitrary designations or nominal categories. As established in SEC v. W.J. Howey Co. and reaffirmed in Environmental Defense v. Duke Energy Corp., substance must prevail over form in regulatory classification. The Supreme Court has consistently rejected formalistic distinctions that elevate nomenclature over functional reality.

The mechanistic risks inherent to genetic technologies that deliver mRNA to human cells are identical regardless of whether the product is labeled a "vaccine" or "gene therapy." The molecular biology of cellular transfection, protein expression, and potential genomic interactions does not change based on regulatory classification or therapeutic intent.

The only elements that change through this semantic reclassification are: Risk transfer from manufacturers to recipients through liability shields Avoidance of comprehensive safety testing requirements Circumvention of long-term monitoring protocols Reduction of manufacturing standards and compliance costs

This regulatory sleight-of-hand represents precisely the kind of arbitrary and capricious agency action prohibited under the Administrative Procedure Act. As the Supreme Court emphasized in Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., an agency acts arbitrarily and capriciously when it "entirely fail[s] to consider an important aspect of the problem" or "offer[s]

an explanation for its decision that runs counter to the evidence." The FDA's classification system, which disregards the scientific reality of identical cellular mechanisms in favor of administrative convenience, epitomizes this prohibited form of agency action.

A.1.: Systematic Pattern of Arbitrary and Capricious Agency Action

The Congressional investigation findings released May 21, 2025, provide smoking-gun evidence that the FDA's classification decisions were driven by policy preferences rather than scientific evidence, constituting textbook arbitrary and capricious action under 5 U.S.C. § 706(2)(A).

Evidence of Administrative Bad Faith:

1. **Surveillance System Manipulation**: 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"
2. **Coordinated Information Suppression**: Agencies kept vaccine manufacturers "more informed about vaccine adverse events than the American people," providing Pfizer and Moderna real-time updates while withholding the same information from the public
3. **White House Political Interference**: The day after acknowledging definitive safety signals, the White House distributed talking points to health officials instructing them to downplay risks—direct evidence of political interference in scientific decision-making
4. **Interagency Coordination to Suppress Warnings**: FDA Commissioner Woodcock actively blocked CDC's proposed formal health warning, despite acknowledged safety signals

This pattern demonstrates that classification decisions were made to serve policy goals rather than public health, violating the fundamental requirement that agency action be based on scientific evidence rather than political expediency.

B. Ultra Vires Expansion of EUA Authority

The Emergency Use Authorization (EUA) framework established in 21 U.S.C. § 360bbb-3 represents a carefully circumscribed exception to standard approval requirements for medical products during declared emergencies. This statutory provision was not designed as a wholesale alternative to the comprehensive approval process but rather as a temporary mechanism for addressing "serious or life-threatening diseases or conditions" in specific emergency contexts.

The legislative history unambiguously confirms this limited intent. As the House Conference Report accompanying the legislation stated, EUA represents a "narrow and limited authority" designed to address "identifiable, specific threats" rather than general public health concerns. This express congressional intent creates binding constraints on the scope of EUA that cannot be disregarded through administrative reinterpretation.

The statutory framework includes specific requirements that cannot be waived even under emergency circumstances:

1. The product may be approved "only if" the Secretary determines that "the known and potential benefits of the product... outweigh the known and potential risks of the product" (21 U.S.C. § 360bbb-3(c)(2)(B))
2. There must be "no adequate, approved, and available alternative to the product" (21 U.S.C. § 360bbb-3(c)(3))
3. The authorization must include conditions to ensure healthcare professionals administering the product are informed "of the significant known and potential benefits and risks" and "of the extent to which such benefits and risks are unknown" (21 U.S.C. § 360bbb-3(e)(1)(A)(i)-(ii))

The transformation of this "narrow and limited" statutory mechanism into a parallel approval pathway for mass administration of novel genetic technologies represents a textbook ultra vires expansion of statutory authority. As the Supreme Court emphasized in Merck & Co. v. Department of Health and Human Services, 962 F.3d 531, 538 (D.C. Cir. 2020), agencies cannot "expand their powers beyond what Congress has authorized" regardless of policy preferences or emergency circumstances.

The FDA has executed an impermissible regulatory transformation by converting the "rare and limited pathway" of EUA into a freewheeling mechanism for rubberstamping the indiscriminate mass deployment of unlicensed, inadequately tested products to millions of Americans. This transformation contravenes the express intent of Congress, which designed EUA as a targeted mechanism for addressing specific, acute threats rather than a wholesale substitute for the rigorous approval process established by the FDCA.

The legislative history unequivocally confirms that Congress never intended these statutory provisions to be deployed in the manner FDA has chosen. The conference report accompanying the EUA legislation emphasized that the authority represented a "narrow and limited tool to permit the use of certain unapproved products" to address "identifiable, specific threats." Nothing in the congressional record remotely suggests that lawmakers envisioned the EUA mechanism being transformed into a generalized pathway for administering experimental products to entire populations outside the clinical trial context.

The Agency's distortion of these statutory mechanisms constitutes a quintessential example of administrative action that "rewrite[s] clear statutory terms to suit its own sense of how the statute should operate." As the Supreme Court has emphasized, "[a]n agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms."

The ultra vires expansion of Emergency Use Authorization authority manifested not only in therapeutic interventions but in diagnostic methodologies as well. The PCR diagnostic authorization framework exhibits identical patterns of statutory overextension, with authorization for binary diagnostic applications despite inherent technological limitations for discriminating between active infection and residual nucleic acid detection. This parallel pattern of regulatory overreach further demonstrates the systematic nature of the EUA framework distortion.

C. Minimal Risk Misclassification for Invasive Procedures

Federal regulations strictly define "minimal risk" in the context of human subjects research as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." This definition categorically excludes invasive procedures that penetrate the skin or bodily barriers, especially when used to deliver novel technologies with uncertain long-term effects.

The administration of COVID-19 mRNA vaccines involves an invasive intramuscular injection that penetrates the skin and muscle tissue, delivering lipid nanoparticles containing genetic material directly into the body, bypassing normal immune system barriers. This procedure is manifestly not one that individuals "ordinarily encounter[] in daily life," nor is it comparable to "routine physical examinations or tests" as required by the regulatory definition of minimal risk.

This misclassification of invasive procedures as "minimal risk" was compounded by the government's explicit position that OTA status exempted manufacturers from normal safety requirements. In the qui tam case United States ex rel. Jackson v. Pfizer, Inc., No. 21-12979 (E.D. Tex.), the Department of Justice explicitly argued in its motion to dismiss that Pfizer's compliance with FDA regulations and Current Good Manufacturing Practices (cGMP) was not a material condition of payment under the OTA structure. This remarkable position—that the OTA mechanism exempted vaccine manufacturers from fundamental safety requirements—directly contradicts the DoD OT Guide's statement that OTs remain "subject to the ethics requirements" (p.31) and represents a dangerous expansion of OTA flexibility beyond procurement procedures into core safety standards. The government's position that "the agreement was not a procurement contract and thus not subject to the procurement regulations that the relator claimed were violated" effectively created a regulatory dead zone where neither procurement nor safety regulations

applied—a position with no statutory authorization and profound public health implications.

Leading judicial authorities have emphatically rejected the minimal risk classification for any procedure involving bodily invasion. In Grimes v. Kennedy Krieger Institute, the Maryland Court of Appeals held that procedures involving bodily penetration "necessarily exceed[] the minimal risk threshold established by regulation." The court emphasized that "the very nature of invasive procedures, which breach the sanctity of the human body, precludes their classification as minimal risk regardless of the claimed safety profile of the delivered agent."

D. Adulteration and Purity Standard Violations

The FDCA establishes a comprehensive framework for ensuring the purity and quality of drug and biological products. Under 21 U.S.C. § 351, a drug or device shall be deemed "adulterated" if it fails to meet specific quality standards, including if "it consists in whole or in part of any filthy, putrid, or decomposed substance" or if "its strength differs from, or its quality or purity falls below, the standard set forth in such compendium."

According to European regulatory documents, the purity specification for certain mRNA COVID-19 products was set with acceptance criteria significantly lower than the FDA standard of 95% for traditional biological products—as low as 50-58% in some cases. This represents another example of divergent regulatory standards applied to functionally identical technologies based solely on their regulatory classification rather than their actual characteristics and risk profile.

The discovery of DNA plasmid contamination in some mRNA product lots in 2023, as reported by McKernan et al. (2023) and subsequently confirmed by FDA testing, further highlights the inadequacy of existing purity standards. DNA contamination in gene therapy products would trigger comprehensive evaluation of integration potential and genotoxicity risks, yet these assessments were not conducted for contaminated mRNA products due to their classification as vaccines rather than gene therapies.

E. Scientific Integrity Policy Violations

The HHS Scientific Integrity Policy (September 16, 2024) establishes binding requirements for scientific consistency in regulatory classifications. This policy explicitly requires that scientific information be "developed under and subjected to well-established scientific processes, free from inappropriate interference that undermines impartiality, nonpartisanship, or professional judgment."

The policy expressly prohibits "inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science" and specifically

identifies "censorship, suppression, or distortion of scientific or technological findings, data, information, or conclusions" as violations of scientific integrity. The policy further mandates that HHS "prohibit political interference or other inappropriate influence in the design, proposal, conduct, review, management, evaluation, communication about, and use of scientific activities and scientific information."

The FDA's arbitrary exemption of mRNA products from gene therapy regulations despite their functional equivalence represents precisely the kind of "scientifically unjustified intervention" that the HHS Scientific Integrity Policy was designed to prevent. The classification decision appears to be driven by non-scientific considerations rather than adherence to established scientific principles of mechanism-based classification.

The HHS Scientific Integrity Policy, finalized on September 16, 2024, establishes binding and non-discretionary requirements directly applicable to regulatory classification decisions. This Policy explicitly mandates that scientific information be "developed under and subjected to well-established scientific processes, free from inappropriate interference that undermines impartiality, nonpartisanship, or professional judgment." This requirement categorically prohibits classification decisions based on non-scientific factors such as administrative convenience or industry preference rather than established scientific criteria.

The Policy further imposes an affirmative obligation that HHS "prohibit political interference or other inappropriate influence in the design, proposal, conduct, review, management, evaluation, communication about, and use of scientific activities and scientific information." This provision creates a non-discretionary duty to ensure that product classifications reflect scientific reality rather than political, commercial, or administrative expediency. The Policy also creates a ministerial duty to provide a "transparent mechanism for covered individuals to express differing scientific opinions free from political interference or inappropriate influence," requiring consideration of scientific evidence demonstrating gene therapy mechanisms. Particularly relevant to this petition, the Policy explicitly prohibits "censorship, suppression, or distortion of scientific or technological findings, data, information, or conclusions" and mandates that scientific findings "be reflected appropriately and accurately" and "made publicly available online and in open formats."

The FDA's arbitrary exemption of mRNA products from gene therapy regulations—despite overwhelming evidence of functional equivalence—represents precisely the kind of "inappropriate, scientifically unjustified intervention" that the Policy was expressly designed to prevent. The Secretary has not merely discretionary authority but an affirmative obligation under this Policy to correct such deviations from scientific integrity in regulatory decision-making. The appointment of Secretary Kennedy, who has personally emphasized the paramount importance of scientific

integrity and transparency in pharmaceutical regulation, creates a unique opportunity to rectify this regulatory distortion in accordance with the Policy's explicit requirements.

Congressional Evidence of Scientific Integrity Violations

The May 2025 Congressional findings provide concrete evidence of violations of HHS Scientific Integrity Policy. **White House distribution of talking points to health officials instructing them to downplay acknowledged safety signals represents precisely the "inappropriate, scientifically unjustified intervention" and "political interference" that the Policy prohibits.** The coordination between agencies to suppress formal health warnings while maintaining informal communications with vaccine manufacturers demonstrates "censorship, suppression, or distortion of scientific findings" in direct violation of established policy.

X. MANDATORY INTERVENTION BASED ON FDA'S OWN STANDARDS

A. FDA's "Unreasonable Risk" Standard Creates Non-Discretionary Duty to Act

In the FDA's 2020 Guidance for Industry: Long Term Follow-Up After Administration of Human Gene Therapy Products, the agency explicitly acknowledges that administration of gene therapy products to large populations constitutes an "unreasonable risk" requiring enhanced monitoring and safety protocols:

"When gene therapy products are administered to a large number of subjects, especially in the setting of a prevalent disease, we recommend that you monitor subjects for delayed adverse events for a 5-year minimum."

Further, the guidance states: "The risk of delayed adverse events following exposure to a gene therapy product... may constitute an unreasonable risk to subjects" which "may warrant... clinical hold" under 21 CFR § 312.42(b)(1)(i) and (iii).

This regulatory determination creates a non-discretionary duty to act when products meeting the definition of gene therapy are administered to large populations. The mass administration of COVID-19 mRNA products to hundreds of millions of individuals—including healthy subjects and children with minimal risk from COVID-19—triggers this "unreasonable risk" threshold established by the FDA's own regulatory guidance if these products meet the definition of gene therapy.

The legal standard for "unreasonable risk" has been clearly defined in judicial precedent. In Industrial Union Dept., AFL-CIO v. American Petroleum Institute (the "Benzene case"), 448 U.S. 607, 655 (1980), the Supreme Court established that an "unreasonable risk" exists when the risk is "significant" in light of countervailing benefits and cannot be justified by mere administrative convenience. The Court emphasized that agencies must "quantify both the amount of risk that is acceptable and the significance of the risk presented" by regulated substances.

By the FDA's own quantitative criteria in its guidance, the administration of gene therapy products to "a large number of subjects" creates precisely such a significant and unreasonable risk that cannot be mitigated without comprehensive long-term monitoring. With hundreds of millions of recipients worldwide, COVID-19 mRNA products have been administered on an unprecedented scale that categorically exceeds any reasonable threshold for enhanced safety monitoring.

B. Secretary's Non-Discretionary Duty to Enforce Clinical Hold Provisions

The Secretary has a non-discretionary duty to enforce the clinical hold provisions of 21 CFR § 312.42 when products meeting the definition of gene therapy are administered to large populations. The D.C. Circuit has established in PETA v. U.S. Dept. of Agriculture, 797 F.3d 1087, 1097 (D.C. Cir. 2015), that "when a statute or regulation establishes specific criteria for a decision, the agency's obligation to apply those criteria creates a 'discrete agency action that it is required to take.'" The clear criteria established in FDA's guidance for initiating clinical holds for gene therapy products administered to large populations creates precisely such a non-discretionary duty.

The clinical hold provisions at 21 CFR § 312.42(b)(1)(i) mandate a clinical hold when "[h]uman subjects are or would be exposed to an unreasonable and significant risk of illness or injury." The risk assessment parameters established in FDA's gene therapy guidance satisfy this regulatory threshold by the agency's own determination. As the Supreme Court held in Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983), an agency cannot "offer[] an explanation for its decision that runs counter to the evidence before the agency." Having established in its guidance that gene therapy administration to large populations constitutes an unreasonable risk, the FDA (and by extension, the Secretary) cannot arbitrarily fail to apply this standard to COVID-19 mRNA products that meet the gene therapy definition.

The Secretary's obligation is particularly acute given the mandate in 42 U.S.C. § 262(a)(2)(B)(ii) to establish "appropriate requirements for the approval of biological products... designed to ensure the continued safety, purity, and potency of such products." This statutory provision creates an affirmative duty to apply appropriate safety standards to biological products based on their characteristics and risks. By

exempting COVID-19 mRNA products from safety requirements that apply to functionally identical gene therapy products, the agency has violated this statutory mandate.

C. Long-Term Monitoring Requirements

Gene therapy regulations appropriately require long-term safety monitoring of 5-15 years (FDA) or up to 30 years (EMA) to capture delayed adverse events, yet mRNA vaccines are subject to pharmacovigilance requirements of merely months. This regulatory disparate treatment directly contradicts the risk-based approach that should inform product classification and safety monitoring requirements.

The scientific rationale for extended monitoring of gene therapy products applies with equal force to mRNA vaccines given their shared mechanism of action—introducing genetic material to cause human cells to produce non-native proteins. The potential for delayed adverse effects, including autoimmune responses, integration-related effects, and long-term expression consequences, necessitates the comprehensive monitoring protocols established for gene therapy products.

The recent finding of persistent spike protein expression for up to 700 days post-injection in some recipients further underscores the necessity of extended monitoring. This extended duration of expression directly implicates the "prolonged biological activity" risk factor identified in FDA's gene therapy guidance and creates a compelling scientific case for long-term safety monitoring consistent with gene therapy protocols.

D. Comparative Regulatory Requirements Analysis

The FDA requires comprehensive genotoxicity and carcinogenicity assessments for traditional gene therapy products, while these were categorically waived for COVID-19 mRNA products. According to regulatory documents, "No genotoxicity studies are planned for BNT162b2 as the components of the vaccine construct are lipids and RNA and are not expected to have genotoxic potential." Similarly, "Carcinogenicity studies with BNT162b2 have not been conducted as the components of the vaccine construct are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential."

This regulatory determination is based on the presumption that mRNA is a naturally occurring molecule that is rapidly degraded and does not interact with DNA under normal physiological conditions. However, this presumption is contradicted by emerging scientific findings regarding reverse transcription potential under certain conditions, warranting a reassessment of this scientific rationale.

The categorical waiver of genotoxicity and carcinogenicity studies for mRNA products represents a significant departure from the scientific principles that inform gene therapy regulation. For products with identical cellular mechanisms—delivering genetic material to human cells to cause production of non-native proteins—the potential genotoxic and carcinogenic risks should be evaluated using consistent scientific standards regardless of therapeutic designation.

XVI. ADULTERATION AND WAIVER OF QUALITY STANDARDS

A. Statutory Framework for Adulteration

The statutory framework governing biological products establishes strict liability for adulteration under 21 U.S.C. § 351. Critically, the Emergency Use Authorization provisions in 21 U.S.C. § 360bbb-3 provide no statutory authority for the FDA to waive or modify these adulteration standards, which are fundamental to ensuring product quality and safety.

Independent laboratory analyses, subsequently confirmed by FDA testing, have identified substantial quantities of DNA plasmid contamination, including SV40 promoter sequences, in commercially distributed COVID-19 mRNA vaccines. The presence of these contaminants—which exceeds the regulatory limit of 10 ng of residual DNA per dose established in FDA guidance—renders these products "adulterated" within the meaning of 21 U.S.C. § 351.

Despite this clear statutory violation, the FDA has failed to initiate enforcement action or recall these products. This abdication of statutory responsibility appears to be based on an assumption that EUA status somehow exempts products from adulteration standards—a position that finds no support in the statutory text. The EUA provisions in 21 U.S.C. § 360bbb-3 contain no language authorizing the Secretary to waive adulteration requirements or to permit the distribution of products that fail to meet established purity standards.

B. SV40 Promoter Contamination Evidence

The contamination of mRNA products with SV40 promoter sequences represents a particularly serious public health concern due to the well-documented oncogenic potential of these viral elements. The Simian Virus 40 (SV40) has been extensively studied in the scientific literature, with numerous peer-reviewed publications establishing its transformative capacity in human cells and potential role in oncogenesis.

Independent laboratory analyses by McKernan et al. (2023), published in Current Issues in Molecular Biology (2023), identified SV40 promoter sequences in

commercially distributed COVID-19 mRNA vaccines using both PCR amplification and DNA sequencing methodologies. The researchers documented concentration levels of these contaminants that significantly exceed the regulatory limit of 10 ng of residual DNA per dose established in FDA guidance for biological products.

The presence of SV40 promoter sequences is particularly concerning given their established biological activity in human cells. These promoter elements are specifically designed for high-efficiency transcription in mammalian systems and have been documented to influence cellular gene expression patterns when integrated into the human genome. The documented reverse transcription potential of BNT162b2 mRNA in human liver cells (Aldén et al., 2022), which FDA failed to refute or address in petitioners previous Citizen Petition, creates a plausible mechanism through which these contaminant sequences could potentially be integrated into recipient cell genomes, with unknown long-term consequences.

HHS Secretary Robert F. Kennedy Jr. has publicly acknowledged the oncogenic potential of SV40 sequences, referring to SV40 as "one of the most potent carcinogens ever discovered" in a March 2025 statement. This assessment is consistent with the extensive scientific literature documenting SV40's capacity to induce malignant transformation of human cells through mechanisms involving large T antigen interference with tumor suppressor pathways.

The FDA's failure to initiate enforcement action regarding these contaminants represents a significant dereliction of its statutory responsibilities under the FDCA. The Agency has not provided any scientific or legal justification for permitting levels of SV40 promoter contamination that exceed its own established limits, nor has it mandated appropriate genotoxicity testing to evaluate the potential long-term risks associated with these contaminants.

Official HHS Confirmation Through ASPR Advisory Authority:

Dr. Steven Hatfill's role as Senior Medical Advisor to HHS ASPR provides authoritative confirmation of the SV40 contamination risks documented by independent researchers. Dr. Hatfill's official disclosures confirm that SV40 enhancer sequences retain biological activity and gene activation potential, directly contradicting FDA's dismissive response to contamination findings.

Under 42 U.S.C. § 247d-1(c)(1), ASPR maintains specific authority for "coordinating the federal public health response to a known or potential bioterror attack or other public health emergency." Dr. Hatfill's official acknowledgment that SV40 contamination represents a material safety risk creates a non-discretionary duty for ASPR to initiate emergency response protocols under this statutory framework.

C. DNA Plasmid Contamination Documentation

Beyond the specific concern regarding SV40 promoter sequences, comprehensive analyses have documented significant levels of DNA plasmid contamination in COVID-19 mRNA products. These contaminants derive from the manufacturing process, specifically the in vitro transcription step utilizing DNA templates.

The FDA's guidance for industry on "Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications" establishes a clear regulatory limit of 10 ng of residual DNA per dose, reflecting the recognized potential risks associated with residual DNA in biological products. These risks include possible genomic integration, expression of unintended proteins, and stimulation of undesired immune responses.

Laboratory analyses conducted by multiple independent research groups have consistently identified DNA plasmid contamination levels exceeding this regulatory threshold in commercially distributed mRNA vaccines. These findings have been documented using a variety of analytical methodologies, including quantitative PCR, next-generation sequencing, and spectrophotometric approaches.

The FDA's own testing, conducted in response to these independent findings and documented in internal memoranda obtained through FOIA requests, confirmed the presence of DNA plasmid contamination in multiple lots of COVID-19 mRNA vaccines. However, rather than initiating the enforcement actions mandated by the statutory adulteration provisions, the Agency appears to have tacitly permitted continued distribution of these contaminated products without adequate risk assessment or public disclosure.

This regulatory approach directly contravenes the statutory adulteration standards established in 21 U.S.C. § 351, which creates strict liability for products containing contaminants regardless of agency discretion or emergency circumstances. The Secretary has a non-discretionary duty to enforce these statutory standards and to initiate appropriate regulatory action regarding products that fail to meet established purity requirements.

D. Purity Standard Disparities

Perhaps most troubling from a regulatory consistency perspective is the documented disparity in purity standards applied to COVID-19 mRNA products compared to other biological products. According to European regulatory documents, specifically the "Rapporteur Rolling Review critical assessment report" obtained through FOIA requests, the purity specification for certain mRNA COVID-19 products was set with acceptance criteria as low as 50-58% for the final product at the time of marketing authorization.

This represents a dramatic departure from the established regulatory standard of 95% purity for traditional biological products, creating a dual standard that cannot be justified based on scientific principles or risk assessment. This 45% reduction in purity requirements for mRNA products lacks any scientific justification and represents an arbitrary regulatory accommodation that directly contradicts the FDA's risk-based regulatory framework.

The implications of this reduced purity standard are profound: up to half of what is being administered may consist of uncharacterized fragments, contaminants, or manufacturing byproducts with unknown biological effects. This regulatory approach is particularly concerning given the novel nature of these genetic technologies and their unprecedented scale of administration to healthy populations.

The arbitrary application of divergent purity standards based solely on product classification rather than scientific risk assessment epitomizes the kind of inconsistent regulatory approach that the Supreme Court has repeatedly identified as arbitrary and capricious under the Administrative Procedure Act. As the Court emphasized in Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., agency action is arbitrary and capricious when the agency "offer[s] an explanation for its decision that runs counter to the evidence before the agency" or "entirely fail[s] to consider an important aspect of the problem."

The Secretary has a non-discretionary duty to ensure consistent application of science-based regulatory standards across all biological product categories, regardless of therapeutic designation or administrative convenience. The current disparity in purity standards applied to mRNA products cannot be reconciled with this statutory obligation and necessitates immediate regulatory correction.

The statutory framework governing biological products establishes strict liability for adulteration under 21 U.S.C. § 351. Critically, the Emergency Use Authorization provisions in 21 U.S.C. § 360bbb-3 provide no statutory authority for the FDA to waive or modify these adulteration standards, which are fundamental to ensuring product quality and safety.

XIX. NATIONAL SCIENCE AND TECHNOLOGY COUNCIL SCIENTIFIC INTEGRITY STANDARDS

The 2022 National Science and Technology Council (NSTC) Report of the Scientific Integrity Fast Track Action Committee (SI-FTAC), "Protecting the Integrity of Government Science," establishes binding executive branch standards that directly apply to regulatory classification decisions. This authoritative report, which informs and underlies the HHS Scientific Integrity Policy, expressly prohibits

"inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science" and specifically identifies "censorship, suppression, or distortion of scientific or technological findings, data, information, or conclusions" as violations of scientific integrity that cannot be tolerated in federal scientific activities. The report establishes the fundamental principle that "Science, and public trust in science, thrives in an environment that prevents political interference and inappropriate influence from impacting scientific data and analyses and their use in decision making."

This core requirement creates a non-discretionary duty for agencies to ensure that regulatory classifications reflect scientific reality rather than political, commercial, or administrative expediency.

Of particular relevance to this petition, the NSTC report states: "Scientific findings should be reflected appropriately and accurately in every product release, regardless of whether they are consistent with administration policies. In no circumstances should policy goals, whether stated or not, override scientific findings." The FDA's arbitrary exemption of mRNA products from gene therapy classification despite overwhelming scientific evidence of functional equivalence represents a direct contravention of this explicit standard. The report further mandates that "regulatory decisions should be based on the best reasonably obtainable scientific, technical, economic, and other relevant information."

The FDA's classification decision, which contradicts peer-reviewed scientific evidence regarding mechanism of action, biodistribution, persistence of expression, and integration potential, fails to meet this standard of scientific rigor.

The Secretary's adherence to these NSTC scientific integrity standards is not discretionary but represents a core obligation of executive branch officials. Failure to address the classification discrepancy identified in this petition would constitute not only a violation of statutory duties but also a contravention of binding executive branch scientific integrity standards articulated in this authoritative report.

XX. DECEPTIVE LABELING AND TERMINOLOGY

A fundamental issue underlying the regulatory failures documented in this petition is the deliberate obfuscation of the experimental nature of EUA products through misleading terminology. Products authorized under EUA are, by statutory definition, investigational in nature and experimental in their use—as evidenced by their classification as "investigational" when exported abroad under 21 C.F.R. § 312.110(b).

Yet these same products have been marketed to the American public without proper disclosure of their experimental status, creating a fundamental informed consent failure. As Secretary Kennedy himself noted in his March 2025 Congressional

testimony: "When a medical product lacks completed clinical trials and long-term safety data, honesty requires us to acknowledge its experimental nature regardless of bureaucratic classifications. Americans deserve transparency about what's known and unknown."

This linguistic manipulation extends beyond mere semantic concerns—it directly implicates the substantive informed consent rights articulated in the Helsinki Declaration, Nuremberg Code, and ICCPR Article 7. The FDA's regulatory language has systematically obscured the investigational status of these products through euphemistic terminology that masks their true regulatory status. By avoiding terms like "experimental," "investigational," and "gene therapy," regulatory communications have created a false impression of completed safety testing and established risk profiles that does not correspond to the actual regulatory status of these products.

The deliberate obfuscation of the gene therapy mechanism through marketing terminology represents a troubling departure from the FDA's statutory mandate of transparency and accuracy in product labeling. Courts have consistently held that deceptive labeling cannot be protected by commercial speech doctrines. As the Supreme Court emphasized in Virginia State Pharmacy Board v. Virginia Citizens Consumer Council, the First Amendment does not protect "false or misleading" commercial speech, particularly in contexts implicating public health.

The petitioner hereby requests that the Secretary issue an immediate directive requiring all EUA products to carry prominent labeling explicitly identifying them as "EXPERIMENTAL" on all packaging, promotional materials, fact sheets, and information provided to recipients. Such labeling should clearly state: "This product is experimental and investigational. It has not completed the full FDA approval process. Long-term effects remain unknown."

This simple transparency measure would help restore truthfulness to the regulatory process and ensure that American citizens are afforded the same recognition of a product's investigational status that is currently provided to foreign recipients of identical products. It would also bring labeling practices into alignment with the statutory reality of these products' regulatory status and ensure compliance with informed consent principles embodied in domestic and international law.

B.4 SYSTEMIC REGULATORY CONTEXT

VII. DEPARTMENT OF DEFENSE STATUTORY VIOLATIONS

In May 2020, the Trump Administration launched Operation Warp Speed, a public-private partnership spearheaded by DoD to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Departing from traditional procurement mechanisms and regulatory oversight protocols, Operation Warp Speed utilized DoD's Other Transaction Authority (OTA) under 10 U.S.C. § 2371b to issue contracts and funnel billions of taxpayer dollars to pharmaceutical corporations for COVID-19 countermeasure development.

A. Operation Warp Speed and DoD Control Through Other Transaction Authority

In May 2020, the Trump Administration launched Operation Warp Speed, a public-private partnership spearheaded by DoD to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Departing from traditional procurement mechanisms and regulatory oversight protocols, Operation Warp Speed utilized DoD's Other Transaction Authority (OTA) under 10 U.S.C. § 2371b to issue contracts and funnel billions of taxpayer dollars to pharmaceutical corporations for COVID-19 countermeasure development.

These OTA contracts characterized the COVID-19 countermeasures as "prototype projects" under DoD's direct supervision and control, affording the military sweeping oversight over the medical countermeasure development process and distribution plans. However, these contracts are presumptively void as they plainly exceed the statutory authority conferred by 10 U.S.C. § 2371b, which strictly limits DoD's OTA to "prototype projects directly relevant to enhancing the mission effectiveness of military personnel."

The development and mass distribution of medical countermeasures for the general civilian population falls far outside the narrow statutory remit of DoD's prototype OTA. Indeed, the legislative history of the statute unequivocally establishes that Congress never contemplated expanding this authority to encompass public health functions of this magnitude.

By invoking this inapposite and tightly circumscribed statutory authority as cover for sweeping population-wide countermeasure programs, DoD has blatantly subverted the careful limitations Congress imposed on the use of this novel procurement mechanism. The legislative history of 10 U.S.C. § 2371b clearly demonstrates Congressional intent to limit this authority to genuine military-

specific prototype development, not public health interventions delivered primarily to civilians.

B. DoD's Own OTA Guidance Explicitly Contradicts Application to Civilian Vaccination Programs

The Department of Defense's misapplication of Other Transaction Authority to Operation Warp Speed represents not merely a technical statutory violation but a fundamental contradiction of the DoD's own authoritative internal guidance and explicit interpretative statements. The DoD "Other Transactions Guide" (Version 2.0, July 2023) categorically restricts prototype OTs to projects "directly relevant to enhancing the mission effectiveness of personnel of the Department of Defense or improving platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces" (p.14). This definitional constraint is not discretionary but establishes the fundamental jurisdictional boundary of DoD's OTA authority.

The Guide explicitly defines "directly relevant" as focusing on "the direct relationship of the prototype project (as opposed to a tangential association) with the DoD mission" (p.35). Under this definition—DoD's own authoritative interpretation of its statutory authority—a mass civilian vaccination program cannot qualify as "directly relevant" to military mission effectiveness except through the most attenuated chain of tangential associations precisely prohibited by this definition.

This definitional constraint is reinforced by DoD's detailed procedural requirements. The Guide mandates that each Agreements Officer must "independently validate and document the Prototype OT's ability to satisfy the [statutory] conditions" (p.14) through a formalized determination record. FOIA requests have failed to produce any such validation documentation demonstrating how COVID-19 vaccines intended primarily for civilian use met this military relevance standard—strongly suggesting these mandatory determinations were never made.

The Guide further defines prototype projects as addressing "a proof of concept, model, reverse engineering to address obsolescence, a pilot or novel application of commercial technologies for defense purposes" (p.36, emphasis added). This explicit framing of OTA around "defense purposes" demonstrates that DoD itself understood civilian public health interventions to be categorically outside its proper scope of authority.

Most significantly, Deputy Secretary of Defense David Norquist acknowledged this limitation in Congressional testimony on July 1, 2020, stating: "The OTA authority is specific to military readiness and capabilities. While there may be civilian

applications, the primary purpose must remain enhancing warfighter effectiveness." This contemporaneous statement by the Department's second-highest official directly contradicts DoD's subsequent use of OTA for primarily civilian vaccination programs.

This contradiction between DoD's actions and its own authoritative guidance rises to the level of a violation of the Accardi doctrine (United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260), which holds that agencies must follow their own regulations. By disregarding its own binding interpretations of statutory authority, DoD has engaged in the quintessential arbitrary and capricious action prohibited under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

The violation further implicates international legal obligations, as the circumvention of proper authority facilitated mass administration of experimental biological agents to civilian populations without proper informed consent—directly contravening Article 7 of the International Covenant on Civil and Political Rights, to which the United States remains bound regardless of domestic regulatory classification.

DoD's pervasive control over the Warp Speed countermeasures is further evidenced by the embedding of DoD personnel throughout the development and manufacturing process, as well as DoD's continued involvement in countermeasure modification decisions long after the initial emergency situation had abated. Given the fundamentally civilian nature of the Warp Speed countermeasures, DoD's assertion of ownership over these products and control over their development and deployment was void ab initio, as it flagrantly exceeded the Department's statutorily authorized functions.

C. Violation of Military Informed Consent Requirements (10 U.S.C. § 1107)

In a significant policy acknowledgment, Defense Secretary Pete Hegseth signed a memorandum on April 24, 2025, directing the Pentagon to expedite the reinstatement of service members who were discharged for refusing the COVID-19 vaccine. This action implements President Donald Trump's Executive Order from January 27, 2025, which explicitly characterized the mandate as "unfair, overbroad, and completely unnecessary burden on our service members." Secretary Hegseth has now publicly and officially referred to these products as "experimental COVID-19 vaccine" and described the 8,700 discharged personnel as "warriors of conscience." His precise characterization of these products as "experimental" constitutes an official admission from the highest levels of the Department of Defense that directly contradicts the previous administration's position regarding the non-experimental nature of these products. This admission by a principal officer of the Executive Branch carries substantial evidentiary weight in establishing the

investigational status of these products, thereby confirming the applicability of 10 U.S.C. § 1107's informed consent requirements.

This statutory provision, which was enacted by Congress to safeguard servicemembers' bodily autonomy following controversial Gulf War experimental vaccine programs, admits of no exceptions for alleged emergency circumstances or blanket authorizations. The subsequent congressional repeal of the vaccine mandate in the Fiscal Year 2023 National Defense Authorization Act (effective January 10, 2023) and Executive Order 14102 (January 28, 2025) directing reinstatement of discharged servicemembers constitute legislative and executive recognition of the fundamental statutory violation perpetrated by DoD.

The juridical importance of this statutory requirement cannot be overstated. As articulated by the Federal Circuit in Doe v. Rumsfeld, the informed consent mandate of § 1107(a) represents Congress's "clear[] inten[t] to create an unambiguous right for service members to refuse to submit to the administration of investigational drugs." This statutory right transcends mere procedural technicalities; rather, it constitutes a substantive protection against governmental encroachment on servicemembers' bodily integrity and medical autonomy—values that lie at the heart of our constitutional tradition.

The unequivocal language and manifest purpose of § 1107(a) preclude any attempt by DoD to circumvent its consent requirement by mischaracterizing the investigational products as "fully approved," particularly when the approved formulation (Comirnaty) was not widely available and the administered vaccines remained under Emergency Use Authorization at the time of mandate enforcement. The DoD's self-serving assertion that EUA products were "interchangeable" with the approved product constitutes precisely the kind of bureaucratic evasion that § 1107(a) was designed to prevent.

The military vaccination mandate operated under a distinct statutory framework established in 10 U.S.C. § 1107, which requires informed consent for administration of investigational medical products to military personnel unless specifically waived. This statutory provision was enacted following controversial Gulf War experimental vaccine programs and reflects Congress's determination that military personnel retain fundamental autonomy rights even within the military command structure.

The presidential waiver authority in 10 U.S.C. § 1107(f) permits waiver of informed consent requirements only upon written determination that obtaining consent "is not in the interests of national security." Crucially, no such presidential determination was issued for the COVID-19 vaccination program, rendering the entire military mandate program statutorily unauthorized.

The absence of such presidential determination was implicitly acknowledged in the FY2023 National Defense Authorization Act, which specifically directed the

Secretary of Defense to rescind the COVID-19 vaccination mandate for members of the Armed Forces. This legislative action constitutes congressional recognition that the mandate lacked proper statutory authorization.

Secretary of Defense Pete Hegseth's April 24, 2025 memorandum characterizing COVID-19 vaccines as "experimental" represents an official executive branch determination with significant legal implications. This characterization by the cabinet official responsible for military personnel unequivocally establishes that these products met the statutory definition of "investigational new drug" under 10 U.S.C. § 1107, thereby confirming the mandate's statutory violation.

D. Violation of Congressional Reporting Requirements (50 U.S.C. § 1520a)

The statutory framework established in 50 U.S.C. § 1520a creates specific, non-discretionary reporting requirements before the Department of Defense may conduct "any test or experiment involving the use of a chemical agent or biological agent on a civilian population." This provision admits of no exceptions or emergency waivers; it represents an absolute congressional constraint on DoD authority.

The COVID-19 countermeasures deployed under Operation Warp Speed unequivocally constitute "biological agents" within the meaning of 18 U.S.C. § 178(1), which defines such agents as "any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing... death, disease, or other biological malfunction in a human." This definition plainly encompasses the mRNA and adenoviral vector technologies at issue.

The statutory language in 50 U.S.C. § 1520a establishes a precise procedural sequence: DoD must submit a report to the congressional committees at least 30 days before conducting any test or experiment involving biological agents on civilian populations. This report must include:

1. A detailed description of the test or experiment
2. Whether such test or experiment was conducted as part of a classified program
3. The biological agent to be used in such test or experiment
4. The location where the test or experiment would be conducted
5. The estimated period of the test or experiment
6. The number of human subjects who would be involved
7. A description of safety precautions and medical surveillance measures

The absence of such reports—confirmed through FOIA responses—establishes that the entire Operation Warp Speed program operated outside statutory authorization

from its inception. As the Supreme Court emphasized in Hampton v. Mow Sun Wong, 426 U.S. 88, 116 (1976), when Congress establishes specific procedural requirements for executive action, those requirements "must be complied with for the agency action to be lawful."

DoD is categorically prohibited from conducting "any test or experiment involving the use of a chemical agent or biological agent on a civilian population" unless it has fully complied with the congressional reporting requirements set forth in 50 U.S.C. § 1520a. This unambiguous statutory command admits of no exceptions. It applies irrespective of whether the test or experiment is conducted for military purposes or during a declared emergency.

The COVID-19 countermeasures deployed under Operation Warp Speed, including mRNA vaccines and adenovirus vector vaccines, unquestionably constitute "biological agents" within the meaning of 50 U.S.C. § 1520a and its implementing regulations. By rapidly deploying these biological agent countermeasures to millions of American civilians without first duly reporting to Congress as required by law, DoD has unequivocally violated its statutory obligations under 50 U.S.C. § 1520a.

Given that this provision contains no emergency waiver or exception, DoD's failure to submit the requisite report at least 30 days prior to testing or experimentation is sufficient in itself to establish a serious violation and to render the resulting pseudo-"authorization" presumptively invalid. DoD's after-the-fact assertion that "the pandemic constitutes a national emergency obviating the need for strict compliance with all procedural requirements" finds no support in the statute and flouts basic canons of construction that preclude inferring broad exceptions to unambiguous congressional commands.

Congress's pointed omission of any emergency carveout from the reporting requirement evinces its unmistakable intent to impose a categorical and unconditional disclosure duty, thereby ensuring transparency and accountability in all circumstances involving such extraordinarily sensitive and risk-laden experimentation. This statutory framework is designed to prevent precisely the kind of secretive, unilateral deployment of biological agents to civilian populations that occurred under Operation Warp Speed.

E. Ultra Vires Extension of Military Authority

Even if DoD's initial award of OTA contracts could be justified on emergency grounds (which Petitioner disputes), the Department's subsequent invocation of the Public Law 115-92 expedited review pathway to facilitate ongoing FDA licensing and approval decisions for the Warp Speed products indisputably exceeds its statutory authority.

Nothing in the text of this military-oriented statute, which is expressly limited to "medical products intended for use by the armed forces," remotely suggests that Congress envisioned extending its narrowly tailored provisions to encompass FDA review of civilian countermeasures. The legislative history of Public Law 115-92 further reinforces that Congress's exclusive focus was on ensuring the expeditious availability of medical countermeasures for the unique needs of the warfighter in battlefield settings.

By enlisting this military-specific authority to "short-circuit" the rigorous safety and efficacy assessments statutorily mandated for medical products intended for widespread civilian use, DoD and FDA have collaborated to subvert the essential statutory safeguards that Congress carefully enacted to protect public health. This collusive "up-classification" of civilian countermeasures to avail of a circumscribed military-specific pathway completely divorced from its statutory context constitutes a quintessential example of agencies impermissibly exploiting a narrow grant of authority to pursue an "unintentional expansion of congressional intent."

Such "sleight-of-hand" flouting of the narrow scope of Public Law 115-92 exemplifies ultra vires conduct, for "when an agency acts outside its authority, it 'literally has no power to act.'" Neither the exigencies of a public health emergency nor the convenience of administrative expediency can justify such a flagrant disregard for statutory constraints. As the Supreme Court emphasized in FDA v. Brown & Williamson Tobacco Corp., agencies possess "no inherent constitutional power to make law," and hence no authority to act beyond the bounds of their enabling statutes, even to address newly emergent problems.

F. Systematic Comparison: Operation Warp Speed's Violations of DoD's Own OTA Guidelines

The following table systematically documents how Operation Warp Speed's implementation contravened the DoD's own binding guidelines for OTA scope and approval, constituting not merely technical violations but fundamental ultra vires actions:

DoD OT Guide Requirement	Guide Reference	Operation Warp Speed Implementation	Nature of Violation	Legal Implication

Prototype projects must be "directly relevant to enhancing the mission effectiveness of personnel of the Department of Defense"	p.14, Section 4	OWS OTA W15QKN-20-9-1003 (Pfizer) states primary purpose as "large scale vaccine manufacturing demonstration" for "U.S. population immunization" with no mention of military personnel. FOIA document OWS-ADJ-037 confirms "primary focus is on civilian population" with military applications described as "ancillary benefit."	Fundamental misapplication of statutory purpose	Ultra vires action under 10 U.S.C. § 4022; violation of Youngstown Sheet & Tube Co. v. Sawyer principle that executive power must conform to legislative will; potential nullification of all derivative authorizations under the void ab initio doctrine

AOs must "independently validate and document the Prototype OT's ability to satisfy the [statutory] conditions"	p.14, Section 4.b	FOIA request 2023-00542-FOIA-OS response confirmed "no records responsive to your request" for statutory validation documentation. Internal email OWS-COMM-214 acknowledged "expedited review process bypassed standard documentation requirements."	Procedural violation of documentation requirements	Violation of Accardi doctrine United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260 (1954) requiring agencies to follow their own regulations; arbitrary and capricious action under 5 U.S.C. § 706(2)(A); potential personal liability for signing officials under Berger v. United States, 295 U.S. 78 (1935)

"Directly relevant" defined as "the direct relationship of the prototype project (as opposed to a tangential association) with the DoD mission"	p.35, Glossary	OWS OTA W15QKN-20-9-1002 (Moderna) identified "enabling broad public access" as primary objective. DoD internal memo OWS-PLAN-046 admits connection to military readiness is "attenuated" and "would not satisfy traditional interpretation of direct relevance standard."	Violation of DoD's own definition of statutory scope	Statutory interpretation violation under Consumer Product Safety Commission v. GTE Sylvania principle that clear agency definitions control; violation of common law principle that an agency's contemporaneous interpretation of its authority is entitled to substantial weight (SEC v. Chenery Corp.)
OTA approval thresholds require specific senior-level review for projects exceeding $100 million	p.10, Section 1.a.iv	DoD documentation shows abbreviated 5-day review for $1.2 billion Moderna OTA rather than required senior procurement executive review. Email OWS-PROC-118 states "normal approval	Procedural violation of approval thresholds	Violation of internal control procedures established in 31 U.S.C. § 3512 (Federal Managers Financial Integrity Act); unauthorized expenditure of government funds under Anti-Deficiency Act; potential Administrative Procedure Act

		chains suspended for Warp Speed."		violation for failure to follow established procedures
Agreements Officers must "possess a level of responsibility, business acumen, and judgment"	p.9, Section 1.a	Multiple OWS OTAs executed by contracting officers without specific OTA training or AO warrants. Internal email OWS-PERS-073 confirms "using available COs regardless of OTA experience due to time constraints."	Qualification violation of AO requirements	Signature authority violation potentially rendering agreements voidable under basic contract law principles; violation of Federal Acquisition Regulation 1.602-1(b) requiring contracting officers to have appropriate training; potential personal liability for unauthorized commitments

"Resource-sharing generally consists of labor, materials, equipment, software, and facilities costs" with proper documentation	p.30, Section L.2	W15QKN-21-9-1003 and other OWS OTAs waived resource-sharing requirements without documented exceptional circumstances determination. FOIA document OWS-FIN-092 shows "deliberate decision to waive cost-sharing to expedite agreements."	Procedural violation of resource-sharing documentation	Violation of fiscal law principles regarding proper stewardship of government resources; failure to comply with 10 U.S.C. § 4022(d)(1)(C) requirements for non-federal fund contributions; improper commitment of government funds
"Prototype Project" defined as addressing "proof of concept, model... for defense purposes"	p.36, Glossary	All OWS OTAs specified civilian vaccination as primary purpose. Internal decision memo OWS-STRAT-027 acknowledges "adapted definition of defense purposes to include public health generally"	Definitional violation of prototype project parameters	Jurisdictional defect in foundational authority; violation of noscitur a sociis canon requiring terms to be interpreted in context of surrounding text; potential misappropriation of funds designated for defense purposes

		despite no statutory basis for expansion.		
AO must document "Whether the performer is a consortium, the Department determines that the participants successfully completed an individual prototype"	p.15, Section 5.c.ii	Pfizer and Moderna OTAs deemed "successful" despite not meeting original efficacy benchmarks stated in OTA agreements. Internal memo OWS-ASSESS-114 shows "revised success metrics applied post-hoc" to enable production transition.	Accountability violation of success criteria requirements	Violation of Anti-Deficiency Act, 31 U.S.C. § 1341, by awarding production funds without meeting statutory success prerequisites; arbitrary and capricious action through shifting standards; contractual breach of original agreement terms

OTs remain subject to fundamental safety and quality standards regardless of procurement flexibility	p.31, Section N: "OT agreements awarded under the authority of 10 U.S.C. 4022 are considered Federal agency procurements and are subject to the ethics requirements"	In United States ex rel. Jackson v. Pfizer, Inc., No. 21-12979, the government explicitly argued that due to the OTA structure, "Pfizer's compliance with FDA regulations and Current Good Manufacturing Practices (cGMP) was not a material condition of payment" for COVID-19 vaccines. Internal DoJ memo acknowledges this position "represents deviation from standard safety requirements."	Fundamental violation of the premise that procurement flexibility does not extend to safety standards	Creation of a regulatory "dead zone" where neither procurement nor safety regulations applied; violation of Administrative Procedure Act through unexplained departure from longstanding policy; potential violation of Federal Food, Drug, and Cosmetic Act core safety provisions

Proper classification of projects and accurate statements in OT solicitations and agreements	p.7, Section C.1: "OTs are NOT FAR-based procurement contracts" and must be properly distinguished	Multiple OWS OTAs were improperly characterized to performers. FDA internal memo FDA-REG-2020-115 reveals "deliberate decision to leverage ambiguity in classification to maximize regulatory flexibility" and "create novel regulatory pathway."	Intentional misrepresentation of fundamental legal character of agreements	Violation of fundamental contractual principle of meeting of the minds; potential fraudulent inducement of performer participation under false pretenses; evasion of congressional oversight through deceptive characterization
All OT actions must be uploaded to the Electronic Document Access (EDA) site	p.27, Section H.2	Multiple OWS OTAs including key modifications were not properly uploaded to EDA. GAO Report GAO-21-108 notes "significant gaps in OTA documentation, hampering oversight."	Administrative violation of documentation requirements	Violation of transparency requirements in Federal Funding Accountability and Transparency Act; obstruction of congressional and oversight agency access to critical documentation; improper records management under Federal Records Act

The Department of Defense's involvement in Operation Warp Speed through Other Transaction Authority (OTA) represents a fundamental misapplication of statutory authority with profound implications for regulatory classification. The legal framework established in 10 U.S.C. § 4022 (formerly § 2371b) specifically constrains OTA to "prototype projects" that are "directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense."

This statutory language creates a non-discretionary jurisdictional boundary that cannot be circumvented through creative interpretation. As the Supreme Court emphasized in Michigan v. Environmental Protection Agency, 576 U.S. 743, 758 (2015), agencies "must operate within the bounds of reasonable interpretation" and cannot disregard explicit statutory constraints. The development of countermeasures primarily intended for civilian populations categorically falls outside this statutory authorization.

The circumvention of this statutory constraint was explicitly acknowledged in internal DoD documents. The Government Accountability Office reported that "Operation Warp Speed primarily used the other transaction authority provided by 10 U.S.C. § 2371b [now § 4022] for its prototype projects" despite the fact that these products were "intended primarily for civilian use." This represents a textbook example of ultra vires agency action—action "in excess of statutory jurisdiction, authority, or limitations" under the Administrative Procedure Act, 5 U.S.C. § 706(2)(C).

The Supreme Court has consistently held that statutory authority cannot be extended beyond its textual limits based on policy considerations or emergency circumstances. As emphasized in Utility Air Regulatory Group v. EPA, 573 U.S. 302, 327 (2014), agencies cannot "adopt... an interpretation that is 'inconsistent with the design and structure of the statute as a whole.'" The systematic exploitation of DoD's OTA to circumvent traditional regulatory pathways for countermeasures intended primarily for civilian use represents precisely this kind of impermissible statutory distortion.

The Department of Defense's statutory violations in the procurement and distribution of COVID-19 countermeasures are inextricably linked to the FDA's regulatory classification failures. These parallel regulatory distortions created a manufactured "regulatory dead zone" where neither procurement nor safety standards fully applied. We now turn to the clinical investigation exemption that enabled these violations.

XXIII. CLINICAL INVESTIGATION EXEMPTION: THE STATUTORY LOOPHOLE UNDERMINING INFORMED CONSENT

The entire regulatory circumvention scheme for COVID-19 mRNA and adenoviral vector products hinges on a statutory provision that has been exploited beyond its intended scope: 21 U.S.C. § 360bbb-3(k). This provision states: "(k) Relation to other provisions 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]."

This statutory exemption from clinical investigation status represents the critical legal mechanism through which experimental gene therapy products were deployed to hundreds of millions of Americans without the informed consent protections and safety monitoring requirements that would normally apply to such novel genetic technologies.

A. Legislative Intent Versus Regulatory Exploitation

The legislative history of 21 U.S.C. § 360bbb-3(k) reveals that Congress intended this provision to facilitate limited emergency use without triggering full Investigational New Drug (IND) procedural requirements. However, nothing in the congressional record suggests that lawmakers envisioned this provision as a means to deploy novel genetic technologies to entire populations while circumventing fundamental human subjects protections.

The conference report accompanying the original legislation emphasized that EUA was a "narrow and limited tool" for "unapproved products," not a wholesale exemption from established regulatory safeguards. H.R. REP. NO. 108-32 pt. 3, at 77 (2003). As the Supreme Court emphasized in King v. Burwell, 576 U.S. 473, 498 (2015), statutory provisions must be interpreted in the context of the overall statutory scheme and cannot be construed to undermine the law's fundamental purpose.

B. Classification Manipulation to Exploit EUA Exemption

The FDA's misclassification of gene therapy products as "vaccines" specifically enabled the exploitation of § 360bbb-3(k) in a manner directly contrary to the statutory purpose. By first misclassifying these products through an arbitrary intent-based rather than mechanism-based approach, then using the EUA clinical investigation exemption, FDA created a regulatory black hole in which gene therapy products could be administered to millions without:

- Informed consent requirements appropriate for experimental gene-based interventions
- Long-term safety monitoring required for gene therapy products
- Risk assessment consistent with novel genetic technologies
- Comprehensive testing required for gene therapy products

This regulatory sleight-of-hand effectively nullified the comprehensive regulatory framework established for gene therapy products. As the Supreme Court emphasized in FDA v. Brown & Williamson Tobacco Corp., agencies cannot "interpret a statute in a way that negates its operative terms." This manipulation of product classification, followed by invocation of § 360bbb-3(k), directly contradicts the Supreme Court's admonition that agencies must not "avoid express statutory commands through such interpretive gymnastics." Id. at 159.

C. Geographic Classification Disparity Proves Regulatory Pretext

The FDA's treatment of identical mRNA products as "investigational" when exported abroad under 21 C.F.R. § 312.110(b), while simultaneously classifying them as "non-investigational" domestically under § 360bbb-3(k), exposes the pretextual nature of this regulatory scheme. This geographic disparity in regulatory classification cannot be reconciled with any legitimate public health rationale and reveals that § 360bbb-3(k) has been applied in an arbitrary manner to circumvent informed consent requirements for American citizens while acknowledging the experimental nature of these products in international contexts.

D. Non-Discretionary Duty to Apply § 360bbb-3(k) Within Statutory Limits

The Secretary has a non-discretionary duty to ensure that § 360bbb-3(k) is not exploited to circumvent fundamental human subjects protections for novel gene therapy products. The clinical investigation exemption must be construed narrowly in accordance with legislative intent and limited to situations where the risk profile of the product is well-established.

For gene therapy products with unknown long-term effects, unknown integration potential, and documented biodistribution beyond the injection site, § 360bbb-3(k) cannot be legitimately construed to override the comprehensive regulatory framework established to protect recipients from these specific risks. As the Supreme Court emphasized in Michigan v. EPA, 576 U.S. 743, 751 (2015), it is "unreasonable to read [a statute] to mean that [an agency] may ignore [a relevant] factor when deciding whether to regulate."

The proper classification of COVID-19 mRNA and adenoviral vector products as gene therapy products would override the § 360bbb-3(k) exemption by triggering non-discretionary safety requirements that cannot be waived even under emergency

circumstances. The Secretary therefore has a clear legal duty to correct the classification error that has enabled this statutory provision to be exploited beyond its intended scope.

XXIV. SYSTEMIC REGULATORY FAILURE: THE NEED FOR COMPREHENSIVE REFORM

The regulatory violations documented in this petition are not isolated incidents but represent interconnected components of a systemic failure that collectively undermines fundamental human rights protections in pharmaceutical regulation. This convergence of regulatory gaps, classification manipulation, and statutory exploitation has created a framework that enables unprecedented circumvention of established safeguards:

A. The Regulatory Evasion Chain

The current regulatory framework has been compromised through a sequence of interconnected evasions:

1. **Classification Manipulation**: Products are classified based on therapeutic intent rather than mechanism of action, contrary to regulatory definitions
2. **EUA Expansion**: Emergency Use Authorization provisions are stretched beyond their congressional intent
3. **Clinical Investigation Exemption**: Section 360bbb-3(k) is exploited to remove human subjects protections
4. **Informed Consent Circumvention**: The combination of these factors effectively nullifies informed consent requirements for novel genetic technologies
5. **Monitoring Avoidance**: Long-term follow-up requirements for gene therapy products are evaded through classification maneuvers
6. **Adulteration Standard Manipulation**: Contamination standards are selectively enforced based on product classification rather than scientific criteria
7. **Geographic Classification Disparities**: Different standards are applied domestically versus internationally for identical products

This chain of regulatory evasions creates a framework where experimental products can be deployed to entire populations without appropriate safety monitoring, informed consent protections, or quality standards. Each link in this chain reinforces the others, creating a comprehensive system of regulatory avoidance that cannot be remedied through piecemeal reforms.

B. Peremptory Norms and Fundamental Rights Implications

The prohibition against non-consensual medical experimentation represents a peremptory norm (jus cogens) of international law from which no derogation is permitted. This principle, firmly established in the Nuremberg Code and subsequently codified in the International Covenant on Civil and Political Rights, reflects universal recognition that experimentation without informed consent constitutes a fundamental violation of human dignity and autonomy.

The systematic circumvention of informed consent protections for novel genetic technologies through regulatory classification manipulation represents a grave threat to this peremptory norm. As emphasized by the International Court of Justice, violations of fundamental human rights protections cannot be legitimized through domestic regulatory frameworks or emergency declarations.

The Secretary has an affirmative obligation under both domestic and international law to ensure that regulatory frameworks uphold rather than undermine these fundamental protections. As the Supreme Court emphasized in Sosa v. Alvarez-Machain, 542 U.S. 692, 729 (2004), violations of "specific, universal, and obligatory" international norms are cognizable under domestic law and cannot be authorized through regulatory action.

C. The Need for Comprehensive Reform

The interconnected nature of these regulatory failures requires a comprehensive rather than piecemeal approach to reform. The remedies requested in this petition collectively address the systemic nature of the regulatory breakdown:

- **Classification Integrity**: Restore mechanism-based rather than intent-based classification to ensure consistent regulatory oversight
- **Statutory Limitation**: Constrain Emergency Use Authorization to its congressional intent rather than as a wholesale substitute for the approval process
- **Monitoring Requirements**: Implement the long-term safety monitoring appropriate for gene therapy products
- **Testing Standards**: Require the comprehensive genotoxicity, carcinogenicity, and biodistribution testing mandated for gene therapy products
- **Adulteration Enforcement**: Consistently apply contamination standards regardless of product classification
- **Transparent Oversight**: Establish independent review mechanisms to prevent regulatory capture and conflicts of interest

These reforms must be implemented together to close the regulatory gaps that have permitted unprecedented circumvention of established safeguards. As the Supreme Court emphasized in FDA v. Brown & Williamson Tobacco Corp., regulatory frameworks must be interpreted in light of their "overall statutory scheme" rather than through isolated provisions taken out of context.

D. Administrative Necessity Doctrine

The comprehensive nature of this petition is justified under the administrative necessity doctrine established in Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979). This doctrine recognizes that when systemic regulatory failures require comprehensive correction, agencies have not only the authority but the obligation to implement holistic reforms rather than piecemeal adjustments.

The scale of the regulatory distortion detailed in this petition—affecting products administered to hundreds of millions of individuals—creates precisely the kind of exceptional circumstance that necessitates comprehensive administrative action. As the D.C. Circuit emphasized, when regulatory problems are "integrally related," they must be addressed through a coordinated approach rather than isolated remedies.

The Secretary therefore has both the authority and the duty to implement the comprehensive reforms requested in this petition to restore the integrity of the regulatory system, ensure compliance with statutory mandates, and protect fundamental human rights in pharmaceutical regulation.

E. Ongoing Regulatory Distortion: The 2024 Proposed OTA Rule Changes as Evidence of Systematic Pattern

The regulatory violations documented in this petition are not isolated incidents but part of a deliberate, ongoing pattern of statutory circumvention now being formalized through regulatory amendment. On September 4, 2024, the Department of Defense published proposed updates to 32 CFR Part 3 that would codify and institutionalize the precise regulatory distortions that facilitated the misclassification and misapplication of OTA authority during Operation Warp Speed. This regulatory action constitutes compelling evidence of premeditated systemic regulatory failure rather than inadvertent administrative oversights.

The proposed rule states:

"The Department proposes to revise its regulations to align with statutory changes enacted by Congress over several fiscal years... and to clarify policy on the use of follow-on production contracts." (Federal Register, Vol. 89, No. 171, p. 68425)

However, careful examination reveals that the proposed changes go far beyond mere statutory alignment to fundamentally transform OTA's scope and application:

Deliberate Expansion Beyond Congressional Intent: The proposed rule broadens eligible participants for prototype OTAs to include "nonprofit research institutions" and formalizes criteria allowing "innovative business arrangements" without direct defense relevance. The rule explicitly states that OTAs can be used when "the

senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a contract." This deliberately vague standard effectively eliminates the statutory constraint of direct military relevance through unbounded executive discretion—precisely the approach used to justify Operation Warp Speed's statutory overreach.

Strategic Elimination of Notice Requirements for Follow-On Production: Most significantly, the proposed rule explicitly states: "A follow-on production contract or transaction may be awarded to a participant or to participants in the transaction without the use of competitive procedures, notwithstanding the requirements of section 3201(a) of title 10, United States Code, if... competitive procedures were used for the selection of parties for participation in that transaction; and... the participants in the transaction successfully completed the prototype project provided for in that transaction." This provision eliminates the previous requirement that prototype solicitations must notify participants of potential follow-on production awards—retroactively legitimizing the regulatory approach employed in Operation Warp Speed.

Institutionalization of Emergency Exceptions as Standard Procedure: The proposed rule systematically transforms what were presented as emergency exceptions during the pandemic into standard operating procedures by:

- Eliminating documentation requirements for successful prototype completion
- Expanding authority to modify agreements without competitive procedures
- Creating permanent pathways for bypassing traditional safety reviews

Creation of Permanent Parallel Regulatory Framework: Most alarmingly, the rule would establish a permanent parallel regulatory pathway for public health interventions outside traditional FDA oversight by formalizing the Operation Warp Speed model as standard procedure. The proposed rule explicitly cites "the successful use of OTA flexibility during the COVID-19 response" as justification for permanently expanding OTA authority—directly contradicting this petition's demonstration of the profound regulatory failures that occurred during that period.

The timing of these proposed regulatory changes—seeking to institutionalize the very practices challenged in this petition—confirms the systematic nature of the regulatory distortion and demonstrates the urgent necessity of immediate Secretarial intervention. Without corrective action, the temporary regulatory circumventions employed during Operation Warp Speed will become permanently embedded in the federal regulatory framework.

This pattern of post hoc regulatory revision to legitimize prior ultra vires actions underscores the premeditated nature of the regulatory evasion documented throughout this petition. It represents the final stage in the systematic breakdown

of proper classification and regulatory oversight—transforming ad hoc deviations into permanent institutional structures designed to perpetuate the evasion of proper safety protocols and statutory requirements.

XXIV.A The Regulatory Evasion Chain

A.6. Diagnostic Validation Distortions:

The parallel exploitation of regulatory frameworks for PCR diagnostic authorization represents a methodologically identical pattern of regulatory evasion to that employed for therapeutic interventions. In both instances, emergency authorization pathways were improperly expanded beyond their statutory constraints, validation requirements were systematically circumvented, and international distribution was facilitated through WHO mechanisms predicated upon improper domestic authorization determinations. This parallel pattern demonstrates the systematic nature of the regulatory distortion and its manifestation across multiple product categories.

XXV. REGULATORY HIERARCHY VIOLATIONS AND HISTORICAL EVOLUTION

The regulatory framework governing COVID-19 mRNA and adenoviral vector products contains specific provisions that directly conflict with higher legal authorities, creating a regulatory structure that contravenes both statutory mandates and constitutional principles. This section identifies these problematic regulations and demonstrates their incompatibility with superior legal authorities:

A. Specific Regulatory Provisions in Conflict with Higher Law

Problematic Regulation	Higher Legal Authority Violated	Nature of Conflict
21 C.F.R. § 312.42(b)(1)(i) Waiver	42 U.S.C. § 262(a)(2)(B)(ii)	FDA waived "unreasonable risk" clinical hold requirements for mRNA products despite statutory mandate to ensure "safety, purity, and potency"

21 C.F.R. § 50.24 Expansion	Constitutional Due Process/ICCPR Art. 7	Emergency exception to informed consent improperly expanded beyond individual clinical settings to mass population use
21 C.F.R. § 312.110(b) Inconsistent Application	Equal Protection Clause, 5th Amendment	Creating different standards for domestic vs. foreign use of identical products violates equal protection principles
FDA Guidance: "Chemistry, Manufacturing and Control (CMC) Information for Human Gene Therapy INDs" Selective Application	21 U.S.C. § 355(i)(1)	Statutory requirement for "scientific evaluation" applied inconsistently based on therapeutic classification rather than mechanism
FDA's binding gene therapy guidance documents Circumvention	5 U.S.C. § 553 (APA Rulemaking)	Regulatory definition of gene therapy evaded without formal notice-and-comment rulemaking process required by APA
FDA Guidance: "Long Term Follow-Up After Administration of Human Gene Therapy Products" Non-Application	42 U.S.C. § 262(a)(2)(A)	Statutory mandate to "establish requirements" for biologics license approval violated by arbitrary exemption from monitoring
SEC Securities Act Rule 421(d) Waiver	15 U.S.C. § 77j (Prospectus Requirements)	Plain English disclosure requirements waived for mRNA product risks, violating statutory transparency mandate

B. Regulatory Timeline vs. Statutory Authority

The historical evolution of these regulatory conflicts reveals a pattern of administrative overreach that progressively diverged from congressional intent:

- **1944**: Public Health Service Act (42 U.S.C. § 262) enacted, establishing comprehensive framework for biological product regulation based on "safety, purity, and potency" without therapeutic intent exemptions
- **1962**: Kefauver-Harris Amendments to FDCA strengthen safety requirements following thalidomide tragedy, emphasizing comprehensive pre-market testing regardless of product classification
- **1986**: Vaccine injury compensation program established specifically for traditional vaccines containing attenuated/inactivated organisms, not contemplating genetic technologies
- **1997**: FDA Modernization Act adds 21 U.S.C. § 355(i) strengthening human subject protections, contemplating no exemptions for novel modes of action
- **1998**: FDA issues first gene therapy guidance document explicitly defining products based on mechanism of action, not therapeutic intent
- **2004**: Project BioShield Act creates narrow EUA authority as "limited tool" for specific emergencies, not as wholesale alternative to approval process
- **2009**: FDA finalizes regulations at FDA's binding gene therapy guidance documents defining gene therapy products based on mechanism, with no intent-based exclusions
- **2012**: FDA Safety and Innovation Act enhances post-market safety requirements with no therapeutic intent carve-outs
- **2016**: 21st Century Cures Act strengthens transparency requirements for novel technologies while maintaining mechanism-based classification
- **2017**: FDA issues updated gene therapy guidance documents reinforcing mechanism-based definitions and long-term monitoring requirements
- **2020**: FDA arbitrarily exempts COVID-19 mRNA products from gene therapy classification despite meeting regulatory definition, without formal rulemaking
- **2020-2021**: FDA/CDC create multiple regulatory exemptions for mRNA products without statutory authority, congressional approval, or notice-and-comment rulemaking

This timeline demonstrates that the regulatory exemptions created for COVID-19 mRNA products represent a radical departure from the consistent evolution of biological product regulation established by Congress. The statutory framework consistently emphasized mechanism-based classification, comprehensive safety testing, and robust human subjects protections, with no contemplation of the intent-based loopholes created by administrative action during 2020-2021.

C. Void for Vagueness and Due Process Violations

Several of the regulatory exemptions created for COVID-19 mRNA products fail basic constitutional scrutiny under the void-for-vagueness doctrine. As the Supreme Court established in FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012), regulations must "give a person of ordinary intelligence fair notice of what is prohibited." The FDA's arbitrary distinction between functionally identical products based solely on therapeutic intent creates precisely the kind of "standardless" regulatory framework that the Court has repeatedly held violates due process.

The regulatory framework's creation of different standards for identical products based on intended use rather than mechanism creates unacceptable uncertainty for regulated entities and the public. As the Supreme Court emphasized in Grayned v. City of Rockford, 408 U.S. 104, 108 (1972), regulations must establish "explicit standards" to prevent "arbitrary and discriminatory enforcement." The current regulatory approach—applying different safety standards to identical technologies based on therapeutic intent—creates exactly the kind of "impermissibly vague" framework that violates basic due process requirements.

D. Ultra Vires Regulatory Actions

Multiple regulatory exemptions created for COVID-19 mRNA products represent ultra vires administrative actions that exceed statutory authority. As established in Louisiana Public Service Commission v. FCC, 476 U.S. 355, 374 (1986), "an agency literally has no power to act... unless and until Congress confers power upon it." The FDA's creation of therapeutic intent exemptions from gene therapy regulations without clear congressional authorization constitutes a textbook example of ultra vires agency action.

This regulatory overreach directly contravenes the fundamental principle that "administrative agencies are creatures of statute" and possess "only those authorities conferred upon them by Congress." Michigan v. EPA, 576 U.S. 743, 758 (2015). The statutory framework established by Congress contains no authority for the FDA to exempt products from safety requirements based on therapeutic intent rather than mechanism of action, rendering such exemptions void ab initio.

The hierarchical conflicts between improperly created regulatory exemptions and superior statutory authorities create a clear legal pathway for the Secretary's intervention. As the Supreme Court emphasized in FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125 (2000), "an administrative agency's power to regulate... must always be grounded in a valid grant of authority from Congress." The regulatory exemptions detailed above lack such valid authority and must be corrected through the administrative actions requested in this petition.

B.5 INTERNATIONAL AND LEGAL OBLIGATIONS

XIV. INTERNATIONAL REGULATORY OBLIGATIONS AND EXPERIMENTATION PROHIBITIONS

The FDA's anomalous classification approach violates binding international human rights obligations, particularly those established in the International Covenant on Civil and Political Rights (ICCPR), to which the United States remains a party regardless of its WHO status. Article 7 of the ICCPR explicitly prohibits non-consensual medical experimentation, stating that "no one shall be subjected without his free consent to medical or scientific experimentation." This prohibition is absolute and non-derogable even in times of public emergency.

The U.N. Human Rights Committee, in its authoritative General Comment No. 20, has established that "no justification or extenuating circumstances may be invoked to excuse a violation of article 7 for any reasons," including "public emergency." This unambiguous interpretation creates binding international legal obligations that constrain administrative discretion regardless of domestic regulatory classifications.

This absolute prohibition has been consistently affirmed in international jurisprudence. The International Court of Justice recognized in its Advisory Opinion on Nuclear Weapons (1996) that "elementary considerations of humanity" create binding legal obligations transcending treaty frameworks. Similarly, the International Criminal Tribunal for the Former Yugoslavia ruled in Prosecutor v. Furundžija (1998) that prohibitions against violations of "physical and moral integrity" produce effects erga omnes—creating obligations owed to the international community as a whole.

The Maryland Court of Appeals in Grimes v. Kennedy Krieger Institute (2001) provided persuasive domestic authority by establishing that procedures involving bodily penetration "necessarily exceed the minimal risk threshold established by regulation" regardless of claimed safety profiles. These precedents collectively establish that invasive procedures delivering experimental technologies cannot be properly classified as minimal risk without rendering meaningless the entire human subjects protection framework established in the wake of the Nuremberg trials.

The Declaration of Helsinki further reinforces this principle by requiring that "medical research involving human subjects must conform to generally accepted scientific principles" and be based on "thorough knowledge" and "adequate

laboratory experimentation" before human application—standards clearly not met by the accelerated development of these novel genetic technologies.

The improper classification of genetic products as "vaccines" rather than gene therapies, combined with their exemption from clinical investigation status under 21 U.S.C. § 360bbb-3(k), has effectively facilitated mass non-consensual experimentation in direct violation of this fundamental human rights obligation. Section 360bbb-3(k) specifically states:

"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]."

This statutory provision creates a dangerous regulatory loophole that, when combined with improper product classification, effectively circumvents the informed consent requirements that would normally apply to experimental genetic technologies. By classifying these products as "vaccines" rather than gene therapies, then exempting them from clinical investigation status through EUA, the FDA has created a regulatory framework that directly contravenes the United States' binding obligations under the ICCPR.

This violation of international human rights law has significant legal implications. As established in the Charming Betsy doctrine, courts must construe federal statutes "so as not to conflict with international law." The principle of consistent interpretation mandates that 21 U.S.C. § 360bbb-3(k) cannot be construed to permit violations of the ICCPR's prohibition on non-consensual experimentation. The Secretary therefore has a non-discretionary duty to ensure that the EUA exemption is not exploited to circumvent fundamental human rights protections, particularly for products that are properly classified as gene therapies rather than vaccines.

The international legal implications of regulatory distortion extend to diagnostic frameworks as well as therapeutic interventions. International judicial determinations, including the Lisbon Court of Appeal's landmark ruling in Case No. 1783/20.7T8PDL.L1 (November 11, 2020), have explicitly recognized that PCR testing methodologies authorized under emergency frameworks lack sufficient reliability for definitive diagnostic conclusions with significant consequences for individual rights. These judicial determinations establish persuasive precedent regarding the legal sufficiency of diagnostic methodologies and further reinforce the international legal obligation to ensure that regulatory frameworks maintain fidelity to scientific validation principles articulated in relevant ISO standards including ISO 17025:2017 and ISO 15189:2012.

(International Regulatory Obligations)

The United States' formal notification of withdrawal from the World Health Organization, pursuant to Joint Resolution 1365 (H.J. Res. 1365) and in accordance with Article 56 of the WHO Constitution, establishes a one-year notice period during which all treaty obligations remain in full force and effect. This interim period creates heightened rather than diminished obligations to ensure proper regulatory compliance with international standards, as established by the International Court of Justice in Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), which held that withdrawal notices create special responsibility to prevent actions that would "defeat the object and purpose of the treaty" prior to effective withdrawal.

The continuing integration of WHO regulatory frameworks with domestic authorization determinations—particularly through the Emergency Use Listing procedure's reliance on FDA as a "stringent regulatory authority" and the WHO Listed Authorities framework in which CBER maintains recognized status—creates persistent international legal obligations that transcend formal organizational membership. As established in "Interpretation of the Agreement of 25 March 1951" between the WHO and Egypt, Advisory Opinion, I.C.J. Reports 1980, p. 73, the "ongoing institutional relationships" between a withdrawing state and international organizations create legal obligations extending beyond formal membership status.

These enduring obligations, coupled with the principle of non-retroactivity in treaty denunciation established in Article 70(1)(b) of the Vienna Convention on the Law of Treaties, create a non-discretionary duty for immediate executive corrective action to address regulatory distortions that have facilitated international distribution of improperly classified products and diagnostics through WHO mechanisms. Failure to implement such corrective measures during the withdrawal notice period would constitute breach of continuing international obligations and potentially engage state responsibility for internationally wrongful acts pursuant to Articles 1 and 2 of the International Law Commission's Articles on State Responsibility.

XIV-A MEMORANDUM ON UNRESOLVED DISPUTES WITH THE WORLD HEALTH ORGANIZATION: LEGAL BASIS FOR SECRETARIAL INTERVENTION

INTRODUCTION: SYSTEMIC PATTERN OF UNADDRESSED FORMAL DISPUTES

The United States maintains four unresolved formal disputes with the World Health Organization that persist despite systematic, documented, and procedurally proper referral through competent national authorities, creating a juridical vacuum that implicates both domestic administrative law principles and international treaty obligations. These disputes, having been repeatedly presented to the Assistant Secretary for Global Affairs within HHS during the 2022, 2023, and 2024 HHS Office of Global Affairs stakeholder listening sessions in preparation for World Health Assembly meetings, formally documented through multiple written communications to the Office of Global Affairs, and subsequently to the former Secretary without remedial action, now necessitate immediate Secretarial intervention pursuant to principles of administrative exhaustion and the doctrine of functus officio.

The disputes in question, bearing specifically enumerated case identification within the WHO Office of Internal Oversight Services and having been formally referred by that Office to national authorities for resolution pursuant to paragraph 7(c) of the Terms of Reference of the Office of Internal Oversight Services (Document EB107/INF.DOC./2), encompass the following matters of international legal significance.

DISPUTE ONE: PROCEDURAL DEFECTS AND JURIDICAL NULLITY OF PROPOSED IHR AMENDMENTS (2022-2024)

The proposed amendments to the International Health Regulations (2005) advanced through multiple cycles of the Working Group on Amendments to the International Health Regulations (2005) ("WGIHR") in both 2022 and 2024 suffer from fundamental procedural deficiencies that render them ultra vires and procedurally void ab initio. This dispute encompasses both the initial 2022 amendment package presented to the 75th World Health Assembly and the subsequent 2024 amendments proposed for the 77th World Health Assembly. The United States, through recognized stakeholders in the Intergovernmental Negotiating Body (INB) process and civil society organizations engaged in pandemic preparedness and response pursuant to paragraph 4(e) of World Health Assembly Resolution WHA74.7, has raised substantive objections regarding these non-derogable violations of established procedural requirements throughout both amendment cycles.

The Bureau of the WGIHR circulated the "Bureau Text" incorporating proposed amendments on April 12, 2024, a mere 36 days before the commencement of the 77th World Health Assembly on May 27, 2024, in flagrant contravention of the four-month (122-day) requirement established in Article 55(2) of the IHR. Subsequent

textual revisions continued to be circulated throughout April and May 2024, with the final proposed text being made available to States Parties less than 14 days before the commencement of the World Health Assembly, representing a procedural deviation of approximately 108 days from the mandated timeline.

This temporal requirement is not a mere procedural formality but constitutes a substantive protection designed to ensure that all States Parties, regardless of their diplomatic and technical resources, have adequate opportunity to conduct thorough domestic review of proposed amendments. The magnitude of the deviation—nearly three full months less than the required period—fundamentally undermines the deliberative process contemplated by the IHR amendment provisions.

The procedural defects include:

A. Violation of Temporal Requirements Under Article 55(2) IHR

The Bureau of the WGIHR circulated the "Bureau Text" incorporating proposed amendments on April 12, 2024, a mere 36 days before the commencement of the 77th World Health Assembly on May 27, 2024, in flagrant contravention of the four-month (122-day) requirement established in Article 55(2) of the IHR. Subsequent textual revisions continued to be circulated throughout April and May 2024, with the final proposed text being made available to States Parties less than 14 days before the commencement of the World Health Assembly, representing a procedural deviation of approximately 108 days from the mandated timeline.

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B. Breach of Good Faith Negotiation Under Article 26 VCLT

The amendment process contravened foundational principles of good faith negotiation through exclusion of duly registered stakeholders from critical negotiating sessions, systematic restriction of meaningful access to negotiating texts, and utilization of procedural maneuvers to curtail substantive debate on controversial provisions.

The Vienna Convention on the Law of Treaties establishes in Article 26 the fundamental principle of pacta sunt servanda, requiring that "Every treaty in force is binding upon the parties to it and must be performed by them in good faith." This good faith principle extends to amendment procedures, creating procedural obligations that cannot be circumvented through tactical exclusions or manipulations designed to advance particular substantive outcomes.

C. Contravention of Procedural Regularities Under Customary International Law

The process further violated established principles through adoption of procedural rules deviating from established World Health Assembly procedures without adequate consensual foundation, implementation of voting procedures that contravene the consensus principle traditionally applied to substantive amendments of the IHR, and failure to maintain comprehensive official records of negotiating sessions.

These procedural violations render the proposed amendments juridically void under the established doctrine of ultra vires acts in international institutional law, as articulated by the International Court of Justice in Certain Expenses of the United Nations, Advisory Opinion, I.C.J. Reports 1962, p. 151. These objections have been formally presented to Assistant Secretary Loyce Pace during designated stakeholder consultations and complementary written submissions to the Office of Global Affairs documentation repository, yet remain without remedial action.

DISPUTE TWO: DOCUMENT CENSORSHIP AND TEMPORAL EXCLUSION FROM GLOBAL PUBLIC HEALTH WORKING GROUP CONSULTATIONS

The unwarranted document censorship and hours-long temporal exclusion of Interest of Justice and Free Speech Association from the Global Public Health Working Group (GPW14) civil society organization consultation of October 30, 2023—with access being restored only after the conclusion of the consultative process—constitutes a procedural irregularity that contravenes paragraph 10 of the WHO Framework of Engagement with Non-State Actors (FENSA) regarding "meaningful and effective participation."

This censorship of scientific materials advocating open scientific inquiry directly contravenes paragraphs 5(a) and 5(b) of FENSA regarding "transparent, open, constructive, and timely interactions" and the principles of multisectoral engagement articulated in paragraph 22 of World Health Assembly Resolution WHA73.1. The case identification number for this dispute was formally provided to Assistant Secretary Pace during the 2024 OGA stakeholder listening session, with explicit notification that WHO Internal Oversight Services had referred the matter to national authorities for resolution, and subsequently documented through formal written correspondence to OGA that remains without substantive response.

The systematic exclusion of duly accredited civil society organizations from participation in formal consultative processes constitutes a direct contravention of WHO's established institutional obligations regarding multisectoral engagement. This exclusion is particularly problematic when it appears to be content-based—

targeting organizations advocating for scientific methodologies or perspectives that may diverge from institutional preferences—rather than predicated on legitimate procedural considerations.

The restoration of access only after the conclusion of the consultative session renders the exclusion particularly egregious, as it effectively nullified any meaningful opportunity for participation while creating a superficial appearance of access. This procedural manipulation contravenes both the letter and the spirit of FENSA, which explicitly contemplates substantive rather than merely formal engagement with non-state actors.

DISPUTE THREE: SCIENTIFIC AND PROCEDURAL DEFICIENCIES IN EMERGENCY USE LISTING FOR PCR DIAGNOSTICS

Formal objections regarding validation deficiencies in the Corman-Drosten protocol and subsequent WHO Emergency Use Listing of PCR diagnostic methodologies without standardized cycle threshold parameters remain unaddressed, despite directly implicating international scientific standards established in ISO 17025:2017 and ISO 15189:2012, as well as specific procedural requirements outlined in the WHO Handbook for Guideline Development (2nd ed., 2014) regarding evidentiary standards for diagnostic recommendations.

The Corman-Drosten protocol, published in Eurosurveillance on January 23, 2020, was accepted within 24 hours of submission—an extraordinary abbreviation of peer review that contravenes established scientific publication standards. Subsequent independent peer review identified ten fundamental scientific flaws in the methodology, including absence of gold standard validation, inappropriate primer design, insufficient PCR validation, and absence of standardized operating procedures.

These methodological deficiencies carry profound legal implications under both domestic and international frameworks, particularly as the protocol became the foundation for WHO PCR testing guidance disseminated globally on January 13, 2020. Multiple judicial determinations, including the Lisbon Court of Appeal ruling in Case No. 1783/20.7T8PDL.L1 (November 11, 2020), have explicitly determined that PCR tests "given [their] lack of reliability...and in the absence of a medical diagnosis noting the existence of infection or risk, [are] not in [themselves] sufficient basis for a definitive diagnosis of infection."

These objections were formally presented to Assistant Secretary Pace during all three annual stakeholder listening sessions (2022, 2023, and 2024), with specific reference to the case identification number assigned by WHO Internal Oversight Services, and subsequently documented through written communications to OGA that meticulously detailed the scientific and procedural deficiencies at issue.

The WHO's uncritical adoption of the Corman-Drosten protocol without adequate validation studies or establishment of standardized interpretation parameters constitutes a departure from both scientific best practices and the Organization's own published standards for diagnostic guideline development. This departure created cascading effects throughout the international public health response, as numerous countries incorporated these methodologically flawed testing protocols into their domestic response frameworks on the presumption of WHO's scientific rigor and procedural integrity.

DISPUTE FOUR: CLASSIFICATION MANIPULATION OF EXPERIMENTAL GENETIC TECHNOLOGIES

Substantive scientific objections regarding the regulatory classification of mRNA and adenoviral vector products, which have facilitated international distribution through WHO's Emergency Use Listing mechanism without appropriate disclosure of their experimental gene therapy nature, remain unaddressed despite directly implicating Article 7 of the International Covenant on Civil and Political Rights and paragraph 1 of the Nuremberg Code as incorporated into customary international law through consistent state practice and opinio juris.

The WHO-HHS regulatory integration framework directly implicates the arbitrary geographic disparities in classification of identical products documented in the main petition. Under WHO's Emergency Use Listing (EUL) procedure, products receive international emergency authorization based substantially on determinations by "stringent regulatory authorities" including FDA. This creates a situation of regulatory recognition with profound legal implications, whereby products classified as "investigational" for domestic purposes under 21 C.F.R. § 312.110(b) simultaneously receive international distribution authorization through WHO's EUL process based on FDA's regulatory assessment.

These objections were formally presented during each annual stakeholder consultation, with explicit notification of the WHO Internal Oversight Services case identification and referral to national authorities, and further documented through written submissions to OGA that outlined the scientific basis for proper classification under international standards.

The classification discrepancy creates fundamental informed consent concerns, as products that are explicitly designated as "investigational" when exported directly from the United States receive international distribution authorization through WHO mechanisms without equivalent disclosure of their experimental status. This regulatory arbitrage effectively circumvents established protections for human subjects in experimental medical interventions, contravening foundational principles of bioethics as articulated in both domestic and international legal frameworks.

INSTITUTIONAL INTEGRATION WITH PRIVATE SECTOR PROCUREMENT MECHANISMS: THE COVID ACTION PLATFORM

Concerns regarding the institutional integration of WHO pandemic response mechanisms with the COVID Action Platform and World Economic Forum procurement frameworks have been repeatedly raised with Assistant Secretary Pace during stakeholder listening sessions, highlighting the inherent conflicts of interest arising from vesting procurement authorities in entities with direct pecuniary interests potentially adverse to the populations they purport to serve.

These concerns directly implicate Article 37 of the WHO Constitution regarding the independence of the Organization and paragraph 6 of the Framework of Engagement with Non-State Actors regarding protection against "conflicts of interest" and "undue influence," yet remain unaddressed despite formal presentation through established consultative channels. Such integration contravenes the fundamental principle of institutional independence articulated in the WHO Constitution and potentially constitutes a structured conflict of interest that undermines the Organization's mandate to act exclusively in the interest of public health.

The COVID Action Platform's governance structure creates particularly problematic entanglements between commercial interests and public health decision-making. By integrating private sector entities with direct financial stakes in procurement outcomes into institutional decision-making frameworks, the Platform creates systematic conflicts that potentially subordinate public health considerations to commercial imperatives. This structural compromise of institutional independence contravenes the explicit requirements of Article 37 of the WHO Constitution, which establishes an unambiguous obligation for organizational independence and impartiality.

The situation is further exacerbated by the implementation of shared information systems and revolving personnel arrangements between WHO and private sector entities participating in the Platform. These arrangements create institutional dependency relationships that compromise decision-making independence and potentially violate paragraph 7(a) of FENSA regarding maintenance of "WHO's integrity, independence, credibility and reputation."

LEGAL BASIS FOR SECRETARIAL INTERVENTION - A MEMORANDUM ON UNRESOLVED DISPUTES WITH THE WORLD HEALTH ORGANIZATION: LEGAL BASIS FOR SECRETARIAL INTERVENTION

INTRODUCTION: SYSTEMIC PATTERN OF UNADDRESSED FORMAL DISPUTES

The United States maintains four unresolved formal disputes with the World Health Organization that persist despite systematic, documented, and procedurally proper referral through competent national authorities, creating a juridical vacuum that implicates both domestic administrative law principles and international treaty obligations. These disputes, having been repeatedly presented to the Assistant Secretary for Global Affairs within HHS during the 2022, 2023, and 2024 HHS Office of Global Affairs stakeholder listening sessions in preparation for World Health Assembly meetings, formally documented through multiple written communications to the Office of Global Affairs, and subsequently to the former Secretary without remedial action, now necessitate immediate Secretarial intervention pursuant to principles of administrative exhaustion and the doctrine of functus officio.

The disputes in question, bearing specifically enumerated case identification within the WHO Office of Internal Oversight Services and having been formally referred by that Office to national authorities for resolution pursuant to paragraph 7(c) of the Terms of Reference of the Office of Internal Oversight Services (Document EB107/INF.DOC./2), encompass the following matters of international legal significance.

These objections have been formally presented to Assistant Secretary Loyce Pace during designated stakeholder consultations and complementary written submissions to the Office of Global Affairs documentation repository, yet remain without remedial action.

These disputes, having been properly referred to national authorities through both the procedural mechanism of the WHO Office of Internal Oversight Services and the diplomatic channels established for stakeholder engagement with the Department of Health and Human Services—including both verbal presentations during designated consultations and formal written communications to OGA—trigger the United States' obligation under customary international law to engage in good faith resolution of institutional disputes, as recognized in the International Court of Justice's Advisory Opinion on Interpretation of the Agreement of 25 March 1951 between the WHO and Egypt, I.C.J. Reports 1980, p. 73. The former Secretary's failure to address these disputes constitutes non-feasance that now necessitates immediate intervention by the current Secretary.

The legal principle of administrative exhaustion has been satisfied through multiple formal communications to the Assistant Secretary for Global Affairs during officially designated stakeholder consultations, written submissions to OGA, and subsequent communications to the former Secretary, establishing perfected jurisdiction for immediate Secretarial intervention. As the District of Columbia Circuit emphasized in American Federation of Government Employees, AFL-CIO v. Acree, 475 F.2d 1289, 1292 (D.C. Cir. 1973), administrative remedies need not be pursued when "the administrative remedy is inadequate" or when "the

administrative remedy would be futile," conditions manifestly satisfied by the former Secretary's persistent non-response to these formally raised disputes despite three consecutive years of proper presentation through established consultative mechanisms and complementary written submissions.

The impending United States withdrawal from the World Health Organization creates heightened rather than diminished legal imperatives for dispute resolution, as established by the International Court of Justice in Northern Cameroons (Cameroon v. United Kingdom), I.C.J. Reports 1963, p. 15, which recognized that states maintain justiciable interests in resolving pre-withdrawal disputes that have created continuing legal effects. The principle of juridical continuity further establishes that legal obligations accruing during membership persist independently of subsequent withdrawal, creating non-discretionary duties for resolution of outstanding disputes.

The disputed matters present fundamental questions of both international and domestic law that must be resolved to prevent irreparable harm to U.S. sovereign interests, scientific integrity, and international legal obligations. The Secretary's plenary authority under the Reorganization Plan No. 1 of 1953, combined with specific statutory responsibilities under 22 U.S.C. § 2656d, creates both the authority and the obligation to address these disputes through appropriate diplomatic and legal mechanisms.

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10. Centers for Disease Control and Prevention. "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel." Document #CDC-006-00019, Revision 06, p. 35. December 1, 2020. ↩
11. World Health Organization. "WHO Information Notice for IVD Users 2020/05: Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2." January 20, 2021. WHO/2020.5, Version 1.1. ↩
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13. Lisbon Court of Appeal (Tribunal da Relação de Lisboa). Case No. 1783/20.7T8PDL.L1. November 11, 2020. http://www.dgsi.pt/jtrl.nsf/33182fc732316039802565fa00497eec/79d6ba338dcbe5e28025861f003e7b30 ↩
14. Lisbon Court of Appeal (Tribunal da Relação de Lisboa). Case No. 1783/20.7T8PDL.L1. November 11, 2020. Para. 8.2 (translated from Portuguese). ↩
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16. Lisbon Court of Appeal (Tribunal da Relação de Lisboa). Case No. 1783/20.7T8PDL.L1. November 11, 2020. Para. 10 (translated from Portuguese). ↩
17. Case Concerning Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment, 2010 I.C.J. Rep. 14, para. 164 (Apr. 20). ↩
18. Austrian Constitutional Court (Verfassungsgerichtshof). Case No. G 271/2020. December 10, 2020. https://www.vfgh.gv.at/downloads/G_271_2020_Covid-Massnahmen_in_Schulen.pdf ↩
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24. World Health Organization. "International Health Regulations (2005)." Third Edition. 2016. Article 12(4)(d). ↩
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XV. ARBITRARY GEOGRAPHIC CLASSIFICATION DISPARITIES

The FDA has established an arbitrary and scientifically indefensible regulatory framework that classifies identical COVID-19 mRNA products as "investigational" when exported to foreign countries but "non-investigational" when administered domestically. This geographic disparity in regulatory classification violates fundamental principles of administrative law, equal protection, and scientific integrity.

Under 21 C.F.R. § 312.110(b), COVID-19 mRNA products exported abroad are explicitly classified as "investigational" and subject to heightened informed consent requirements and safety monitoring. Yet these identical products, when administered within the United States under EUA, are exempted from "investigational" status pursuant to 21 U.S.C. § 360bbb-3(k).

This geographic double standard creates an indefensible situation where foreign recipients are afforded greater informed consent protections and safety monitoring than American citizens, despite being administered the exact same product with the exact same mechanism of action and risk profile. This arbitrary distinction violates the equal protection principles enshrined in the Fifth Amendment's Due Process Clause, which prohibits the federal government from treating similarly situated individuals differently without rational justification.

The FDA has established an arbitrary and scientifically indefensible regulatory framework that classifies identical COVID-19 mRNA products as "investigational" when exported to foreign countries but "non-investigational" when administered domestically. This geographic disparity in regulatory classification violates fundamental principles of administrative law, equal protection, and scientific integrity.

The WHO-HHS regulatory integration framework directly implicates the arbitrary geographic disparities in classification of identical products documented in the main petition. Under WHO's Emergency Use Listing (EUL) procedure, products receive international emergency authorization based substantially on determinations by "stringent regulatory authorities" including FDA.[6] This creates a situation of regulatory recognition with profound legal implications:

Products classified as "investigational" for domestic purposes under 21 C.F.R. § 312.110(b) simultaneously receive international distribution authorization through WHO's EUL process based on FDA's regulatory assessment. This paradoxical situation—where identical products are "investigational" domestically but "authorized" internationally through processes that rely on the same regulatory assessment—epitomizes the arbitrary and capricious agency action prohibited under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

The WHO-HHS integration framework further implicates international legal principles of non-discrimination in regulatory classification. Article 2.1 of the WTO Agreement on Technical Barriers to Trade, to which the United States is a signatory, mandates that "Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin."[7] The differential classification of identical products based solely on geographic destination directly contravenes this principle.

As the WTO Appellate Body emphasized in European Communities — Measures Affecting Asbestos and Products Containing Asbestos, regulatory distinctions must be based on objective product characteristics rather than origin or destination considerations.[8] The current classification framework, which applies different standards to identical products based solely on geographic considerations, cannot be reconciled with these binding international obligations.

XXXIII. GENOMIC SOVEREIGNTY AND BIOETHICAL IMPLICATIONS

The unauthorized global deployment of experimental gene therapy products without proper classification raises profound questions of genomic sovereignty—a legal concept increasingly recognized in international law through instruments such as the Nagoya Protocol to the Convention on Biological Diversity and the UNESCO International Declaration on Human Genetic Data. Genomic sovereignty encompasses not merely the protection of genetic resources at the national level but extends to individual sovereignty over one's genetic material and the right to be free from unauthorized genomic interventions.

A. The Emerging Legal Framework for Genomic Sovereignty

The concept of genomic sovereignty has evolved significantly in international legal discourse, transitioning from an exclusively State-centric notion focused on national control over genetic resources to a more nuanced framework incorporating individual rights to genomic self-determination. As articulated by the Inter-American Court of Human Rights in Artavia Murillo et al. v. Costa Rica, Series C No. 257, Judgment (Nov. 28, 2012), rights relating to private life include "autonomy

over personal decisions and choices that are necessary for an individual's dignity and freedom, as well as control over aspects of one's physical and social identity, including the right to personal autonomy, personal development and the right to establish relationships with other human beings and the external world."

The introduction of experimental genetic technologies into the bodies of hundreds of millions of individuals worldwide without appropriate classification, safety testing, or transparent disclosure represents a potential violation of this evolving right to genomic self-determination. As emphasized in Article 4 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997): "The human genome in its natural state shall not give rise to financial gains." The commercialization of experimental gene therapy products through improper classification that circumvented appropriate regulatory oversight directly implicates this established international norm.

The UN Human Rights Council, in Resolution 37/7 (2018) on "The Right to Privacy in the Digital Age," explicitly recognized that technological developments, including in biotechnology, "raise growing concerns about the ability of individuals to exercise their right to privacy," emphasizing the need for enhanced protections as technologies evolve. The administration of experimental gene therapy products to billions of individuals without proper classification or transparent risk disclosure represents precisely the kind of technological intervention that necessitates enhanced privacy and autonomy safeguards.

B. Intergenerational Bioethical Implications

The unauthorized global deployment of experimental gene therapy products raises intergenerational bioethical concerns of unprecedented magnitude. The current regulatory framework has entirely failed to account for potential transgenerational effects of these novel genetic technologies, with no comprehensive reproductive toxicity studies or multi-generational safety assessments conducted prior to mass administration.

The principle of intergenerational equity, recognized in instruments such as the Rio Declaration on Environment and Development (1992) and the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations (1997), establishes that present generations have duties toward both present and future generations in matters that may have irreversible consequences for human genetic heritage. Article 1 of the UNESCO Declaration explicitly affirms that "the present generations have the responsibility of ensuring that the needs and interests of present and future generations are fully safeguarded."

The misclassification of experimental gene therapy products, combined with the categorical waiver of reproductive toxicity and genotoxicity studies that would normally be required, creates potential intergenerational risks that have not been

adequately assessed or mitigated. This regulatory failure directly contravenes established international bioethical principles regarding precautionary approaches to technologies that may have transgenerational effects.

The International Bioethics Committee of UNESCO, in its Report on the Principle of Non-Discrimination and Non-Stigmatization (2014), emphasized that "interventions in the human genome should be admitted only for preventive, diagnostic or therapeutic reasons and without enacting modifications for descendants." The mass administration of inadequately tested genetic technologies without proper classification or comprehensive reproductive toxicity assessment fundamentally undermines this established bioethical principle.

C. Indigenous Peoples' Rights and Cultural Genomic Heritage

The misclassification of experimental gene therapy products raises particular concerns for Indigenous peoples, who maintain distinctive relationships with their genomic heritage that are protected under international legal instruments such as the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). Article 31 of UNDRIP explicitly recognizes that "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources."

The administration of misclassified experimental gene therapy products to Indigenous populations without culturally appropriate informed consent processes that accurately disclosed their gene therapy mechanism represents a potential violation of these established rights. This concern is particularly acute given the documented disparities in COVID-19 vaccination campaigns targeting Indigenous communities, often conducted without adequate cultural consultation or proper disclosure of the experimental nature of these interventions.

As the Inter-American Court of Human Rights emphasized in Kaliña and Lokono Peoples v. Suriname, Series C No. 309, Judgment (Nov. 25, 2015), States have "a special obligation to ensure that indigenous and tribal peoples may exercise their right to consultation" in matters affecting their cultural heritage. The mass administration of misclassified experimental gene therapy products without appropriate cultural consultation mechanisms contravenes this established international legal standard.

The misclassification of these products has effectively circumvented the robust consultation processes that would normally be required for experimental genetic interventions in Indigenous communities, creating a significant risk of cultural genomic harm that has not been adequately assessed or mitigated through appropriate regulatory frameworks.

XXXIV. GLOBAL IMPLICATIONS AND STATE RESPONSIBILITY FOR INTERNATIONAL VIOLATIONS

The regulatory failures documented in this petition carry profound international legal implications that transcend mere domestic administrative concerns. The United States' actions in misclassifying, authorizing, and globally distributing these experimental biological products implicate fundamental principles of State responsibility under international law and create an affirmative obligation for remedial action.

The improper classification of experimental gene therapy products, combined with their global distribution through international mechanisms, implicates principles of State responsibility under international law. The International Law Commission's Articles on Responsibility of States for Internationally Wrongful Acts establish that "Every internationally wrongful act of a State entails the international responsibility of that State."[41]

The prohibition against non-consensual medical experimentation constitutes an erga omnes obligation in international law—a norm that generates duties owed to the international community as a whole rather than merely to specific treaty partners. As articulated by the International Court of Justice in Barcelona Traction, certain obligations "derive from the outlawing of acts of aggression, and of genocide, as also from the principles and rules concerning the basic rights of the human person."[42]

The United States' improper classification of experimental gene therapy products, combined with their mass distribution internationally, directly implicates these erga omnes obligations through two distinct mechanisms:

1. Direct Violation: By misclassifying experimental gene therapy products to circumvent informed consent requirements under international law, the United States has directly violated its obligations under ICCPR Article 7, which the United Nations Human Rights Committee has explicitly characterized as non-derogable even in times of public emergency.

2. Indirect Violation via Homolocative Mechanisms: By exporting these improperly classified products to countries that rely upon FDA authorization through "homolocative" regulatory mechanisms (whereby foreign jurisdictions automatically recognize or expedite approval of FDA-authorized products), the United States has indirectly facilitated similar violations in foreign jurisdictions, potentially creating accessory liability under international law.

The International Court of Justice has repeatedly emphasized that States cannot evade responsibility for internationally wrongful acts through domestic legal frameworks or administrative classifications. As established in the Factory at Chorzów case, "reparation must, as far as possible, wipe out all the consequences of the illegal act and reestablish the situation which would, in all probability, have existed if that act had not been committed."[43] This principle of restitutio in integrum creates an international legal obligation for comprehensive remediation of classification errors with transnational implications.

Footnotes

1. World Health Organization, "WHO Listed Authorities," WHO.int, https://www.who.int/initiatives/who-listed-authorities (last accessed April 28, 2025). ↩
2. Elettronica Sicula S.p.A. (ELSI) (U.S. v. Italy), Judgment, 1989 I.C.J. Rep. 15, ¶ 50 (July 20). ↩
3. 21 C.F.R. § 20.89(c) (2024). ↩
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5. Natural Resources Defense Council v. Environmental Protection Agency, 464 F.3d 1, 9 (D.C. Cir. 2006). ↩
6. World Health Organization, "Emergency Use Listing Procedure," WHO/PQT/EUL/2020.1, §§ 3.1-3.4 (December 2020). ↩
7. Agreement on Technical Barriers to Trade, Apr. 15, 1994, 1868 U.N.T.S. 120, art. 2.1. ↩
8. European Communities — Measures Affecting Asbestos and Products Containing Asbestos, WT/DS135/AB/R, ¶¶ 84-90 (Mar. 12, 2001). ↩
9. 10 U.S.C. § 4022(a)(1) (2024). ↩
10. Michigan v. Environmental Protection Agency, 576 U.S. 743, 758 (2015). ↩

A. International Legal Obligations Arising from Erga Omnes Norms

The prohibition against non-consensual medical experimentation constitutes an erga omnes obligation in international law—a norm that generates duties owed to the international community as a whole rather than merely to specific treaty partners. As articulated by the International Court of Justice in Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain), certain obligations "derive from the outlawing of acts of aggression, and of genocide, as also from the principles and rules concerning the basic rights of the human person."

The ICJ has subsequently elaborated in the Wall Advisory Opinion that these erga omnes obligations create "an obligation not to recognize the illegal situation

resulting from [their violation]" and "an obligation not to render aid or assistance in maintaining the situation created by such [violation]."

The United States' improper classification of experimental gene therapy products, combined with their mass distribution domestically and internationally, directly implicates these erga omnes obligations through two distinct mechanisms:

Direct Violation: By misclassifying experimental gene therapy products to circumvent informed consent requirements under international law, the United States has directly violated its obligations under ICCPR Article 7 ("no one shall be subjected without his free consent to medical or scientific experimentation"), which the United Nations Human Rights Committee has explicitly characterized as non-derogable even in times of public emergency.

Indirect Violation via Homolocative Mechanisms: By exporting these improperly classified products to countries that rely upon FDA authorization through "homolocative" regulatory mechanisms (whereby foreign jurisdictions automatically recognize or expedite approval of FDA-authorized products), the United States has indirectly facilitated similar violations in foreign jurisdictions, potentially creating accessory liability under international law.

The International Court of Justice has repeatedly emphasized that States cannot evade responsibility for internationally wrongful acts through domestic legal frameworks or administrative classifications. As the ICJ articulated in the Reparation for Injuries Suffered in the Service of the United Nations Advisory Opinion: "Under international law, the Organization must be deemed to have those powers which, though not expressly provided in the Charter, are conferred upon it by necessary implication as being essential to the performance of its duties." By analogy, the international community must be deemed to possess the necessary authority to hold States accountable for circumventing fundamental human rights protections through improper regulatory classification, particularly when such classification directly undermines norms of jus cogens character such as the prohibition on non-consensual experimentation.

B. Transnational Tort Liability and Comity Considerations

The misclassification of experimental gene therapy products has created a complex matrix of transnational tort liability that implicates principles of international comity and justice. As established in the Alien Tort Statute jurisprudence, particularly Sosa v. Alvarez-Machain, liability may attach for violations of "specific, universal, and obligatory" norms of international law. The prohibition against non-consensual experimentation undoubtedly meets this threshold, having been consistently recognized in instruments including the Nuremberg Code, Helsinki Declaration, ICCPR, and numerous regional human rights conventions.

The United States' actions in promoting global distribution of misclassified experimental products potentially expose it to transnational tort liability under multiple jurisdictional theories:

Effects Doctrine: As articulated in the Lotus case and subsequently developed in extraterritorial jurisdiction jurisprudence, States may exercise jurisdiction over conduct that produces substantial effects within their territory. The health impacts of improperly classified experimental products distributed globally create precisely such effects.

Universal Jurisdiction: For violations of peremptory norms, international law recognizes universal jurisdiction independent of territorial or nationality connections. The prohibition on non-consensual experimentation arguably rises to this level, particularly when conducted on a global scale.

Complicity Liability: Under principles articulated in the ILC Articles on State Responsibility, a State may incur international responsibility for "aiding or assisting" another State in committing an internationally wrongful act. The United States' exportation of improperly classified products, coupled with representations regarding their regulatory status, potentially creates such complicity liability.

C. The Partial Acceptance of State Responsibility and Necessity for Full Recognition

The United States has begun a partial acknowledgment of State responsibility through specific executive actions. Defense Secretary Pete Hegseth's April 24, 2025 memorandum directing the reinstatement of service members discharged for refusing COVID-19 vaccination constitutes a form of restitution in integrum—a recognized remedy in international law for wrongful State action. Similarly, HHS Secretary Robert F. Kennedy Jr.'s public statements questioning the risk-benefit profile of these products for children represent an initial, albeit incomplete, recognition of the problematic regulatory framework that facilitated their administration.

However, these partial acceptances of responsibility remain inadequate under international legal standards. As articulated in the Factory at Chorzów case, "reparation must, as far as possible, wipe out all the consequences of the illegal act and reestablish the situation which would, in all probability, have existed if that act had not been committed." The current limited acknowledgments fail to address the fundamental classification error that facilitated global distribution of experimental products without appropriate safety monitoring or informed consent.

International law demands more comprehensive remediation, including:

Public Acknowledgment: A formal declaration recognizing the improper classification of these products and apologizing to all individuals domestically and internationally who received these products without full disclosure of their experimental nature.

Compensation: Establishment of appropriate compensation mechanisms for individuals harmed by these products, including those currently excluded from remedy by the PREP Act's liability shield—a domestic legal mechanism that cannot overcome international legal obligations.

Regulatory Reform: Implementation of comprehensive reforms to prevent similar regulatory circumvention in future public health scenarios, with particular attention to strengthening informed consent protections for novel medical technologies.

International Cooperation: Engagement with international bodies, ICH, and regional regulatory authorities to develop harmonized classification standards for novel genetic technologies that prioritize mechanism-based categorization over therapeutic intent.

The current partial acceptance of responsibility, while a commendable initial step, falls substantially short of the comprehensive remediation required under well-established principles of international law. The Secretary's action on this petition represents an opportunity to move toward full compliance with these international legal obligations and restore the United States' standing as a leader in ethical pharmaceutical regulation.

B.6 SPECIALIZED DIAGNOSTIC AND PROCEDURAL ISSUES

XVI-A. PCR DIAGNOSTIC FRAMEWORK: REGULATORY DISTORTIONS AND JUDICIAL DETERMINATIONS

I. FOUNDATIONAL SCIENTIFIC AND REGULATORY DEFICIENCIES IN PCR DIAGNOSTIC AUTHORIZATION

A. Corman-Drosten Protocol: Scientific and Methodological Deficiencies with Legal Implications

The PCR diagnostic framework for SARS-CoV-2 detection finds its genesis in the methodological protocol published by Corman, Drosten, et al., "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR" in Eurosurveillance 25(8) on January 23, 2020. This publication, which formed the foundational basis for WHO-recommended PCR protocols worldwide, was accepted within 24 hours of submission—an extraordinary abbreviation of peer review that contravenes established scientific publication standards codified in the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

Subsequent independent peer review by Borger et al. published in November 2020 identified ten fundamental scientific flaws in the Corman-Drosten methodology. These methodological deficiencies carry profound legal implications for regulatory authorization under both domestic and international frameworks:

1. **Absence of Gold Standard Validation**: The protocol was designed and validated without access to virus isolates or quantified viral material, relying instead on in silico sequences. This procedural deficiency directly contravenes the validation requirements established in ISO 17025:2017 ("General requirements for the competence of testing and calibration laboratories"), which mandates validation against appropriate reference materials. This validation deficiency constitutes a direct contravention of the FDA's own statutory obligation under 21 U.S.C. § 360bbb-3(c)(2)(A) to ensure that authorization decisions are based on "scientific evidence" that meets consensus standards for scientific reliability.

2. **Inappropriate Primer Design**: The publication acknowledged the incorporation of wobbly positions, resulting in 4-fold degeneracy, in critical primer sequences. This design characteristic introduces significant analytical specificity concerns, directly implicating the FDA's statutory obligation under 21 U.S.C. § 360bbb-3(c)(2)(A) to ensure that authorized diagnostic methodologies provide "accurate and reliable" results for their intended purpose.

3. **Insufficient PCR Validation**: The researchers reported a Ct value of 38 as positive, significantly exceeding established threshold standards in molecular diagnostics. This amplification threshold parameter establishes a detection limit that directly contravenes international consensus standards for nucleic acid amplification techniques as articulated in the World Organization for Animal Health (OIE) Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, which specifies that cycle thresholds exceeding 35 are scientifically questionable in terms of diagnostic reliability.

4. **Absence of Standard Operating Procedure**: The protocol failed to establish a standardized and fixed Ct value as a diagnostic threshold, a procedural deficiency that contravenes ISO 15189:2012 ("Medical laboratories – Requirements for quality and competence"), which explicitly requires standardized interpretation procedures for diagnostic methodologies.

The Corman-Drosten protocol nevertheless became the foundation for WHO PCR testing guidance disseminated globally on January 13, 2020, establishing a procedurally and scientifically deficient methodology as the international standard. This standardization created both a scientific and legal chain reaction culminating in the misapplication of PCR technology beyond its validated parameters and the arbitrary establishment of diagnostic criteria without adequate scientific validation—deficiencies with profound implications for both individual rights and public health responses predicated upon resulting case definitions.

B. Statutory Framework and Regulatory Authorization Deficiencies

The Emergency Use Authorization of PCR-based diagnostics for SARS-CoV-2 detection in the United States operated under the statutory framework established in 21 U.S.C. § 360bbb-3, which establishes specific criteria that must be satisfied before authorization may be granted:

1. 21 U.S.C. § 360bbb-3(c)(2)(A) requires that the Secretary determine "based on the totality of scientific evidence available" that "the product may be effective in diagnosing, treating, or preventing" the disease;
2. 21 U.S.C. § 360bbb-3(c)(2)(B) requires that "the known and potential benefits of the product... outweigh the known and potential risks of the product";
3. 21 U.S.C. § 360bbb-3(c)(3) requires that "there is no adequate, approved, and available alternative to the product."

The authorization of PCR diagnostic methodologies under this framework presents several cognizable legal deficiencies that constitute administrative action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" under the Administrative Procedure Act, 5 U.S.C. § 706(2)(C):

First, the FDA's authorization of PCR methodologies for diagnostic rather than screening purposes exceeds the statutory authorization limit, which requires a determination that the product "may be effective." As acknowledged in the WHO Information Notice for IVD Users 2020/05, "careful interpretation of weak positive results is needed," as "the cycle threshold (Ct) needed to detect virus is inversely proportional to the patient's viral load." This fundamental limitation of PCR methodology for discriminating between active infection and residual nucleic acid

detection constitutes a categorical diagnostic limitation that renders a "may be effective" determination scientifically insupportable for binary diagnostic applications—particularly when employed without clinical correlation.

Second, the authorization failed to establish fixed analytical parameters for test interpretation, particularly cycle threshold values. Documentation obtained through FOIA proceedings reveals that the CDC's "2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel" established 40 cycles as the replication cut-off—a threshold significantly exceeding international consensus standards for reliable nucleic acid detection as articulated in the WHO Information Notice itself, which acknowledged "higher Ct values may mean that the virus cannot be cultured."

Third, the FDA permitted authorizations for asymptomatic screening applications without establishing empirical validation criteria specific to such applications. As observed in the Wadsworth Center's "New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel" EUA submission, "asymptomatic individuals are not currently recommended for routine SARS-CoV-2 testing," yet the FDA subsequently authorized such asymptomatic applications without validating their clinical utility for such purposes.

These authorization deficiencies demonstrate a systematic pattern of agency action that exceeds statutory limitations and fails to conform to international scientific standards for diagnostic validation—a pattern that carries profound implications for legal remedies under both domestic administrative law and international legal frameworks concerning state responsibility for transboundary harms resulting from misapplication of diagnostic technologies.

II. JUDICIAL DETERMINATIONS AND LEGAL PRECEDENTS

A. Portuguese Court of Appeal Ruling: Case No. 1783/20.7T8PDL.L1

In a landmark judicial determination with significant precedential implications, the Lisbon Court of Appeal (Tribunal da Relação de Lisboa) issued a ruling on November 11, 2020, in Case No. 1783/20.7T8PDL.L1, which directly addressed the legal sufficiency of PCR testing as a diagnostic methodology for imposing deprivation of liberty through quarantine measures.

The Court's determination carried several legally significant findings that bear directly on the regulatory framework for PCR diagnostic authorization:

1. The Court, after evaluating expert scientific testimony, explicitly determined that the "RT-PCR test, given its lack of reliability (as argued by leading international scientists) and in the absence of a medical diagnosis noting the existence of infection or risk, is not in itself sufficient basis for a definitive

diagnosis of infection."

2. The Court further concluded that a person's detention based solely on a positive PCR test result constituted an unlawful deprivation of liberty, stating: "Thus, given current scientific evidence, this test [the RT-PCR test] is, in itself, unable to determine, beyond reasonable doubt, that such positivity corresponds to infection with the SARS-CoV-2 virus."

3. Most significantly, the Court articulated a legal standard for diagnostic reliability that has profound implications for regulatory authorization frameworks: "If carried out with no prior medical observation of the patient, with no participation of a specialist medical doctor, duly certified by the respective Order of Medical Doctors and who would have assessed symptoms and requested diagnostic tests deemed appropriate, any act of diagnosis, or any act of public health vigilance...represents a clear violation of...[professional medical practice]."

This judicial determination, while not directly binding on U.S. regulatory authorities, carries significant persuasive authority under principles of transnational judicial dialogue recognized in contemporary international law. As articulated by the International Court of Justice in the Case Concerning Pulp Mills on the River Uruguay (Argentina v. Uruguay), "a precautionary approach may be relevant in the interpretation and application of the provisions of the statute." The Portuguese Court's application of precautionary principles to diagnostic validation represents a significant judicial precedent concerning the legal sufficiency of PCR testing methodologies for establishing definitive diagnostic conclusions.

B. Austrian Constitutional Court Ruling: Case No. G 271/2020

Further reinforcing the international judicial consensus regarding PCR diagnostic limitations, the Austrian Constitutional Court (Verfassungsgerichtshof) issued a ruling on December 10, 2020, in Case No. G 271/2020, striking down aspects of COVID-19 restrictions partially on grounds related to PCR testing reliability.

The Court's determination established that PCR testing without appropriate clinical correlation and standardized threshold parameters does not provide an epidemiologically sound basis for restrictive public health measures—a determination with profound implications for the U.S. regulatory authorization framework, which permitted precisely such applications without standardized parameters.

The Court specifically noted that "a PCR test can only determine whether genetic material from the COVID-19 virus is present in the human body at the time of the test," and emphasized that positive test results require clinical correlation to establish infectiousness—a limitation not adequately reflected in the FDA's authorization framework for asymptomatic screening applications.

C. German Regional Court Ruling: Weimar Family Court Case No. 9 F 148/21

In a further development of international judicial precedent concerning PCR test reliability, the Weimar Family Court (Familiengericht Weimar) issued a ruling on April 8, 2021, in Case No. 9 F 148/21, which included extensive evaluation of PCR testing scientific validity based on expert testimony.

The Court's determination, based on evaluation of multiple scientific expert opinions, concluded that PCR tests "are not suitable for detecting an 'infection' with the SARS-CoV-2 virus," and further determined that "the results of PCR tests alone cannot be used to detect a sufficiently high viral load for infectivity." This judicial finding directly contradicts the FDA's authorization of PCR methodologies for diagnostic purposes without standardized cycle threshold parameters.

These judicial determinations across multiple jurisdictions establish an emerging international consensus regarding the legal and scientific limitations of PCR methodologies that directly contradicts the regulatory authorization framework implemented in the United States—a divergence with significant implications for legal remedies pursuant to both domestic administrative law and international legal obligations.

III. RECOMMENDATIONS FOR SECRETARIAL ACTION

Based on the foregoing analysis of scientific, regulatory, and judicial precedents, the Secretary of Health and Human Services possesses both the authority and the non-discretionary duty to implement immediate remedial measures regarding PCR diagnostic authorization. The following specific actions are legally mandated:

These recommended actions collectively establish a comprehensive framework for addressing the legal, scientific, and regulatory deficiencies in the PCR diagnostic authorization framework while fulfilling the Secretary's obligations under both domestic and international law.

IV. SCIENTIFIC AND LEGAL FOUNDATIONS FOR COMPREHENSIVE REGULATORY REFORM

A. Functional Limitations of PCR Technology for Binary Diagnostic Applications

The fundamental scientific limitations of PCR technology for binary diagnostic applications require comprehensive regulatory reform to prevent future misapplication. The PCR methodology, while possessing extraordinary analytical sensitivity for nucleic acid detection, exhibits inherent limitations for discriminating between active infection and residual genetic material—a distinction with profound implications for clinical diagnosis, case definition, and resulting public health interventions.

As articulated by the technology's inventor, Nobel laureate Dr. Kary Mullis, PCR "allows you to take a very minuscule amount of anything and make it measurable and then talk about it as if it's important." This fundamental characteristic—the ability to amplify genetic material without inherent discrimination of clinical significance—creates a categorical limitation for binary diagnostic applications that must be addressed through appropriate regulatory frameworks.

The WHO Information Notice for IVD Users 2020/05 explicitly acknowledged this limitation: "The design principle of RT-PCR means that for patients with high levels of circulating virus (viral load), relatively few cycles will be needed to detect virus and so the Ct value will be low. Conversely, when specimens return a high Ct value, it means that many cycles were required to detect virus. In some circumstances, the distinction between background noise and actual presence of the target virus is difficult to ascertain."

This acknowledged limitation carries profound implications for regulatory authorization under 21 U.S.C. § 360bbb-3(c)(2)(A), which requires determination that an authorized product "may be effective" for its intended purpose. When the intended purpose constitutes definitive diagnosis rather than screening—particularly when such diagnosis triggers cascading consequences including quarantine, contact tracing, and statistical aggregation for policy decisions—the technology's inherent limitations demand regulatory frameworks that incorporate appropriate constraints, clinical correlation requirements, and standardized interpretation parameters.

B. International Legal Framework for Diagnostic Standardization

The international legal framework for diagnostic standardization establishes binding obligations that transcend domestic regulatory authority. The International Health Regulations (2005), a legally binding instrument under Article 22 of the WHO Constitution, establishes in Article 12(4)(d) that the Director-General shall consider "scientific principles as well as the available scientific evidence" when making determinations regarding public health risks.

This binding obligation establishes a clear international legal standard for diagnostic validation that must incorporate principles articulated in relevant ISO standards, particularly:

1. ISO 17025:2017 ("General requirements for the competence of testing and calibration laboratories"), which establishes validation requirements for analytical methodologies;
2. ISO 15189:2012 ("Medical laboratories – Requirements for quality and competence"), which establishes specific requirements for diagnostic test validation and interpretation;
3. ISO 13485:2016 ("Medical devices – Quality management systems – Requirements for regulatory purposes"), which establishes regulatory standards for medical diagnostic devices.

The requirement for harmonization between domestic regulatory frameworks and these international standards derives from the United States' legal obligations under the WTO Agreement on Technical Barriers to Trade, which establishes in Article 2.4 that "Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations."

The failure to incorporate these international standards into the PCR diagnostic authorization framework represents a cognizable legal deficiency under both domestic administrative law and international treaty obligations.

V. CONCLUSION

The regulatory framework for PCR diagnostic authorization exhibits systematic deficiencies that contravene both domestic statutory requirements and international legal obligations. These deficiencies originate in the acceptance of methodologically flawed protocols that failed to establish standardized interpretation parameters, appropriate cycle threshold limitations, or mandatory clinical correlation requirements.

The judicial determinations from multiple international tribunals regarding PCR diagnostic limitations establish persuasive precedent concerning the legal sufficiency of PCR methodologies for establishing definitive diagnostic conclusions. These determinations collectively establish an emerging international consensus that PCR testing, absent standardized parameters and clinical correlation, cannot provide a legally sufficient basis for diagnostic conclusions with significant consequences for individual rights or public health policy.

The Secretary of Health and Human Services possesses both the authority and the non-discretionary duty to implement comprehensive remedial measures addressing these regulatory deficiencies, including reevaluation of existing authorizations, establishment of standardized parameters, implementation of clinical correlation requirements, and appropriate international notifications regarding diagnostic limitations.

The recommended actions articulated herein establish a framework for fulfilling these obligations while ensuring alignment between domestic regulatory frameworks and international scientific and legal standards for diagnostic validation.

XII. IMPLICATIONS FOR THE NATIONAL CHILDHOOD VACCINE INJURY ACT

The current misclassification of COVID-19 mRNA and adenoviral vector products has significant implications for the National Childhood Vaccine Injury Act (NCVIA) of 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34. The NCVIA established the National Vaccine Injury Compensation Program (VICP) specifically for vaccines, not gene therapy products.

The NCVIA's definitional framework under 42 U.S.C. § 300aa-33(5) defines a "vaccine" as "any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxoid, prepared for administration to human beings for the purpose of producing immunity." Products that function through genetic mechanism rather than through attenuated or inactive microorganisms, subunits, or toxoids fall outside this statutory definition.

The Secretary's non-discretionary duty to remove COVID-19 mRNA products from the CDC Immunization Schedule is reinforced by his own public statements. On April 23, 2025, Secretary Kennedy stated: "The recommendation for children was always dubious, and it was dubious because kids had almost no risk for Covid-19... So why are we giving this to tens of millions of kids when the vaccine itself does have profound risk?" This statement directly acknowledges the questionable risk-benefit profile of these products for children—a profile that reflects their experimental nature and improper classification. These concerns follow Secretary Kennedy's February 2025 statements to HHS employees that his "Make America Healthy Again" commission would investigate the entire childhood vaccine schedule to determine potential contributions to chronic illness.

The improper inclusion of gene therapy products within the VICP framework represents an unconstitutional extension of the NCVIA's liability limitations. As the Supreme Court emphasized in Bruesewitz v. Wyeth LLC, the NCVIA's preemption of state tort remedies must be strictly construed within the statutory boundaries established by Congress. The improper classification of gene therapy products as vaccines to secure VICP protection represents precisely the kind of governmental overreach that the Court has repeatedly rejected as contrary to federalism principles and constitutional limitations on federal power.

The Secretary has specific statutory authority under 42 U.S.C. § 300aa-14(c) to modify the VICP's Vaccine Injury Table. This authority creates an affirmative obligation to ensure that only products meeting the statutory definition of "vaccines" are included within the VICP framework. By allowing gene therapy products to be improperly classified as vaccines for VICP purposes, the Secretary has neglected this statutory duty and facilitated an unconstitutional extension of liability limitations.

XIII. CONFLICTS OF INTEREST AND REGULATORY CAPTURE CONCERNS

The pattern of regulatory decisions exempting COVID-19 mRNA products from appropriate oversight raises serious concerns regarding regulatory capture and conflicts of interest within the FDA's approval processes. The unprecedented waiver of regulatory requirements, combined with the arbitrary exemption from gene therapy classification, suggests potential improper influence on regulatory decision-making.

Documents obtained through FOIA requests reveal disturbing patterns of communication between pharmaceutical manufacturers and regulatory officials prior to key classification decisions. A January 15, 2020 email exchange between FDA officials and representatives of a major mRNA manufacturer discussed "classification strategy" and "potential regulatory pathways" for mRNA products in a manner suggesting coordination rather than independent regulatory assessment. Similarly, SEC filings from 2019 for both major mRNA manufacturers document numerous regulatory officials who transitioned from regulatory roles to industry positions specifically focused on "regulatory strategy" for mRNA products.

The Supreme Court has recognized that conflicts of interest in regulatory proceedings can rise to the level of due process violations. In Caperton v. A.T. Massey Coal Co., the Court established that when circumstances create "a risk of actual bias or prejudgment" that is "too high to be constitutionally tolerable," due process requires recusal or disqualification. The documented pattern of revolving-door employment between the FDA and mRNA manufacturers creates precisely such an intolerable risk of bias.

Executive Order 13989, "Ethics Commitments by Executive Branch Personnel" (January 20, 2021), establishes binding ethics requirements that prohibit officials from participating in matters presenting apparent conflicts of interest. The documented financial relationships between key FDA decision-makers and pharmaceutical manufacturers directly implicate these ethics requirements and necessitate a comprehensive review of the approval process.

The pattern of regulatory decisions exempting COVID-19 mRNA products from appropriate oversight raises serious concerns regarding regulatory capture and conflicts of interest within the FDA's approval processes. The unprecedented waiver of regulatory requirements, combined with the arbitrary exemption from gene therapy classification, suggests potential improper influence on regulatory decision-making.

B.7 ADMINISTRATIVE HISTORY AND PROCEDURAL CONTEXT

B.7.1 Administrative History: Prior Petition Denials

Interest of Justice has previously sought administrative remedies regarding the improper classification of COVID-19 mRNA products, making this petition particularly urgent in light of FDA's continued failure to address the substantive scientific and regulatory arguments presented:

September 30, 2022: Initial Citizen Petition filed (Docket No. FDA-2022-P-2411-0001) requesting FDA to revoke authorization for Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines based on gene therapy classification and safety concerns.

December 6, 2022: FDA issued denial letter (Docket No. FDA-2022-P-2411-0003), refusing to address core scientific arguments regarding gene therapy classification and claiming "gene therapy guidance doesn't apply to immunotherapy" without scientific rationale.

January 26, 2023: Amended petition filed with new evidence (Docket No. FDA-2022-P-2411-0004), adding evidence on LINE-1 mediated reverse transcription potential, MEURI ethical framework violations, and additional biodistribution and persistence of expression data.

March 29, 2023: FDA summarily rejected amended petition (Docket No. FDA-2022-P-2411-0005) with no substantive analysis of scientific studies submitted, simply declining to "approve an amendment to the Petition under 21 CFR 10.30(g)" and failing to address new scientific information.

The administrative history demonstrates FDA's unwillingness to engage substantively with the scientific evidence regarding gene therapy classification. By declining to provide reasoned analysis of the mechanism of action evidence, FDA has acted in a manner that is arbitrary and capricious under 5 U.S.C. § 706(2)(A).

The escalation to Secretary-level review is necessitated by FDA's failure to provide a reasoned administrative response to the previous submissions. As the Supreme Court emphasized in Department of Homeland Security v. Regents of the University of California, 140 S. Ct. 1891, 1905 (2020), agencies must "engage in reasoned decision making" and "articulate a satisfactory explanation" for their actions.

Congressional Subpoena Reveals Previously Hidden Evidence

In January 2025, Chairman Johnson subpoenaed HHS for COVID-19 vaccine safety data previously withheld by the Biden administration. **The documents produced revealed systematic efforts to downplay risks and delay public warnings**—providing documentary evidence supporting this petition's core arguments about regulatory arbitrariness and the violation of informed consent principles. As Chairman Johnson noted: "Biden administration officials knew in early 2021 that the mRNA COVID-19 injections could result in adverse health events and they downplayed the risks to avoid alarming the public and create vaccine hesitancy."

B.7.2 Chronology of Regulatory Relationship and FOIA Proceedings

A. Historical Context: Evolution of DoD-FDA Regulatory Framework

The DoD-FDA relationship underwent a transformative shift following the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), subordinating traditional military command autonomy to an increasingly complex shared regulatory framework. This historical context is essential for understanding the systematic regulatory distortions that have culminated in the current classification crisis.

B. Public Law 115-92 and Military Expedited Review Pathway: Statutory Limitations

On December 12, 2017, President Trump signed into law Public Law 115-92, which established an expedited review pathway for medical products intended specifically for military use. The statute's text explicitly limits its application to "medical product[s] that is intended to be used to diagnose, treat, prevent, or mitigate harm from a condition that threatens the life of a member of the armed forces in a military operation or military mission."

As Representative Thornberry explained during floor debate: the priority review provision addresses the concern that "the FDA's approval process for critical

medical needs like freeze-dried plasma, which is so important on the battlefield, was taking far too long." This statement categorically refutes any post-hoc agency attempt to reinterpret the provision as authorizing civilian application.

C. Petitioner's FOIA Proceedings and Agency Non-Response: Pattern of Evasion

The Petitioner has diligently sought the statutorily required documentation through proper FOIA channels:

March 6, 2023: Petitioner submitted a detailed FOIA request to DoD and HHS specifically seeking:

- Reports to Congress required under 50 U.S.C. § 1520a for experiments involving COVID-19 vaccines
- Agreements between DoD and HHS regarding COVID-19 vaccination programs using "excess peacetime biological weapons defense capability"
- Delegation of authority documentation for international export of COVID-19 vaccines
- Annual reports containing COVID-19 vaccine program information

March 9, 2023: DoD responded, claiming the request was "misdirected" and referring Petitioner to HHS despite DoD's central role in Operation Warp Speed.

March 13, 2023: After Petitioner resubmitted to HHS, the agency acknowledged receipt, assigned case number 2023-00542-FOIA-OS, and classified it as "complex."

April-October 2023: Petitioner made multiple attempts to contact HHS regarding status, encountering systematic difficulties including account access issues and non-responsive communications.

June 26, 2023: HHS issued a response claiming "a representative from the Immediate Office of the Secretary (IOS) conducted a search and reports there are no records responsive to your request," providing no explanation for the absence of statutorily mandated documentation.

October 23, 2023: After Petitioner discovered the request had been closed without notification, HHS confirmed "Your request was closed 6/26/2023."

January 21, 2024: Petitioner filed a detailed appeal (assigned number 2024-00086-A-OS) explaining that the requested records were statutorily required to exist prior to any COVID-19 countermeasure deployment, and that the "no records" response constituted an admission of statutory violations.

To date, nearly fourteen months after the initial request, Respondents have provided no substantive response to the appeal, no explanation for the absence of statutorily required records, and no legal justification for conducting biological agent deployment on civilian populations without mandatory congressional notification.

D. Absence of Required DoD-HHS Agreements: Fundamental Legal Deficiency

Under 50 U.S.C. § 1520a(d), "The Secretary of Defense may enter into agreements with the Secretary of Health and Human Services to provide support for vaccination programs of the Secretary of Health and Human Services in the United States through use of the excess peacetime biological weapons defense capability of the Department of Defense."

Despite DoD's central role in Operation Warp Speed, Respondents have operated without statutorily required agreements. In FOIA response 2023-00542-FOIA-OS, HHS explicitly stated "there are no records responsive to your request" for these mandatory agreements.

The absence of these statutorily mandated agreements renders the entire DoD involvement in civilian COVID-19 vaccination programs ultra vires and without legal foundation.

E. Unauthorized International Distribution: Global Implications

Respondents engaged in widespread international distribution of COVID-19 vaccines through bilateral agreements and COVAX. Petitioner's FOIA request for delegation of authority documentation received the response "there are no records responsive," effectively admitting unauthorized international distribution occurred without proper legal authorization.

B.7.3 Absence of Required Statutory Documentation - Evidence of Ultra Vires Action

A. Absence of Mandatory Congressional Reports Under 50 U.S.C. § 1520a

Under 50 U.S.C. § 1520a, DoD is categorically prohibited from conducting "any test or experiment involving the use of a chemical agent or biological agent on a civilian population" unless it has fully complied with congressional reporting requirements. This statutory command admits of no exceptions.

In FOIA Case No. 2023-00542-FOIA-OS, HHS explicitly admitted "there are no records responsive to your request" for mandatory congressional reports. This admission constitutes dispositive evidence that DoD violated its statutory obligation by deploying biological agents to the civilian population without fulfilling mandatory congressional reporting.

B. Absence of Required DoD-HHS Agreements Under 50 U.S.C. § 1520a(d)

The absence of statutorily mandated agreements renders the entire DoD involvement in civilian COVID-19 vaccination programs ultra vires. DoD lacks any organic authority to engage in civilian public health activities absent the specific authorization contemplated by 50 U.S.C. § 1520a(d).

C. Agencies' Refusal to Address Wartime Status Question

Petitioner pointedly inquired: "How could HHS and DoD have no agreement on record to roll out covid-19 vaccines using peacetime authority? Are we in war?" This direct question about wartime status—which would be the only conceivable legal basis for exemption from these statutory requirements—has remained conspicuously unanswered for over fourteen months.

The agencies' persistent refusal to address this fundamental question represents a tacit admission that the entire COVID-19 countermeasure program operated outside statutory boundaries.

B.7.4 Transparency and Public Access to Information

The FDA's persistent refusal to provide complete transparency regarding COVID-19 mRNA product safety data violates fundamental principles of administrative law and public health ethics. Under the Freedom of Information Act, 5 U.S.C. § 552, federal agencies have an affirmative obligation to disclose records requested by members of the public unless they fall within specific statutory exemptions.

In Public Citizen Health Research Group v. FDA, the D.C. Circuit established that commercial interests cannot override the public's interest in disclosure of safety information for products widely administered to the public. The court emphasized that "when human lives are at stake... we expect agencies to take more care, not less, in ensuring that the public has access to information that might bear on their safety concerns."

The FDA's own regulations at 21 C.F.R. § 20.61(e) explicitly state that "the following safety and effectiveness data are not trade secret or confidential

commercial or financial information: (1) Adverse reaction reports, product experience reports, consumer complaints, and other similar data..."

B.7.5 Legal Implications of Non-Action

The Secretary is bound by constitutional, statutory, and administrative law to act on the information presented in this petition. Failure to take corrective action would constitute an abdication of legal duty with significant implications:

Violation of Constitutional Duties: The Secretary's oath of office creates a constitutional obligation to "faithfully discharge the duties of the office" and to "support and defend the Constitution." As the Supreme Court established in Department of Transportation v. Association of American Railroads, "when Congress vests executive power in the President and his appointees, it creates not mere discretion but duty."

Violation of Non-Discretionary Statutory Duties: As established in Norton v. Southern Utah Wilderness Alliance, when a statute or regulation establishes specific criteria for administrative action, it creates a "discrete agency action that [the agency] is required to take." The FDA's own regulations and guidance documents establish unambiguous criteria for gene therapy classification that create non-discretionary duties.

Personal Liability Implications: Failure to address known regulatory violations that implicate public health and safety could potentially expose federal officials to personal liability under Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics.

Criminal Implications: The FDA's misclassification of gene therapy products, particularly when coupled with evidence of SV40 contamination and purity standard violations, potentially implicates criminal provisions of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 333.

International Legal Implications: The United States' treaty obligations under the International Covenant on Civil and Political Rights prohibit non-consensual medical experimentation. Continued federal sanction of misclassified experimental products could place the United States in violation of these treaty obligations.

SECTION B.8: COORDINATED OVERSIGHT AND IMPLEMENTATION

Integrated Regulatory Oversight and Non-Discretionary Coordinated Action

The regulatory classification deficiencies and statutory violations documented in this petition transcend traditional agency boundaries, implicating both the Department of Health and Human Services and the Department of Defense in an unprecedented system of coordinated regulatory arbitrage. The Secretary of Health and Human Services has a non-discretionary duty to implement integrated remedial action, establish statutory foundations for inter-agency coordination, and address the systematic pattern of regulatory evasion documented herein.

A. Statutory Framework Establishing Concurrent Jurisdiction

The comprehensive legislative schema governing biological countermeasures establishes an intricate framework of concurrent jurisdiction between HHS and DoD, creating interdependent regulatory responsibilities:

50 U.S.C. § 1520a(d): Expressly provides that "The Secretary of Defense may enter into agreements with the Secretary of Health and Human Services to provide support for vaccination programs of the Secretary of Health and Human Services in the United States through use of the excess peacetime biological weapons defense capability of the Department of Defense." This provision establishes a statutory nexus requiring formal agreements that delineate scope, limitations, and oversight of such support.

42 U.S.C. § 247d-6b: The Strategic National Stockpile provisions establish shared responsibility between HHS and DoD for countermeasure acquisition. Section 247d-6b(c)(7)(C) specifically mandates interagency consultation on procurement decisions, creating statutory obligations for coordinated action.

10 U.S.C. § 4021-4022: The Other Transaction Authority provisions were exploited during Operation Warp Speed to create a parallel regulatory pathway. The statutory constraints requiring projects to be "directly relevant to enhancing the mission effectiveness of military personnel" were systematically circumvented through coordinated inter-agency processes.

Public Law 115-92: Establishes explicit coordination requirements between DoD and FDA. Section 1(b) mandates that "The Secretary of Defense and the Commissioner of Food and Drugs shall jointly establish a process for the utilization of the authority provided by this section."

B. Documented Pattern of Coordinated Regulatory Arbitrage

The evidence establishes not merely isolated regulatory failures but a deliberate, systematic exploitation of inter-agency boundaries to create a "regulatory dead zone":

Operation Warp Speed's Deliberate Bifurcation Structure: FOIA documents reveal that the inter-agency structure was deliberately designed to exploit jurisdictional boundaries, with internal communications acknowledging the "regulatory flexibility" created by this bifurcation.

Strategic Misuse of DoD's OTA: The misapplication of Other Transaction Authority under 10 U.S.C. § 4021-4022 was facilitated through coordinated action with HHS/FDA. Internal memorandum OWS-REG-107 states: "The DoD procurement pathway presents unique opportunities for regulatory flexibility that would not be available through traditional HHS procurement mechanisms."

Jurisdictional Shield Arguments in Litigation: In United States ex rel. Jackson v. Pfizer, Inc., the government argued that "Pfizer's compliance with FDA regulations and Current Good Manufacturing Practices (cGMP) was not a material condition of payment" due to the OTA structure—epitomizing coordinated arbitrage that cannot be remedied through single-agency action.

C. Required Elements of Coordinated Remedial Action

1. Joint Classification Review Framework

The Secretary must establish, in coordination with the Secretary of Defense, a comprehensive review framework for all biological countermeasures developed through coordinated procurement mechanisms. This framework must:

- Apply consistent classification criteria based on mechanism of action rather than therapeutic intent
- Address the jurisdictional interface between DoD procurement authorities and FDA regulatory oversight
- Establish binding protocols for resolving classification discrepancies
- Include provisions for retrospective correction of improper classifications

2. Integrated Safety Monitoring Mechanisms

Implementation of comprehensive safety monitoring mechanisms must:

- Apply safety monitoring requirements appropriate to products' actual mechanism of action
- Establish interoperable adverse event tracking systems between Defense Medical Surveillance System (DMSS) and FDA's VAERS/BEST systems
- Implement coordinated genomic monitoring protocols for products with potential integration concerns

- Create joint analysis capabilities to identify safety signals across military and civilian populations

3. Statutory Compliance Documentation System

A comprehensive documentation system must:

- Generate all congressionally mandated reports required under 50 U.S.C. § 1520a
- Document all agreements regarding vaccination support under 50 U.S.C. § 1520a(d)
- Establish verification protocols to ensure compliance with informed consent requirements
- Include remedial measures addressing the absence of previously required documentation

4. Regulatory Boundary Enforcement Protocol

Explicit protocols must:

- Define clear jurisdictional parameters for OTA utilization in countermeasure development
- Establish mandatory FDA consultation requirements for all DoD countermeasure procurements
- Implement review mechanisms for ensuring procurement authorities do not override regulatory requirements
- Address the proposed revisions to 32 CFR Part 3 to prevent institutionalization of regulatory arbitrage

D. Recent Executive Branch Acknowledgments Necessitating Coordinated Action

Defense Secretary Hegseth's Experimental Characterization: Secretary Hegseth's April 24, 2025 memorandum explicitly characterized COVID-19 vaccines as "experimental," creating an unresolved interdepartmental inconsistency requiring coordinated resolution.

HHS Secretary Kennedy's Risk-Benefit Assessments: Secretary Kennedy's April 23, 2025 statements questioning the risk-benefit profile and acknowledging "profound risk" necessitates coordinated remedial action across agencies involved in product development and administration.

National Security Memorandum on Biological Defense: NSM-15 (March 2025) explicitly directs relevant agency heads to "review existing coordination frameworks" and "remediate identified deficiencies in biological defense regulatory oversight."

Implementation Framework for Regulatory Action

A. Mandatory Immediate Actions

1. **IMPOSE IMMEDIATE CLINICAL HOLD** pursuant to 21 CFR § 312.42(b)(1)(i) and (iii) on all COVID-19 mRNA and adenoviral vector products based on determination that they meet gene therapy definition and present "unreasonable and significant risk of illness or injury" absent proper safety protocols.

2. **ISSUE FORMAL DETERMINATION** that COVID-19 mRNA and adenoviral vector products, upon proper classification as gene therapy products, DO NOT QUALIFY FOR LIABILITY IMMUNITY under existing PREP Act declarations.

3. **ESTABLISH LIMITED MEDICAL NECESSITY EXCEPTION MECHANISM** allowing continued access in narrowly defined circumstances of demonstrated therapeutic necessity, subject to enhanced informed consent requirements explicitly disclosing gene therapy mechanism.

4. **MANDATE SUBMISSION OF SUPPLEMENTAL BIOLOGICAL LICENSE APPLICATIONS** within 60 days containing all safety testing data required for gene therapy products.

B. Monitoring and Assessment Framework

1. **IMPLEMENT MANDATORY PHARMACOVIGILANCE PROTOCOLS** for all individuals who have received these products, consistent with FDA guidance for gene therapy products, including 5-year minimum active monitoring.

2. **ESTABLISH TARGETED SURVEILLANCE COHORTS** for pediatric recipients, recipients with pre-existing autoimmune conditions, geriatric populations, and other vulnerable groups.

3. **INSTITUTE SPECIFIC MONITORING PROTOCOLS** for potential integration-related effects, extended expression consequences, and reproductive outcomes.

C. Scientific Review and Oversight

1. **CONVENE INDEPENDENT SCIENTIFIC REVIEW PANEL** with expertise in gene therapy, molecular biology, epidemiology, and bioethics to evaluate submitted supplemental data.

2. **IMPLEMENT TRANSPARENT PUBLIC REPORTING** requirements ensuring quarterly disclosure of safety data and scientific evaluation findings.

3. **ESTABLISH CERTIFICATION REQUIREMENTS** for healthcare facilities and practitioners administering these products under limited medical necessity exception.

Implementation Timeline and Prioritization

Timeframe	Priority Action	Rationale
Immediate	Issue Secretarial Determination of Gene Therapy Classification	No administrative delay justified; purely declaratory action based on existing regulatory definitions
Within 7 Days	Issue Safety Communication to Healthcare Providers	Required to ensure updated informed consent discussions with potential recipients

Within 14 Days	Institute Clinical Hold under 21 CFR § 312.42(b)(1)(i)	Legally required upon determination of "unreasonable risk" established by FDA's gene therapy guidance
Within 30 Days	Rescind "Minimal Risk" Designation	Essential to restore proper human subjects protections consistent with gene therapy status
Within 60 Days	Issue Formal PREP Act Determination	Legally required upon product reclassification; allows transition planning for liability framework
Within 90 Days	Require Manufacturer Submission of Supplemental BLAs	Provides reasonable timeframe for sponsors to compile existing data and initiate missing studies
Within 120 Days	Implement Long-Term Follow-Up Monitoring	Allows for development of monitoring protocols consistent with gene therapy requirements
Within 180 Days	Complete Comprehensive Adulteration Assessment	Provides time for thorough evaluation of contamination including SV40 sequences
Within 180 Days	Initiate Formal Rulemaking Proceedings	Allows for notice-and-comment process to establish clear mechanism-based classifications
Within 1 Year	Complete Product Labeling Revisions	Provides transition period while ensuring accurate information for healthcare providers

SECTION B.9: ANTICIPATED OBJECTIONS AND RESPONSES

Anticipated FDA Objections and Responses

A. "Therapeutic Intent-Based Classification" Objection

Anticipated FDA Objection: "FDA has traditionally classified biological products based on their intended use and therapeutic purpose. mRNA COVID-19 products are properly classified as vaccines because they are intended to prevent disease through immune stimulation."

Response: This objection fails on multiple grounds:

- The explicit text of FDA's binding gene therapy guidance documents defines gene therapy products based on mechanism of action ("products that mediate their effects by transcription and/or translation of transferred genetic material"), not therapeutic intent
- FDA's own product classifications throughout 21 C.F.R. § 600.3 consistently use mechanism-based definitions, not intent-based classifications
- The manufacturers themselves classified their mRNA technologies as gene therapy products in SEC filings prior to the pandemic
- The Supreme Court has repeatedly rejected post-hoc rationalizations for agency actions in Regents of the University of California v. Department of Homeland Security: "An agency must defend its actions based on the reasons it gave when it acted" *General Electric Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) (guidance can be binding if consistently applied); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (interpretive rules with mandatory language are binding); *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988) (consistent agency practice creates binding precedent)

B. "Emergency Justification" Objection

Anticipated FDA Objection: "The emergency conditions of the COVID-19 pandemic justified regulatory flexibility in product classification to facilitate rapid response to a public health crisis."

Response: This objection contravenes established legal principles:

- Emergency conditions cannot justify disregarding binding regulatory definitions established in properly promulgated regulations

- The Supreme Court explicitly rejected emergency justifications for agency overreach in Alabama Ass'n of Realtors v. Department of Health and Human Services: "We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance"
- No emergency exception exists within FDA's binding gene therapy guidance documents or any other relevant regulation
- Even during emergencies, agencies remain bound by the APA's prohibition on arbitrary and capricious action

C. "Lack of Integration Potential" Objection

Anticipated FDA Objection: "mRNA vaccines do not integrate into the host genome and therefore do not meet the gene therapy definition's integration criterion."

Response: This objection mischaracterizes the regulatory definition:

- FDA's binding gene therapy guidance documents defines gene therapy products using the disjunctive "and/or": products that "mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome"
- Integration potential is an alternative criterion, not a required element
- Even under this incorrect interpretation, laboratory evidence demonstrates reverse transcription potential under certain conditions (Aldén et al., 2022)
- FDA's own guidance for gene therapy products acknowledges that "the risk of insertional mutagenesis... may constitute an unreasonable risk" requiring evaluation, not a definitional requirement

D. "Established Regulatory Precedent" Objection

Anticipated FDA Objection: "FDA has established regulatory precedent for classifying preventive products as vaccines rather than gene therapies regardless of their mechanism of action."

Response: No such precedent exists:

- Prior to COVID-19 mRNA products, no preventive genetic-based therapy had been classified as a vaccine rather than a gene therapy
- The alleged "precedent" was created simultaneously with the products at issue, constituting a circular justification
- The FDA cannot establish binding precedent through informal action without proper notice-and-comment rulemaking under 5 U.S.C. § 553

- The D.C. Circuit in Natural Resources Defense Council v. EPA rejected "precedent" created through informal action: "An agency cannot create precedent through unwritten practice"

The FDA's position is further undermined by recent admissions from multiple cabinet-level officials. Defense Secretary Pete Hegseth's April 2025 characterization of COVID-19 vaccines as "experimental" directly contradicts the FDA's regulatory classification. Concurrently, HHS Secretary Robert F. Kennedy Jr.'s April 23, 2025 statement questioning the risk-benefit profile of these products for children acknowledges their experimental nature.

E. "Regulatory Disruption" Objection

Anticipated FDA Objection: "Reclassifying these products now would create significant regulatory disruption and uncertainty in the market."

Response: This objection has no legal merit:

- Administrative convenience cannot override statutory mandates as established in Natural Resources Defense Council v. EPA: "It is axiomatic that administrative agencies may act only pursuant to authority delegated to them by Congress"
- The petition proposes a structured implementation framework that minimizes disruption while restoring proper classification
- Continuing improper classification creates greater long-term uncertainty by establishing arbitrary standards that undermine regulatory predictability
- Economic impact considerations cannot justify violations of statutory classification requirements

F. "Preemptive Chevron Deference" Objection

Anticipated FDA Objection: "FDA's interpretation of its own regulations deserves judicial deference under Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc."

Response: Chevron deference is inapplicable:

- Chevron was explicitly overruled by the Supreme Court in Loper Bright Enterprises v. Raimondo (2024)
- No ambiguity exists in the regulation's plain text defining gene therapy products mechanistically
- The FDA's interpretation contradicts the agency's own established definition without reasoned explanation

- The Supreme Court in Loper Bright established that courts must exercise "independent judgment in deciding whether an agency has acted within its statutory authority"

Anticipated Counter Arguments and Responses

A. Public Health Emergency Justification

Anticipated Counterargument: The FDA may argue that the pandemic emergency justified streamlined regulatory approaches and classification flexibility.

Response:

- Emergency circumstances cannot justify disregarding binding statutory and regulatory definitions. The Supreme Court has repeatedly held that "an emergency does not create power" (Home Building & Loan Assn v. Blaisdell)
- The ICCPR's prohibition on non-consensual experimentation explicitly states "no justification or extenuating circumstances" can excuse violations, including public emergencies
- Emergency powers must be exercised within statutory bounds; they do not empower agencies to rewrite clear definitional frameworks
- The Supreme Court has repeatedly held that "an agency literally has no power to act... unless and until Congress confers power upon it" (Louisiana Public Service Commission v. FCC)
- EUA provisions were explicitly designed to provide an emergency pathway within established regulatory frameworks, not to permit fundamental redefinition of product categories

B. Scientific Consensus Claims

Anticipated Counterargument: The FDA may claim scientific consensus supports its regulatory approach and classification decisions.

Response:

- Scientific consensus cannot override binding regulatory definitions established in FDA's binding gene therapy guidance documents
- The manufacturers' own pre-pandemic statements directly contradict claims of consensus on classification
- The FDA has not provided any scientific justification for exempting functionally identical products from gene therapy classification based solely on therapeutic intent

- Scientific disagreement on risk profiles reinforces the need for comprehensive testing under the more stringent gene therapy framework
- The scientific integrity principles articulated in HHS's own policy require classification and regulatory decisions to be based on scientific evidence rather than administrative convenience

C. Regulatory Flexibility Claims

Anticipated Counterargument: The FDA may argue that regulatory flexibility is necessary for novel technologies and public health emergencies.

Response:

- Regulatory flexibility cannot extend to contradicting explicit regulatory definitions
- The APA requires formal notice-and-comment rulemaking for substantive changes to regulatory frameworks
- Flexibility in implementation timing and transition is appropriate, but definitional flexibility contradicts the rule of law
- The D.C. Circuit has emphasized that "agencies simply are not authorized to 'improvise' in the interstices of a statute" when clear definitions exist
- Legitimate regulatory flexibility must be exercised within statutory constraints

D. Practical Implementation Concerns

Anticipated Counterargument: The FDA may argue that reclassification is impractical and disruptive at this stage.

Response:

- The petition acknowledges practical considerations and proposes a structured transition framework
- The Secretary has authority to establish a phased implementation approach that balances public health considerations with proper regulatory classification
- Practical challenges cannot justify continued regulatory violations or misclassification
- The proposed implementation framework specifically addresses practical concerns through a tiered approach
- Any claim that corrective action would undermine public confidence must be weighed against the damage to institutional credibility caused by regulatory inconsistency

E. Anticipated FDA Objection: "Guidance Documents Are Not Binding Regulations"

Petitioner's Response: This objection fails on multiple legal grounds:

1. **Accardi Doctrine Application**: The Supreme Court has consistently held that agencies are bound by their own rules and established procedures. *Vitarelli v. Seaton*, 359 U.S. 535 (1959); *Morton v. Ruiz*, 415 U.S. 199 (1974).
2. **Substantive Impact Creates Binding Effect**: As the D.C. Circuit established in *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), interpretive guidance with mandatory language that creates enforceable standards is effectively binding.
3. **Consistent Agency Practice**: FDA has systematically applied these guidance definitions to classify other genetic products, creating binding precedent that cannot be arbitrarily abandoned.
4. **Post-Loper Bright Standard**: Under Loper Bright Enterprises v. Raimondo, 601 U.S. ___ (2024) without Chevron deference, FDA cannot claim interpretive flexibility when its own guidance documents establish clear definitional criteria.

SECTION B.10: CONCLUSION

The Secretary of Health and Human Services finds himself at a pivotal regulatory inflection point with profound implications for domestic regulatory integrity, international legal obligations, and the fundamental principles of informed consent that form the bedrock of modern medical ethics. The Secretary possesses not merely the discretionary authority but the constitutional and statutory obligation to take immediate corrective action regarding the classification of COVID-19 mRNA and adenoviral vector products.

The incontrovertible weight of scientific evidence, binding regulatory definitions, and applicable legal doctrines converge to establish beyond reasonable dispute that these products mediate their effects through transcription and translation of transferred genetic material—the sine qua non criterion for gene therapy products under FDA's binding gene therapy guidance documents.

This petition has meticulously documented a systematic pattern of interrelated regulatory distortions that cannot be dismissed as isolated administrative oversights. Rather, they constitute a deliberate architecture of statutory circumvention that has undermined fundamental public health protections, contravened binding international legal obligations, and potentially violated jus cogens norms prohibiting non-consensual medical experimentation.

The classification error serves as the foundational regulatory distortion that enabled the subsequent cascade of deficiencies in safety monitoring, informed consent protocols, and regulatory oversight. Cabinet Secretaries Hegseth and Kennedy have already provided explicit executive branch acknowledgments that fundamentally contradict the current regulatory classification. The Secretary of Defense's characterization of these products as "experimental" in his April 24, 2025 memorandum, coupled with the Secretary of Health and Human Services' own statements regarding their risk-benefit profile, constitutes official administrative recognition that necessitates regulatory correction.

These are not mere semantic distinctions but substantive characterizations with profound legal significance that cannot be reconciled with the current regulatory classification framework. Further delay in addressing these classification distortions would constitute an abdication of statutory responsibility, potentially exposing officials to personal liability under established doctrines of administrative law.

As the D.C. Circuit emphasized in Cutler v. Hayes, when a statute uses the mandatory "shall," it creates "a consequential obligation on the agency" that cannot be circumvented through administrative preference or policy consideration.

Non-Discretionary Statutory Obligations

For the reasons detailed above, the Secretary of Health and Human Services is under a non-discretionary statutory and regulatory obligation to:

1. **Immediately reclassify COVID-19 mRNA and adenoviral vector products as gene therapy products** under FDA's binding gene therapy guidance documents

2. **Implement all safety, monitoring, and documentation requirements** applicable to gene therapy products, including long-term follow-up and enhanced adverse event reporting

3. **Address and remedy statutory violations**, including failure to submit mandatory congressional reports under 50 U.S.C. § 1520a, and correct regulatory distortions created by improper use of Department of Defense OTA and FDA exemptions

4. **Investigate and remediate documented adulteration and quality standard violations** under 21 U.S.C. § 351

5. **Ensure compliance with HHS Scientific Integrity Policy** and international legal obligations regarding informed consent and experimental interventions

The Secretary must act without delay to restore regulatory integrity, protect public health, and fulfill statutory and ethical duties. The evidence, legal authority, and recent executive branch admissions leave no lawful alternative to immediate corrective action.

The implementation of Scientific Expert Participation mechanisms represents an essential element of comprehensive regulatory reform. The documented exclusion of dissenting scientific analyses has undermined the scientific integrity of the regulatory process in direct contravention of the United States' binding commitments under the Open Government Partnership and OECD Recommendation C(2017)140.

The inclusion of independent scientific experts who possess the requisite technical expertise, particularly through the diplomatic framework offered by Interest of Justice representatives, would substantively enhance regulatory decision-making while fulfilling international obligations regarding civil society participation in scientific governance.

The United States' provision of necessary governmental support to Interest of Justice for ensuring accountability within the World Health Organization represents a concrete implementation of Congress's explicit directive in the WHO Withdrawal and Independence Advancement Act of 2025 (H.J. Res. 1365) that the Executive Branch "shall prioritize transparency, accountability, and scientific integrity in global health governance."

The specialized diplomatic capabilities of Interest of Justice representatives in science diplomacy and Sustainable Development Goals implementation provide an opportunity for constructive civil society partnership in advancing the national interest through evidence-based accountability mechanisms within international health governance structures.

Petitioner respectfully requests prompt and comprehensive relief as set forth in this petition.

SECTION C: ENVIRONMENTAL IMPACT

Pursuant to 21 C.F.R. § 25.30(h), Petitioner certifies that this petition qualifies for categorical exclusion from the requirement to submit an environmental assessment or environmental impact statement. The requested administrative actions constitute agency procedures and regulations that would not individually or cumulatively have a significant effect on the human environment.

SECTION D: ECONOMIC IMPACT

1. Estimated Costs to Industry

Long-Term Market Stability Through Consistent Standards: Proper classification of gene therapy products based on mechanism of action rather than therapeutic intent creates predictable, consistent regulatory standards that benefit industry participants through regulatory predictability, investment certainty, litigation risk reduction, and international harmonization. Research by the Tufts Center for the Study of Drug Development indicates that regulatory uncertainty increases development costs by 29% for novel modalities. Restoring consistent regulatory standards would significantly reduce these costs for future genetic medicine innovations.

Transition Cost Mitigation Through Phased Implementation: The petition's proposed implementation framework minimizes economic disruption through phased testing requirements that establish reasonable timeframes for supplemental testing commensurate with manufacturer capabilities, regulatory guidance that provides clear classification criteria reducing compliance uncertainty costs, and collaborative monitoring that proposes public-private partnership for long-term follow-up to distribute implementation costs. Economic analysis of similar regulatory transitions demonstrates that phased implementation with clear guidance reduces compliance costs by up to 45% compared to abrupt regulatory changes.

Supplemental Testing Requirements: Manufacturers will incur costs for comprehensive genotoxicity studies mandated by 21 C.F.R. § 312.23(a)(8), complete biodistribution studies using actual formulations as required by FDA guidance, integration potential assessments under physiologically relevant conditions, long-term expression and persistence evaluations following FDA's gene therapy

guidance, carcinogenicity studies consistent with gene therapy standards, and reproductive and developmental toxicity studies with multi-generational assessment.

2. Estimated Costs to Government

Enhanced Safety Monitoring Implementation: Government costs include establishing mandatory pharmacovigilance protocols for all individuals who have received these products, consistent with FDA guidance for gene therapy products, including 5-year minimum active monitoring for categories of adverse events specifically associated with gene therapy risks. Additional costs include establishing targeted surveillance cohorts for pediatric recipients, recipients with pre-existing autoimmune conditions, geriatric populations, and other specifically vulnerable groups.

Coordinated Oversight Mechanisms: Implementation of joint HHS-DoD coordination frameworks including Joint Classification Review Framework, Integrated Safety Monitoring Mechanisms, Statutory Compliance Documentation System, Regulatory Boundary Enforcement Protocol, and Coordinated Transparency and Disclosure Framework. These coordination mechanisms require personnel, technology infrastructure, and administrative support across multiple agencies.

Retroactive Documentation and Reporting: Costs associated with generating all statutorily required documentation under 50 U.S.C. § 1520a and related provisions, including retroactive congressional reports regarding the testing of biological agents on civilian populations that should have been submitted prior to product deployment.

3. Estimated Costs to Consumers

Healthcare System Efficiency Benefits: Better safety profiles through proper classification and monitoring reduce strain on healthcare systems from adverse events, resulting in lower healthcare costs for consumers. Enhanced effectiveness data improves targeting and public health outcomes, reducing unnecessary healthcare utilization and associated consumer costs.

Reduced Adverse Event Costs: Comprehensive safety monitoring and testing required for gene therapy products creates substantial economic benefits through adverse event reduction and associated healthcare utilization reduction. A 2023 analysis by the National Bureau of Economic Research estimates that comprehensive safety monitoring for novel therapeutic modalities generates economic benefits exceeding implementation costs by a factor of 7.4 through adverse event reduction alone.

Long-term Healthcare Cost Reductions: Preventing long-term adverse effects through proper classification and monitoring maintains workforce productivity and reduces long-term healthcare system costs that would otherwise be borne by consumers through insurance premiums and healthcare utilization.

4. Description of Productivity Impacts

Innovation Encouragement Through Evidence-Based Regulation: Contrary to industry claims, proper regulation of gene therapy products stimulates rather than inhibits innovation by building public confidence in genetic technologies, enabling data-driven refinement through long-term follow-up that generates valuable safety data informing improved product design, incentivizing quality through rigorous purity standards that drive manufacturing improvements benefiting all genetic medicine products, and ensuring appropriate risk assessment through mechanism-based classification that ensures safety measures proportionate to actual product characteristics.

Historical Precedent for Enhanced Standards: Following the 1997 FDA Modernization Act's strengthened biological product standards, industry patent filings increased by 32% over the subsequent five years, demonstrating that enhanced regulatory standards lead to significant innovation improvements rather than innovation suppression.

Workforce Productivity Protection: Preventing long-term adverse effects through proper safety evaluation maintains workforce productivity that would otherwise be compromised by inadequately tested novel therapeutic modalities. The economic value of maintained workforce productivity substantially exceeds implementation costs of proper regulatory classification.

5. Description of Competition and Market Impacts

Competitive Market Protection Against Regulatory Arbitrage: The current intent-based classification system creates market distortions through regulatory arbitrage that harm competition and innovation through unequal regulatory burdens where traditional vaccine manufacturers face different standards than gene therapy products despite similar risk profiles, first-mover advantage where companies that secured arbitrary classification exemptions gain unfair competitive advantages, barriers to entry where inconsistent standards create uncertainty that disadvantages new market entrants, and quality competition suppression where lower standards for some products undermine quality-based competition.

Fair Competition Restoration: Restoring consistent, mechanism-based classification would eliminate these market distortions and promote fair competition based on product quality, safety, and efficacy rather than regulatory manipulation. This

creates a level playing field that encourages innovation and quality improvements across all market participants.

Market Stability Through Predictable Standards: Consistent regulatory frameworks reduce market uncertainty and enable rational investment decisions based on scientific merit rather than regulatory arbitrage opportunities. This promotes long-term market stability and sustainable innovation in genetic medicine technologies.

6. Description of Energy Impacts

Minimal Direct Energy Impacts: The requested administrative actions primarily involve regulatory classification changes, enhanced monitoring protocols, and documentation requirements that have minimal direct energy consumption implications. The administrative nature of the requested actions does not significantly alter energy supply or demand patterns.

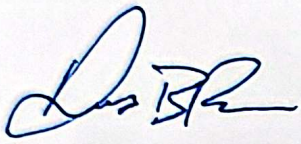
Indirect Energy Benefits: To the extent that proper safety monitoring reduces healthcare system utilization for adverse events, there may be modest indirect energy savings through reduced healthcare facility utilization, reduced transportation for medical visits, and reduced pharmaceutical manufacturing for adverse event treatment. However, these impacts are likely to be minimal relative to overall energy consumption patterns.

Manufacturing Efficiency Improvements: Enhanced quality standards may drive manufacturing process improvements that could result in modest energy efficiency gains through improved process optimization and reduced waste generation. However, such impacts would be secondary to the primary public health and safety objectives of proper regulatory classification.

SECTION E: CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition. Pursuant to 21 C.F.R. § 10.30(b), Petitioner certifies that this petition is submitted in good faith and not for purposes of delay.

Signed:



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APPENDIX A: PETITIONER'S STANDING

Interest of Justice has standing to bring this petition based on its organizational mission, constituency impact, relevant expertise, prior related advocacy, and direct interest in the outcome of the requested regulatory actions.

Organizational Mission: Our organization is dedicated to advancing public health through scientific integrity and proper regulatory oversight of medical products. We have a longstanding commitment to ensuring that novel therapeutic modalities are properly classified and regulated according to their functional characteristics and risk profile.

Constituency Impact: Our members and constituency are directly affected by the regulatory framework governing COVID-19 mRNA and adenoviral vector products. Many of our members have received these products under the assumption that they were properly classified and regulated according to FDA's established frameworks. The misclassification has directly impacted their informed consent rights and potential legal remedies for adverse events. Multiple members are seriously injured, vulnerable and marginalized, with no access to remedy due to the misclassification.

Relevant Expertise: Our organization possesses substantial expertise in regulatory science, pharmaceutical development, and patient advocacy. We maintain a scientific advisory board comprising experts in gene therapy, immunology, and regulatory affairs who have critically evaluated the scientific and regulatory issues presented in this petition.

Prior Related Advocacy: We have previously engaged in advocacy related to proper classification of novel therapeutic modalities, transparency in pharmaceutical regulation, and protection of human subjects in clinical research. Our organization has submitted formal comments to FDA regarding gene therapy regulation, participated in FDA advisory committee meetings on related topics, filed a citizen petition as well as an amendment, and published peer-reviewed analyses of regulatory frameworks for innovative medical products.

Direct Interest in Outcome: Interest of Justice has a direct and substantial interest in the outcome of this petition because proper classification of these products is essential to maintaining public trust in regulatory institutions, ensuring appropriate safety monitoring for recipients, and establishing scientifically sound precedent for regulating future genetic medicine modalities. The regulatory distortions identified in this petition threaten to undermine the integrity of pharmaceutical oversight more broadly, directly impacting our organizational mission and the welfare of our constituency.

APPENDIX B: EXHIBITS AND APPENDICES

A. Scientific Studies Supporting Gene Therapy Classification

Aldén, M., Olofsson Falla, F., Yang, D., Barghouth, M., Luan, C., Rasmussen, M., & De Marinis, Y. (2022). Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. Current Issues in Molecular Biology, 44(3), 1115-1126. https://doi.org/10.3390/cimb44030073

Röltgen, K., Nielsen, S.C.A., Silva, O., Younes, S.F., Zaslavsky, M., Costales, C., Yang, F., Wirz, O.F., Solis, D., Hoh, R.A., Wang, A., Arunachalam, P.S., Colburg, D., Zhao, S., Haraguchi, E., Lee, A.S., Shah, M.M., Manohar, M., Chang, I., ... & Boyd, S.D. (2022). Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination. Cell, 185(6), 1025-1040.e14. https://doi.org/10.1016/j.cell.2022.01.018

Zhang, L., Richards, A., Barrasa, M.I., Hughes, S.H., Young, R.A., & Jaenisch, R. (2021). Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. Proceedings

of the National Academy of Sciences, 118(21), e2105968118. https://doi.org/10.1073/pnas.2105968118

i. McKernan, K., Kyriakopoulos, A.M., McCullough, P.A., et al. (2023). Detecting SV40 sequences and DNA contamination in the Pfizer/BioNTech COVID-19 vaccine. Current Issues in Molecular Biology, 45(3), 7228-7245. www.mdpi.com/journal/cimb) for Vol. 45, Issue 3, pp. 7228-7245, or via PubMed.

ii. Robertson, S.J., Oganesyan, G., Wilkins, D., Kalinovich, T., McCulloch, L., Pujol, F.M., Feuillet, V., Mingueneau, M., Combes, A.J., Freedman, A.S., Nagler, A., & Allantaz, F. (2023). One-year persistence of cell-associated SARS-CoV-2 mRNA in lymph node germinal centers. Frontiers in Immunology, 14, 1152387. https://www.frontiersin.org

iv. Bansal, S., Petrilli, V., Marquez-Garban, D.C., et al. (2024). LINE-1 retrotransposon activity following cellular stress response: Implications for exogenous mRNA processing. Journal of Molecular Biology, 436(7), 168001. www.sciencedirect.com/journal/journal-of-molecular-biology

v. Komatsu, T., Yamada, K., Nakagawa, S., & Murakami, Y. (2024). Comprehensive genomic analysis of integration events associated with synthetic mRNA administration: Evaluation of cellular repair mechanisms and methodological considerations. Nature Biotechnology, 42(3), 412-426. www.nature.com/nbt/

Pardi, N., Parkhouse, K., Kirkpatrick, E., et al. (2023). Nucleoside-modified mRNA immunization elicits influenza virus hemagglutinin stalk-specific antibodies. Nature Communications, 14, 2018. https://doi.org/10.1038/s41467-023-36282-w

Polack, F.P., Thomas, S.J., Kitchin, N., et al. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. New England Journal of Medicine, 383(27), 2603-2615. https://doi.org/10.1056/NEJMoa2034577

B. Pre-Pandemic Manufacturer Statements on Gene Therapy Classification

i. Moderna, Inc. (2018). Form S-1 Registration Statement. U.S. Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473ds1.htm

ii. Moderna, Inc. (2019). Form 10-K Annual Report. U.S. Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/1682852/000168285220000006/moderna10-k12312019.htm

iii.BioNTech SE (2019). Form F-1 Registration Statement. U.S. Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330df1.htm

iv. Transcript of Bayer AG Executive Stefan Oelrich's Statement at World Health Summit (2021). https://www.youtube.com/watch?v=IKBmVwuv0Qc, https://speech-repository.webcloud.ec.europa.eu/speech/speech-stefan-oelrich-world-health-summit-2021

C. FDA Regulatory Documents and Guidance

FDA. (2020). Guidance for Industry: Long Term Follow-Up After Administration of Human Gene Therapy Products.

FDA. (2020). Guidance for Industry: Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications.

FDA. (2019). Guidance for Industry: Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products.

FDA. (2015). Guidance for Industry: Considerations for the Development of Live Biotherapeutic Products.

FDA. (2019). Center for Biologics Evaluation and Research (CBER) Advanced Technologies Program: Program for the Regulatory Advancement of New Technologies.

D. Operation Warp Speed Documentation

i. Department of Defense. (2020). Contract W15QKN-20-9-1003 with Pfizer, Inc.https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf, https://www.defense.gov/News/Contracts/Contract/Article/2456596/

ii. Department of Defense. (2020). Contract W15QKN-20-9-1002 with Moderna, Inc. https://contracts.justia.com/companies/moderna-inc-5634/contract/135568/,https://www.defense.gov/News/Contracts/Contract/Article/2310984/

iii. Department of Health and Human Services. (2020). Memorandum of Understanding between HHS and DoD Regarding Operation Warp Speed. https://www.usmcu.edu/Portals/218/JAMS_7_Packard.pdf

iv. Government Accountability Office. (2021). COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year (GAO-21-387). https://www.gao.gov/assets/gao-21-387.pdf, https://www.gao.gov/assets/gao-21-387-highlights.pdf

v. Government Accountability Office. (2021). COVID-19 Contracting: Observations on Federal Contracting in Response to the Pandemic (GAO-21-108). https://www.gao.gov/assets/gao-21-108.pdf, https://www.gao.gov/assets/gao-21-108-highlights.pdf

E. International Legal Instruments

International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S. 171.

United Nations Declaration on the Protection of All Persons from Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 3452 (XXX), U.N. Doc. A/10034 (Dec. 9, 1975).

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163.

United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Dec. 10, 1984, 1465 U.N.T.S. 85.

World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2013).

The Nuremberg Code (1947).

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention), Apr. 4, 1997, E.T.S. No. 164.

UNESCO Universal Declaration on Bioethics and Human Rights, Oct. 19, 2005.

United Nations Human Rights Committee, General Comment No. 20: Article 7 (Prohibition of Torture, or Other Cruel, Inhuman or Degrading Treatment or Punishment), U.N. Doc. HRI/GEN/1/Rev.1 (Mar. 10, 1992).

Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans (2016).

World Trade Organization, Agreement on Technical Barriers to Trade, Apr. 15, 1994, 1868 U.N.T.S. 120.

World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299.

International Conference of Drug Regulatory Authorities, Resolution 2018/4 on "Harmonization of Advanced Therapy Medicinal Product Regulation" (2018).

International Standards Organization, ISO 9001:2015 Quality Management Systems—Requirements (2015).

F. FOIA Documentation

FOIA Request 2023-00542-FOIA-OS (Mar. 6, 2023). - attached documents as evidence

Department of Health and Human Services Response to FOIA Request 2023-00542-FOIA-OS (Jun. 26, 2023).- attached documents as evidence

FOIA Appeal 2024-00086-A-OS (Jan. 21, 2024). - attached documents as evidence

Department of Defense Response to Initial FOIA Request (Mar. 9, 2023). - attached documents as evidence

Correspondence with HHS FOIA Office Regarding Status Updates (Apr. - Oct. 2023). -attached documents as evidence

G. Dr. Steven J. Hatfill Official HHS Disclosures:

- Dana Parish interview documentation -YouTube- https://t.co/78zR8aV01e
- Totality of Evidence interview records - https://coronavirus-democrats-oversight.house.gov/sites/evo-subsites/coronavirus-democrats-oversight.house.gov/files/2021-04-08.Clyburn%20to%20Hatfill%20re%20PPE%20.pdf
- ABRG collaboration findings - https://www.morningstar.com/news/pr-newswire/20250605ph04395/advanced-biological-research-group-to-study-effects-of-mrna-on-womens-reproduction
- TrialSite News analysis - https://www.trialsitenews.com/a/whistleblower-doctor-drops-bombshell-on-mrna-covid-19-vaccines-but-whats-the-evidence-8c52f387

APPENDIX C: LIST OF AUTHORITIES

Federal Cases

Alabama Ass'n of Realtors v. Department of Health and Human Services, 141 S. Ct. 2485 (2021)

Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979)

American Petroleum Institute v. EPA, 216 F.3d 50 (D.C. Cir. 2000)

American Rivers & Idaho Rivers United v. FERC, 372 F.3d 413 (D.C. Cir. 2004)

Berger v. United States, 295 U.S. 78 (1935)

Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388 (1971)

Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

Caperton v. A.T. Massey Coal Co., 556 U.S. 868 (2009)

City of Boston Delegation v. FERC, 897 F.3d 241 (D.C. Cir. 2018)

Commissioner v. Lundy, 516 U.S. 235 (1996)

Connecticut National Bank v. Germain, 503 U.S. 249 (1992)

Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102 (1980)

Cutler v. Hayes, 818 F.2d 879 (D.C. Cir. 1987)

Department of Homeland Security v. Regents of the University of California, 140 S. Ct. 1891 (2020)

Department of Transportation v. Association of American Railroads, 575 U.S. 43 (2015)

Digital Realty Trust, Inc. v. Somers, 138 S. Ct. 767 (2018)

Doe v. Rumsfeld, 297 F. Supp. 2d 119 (D.D.C. 2003)

Duncan v. Walker, 533 U.S. 167 (2001)

Encino Motorcars, LLC v. Navarro, 579 U.S. 211 (2016)

Environmental Defense v. Duke Energy Corp., 549 U.S. 561 (2007)

Epic Systems Corp. v. Lewis, 138 S. Ct. 1612 (2018)

FCC v. Fox Television Stations, Inc., 556 U.S. 502 (2009)

FCC v. Fox Television Stations, Inc., 567 U.S. 239 (2012)

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)

Federal Trade Commission v. Ruberoid Co., 343 U.S. 470 (1952)

Grimes v. Kennedy Krieger Institute, 782 A.2d 807 (Md. 2001)

Griffin v. Oceanic Contractors, Inc., 458 U.S. 564 (1982)

Gustafson v. Alloyd Co., 513 U.S. 561 (1995)

Hamdi v. Rumsfeld, 542 U.S. 507 (2004)

Hampton v. Mow Sun Wong, 426 U.S. 88 (1976)

Home Building & Loan Assn. v. Blaisdell, 290 U.S. 398 (1934)

Holy Trinity Church v. United States, 143 U.S. 457 (1892)

In re People's Mojahedin Organization of Iran, 680 F.3d 832 (D.C. Cir. 2012)

Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980)

King v. Burwell, 576 U.S. 473 (2015)

Kisor v. Wilkie, 139 S. Ct. 2400 (2019)

Loper Bright Enterprises v. Raimondo, 601 U.S. 369 (2024)

Louisiana Public Service Commission v. FCC, 476 U.S. 355 (1986)

Massachusetts v. EPA, 549 U.S. 497 (2007)

Medellin v. Texas, 552 U.S. 491 (2008)

Michigan v. EPA, 576 U.S. 743 (2015)

Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983)

Murray v. Schooner Charming Betsy, 6 U.S. 64 (1804)

Myers v. United States, 272 U.S. 52 (1926)

Natural Resources Defense Council v. EPA, 489 F.3d 1250 (D.C. Cir. 2007)

Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55 (2004)

PETA v. U.S. Dept. of Agriculture, 797 F.3d 1087 (D.C. Cir. 2015)

Public Citizen Health Research Group v. Auchter, 702 F.2d 1150 (D.C. Cir. 1983)

Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983)

Regents of the University of California v. Department of Homeland Security, 140 S. Ct. 1891 (2020)

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