**Securitisation of Public Health Law – US Origin**

Katherine Watt, American Catholic writer and paralegal

In this paper, I describe the legislative transfer of the US Department of Defense chemical and biological warfare program, to the public health emergencies program operated by the US Department of Health and Human Services, between 1969 and the present.

The American transfer of chemical and biological weapons development and use from military programs to public health programs has occurred in parallel to, and in compliance with, analogous developments in international law during the same interval, most notably the United Nations World Health Organization International Health Regulations, 2005 (IHR), and its implementation in WHO member-states.

These legal developments present the question:

> What legal recourse do victims of regulation-exempt biochemical products have, under international and domestic law, when material acts undertaken by putative national governments violate international treaties, conventions and federal laws prohibiting stockpiling and use of chemical and biological weapons, and simultaneously comply with other international treaties, conventions and federal laws governing *public health emergency management* and *countermeasure* development and use?

Since January 2020, acts of putative national governments have violated (among other international legal instruments) the 1975 UN Convention UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction and the 1997 UN Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, under the auspices of member-state compliance with WHO International Health Regulations, 2005.

In the United States, our putative national government has also been violating federal laws implementing the international biological and chemical weapons conventions (18 USC 175 and 18 USC 229), along with federal laws prohibiting torture (18 USC 2340A), murder (18 USC 1111) and genocide (18 USC 1091), through acts that comply with federal laws authorizing public health emergency management (42 USC 247d) and use of emergency use authorized (EUA) biochemical products (21 USC 360bbb-3).

*A note about style conventions*.

Terms and phrases cited in relevant statutes, regulations and other legal documents are denoted with *italics*. Terms and phrases used fraudulently by governments to lie to the public about acts and materials, are denoted with "quotation marks."

*Overview: Enabling statutes, regulations, executive orders and guidance documents*.

At least six Congressionally-authorized statutory frameworks and related budget appropriations, reinforced through Presidential Executive Orders and related executive branch declarations,[1] and implemented through hundreds of regulations[2] and regulatory amendments,[3] mostly promulgated through the Federal Register since 1969, authorized and funded the development and coordinated worldwide use of biologically-active materials exempt from standard Food and Drug Administration (FDA) regulations governing product development, testing, manufacturing, labeling, distribution, prescription, administration and monitoring.

These products are classified as *countermeasures* and *prototypes*, product categories that are legally distinct from regulated *drugs*, *vaccines* and *biologics*.

Since 2020, these biochemical *countermeasure* products have been labeled and marketed by the US Government and pharmaceutical manufacturers, including Pfizer, Moderna, Johnson & Johnson and their manufacturing subcontractors, as "safe and effective vaccines."

This program has been administratively facilitated through the legal transfer of the US Government's Chemical and Biological Warfare Program, formerly operated by the Department of Defense (DoD), to the Public Health Emergency (PHE) Emergency Use Authorization (EUA) Medical Countermeasures (MCM) program housed within the Department of Health and Human Services (HHS).

The PHE-EUA-MCM program is jointly operated by DoD, HHS, Department of Homeland Security, Department of State, Department of Justice, most other federal agencies and their subordinate departments, divisions, offices, authorities, enterprises, committees, advisory boards and employees.

One of the coordinating committees is the Public Health Emergencies Medical Countermeasures Enterprise (PHEMCE) established by HHS in 2006 and authorized by Congress in 2019. PHEMCE members include the HHS Secretary; [HHS] Assistant Secretary for Preparedness and Response (ASPR); Director of the Centers for Disease Control and Prevention (CDC); Director of the National Institutes of Health (NIH); Commissioner of Food and Drugs (FDA); Secretary of Defense (DoD); Secretary of Homeland Security (DHS); Secretary of Agriculture (USDA);

Secretary of Veterans Affairs (VA); Director of National Intelligence; and representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority (BARDA), the Director of the Strategic National Stockpile (SNS), the Director of the National Institute of Allergy and Infectious Diseases (NIAID), and the Director of the Office of Public Health Preparedness and Response, as the [HHS] Secretary determines appropriate.

Six of the enabling statutes include:

- Chemical and Biological Warfare program, Title 50, War and National Defense, Chapter 32, §1511 et seq., enacted Nov. 19, 1969 (PL 91-121);
- Public Health Emergencies (PHE) program, Title 42, Public Health Service, Ch. 6A, §247d et seq., established July 13, 1983 (PL 98-49);
- National Vaccine Program and Vaccine Injury Compensation Program (VICP) under Title 42, Public Health Service, Ch. 6A, §300aa-1 et seq., established Nov. 14, 1986 (PL 99-660);
- Expanded access to unapproved therapies and diagnostics program (later *emergency use authorization* or EUA program), Title 21, Food and Drugs, Ch. 9, §360bbb et seq, adopted Nov. 21, 1997 (PL 105-115);
- National All-Hazards Preparedness for Public Health Emergencies program, Title 42, Public Health Service, Ch. 6A, §300hh et seq, adopted June 12, 2002 (PL 107-188) and
- Research projects: transactions other than contracts and grants program, (Other Transaction Authority or OTA), Title 10, Armed Forces, Subchapter A, Part V (Acquisitions), Subpart E (Research and Engineering), §4021 et seq., originally adopted July 29, 1958 (PL 85-568) for NASA, expanded for DOD use for "prototype" contracting on Nov. 25, 2015 (PL 114-92).

*1969 - Chemical and Biological Warfare Program*

The 1969 Armed Forces Appropriations Act, codified at 50 USC 1511 et seq. authorized the DOD Chemical and Biological Warfare program, including use of human subjects for chemical, biological, radiological and nuclear (CBRN) weapons research and development; Presidential suspension of otherwise applicable statutes and regulations under national emergency conditions as unilaterally declared by the executive branch, including nullification of informed consent rights for human recipients of biologically-active and potentially toxic products; and limited Congressional reporting requirements.

Subsequent amendments, often passed through annual National Defense Authorization Acts (NDAAs),[4] expanded components of the Chemical and Biological Warfare Program; redefined CBRN weapons as *medical countermeasures, security countermeasures, covered countermeasures,* and *qualified pandemic or epidemic products;* transferred many components to statutory frameworks governing Health and Human Services programs under *public health emergency* conditions; and reduced or eliminated most Congressional reporting requirements relating to DoD Chemical and Biological Warfare, Biological Defense Research and related programs.

Key provisions of the Chemical and Biological Warfare program as of December 2022.[5]

*1983 - Public Health Emergency Program*

In 1983, Congress passed the Public Health Service Act Amendment, subsequently built up to create a sweeping Public Health Emergency program under the direction of the Secretary of Health and Human Services. The Public Health Emergency program at 42 USC 247d falls under Title 42, Public Health and Welfare, Chapter 6A, Public Health Service, Subchapter II, Powers and Duties, Part B, Federal-State Cooperation.

The Public Health Emergency framework added a new category of national emergency under which Constitutional and statutory protections for American lives, liberties and property, may be suspended unilaterally by the President and his Cabinet secretary delegees, without Congressional oversight [42 USC 247d-6d(b)(9)] or judicial review [42 USC 247d-6d(b)(7)], and without respect to Constitutional provisions reserving unenumerated powers to state and local governments and to the People themselves [42 USC 247d-6d(b)(8)].

Public health emergencies joined wars, natural disasters and other emergency circumstances capable of subordinating or federalizing state, local and tribal government authorities, which had been previously codified by the 1973 War Powers Resolution (PL 93-148), 1976 National Emergencies Act (PL 94-412), 1988 Robert T. Stafford Disaster Relief and Emergency Act (PL 100-707), 2001 Authorization for Use of Military Force (PL 107-40), 2001 PATRIOT Act (PL 107-56), 2002 Homeland Security Act (PL 107-296) and related provisions.[6]

Through the 1983 act and subsequent amendments,[7] Congress authorized concentration of federal governing power in the hands of the Secretary of Health and Human Services during any *public health emergency* (PHE) as determined and extended by the HHS Secretary at his or her sole discretion.

Key provisions of Public Health Emergencies program as of December 2022.[8]

*1986 - National Vaccine Program; Vaccine Injury Compensation Program*

In 1986, Congress established the first National Vaccine Program and Vaccine Injury Compensation Program (VICP), codified at 42 US §300aa-1 et seq.

The relevance of this Congressional act for the production and dispensing of "Covid-19 vaccines" is that it set up a legal model and precedent providing civil and criminal immunity for producers, "vaccinators" and others who manufacture and/or use products classified by the US Department of Health and Human Services, operating through subagencies including Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), as "vaccines."

In 2005, Congress replicated the VICP model through the Countermeasures Injury Compensation Program (CICP), established through the Public Readiness and Emergency Preparedness (PREP) Act (PL 109-148). The CICP framework authorizes *covered persons,* including (i) the United States; (ii) manufacturers and distributors of *countermeasures*; (iii) *program planners*; (iv) *qualified persons* who prescribe, administer, or dispense covered countermeasures; and (v) officials, agents, or employees of a person or entity described in the prior clauses. 42 USC 247d-6d(i)(2)

*Covered persons* and *qualified persons* were thereby authorized by Congress to produce, distribute and use biochemical products exempt from FDA drug regulations, with legal impunity for all injuries or deaths suffered by recipients, provided the products are classified by the HHS Secretary as *countermeasures* and used during a declared *public health emergency*.[9]

The public rationale for VICP and CICP liability immunities for producers who manufacture and clinicians who administer regulation-exempt biochemical products was that manufacturers and clinicians would hesitate to develop, produce, distribute and use such products if they faced legal liability for chronic diseases, injuries and deaths caused by the products.

Oversight functions written into the National Vaccine Program law purported to establish safety and efficacy protections for product recipients through regulations governing clinical trials; data reporting; manufacturing processes; factory inspection; product testing and labeling throughout the supply chain prior to distribution through interstate commerce; dispensing; informed consent at point of injection; and adverse event monitoring, coupled with recall power for advisory committees, after injection.

The pioneering work of the Informed Consent Action Network (ICAN) and Children's Health Defense (CHD), culminating in a July 9, 2018 stipulation,[10] confirmed that such oversight functions have never been performed by US Government officials, and none of the currently-available "vaccines" produced by or for American pharmaceutical companies and administered to infants, children and adults in the United States and worldwide, have been demonstrated to be safe

or effective. It is now more widely understood that federally-directed production and use of regulation-exempt biochemical products known as "vaccines" to injure, sicken and kill Americans, and provide liability exemption for sponsors, pharmaceutical manufacturers and "vaccinators," has been domestic and international policy and practice since at least 1986.

Key provisions of National Vaccine Program as of December 2022.[11] Key provisions of National Vaccine Injury Compensation Program as of December 2022.[12]

*1997-1998 - Emergency Use Authorization Program and Strategic National Stockpile Program*

Food and Drug Administration drug safety regulation, clinical trial standards, and protection of human subjects (informed consent) have been corrupted under *public health emergency* conditions, primarily through 21 USC 360bbb, Expanded access to unapproved therapies and diagnostics, adopted in 1997 and amended and expanded thereafter.

The 2004 Project Bioshield Act amendments codified at 21 USC 360bbb-3, Authorization for medical products for use in emergencies, commonly known as the Emergency Use Authorization (EUA) program, represent the key expansion that enabled the worldwide deployment of regulation-exempt biochemical products nationwide and worldwide, by rendered standard informed consent and drug safety regulations legally inapplicable.

As summarized below under the "Case Study" heading, the EUA Program authorized the HHS Secretary, at his or her sole discretion, to knowingly, deliberately suspend federal drug safety regulation[13] for the duration of any *public health emergency* as determined and extended by the HHS Secretary at his or her sole discretion, including but not limited to:

- non-clinical, pre-clinical and clinical trial standards
- data collection
- regulatory review procedures
- raw material, manufacturing process and product testing standards
- product adulteration, labeling and serialization standards
- product distribution and storage standards
- advertising and marketing standards
- physician prescription requirements
- product dispensing standards
- informed consent obligations on investigators and rights for individual human recipients;
- adverse effect monitoring and reporting
- product safety enforcement and recall provisions

In a related Congressional act in 1998, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, FY1999 (PL 105-277), Congress converted the status of the DoD's chemical and biological weapons stockpiles from illegal to legal.

Biological weapon stockpiling and use are illegal under the terms of the UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, which entered into force in 1975 and was codified as a federal crime in 1990 under 18 USC 175.

Chemical weapon stockpiling and use are illegal under the UN Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, which entered into force in 1997, and was codified as a federal crime at 18 USC 229 in the Chemical Weapons Convention Implementation Act of 1998 (PL 105-277 at 112 STAT. 2681–856).

Instead of destroying US military chemical and biological weapons stockpiles, Congress reclassified the products as components of the National Pharmaceutical Stockpile, later renamed the Strategic National Stockpile (SNS), through the Department of Health and Human Services Appropriations Act, 1999, using a $51,000,000 appropriation to the Public Health and Social Services Emergency Fund (PHSSEF). (PL 105-277 at 112 STAT. 2681–358).

The 1998 Congressional act also transferred management and use of prohibited biological and chemical product stockpiles, including products labeled as "vaccines," to the Centers for Disease Control and Prevention within the Department of Heath and Human Services.

Key provisions of 21 USC 360bbb, Expanded access to unapproved therapies and diagnostics, as of December 2022.[14]

*2002 - National All-Hazards Preparedness for Public Health Emergencies*

In 2002, Congress passed the National All-Hazards Preparedness for Public Health Emergencies law, codified at 42 USC 300hh et seq.

This Congressional act and subsequent amendments, mostly enacted through the same laws that developed the 1983 Public Health Emergencies framework listed at Endnote 7, expanded and centralized the managerial structure or chain-of-command. The statutes established and funded parallel offices or directorates of *emergency preparedness and response* within Health and Human Services (i.e. Assistant Secretary for Preparedness and Response/ASPR), Department of Defense, Department of Homeland Security, Department of Justice and other federal agencies.

Coordinating committees comprised of representatives of these federal agencies are authorized to meet and establish supervisory procedures to direct, control and fund public health emergency response and regulation-exempt biochemical product development and deployment programs at the federal, state, local and tribal levels.

These coordinating committees include but are not limited to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), established informally by HHS in 2006 and authorized by Congress in 2019,[15] and other public, private, hybrid and quasi-governmental entities, including the FDA Medical Countermeasures Initiative (MCMi); HHS Biomedical Advanced Research and Development Authority (BARDA); and the Medical Chemical, Biological, Radiological, Nuclear [CBRN] Defense Consortium (MCDC).

Key provisions of 42 USC 300hh, National All-Hazards Preparedness for Public Health Emergencies program as of December 2022.[16]

*2015 - Research projects: transactions other than contracts and grants*

Reduction of Congressional contract oversight pertaining to procurement of medical countermeasures originated in 1958, if not earlier, through Other Transactions Authority (OTA), which suspends most normal financial controls on federal spending.

Congress authorized DoD to use OTA for prototype procurement in 2015, by adopting 10 USC 2371 et seq, Research projects: transactions other than contracts and grants.

The laws were subsequently renumbered and reorganized at 10 USC 4021 et seq, including 10 USC 4022, Authority of the Department of Defense to carry out certain prototype projects under Other Transactions Authority.[17]

The US military used OTA contracting authority to collaborate with pharmaceutical manufacturers for development, production and distribution of biochemical products labeled as *countermeasures* and "vaccines," for several years prior to the worldwide presentation of Covid-19 in 2020.

However, the most extensive and far-reaching use of military OTA contracting authority to date has been for "Covid-19 vaccines" and other *countermeasures* procured from corporate and academic members of the Medical CBRN [Chemical Biological Radiological Nuclear] Defense Consortium (MCDC) program,[18] coordinated by Advanced Technology International (ATI) and other weapons-procurement corporations.

US-DoD contracts for Covid-19 products are also described as *voluntary agreements* under the Defense Production Act (DPA). *Voluntary agreements* are exempt from standard contract law interpretation and anti-trust laws, and provide comprehensive legal defenses for contract parties during civil and criminal litigation stemming from use of procured products.

US-DoD contracts for Covid-19 products under Operation Warp Speed and related programs procured *large-scale manufacturing demonstrations* and production of *prototypes*, but did not procure clinical trials.

These facts formed the basis for Pfizer's motion to dismiss whistleblower Brook Jackson's False Claims Act case. Pfizer argued, successfully as of a March 31, 2023 order dismissing her case, that Pfizer and its subcontractors could not have defrauded the US Government or US military, even accepting as true Jackson's claim that the alleged clinical trials were operated in violation of FDA clinical trial regulations and harmed and killed participants, because the contracts did not require Pfizer or the FDA to conduct or supervise conduct of regulation-compliant clinical trials or produce regulation-compliant drugs, devices or biologics.[19]

The US Government supported Pfizer's motion to dismiss, confirming in October 2022 that compliance with FDA clinical trial regulations was "out of scope" and not a "necessary" condition for DoD payment to Pfizer for goods and services rendered under the OTA contracts.[20]

Key provisions of 10 USC 4022, Research projects: transactions other than contracts and grants, as of December 2022, at footnote.[21]

*Covid-19 'vaccines:' case study*

21 USC 360bbb-3(k), [Authorization for medical products for use in emergencies, Relation to other provisions] is a crucial provision at the intersection of the six statutory pillars outlined above.

This law provides that *use* of EUA-covered, regulation-exempt medical countermeasure (MCM) products including masks, diagnostic tests, injectable biochemical products, and other products that would otherwise be classified and regulated as "investigational" drugs, devices and biologics, once classified as EUA *covered countermeasures* during a *public health emergency* by the HHS Secretary and his/her delegees, “shall not be considered to constitute a clinical investigation.”

Jan. 27, 2020 was the effective date of US Secretary of Health and Human Services Alex Azar's *Determination that a Public Health Emergency Exists,* signed Jan. 31, 2020.[22] The determination was recorded in the Federal Register as taking effect Feb. 4, 2020. 85 Federal Register 7316. It has been extended continuously since, most recently by HHS Secretary Xavier Becerra effective March 15, 2023 and in force as of this writing in May 2023. 88 Federal Register 16644.

Effective Feb. 04, 2020, HHS Secretary Azar issued a Notice of *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19*.[23] 85 Federal Register 15198. The PREP Act declaration has also been extended continuously since and amended eleven times, most recently by HHS Secretary Xavier Becerra effective May 11, 2023. 88 Federal Register 30769.

Government announcements about the termination of the public health emergency notwithstanding, the PREP Act declaration remains in force as of this writing in May 2023.

To the extent that *use* of Covid-19 products after Feb. 04, 2020 "shall not constitute clinical investigation," *use* of such products is authorized even if there is no safety or efficacy data, even if such products are toxic and ineffective.

Investigators, researchers, physicians, nurses, pharmacists and other individuals involved in product dispensing, use, or administration to human beings have had and today have no legal obligations to comply with laws and regulations that apply to use of other experimental, investigational, unapproved or approved drugs, devices and biological products, including compliance with informed consent laws, medical monitoring of recipients during product use and post-administration monitoring and reporting of effects, injuries and deaths.

Recipients of such products are not legally recognized as human subjects of clinical research or patients receiving experimental, authorized or approved products, because *use* of the products "shall not constitute clinical investigation."

There is no stopping condition, because there is no legally-relevant clinical investigation to be stopped.

On the basis of a self-declared *public health emergency* and self-declared classification of products as *emergency use authorized medical countermeasures*, including an unreviewable determination as to the relative risks posed by a compound classified as pathogen as compared to *medical countermeasure* products, the Secretary of Health and Human Services can suspend informed consent obligations for those who administer regulation-exempt, EUA biochemical products and informed consent rights for those who submit to regulation-exempt EUA biochemical products, on behalf of the entire American population.

Under standard FDA regulations governing non-EUA investigational drugs, devices and biologics, "vaccinators" would be legally required to obtain such information from manufacturers and suppliers and disclose such information to biochemical product recipients prior to administration.

But classified as *covered persons* or *qualified persons,* "vaccinators" are authorized by the HHS Secretary to mischaracterize and withhold information about EUA products, including ingredients;

vial contents; chain-of-custody and serialization; potential individual risks and benefits based on individual health conditions; treatment alternatives; and right to refuse treatment.

*Summary of relevant provisions*

- 10 USC 4022: DOD is authorized to contract with pharmaceutical corporations to produce and distribute 'prototype' products for use on the general public. *See also* Defense Production Act of 1950, 50 USC 4501 et seq.
- 21 USC 360bbb-3(c)(2)(A): The only required product efficacy standard authorizing "use" of such products is that "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that — the product may be effective in diagnosing, treating, or preventing—(i) such disease or condition [SARS-CoV-2]; or (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent," with all risk and benefit assessments reserved to HHS Secretary alone, no data required and no data or decisional review by Congress, courts or individual recipients authorized.
- 21 USC 360bbb-3(c)(2)(B): There are no safety standards required prior to "use" of medical countermeasures, which are authorized for production and use "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that... the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration," with all risk and benefit assessments reserved to HHS Secretary alone, no data required and no data or decisional review by Congress, courts or individual recipients authorized.
- 21 USC 360bbb-3(e)(1)(A)(ii): Authorizes HHS Secretary blanket waiver of informed consent for entire American population for "unapproved products."
- 21 USC 360bbb-3(e)(2)(A): Authorizes HHS Secretary blanket waiver of informed consent for entire American population for "unapproved use of an approved product."
- 21 USC 360bbb-3(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]."
- 21 USC 360bbb-3a(c); 21 USC 360bbb-3a(d); 21 USC 360bbb-3(e)(2)(B)(ii): EUA medical countermeasures "shall not be deemed adulterated or misbranded" even if noncompliant with regulations governing clinical research, manufacturing, testing, purity,

quality, batch and lot variability, adulteration, expiration dates, labeling, serialization, marketing, branding, dispensing and prescriptions.

- 21 USC 355g: Authorizes use of "real world evidence" (mass administration of products to general public prior to or in parallel with standard nonclinical, preclinical and clinical safety and efficacy studies) followed by collection of private/proprietary information about the effects, from health insurance systems, government databases (Medicare, Medicaid, Defense Medical Epidemiology Database, Veterans Health Administration) for the purposes of FDA regulatory action.
- 21 USC 355(i)(4): Authorizes HHS Secretary blanket waiver of informed consent for entire American population, for products classified by HHS as "minimal risk drugs."
- 21 USC 360j(g)(3)(D)(i) - Authorizes HHS Secretary blanket waiver of informed consent for entire American population, for products classified by HHS as "minimal risk devices."
- 42 USC 247d-6a(d)(2)(A): Manufacturers, as contractors, are considered HHS employees for purposes of legal immunity under Federal Tort Claims Act.
- 42 USC 247d-6b(c)(5)(B)(iii): One of the factors to be considered by HHS secretary in making determinations about EUA products (qualified security countermeasures) and use of Special Reserve Fund/Strategic National Stockpile appropriations for procurement is "whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure."
- 42 USC 247d-6d(b)(7): Blocks access to courts for judicial review of facts and/or law relating to HHS Secretary public health emergency declarations and emergency use authorization medical countermeasures product classifications.
- 42 USC 247d-6d(b)(8): Preempts authority of state, local and tribal governments and individuals to manage public health emergency and medical countermeasures classification and regulation outside of HHS/DOD control.
- 42 USC 247d-6d(b)(9): Narrowly limits obligation for HHS to report to Congress on public health emergency status and medical countermeasures classifications, and does not authorize Congress to review, override or terminate HHS declarations, determination, and decisions.
- 42 USC 247d-6d(c)(4): Authorizes "just following orders" defense for *covered persons* facing civil or criminal litigation.
- 42 USC 247d-6d(c)(5): Blocks access for plaintiffs, to civil courts for judicial review, and no entity to whom civil liability can attach, for injuries and deaths caused by covered medical countermeasures, unless and until HHS and/or Attorney General/DOJ first file enforcement action against manufacturers, *qualified persons* (vaccinators) and/or other *covered persons* and prove willful misconduct proximate to injury or death.
- 50 USC 4558(j) and 50 USC 4558(o): Military contractors producing and distributing biochemical weapons under *voluntary agreements* during *emergencies* are exempt from contract law and anti-trust law.

*Discussion*

The interlocking corruption of federal emergency management, public health and drug safety laws, for the purpose of covert and intentional deployment of regulation-exempt biochemical products into recipients, by the US Government, under the fraudulent characterization of the products as "Covid-19 vaccines," was deployed fully starting Jan. 27, 2020 and continues to be fully operational at the present time, more than three years later.

These statutes, regulations and related HHS Secretary declarations, Presidential Executive Orders and Congressional appropriations suspend ordinary federal procurement contracting laws and ordinary federal drug safety regulation and informed consent laws; and authorize pharmaceutical corporations, the Department of Defense and the Department of Health and Human Services, in conjunction with several other federal agencies, to develop, produce, fraudulently market, and distribute biochemical product *prototypes* to American doctors, nurses, pharmacists, medical students and other medical personnel.

These "vaccinators" are authorized to use the regulation-exempt EUA products to injure and kill human beings with legal impunity using procedures and products (including withholding of effective non-EUA treatments; and use of restraints, starvation, dehydration, isolation, sedatives, Remdesivir/Veklury and ventilators) to drive public panic and submission to the EUA biochemical products, including injections colloquially known as "Covid-19 vaccines."

The same conclusions may be reached from observations of acts taken and not taken by American drug safety regulators at the Food and Drug Administration (FDA) since EUA biochemical products were first injected into human beings between March and November 2020 during fraudulent "clinical trials," and then entered mass distribution in mid-December 2020.

If the products were intended for medicinal, healing or protective purposes, and were subject to FDA regulation governing research and development, production and use of medical drugs, biologics and devices, the HHS Secretary, FDA regulators and their counterparts in other countries would have stopped the programs as soon as the evidence of injuries and deaths became available, which occurred within the first few weeks of the fraudulent "clinical trials" launched under Operation Warp Speed but only came to public attention much later, through the efforts of independent data analysts reviewing leaked documents and documents disclosed under FOIA litigation and SEC laws.

Instead, regulators have abandoned all attempts to regulate these products, monitor their use and publish timely, accurate data about injuries and deaths caused by the products. FDA and other putative regulators have refused to even answer the question: “What is the stopping condition?”

FDA and other governments' drug regulatory agencies have not withdrawn fraudulent "authorizations" or "approvals" of the drugs, devices and protocols, despite millions of documented injuries and deaths experienced by recipients of the products during the initial deployment phase, because the products are not medicines.

The products are regulation-exempt, harmful biochemical products intentionally deployed by actors within the US Government and pharmaceutical/"biodefense" industry.

Further, if the products were intended for medicinal, healing or protective purposes and moving across state and international borders under regulatory frameworks intended to protect patient safety, they would be eligible for independent third-party purchase from manufacturers and drug suppliers, and eligible for independent testing to verify that contents match labels and corroborate or disprove claims about safety and efficacy.

Instead, third party access to and testing of vial contents is prohibited under the terms of the DoD-mediated supply and distribution contracts between purchasing governments, manufacturing corporations and "vaccination" sites, on penalty of federal criminal or civil prosecution.[24]

*Conclusion*

As stated at the introduction, these developments in American domestic law and international law beg the question:

> What legal recourse do victims of intentionally-harmful biochemical products have when national governments violate the terms of international treaties, conventions and federal laws prohibiting chemical and biological warfare, by executing the terms of opposing international treaties, conventions and federal laws dictating development and use of harmful biochemical products during declared public health emergencies?

---

[1] 1983-present, relevant Presidential Executive Orders, proclamations and related acts, partial list: Executive Order 12452, 1983 (expanded list of communicable diseases subjecting citizens to forcible apprehension and detention under HHS Secretary quarantine authority); EO 13139, 1999 (forced experimental, unapproved 'vaccines' on armed forces without informed consent); Proclamation 7463, 2001 (Declaration of National Emergency by Reason of Certain Terrorist Attacks, renewed annually since); EO 13295, 2003 (added **symptomatic SARS** to quarantinable communicable diseases); EO 13375, 2005 (added **symptomatic influenza** to quarantinable communicable diseases; National Security Presidential Directive 51, 2007; EO 13527, 2009 (*Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack)***;** EO 13601, 2012 (*National Defense Resources Preparedness*)**;** EO 13674, 2014 (added **asymptomatic, suspected SARS** to quarantinable communicable diseases); EO 13747, 2016 (*Advancing the **Global Health Security Agenda** to Achieve a World Safe and Secure from Infectious Disease Threats*); EO 13887, 2019 (*Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health;* directed **rapid-deployment mRNA/DNA/LNP/nanotech drugs and devices**); Proclamation 9994, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak,

renewed annually since); EO 13909, 2020 (*Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID–19):* EO 13910, 2020 (*Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID–19*); EO 13911, 2020 (*Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources To Respond to the Spread of COVID–19)*; EO 14047, 2021 (added **measles** to the list of quarantinable communicable diseases); EO 14081, 2022 (*Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*.)

[2] 6 CFR 46, Protection of Human Subjects, Department of Homeland Security; 7 CFR 1c, Protection of Human Subjects, Department of Agriculture; 10 CFR 745, Protection of Human Subjects, Department of Energy; 14 CFR 1230, Protection of Human Subjects, National Aeronautics and Space Administration; 15 CFR 27, Protection of Human Subjects, Department of Commerce; 20 CFR 431, Protection of Human Subjects, Social Security Administration; 21 CFR 50, Protection of Human Subjects, clinical investigations regulated by FDA; 21 CFR 50.23, Protection of Human Subjects, Exception from general requirements; 21 CFR 50.24, Protection of Human Subjects, Exception from informed consent requirements for emergency research; 1 CFR 50.27, Documentation of Informed Consent; 21 CFR 56, Institutional Review Boards, clinical investigations regulated by FDA; 21 CFR 58, **Good Laboratory Practice** [cGLP] for Nonclinical Laboratory Studies; 21 CFR 180, Food Additives Permitted in Food or In Contact with Food on an Interim Basis Pending Additional Study; 21 CFR 210, **Current Good Manufacturing Practice [cGMP]** In Manufacturing, Processing, Packing, Or Holding Of Drugs; General; 21 CFR 211, **Current Good Manufacturing Practice** [cGMP] for Finished Pharmaceuticals; 21 CFR 310, New Drugs; 21 CFR 312, Investigational New Drug Application, **Clinical Trials [cGCP]**; 21 CFR 312.1, Scope; 21 CFR 312.21, Phases of an investigation; 21 CFR 312.23, Investigational New Drug [application] content and format; 21 CFR 312.32, Investigational New Drug safety reporting; 21 CFR 312.44, Termination [procedures under which FDA may terminate an IND]; 21 CFR 312.50, General responsibilities of sponsors; 21 CFR 312.52, Transfer of obligations to a contract research organization; 21 CFR 312.53, Selecting investigators and monitors; 21 CFR 312.56, Review of ongoing investigations; 21 CFR 312.60, General responsibilities of investigators; 21 CFR 312.61, Control of the investigators drug; 21 CFR 312.62, Investigator recordkeeping and record retention; 21 CFR 312.64, Investigator reports; 21 CFR 312.66, Assurance of IRB review; 21 CFR 312.70, Disqualification of a clinical investigator; 21 CFR 314, Applications for FDA Approval to Market a New Drug; 21 CFR 314.170, Adulteration and misbranding of an approved drug; 21 CFR 320, Bioavailability and Bioequivalence Requirements; 21 CFR 330, Over-the-Counter (OTC) Human Drugs Which Are Generally Regarded as Safe and Effective and Not Misbranded; 21 CFR 361, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research; 21 CFR 600, Biological Products: General; 21 CFR 601, Biological Products: Licensing; 21 CFR 630, Requirements For Blood And Blood Components Intended For Transfusion Or For Further Manufacturing Use; 21 CFR 812, Investigational Device Exemptions; 21 CFR 820, Quality System Regulation, Current Good Manufacturing Practice; 21 CFR 1271, Human Cells, Tissues, and Cellular and Tissue-based Products; 22 CFR 225, Protection of Human Subjects, Agency for International Development [US-AID]; 24 CFR 60, Protection of Human Subjects, Department of Housing and Urban Development; 29 CFR 21, Protection of Human Subjects, Department of Labor; 32 CFR 219, Protection of Human Subjects, Department of Defense; 34 CFR 97, Protection of Human Subjects, Department of Education; 38 CFR 16, Protection of Human Subjects, Department of Veterans Affairs; 40 CFR 26, Protection of Human Subjects, Environmental Protection Agency; 42 CFR 70, Interstate Quarantine; 42 CFR 71, Foreign Quarantine; 45 CFR 46, Protection of Human Subjects, Department of Health And Human Services; 45 CFR 690, Protection of Human Subjects, National Science Foundation; 49 CFR 11, Protection of Human Subjects, Department Of Transportation; AR 70-25 - Army Regulation, Use of Volunteers as Subjects of Research; OTSG Reg. 15-2, Office of the Surgeon General, Human Subjects Research Review Board.

[3] 1981-present, relevant HHS Proposed Rules, Final Rules, Notices, and Guidance for Industry, partial list: HHS-Food and Drug Administration Final Rule Protections for Human Subjects; Prisoners Used as Subjects in Research (1981); HHS-FDA Final Rule Protection of Human Subjects; Informed Consent (1981); HHS Interim Final Rule: Informed Consent for Human Drugs and Biologics; Determination that Informed Consent is Not Feasible (1990); 1991 Common Rule (1991); HHS-FDA Guidance for Human Somatic Cell Therapy and Gene Therapy (1998); HHS Interim Final Rule - Human Drugs and Biologics; Determination That Informed Consent Is NOT Feasible or Is Contrary to the Best Interests of Recipients; Revocation of 1990 Interim Final Rule; Establishment of New Interim Final Rule (1999); HHS-FDA Draft Guidance Re: Emergency Use Authorization of Medical Products (2005); HHS-FDA Interim Final Rule, Medical Devices; Exception From General Requirements for Informed Consent (2006) HHS-FDA Guidance: Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Effects (2006); HHS-FDA Guidance - Emergency Use Authorization of Medical Products (2007); HHS Interim Final Rule - FDA Exceptions or Alternatives

to Labeling Requirements for Products Held by the Strategic National Stockpile. (2007); HHS-FDA Final Rule: Medical Devices; Exception From General Requirements for Informed Consent (2011); HHS-FDA Guidance: Potency Tests for Cellular and Gene Therapy Products (2011); HHS-FDA Preclinical Assessment of Investigational Cellular and Gene Therapy Products (2013**);** HHS-FDA Guidance: Decisions for Investigational Device Exemption Clinical Investigations (2014); HHS-FDA Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products (2015); HHS-FDA Guidance: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products (2015); HHS Final Rule - HHS Clinical Trials Registration and Results (2016); HHS Workshop Summary - The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile (2016); HHS-FDA Guidance: Emergency Use Authorization of Medical Products and Related Authorities (2017); HHS Final Rule - Federal Policy for the Protection of Human Subjects (2017); HHS Final Rule - Control of Communicable Diseases (2017); HHS-FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects (2017); HHS-FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (2017); HHS Final Rule - Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period (2018); HHS-FDA Guidance: Development and Licensure of Vaccines to Prevent COVID-19 (2020); HHS-FDA Guidance: Emergency Use Authorization for Vaccines to Prevent COVID-19 (2020); HHS-FDA Guidance: Real-World Data - Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products (2021); HHS-FDA Guidance: Real-World Data - Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products (2021); HHS Interim Final Rule - Possession, Use, and Transfer of Select Agents and Toxins—Addition of SARS–CoV/SARS–CoV–2 Chimeric Viruses Resulting From Any Deliberate Manipulation of SARS–CoV–2 To Incorporate Nucleic Acids Coding for SARS–CoV Virulence Factors to the HHS List of Select Agents and Toxins (2021); HHS Final Rule - National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table (2022); HHS-FDA Proposed Rules: Protection of Human Subjects and Institutional Review Boards (2022)

[4] 1969-present, relevant Congressional acts regarding **Chemical and Biological Warfare Program**, reporting to Congress, suspension of informed consent duties and rights, partial list. Armed Forces Appropriations Act of 1969 (PL 91-121). Section 409 authorized DOD to use human subjects for chemical and biological weapons testing, established reporting requirements (DOD reports to Congress) and **authorized President to suspend informed consent and all other provisions during any declared war or national emergency**; National Cancer Act of 1971 (PL 92-216); National Research Service Award Act of 1974 (PL 93-348); Department of Defense Appropriations Authorization Act of 1978 (PL 95-79); Congressional Reports Elimination Act of 1982 (PL 97-375); NDAA for FY1991 (PL 101-510); NDAA for FY1994, (PL 103-160); NDAA for FY96 (PL 104-106); Antiterrorism and Effective Death Penalty Act; Illegal Immigration Reform and Immigrant Responsibility Act; Prison Litigation Reform Act of 1996 (PL 104-132); NDAA for FY98 (PL 105-85); NDAA for FY1999 (PL 105-261); NDAA for FY 2005 (PL 108-375); NDAA for FY2017 (PL 114-328).

[5] 50 USC Chapter 32 - **Chemical and Biological Warfare**. §1511. Repealed; §1512. Transportation, open air testing, and disposal; Presidential determination; report to Congress; notice to Congress and State Governors; § 1512a. Transportation of chemical munitions; §1513. Deployment, storage, and disposal; notification to host country and Congress; international law violations; reports to Congress and international organizations; §1514. "United States" defined; **§1515. Suspension; Presidential authorization**; §1516. Delivery systems; §1517. Immediate disposal when health or safety are endangered; § 1518. Disposal; detoxification; report to Congress; emergencies; §1519. Lethal binary chemical munitions; §1519a. Limitation on procurement of binary chemical weapons; §1520. Repealed. Pub. L. 105–85, div. A, title X, § 1078(g), Nov. 18, 1997, 111 Stat. 1916, and Pub. L. 105–277, div. I, title VI, § 601, Oct. 21, 1998, 112 Stat. 2681–886; §1520a. **Restrictions on use of human subjects for testing of chemical or biological agents**; § 1521. Destruction of existing stockpile of lethal chemical agents and munitions; § 1521a. Destruction of existing stockpile of lethal chemical agents and munitions; §1522. Conduct of chemical and biological defense program; §1523. Annual report on chemical and biological warfare defense; §1524. **Agreements to provide support to vaccination programs of Department of Health and Human Services**; §1525. Assistance for facilities subject to inspection under Chemical Weapons Convention; §1526. Effective use of resources for nonproliferation programs; §1527. Improved biosafety for handling of select agents and toxins; §1528. Congressional notification of biological select agent and toxin theft, loss, or release involving the Department of Defense.

[6] 1973-present, relevant Congressional acts regarding establishment and expansion of **executive branch emergency powers**, partial list. War Powers Resolution of 1973 (93-148); National Emergencies Act of 1976 (PL 94-412); Robert T. Stafford Disaster Relief and Emergency Act of 1988 (PL 100-707); Authorization for Use of Military Force of 2001 (PL 107–40); Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 (PL 107-56); Homeland Security Act of 2002 (PL 107-296); NDAA/John Warner Defense Authorization Act for FY2007 (PL 109-364), **authorized deployment of US military on American soil against American citizens during "natural disaster, epidemic, or other serious public health emergency, terrorist attack or incident, or other condition in any State or possession of the United States."** [repealed, NDAA for FY2008; passed again in NDAA for FY2012].; NDAA for FY2008 (PL 110-181); NDAA for FY2012 (PL 112-81); Disaster Relief Appropriations Act of 2013 (PL 113-2); NDAA for FY2017 (PL 114-328); Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (2017). 10 USC 282 (renumbered from 10 USC 382) "permits Department of Defense to provide support to the Department of Justice under certain circumstances in emergency situations involving Weapons of Mass Destruction, including biological weapons and materials."

[7] 1983-present, relevant Congressional acts regarding establishment and expansion of **Public Health Emergencies Program**, partial list. **Public Health Service Act Amendment** of 1983 (PL 98-49); Health Omnibus Programs Extension Act of 1988 (PL 100-607); National Institutes of Health Revitalization Act of 1993 (PL 103-43); Food and Drug Administration Modernization Act of 1997 (PL 105-115); Omnibus Consolidated and Emergency Supplemental Appropriations of 1998, for FY1999 (PL 105-277); **Public Health Improvement Act** of 2000 (PL 106-505); **Public Health Security and Bioterrorism Preparedness and Response Act** of 2002 (PL 107-188); **NDAA for FY2004** (PL 108-136) [Added 21 USC 360bbb-3, "*Authorization for Medical Products for Use in Emergencies*" under Federal Food Drug and Cosmetics Act, 21 USC 360bbb added in 1997, "*Expanded Access to Unapproved Diagnostics and Therapies*." Added 10 USC 1107a, *Emergency Use Products*, authorizing US President to waive informed consent rights of military personnel during declared emergencies and redefining the meaning of the right to be "informed of an option to accept or refuse administration of a product."]; **Project Bioshield Act** of 2004 (PL 108-276); DOD Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2005, including **Public Readiness and Emergency Preparedness (PREP) Act** (PL 109-148); **Pandemic and All-Hazards Preparedness Act** of 2006 (PL 109-417); National Institute of Health Reform Act of 2007 (PL 109-482); Food and Drug Administration Amendments Act of 2007 (PL 110-85); Patient Protection and Affordable Care Act of 2010 (ObamaCare) including Biologics Price Competition and Innovation Act of 2009 (PL 111-148); Food and Drug Administration Safety and Innovation Act of 2012 (PL 112-144); **Pandemic and All-Hazards Preparedness Reauthorization Act** of 2013 (PL 113-5); Medicare Access and CHIP Reauthorization (MACRA) Act of 2014 (PL 114-10); **21st Century Cures Act** of 2016 (PL 114-255); FDA Reauthorization Act of 2017 (PL 115-52); NDAA for FY 2018 (PL 115-91); **Act to amend FDCA EUA statute**, 21 USC 360bbb-3, of 2017 (PL 115-92); **Pandemic and All-Hazards Preparedness and Advancing Innovation Act** of 2019 (PL 116-22); Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (PL 116-123); Families First Coronavirus Response Act of 2020 (PL 116-127); Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 (PL 116-136); Paycheck Protection Program and Health Care Enhancement Act of 2020 (PL 116-139); Consolidated Appropriations Act of 2020 (PL 116-260); American Rescue Plan/Consolidated Appropriations Act of 2021 (PL 117-2); NDAA for FY2022 (PL 117-81); Consolidated Appropriations Act of 2022 (PL 117-103).

[8] 42 USC § 247d. **Public health emergencies**; §247d–1. Vaccine tracking and distribution; §247d–3a. Improving State and local public health security; §247d–3b. Partnerships for State and regional hospital preparedness to improve surge capacity; §247d–3c. Guidelines for regional health care emergency preparedness and response systems; §247d–4. Facilities and capacities of the Centers for Disease Control and Prevention; §247d–4a. Infectious Diseases Rapid Response Reserve Fund; §247d–4b. Children's Preparedness Unit; §247d–5. Combating antimicrobial resistance; §247d–6. **Public health countermeasures to a bioterrorist attack**; §247d–6a. Authority for use of certain procedures regarding qualified countermeasure research and development activities; § 247d–6b. **Strategic National Stockpile and security countermeasure procurements**; §247d–6d. **Targeted liability protections for pandemic and epidemic products and security countermeasures**; §247d–6e. **Covered countermeasure process** [Countermeasures Injury Compensation Program]; §247d–7. Demonstration program to enhance bioterrorism training, coordination, and readiness; §247d–7a. Grants regarding training and education of certain health professionals; §247d–7b. Emergency system for advance registration of volunteer health professional; §247d–7c. Supplies and services in lieu of award funds; §247d–7d. Security for countermeasure development and production;

§247d–7e. Biomedical Advanced Research and Development Authority; §247d–7f. Collaboration and coordination; §247d–7g. National Biodefense Science Board and working groups.

[9] 2017: "The Public Readiness and Emergency Preparedness Act (PREP Act) of 2005 amended the PHSA to authorize the HHS Secretary to issue a declaration that provides immunity from liability (except for willful misconduct) to covered persons against legal claims arising from administration or use of [medical countermeasures] recommended by the Secretary to address pandemic or epidemic diseases or threats, or CBRN threats to health that the Secretary determines constitute a present or future PHE. **Covered persons can include manufacturers; researchers, distributors, states, local governments, private sector partners, and others involved in countermeasure programs; qualified persons who prescribe, administer, or dispense countermeasures; officials, agents, employees of all of these groups, and the U.S. Government.**" US Department of Homeland Security, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (2017)

[10] 2018: *Informed Consent Action Network v. US Department of Health and Human Services*, 18-CV-03215, USDC, Southern District of New York, Doc. 18.

[11] 42 USC § 300aa-1 et seq. **National Vaccine Program** § 300aa–1. Establishment; § 300aa–2. Program responsibilities; § 300aa–3. Plan; § 300aa–4. Repealed; § 300aa–5. National Vaccine Advisory Committee; § 300aa–6. Authorization of appropriations.

[12] 42 USC §300aa–10 et seq. **National Vaccine Injury Compensation Program** §300aa–10. Establishment of program; §300aa–11. Petitions for compensation; §300aa–12. Court jurisdiction; §300aa–13. Determination of eligibility and compensation; §300aa–14. Vaccine Injury Table; §300aa–15. Compensation; §300aa–16. Limitations of actions; §300aa–17. Subrogation; §300aa–18. Repealed.; §300aa–19. Advisory Commission on Childhood Vaccines; §300aa–21. Authority to bring actions; §300aa–22. Standards of responsibility; §300aa–23. Trial; §300aa–25. Recording and reporting of information; §300aa–26. Vaccine information; §300aa–27. Mandate for safer childhood vaccines; §300aa–28. Manufacturer recordkeeping and reporting; §300aa–31. Citizen's actions; §300aa–32. Judicial review; §300aa–33. Definitions; §300aa–34. Termination of program

[13] 2009: "At the workshop, participants noted that EUA has a broader use beyond enabling the use of an unapproved product or extending the use of an approved product to populations for which it was not approved. In particular, it can also be used to address labeling requirements and other challenges that arise because of constraints inherent in a public health response. **'From a legal perspective, there are a lot of situations where EUA helps get past all those requirements,'** said [Susan E. Sherman, J.D., M.S., a senior attorney with the Office of the General Counsel, HHS] **'You can change the labeling. You can change the information. You can change the dosage. You can give it to populations for which wasn't approved.'** " US-HHS FDA Workshop Summary, *Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model* (2009).

[14] 21 USC § 360bbb. **Expanded access to unapproved therapies and diagnostics**; §360bbb–0. Expanded access policy required for investigational drugs; §360bbb–0a. Investigational drugs for use by eligible patients; §360bbb–1. Dispute resolution; §360bbb–2. Classification of products; §360bbb–3. **Authorization for medical products for use in emergencies [Emergency Use Authorization/EUA products]**; §360bbb–3a. Emergency use of medical products; §360bbb–3b. Products held for emergency use; §360bbb–3c. Expedited development and review of medical products for emergency uses; §360bbb–4. Countermeasure development, review, and technical assistance; §360bbb–4a. Priority review to encourage treatments for agents that present national security threats; §360bbb–4b. Medical countermeasure master files; §360bbb–5. Critical Path Public-Private Partnerships; §360bbb–6. Risk communication; §360bbb–7. Notification; §360bbb–8. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments; §360bbb–8a. Optimizing global clinical trials; §360bbb–8b. Use of clinical investigation data from outside the United States; §360bbb–8c. Patient participation in medical product discussion; §360bbb–8d. Notification, nondistribution, and recall of controlled substances.

[15] 42 USC 300hh-10a. **Public Health Emergency Medical Countermeasures Enterprise** membership shall include: (1) The [HHS] Assistant Secretary for Preparedness and Response; (2) The Director of the Centers for Disease Control and Prevention; (3) The Director of the National Institutes of Health; (4) The Commissioner of Food and Drugs; (5) The Secretary of Defense; (6) The Secretary of Homeland Security; (7) The Secretary of Agriculture; (8) The Secretary

of Veterans Affairs; (9) The Director of National Intelligence; (10) Representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases, and the Director of the Office of Public Health Preparedness and Response, as the [HHS] Secretary determines appropriate.

[16] 42 USC § 300hh. **Public health and medical preparedness and response functions**; §300hh–1. National Health Security Strategy; §300hh–2. Enhancing medical surge capacity; §300hh–10. Coordination of preparedness for and response to all-hazards public health emergencies; §300hh–10a. **Public Health Emergency Medical Countermeasures Enterprise**; §300hh–10b. National Advisory Committee on Children and Disasters; §300hh–10c. National Advisory Committee on Seniors and Disasters; §300hh–10d. National Advisory Committee on Individuals With Disabilities and Disasters; §300hh–10e. Advisory Committee Coordination; §300hh–11. National Disaster Medical System; §300hh–12. Transferred; §300hh–13. Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies; §300hh–14. Protection of health and safety during disasters; §300hh–15. Volunteer Medical Reserve Corps; §300hh–16. At-risk individuals; §300hh–17. Emergency response coordination of primary care providers; §300hh–31. Epidemiology-laboratory capacity grants; §300hh–32. Enhanced support to assist health departments in addressing vector-borne diseases; §300hh–33. Public health data system modernization

[17] NDAA for FY-2016 (PL 114-92), Section 815 added 'prototype' procurement contracting language (Other Transactions Authority - OTA), authorizing DOD to contract with pharmaceutical corporations to produce bioagents labeled as medical countermeasures or security countermeasures. Codified at 10 USC 2371b, renumbered 10 USC 4022.

[18] https://www.medcbrn.org/current-members/. Accessed May 22, 2023: "Accelerating DoD's Fielding of Prototypes for Medical Countermeasures."

[19] US District Court, Eastern District of Texas, Beaumont Division, *United States of America ex. rel. Brook Jackson v. Ventavia Research Group, LLC, Pfizer Inc., ICON PLC*, Case No. 1:21:cv-00008-MJT, Doc. 70, Oct. 4, 2022, US Statement of Interest Supporting Dismissal of the Amended Complaint, at p. 10.

[20] US District Court, Eastern District of Texas, Beaumont Division, *United States of America ex. rel. Brook Jackson v. Ventavia Research Group, LLC, Pfizer Inc., ICON PLC*, Case No. 1:21:cv-00008-MJT, Doc. 37, April 22, 2022 Pfizer Motion to Dismiss, at pp. 3-4, 6-8.

[21] 10 USC §4021. **Research projects: transactions other than contracts and grants;** § 4022. **Authority of the Department of Defense to carry out certain prototype projects**; §4023. Procurement for experimental purposes; §4024. Merit-based award of grants for research and development; §4025. Prizes for advanced technology achievements; §4026. Cooperative research and development agreements under Stevenson-Wydler Technology Innovation Act of 1980; [§4027. Disclosure requirements for recipients of research and development funds]

[22] Notice of **Determination that a Public Health Emergency Exists, effective Jan. 27, 2020**. 85 Federal Register 7316, Feb. 07, 2020.

[23] Notice of **Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, effective Feb. 04, 2020**. 85 Federal Register 15198, March 17, 2020.

[24] 2021: CDC *COVID-19 Vaccination Program Provider Requirements and Support*, https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html#provider-agreement (updated 06/11/2021). **Diversion of COVID-19 Vaccines Prohibited**: "At this time, all COVID-19 vaccine in the United States has been purchased by the United States Government for administration exclusively through the CDC COVID-19 Vaccination Program. The vaccine and all related ancillary supplies, including the COVID-19 Vaccination Cards, remains U.S. government property until vaccine is administered to the recipient...COVID-19 vaccination providers are prohibited from selling USG-purchased COVID-19 vaccine (and ancillary materials purchased by the USG for use in the Vaccination Program), soliciting or receiving any inducement, whether direct or indirect, for vaccinating (or providing COVID-19 vaccine to be used for vaccinating) any individual who is not currently eligible to receive

COVID-19 vaccine as a member of a group currently authorized under prioritization specified by HHS/CDC /ACIP, the state/territory's governor or other relevant public health authority, or otherwise diverting COVID-19 vaccine from the CDC COVID-19 Vaccination Program. Such use constitutes fraud and is a violation of the terms of the provider agreement. It shall be cause for immediate termination from the CDC COVID-19 Vaccination Program and criminal or civil prosecution for violation of 18 U.S.C. §1001 or other relevant federal statutes.