JMJ

St. Benedict Memo

September 2025

St. Benedict is a saint invoked against poisoning. Inscription “SMQLIVB” on the St. Benedict medal: Sunt mala quae libas, ipse venena bibas.

Evil are the things thou proferrest; drink thou thy own poison.

Contents

Author: Katherine Watt, Catholic American writer and paralegal

Front Matter

1905 - *Jacobson v. Massachusetts,* 197 US 11, 34 quoting *Viemeister v. White*, 179 N. Y. 235 (1904):

> ...While not accepted by all, [vaccination] is accepted by the mass of the people, as well as by most members of the medical profession. It has been general in our state, and in most civilized nations for generations. It is generally accepted in theory, and generally applied in practice, both by the voluntary action of the people, and in obedience to the command of law. Nearly every state in the Union has statutes to encourage, or directly or indirectly to require, vaccination; and this is true of most nations of Europe. . .
>
> A common belief, like common knowledge, does not require evidence to establish its existence, but may be acted upon without proof by the legislature and the courts...
>
> The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases...
>
> While the power to take judicial notice is to be exercised with caution and due care taken to see that the subject comes within the limits of common knowledge, still, when according to the memory and conscience of the judge, instructed by recourse to such sources of information as he deems trustworthy, the matter is clearly within those limits, the power may be exercised by treating the fact as proved without allegation or proof..."

* * *

Summary of Findings and Conclusions

I study US and international law surrounding communicable disease control, pandemic preparedness and response, biological product and vaccine manufacturing and biological agents.

In January 2025, attorneys representing Dutch plaintiffs invited me to participate as a witness in a civil case before the District Court of Northern Netherlands at Leeuwarden (Case reference: C/17/190788; Case number: 23/172)

In March 2025, the attorneys submitted a petition for provisional evidence, including a list of questions on which the plaintiffs sought my testimony.

As a preliminary matter, I note that there is no single, unique, distinct, determinate or stable material substance to comprise "the" Covid-19 mRNA vaccine or any single annual "formulation." Each quantity of solid, semi-solid or liquid matter, supplied to users with or without instructions to mix the contents with liquid saline solution, may contain living organisms and sub-units from several different species of bacteria, plant, fungi and animal organisms (heterogenous organic matter), along with inorganic matter.

Each component may or may not be listed in printed material accompanying the container or submitted to putative regulators. If listed, each indeterminate article of organic or inorganic matter may or may not be listed as present in a discrete quantity, and the quantity actually present in the container may or may not correspond with the stated quantity at any given moment in time.

Wide spatial and temporal variability of physical composition, and the intrinsic inaccuracy of labeling implied by such variability, are legal: there are no US laws or regulations requiring products to be placed in containers in compliance with any physical standards or temporal stability standards, and there are no US laws or regulations requiring accurate, complete labeling or other forms of accurate, complete information disclosure.

Questions presented and brief answers

What are the legal frameworks governing development, manufacture, labeling, distribution and use of viruses and vaccines under US law?

Under US law, viruses and vaccines are designated, categorized or classified as "biological products." The primary US statutes governing establishments in which biological products are propagated or manufactured, placed into containers, and labeled, are 42 USC 262-263, also known as Public Health Service Act Sec. 351-352, *Regulation of biological products*.

The primary US regulations implementing the "biological product" statutes may be found at Title 21, Subchapter F, Code of Federal Regulations (21 CFR 600-680), and associated non-binding Guidance for Industry documents published by the US Food and Drug Administration.

Biological product law exists within a network or web of other, related law governing subjects including drug manufacturing quality control; communicable disease surveillance and control activities; biological defense research, development, procurement and stockpiling activities; and pandemic preparedness and response research, development, procurement and stockpiling activities.

Congress established the first federal law authorizing federal officers to "regulate" sale and interstate traffic in "viruses, serums, toxins, and analogous products" in 1902 (PL 57-244). Congress did not define the product terms, including the term 'virus,' in the law.

In 1919, US regulators defined 'virus' for the first time by regulation: "A virus is a product containing the minute living cause of an infectious disease." Paragraph 7.I., Feb. 12, 1919, *Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products in the District of Columbia and in Interstate Traffic,* Surgeon-Generals, US-Army, US Navy and Public Health and Marine-Hospital Service, approved by Secretary of Treasury.

Current US regulatory definition for virus: "A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa." 21 CFR 600.3(h)(1) as of 1973.

Apart from one three-month period between November 2002 and February 2003, Congress has never defined the term 'vaccine' in anything other than intent- or labeling-based, non-physico-chemical terms.

Between Nov. 25, 2002 and Feb. 20, 2003 under provisions of the National Childhood Vaccine Injury Act (NCVIA), Congress defined 'vaccine:'

> "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccine's product license application and product label." 42 USC 300aa-33(7) as of Nov. 25, 2002

Congress also made conforming amendments at 42 USC 300aa-33(3) [defining the term 'manufacturer'] and at the definition of "vaccine-related injury or death" at 42 USC 300aa-33(5), excluding from being classified as an adulterant or contaminant "any component or ingredient listed on a product's license application or label."

In February 2003 (PL 108-7), Congress repealed the provisions enacted in November 2002, including the definition for 'vaccine,' noting that the Public Health Service Act should be applied as if the November 2002 amendments had never been enacted.

The term 'vaccine' has not been defined by US regulation.

What are the legal frameworks governing research, development, transfer and use of biological and bacteriological weapons under US law?

The primary US statutes governing possession, stockpiling and use of biological agents are 18 USC 175-178, *Biological weapons*; 50 USC 1511 et seq, *Chemical and Biological Warfare*; and 42 USC 262a, *Enhanced control of dangerous biological agents and toxins*. The primary US regulations implementing "biological agent" statutes may be found at 42 CFR 73, *Select agents and toxins*.

Under US law, prohibited conduct "with respect to biological weapons" includes the acts of "whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon" and the acts of "whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." 18 USC 175(a), 18 USC 175(b)

"For use as a weapon" is currently defined as "includes the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for other than prophylactic, protective, bona fide research, or other peaceful purposes." 18 USC 178(c)

"Biological agent" is currently defined under 18 USC 178 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—(A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment."

"Biological agent" is currently defined under 50 USC 1520a as

> "any micro-organism (including bacteria, viruses, fungi, rickettsiae, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance,

> whatever its origin or method of production, that is capable of causing—(1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (2) deterioration of food, water, equipment, supplies, or materials of any kind; or (3) deleterious alteration of the environment."

On what basis are viruses, vaccines, gene therapies and other biological products distinguished from biological and bacteriological weapons under US law?

Under US law, "biological products" are distinguished from "biological agents" on the basis of classification acts performed by the Secretary of Health and Human Services and Secretary of Agriculture, on the basis of imputed intent, and on the basis of printed material on container labels, packages, package inserts, fact sheets and application forms.

There is no physical basis on which "biological products" can feasibly be distinguished from "biological agents," because all biologically-active substances are capable of causing death, disease or other biological malfunction in a human, an animal, a plant, or another living organism. The capacity to cause death, disease and biological malfunction is most pronounced when biological matter is delivered directly into the blood of the recipient organism, by means of injection or other breaking of skin, lung and digestive tract barriers.

Are there any legal requirements for scientifically validated materials and methods to be used in support of statements as to safety and efficacy for viruses, vaccines, gene therapies, and other biological products?

No.

What is the relationship between US-FDA regulatory functions and decisions regarding international commerce in viruses, vaccines, gene therapies and other biological products, and the regulatory agencies of other countries, particularly in Europe?

Through Mutual Recognition Agreements (trade agreements), European and other non-US regulatory agencies may legally rely on or defer to regulatory acts performed by the US Food and Drug Administration and pharmaceutical corporations, without conducting independent batch testing or other forms of product quality control.

Have the individuals who ordered, purchased and administered Covid-19 (mRNA) injections participated in war crimes and/or acts of genocide?

Yes. Individuals who ordered, purchased and administered "Covid-19 mRNA injections" have participated in legalized war crimes including torture, mutilation and murder.

Criminal prosecution is precluded on the basis of anticipated assertion of "legitimate medical or dental purposes" under US and international legal frameworks which do not require presentation or validation of physical evidence supporting claims as to the identity or composition of injected vaccine products, and do not require presentation or validation of physical evidence supporting claims as to the therapeutic or beneficial character of variable and uncontrollable physiological effects which biologically-active components of vaccines are capable of inducing or causing in living recipients.

Background

After learning about the World Health Organization International Health Regulations, 2005 edition, in January 2022, including provisions requiring "adjustment of domestic legislative and administrative arrangements," I assembled an outline of relevant US federal laws enacted by the US Congress and US Presidents, and published the material under the title American Domestic Bioterrorism Program on April 28, 2022.

Corroboration of my finding that US biological product law legalizes introduction of unidentified, unstandardized, and unregulated products into interstate and international commerce came through documents filed in the American case titled *United States of America, ex. rel. Brook Jackson v. Ventavia Research Group, LLC; Pfizer, Inc.; ICON PLC* (US District Court for the Eastern District of Texas, Case No. 1:21-cv-00008) under the False Claims Act, 31 USC 3729 et seq.

Jackson, a former employee of Pfizer subcontractor Ventavia, filed her complaint in January 2021, alleging that contractors supplying vaccines to the US Department of Defense had presented false claims for payment and had knowingly used false records or statements material to a false claim for payment, on grounds that the defendants had not conducted valid, regulation-compliant clinical trials to support claims as to the safety and effectiveness of vaccines produced under contract for the Department of Defense.

In support of its April 2022 motion to dismiss Jackson's complaint, Pfizer argued:

> "Because of pandemic-related exigencies, the agreement was not a standard federal procurement contract, but rather a 'prototype' agreement executed pursuant to 10 U.S.C. § 2371b [renumbered 10 USC 4022 PL 116-283, Jan. 2021 effective Jan. 2022]…The [contract's Statement of Work] describes a 'large scale vaccine manufacturing demonstration' that imposes no requirements relating to Good Clinical Practices ('GCP') or related FDA regulations…(April 22, 2022 Pfizer Motion to Dismiss, pp. 6-8)

In October 2022, the US Department of Justice filed a statement of interest in support of Pfizer's motion to dismiss. DOJ argued:

> …[the] complaint does not identify any provision in the SOW [Statement of Work] for the Project Agreement between Pfizer and the Army that conditioned Government payment for the vaccine on Pfizer's compliance with the clinical trial protocol or regulations. The SOW, which is attached to the complaint, further specifies that the Army did not regulate the conduct of the clinical trial, which is "out-of-scope" for the purchase agreement between the Army and Pfizer. In short, the complaint does not plead factual content to support a conclusion that compliance with the clinical trial protocol or regulations was necessary under the contract between Pfizer and the Army such that clinical trial violations would give rise to a claim for express or implied certification liability. (Oct. 4, 2022 US-DOJ Statement of Interest, p. 10)

These claims by Pfizer and by the US Department of Justice led me to further investigate the history of how Congress enacted US federal laws governing biological product manufacturing, distribution and use under emergency conditions, to allow interstate commerce in unidentified, unstandardized, unregulated products labeled and falsely presented as identified, standardized and regulated vaccines and other "countermeasures," starting in 1997 with enactment of 21 USC 360bbb, *Expanded access to unapproved therapies and diagnostics*.

As I read historical records about how the legal conditions for "emergency use" products were established by Congress, I learned that in 1902, Congress had established the same legal conditions for routine, systematic introduction into interstate commerce and use of unidentified, unstandardized, unregulated biological products.

I began to understand that the non-existence of scientific and legal evidentiary standards pre-dated 2020. The standards that don't exist for emergency and non-emergency products manufactured since 2020, also didn't exist for vaccines and other biological products manufactured before 2020.

In other words, laws enacted since 1997 enable more rapid, "emergency" introduction into interstate commerce of unidentified, unstandardized, unregulated products and product classes or categories (vaccines and other biological products), whose introduction into interstate commerce has been authorized routinely and systematically since 1902.

Many terms for these products are used in addition to vaccine, immunization and biological product, such as medical countermeasure, security countermeasure, qualified pandemic product. The lists are long[1] and new terms and phrases are added frequently. All terms and phrases denoting physical matter resulting from processes performed by living biological organisms (such as fermentation and putrefaction) fall under the category of "biological products" in the context of product regulation and under the category of "biological agents" in the context of legal restrictions or prohibitions on stockpiling and use of biological and chemical weapons.

The US Congress may be understood as the producer of consecutive and concurrent theatrical productions or broadcast performances, providing legal authority and funding for scriptwriters, press agents, publishers, directors, actors, costumers, prop-makers, set-builders, stage managers, crew members, cinematographers, photographers, sound technicians, film editors, casting calls, auditions, actor training, rehearsals, advertisements and performances.

[1] Some terms and phrases used to denote or classify biological products in American and international legal instruments: allergen; allergenic product; analogous product; antigen; antitoxin; arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound); attenuated infectious vaccine; bacteria; biopharmaceutical; biosimilar; biosimilar biological product; biotechnology; biotechnology product; blood, blood component or derivative cell therapies; cells pulsed with immunogen; cellular therapy products; component of pathogen; conjugates; crude or purified antigens isolated from killed or living cells; crude or purified antigens secreted from living cells; diagnostic antigen; emerging technology in the context of the pharmaceutical and related industries; first interchangeable biosimilar biological product; fraction of pathogen; gene; gene therapies; genetically-modified organism (GMO); human blood and blood components; human cellular and gene therapy products; human somatic cell therapy and gene therapy; immunogen; immunotoxin; intentionally altered genomic DNA; living vectored cells expressing specific heterologous immunogens; microbial culture; microbial derived proteins; monoclonal antibody; parasite; pathogen; peptide; plasma-derived pharmaceutical; plasma-derived product; plasmid; plasmid DNA vaccine; polynucleotides; polypeptide; protein; recombinant nucleic acid molecules; recombinant or synthetic carbohydrate, protein or peptide antigens; recombinant protein; reference product; regenerative medicine therapies; regenerative medicine advanced therapy; somatic cell therapy; synthetic biological product; synthetic nucleic acid molecules; therapeutic biological product; therapeutic biotechnology; therapeutic biotechnology-derived biological product; therapeutic recombinant DNA-derived product; therapeutic serum; toxin; toxoid; vaccine; virus; well-characterized platform technology; well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products; whole, inactivated pathogen.

Report Contents and Limitations

In support of the conclusions drawn, this report contains four sections and an appendix.

Section 1 provides information about the absence of legal definitions for the term 'disease,' and a summary of 'disease'-related terms and phrases as defined by Presidential executive orders, US statutes and regulations and World Health Organization legal instruments.

Section 2 provides a brief description of Mutual Recognition Agreements and the Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices that entered into force in July 2019.

Section 3 provides summaries of key US Congressional acts enacted by the US Congress and US Presidents, and implemented by US Cabinet secretaries, between 1938 and 2006. Each summary heading includes the year, US Code citation, title (general subject matter), and specific subjects addressed by the law, to enable the reader to trace the development of laws by year and subject.

The simulation of biological product standardization and manufacturing quality control, by means of statutes and regulations that do not prescribe physico-chemical definitions or standards and do not prescribe applicable, enforceable methods to assess physical compliance with non-existent standards, began in 1902, with Congressional enactment of the Virus-Toxin law. This report begins in 1938, with the Federal Food Drug and Cosmetic Act, and 1944, with the Public Health Service Act, because those two laws consolidated and expanded previous lawmaking on interstate commerce in drug products and biological products, and those two laws, following decades of amendment, reorganization and expansion, are still in force and effect. This report concludes in 2006. By 2006, Congress had put in place the key legal provisions through which biologically-active material capable of causing biological malfunction can be legally placed into containers, labeled, distributed interstate and exported abroad, and used under pretextual, false claims that the purpose of such use is for preventing or mitigating infectious disease symptoms and transmission, as components of public health, communicable disease control and pandemic response programs. Since 2006[2], these laws have been amended, reorganized (sections renumbered, offices and programs renamed, functions transferred) and expanded to better facilitate nationwide and international campaigns, and to render systems capable of moving at greater speed. The basic elements have not substantially changed. In some but not all statute summaries, I included information about appropriations; suffice to say, Congress has consistently authorized federal spending for programs.

Section 4 provides excerpts from relevant international legal instruments.

The Appendix provides a list of some additional supporting documents, with a few excerpts. This list is only a small subset of available documentary evidence.

[2] Key Congressional acts since 2006 expanding the programs by, for example, authorizing the HHS Biomedical Advanced Research and Development Authority (BARDA), authorizing the HHS Secretary to use "other transaction" contracting authority, and establishing the multi-agency Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), include Pandemics and All-Hazards Preparedness Act (PL 109-417, Dec. 19, 2006); Pandemic and All Hazards Preparedness Reauthorization Act (PL 113-5, March 13, 2013); Pandemic and All-Hazards Response and Advancing Innovation Act (PL 116-22, June 24, 2019)

Section 1
No legal definition for 'disease'

Common law, statutory law and administrative law preclude judicial review of government acts allegedly undertaken for disease surveillance and control.

Common law: disease causation and vaccination as method to prevent spread as matters of "common belief"

In 1905, the US Supreme Court issued a ruling in *Jacobson v. Massachusetts*, 197 US 11, quoting from a New York Court of Appeals decision, *Viemeister v. White*, 179 N. Y. 235 (1904), which upheld a school board's smallpox vaccination requirement for a child's school attendance:

> "...The appellant claims that vaccination does not tend to prevent smallpox, but tends to bring about other diseases, and that it does much harm with no good. It must be conceded that some laymen, both learned and unlearned, and some physicians of great skill and repute, do not believe that vaccination is a preventive of smallpox.
>
> The common belief, however, is that it has a decided tendency to prevent the spread of this fearful disease and to render it less dangerous to those who contract it. While not accepted by all, it is accepted by the mass of the people as well as by most members of the medical profession. It has been general in our state and in most civilized nations for generations. It is generally accepted in theory and generally applied in practice, both by the voluntary action of the people and in obedience to the command of law.
>
> A common belief, like common knowledge, does not require evidence to establish its existence, but may be acted upon without proof by the legislature and the courts.
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> While the power to take judicial notice is to be exercised with caution and due care taken to see that the subject comes within the limits of common knowledge, still, when according to the memory and conscience of the judge, instructed by recourse to such sources of information as he deems trustworthy, the matter is clearly within those limits, the power may be exercised by treating the fact as proved without allegation or proof..." *Viemeister v. White*, 179 NY 235

In 1974, the Supreme Court issued a ruling in *Marshall v. US* (414 U. S. 417), a case about whether a thrice-convicted felon should be eligible for an experimental narcotics treatment program. The *Marshall* court cited a 1968 case (*Powell v. Texas*, 392 US 514), to point out "...the inescapable fact is that there is no agreement among members of the medical profession about what it means to say that "alcoholism" is a "disease." One of the principal works in this field [E. Jellinek, *The Disease Concept of Alcoholism* (1960)] states that 'alcoholism has too many definitions and disease has practically none.'…"

The Marshall court continued:

> The holding in *Powell* was a candid acknowledgment that the medical uncertainties afford little basis for judicial responses in absolute terms. When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation, even assuming, *arguendo,* that judges with more direct exposure to the problem might make wiser choices. *Marshall v. US*, 414 U. S. 417, 427

In 2020, the US Supreme Court issued a ruling in *South Bay Pentecostal v. Newsom* (590 U. S. ____ (2020), No. 19A1044). Chief Justice John Roberts cited *Jacobson* in holding that:

> The precise question of when restrictions on particular social activities should be lifted during the pandemic is a dynamic and fact-intensive matter subject to reasonable disagreement. Our Constitution principally entrusts "[t]he safety and the health of the people" to the politically accountable officials of the States "to guard and protect." *Jacobson* v. *Massachusetts*, 197 U. S. 11, 38 (1905).

Justice Roberts cited *Marshall* in holding that

> "...When those officials "undertake[ ] to act in areas fraught with medical and scientific uncertainties," their latitude "must be especially broad." *Marshall* v. *United States*, 414 U. S. 417, 427 (1974).

Justice Roberts cited a 1985 case (*Garcia v. San Antonio Metropolitan Transit Authority*, 469 US 528) in holding that:

> Where those broad limits are not exceeded, they should not be subject to second-guessing by an "unelected federal judiciary," which lacks the background, competence, and expertise to assess public health and is not accountable to the people. *Garcia* v. *San Antonio Metropolitan Transit Authority*, 469 U. S. 528, 545 (1985).

Statutory law and administrative law: designation of "communicable diseases" by Presidential executive order - 42 USC 262 and 42 USC 264

In 1944, when enacting 42 USC 262 (regulation of biological products "applicable to diseases of man") and 42 USC 264 (communicable disease control) through the Public Health Service Act (PL 78-410), Congress did not define the term "disease" and did not direct the Public Health Service Surgeon General or Federal Security Agency Administrator to prescribe regulations defining the term "disease."

Congress authorized the President to designate "such communicable diseases as may be specified from time to time" by Executive order, and authorized the Surgeon General with the approval of the FSA Administrator at the time (HEW and HHS Secretary subsequently, after reorganizations) to "make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or

possession" and "provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings and other measures, as in his judgment may be necessary."

In 1944, Congress did not require the President, Surgeon General, FSA Administrator (later HEW Secretary, currently HHS Secretary) to present physico-chemical evidence supporting the legal classification of a disease as caused by a communicable, transmissible, infectious or contagious agent, nor to present physico-chemical evidence supporting assertions that any agent could be extracted from a living organism in stable form or readily passed from one living person or animal to another.

At no point since 1944 have Congress, Presidents or any federal agencies or officers required or presented physico-chemical evidence for any physico-chemically unique, identifiable, stable biological agent having the capacity to cause disease, or to transmit from one living organism to another, in a one-to-one, reproducible, predictable, preventable, cause-and-effect manner.

In 1946, President Truman issued the first Presidential executive order (EO 9708) specifying quarantinable communicable diseases under 42 USC 264(b), including anthrax, chancroid, cholera, dengue, diphtheria, favus, gonorrhea, granuloma inguinale, infectious encephalitis, leprosy, lymphogranuloma venereum, meningococcus meningitis, plague, poliomyelitis, psittacosis, ringworm of the scalp, scarlet fever, smallpox, streptococcic sore throat, syphilis, trachoma, tuberculosis, typhoid fever, typhus and yellow fever.

In 1954, President Eisenhower issued Executive Order 10532, adding relapsing fever (louse-borne) to the list. In 1962, President Kennedy issued Executive Order 11070, adding chickenpox and replacing scarlet fever and streptococcic sore throat with hemolytic streptococcal infections.

In 1983, President Reagan issued Executive Order 12452, revoking Executive Orders 9708, 10532 and 11070 and providing a new list: cholera or suspected cholera; diphtheria; infectious tuberculosis; plague; suspected smallpox; yellow fever; suspected viral hemorrhagic fevers (Lassa, Marburg, Ebola, Congo-Crimean and others not yet isolated or named).

In 2003, President Bush issued Executive Order 13295, revoking EO 12452 and providing a new list: cholera; diphtheria; infectious tuberculosis; plague; smallpox; yellow fever; viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named), and Severe Acute Respiratory Syndrome (SARS), defined as "a disease associated with fever and signs and symptoms of pneumonia or other respiratory illness, is transmitted from person to person predominantly by the aerosolized or droplet route, and, if spread in the population, would have severe public health consequences."

EO 13295 ordered that the HHS Secretary: "in the Secretary’s discretion, shall determine whether a particular condition constitutes a communicable disease of the type specified" and assigned "the functions of the President" under 42 U.S.C. 265 [suspension of entries and imports from designated places to prevent spread of communicable diseases] and 267(a)) [quarantine stations, grounds, and anchorages, control and management] to the HHS Secretary.

In 2005, President Bush issued Executive Order 13375, adding "influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic."

In 2014, President Obama issued Executive Order 13674, amending the 2003 Bush EO, to replace the SARS section with a new version: “Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This subsection does not apply to influenza."

In 2021, President Biden issued Executive Order 14047, adding measles.

As of 2025, the list of communicable diseases subject to regulatory control by the HHS Secretary, designated by Presidential Executive Order, includes cholera; diphtheria; infectious tuberculosis; measles; plague; smallpox; yellow fever; viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named); "Severe acute respiratory syndromes [SARS], which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled;" and "influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic."

Statutory and administrative law: Administrative Procedure Act of 1946; exclusion of judicial review

In 1966 (PL 89-554), Congress revised, codified, and enacted, as Title 5 of the United States Code, provisions relating to "the organization of the Government of the United States and to its civilian officers and employees."

The 1966 codification incorporated sections of the Administrative Procedure Act of 1946 (PL 79-404), which set forth procedures through which executive agencies adopt and publish agency rules and regulations.

In the 1946 law, Congress provided for judicial review "except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion." APA, PL 79-404, Section 10.

In the 1966 law, Congress codified this provision at 5 USC 701: "(a) This chapter applies, according to the provisions thereof, except to the extent that (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 USC 701(a)

Statutory and administrative agency definitions for "communicable disease" and related terms

Layered atop the absence of any legal definition of the basic term 'disease' apart from lists of purported specific diseases established by Presidential executive order without physico-chemical evidentiary foundations, are circular definitions promulgated for adjectival forms such as communicable disease, infectious disease, quarantinable disease, vaccine-preventable disease, and disease "in a communicable stage," "in a precommunicable stage," and "in a qualifying stage."

As of 1988 and amended in 1999, for purposes of 21 CFR 312 (drugs intended to treat life-threatening and severely-debilitating illnesses), HHS defined the term “life-threatening” to mean "diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival" and HHS defined the term “severely debilitating” to mean "diseases or conditions that cause major irreversible morbidity." 21 CFR 312.81 (53 FR 41523; 64 FR 401)

In 2000, HHS issued a Final Rule under the authority of 42 USC 264, addressing control of communicable diseases; apprehension and detention of persons with specific diseases; and transfer of regulations from 21 CFR 1240 to 42 CFR 70.

HHS defined "communicable diseases" to mean "illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment." 42 CFR 70 (65 FR 49908)

In 2002, Congress defined the term "qualifying stage with respect to a communicable disease" to mean "that such disease is in a communicable stage; or is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals." 42 USC 264(d)(2) (PL 107-188)

World Health Organization, International Health Regulations (2005) defined "disease" to mean "an illness or medical condition irrespective of origin or source that presents or could present significant harm to humans" and noted, among the "innovations" of the WHO-IHR (2005): "scope not limited to any specific disease or manner of transmission."

Wikipedia defines "notifiable diseases," also known as "reportable diseases," as "any disease that is required by law to be reported to government authorities," and cites the WHO-IHR (2005), describing notification as based on the identification within a State Party’s territory of an "event that may constitute a public health emergency of international concern." In the United States, notifiable diseases are defined by case definitions for each alleged disease, through lists maintained by the CDC National Notifiable Diseases Surveillance System.

In 2006, Congress defined the term “infectious disease” to mean "a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person." 42 USC 247d-6a(a)(2)(B) (PL 109-417)

As of 2009, under provisions for "expanded access to investigational drugs for treatment use," HHS defined "immediately life-threatening disease or condition" to mean "a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment." 21 CFR 312.300 (74 FR 40943)

HHS defined "serious disease or condition" to mean "a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one." 21 CFR 312.300 (74 FR 40943)

As of 2012, HHS defined "quarantinable communicable disease" to mean "any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act, [42 USC 264] Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005 and any subsequent Executive Orders." 42 CFR 70.1 (77 FR 75880 and 75885)

As of 2017, HHS defined "qualifying stage" of a quarantinable disease as "statutorily defined (42 U.S.C. 264(d)(2))" [as of 2002, PL 107-188] "to mean: (1) The communicable stage of a quarantinable communicable disease; or (2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals." 42 CFR 70.1 (82 FR 6970)

As of 2017, HHS defined "communicable stage" to mean "the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual." 42 CFR 70.1 (82 FR 6969).

As of 2017, HHS defined "precommunicable stage" to mean "the stage beginning upon an individual's earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage." 42 CFR 70.1 (82 FR 6969)

As of 2017, HHS defined "non-quarantinable communicable diseases of public health concern" as "those diseases that because of their potential for spread, particularly during travel, may require a public health intervention." HHS presented this definition, not as part of a Final Rule establishing a definition under a regulation, but simply as a paragraph in a Federal Register notice. (82 FR 6892)

A 2019 Congressional Research Service report, *Global Vaccination: Trends and U.S. Role*. (R45975), defined "vaccine-preventable disease" as "an infectious disease for which an effective preventive vaccine exists," citing as source "(CDC), *Vaccines and Preventable Diseases*, https://www.cdc.gov/vaccines/vpd/index.html" [As of August 2025, this link redirected to a page listing "Vaccines by Disease."]

Discussion

The 1905 *Jacobson* ruling and the 2020 *South Bay Pentecostal* ruling reinforce the principle of judicial non-review of scientific, medical and public "common beliefs" and executive and administrative agency acts predicated on those "common beliefs," even if the beliefs are wholly false, and known to be false yet intentionally promoted for public belief by deceitful actors positioned and motivated to suppress contradicting evidence.

The principle of judicial non-review is also reinforced by provisions of the 1946 Administrative Procedure Act, as codified in 1966, and provisions of vaccination and public health emergency laws through which Congress has explicitly committed agency acts to agency discretion. 21 USC 360bbb-3(i), for example, commits to agency discretion actions taken by the HHS Secretary, DHS Secretary and Secretary of Defense to "determine" whether an emergency exists, and actions taken by the HHS Secretary to "conclude" that "an agent...can cause a serious or life-threatening disease or condition" and that a product "may be effective in diagnosing, treating, or preventing such disease or condition."

The more uncertain the scientific or medical basis for a government biomedical policy, program or product, the less judicial review is brought to bear on legislative and executive governmental acts.

Scientific and medical bases for government policies, programs and products are completely fraudulent for communicable disease classification and case diagnosis, for infectious agent classification, and for vaccination as a method to prevent alleged infection and alleged transmission, and cause-and-effect relationships are imputed, in circular form, without evidentiary foundation.

Disease is presumed to be "an illness caused by an agent or toxin," as reflected in 7 USC 8401(a)(1)(B)(i)(III) and (IV) under "criteria" for determining whether to include an agent or toxin on the agricultural "biological select agents and toxins" list.

A virus "is a product containing the minute living cause of an infectious disease" according to the first US regulatory definition published in 1919, and is currently "interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa." 21 CFR 600.3(h)(1)

There are no required or feasible physico-chemical definitions, claim validation methods or evidentiary review procedures for events, conditions, substances or causation.

Section 2
Mutual Recognition Agreements

Mutual Recognition Agreements or MRAs are international treaties or trade agreements governing the import and export of regulated, manufactured consumer products.

MRAs have been negotiated and signed to enable regulators representing different countries to share information about their regulatory reviews, keep the regulatory information confidential from the public, and defer to each others' legal decisions concerning regulatory compliance, without conducting independent evidentiary collection and assessments.

Political and commercial momentum for MRAs developed in the mid-1980s, exemplified by a May 7, 1985 European Council resolution "on a new approach to technical harmonization and standards," followed by EC Resolution 90/C 10/01, "on a global approach to conformity assessment" adopted Dec. 21, 1989, accompanied by the founding of the International Committee for Harmonisation in 1990.

The US-European Union Mutual Recognition Agreement was negotiated in 1997 and 1998, signed in London on May 18, 1998, and entered into force Dec. 1, 1998.

The US-EU MRA covers several manufacturing sectors, including telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical Good Manufacturing Practices (GMPs) and medical devices.

US-FDA inserted the 1998 MRA sectoral annex provisions on pharmaceutical GMPs into the US Code of Federal Regulations at 21 CFR 26, by Federal Register Notice of Final Rule. (63 FR 60122, Nov. 6, 1998)

US and EU officials negotiated an "amended sectoral annex for pharmaceutical good manufacturing practices," signed Jan.19, 2017, which entered into full force July 11, 2019 after a transition period.

Among other provisions relevant to the non-regulation of non-medicines known as Covid-19 vaccines, Article 9 of the 2017 sectoral annex for GMP "relieves" the "qualified persons" in EU countries who receive drug products imported from the United States of "responsibility for carrying out" batch testing controls under Article 51, Paragraph 2 of EU Directive 2001/83/EC, Community code relating to medicinal products for human use, as adopted by European Parliament and European Council Nov. 6, 2001.

> Article 9
>
> Batch testing
>
> In the EU, as provided in Article 51 paragraph 2 of Directive 2001/83/EC and in Article 55 paragraph 2 of Directive 2001/82/EC, the qualified person will be relieved of responsibility for carrying out the controls laid down in Article 51 paragraph 1 of

Directive 2001/83/EC and in Article 55 paragraph 1 of Directive 2001/82/EC provided that these controls have been carried out in the United States, the product was manufactured in the United States and that each batch/lot is accompanied by a batch certificate (in alignment with the WHO certification scheme on the quality of medicinal products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

As of March 2024, US-FDA had signed, in-force MRAs covering pharmaceuticals intended for human use with at least 29 countries in Europe.

Most European countries were folded into the US-EU MRA treaty through the European Union, with each country's government recognizing the treaty and the amended sectoral annex between November 2017 and November 2019.

- Nov. 1, 2017 - Austrian Agency for Health and Food Safety; Croatian Agency for Medicinal Products and Medical Devices; French National Agency for Medicines and Health Products Safety; Italian Medicines Agency; Malta Medicines Regulatory Authority; Spanish Agency of Medicines and Medical Devices; Sweden Medical Products Agency
- March 1, 2018 - Czech Republic State Institute for Drug Control; Greece National Organisation for Medicines; Hungary National Institute of Pharmacy and Nutrition; Romania National Agency for Medicines and Medical Devices
- June 1, 2018 - Ireland Health Products Regulatory Authority; Lithuania State Medicines Control Agency
- Sept. 14, 2018 - Portugal National Authority of Medicines and Health Products
- Nov. 16, 2018 - Belgian Federal Agency for Medical and Health Products; Danish Medicines Agency; Finnish Medicines Agency; Latvia State Agency of Medicines
- Feb. 7, 2019 - Poland, Main Pharmaceutical Inspectorate; Slovenia Agency for Medicinal Products and Medical Devices
- April 29, 2019 - Bulgarian Drug Agency; Cyprus Ministry of Heath - Pharmaceutical Services
- June 10, 2019 - Luxembourg Ministry of Health, Division of Pharmacy and Medicines; Netherlands Healthcare Inspectorate
- June 26, 2019 - German Central Office of the Federal States for Health Protection for Drugs and Medical Devices
- July 11, 2019 - Slovakia State Institute for Drug Control
- Nov. 28, 2019 - Estonia State Agency of Medicines

Although Switzerland and United Kingdom are not member-states of the European Union, both are also parties to MRAs with the United States, effective Nov. 1, 2017 for the UK Medicines and Healthcare products Regulatory Agency (MHRA), and July 27, 2023 for the Swiss Agency for Therapeutic Products (Swissmedic).

Section 3
United States Congressional Acts

1938 - 21 USC 355(i) [FDCA 505(i)]
Title 21: Food and Drugs
New drugs
Exemptions of drugs for research

In 1938 (PL 75-717), Congress enacted the Federal Food Drug and Cosmetic Act [FDCA], amending and expanding provisions of the 1906 Pure Food and Drug Act (PL 59-384).

Under provisions governing approval of applications for new drugs to enter into interstate commerce, Congress authorized the putative regulator (Secretary of Agriculture at the time[3]) to "promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs." 21 USC 355(i) as of 1938.

Congress defined the term drug:

> The term "drug" means
>
> (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories. FDCA 201(g)

[3] Through President Franklin Roosevelt's Reorganization Plan No. 4 of 1940, promulgated by authority under the 1939 Reorganization Act (PL 76-19) of Congress, most functions of the USDA Food and Drug Administration were transferred to the Federal Security Agency, under the direction and supervision of the FSA Administrator. The Chief of the Food and Drug Administration was renamed the Commissioner of Food and Drugs. (54 Stat. 1234, 1237)

1944 - Public Health Service Act
Title 42: Public Health and Welfare
General Powers and Duties

In 1944 (PL 78-410), Congress passed the Public Health Service Act, consolidating and expanding federal public health laws enacted and developed during preceding decades.

Title III of the act, General Powers and Duties, included seven parts: Part A, Research and Investigations; Part B, Federal-State Cooperation; Part C, Hospitals, Medical Examinations and Medical Care; Part D, Lepers; Part E, Narcotics Addicts; Part F, Biological Products; and Part G, Quarantine and Inspection.

Of those seven sections, four were key pillars of communicable disease control and vaccination programs: Research and Investigation, Federal-State Cooperation; Biological Products and Quarantine and Inspection.

Congress consolidated authorization and funding for federal development (in partnership with drug companies) of disease classification and diagnosis programs, and programs for development of products alleged to prevent or treat such diseases as defined by the Public Health Service, through the Research and Investigation section. (Part A)

Congress consolidated authorization and funding for programs offering State governments funding in exchange for support and implementation of federal communicable disease surveillance, diagnosis, quarantine and vaccination programs, which had been designated as "Prevention of Epidemics" programs prior to 1944, through the Federal-State Cooperation section. (Part B)

Congress consolidated authorization and funding for programs purporting to regulate establishments propagating and manufacturing vaccines and other biological products, through the Biological Products section. (Part F)

Congress consolidated authorization and funding for programs purporting to diagnose cases of purportedly communicable diseases, collect and disseminate information about outbreaks, and control the movement of people, animals and goods allegedly infected or contaminated, through the Quarantine and Inspection section. (Part G)

1944 - 42 USC 241 et seq
Title 42: Public Health and Welfare
Public Health Service, General Powers and Duties
Part A - Research and Investigation

In 1944 (PL 78-410), Congress authorized and directed the Surgeon General to "encourage, cooperate with, and render assistance to other...public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control and prevention of physical and mental disease and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams." 42 USC 241

Congress authorized the Surgeon General to collect and publish information; provide PHS research facilities; set up research fellowships; make grants to universities, hospitals and individuals; obtain assistance from experts in the US and abroad; admit persons for study and treatment at PHS hospitals; and adopt other means (as recommended by the national health advisory council and national advisory cancer council). 42 USC 241(a) through (f)

Under another section of the 1944 PHSA, Congress authorized funding for carrying out the research and investigation provisions, including "expenditure for personal services and rent at the seat of Government, for books of reference, periodicals, and exhibits, and for printing and binding." [PHSA 509]

1944 - 42 USC 243 et seq
Title 42: Public Health and Welfare
Public Health Service, General Powers and Duties
Part B - Federal-State Cooperation

In 1930, (PL 71-106, *An Act to provide for coordination of public-health activities of the Government)* Congress, without defining "public health," had authorized the Treasury Secretary to detail PHS officers to any federal executive department or "independent establishment which is carrying on a public-health activity...to cooperate in such work," and to pay PHS officers for such work. Congress authorized the PHS Surgeon General to detail PHS employees to "educational and research institutions" to study and disseminate information on "scientific problems relating to public health;" and to make federal PHS facilities available to health officials and scientists. Congress authorized the Treasury Secretary to set up facilities to coordinate research and "demonstrations of sanitary methods and appliances." To support those programs, Congress funded "educational exhibits...the preparation of public-health exhibits designed to demonstrate the cause, prevalence, methods of spread, and measures for preventing disease dangerous to the public health..." including "acquiring, transporting, and displaying exhibit material."

In 1944 (PL 78-410), Congress further developed the federal-state cooperation program, authorizing the Surgeon General to accept help from State and local authorities in enforcing quarantine regulations; to help State and local authorities enforce their State and local quarantine rules; and to "advise" the States "on matters relating to the preservation and improvement of public health." 42 USC 243 [PHSA 311, *In general*]

Congress directed the Surgeon General to convene an annual conference of State health authorities, and other conferences if useful "in his opinion," with each State to be entitled to a single vote at such conferences. 42 USC 244 [PHSA 312, *Health conferences*]

Congress directed the Surgeon General to prepare and distribute forms for the collection and compilation of mortality, morbidity and vital statistics, and to publish public health reports. 42 USC 245 [PHSA 313, *Collection of vital statistics*]

Congress authorized the Surgeon General to provide grants to States for the prevention, treatment and control of venereal diseases and tuberculosis, and to "assist, through grants and as otherwise provided in this section, States, counties, health districts, and other political subdivisions of the States in establishing and maintaining adequate public health services, including grants for demonstrations and for the training of personnel for State and local health work." Congress provided funds for the PHS demonstration and training grant programs. 42 USC 246(a) through (c) [PHSA 314, *Grants and services to States*]

Congress authorized the Surgeon General, with the FSA Administrator, to "make allotments" among the several States on the basis of population, "the size of the venereal disease problem, the size of the tuberculosis problem, and the size of other special health problems," and the financial need of the respective States. Congress directed that the money be expended "in accordance with plans presented by the health authority and approved by the Surgeon General,"

and on condition that the States and local political subdivisions would spend State and local money "for the same general purpose." Congress authorized the Surgeon General to withhold certification for federal payouts, in the event he identified a State or local health authorities' failure to comply with the federal public health laws, the State or local governments' public health plan, or federal regulations. 42 USC 246(d) through (i) [PHSA 314, *Grants and services to States*]

Congress authorized the Surgeon General to use the available funds to pay for "printing and binding of the findings of investigations" and for pay, allowances and travel expenses of PHS personnel. 42 USC 246(j) [PHSA 314, *Grants and services to States*]

Congress directed the Surgeon General to "issue information related to public health, in the form of publications..." and "to publish weekly reports of health conditions" in the US and other countries. 42 USC 247, [PHSA 315, *Health education and information*]

1944 - 42 USC 262-263
Title 42: Public Health and Welfare
Public Health Service, General Powers and Duties
Part F - Regulation of biological products;
Preparation of biological products

In 1944 (PL 78-410), Congress consolidated and expanded provisions governing a licensing process appearing to regulate establishments engaged in the propagation, labeling, sale, barter and exchange of biological products, defined in the law to mean

> "any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man."

The establishment-licensing provisions passed by Congress in 1944, incorporated provisions of the 1902 Virus-Toxin law (*An Act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes*, which had been in effect between 1902 and 1944.

42 USC 262 [PHSA 351] - Regulation of biological products

In 1944 (PL 78-410), Congress prohibited intrastate, interstate and import-export trafficking of "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood components or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man," unless the product had been "propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the [Federal Security Agency] Administrator and each package was "plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results." 42 USC 262(a)

Congress prohibited falsely labeling, marking or altering any package. 42 USC 262(b).

Congress authorized Public Health Service agents to enter and inspect establishments. 42 USC 262(c)

Congress provided that "licenses for the maintenance of establishments for the propagation or manufacture and preparation of products...may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations" and "licenses for new products may be issued only upon a showing that they meet such standards." 42 USC 262(d)

42 USC 262(d) provided that all such licenses "shall be issued, suspended, and revoked as prescribed by regulations" and that "all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for

sale, barter or exchange in the United States, shall be issued upon condition that the licensees will permit the inspection of their establishments."

Congress directed that regulations be "prescribed" by a three-member committee comprised of the Surgeon Generals of the Army, Navy and Public Health Service, subject to approval by the Administrator of the Federal Security Agency that had been established by President Roosevelt in 1939.[4] 42 USC 262(d)

Congress prohibited "interference" with officers of the Public Health Service performing duties. 42 USC 262(e)

Congress provided for penalties for violators, of fines of not more than $500 or imprisonment up to one year, or both, in the discretion of the court. 42 USC 262(f).

Congress provided that "nothing in the biological product manufacturing regulation statute shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]. 42 USC 262(g)

42 USC 263 [PHSA 352] Preparation of biological products

In 1944 (PL 78-410), Congress authorized the Public Health Service to "prepare for its own use any product described in [PHSA 351/42 USC 262, *Regulation of biological products*] and any product necessary to carrying out any of the purposes of [PHSA 301/42 USC 241, *Research and investigation*]. 42 USC 263(a)

Congress authorized the Public Health Service to "prepare any [biological] product described in [42 USC 262] for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section." 42 USC 263(b)

[4] In 1953, by executive order for reorganization, President Eisenhower abolished the Federal Security Agency, led by the FSA Administrator, and replaced the FSA with the Department of Health, Education and Welfare (HEW), led by the HEW Secretary. In 1958, Congress removed the Surgeon Generals of the Army and Navy from the committee tasked with "prescribing" regulations, leaving the responsibility with the Surgeon General of the Public Health Service, subject to the approval of the Secretary of Health, Education and Welfare. In 1966, by executive order for reorganization, President Johnson transferred all functions of the Public Health Service and PHS Surgeon General, including prescription of biological product manufacturing regulations, to the HEW Secretary. In 1979, these authorities transferred to the Secretary of the Department of Health and Human Services (HHS), who holds them as of 2025.

Discussion

The 1944 "regulation of biological products" law authorized classification of biological products as "applicable to the prevention, treatment, or cure of diseases or injuries of man" without requiring presentation of physical evidence in support of claims, without requiring compliance with any evidentiary standards, and without authorizing fact-finding procedures or venues such as courts or legislative hearings.

The word "vaccine" did not appear in the law. Congress added it, without definition, in 1970.

The words "continued safety, purity and potency" appear in the law, but Congress did not enact physico-chemical definitions for those terms, or direct agency administrators to prescribe physico-chemical definitions. Congress did not designate valid tests able to demonstrate compliance with physico-chemical standards, or direct agency administrators to prescribe valid tests. Congress did not establish evidentiary standards, or authorized fact-finding procedures or venues.

A product was deemed "applicable to the prevention, treatment or cure of diseases or injuries of man" and "safe, pure and potent" if the manufacturers and regulators asserted and labeled it as applicable, safe, pure and potent while holding an active establishment license issued by the US Department of Treasury until 1939, Federal Security Agency (1939-1953), Department of Health, Education and Welfare (1953-1979), and Department of Health and Human Services (1979-present).

Congress did not require labels to contain information about the physical identity or composition of the contents. As a result, the law did not establish any physical basis on which any manufacturer, packager, regulator or consumer could find any label's contents to be false, or find any container's contents to be adulterated or contaminated.

Congress did not require Public Health Service inspectors to obtain or test samples, to establish physical quality standards or tests capable of identifying container contents or assessing the purity, safety or potency of container contents. Congress did not require Public Health Service inspectors to report findings to prosecutors, did not require prosecutors to investigate and enforce standards, and did not designate a court in which criminal charges could be filed and evidentiary review conducted.

Nationwide vaccination programs using products labeled as vaccines applicable to diphtheria, tetanus, pertussis and polio were carried out under the 1944 PHSA framework by 1955, followed later by use of products labeled as applicable to measles, mumps, rubella and other diseases purportedly prevented by products listed on immunization schedules.

Regulations: Definitions as of September 1947 (12 FR 6218)

42 CFR 73.1(k) "Dating period" means the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results.

42 CFR 73.1(m) The word "standards" means specifications and procedures applicable to an establishment or to the production, content, testing, labeling or release of products prepared therein, which are prescribed in this part and which are designed to insure the continued safety, purity and potency of such products.

42 CFR 73.1(n) "The word "continued" as applied to the safety, purity and potency of products, is interpreted to apply to the dating period.

42 CFR 73.1(o) The word "safety" is interpreted to apply to the relative freedom from harmful effect to the recipient when a product is prudently administered taking into consideration the character of the product in relation to the condition of the patient at the time.

42 CFR 73.1(p) The word "purity" is interpreted to mean the degree of freedom from extraneous matter, whether harmful to the recipient, deleterious to the product or otherwise, in the finished product.

42 CFR 73.1(q) The word "potency" is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result."

Regulations: Definitions as of November 1973 (38 FR 32048)

21 CFR 600.3(l) - “Dating period” means the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results.

21 CFR 600.3(n) - The word "standards” means specifications and procedures applicable to an establishment or to the manufacture or release of products, which are prescribed in this subchapter and which are designed to insure the continued safety, purity and potency of such products.

21 CFR 600.3(o) - The word “continued” as applied to the safety, purity and potency of products is interpreted to apply to the dating period.

21 CFR 600.3(p) - The word “safety” means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

21 CFR 600.3(q) - The word “sterility” is interpreted to mean freedom from viable contaminating microorganisms, as determined by the tests prescribed in Sec. 610.12 of this chapter

21 CFR 600.3(r) - "Purity" means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. "Purity" includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

21 USC 600.3(s) - The word "potency" is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

Regulations: Definitions as of August 2025

[38 FR 32048, Nov. 20, 1973, as amended at 40 FR 31313, July 25, 1975; 55 FR 11014, Mar. 26, 1990; 61 FR 24232, May 14, 1996; 62 FR 39901, July 24, 1997; 64 FR 56449, Oct. 20, 1999; 65 FR 66634, Nov. 7, 2000; 69 FR 18766, Apr. 8, 2004; 70 FR 14982, Mar. 24, 2005; 73 FR 39610, July 10, 2008; 77 FR 26174, May 3, 2012; 85 FR 10063, Feb. 21, 2020]

21 CFR 600.3(l) - *Dating period* means the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results.

21 CFR 600.3(n) - The word *standards* means specifications and procedures applicable to an establishment or to the manufacture or release of products, which are prescribed in this subchapter or established in the biologics license application designed to insure the continued safety, purity, and potency of such products.

21 CFR 600.3(o) - The word *continued* as applied to the safety, purity and potency of products is interpreted to apply to the dating period.

21 CFR 600.3(p) - The word *safety* means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

21 CFR 600.3(q) - The word *sterility* is interpreted to mean freedom from viable contaminating microorganisms, as determined by the tests conducted under §610.12 of this chapter.

21 CFR 600.3(r) - *Purity* means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. *Purity* includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

> 21 CFR 600.3(s) - The word *potency* is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.
>
> 21 CFR 610.12(h)(2) - A manufacturer is not required to comply with the sterility test requirements if the Director of the Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research, as appropriate, determines that data submitted in the biologics license application or supplement adequately establish that the route of administration, the method of preparation, or any other aspect of the product precludes or does not necessitate a sterility test to assure the safety, purity, and potency of the product.

Discussion

Safety, purity and potency have been defined in relative terms, or linguistic terms (i.e. "the word [...] is interpreted to mean"), but not in objective, ascertainable or measurable physico-chemical terms.

Use of the qualifier term "applicable to" in the 1947 definition for the word "standards" enabled the non-standardization of products in themselves.

By 1973, by omission, the definition for the word "standards" excluded specifications and procedures applicable to any product in itself.

No physico-chemical product standards have been established or prescribed by federal regulators.

No valid product testing standards or methods have been established or prescribed by federal regulators, and regulations that established or prescribed invalid standards or methods prescribed, also included provisions authorizing those invalid standards to be deemed inapplicable to any product.

1944 - 42 USC 264
Title 42: Public Health and Welfare
Public Health Service, General Powers and Duties
Part G - Quarantine and inspection, communicable disease control

In 1944 (PL 78-410), through the Public Health Service Act, Congress consolidated communicable disease control law and programs under the control of the Surgeon General of the Public Health Service.

For background, in 1878 (45th Congress, Session II, Ch. 66) Congress had passed the National Quarantine Act, authorizing the Marine-Hospital Service (precursor to the Public Health Service) to supervise foreign quarantine programs. The act was titled: *An act to prevent the introduction of contagious or infectious diseases into the United States*.

State and local laws addressing disease control had already been adopted by many States and municipalities; the 1878 quarantine act was the first federal law governing disease surveillance, isolation and "disinfection" of passengers and goods on inbound ships, coming from foreign ports, on the pretext of communicable disease control. The alleged infectious diseases mentioned by name in the act were cholera and yellow fever.

In 1890 (51st Congress, Session I, Ch. 51) Congress authorized the Marine-Hospital Service to supervise interstate quarantine, controlling movement of people and goods across State borders within the United States. The act was titled: *An act to prevent the introduction of contagious diseases from one State to another and for the punishment of certain offenses*.

Congress established that "whenever it shall be made to appear to the satisfaction of the President that cholera, yellow-fever, small-pox or plague exists in any State or Territory, or in the District of Columbia," the President was authorized to direct the Treasury Secretary to promulgate regulations to prevent the spread of the disease across State borders, and to employ inspectors to enforce such regulations.

Congress funded Public Health Service programs including research at the Hygienic Lab; treatment of patients at marine hospitals; operation of quarantine stations and medical inspection of aliens arriving on foreign ships at US ports; and federal payments to state and local health boards for "prevention of epidemics."

In passing the foreign quarantine law in 1878 and the interstate quarantine law in 1890, Congress did not cite or present physical evidence to support the premise that diseases are caused by communicable or contagious pathogens in a one-to-one, cause-and-effect relationship. Congress did not provide physical definitions for "contagious diseases," or direct the President, Treasury Secretary or Marine Hospital Service to cite or present physical evidence or establish physical definitions when issuing orders or conducting inspection and quarantine programs.

In 1944, Congress consolidated the existing quarantine laws and programs under the Public Health Service Act Sec. 361, codified at 42 USC 264.

Congress authorized the Surgeon General, with the approval of the Federal Security Agency Administrator, to "make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." Congress listed, as subjects for regulation, "inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary." 42 USC 264(a)

Congress prohibited the Surgeon General from prescribing regulations for "the apprehension, detention, or conditional release of individuals," directing that "regulations...shall not provide for the apprehension, detention, or conditional release of individuals" but included an exception: "except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General." 42 USC 264(b)

Congress limited application of communicable disease control regulations, "insofar as they provide for the apprehension, detention, examination, or conditional release of individuals...only to individuals coming into a State or possession from a foreign country, the Territory of Hawaii, or a possession," 42 USC 264(c), but Congress authorized an exception, " as provided in subsection (d)".

Congress authorized Surgeon General regulations to "provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage" and either "moving or about to move from a State to another State" or " a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State." Congress directed the Surgeon General to make such regulations "on recommendation of the National Advisory Health Council," and authorized the regulations to provide that "if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary." 42 USC 264(d).

Discussion

In 1944, when consolidating federal quarantine law, Congress did not cite physical evidence to support the premise that diseases are caused by communicable or infectious pathogens in a one-to-one, cause-and-effect relationship, and Congress did not provide physical definitions for communicable diseases, or "in a communicable stage," or direct the President to cite physical evidence or establish physical definitions when issuing executive orders listing communicable diseases.

Congress did not direct the Surgeon General to establish, by regulation, physical definitions for communicable diseases. Congress did not establish standards of evidence against which claimed communicable diseases could be assessed, did not direct the Surgeon General to establish such standards by regulation, and did not provide any process for evidentiary review of Presidential or Surgeon General determinations.

Congress authorized the detention regulations to be applied “only” to people entering the United States from abroad, except Congress also authorized their application to people traveling between US states, or spending time with other people who might be traveling between US states.

1950 - 50 USC Ch. 55 (Sec. 4501 et seq)
Title 50: War and National Defense
Defense Production Act
Voluntary Agreements, criminal and civil liability, defenses

In 1950 (PL 81-774), Congress enacted the Defense Production Act, establishing as federal policy, "to oppose acts of aggression and to promote peace by insuring respect for world law and the peaceful settlement of differences among nations....to support collective action through the United Nations and through regional arrangements for mutual defense in conformity with the Charter of the United Nations...[and] to develop and maintain whatever military and economic strength is found to be necessary to carry out this purpose."

Congress declared:

> Under present circumstances, this task requires diversion of certain materials and facilities from civilian use to military and related purposes. It requires expansion of productive facilities beyond the levels needed to meet the civilian demand. In order that this diversion and expansion may proceed at once, and that the national economy may be maintained with the maximum effectiveness and the least hardship normal civilian production and purchases must be curtailed and redirected. It is the objective of this Act to provide the President with authority to accomplish these adjustments in the operation of the economy. It is the intention of the Congress that the President shall use the powers conferred by this Act to promote the national defense, by meeting, promptly and effectively, the requirements of military programs in support of our national security and foreign policy objectives, and by preventing undue strains and dislocations upon wages, prices, and production or distribution of materials for civilian use, within the framework, as far as practicable, of the American system of competitive enterprise.

Congress authorized the President "to consult with representatives of industry, business, financing, agriculture, labor and other interests, with a view to encouraging the making by such persons with the approval by the President of voluntary agreements and programs to further the objective of this Act." DPA, Sec. 708(a), codified at 50 USC 2158(a), later renumbered to 50 USC 4558(a).

Congress provided that acts or omissions pursuant to the Act, if requested by the President pursuant to a voluntary agreement or program, "shall not be construed to be within the prohibitions of the antitrust laws or the Federal Trade Commission Act." DPA Sec. 708(b)/50 USC 4558(b)

Congress authorized the President to delegate the authority to make voluntary agreements to other federal officials, with the advice and consent of the Senate, subject to consultation with the Attorney General and Chairman of the Federal Trade Commission. DPA Sec. 708(c)/50 USC 4558(c)

Congress did not define the term 'voluntary agreement.'

Discussion:

Through the "voluntary agreements" provisions of the Defense Production Act, Congress legalized racketeering, collusion and other forms of organized crime when carried out by the US Government working with private corporations.

In 1975, (PL 94-152) Congress amended the provisions of 50 USC 4558 to provide defenses for persons subject to civil or criminal prosecution, and in 1991 (PL 102-99), Congress provided for preemption of contract law during emergencies.

In 2012 President Obama issued an Executive Order delegating authority to enter into voluntary agreements to the Secretary of Health and Human Services for "health resources" defined to mean "drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population." (Executive Order 13603)

In 2020, President Trump issued an Executive Order delegating voluntary agreement authority to the HHS Secretary and DHS Secretary. (Executive Order 13911)

1955, 1956 - 42 USC 246 [PHSA 314]
Title 42: Public Health and Welfare
PHS General Powers and Duties Part B, Federal-State Cooperation
Grants and services to States

In 1955 (PL 84-377), Congress passed "An act to provide grants to assist States to meet the cost of poliomyelitis vaccination programs, and for other programs," to be cited as the Poliomyelitis Vaccination Assistance Act of 1955.

The federal grant program -- codified as a statutory note under 42 USC 246, *Grants and services to States* -- supplemented polio vaccination programs conducted by the National Foundation for Infantile Paralysis (later renamed March of Dimes).

In 1955 (PL 84-377), Congress authorized appropriation of "such sums as may be necessary," for making payments to States which had submitted applications for grants for polio vaccination programs to the PHS Surgeon General, and had those applications approved. The funds were to remain available until Feb. 15, 1956. Sec. 2, *Authorization of Appropriations*

Congress directed the Surgeon General to allot amounts for purchase of vaccine [under Sec. 6(a)] based on a formula derived from one-third the number of "unvaccinated eligible persons" in each State, multiplied by the per-person cost of the polio vaccine times the States's "allotment percentage." Congress defined each State's "allotment percentage" as the per capita income of the US divided by the per capita income of the State, as determined by the Surgeon General using information from the Department of Commerce. Sec. 3(a)(1), *Allotments to States*.

Congress directed the Surgeon General to allot each State an additional amount (equal to 20% of the allotments under the formula in the preceding section), for planning vaccination programs and conducting programs through State public agencies [under Sec. 6(b)]. Sec. 3(a)(2), *Allotments to States*.

Congress directed States to submit applications including provisions for all vaccine bought with federal funds to be used for the vaccination of "eligible persons," pursuant to a plan setting forth methods for vaccines to be made available "through public agencies, approved nonprofit organizations, private physicians or otherwise;" for administration of the plan; for States to report to the Surgeon General; and for accounting procedures. Sec. 3, *State applications for funds*

Congress authorized the Surgeon General to set priority status for some categories of eligible persons and prohibited States from using "means tests" or other financial assessments to limit eligibility. Sec. 3, *State applications for funds*

Congress directed that the States could use federal funds from the allotment under Sec. 3(a)(1) only for the purchase of vaccine, and funds from the allotment under Sec. 3(a)(2) only for planning and conducting programs through State public agencies, except that excess funds could be reassigned for vaccine purchase. Sec. 6, *Use of funds paid to states*

Congress authorized the Surgeon General to directly furnish polio vaccine to any State "in lieu of such State's allotment (or such portion thereof)," upon the request of the State. Sec. 7, *Furnishing of vaccine by Surgeon General*

Congress directed the Surgeon General to monitor State agencies administering vaccination plans, and authorized the Surgeon General to suspend payments and vaccine supplies to States found to be "not complying substantially" with the federal grant program terms or the State's approved application, and States found to be diverting funds or vaccines from the authorized purposes. Congress authorized the Surgeon General to direct the State agency to correct the violations, or, if compliance impossible, to direct the State agency to repay the "diverted or improperly expended" funds or costs of diverted vaccines. Sec. 8, *Diversion of federal funds*

Congress directed the Surgeon General to exercise his functions under the supervision and direction of the Secretary of Health Education and Welfare. Sec. 9, *Exercise of functions*

Congress defined "eligible person" as "any individual who has not attained the age of twenty years and any expectant mother." Sec. 10(b)(1), *Definitions*

Congress directed the Surgeon General to "determine" the number of "eligible persons" -- expectant mothers, and infants, children and adolescents under age 20 -- as of June 30, 1955, using estimates based on Department of Commerce information. Sec. 10(b)(2)

Congress defined the number of "unvaccinated eligible persons" to mean the "eligible persons" population number, reduced by the number vaccinated during 1954 and reduced by two-thirds of the number the Surgeon General estimated would receive vaccines under the NFIP program. Sec. 10(b)(3)

Congress directed the Surgeon General to "determine" the cost of the polio vaccine "on the basis of information available to him; and such cost may be determined from time to time or as of a specified date and may be determined to be a single figure for all States or varied in accordance with actual cost." Sec. 10(d)

Congress defined the term "approved nonprofit organization" as "a nonprofit organization approved by the State agency responsible for administration...of the State plan." Sec. 10(e)

In 1956, (PL 84-411), Congress passed an act to extend the duration of the Poliomyelitis Vaccination Assistance Act of 1955, Sec 2 and Sec 6(a) and 6(b) grant programs, through June 30, 1957.

1962 - 21 USC 355(i) [FDCA 505(i)]
Title 21: Food and Drugs
New drugs
Exemptions of drugs for research

In 1962, (PL 87-781), Congress amended the exemptions section enacted in 1938 (PL 75-717), to add "and effectiveness" immediately after "safety" -- authorizing promulgation of "regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs" -- and to add four new provisions.

Congress authorized the HEW Secretary, "within the discretion of the Secretary," to prescribe regulations conditioning exemptions on sponsors submitting reports on preclinical tests, including tests on animals, "adequate to justify the proposed clinical testing" before any clinical testing.

Congress authorized the HEW Secretary, at his discretion, to condition exemptions on sponsors obtaining a signed agreement from each investigator "that patients to whom the drug is administered will be under his personal supervision...and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings."

Congress authorized the HEW Secretary, at his discretion, to condition exemptions on record-keeping by sponsors, and provision of records to the HEW Secretary, "of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug" in the event of the filing of a new drug application. 21 USC 355(i) as of 1962

Congress directed the HEW Secretary that regulations "shall" condition an exemption on investigation sponsors "requiring that experts using such drugs certify that they will inform humans to whom such drugs or any controls connected therewith are administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." 21 USC 355(i) as of 1962

Discussion

Congress authorized sponsors, manufacturers and investigators to use investigational drugs on human subjects without providing disclosures as to "investigational purposes," if the experts "deem it not feasible or...contrary to the best interests of such human beings."

One element of infeasibility, for biological products and vaccines, is that the contents of containers are not physico-chemically identifiable by or known to sponsors, manufacturers, investigators or regulators, and therefore cannot feasibly be disclosed to product recipients.

1962-1978 - 42 USC 247b [PHSA 317]
Title 42: Public Health and Welfare
PHS General Powers and Duties, Part B - Federal-State Cooperation
Grants for Intensive Vaccination Programs

In 1962 (PL 87-868), Congress passed the Vaccination Assistance Act of 1962, adding a new section to the Federal-State Cooperation provisions enacted in 1944 (PL 78-410, Public Health Service Act).

Congress titled the new section "Grants for Intensive Vaccination Programs," codified at 42 USC 247b [PHSA 317]. The program supplemented other immunization programs conducted by States with federal funding under "maternal and child health services" grant programs authorized by the Social Security Act of 1935 (PL 74-271, Sec. 501, 42 USC 701 et seq).

In 1962 (PL 87-868), Congress authorized appropriations of $11 million to $14 million per year for FY1963-1965, for the PHS Surgeon General to make grants to States and political subdivisions of States, to be used for purchase of vaccines for "intensive community vaccination programs against poliomyelitis, diphtheria, whopping cough and tetanus" to be used on "children under the age of five years" and additional groups of children upon Surgeon General findings that "they are not normally served by school vaccination programs." Congress authorized grant funds to also be used for salaries and related expenses for State and local health personnel "needed for planning, organizational and promotional activities...including studies to determine the immunization needs of communities and the means of best meeting such needs [and] expenses...to maintain additional epidemiologic and laboratory surveillance." 42 USC 247b(a)

Congress defined 'intensive community vaccination program' to mean

> a program of limited duration which is so designed and conducted as to achieve, with the cooperation of practicing physicians, official health agencies, voluntary organizations, and volunteers, the immunization against poliomyelitis, diphtheria, whooping cough, and tetanus over the period of the program of all, or practically all, susceptible persons in a community, particularly children who are under the age of five years, and which includes plans and measures looking toward the strengthening of ongoing community programs for the immunization against such diseases of infants and for maintenance of immunity in the remainder of the population. Nothing in this section shall be construed to require any State or any political subdivision or instrumentality of a State to have an intensive community vaccination program which would require any person who objects to immunization to be immunized or to have any child or ward of his immunized. 42 USC 247b(b)

Congress authorized the Surgeon General to make payments in advance or by reimbursement, "in such installments, and on such terms and conditions as the Surgeon General finds necessary," and authorized the Surgeon General to purchase and furnish vaccines to States and political subdivisions of States in lieu of money grants, upon request by the State. 42 USC 247b(c)(1)

Congress directed States and political subdivisions applying for money grants or vaccines, to assure the Surgeon General that each State would "furnish any physician...with such amounts of vaccines as are reasonably necessary...to immunize his patients who are in the group" designated as recipients of the vaccines. 42 USC 247b(c)(2)

Congress authorized the Surgeon General to assign PHS officers and employees to work in States and political subdivisions on immunization programs, and to reduce the amount of a grant by the amount of the pay, allowances, traveling expenses, and other costs of the assignment. 42 USC 247b(d)

Congress provided that funds granted to a State or to a political subdivision under the Social Security Act [PL 74-271 Title V; SSA 501 et seq; 42 USC 701-731, *Grants to States for maternal and child welfare*], other provisions of the Public Health Service Act, or other Federal law "for the purchase of vaccine or for organizing, promoting, conducting, or participating in immunization programs," could also be used for the purposes authorized under 42 USC 247b, *Grants for Intensive Vaccination Programs*.

In 1970 (PL 91-464), Congress renamed 42 USC 247b [PHSA 317] as "Communicable Disease Control and Vaccination Assistance," authorized $75-$90 million per year for FY 1971-1972, and amended and reorganized provisions at paragraphs (a) through (g). Congress defined the term 'communicable disease program' to mean:

> a program which is designed and conducted so as to contribute to national protection against tuberculosis, venereal disease, rubella, measles, Rh disease, poliomyelitis, diphtheria, tetanus, whooping cough or other communicable diseases which are transmitted from State to State, are amenable to reduction, and which are determined by the Secretary on the recommendation of the National Advisory Health Council to be of national significance. 42 USC 247b(b) as of 1970

In 1972 (PL 92-449), Congress renamed 42 USC 247b [PHSA 317] as "Grants for Vaccination Programs and Other Communicable Disease Control Programs" and amended and reorganized provisions at paragraphs (a) through (i).

Congress defined the term 'communicable disease control program' to mean:

> a program which is designed and conducted so as to contribute to national protection against tuberculosis, rubella, measles, Kh disease, poliomyelitis, diphtheria, tetanus, whooping cough, or other communicable diseases (other than venereal disease) which are transmitted from State to State, are amenable to reduction, and are determined by the Secretary to be of national significance.
>
> Such term includes vaccination programs, laboratory services, and studies to determine the communicable disease control needs of States and political subdivisions of States and the means of best meeting such needs. 42 USC 247b(h) as of 1972.

Congress directed the HEW Secretary to "develop a plan under which personnel, equipment, medical supplies, and other resources of the Service and other agencies under his jurisdiction may be effectively utilized to meet epidemics of, or other health emergencies involving, any disease referred to in subsection (h)(1)." 42 USC 247b(e) as of 1972.

Congress directed the HEW Secretary to submit annual reports to the President, for submission to Congress, on "the effectiveness of all Federal and other public and private activities in preventing and controlling the diseases referred to in subsection (h)(1); the extent of the problems presented by such diseases; the effectiveness of the activities, assisted under grants under this section, in preventing and controlling such diseases; and setting forth a plan for the coming year for the prevention and control of such diseases." 42 USC 247b(g) as of 1972

In 1976, (PL 94-317), Congress amended and renamed 42 USC 247b [PHSA 317] as "Disease Control Programs."

Congress defined the term 'disease control program' to mean

> a program which is designed and conducted so as to contribute to national protection against diseases or conditions of national significance which are amenable to reduction, including tuberculosis, rubella, measles, poliomyelitis, diphtheria, tetanus, pertussis, mumps, and other communicable diseases (other than venereal diseases), and arthritis, diabetes, diseases borne by rodents, hypertension, pulmonary diseases, cardiovascular diseases, and Rh disease.
>
> Such term also includes vaccination programs, laboratory services, studies to determine the disease control needs of the States and the means of best meeting such needs, the provision of information and education services respecting disease control, and programs to encourage behavior which will prevent disease and encourage the use of preventive measures and diagnostic procedures... 42 USC 247b(f) as of 1976

Congress directed grant applicants to "conduct...programs...to develop an awareness in those persons in the area served...who are most susceptible to the diseases or conditions...of appropriate preventive behavior and measures (including immunizations) and diagnostic procedures for such diseases, and to facilitate their access to such measures and procedures." 42 USC 247b(b)(2)(B) as of 1976.

Congress directed the HEW Secretary, in reviewing grant applications from States and political subdivisions, to "give special consideration to applications for programs which will increase to at least 80 per centum the immunization rates of any population identified as not having received, or as having failed to secure, the generally recognized disease immunizations." 42 USC 247b(b)(2) as of 1976

In 1976 (PL 94-380, summarized below), Congress added the National Swine Flu Immunization Program of 1976 to 42 USC 247b, as paragraphs (j), (k) and (l), including liability immunity for "program participants" (manufacturers, distributors and public health agencies) and "medical and other health personnel who provide inoculations."

In 1978 (PL 95-626), Congress amended and renamed 42 USC 247b as "Project Grants for Preventive Health Services," which, following many amendments in the intervening decades, remains its title as of 2025.

1969 - 50 USC 1511-1528
Title 50: War and National Defense
Chemical and Biological Warfare

On Nov. 19, 1969 (PL 91-121) Congress and President Nixon enacted the Defense Authorization Act, funding and setting up reporting requirements that the Defense Secretary report to Congress, twice each year, "the amounts spent during the preceding six-month period for research, development, test and evaluation and procurement of all lethal and nonlethal chemical and biological agents" and requiring the Secretary to include "a full explanation of each expenditure, including the purpose and necessity therefor." 50 USC 1511

Congress directed the Defense Secretary to notify the HHS Secretary about "the particulars of the proposed transportation, testing or disposal," of chemical and biological agents, with opportunity for the HHS Secretary, Surgeon General or other persons to "recommend...precautionary measures...to protect the public health and safety." 50 USC 1512(2)

Congress authorized the President to make determinations that "overriding considerations of national security require...transportation or testing be conducted" 50 USC 1512(3); and authorized the President to suspend the operation of the law or any portion of it "during the period of a war declared by Congress and during the period of any national emergency declared by Congress or by the President." 50 USC 1515

A week later, on Nov. 25, 1969, Nixon published a statement announcing US renunciation of first use of lethal chemical weapons, incapacitating chemicals, and lethal biological agents and weapons together with a plan to "confine its biological research to defensive measures such as immunization and safety measures." The same day Henry Kissinger, Chair, Joint Chiefs of Staff, issued National Security Decision Memorandum 35, exempting from the renunciation of chemical weapons "the use of riot control agents or herbicides;" confining "bacteriological/biological programs" to "research and development for defensive purposes (immunization, safety measures, et cetera)"; and exempting from the renunciation of bacteriological weapons, "research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required."

On Feb. 20, 1970, Kissinger issued NSDM 44, renouncing "the production for operational purposes, stockpiling and use in retaliation of toxins produced either by bacteriological or biological processes or by chemical synthesis," with the provision: "The United States military program for toxins will be confined to research and development for defensive purposes only."

Discussion

The Chemical and Biological Warfare chapter passed in 1969 did not include definitions for terms and phrases used in the law, including "lethal and nonlethal chemical and biological agents," "lethal chemicals," or "biological warfare agents." NSDM 35 and NSDM 44 did not define, in physical terms, lethal chemical weapons, incapacitating chemical weapons, bacteriological/biological agents, riot control agents, herbicides, toxins or other terms and phrases that appear in the documents.

1970 - 42 USC 262
Title 42: Public Health and Welfare
Regulation of biological products

In 1970, Congress and President Nixon added the words "vaccine, blood, blood component or derivative, allergenic product" to the list of biological products subject to manufacturing regulation under the 1944 Public Health Service Act.

Discussion

Congress did not define the term 'vaccine' in the statute by physical characteristics and did not direct the Public Health Service Surgeon General, Secretary of Health, Education and Welfare, or National Institutes of Health officers to define 'vaccine' in regulations by physical characteristics.

1970 - 42 USC 233 [PHSA 223]
Title 42: Public Health and Welfare
Defense of certain malpractice and negligence suits

In 1970 (PL 91-623) Congress enacted 42 USC 233, *Defense of certain malpractice and negligence suits*, providing an exclusive remedy under the 1946 Federal Tort Claims Act [28 USC 1346(b)[5] and 28 USC 2672[6]] for "damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment" and providing for the Attorney General to defend any such action brought in any court against any commissioned officer or employee of the Public Health Service. 42 USC 233(a) through (f)

In 2002 (PL 107-296) and 2003 (PL 108-20), Congress added provisions, under 42 USC 233, pertaining to liability protections for use of smallpox "countermeasures."

These provisions were among precursors to the PREP Act Congress passed in 2005 (PL 109-148).

[5] 28 USC 1346(b) - Judiciary and Judicial Procedure; district courts, jurisdiction; US as a defendant
[6] 28 USC 2672 - Tort Claims Procedure, Administrative adjustment of claims

1975 - 50 USC 1511-1528
Title 50: War and National Defense
Chemical and Biological Warfare

In 1975, (PL 94-106), Congress and President Gerald Ford defined "lethal binary chemical munitions" under the Chemical and Biological Warfare section (50 USC 1511-1528)

> ...lethal binary chemical munitions means
>
> (1) any toxic chemical (solid, liquid, or gas) which, through its chemical properties, is intended to be used to produce injury or death to human beings, and
>
> (2) any unique device, instrument, apparatus, or contrivance, including any components or accessories thereof, intended to be used to disperse or otherwise disseminate any such toxic chemical. 50 USC 1519(b)

1975 - 50 USC 4558 [DPA 708]
Title 50: War and National Defense
Defense Production Act, voluntary agreements

In 1975, (PL 94-152), Congress amended the Defense Production Act at Sec. 708.

One of the changes added a provision authorizing a defense for persons charged with violation of antitrust laws through civil or criminal actions.

Congress authorized the defense, "with respect to any act or omission to act to develop or carry out any voluntary agreement under this section, that such act or omission to act was taken in good faith by that person in the course of developing a voluntary agreement..., or to carry out a voluntary agreement...; and such person fully complied with this section and the rules promulgated hereunder, and acted in accordance with the terms of the voluntary agreement." 50 USC 4558(j) as of 1975

1976 - 42 USC 241; 42 USC 247v
Title 42: Public Health and Welfare, Public Health Service
Research and Investigation
Grants for Intensive Vaccination Programs
Liability protection procedures

In April 1976 (PL 94-266, H.J. Res. 890), Congress passed emergency supplemental appropriations for programs including "preventative health services."

Congress authorized $135,064,000 for the Department of Health, Education and Welfare, Center for Disease Control, "for carrying out...a comprehensive nationwide influenza immunization program....Provided, that vaccines may be supplied to State and local health agencies without charge."

In August 1976 (PL 94-380), Congress amended provisions governing PHS *Grants for Vaccination Programs and Other Communicable Disease Control Programs*, established at 42 USC 247b [PHSA 317] in 1962 (PL 87-868) as *Grants for Intensive Vaccination Programs*.

In August 1976 (PL 94-380, National Swine Flu Immunization Program of 1976) Congress added three subsections, codified at 42 USC 247b(j), (k) and (l). Subsection (j) established a nationwide swine flu immunization program. Subsection (k) established liability claim procedures to "protect agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccines" and defined the term "program participant." Subsection (l) provided definitions for phrases not defined elsewhere.

Congress authorized the HEW Secretary to establish, conduct, and support (by grant or contract) needed activities to carry out a national swine flu immunization program, to run through Aug. 1, 1977. 42 USC 247b(j)(1)

Congress directed the swine flu program to include the "development of a safe and effective swine flu vaccine;" preparation and procurement of "such vaccine" in sufficient quantities for the immunization of the population of the States; making grants to State health authorities to operate programs to administer vaccine to their populations, and furnishing sufficient quantities; furnishing appropriate quantities to Federal health authorities; training personnel for immunization activities and for "research on the nature, cause, and effect of the influenza against which the swine flu is designed to immunize, the nature and effect of such vaccine, immunization against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza;" and "such other activities as are necessary to implement the swine flu program." 42 USC 247b(j)(1)(A)-(E), (G) as of 1976.

Congress directed that the swine flu immunization program include development of a "written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered...[including procedures providing] the information necessary to advice individuals with respect to their rights and remedies arising out of the administration of such

vaccine." Congress directed the HEW Secretary to develop the informed consent form in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [established by Congress in 1974 (PL 93-348)]. 42 USC 247b(j)(1)(F)

Congress directed the HEW Secretary to submit quarterly reports on the current supply of the swine flu vaccine, the number of persons inoculated during each quarterly report period, the "immune status of the population," the amount of funds expended during each report period, and "the epidemiology of influenza in the United States" during each report period. 42 USC 247b(j)(2)

Congress provided that procurement contracts for vaccine "shall be subject to renegotiation to eliminate any profit realized," with an exception for "an amount not exceeding a reasonable profit" for "vaccine against the strain of influenza virus known as influenza A/Victoria/75." Congress directed the HEW Secretary to prescribe criteria for renegotiation of contracts, specifying that insurance premiums included in vaccine pricing, that might be refunded to manufacturers under any future, "retrospective, experience-rating plan[7] or similar rating plan" would, in turn, be refunded to the United States. 42 USC 247b(j)(3)

At subsection (k), Congress established protection from liability for program participants.

Congress provided, as findings, that to achieve program participation by "the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine," and to ensure the availability of vaccine in interstate commerce, "it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccine." 42 USC 247b(k)(1)(A)(i)

Congress found that, to provide such liability protection and establish orderly procedures, "it is necessary that an exclusive remedy for such claimants be provided against the United States because of its unique role in the initiation, planning, and administration of the swine flu program," and that "it is necessary" to institute a procedure for handling of claims "until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act." 42 USC 247b(k)(1)(A)(ii) and (iii)

Congress stated that the purpose of subsection (k) was to establish a procedure under which all claims for personal injury or death, "except as otherwise provided" in subsection (k), would be asserted directly against the United States under 28 USC 1346(b) and 28 USC Ch. 171 [Federal Tort Claims Act of 1946, PL 79-601] to "assure an orderly procedure;" and to "achieve participation" of manufacturers of distributors of vaccine, and of public and private agencies and medical and other health personnel who provide inoculations without charge in compliance with informed consent forms and procedures. 42 USC 247b(k)(1)(B)

[7] Experience-rating adjusts insurance premium rates based on an insured party's historical losses compared to others with similar characteristics, assuming that past loss patterns will likely continue.

Congress provided: "The United States shall be liable with respect to claims...for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant," for claims submitted after Sept. 30, 1976, in the same manner that the US would be liable in any other action brought under the Federal Tort Claims Act of 1946, with a few exceptions. 42 USC 247b(k)(2)(A)

Congress provided that the liability of the United States could be based on any theory of liability applicable in the place where the act or omission occurred, including negligence, strict liability in tort and breach of warranty. 42 USC 247b(k)(2)(A)(i).

Congress rendered inapplicable, an exception precluding liability under the FTCA [28 USC 2680(a)[8]] for acts or omissions of government employees executing statutes or regulations, or exercising discretionary functions for federal agencies. 42 USC 247b(k)(2)(A)(ii)

By rendering the exception inapplicable, Congress allowed injured individuals to file claims based on acts or omissions of government employees executing statutes or regulations, or exercising discretionary functions of federal agencies.

Congress authorized claimants to file initial administrative claims, if their civil action against the United States for personal injury or death was dismissed because the plaintiff failed to first file an administrative claim within two years of the incident [28 USC 2401(b)[9]], past the deadline. Congress extended the deadline to authorize claimants to file administrative claims within 30 days after dismissal of their civil action, or within two years after the date the claim arose (the injury or death), whichever is later. 42 USC 247b(k)(2)(A)(iii)

Congress defined the term 'program participant' to mean "the manufacturer or distributor of the swine flu vaccine used in an inoculation under the swine flu program, the public or private agency or organization that provided an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements...and the medical and other health personnel who provided or assisted in providing an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements." 42 USC 247b(k)(2)(B).

Congress provided for claims against the United States to be the exclusive or only remedy available to plaintiffs alleging personal injury or death caused by the acts or omissions of government employees or program participants. 42 USC 247b(k)(3)

[8] 28 USC 2680, *Tort Claims Procedure, Exceptions* - The provisions of this chapter and section 1346(b) of this title shall not apply to— (a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

[9] 28 USC 2401(b), *Time for commencing action against the United States* (PL 80-773, Judicial Code and Judiciary, June 25, 1948

Congress directed the Attorney General to defend any civil action brought against government employees or program participants, or "any liability insurer thereof;" directed any government employee or program participant who received a civil complaint to deliver the papers to an individual within the Department of Health, Education and Welfare designated by the HEW Secretary to receive them; and directed the HEW officer to deliver the papers to the US attorney for the district in which the vaccination incident took place, to the Attorney General and to the HEW Secretary. 42 USC 247b(k)(4)

Congress directed the Attorney General to certify that eligible civil actions were "based upon a claim alleging personal injury or death arising out of the administration of vaccine under the swine flu program" and thereby "deem" the proceeding an action against the United States under the FTCA. For cases filed in federal district courts, the United States would be substituted as the party defendant, taking the place of the individual manufacturer, distributor, public or private agency employee, or medical or health personnel.

For complaints filed in State courts, Congress authorized the Attorney General to remove the case to the US district court for the place where the incident took place, deem the case an FTCA case, and substitute the United States as the party defendant. 42 USC 247b(5)(A)

Congress provided that the Attorney General's certification "with respect to program participant status shall conclusively establish such status" authorizing removal from State to federal court, and that if the federal court later determined that the liability protection procedures were inapplicable to the matter, the case would be remanded back to State court. 42 USC 247b(k)(B)

Congress provided that civil actions against the United States for personal injury or death caused by swine flu vaccination could be precluded, if the injured party obtained compensation or other benefits from the United States under other provisions of law, and that if so, the civil action should be dismissed. Congress authorized plaintiffs whose claims were dismissed on the basis of compensation obtained under other laws, to file for such benefits past the time limitations otherwise applicable, suspending the running of the clock during the time the civil case under FTCA was moving through the process. 42 USC 247b(5)(C)

Congress ordered program participants to "cooperate with the United States in the processing or defense of a claim or suit...based upon alleged acts or omissions of the program participant," and authorized the district court to revoke the person's status as a "program participant," substitute him or her as the defendant in place of the United States, and remand the suit to the court in which it was instituted, "upon finding that the program participant has failed to so cooperate." 42 USC 247b(k)(6)

Congress authorized the United States to recover, from any program participant, any portion of money damages paid to a claimant following an administrative claim or a court judgment, "resulting from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract...or from any negligent conduct on the part of any party participant in carrying out any obligation or responsibility." Congress authorized the United States to bring actions against program participants for recovery in the federal district court in which the person lived or worked. 42 USC 247b(k)(7)

Congress directed the HEW Secretary to report to Congress within one year (of Aug. 12, 1976 date of enactment), on settlement and litigation activities; and "the number, value, nature and status of all claims made" under the swine flu vaccine liability claim processing program, including the status of recovery claims against program participants; and to submit to Congress semi-annual reports thereafter. 42 USC 247b(k)(8)

Congress defined "the phrase 'arising out of the administration,' with reference to a claim for personal injury or death under the swine flu program" as "includes a claim with respect to the manufacture or distribution of such vaccine in connection with the provision of an inoculation using such vaccine under the swine flu program." 42 USC 247b(l)(1)

Congress defined the term 'swine flu vaccine' to mean "the vaccine against the strain of influenza virus known as influenza A/New Jersey/76 (Hsw 1N1), or a combination of such vaccine and the vaccine against the strain of influenza virus known as influenza A/Victoria/75." 42 USC 247b(l)(3)

Congress directed the HEW Secretary to conduct a study "of the scope and extent of liability for personal injuries or death arising out of immunization programs and alternative approaches to providing protection against such liability (including a compensation system) for such injuries," and to report the findings of the study to Congress within one year (of Aug. 12, 1976 date of enactment). 42 USC 247b, Note

In September 1976 (PL 94-420, Congress authorized the Administrator of Veterans Affairs to authorize administration of vaccine to eligible veterans in any VA health care facility, and authorized the HEW Secretary to provide vaccine at no cost to the VA. Congress precluded claims for damages for personal or death against VA employees under 42 USC 247b(k), "allegedly arising from the malpractice or negligence of personnel granted immunity" under 38 USC 4116 [*Malpractice and negligence suits against VA employees: defense by United States*, later renumbered 38 USC 7316]. Congress directed that claims against VA personnel be considered and processed under 42 USC 4116, and provided that the authority to recover against such program participants for money damages attributed to their acts or omissions "shall not be applicable."

The swine flu immunization campaign began in early October 1976 and was suspended in December 1976, following deaths and injuries among vaccinees.

Other influenza vaccine campaigns proceeded.

1977 - 50 USC 1520
Title 50: War and National Defense
Chemical and Biological Warfare
Use of human subjects for the testing of chemical or biological agents

In 1977 (PL 95-79), Congress and President Carter imposed some reporting conditions on Department of Defense use of chemical and biological agents on human targets, under the Chemical and Biological Warfare section enacted in 1969 (PL 91-121, summarized above)

Congress added a provision requiring the Defense Secretary to provide annual reports, after the fact, about all "experiments and studies...whether directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents" conducted during the previous year, such reports to be submitted to Senate and House Armed Services committees. 50 USC 1520(a)(1)

Congress required the Defense Secretary to give reports to Congressional Armed Services committees about plans to conduct experiments "involving the use of human subjects for the testing of chemical or biological agents" 30 days before the planned start date. 50 USC 1520(a)(2)

Congress authorized the Department of Defense and contractors to conduct "any test or experiment involving the use of any chemical or biological agent on civilian populations," provided that local civilian officials were notified 30 days in advance. 50 USC 1520(b)(1)

1982 - 50 USC 1520; 50 USC 1511
Title 50: War and National Defense
Chemical and Biological Warfare

In 1982 (PL 97-375), Congress and President Reagan amended 50 USC 1520(a), relating to Defense Secretary reports to Congress about "experiments...which involve the use of human subjects for the testing of chemical or biological agents," to strike the post-test reporting requirement from 50 USC 1520(a)(1), eliminate the requirement for pre-test notice to Congress, reduce the frequency for post-test reports from twice a year to once a year, and insert the provision for post-test reports at 50 USC 1511(a), adding it to the Defense Secretary report to Congress about expenditures "for research, development, test and evaluation and procurement of lethal and nonlethal chemical and biological agents."

1983 - 42 USC 247d
Title 42: Public Health and Welfare
Public health emergencies

In 1983 (PL 98-49) Congress added to the Public Health Service Act Section 319, *Public health emergencies*, codified at 42 USC 247d.

The new section provided that "if" the HHS Secretary "determines...that a disease or disorder presents a public health emergency or a public health emergency otherwise exists and the Secretary [referring to himself] has the authority to take action with respect to such emergency" then the HHS Secretary "may take such as action as may be appropriate to respond to the public health emergency," including making grants, entering into contracts and "conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder."

Congress provided that the HHS Secretary might "consult" with the NIH Director, FDA Commissioner, CDC Director or Administrator of the Alcohol, Drug Abuse and Mental Health Administration in determining whether a public health emergency "exists." 42 USC 247d(a)

Congress established a Public Health Emergency Fund in the Treasury, for the HHS Secretary to spend "without fiscal year limitation," and authorized $30 million for fiscal year 1984 and appropriations each year thereafter to keep the fund topped up at $30 million at the beginning of each fiscal year. 42 USC 247d(b)(1)

Congress directed the HHS Secretary to report to the Senate Labor and Human Resources Committee and House Committee on Energy and Commerce each year about expenditures made from the Public Health Emergency Fund the prior fiscal year, with descriptions of each public health emergency for which expenditures were made and activities undertaken. 42 USC 247d(b)(2)

Discussion

Congress did not require the HHS Secretary to collect or provide any physical evidence when determining if a disease, disorder or public health emergency "exists."

Congress did not establish any standard of evidence against which an HHS Secretary determination could be assessed for meeting or failing to meet an evidentiary threshold.

Congress did not authorize any legislative or judicial process to review or overturn HHS Secretary determinations.

The 1983 version of the public health emergencies law codified at 42 USC 247d was very short. Congress repealed and replaced it with an expanded version in 2000 (PL 106-505). Through the PREP Act in 2005 (PL 109-148), Congress added sections providing liability protections for "pandemic and epidemic products and security countermeasures."

1985 - 50 USC 1511-1528
Title 50: War and National Defense
Chemical and Biological Warfare

In 1985 (PL 99-145), Congress and President Reagan added a provision on "Destruction of existing stockpile of lethal chemical agents and munitions" to the Chemical and Biological Warfare section. 50 USC 1521.

At 50 USC 1521(p)(1), the law defined the term "chemical agent and munition" to mean "an agent or munition that, through its chemical properties, produces lethal or other damaging effects on human beings, except that such term does not include riot control agents, chemical herbicides, smoke and other obscuration materials."

At 50 USC 1521(p)(3), the law defined "lethal chemical agent and munition" to mean "a chemical agent or munition that is designed to cause death, through its chemical properties, to human beings in field concentrations."

1986 - 18 USC 2331 et seq
Title 18: Crimes and Criminal Procedure
Terrorism

In 1986, (PL 99-399, Omnibus Diplomatic Security and Antiterrorism Act), Congress and President Reagan added a new section to Title 18, Crimes and Criminal Procedure: Terrorism.

Codified at 18 USC 2331 et seq, the new law asserted extraterritorial jurisdiction over "terrorist acts abroad against United States nationals," and established criminal penalties for those who kill US nationals "while such national is outside the United States;" attempt or conspire to kill US nationals abroad; or engage in physical violence with intent to cause serious bodily injury or with the result that serious bodily injury is caused.

1986 - 42 USC 300aa-1 to 300aa-6
Title 42: Public Health and Welfare
Vaccines
National Vaccine Program

In 1986, Congress and President Ronald Reagan enacted PL 99-660: the State Comprehensive Mental Health Services Plan Act of 1986.

The National Childhood Vaccine Injury Act (Title III of PL 99-660) passed by Congress had two main parts, establishing the National Vaccine Program and the National Vaccine Injury Compensation Program.

The first part set up the National Vaccine Program under the Public Health Service Act, and was codified at 42 USC 300aa-1 to 300aa-6.

Congress directed the Secretary of health and Human Services to establish a National Vaccine Program "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 USC 300aa-1

Congress directed the HHS Secretary to appoint a Director of the National Vaccine Program to coordinate nine program areas including (1) vaccine research; (2) development; (3) safety and efficacy testing; (4) licensing of vaccine manufacturing companies and vaccines; (5) production and procurement of vaccines; (6) distribution and use of vaccines, supported by "assistance to States, localities and health practitioners...including efforts to encourage public acceptance of immunizations;" (7) "evaluating the need for vaccines, the effectiveness of vaccines, and the adverse effects of vaccines and immunizations;" (8) exchange of information and funding between US government and non-governmental organizations; and (9) implementation of the National Vaccine Program. 42 USC 300aa-2

Federal agencies to be coordinated by the Director to carry out these nine program areas included NIH, CDC, FDA-Office of Biologics Research and Review (OBRR, later renamed Center for Biologics Evaluation and Research-CBER), Department of Defense, US-Agency for International Development, National Center for Health Statistics, National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration, along with non-governmental organizations "engaged in the development and production of vaccines."

Congress directed the Director of the National Vaccine Program to draft an implementation plan and set priorities for research, development, testing, licensing, production, procurement, distribution and use of vaccines and to submit annual reports about the implementation of the National Vaccine Program to Congressional committees. 42 USC 300aa-3, 42 USC 300aa-4

Congress established a National Vaccine Advisory Committee (NVAC[10]) of vaccine researchers, vaccine manufacturers, doctors, parents, and State and local health officials, tasked with "recommending ways to encourage the availability of an adequate supply of safe and effective vaccination products and recommend research priorities." 42 USC 300aa-5

To fund the first eight tasks National Vaccine Program, Congress appropriated $15 million for 1987-1991.

To fund the ninth task — implementation of the National Vaccine Program — Congress appropriated $125 million for 1987-1991. 42 USC 300aa-6

[10] Note on vaccine committees: Congress and federal executive officers have set up several vaccine-related committees since the 1960s, including NVAC established in 1986 through 42 USC 300aa-5; Immunization Practices Advisory Commission (IPAC) established by the PHS Surgeon General in 1964 and renamed the Advisory Commission for Immunization Practices (ACIP) in 1965; and the Advisory Commission on Childhood Vaccines (ACCV), established by Congress in 1986 through 42 USC 300aa-19 and tasked with advising the HHS Secretary on implementation of the National Vaccine Injury Compensation Program (VICP or NVICP).]

1986 - 42 USC 300aa-10 to 300aa-33
Title 42: Public Health and Welfare
Vaccines
National Vaccine Injury Compensation Program

The second part of the NCVIA passed by Congress in 1986 (PL 99-660) established the National Vaccine Injury Compensation Program, or VICP, codified at 42 USC 300aa-10 to 300aa-33.

Through the VICP program, Congress set up an alternative compensation system for people injured by vaccines, their caretakers, and survivors of those killed by vaccines, to divert petitioners out of civil courts typically involved in adjudicating product liability claims.

At that time, available products used on babies and children were alleged to prevent seven named, allegedly uniquely-diagnosable, alleged disease-states allegedly caused by specific, isolatable, identifiable pathogens allegedly contained, in whole or in part, in vaccine containers: polio, diphtheria, tetanus, pertussis, measles, mumps and rubella.

Although they are also important to understand, this report does not lay out VICP procedural steps in detail; relationships between special masters, Court of Federal Claims, district court judges; attorney fee payment rules; funding of the compensation trust fund (VITF) through excise taxes levied on vaccine bottlers and investment of proceeds; or relationships between VICP procedures and standard tort litigation.

This report focuses on VIT table components and some of the evidentiary elements of the VICP procedure.

42 USC 300aa-11 - Types of claims authorized for compensation

Congress authorized petitioners to use the VICP program to seek eligibility review and compensation for three basic types of claims.

The first, and most likely to be deemed eligible, became known as "on-table" injuries, and included any "illness, disability, injury, or condition" including death, set forth in the Vaccine Injury Table as caused by one of the seven vaccines generally required for school attendance as of 1986 (diphtheria, tetanus, pertussis, polio, measles, mumps and rubella) if the "first symptom or manifestation" of the injury, significant aggravation or death occurred within the time period after administration identified in the VIT table: generally 24 hours to 3 days or 15 days. 42 USC 300aa-11(c)(1)(C)(i)

The second and third categories, less likely to be deemed eligible, became known as "off-table" injuries. The second category included injuries not identified in the VIT table, but allegedly caused by a vaccine listed on the VIT table. 42 USC 300aa-11(c)(1)(C)(ii)(I). The third category included injuries caused by a vaccine identified in the VIT table but whose symptom onset occurred outside the time period after administration identified in the table. 42 USC 300aa-11(c)(1)(C)(ii)(II)

42 USC 300aa-12 Parties; HHS Secretary to be named as respondent; limits on discovery

Congress directed petitioners to name the Secretary of Health and Human Services as the respondent in their petitions. 42 USC 300aa-12(b)(1)

Congress did not authorize petitioners to name vaccine developers, manufacturers, regulators, or vaccine administrators (doctors, nurses) as parties.

Congress directed petitioners to collect and submit medical and financial information to support the injury claims and compensation amounts.

Congress prohibited discovery (collection and disclosure of evidence) apart from medical reports about injuries and financial reports about caregiving expenses and lost income. 42 USC 300aa-12(c).

Congress, in other words, barred the collection and exchange of information about product design, testing, manufacturing, identification, misbranding, mislabeling, quality standards, adulteration or contamination during processing, storage and use, and all other product-related factors.

42 USC 300aa-13 - Determination of eligibility and compensation

Congress assigned the initial burden of proof for "on-table" injuries to the petitioner, to demonstrate by a preponderance-of-the-evidence standard, that the injured party "sustained, or had significantly aggravated, any illness, disability, injury or condition [set forth in the VIT] or died from the administration of such vaccine, and the first symptom or manifestation of the onset or...significant aggravation...or the death occurred within the time period after vaccine administration" set forth in the VIT. 42 USC 300aa-13(a)(1)(A)

Congress directed that, if the petitioner provided medical reports supporting the claim that the injured person sustained a VIT-listed injury, from a VIT-listed vaccine, within the VIT-listed time period, the HHS Secretary as respondent would have an opportunity to rebut the conclusion, if he could demonstrate by a preponderance-of-the-evidence that "the illness, disability, injury, condition, or death...is due to factors unrelated to the administration of the vaccine." 42 USC 300aa-13(a)(1)(B)

Congress provided that the term 'factors unrelated to the administration' "does not include any idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness or condition," but that the term may include "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury or death." 42 USC 300aa-13(a)(2)(A) and (B)

42 USC 300aa-14 - Vaccine Injury Table (VIT) and Qualifications and Aids to Interpretation

Through the NCVIA, Congress established an initial Vaccine Injury Table; an initial set of "Qualifications and Aids to Interpretation;" and authorized the HHS Secretary to revise, by Federal Register rulemaking, the VIT table and the interpretive provisions. 42 USC 300aa-14(a), (b) and (c)

The VIT table and "qualifications and aids to interpretation" are codified at 42 CFR 100.

Compensable injuries listed in the first, 1986 VIT table included anaphylaxis occurring within 24 hours of administration of a listed vaccine; encephalitis (brain damage) symptoms occurring within 3 days (for diphtheria, tetanus, pertussis and polio vaccines) and 15 days (for measles, mumps and rubella vaccines); shock-collapse or hypotonic-hyporesponsive collapse symptoms occurring within 3 days (DTP, polio) or 15 days (MMR); residual seizure disorder occurring within 3 days (DTP, polio) or 15 days (MMR); or any acute complication of any of the above injuries that had occurred within the time period.

For polio vaccines other than Inactivated Polio Vaccine, compensable injuries also included paralytic polio occurring within 30 days to six months depending on the "immunodeficient" status of the injured person.

Qualifications and aids to interpretation listed by Congress in the first interpretation guidelines, and subject to unilateral revision by the HHS Secretary thereafter, provided for a few forms of medical evidence to be deemed relevant and admissible.

Shock collapse or hypotonic-hyporesponsive collapse claims could be supported by symptoms such as "decrease of decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest."

To make a claim for residual seizure disorder, the injured person was required to have not suffered a seizure or convulsion without fever or with a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine, and -- for MMR vaccines -- to have endured the first seizure (without fever or with fever less than 102) within 15 days after administration and 2 or more seizures (without fever or with fever less than 102) within 1 year after the administration. For all other vaccines, the petitioner had to demonstrate that the first seizure (without fever or with fever less than 102) occurred within 3 days, and 2 or more seizures occurred within 1 year.

To make a claim for encephalopathy (brain damage), the injured person was required to demonstrate manifestations such as "focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions."

Congress noted that neurological signs and symptoms might be temporary or might result in permanent impairment, might include "high pitched and unusual screaming, persistent

unconsolable crying, and bulging fontanel" which would be compatible with encephalopathy but would not, alone, be considered "conclusive evidence." Congress added that encephalopathy "usually can be documented with slow wave activity on an electroencephalogram."

Congress did not provide a definition for anaphylaxis or anaphylactic shock in the first interpretation guidelines enacted in 1986. HHS secretaries have since added and revised a definition for anaphylaxis at 42 CFR 100.3(c)(1), narrowly limiting diagnosis of anaphylaxis to "an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems…" (as of 82 FR 6301, Jan. 19, 2017) thus excluding and suppressing scientific and medical knowledge that anaphylaxis also denotes injuries to organ systems that become observable weeks, months or years after the initial injury, in the form of chronic disease or multiple, non-discrete events.

Discussion

To repeat a key point: Congress provided grounds for the HHS Secretary, as respondent, to rebut the presumption that a vaccine had caused brain damage and thereby render it an "off-table" injury, by attributing the damage causation to unspecified "infection, toxins, trauma, or metabolic disturbances" that are known to be injurious agents or observable effects of injurious, foreign biological matter delivered into the blood of living animals and humans through accidental wounds or through intentional wounds caused by vaccine needles and syringes.

And Congress authorized the HHS Secretary to revise, at will, the "qualifications and aids to interpretation" by which vaccines and patient symptoms (medical files) are assessed for the purposes of finding injuries to be, or to not be, vaccine-caused.

Synopsis from *Innovation and Challenge: the First Year of the National Vaccine Injury Compensation Program* (1991, Wendy K. Mariner)

> The Program provides "no-fault," cause-based compensation. Unlike general benefit programs, compensation is limited to injuries from a single source—seven vaccines generally required for children before they enter day care or school. Yet compensation is available regardless of whether anyone is at fault or might be legally liable for the injury or death.

Synopsis from *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily* (1999, General Accounting Office/GAO):

> Under VICP, vaccines on the injury table are presumed to have caused the listed injury if incurred within specific time periods. For example, under the original table, someone suffering neurological damage from seizures within 3 days after receiving a vaccine against pertussis would receive compensation if HHS could not prove that the condition was due to factors unrelated to the administration of the vaccine.

Synopsis from *Bruesewitz v. Wyeth* (2011, SCOTUS):

> Fast, informal adjudication is made possible by the Act's Vaccine Injury Table, which lists the vaccines covered under the Act; describes each vaccine's compensable, adverse

> side effects; and indicates how soon after vaccination those side effects should first manifest themselves.
>
> Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation.
>
> A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Synopsis, *Recalibrating Vaccination Laws* (2017, Efthimios Parasidis)

> The distinction between on- and off-table injuries has immense legal significance. Specifically, causation is presumed for on-table injuries, and the government has the burden of disproving causation.
>
> For off-table injuries, however, the petitioner is responsible for proving that a vaccine caused their injury. This includes general causation—a medical theory linking the vaccine with an adverse health consequence—and specific causation, which is whether the vaccine caused the petitioner's injuries.

<u>42 USC 300aa-33 - Definitions</u>

Congress defined the term "vaccine-related injury or death" to mean "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 USC 300aa-33(5)

Congress did not define the terms 'vaccine,' 'adulterant,' or 'contaminant' in the definitions section of the NCVIA in 1986, or direct the HHS Secretary to define the terms by agency regulations. Congress did not identify analytical methods by which a petitioner, manufacturer, regulator or VICP claim reviewer could identify or distinguish among vaccine components to determine whether an isolatable substance could be classified or categorized as a vaccine, adulterant or contaminant; how a substance could be classified in or excluded from the category of "intentionally added;" or how a substance or mixture of substances could be identified or excluded as an injury-causative agent.

In November 2002 (PL 107-296), Congress added a definition for vaccine at 42 USC 300aa-33(7) which read: "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccine's product license application and product label."

Congress also made conforming amendments at 42 USC 300aa-33(3) [definition of 'manufacturer'] and at the definition of "vaccine-related injury or death" at 42 USC 300aa-33(5), excluding from being classified as an adulterant and contaminant "any component or ingredient listed on a product's license application or label." The sentence added to 300aa-33(5) read: "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label."

In February 2003 (PL 108-7), Congress repealed the provisions enacted in November 2002, including the definition for 'vaccine,' noting that the Public Health Service Act should be applied as if the November 2002 amendments had never been enacted.

The November 2002 to February 2003 maneuvers were related to an autism case then moving through the VICP process (*Leroy v. Secretary of HHS*), in which petitioner parents of a brain-damaged child attempted to classify the additive thimerosal as an adulterant or contaminant, whose inclusion in vaccines would place their case outside the jurisdiction of the court reviewing their VICP eligibility and compensation claims. The court ruled against the parents, finding that thimerosal could not be classified as an adulterant or contaminant, because it was intentionally added to vaccines to ostensibly serve as a preservative.

42 USC 300aa-19; 42 USC 300aa-25 to 300aa-28 - Advisory Commission on Childhood Vaccines; adverse event reporting by health care providers; record-keeping and reporting by manufacturers

Through the NCVIA, Congress established an Advisory Commission on Childhood Vaccines (ACCV), and assigned the ACCV duties to advise the HHS Secretary on implementation of the NVICP; recommend changes to the Vaccine Injury Table (VIT); provide advice "regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions;" survey Federal, state and local programs relating to the "gathering of information on injuries associated with the administration of childhood vaccinations;" advise the HHS Secretary on "means to obtain, compile, publish and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines;" and recommend to the National Vaccine Program Director, "research related to vaccine injuries which should be carried out." 42 USC 300aa-19

Through the NCVIA, Congress directed health care providers who administer vaccines to report "specified adverse experiences, occurring within specified time intervals" to a database to be set up and administered by FDA and CDC, launched in November 1990 as VAERS [Vaccine Adverse Event Recording System]. 42 USC 300aa-25

Congress directed the HHS Secretary to develop information materials for health care providers to distribute to legal representatives of children receiving vaccines listed in the Vaccine Injury Table. Information sheets were to contain information about "the frequency, severity and potential long-term effects of the [alleged] disease to be [allegedly] prevented by the vaccine;" vaccinations required for school attendance and under recommended immunization schedules; warning signs and symptoms of adverse reactions to look for and report to the vaccinator; how and to whom to report "any major adverse reactions;" contraindications and identification of

characteristics of potential recipients who might be at higher risk of a "major adverse reaction" and the availability of the VICP compensation program. 42 USC 300aa-26

Through the NCVIA, Congress established a so-called "mandate for safer vaccines," ostensibly directing the HHS Secretary to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and...make or assure improvements in...the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."

Congress directed the HHS Secretary to set up a task force, comprised of NIH Director, FDA Commissioner and CDC Director, to consult with the Advisory Commission on Childhood Vaccines, and to submit reports every two years to Congressional committees describing actions taken to improve the safety of vaccines. 42 USC 300aa-27.

By stipulation signed in July 2018 in a case brought by Informed Consent Action Network (ICAN), HHS provided corroborating evidence supporting the conclusion or negative inference that "mandate for safer vaccines" studies have not been conducted; reports have not been compiled (because studies were not conducted) and reports have not been provided to Congress (because reports were not compiled).

Through the 1986 NCVIA, Congress required vaccine manufacturers to “(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity" and "(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted…” 42 USC 300aa-28.

Discussion

Congress did not define the term 'vaccine' by physical composition. Congress did not direct the HHS Secretary to define the term 'vaccine' by physical composition. Congress did not enact provisions designating analytical tests that could be used to identify 'vaccines' by physical components or assess quality or safety characteristics, did not designate any third party (such as the US Pharmacopeia-National Formulary) to designate such analytical tests, and did not direct the HHS Secretary or FDA Commissioner to designate such analytical tests.

Congress also did not require vaccine-bottlers to collect or report information about adverse effects experienced by living recipients of products after containers leave bottling facilities.

Congress did not define the phrase "imminent or substantial public health hazard" or any of its constituent terms, and did not direct the HHS Secretary or FDA Commissioner to define them.

Because the contents of vaccine containers are unstable mixtures of biological matter (living and dead, bacteria, fungi, plant, insect, animal, human), chemicals and nutrient solutions, any process or batch testing that a vaccine-bottler or regulator conducts cannot fully identify the biological and chemical matter contained in any “batch, lot or other quantity,” and cannot meaningfully characterize any product in terms of purity, potency, safety or “potential imminent or substantial public health hazard.”

Thus, there is no way for vaccine manufacturers to collect or report meaningful product identity or product quality information to support any finding that any product presents or does not present an “imminent or substantial public health hazard.”

Under the VICP framework, the HHS Secretary occupies several roles.

He is the respondent, similar to the defendant in a civil tort case or a criminal prosecution. By Congressional statute, he stands as the respondent alone, unaccompanied by his collaborators among epidemiologists, military researchers, drug company executives and employees, FDA regulators, doctors, nurses, and pharmacists.

The HHS Secretary selects vaccines, vaccine-caused injuries, and time periods during which signs and symptoms of injury must occur, for inclusion in the VIT table, for a claim to be deemed compensable. His VIT decisions create two broad categories of injury: "on-table" and "off-table." The HHS Secretary also determines "qualifications and aids to interpretation" by which signs and symptoms documented in a medical file are to be assessed as to whether they meet the conditions described in the VIT table.

These decisions are, like many other determinations in the communicable disease/biodefense/biological product context, made unilaterally by the HHS Secretary alone, without any requirement for production of physical evidence, without standards of evidence against which claims can be tested, and without evidentiary review procedures through which judges or legislators can hear and rule on challenges to HHS determinations.

In the VICP process, the special masters (attorneys appointed by federal court to act as administrative law judges) and the supervising judges serve only ministerial functions. They ensure that medical evidence is submitted in proper formats, and they apply the conditions for eligibility previously established by the HHS Secretary through the VIT table.

For each case, the HHS Secretary is authorized to accept a finding that the petitioner's injuries fall within the narrow terms of the VIT table conditions, or — at his discretion — challenge the presumption of injury causation by alleging that "factors" other than administration of a vaccine caused the injuries. As summarized above, the list of "unexplained" or "hypothetical" causes that Congress barred the HHS Secretary from using by the first part of the "factors unrelated" definition, remain available for his use under the list in the second part, of non-specific conditions and agents listed as "infection, toxins, trauma...or metabolic disturbances."

Those four terms — infection, toxins, trauma, metabolic disturbances — denote agents and injurious effects of blood poisoning, by foreign biological matter, of a living animal or human: the act known as vaccination or immunization.

1986 - 42 USC 262
Title 42: Public Health and Welfare
Regulation of biological products
Recall authority
Export of partially processed biological products

In 1986, through the same National Childhood Vaccine Injury Act (PL 99-660), Congress revised two sections of 42 USC 262.

42 USC 262(d)(2) - Recall authority

One change, codified at 42 USC 262(d)(2)(A) and (B), authorized the HHS Secretary to "issue an order immediately ordering the recall of such batch, lot or other quantity" of biological product "upon a determination that a batch, lot or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health."

Congress provided for application of 5 USC 554 (agency hearings with opportunities for manufacturers to challenge recall orders), and civil penalties up to $100,000 per day to be assessed against violators.

Congress did not define "imminent or substantial hazard to the public health," and did not direct the HHS Secretary to define the terms or to prescribe agency regulations governing the recall process. *See* FDA Regulatory Procedures Manual, Ch. 7 (Recall Procedures, Version 10, July 2021), which mentions "imminent or substantial hazard" but under Implementing Regulations, Procedures and Industry Guidance [Guidance for Industry], at p. 16/153, notes "N/A" for "not applicable."

42 USC 262(h) and 21 USC 382 - Exports of certain unapproved products -

A second change in 1986, codified at 42 USC 262(h) and 21 USC 382, authorized export of "partially processed biological products" to listed countries including Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

The provision authorized biological products to be exported "not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man...[and] intended for further manufacture into final dosage form outside the United States in a country listed" upon approval of an application submitted to the HHS Secretary.

Congress provided that the HHS Secretary "may not approve an application" unless he determines that the product is "manufactured, processed, packaged, and held in conformity with current good manufacturing practice and the outside of the shipping package is labeled with the following statement: 'This product may be sold or offered for sale only in the following countries: ___ '," filling in the space with the list of importing countries. 42 USC 262(h)(1)(A)

Applications were to "describe the partially processed biological product to be exported," list the countries to which the product is to be exported; certify that the product would not be exported to any other country, identify the manufacturing establishments, and certify that the final product to be developed was approved in the importing country, or approval was being sought. 42 USC 262(h)(1)(B)

Congress provided that partially processed biological products intended for export were not subject to the other licensing provisions of 42 USC 262. 42 USC 262(h)(2)

Congress authorized the HHS Secretary to determine that prohibition of export of partially processed biological products is necessary for "protection of the public health in the United States or the country to which it is to be exported" and not approve an application on that basis. 42 USC 262(h)(3).

Discussion

Congress did not identify the party or parties authorized to submit applications.

Congress did not define physical standards, or direct the HHS Secretary to define physical standards, for the HHS Secretary to use in determining whether a product was or was not a "partially processed" biological product, nor how any partially processed biological product related to "protection of the public health."

1987 - 26 USC 4132
Title 26: Internal Revenue Code
Manufacturers Excise Taxes, Certain Vaccines

In 1987 (PL 100-203), Congress and President Reagan defined the term 'vaccine' through the Internal Revenue Code, as “any substance designed to be administered to a human being for the prevention of 1 or more diseases." 26 USC 4132(a)(6)

The tax code definition was written into law to supply revenue for the Vaccine Injury Compensation Trust Fund established in 1986 through the National Childhood Vaccine Injury Act (PL 99-660).

The tax code law defined 'taxable vaccines,' "for purposes of this subchapter” as

> “any vaccine which is listed in the table contained in 26 USC 4131(b)(1) and which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing." 26 USC 4132(a)(1).

The tax code as adopted in 1987 further provided:

> The term 'DPT vaccine' means any vaccine containing pertussis bacteria, extracted or partial cell bacteria, or specific pertussis antigens. 26 USC 4132(a)(2)
>
> The term 'DT vaccine' means any vaccine (other than a DPT vaccine) containing diphtheria toxoid or tetanus toxoid." 26 USC 4132(a)(3)
>
> The term 'MMR' vaccine means any vaccine against measles, mumps or rubella. 26 USC 4132(a)(4)
>
> The term 'polio vaccine' means any vaccine containing polio virus. 26 USC 4132(a)(5)

Since 1987, the definitions at 26 USC 4132 have been updated and now include:

> Any vaccine containing diphtheria toxoid... containing tetanus toxoid...containing pertussis bacteria, extracted or partial cell bacteria, or specific pertussis antigens...against measles... against mumps...against rubella... containing polio virus...Any HIB vaccine...Any vaccine against hepatitis A...against hepatitis B... against chicken pox...against rotavirus gastroenteritis... Any conjugate vaccine against streptococcus pneumoniae... Any trivalent vaccine against influenza or any other vaccine against seasonal influenza...Any meningococcal vaccine... Any vaccine against the human papillomavirus.

Discussion

The term 'vaccine' is not defined in physical terms in the biological product manufacturing regulation statute adopted by Congress (42 USC 262), nor in product manufacturing regulations promulgated by the Department of Health and Human Services and ostensibly under the manufacturing regulatory oversight of the Food and Drug Administration.

There are no legal requirements that manufacturers demonstrate any stable, discernible physical characteristics for biological products.

There are no legal requirements that regulators set or enforce design or manufacturing standards, nor that existing manufacturers demonstrate compliance with design or manufacturing standards to continue holding licenses authorizing the establishment to produce, package, label and distribute vaccines, nor that new companies entering the supply chain for the first time demonstrate compliance with design or manufacturing standards to obtain new biologics licenses for their companies.

There are no legal requirements that regulators develop, approve or order the use of validated tests to assess physical evidence for compliance with non-existent standards, and no such tests exist.

There are no legal provisions authorizing fact-finding procedures or venues in which review of physical evidence (which need not be adduced) could be conducted.

1989 - 10 USC 2371
Title 10: Armed Forces
Advanced research projects: cooperative agreements and other transactions

In 1989 (PL 101-189), Congress added a provision authorizing non-traditional contracting for DARPA research projects, codified at 10 USC 2371.

Congress authorized the Defense Secretary, in carrying out advanced research projects through the Defense Advanced Research Projects Agency (DARPA) to enter into cooperative agreements and other transactions with "any person, any agency or instrumentality of the United States, any unit of State or local government, any educational institution, and any other entity." 10 USC 2371(a)

Congress authorized clauses in cooperative agreements and other transactions, requiring a party to make payments to the DoD or any other federal agency, as a condition for receiving support under the agreement. 10 USC 2371(b)(1)

Congress authorized the payments received by the federal government to be credited to a new Treasury account and merged with other funds for support of advanced research projects. 10 USC 2371(b)(2); 10 USC 2371(e)

Congress authorized the other transactions authority (OTA) to be "exercised without regard to" 31 USC 3324 (limiting the payment of advances for services or articles to be supplied to the US Government). 10 USC 2371(c)

Congress directed the Defense Secretary to ensure that other transactions would not provide for research that duplicates research conducted under existing DoD programs; that the federal funds provided under each transaction would not exceed the total amount provided by other parties; and that the other transactions authority would be used only when the use of standard contracts or grants is "not feasible or appropriate." 10 USC 2371(d)

Congress directed the Defense Secretary to submit annual reports to congressional committees, providing a general description of the cooperative agreement or other transaction, including the technologies for which advanced research is provided; the potential military and commercial utility of such technologies; reasons for not using a contract or grant; the amount of payments received by the Federal Government, and the amounts credited to the Treasury account. 10 USC 2371(f)

1990 - 18 USC 175-178
Title 18: Crimes and Criminal Procedure
Biological Weapons

In 1990 (PL 101-298), Congress and President George H.W. Bush enacted the first US federal law purporting to criminalize biological weapons.

Sections 175 through 178 were added at Chapter 10, Biological Weapons, under Title 18, Crimes and Criminal Procedure.

The law authorized fines and imprisonment of individuals who knowingly develop, produce, stockpile, transfer, acquire, retain, or possess any biological agent, toxin or delivery system for use as a weapon, or who knowingly assist a foreign state or any organization to do so..

> 18 USC 175. Prohibitions with respect to biological weapons
>
> (a) IN GENERAL. Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, shall be fined under this title or imprisoned for life or any term of years, or both, shall be fined under this title or imprisoned for life or any term of years, or both. There is extraterritorial Federal jurisdiction over an offense under this section committed by or against a national of the United States. 18 USC 175(a), as of 1990

The law defined "for use as a weapon" to exclude acts committed (development, production, transfer, acquisition, retention, possession) using physical matter (any biological agent, toxin, or delivery system) "for prophylactic, protective or other peaceful purposes."

> Definition. For purposes of this section, the term 'for use as a weapon' does not include the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for prophylactic, protective, or other peaceful purposes. 18 USC 175(b), as of 1990.

The law authorized the Attorney General to request warrants for seizure for physical matter — "any biological agent, toxin or delivery system that exists by reason of conduct prohibited" by the first part of the law or "is of a type or in a quantity that under the circumstances has no apparent justification for prophylactic, protective or other peaceful purposes." 18 USC 176(a)(1)(A) and 176(a)(1)(B) as of 1990.

The law authorized the Attorney General, "in exigent circumstances" to seize and destroy prohibited biological agents, toxins and delivery systems upon probable cause but without a warrant. 18 USC 176(a)(2) as of 1990.

The law authorized those from whom biological agents had been taken, to obtain a hearing; placed the burden of persuasion on the government; and set the evidentiary standard at "preponderance of the evidence." 18 USC 176(b) as of 1990.

The law established, as an "affirmative defense" against forfeiture, that the physical matter "is for a prophylactic, protective or other peaceful purpose and...is of a type and quantity reasonable for that purpose." 18 USC 176(c) as of 1990.

The law authorized the Attorney General to obtain injunctions against prohibited conduct and again provided, as an affirmative defense, that the conduct "is for a prophylactic, protective or other peaceful purpose...and such biological agent, toxin or delivery system is of a type and quantity reasonable for that purpose." 18 USC 177(a) and 177(b) as of 1990.

Congress defined the term 'biological agent' to mean

> any micro-organism, virus or infectious substance, capable of causing—
>
> (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
>
> (B) deterioration of food, water, equipment, supplies, or material of any kind; or
>
> (C) deleterious alteration of the environment. 18 USC 178(1).

Congress law defined the term 'toxin' to mean

> whatever its origin or method of product--
>
> (A) any poisonous substance produced by a living organism; or
>
> (B) any poisonous isomer, homolog, or derivative of such a substance. 18 USC 178(2).

Congress defined the term 'delivery system' to mean

> (A) any apparatus, equipment, device of means of delivery specifically designed to deliver or disseminate a biological agent, toxin, or vector; or
>
> (B) any vector. 18 USC 178(3)

Congress defined the term 'vector' to mean

> a living organism capable of carrying a biological agent to a host. 18 USC 178(4)

Discussion

The 1990 biological weapons law did not define prophylactic, protective or peaceful purposes, and did not set forth standards for physical composition or physiological effects capable of enabling a fact-finder to determine whether a biological agent, toxin or delivery system was of a type and quantity reasonable for, or with apparent justification for, prophylactic, protective or peaceful purposes.

1990 - 10 USC 2370
Title 10: Armed Forces
Biological defense research program; reporting

In 1990, (PL 101-510), Congress and President George H.W. Bush directed the Defense Secretary to provide annual reports to Congress addressing "research, development, test, and evaluation conducted...for the purposes of biological defense" during the preceding fiscal year. 10 USC 2370(a) as of 1990.

Reports were to contain descriptions of "each biological or infectious agent or toxin...used;" descriptions of the biological properties of each agent; locations of each biological defense research facility; amounts spent at each facility; the biosafety level [BSL] of each facility; and documentation of coordination with local health, fire and police officials as part of the facility safety plan for each BSL site. 10 USC 2370(b).

Congress defined 'biosafety level' as "the applicable biosafety level described in the publication entitled 'Biosafety in Microbiological and Biomedical Laboratories' (CDC-NIH, 1984)." 10 USC 2370(c)

Congress defined 'biological defense research facility' as "a location at which research, development, test, and evaluation for purposes of biological defense involving any biological or infectious agent or toxin (whether or not listed in a CDC publication) is conducted."

Congress repealed 10 USC 2370 in 1996 (PL 104-106).

1991 - 50 USC 4558 [DPA 708]
Title 50: War and National Defense
Defense Production Act, voluntary agreements

In 1991, (PL 102-99), Congress amended the Defense Production Act at Sec. 708.

One of the changes added the phrase "plan of action" to the covered agreements, so that the provisions applied to "voluntary agreements and plans of action." Congress defined 'plan of action' to mean "any of 1 or more documented methods adopted by participants in an existing voluntary agreement to implement that agreement." Congress did not define the term 'voluntary agreement.'

In 1991, Congress replaced the 1975 text of 50 USC 4558(j), Defenses. As amended, Congress authorized any person subject to any civil or criminal action, "brought under the antitrust laws (or any similar law of any State) with respect to any action taken to develop or carry out any voluntary agreement or plan of action," to have as an available defense, "that such action was taken in the course of developing a voluntary agreement initiated by the President or a plan of action adopted under any such agreement; or to carry out a voluntary agreement initiated by the President and approved in accordance with this section or a plan of action adopted under any such agreement, and such person complied with the requirements of this section and any regulation prescribed under this section; and acted in accordance with the terms of the voluntary agreement or plan of action." 50 USC 4558(j)(1) as of 1991

Congress established, as "scope of defense," that the defense "shall be available only if and to the extent that the person asserting the defense demonstrates that the action was specified in, or was within the scope of, an approved voluntary agreement...or a plan of action adopted under any such agreement," with an exception (thus authorizing the defense) for "actions taken to develop a voluntary agreement or plan of action." 50 USC 4558(j)(2) as of 1991

Congress placed the burden of proof for establishing elements of the defense on any person raising the defense. 50 USC 4558(j)(3) as of 1991

Congress provided that the defense "shall not be available if the person against whom the defense is asserted [the plaintiff or prosecutor] shows that the action was taken for the purpose of violating the antitrust laws." 50 USC 4558(j)(4) as of 1991

In 1991, Congress added a provision authorizing "Preemption of contract law in emergencies," providing that "in any action in any Federal or State court for breach of contract, there shall be available as a defense that the alleged breach of contract was caused predominantly by action taken during an emergency to carry out a voluntary agreement or plan of action authorized and approved in accordance with this section. Such defense shall not release the party asserting it from any obligation under applicable law to mitigate damages to the greatest extent possible." 50 USC 4558(o) as of 1991.

Discussion

In 2012, (Executive Order 13603, *National Defense Resources Preparedness*), President Obama delegated authorities under the Defense Production Act of 1950, including the authority to enter into voluntary agreements and plans of action, "to the heads of agencies otherwise delegated authority under this order." Obama delegated authority for "health resources" to the HHS Secretary and defined health resources to mean "drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population."

In 2020 (Executive Order 13911, *Delegating Additional Authority Under the Defense Production Act with Respect to Health and Medical Resources to Respond to the Spread of COVID-19*), President Trump delegated voluntary agreement authority to the HHS Secretary and DHS Secretary.

Through the "voluntary agreements" provisions of the Defense Production Act, Congress legalized racketeering, collusion and other forms of organized crime when carried out by the US Government working with private corporations.

1992 - 18 USC 2331 et seq
Title 18: Crimes and Criminal Procedure
Terrorism

In 1992, (PL 102-572), Congress added a definition for the term 'international terrorism.'

As summarized above, in 1986 (PL 99-399, Omnibus Diplomatic Security and Antiterrorism Act), Congress and President Reagan had added a new section on terrorism, 18 USC 2331 et seq, asserting extraterritorial jurisdiction over "terrorist acts abroad against United States nationals," and establishing criminal penalties for those who kill US nationals "while such national is outside the United States;" attempt or conspire to kill US nationals abroad; or engage in physical violence with intent to cause serious bodily injury or with the result that serious bodily injury is caused.

In 1992, Congress reorganized and renumbered several sections, added definitions, and added a provision authorizing civil remedies.

Congress defined 'international terrorism' to mean:

> activities that
>
> (A) involve violent acts or acts dangerous to human life that are a violation of the criminal laws of the United States or of any State, or that would be a criminal violation if committed within the jurisdiction of the United States or of any State;
>
> (B) appear to be intended-
>
> > (i) to intimidate or coerce a civilian population;
> >
> > (ii) to influence the policy of a government by intimidation or coercion; or
> >
> > (iii) to affect the conduct of a government by assassination or kidnapping; and
>
> (C) occur primarily outside the territorial jurisdiction of the United States, or transcend national boundaries in terms of the means by which they are accomplished, the persons they appear intended to intimidate or coerce, or the locale in which their perpetrators operate or seek asylum. 18 USC 2331(1)

Congress defined the term 'act of war' to mean

> any act occurring in the course of-
>
> (A) declared war;
>
> (B) armed conflict, whether or not war has been declared, between two or more nations; or

(C) armed conflict between military forces of any origin." 18 USC 2331(4)

Congress added, to the criminal penalties established in 1986, a civil remedy, providing that "any national of the United States injured in his or her person, property, or business by reason of an act of international terrorism, or his or her estate, survivors, or heirs, may sue therefor in any appropriate district court of the United States and shall recover threefold the damages he or she sustains and the cost of the suit, including attorney's fees." 18 USC 2333

Congress excluded civil claims for "injury or loss by reason of an act of war." 18 USC 2336(a)

Congress excluded civil claims against "the United States, an agency of the United States, or an officer or employee of the United States or any agency thereof acting within his or her official capacity or under color of legal authority; or a foreign state, an agency of a foreign state, or an officer or employee of a foreign state or an agency thereof acting within his or her official capacity or under color of legal authority." 18 USC 2337

1993 - 50 USC 1522-1524
Title 50: War and National Defense
Chemical and Biological Warfare

In 1993 (PL 103-160), Congress and President William Clinton provided additional direction and funding procedures for US Department of Defense chemical and biological defense programs.

Congress directed the Defense Secretary to "carry out the chemical and biological defense program of the United States." 50 USC 1522

The legislation included a "sense of Congress" note: "that the President should strengthen Federal interagency emergency planning" by FEMA and federal, state and local agencies, "for development of a capability for early detection and warning of and response to (1) potential terrorist use of chemical or biological agents or weapons; and (2) emergencies or natural disasters involving industrial chemicals or the widespread outbreak of disease." 50 USC 1522 note.

Congress directed the Defense Secretary to report on chemical and biological warfare defense programs, inventories, and other elements in his annual report to Congress under 10 USC 113(c). 50 USC 1523. Congress directed the report to assess "readiness of the Armed Forces to fight in a chemical-biological warfare environment;...steps...to improve such readiness;...requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical or biological weapons." 50 USC 1523

Congress directed the report to include quantities, characteristics, and capabilities of fielded chemical and biological defense equipment to meet wartime and peacetime requirements for support of the Armed Forces, including individual protective items;...status of research and development programs, and acquisition programs, for required improvements in chemical and biological defense equipment and medical treatment, including...assessment of the ability of the DoD and the industrial base to meet those requirements....measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Armed Forces...status of nuclear, biological, and chemical (NBC) warfare defense training and readiness among the Armed Forces and measures being taken to include realistic nuclear, biological, and chemical warfare simulations in war games, battle simulations, and training exercises...measures taken to improve overall management and coordination of the chemical and biological defense program....Problems encountered in the chemical and biological warfare defense program during the past year and recommended solutions to those problems for which additional resources or actions by the Congress are required...description of the chemical warfare defense preparations that have been and are being undertaken...under article X of the Chemical Weapons Convention...and summary of other preparations undertaken by DoD...to prepare for and...assist in the implementation of the convention. 50 USC 1523

In 1993, Congress authorized the Defense Secretary to "enter into agreements with the Secretary of Health and Human Services to provide support for vaccination programs...through use of the excess peacetime biological weapons defense capability of the Department of Defense." 50 USC 1524.

1993 - 10 USC 2371
Title 10: Armed Forces
Advanced research projects: cooperative agreements and other transactions
Authority of ARPA to carry out certain prototype projects

In 1993 (PL 103-160), Congress added a statutory note to 10 USC 2371, authorizing the Director of the Advanced Research Projects Agency (previously and subsequently known as DARPA) to use the authority under 10 USC 2371 for cooperative agreements and other transactions other than contracts and grants, to "carry out prototype projects that are directly relevant to weapons or weapon systems proposed to be acquired or developed by the Department of Defense."

Congress held, as inapplicable to weapon prototype projects, the original 1989 provisions that the government's payments supporting such research and development projects not exceed the other parties' payments, and that the OTA authority only be used when standard contracts or grants are not feasible or appropriate.

1993 - 10 USC 2370a
Title 10: Armed Forces
Biological defense research program
Medical countermeasures against biowarfare threats

In 1993, (PL 103-160) Congress and President Clinton added a new section under the research and development chapter (Ch. 139), under the biological defense research program established in 1990 (PL 101-510) and codified at 10 USC 2370.

The new section, "Medical countermeasures against biowarfare threats: allocation of funding between near-term and other threats," was codified at 10 USC 2370a.

The law allocated up to 80 percent of funds "for the medical component of the Biological Defense Research Program (BDRP)" for "product development, or for research development, test or evaluation of medical countermeasures against near-term validated biowarfare threat agents, and up to 20 percent of funds for products against "mid-term or far-term validated biowarfare threat agents." 10 USC 2370a(a) as of 1993.

Congress defined 'validated biowarfare threat agent' as a "biological agent" named in the biological warfare threat list published by the Defense Intelligence Agency and identified as a threat by the Deputy Chief of Staff of the Army for Intelligence. 10 USC 2370a(b)(1)

Congress defined near-term as a biowarfare threat agent being developed for weaponization within five years; mid-term as "emerging biowarfare threats" that are the object of research by a foreign threat country and will be ready for weaponization within five to 10 years; and far-term as "future biowarfare threats" that are the object of research by a foreign threat country and will be ready for weaponization within 10 to 20 years. 10 USC 2370a(b)(2)-(4).

Congress defined "weaponization" as "incorporation into usable ordnance or other militarily useful means of delivery." 10 USC 2370a(b)(5).

Congress repealed 10 USC 2370a in 2004 (PL 108-375).

1994 - 18 USC 2340
Title 18: Crimes and Criminal Procedure
Torture

In 1994 (PL 103-236 and PL 103-415), Congress implemented provisions of the UN Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, which had opened for signatures in 1984 and entered into force in 1987, by adding sections 2340, 2340A and 2340B to Title 18, Crimes and Criminal Procedure

Congress defined 'torture' to mean "an act committed by a person acting under the color of law specifically intended to inflict severe physical or mental pain or suffering (other than pain or suffering incidental to lawful sanctions) upon another person within his custody or physical control." 18 USC 2340(1)

Congress defined 'severe mental pain or suffering' to mean

> the prolonged mental harm caused by or resulting from—
>
> (A) the intentional infliction or threatened infliction of severe physical pain or suffering;
>
> (B) the administration or application, or threatened administration or application, of mind-altering substances or other procedures calculated to disrupt profoundly the senses or the personality;
>
> (C) the threat of imminent death; or
>
> (D) the threat that another person will imminently be subjected to death, severe physical pain or suffering, or the administration or application of mind-altering substances or other procedures calculated to disrupt profoundly the senses or personality. 18 USC 2340(2)

Congress defined "United States" as "includes all areas under the jurisdiction of the United States including any of the places described in sections 5[11] and 7[12] of this title and section 46501(2) of title 49[13] []."

Congress established penalties applicable to "whoever outside the United States commits or attempts to commit torture," including fines, imprisonment not more than 20 years, or both, and if death results to any person from prohibited torture conduct, imprisonment for any term of years or for life. 18 USC 2340A(a)

Congress provided for US jurisdiction over prohibited torture activity "if (1) the alleged offender is a national of the United States; or (2) the alleged offender is present in the United States, irrespective of the nationality of the victim or alleged offender." 18 USC 2340A(b)

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[11] 18 USC 5: "The term “United States”, as used in this title in a territorial sense, includes all places and waters, continental or insular, subject to the jurisdiction of the United States, except the Canal Zone."
[12] 18 USC 7: *Special maritime and territorial jurisdiction of the United States defined*
[13] 49 USC 46501(2): *Special aircraft jurisdiction of the United States*

In 2001 (PL 107-56) added a conspiracy provision: "A person who conspires to commit an offense under this section shall be subject to the same penalties (other than the penalty of death) as the penalties prescribed for the offense, the commission of which was the object of the conspiracy." 18 USC 2340A(c)

In 2004 (PL 108-375), Congress amended the definition of "United States" to "the several States of the United States, the District of Columbia, and the commonwealths, territories, and possessions of the United States."

Congress provided that the federal torture law should not "be construed as precluding the application of State or local laws on the same subject," and should not "be construed as creating any substantive or procedural right enforceable by law by any party in any civil proceeding." 18 USC 2340B

Discussion

Congress did not prohibit commission of torture, or attempts and conspiracies to commit torture that occur in the United States.

1994 - 18 USC 2332a
Title 18: Crimes and Criminal Procedure
Terrorism, Use of weapons of mass destruction

In 1994 (PL 103-322), Congress and President Clinton added a new "weapon of mass destruction" section to the federal law on terrorism (18 USC 2331 et seq, added in 1986, PL 99-399).

In 1994, Congress enacted 18 USC 2332a, Use of weapons of mass destruction

> (a) Offense. -- A person who uses, threatens, or attempts or conspires to use, a weapon of mass destruction
>
> > (1) against a national of the United States while such national is outside of the United States;
> >
> > (2) against any person within the United States; or
> >
> > (3) against any property that is owned, leased or used by the United States or by any department or agency of the United States, whether the property is within or outside of the United States,
>
> shall be imprisoned for any term of years or for life, and if death results, shall be punished by death or imprisoned for any term of years or for life. 18 USC 2332a(a) as of 1994

As of 1994, Congress defined 'weapon of mass destruction' to mean:

> (A) Any destructive device as defined in section 921 of this title [18 USC 921, describing "any explosive, incendiary, or poison gas—(i) bomb, (ii) grenade, (iii) rocket...(iv) missile...(v) mine..."]
>
> (B) poison gas
>
> (C) any weapon involving a disease organism
>
> (D) any weapon that is designed to release radiation or radioactivity at a level dangerous to human life. 18 USC 2332a(b)(2)

1996 - 10 USC 2370
Title 10: Armed Forces
Biological defense research program

In 1996 (PL 104-106), Congress and President William Clinton repealed the requirement that the Defense Secretary report to Congress on the biological defense research program that had been put in place in 1990 at 10 USC 2370.

1996 - 50 USC 1511 to 1528
Title 50: War and National Defense
Chemical and Biological Warfare

In 1996 (PL 104-106), Congress and President Clinton eliminated the requirement that the Defense Secretary provide reports to Congress under 50 USC 1511, about "amounts spent...for research, development, test and evaluation and procurement of all lethal and nonlethal chemical and biological agents" and "experiments...which involve the use of human subjects for the testing of chemical or biological agents."

Provisions at 50 USC 1520 (addressing use of human subjects to test chemical and biological agents and reporting requirements) remained in effect until repealed and replaced by 50 USC 1520a in 1997 and 22 USC 6701 et seq in 1998.

The 1997 and 1998 legislation (summarized below) maintained exemptions authorizing use of chemical and biological agents on human subjects and civilian populations "carried out for purposes not prohibited," including peaceful purposes, protective purposes, unrelated military purposes and law enforcement purposes.

1996 - 18 USC 175-178
Title 18: Crimes and Criminal Procedure
Biological Weapons

In 1996 (PL 104-132), Congress and President Clinton amended the law prohibiting biological weapons that had been enacted in 1990 (see above), to add terms and phrases relating to biological products, biotechnology, bioengineering and recombinant molecules.

After the 1996 amendments, the biological weapons law read:

> 18 USC 175. Prohibitions with respect to biological weapons
>
> (a) IN GENERAL. Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens or conspires to do the same, shall be fined under this title or imprisoned for life or any term of years, or both...
>
> 18 USC 178. Definitions. As used in this chapter
>
> (1) the term 'biological agent' means any micro-organism, virus, or infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of such microorganism, virus, infectious substance or biological product capable of causing—
>
> (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
>
> (B) deterioration of food, water, equipment, supplies, or material of any kind; or
>
> (C) deleterious alteration of the environment;
>
> (2) the term 'toxin' means, the toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including—
>
> (A) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or
>
> (B) any poisonous isomer or biological product, homolog, or derivative of such a substance;
>
> (4) the term 'vector' means a living organism or molecule, including a recombinant molecule or biological product that may be engineered as a result of biotechnology, capable of carrying a biological agent or toxin to a host.

1996 - 18 USC 2332a
Title 18: Crimes and Criminal Procedure
Terrorism, Use of weapons of mass destruction

In 1996 (PL 104-132), Congress and President Clinton amended the law criminalizing use of weapons of mass destruction.

As of 1994 (PL 103-322, summarized above), 18 USC 2332a read:

> 18 USC 2332a. Use of weapons of mass destruction
>
> (a) Offense. A person who uses, or attempts or conspires to use, a weapon of mass destruction... shall be imprisoned for any term of years or for life, and if death results, shall be punished by death or imprisoned for any term of years or for life...
>
> (b) Definitions. For purposes of this section...
>
> (2) the term 'weapon of mass destruction' means...
>
> (C) any weapon involving a disease organism.

In 1996, Congress enacted several text changes, so that these sections read:

> 18 USC 2332a. Use of weapons of mass destruction
>
> (a) Offense -- A person who <u>without lawful authority</u> uses, threatens or attempts or conspires to use, a weapon of mass destruction, <u>including any biological agent, toxin or vector (as those terms are defined in section 178 of this title)</u>...

Congress also extended the former (a)(2) paragraph: to add the phrase "and the results of such use affect interstate or foreign commerce or, in the case of a threat, attempt, or conspiracy, would have affected interstate or foreign commerce" such that the provision read:

> "A person who, without lawful authority, uses, threatens, or attempts or conspires to use, a weapon of mass destruction
>
> (1) against a national of the United States while such national is outside of the United States; (2) against any person within the United States, and the results of such use affect interstate or foreign commerce or, in the case of a threat, attempt, or conspiracy, would have affected interstate or foreign commerce; or (3) against any property that is owned, leased or used by the United States or by any department or agency of the United States, whether the property is within or outside of the United States, shall be imprisoned for any term of years or for life, and if death results, shall be punished by death or imprisoned for any term of years or for life." 18 USC 2332a(a) as of 1996

1996 - 18 USC 2332b
Title 18: Crimes and Criminal Procedure
Terrorism, Acts of terrorism transcending national boundaries

In 1996 (PL 104-132), Congress and President Clinton added a new section to the criminal code, addressing "acts of terrorism transcending national boundaries," codified at 18 USC 2332b.

Congress prohibited offenses, threats, attempts and conspiracies of

> whoever...involving conduct transcending national boundaries and in a circumstance described in subsection (b)—
>
> > (A) kills, kidnaps, maims, commits an assault resulting in serious bodily injury, or assaults with a dangerous weapon any person within the United States; or
> >
> > (B) creates a substantial risk of serious bodily injury to any other person by destroying or damaging any structure, conveyance, or other real or personal property within the United States. 18 USC 2332b(a)

Congress established, as bases for jurisdiction, if any of the offenders (principals, co-conspirators and accessories) uses the mail or any facility of interstate or foreign commerce in furtherance of the offense; if the offense obstructs, delays, or affects interstate or foreign commerce, or would have so obstructed, delayed, or affected interstate or foreign commerce if the offense had been consummated; if the victim, or intended victim, is the United States Government, a member of the uniformed services, or any official, officer, employee, or agent of the legislative, executive, or judicial branches, or of any department or agency, of the United States; if the structure, conveyance, or other real or personal property is, in whole or in part, owned, possessed, or leased to the United States, or any department or agency of the United States; if the offense is committed in the territorial sea (including the airspace above and the seabed and subsoil below, and artificial islands and fixed structures erected thereon) of the United States; or if the offense is committed within the special maritime and territorial jurisdiction of the United States. 18 USC 2332b(b)

Congress provided for penalties including death penalty or imprisonment up to life "for a killing, or if death results to any person from any other conduct prohibited by this section;" imprisonment up to life for kidnapping; imprisonment up to 35 years for maiming; and imprisonment up to 30 years for assault with a dangerous weapon or assault resulting in serious bodily injury. 18 USC 2332b(c)

Congress defined "conduct transcending national boundaries" as "conduct occurring outside of the United States in addition to the conduct occurring in the United States."

Congress defined "Federal crime of terrorism" as an offense that "is calculated to influence or affect the conduct of government by intimidation or coercion, or to retaliate against government conduct;" and is a violation of federal laws prohibiting violence and destruction, including 18 USC 175 (relating to biological weapons), 18 USC 2332 (relating to acts of international terrorism), 2332a (relating to use of weapons of mass destruction), 2339A (relating to providing material support to terrorists), 2339B (relating to providing material support to terrorist organizations), or 2340A (relating to torture). 18 USC 2332b(g)

1996 - 18 USC 2332c
Title 18: Crimes and Criminal Procedure
Terrorism, Use of chemical weapons

In 1996 (PL 104-132), before the UN Convention on Chemical Weapons entered into force, Congress and President Clinton added a new section to the criminal code, addressing chemical weapons of mass destruction.

The law provided that "A person shall be punished...if that person, without lawful authority, uses, or attempts or conspires to use, a chemical weapon" against US nationals abroad, against any person within the United States, or against any property owned, leased or used by the United States or its departments or agencies, abroad or within the United States.

The law provided for penalties of imprisonment for any term of years or for life, or, if death resulted from use of chemical weapons, death or imprisonment for any term of years or for life.

The law defined "chemical weapon" as

> any weapon that is designed or intended to cause widespread death or serious bodily injury through the release, dissemination, or impact of toxic or poisonous chemicals or precursors of toxic or poisonous chemicals. 18 USC 2332c(b)(2) as of 1996.

Congress repealed 18 USC 2332c two years later, in 1998 (PL 105-277), replacing it with a new section of the criminal code (18 USC 229) through the Chemical Weapons Convention Implementation Act.

1996 - 42 USC 262
Title 42: Public Health and Welfare
Regulation of biological products, Enhanced penalties and control of biological agents.

In 1996 (PL 104-132), Congress and President Clinton directed the Secretary of Health and Human Services to establish regulatory control of biological agents under 42 USC 262; the provisions were set out as a note under 42 USC 262, not a new numbered section.

Congress directed the HHS Secretary to establish and maintain a list of "each biological agent that has the potential to pose a severe threat to public health and safety."

Congress directed the HHS Secretary to "consider," in determining whether to include biological agents on the list, "the effect on human health of exposure to the agent; the degree of contagiousness of the agent and the methods by which the agent is transferred to humans; the availability and effectiveness of immunizations to prevent and treatments for any illness resulting from infection by the agent; and any other criteria that the Secretary considers appropriate."

Congress directed the HHS Secretary to establish and enforce safety procedures for the transfer of listed biological agents, including training for proper handling, proper laboratory facilities, "safeguards to prevent access to such agents for use in domestic or international terrorism;" procedures to protect public safety in the event of improper handling or transfer, and "appropriate availability of biological agents for research, education and other legitimate purposes."

Congress defined "biological agent" by incorporating the definition at 18 USC 178, biological weapons.

HHS officers implemented the "enhanced control of biological agents" provisions through new agency regulations published in October 1996, (61 FR 55190) and codified at 42 CFR 72, which had been used since 1980 and possibly earlier to regulate "interstate shipment of etiologic agents."

In March 2005 (70 FR 13294, 13316), HHS implemented the Congressional programs authorized in 2002 (PL 107-188) and published updated "select agents and toxins" regulations, codified at 42 CFR 73, where they are located as of 2025.

In January 2008 (73 FR 3874), HHS removed 42 CFR 72, which had been replaced by the provisions at 42 CFR 73.

1996 - 42 USC 262
Title 42: Public Health and Welfare
Regulation of biological products, Export of partially processed biological products

In 1996 (PL 104-134), Congress amended 42 USC 262 to condense provisions authorizing export of "partially processed biological products" first enacted in 1986 (PL 99-660, summarized above).

After revisions, 42 USC 262(h) provided that "a partially processed biological product which (1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man; (2) is not intended for sale in the United States; and (3) is intended for further manufacture into final dosage form outside the United States, shall be subject to no restriction on the export of the product" under the Public Health Service Act (PHSA) or Federal Food Drug and Cosmetic Act (FDCA) "if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice [cGMP] requirements or meets international manufacturing standards as certified by an international standards organization recognized by the HHS Secretary and meets the requirements of 21 USC 381(e).

21 USC 381(e) exempts exported products from being deemed adulterated or misbranded if the product "accords to the specifications of the purchaser;" is not illegal in the importing country; is labeled as "intended for export;" and is not sold or offered for sale in domestic commerce.

Discussion

Under the system of legalized biological product non-regulation/regulatory simulation in place since 1902, there are no applicable, applied, enforceable or enforced current good manufacturing practice [cGMP] requirements or international manufacturing standards for biological products.

Those were the inapplicable, unenforced pretextual manufacturing standards from which Congress exempted "partially processed biological products" intended for export to foreign countries.

1996 - 7 USC 136
Title 7: Agriculture
Environmental Pesticide Control, Definitions

In 1996 (PL 104-170), Congress and President Clinton amended 7 USC 136 to add two new definitions.

Congress defined 'public health pesticide' to mean

> any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health. 7 USC 136(nn)

Congress defined 'vector' to mean

> any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats. 7 USC 136(oo)

1996 - 18 USC 2441
Title 18: Crimes and Criminal Procedure
War Crimes

In 1996 (PL 104-192) Congress enacted legislation implementing the 1949 Geneva Conventions. The war crimes provisions were codified first at 18 USC 2401, and then renumbered two months later (PL 104-294) at 18 USC 2441, where they are located as of 2025.

Congress defined, as a criminal offense, the commission of a "grave breach of the Geneva Conventions" whether inside or outside the United States, under "circumstances" described in subsection (b) and provided for fines, imprisonment and the death penalty if death results to the victim. 18 USC 2441(a)

Congress defined, as "circumstances," that the person committing the breach or the victim of the war crime, is a member of the US Armed Forces, or a "national of the United States" as defined in Section 101 of the Immigration and Nationality Act [8 USC 1101]. 18 USC 2441(b)

The Immigration and Nationality Act defines "national of the United States" to mean a citizen of the United States, or a person who, though not a citizen of the United States, owes permanent allegiance to the United States. 8 USC 1101(a)(22)(A) and (B)

Congress defined ‘grave breach' to means "conduct defined as a grave breach in any of the international conventions relating to the laws of warfare signed at Geneva" on Aug. 12, 1949 "or any additional protocol to which the United States is a party." 18 USC 2441(c)

The US, under the administration of President Carter, signed two additional protocols adopted in 1977 (Additional Protocol I and Additional Protocol II) but the US is not a party to the 1977 protocols, because the Senate has not ratified them.

1996 - 50 USC 1522
Title 50: War and National Defense,
Research activities of DARPA relating to chemical and biological warfare defense technology.

In 1996 (PL 104-201) Congress and President Clinton amended 50 USC 1522, to authorize the Director of the Defense Advanced Research Projects Agency (DARPA) to "conduct a program of basic and applied research and advanced technology development on chemical and biological warfare defense technologies."

Congress instructed the DARPA Director to "avoid unnecessary duplication" and coordinate activities with those of military departments and defense agencies, and directed that DARPA budget requests be set forth as a separate program element.

1996 - 50 USC 2301 et seq
Title 50: War and National Defense
Defense against weapons of mass destruction
Domestic preparedness

In 1996 (PL 104-201), Congress and President Clinton added Chapter 40 to Title 50, War and National Defense, codified at 50 USC 2301 et seq., addressing defense against weapons of mass destruction and domestic preparedness.

At the findings section, Congress stated that WMDs are increasingly available; and that technical information and "raw materials for chemical, biological and radiological weapons are widely available for legitimate commercial purposes." Congress claimed that the former Soviet Union "produced and maintained a vast array" of WMDs; that former Soviet states retained facilities, materials and technologies capable of producing more WMDs; that the disintegration of the former Soviet Union disrupted systems for accounting for weapons; that organized crime and corruption increased the potential for proliferation. Congress claimed that hostile nations and terrorist groups thus had more ability to acquire WMDs "greater than at any time in history." Congress stated that "facilities required for production of radiological, biological and chemical weapons are much smaller and harder to detect than nuclear weapons facilities, and biological and chemical weapons can be deployed by alternative delivery means other than long-range ballistic missiles;" such that "conventional counterproliferation efforts would do little to detect or prevent the rapid development of a capability to suddenly manufacture several hundred chemical or biological weapons with nothing but commercial supplies and equipment."

Congress stated that the United States lacked "adequate planning and countermeasures to address the threat of nuclear, radiological, biological and chemical terrorism;" that the Department of Energy had established a Nuclear Emergency Response Team "but no comparable units exist to deal with emergencies involving biological or chemical weapons or related materials."

Congress stated that state and local response personnel were inadequately prepared, and that "development of, and allocation of responsibilities for, effective countermeasures...requires well-coordinated participation by many Federal agencies, and careful planning by the Federal Government and State and local governments."

Congress stated that training and exercises could improve preparedness of State and local personnel; that sharing of expertise and capabilities of the Department of Defense, "which traditionally has provided assistance...in neutralizing, dismantling and disposing of explosive ordnance, as well as radiological, biological and chemical materials, can be a vital contribution to the development and deployment of countermeasures against nuclear, biological, and chemical weapons of mass destruction;" and that the US "lacks effective policy coordination regarding the threat posed by the proliferation of weapons of mass destruction." 50 USC 2301.

Congress defined the term 'weapon of mass' destruction to mean

> any weapon or device that is intended, or has the capability, to cause death or serious bodily injury to a significant number of people through the release, dissemination, or impact of --
>
> (A) toxic or poisonous chemicals or their precursors;
>
> (B) a disease organism; or
>
> (C) radiation or radioactivity. 50 USC 2302(1)

Congress directed the President to take immediate action to "enhance the capability" of the federal government "to prevent and respond to terrorist incidents involving weapons of mass destruction" and to provide support to improve State and local emergency response agencies' capabilities to prevent and respond at local and national levels. Congress directed the President to assess capabilities, identify requirements of improvements, and recommend measures to be taken "including additional resources and legislative authorities that would be required." 50 USC 2311.

Congress directed the Secretary of Defense to train and advise civilian personnel "regarding emergency responses to a use or threatened use of a weapon of mass destruction or related materials" and to coordinate with the FEMA Director, Secretary of Energy and heads of any other Federal, State and local government agencies. Congress described assistance to include training in the use, operation, and maintenance of equipment for detecting a chemical or biological agent or nuclear radiation; monitoring the presence of such an agent; protecting emergency personnel and the public; and decontamination, along with setting up a "hot line," providing for use of the National Guard, and loan of equipment. 50 USC 2312.

Congress directed the Secretary of Defense to designate a lead official within DoD to coordinate programs, to set up a "domestic terrorism rapid response team" and to incorporate rapid response team guidance into FEMA emergency response plans written under the Stafford Act. 50 USC 2313, 50 USC 2314.

Congress directed the Defense Secretary to conduct programs to test and improve responses of Federal, State and local agencies to emergencies involving biological weapons, chemical weapons and related materials, to include annual exercises carried out from 1997-2001. 50 USC 2315.

Congress directed the President to provide reports to Congress on federal programs to counter terrorist WMD threats. 50 USC 2316

Congress directed the heads of federal agencies to develop a "rapid response information system," including inventories of physical equipment held by each agency, and a database on chemical and biological materials. 50 USC 2317

Congress directed the President to designate a National Coordinator for Nonproliferation Matters, and set up a Committee on Nonproliferation as a subcommittee of the National Security Council, to include Secretary of State, Secretary of Defense, CIA Director, Attorney General, Secretary of Energy, FEMA Administrator, Treasury Secretary, Commerce Secretary and other members as designated by president. Congress tasked the committee with coordinating federal programs, making recommendations to the President, coordinating Federal, State and local capabilities to "manage crises involving nuclear, radiological, biological or chemical weapons...and to manage the consequences of a use of such weapon or related materials or technologies." 50 USC 2352

Congress directed the President — through the committee — to develop a "comprehensive preparedness program," to include: plans for countering proliferation of weapons of mass destruction and related materials and technologies;...training and equipping Federal, State, and local officials for managing a crisis;...providing for regular sharing of information among intelligence, law enforcement, and customs agencies;... training and equipping...personnel to counter the smuggling of weapons of mass destruction and related materials and technologies;... establishing appropriate centers for analyzing seized nuclear, radiological, biological, and chemical weapons, and related materials and technologies;...establishing...legal controls and authorities relating to the exporting of nuclear, radiological, biological, and chemical weapons, and related materials and technologies;...encouraging and assisting governments of foreign countries to implement and enforce laws...regarding the smuggling of weapons of mass destruction;...[controlling and reducing nuclear weapons and fissile materials in the US and Russia];...and studying the merits and costs of establishing a global network of means for detecting and responding to terroristic or other criminal use of biological agents against people or other forms of life in the United States or any foreign country. 50 USC 2353

1996 - 10 USC 382/10 USC 282; 18 USC 175a; 18 USC 2332c/18 USC 229F
Title 10: Armed Forces
Military assistance to civilian law enforcement in emergency situations involving biological or chemical weapons

In 1996 (PL 104-201) Congress and President Clinton added a new section to Title 10, Armed Forces, authorizing the Secretary of Defense to provide assistance to Department of Justice law enforcement activities during emergency situations involving biological or chemical weapons of mass destruction, if the Defense Secretary and Attorney General jointly "determine that an emergency situation exists;" and the Defense Secretary determines that providing assistance will not adversely affect military preparedness.

Congress defined 'emergency situations involving a biological or chemical weapon of mass destruction' to mean:

> a circumstance involving a biological or chemical weapon of mass destruction --
>
> (1) that poses a serious threat to the interests of the United States; and
>
> (2) in which --
>
> > (A) civilian expertise and capabilities are not readily available to provide the required assistance to counter the threat immediately posed by the weapon involved;
> >
> > (B) special capabilities and expertise of the Department of Defense are necessary and critical to counter the threat posed by the weapon involved; and
> >
> > (C) enforcement of section 175 or 2332c of title 18 would be seriously impaired if the Department of Defense assistance were not provided.

Congress directed the Defense Secretary and Attorney General to prescribe regulations about the types of assistance, precluding "arrest" actions and direct participation in conducting search and seizure of evidence, and direct participation in the collection of intelligence. But, Congress added, regulations could authorize military participation in arrests, searches, seizures and intelligence-collection, if "the action is considered necessary for the immediate protection of human life, and civilian law enforcement officials are not capable of taking the action" or the action is otherwise authorized.

Congress added provisions at the biological weapons law [18 USC 175a] and chemical weapons law [18 USC 2332c, later 18 USC 229F], authorizing the Attorney General to request military assistance in emergency situations.

Congress renumbered 10 USC 382 in Dec. 2016 (PL 114-328) to 10 USC 282.

1997 - US Senate ratification of UN Chemical Weapons Convention
Senate Resolution 75, 105th Congress

The United States is a party to the UN Chemical Weapons Convention; the US Senate ratified the treaty by vote April 24, 1997 (Senate Resolution 75, 105th Congress) with conditions.

Condition 9 addressed "protection of advanced biotechnology" and directed the US President to certify each year that "the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1 of the Annex on Chemicals."

Condition 11 addressed "enhancement to robust chemical and biological defenses" describing chemical and biological threats and lack of "readiness," directing the Defense Secretary to ensure readiness and to submit annual reports to Senate and House committees on chemical and biological weapons defense activities, including "assessment of current and projected vaccine production capabilities and vaccine stocks."

1997 - 50 USC 1511-1528
Title 50: War and National Defense
Chemical and Biological Warfare

In 1997 (PL 105-85 and PL 105-115), Congress enacted several new provisions governing use by the Department of Defense of human subjects for testing of chemical and biological agents, and reporting about human subjects testing to Congress.

The new provisions enacted through PL 105-85 included 50 USC 1520a, "Restrictions on the use of human subjects for testing of chemical and biological agents," pertaining to use of chemical and biological agents on members of armed services and on civilians; and 10 USC 1107 - "Notice of use of an investigational new drug or a drug unapproved for its applied use," pertaining to use of chemical and biological agents described as investigational and unapproved drugs, on members of armed services.

The new provisions enacted through PL 105-115 included 21 USC 360bbb, *Expanded access to unapproved therapies and diagnostics*, pertaining to use of chemical and biological agents, described as unapproved therapies and diagnostics, on civilians, and amendments to 21 USC 355, *New drugs*.

50 USC 1520a - Restrictions on the use of human subjects for testing of chemical and biological agents.

In 1997, (PL 105-85) Congress prohibited Secretary of Defense from conducting, directly or by contract, "(1) any test or experiment involving the use of a chemical agent or biological agent on a civilian population; or (2) any other testing of a chemical agent or biological agent on human subjects." 50 USC 1520a(a)

Congress excluded, from the prohibition, tests and experiments on civilian populations and human subjects carried out for:

> (1) Any peaceful purpose that is related to a medical, therapeutic, pharmaceutical, agricultural, industrial, or research activity.
>
> (2) Any purpose that is directly related to protection against toxic chemicals or biological weapons and agents.
>
> (3) Any law enforcement purpose, including any purpose related to riot control. 50 USC 1520a(b)

Congress required the Secretary of Defense to obtain "informed consent" from each human subject in advance of testing, 50 USC 1520a(c).

Congress required the Secretary of Defense to submit a report to Congressional committees (Senate Armed Services, House National Security), within 30 days after DoD approval of study plans, on studies "involving the use of human subjects for the testing of a chemical agent or a

biological agent," and authorizing the studies to begin 30 days after the date the Congressional committees received the report. 50 USC 1520a(d).

Through the 1997 law, Congress adopted a definition of 'biological agent' similar to the one adopted in 1990 Biological Weapons law and amended in 1996 (18 USC 178), but with the added phrase "including bacteria, viruses, fungi, rickettsia, or protozoa."

Congress defined 'biological agent' to mean

> any micro-organism (including bacteria, viruses, fungi, rickettsiae, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, that is capable of causing—
>
> > (1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
> >
> > (2) deterioration of food, water, equipment, supplies, or materials of any kind; or
> >
> > (3) deleterious alteration of the environment. 50 USC 1520a(e)

1523 - Annual report on chemical and biological warfare defense

In 1997, (PL 105-85), Congress revised reporting requirements under 50 USC 1523(b).

In 1993 (103-160, summarized above), Congress added a provision directing the Defense Secretary to include, in his annual general report to Congress under 10 USC 113(c), a section on "chemical and biological warfare defense" programs conducted during the prior year, specifying eight subject areas: quantities, characteristics, and capabilities of fielded chemical and biological defense equipment; status of research, development and acquisition programs, including assessment of DoD and industrial base capacities; status of training and readiness; measures taken to improve coordination; problems encountered, recommended solutions; and implementation of the Chemical Weapons Convention. 50 USC 1523(b)(1)-(8)

In 1997, Congress added a ninth subject area, requiring the annual general DoD report, in the section on chemical and biological warfare defense, to provide

> A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with—
>
> > (A) a detailed justification for the testing;
> >
> > (B) a detailed explanation of the purposes of the testing;

(C) a description of each chemical or biological agent tested; and

(D) the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject." 50 USC 1523(b)(9)

Congress eliminated the reporting requirements under 50 USC 1523 in 2016 (PL 114-328), effective Dec. 31, 2021.

50 USC 1520 - Use by the Department of Defense of human subjects for testing of chemical or biological agents

In the same 1997 act (PL 105-85), Congress repealed 50 USC 1520, a provision about use by the Department of Defense of human subjects for testing of chemical or biological agents, accounting to congressional committees with respect to experiments and studies, and notification of local civilian officials, which had been in place since 1977 (PL 95-79) as amended in 1982 (PL 97-375).

Congress repealed 50 USC 1520 as superseded by 50 USC 1520a, governing use of human subjects, and 50 USC 1523(b)(9), governing reporting to Congress.

Discussion

Congress exempted, from 50 USC 1520a prohibitions and informed consent provisions, tests and experiments conducted on human subjects for any imputed "peaceful purpose that is related to a medical, therapeutic, pharmaceutical, agricultural, industrial, or research activity; any purpose that is directly related to protection against toxic chemicals or biological weapons and agents; and any law enforcement purpose."

Congress excluded from 50 USC 1520a, acknowledgement of several facts: there is no feasible way to obtain or disclose information about the contents of unstable, indeterminate mixtures of biological and chemical matter; there are no laws or regulations requiring biological product suppliers to state accurate, complete information about contents on container labels or other printed matter; neither Congress nor government regulators have established physical standards for identity, purity, stability, or non-toxicity; and there are no laws or regulations requiring the government regulators to test or to make accurate predictions about the effects unstable mixtures may have on individual physiological processes and organ functioning.

In other words, there is no possibility of providing informed consent, because no physical definition of container contents is legally required, obtainable or available.

1997 - 10 USC 1107
Title 10: Armed Forces
Medical and dental care
Notice of use of investigational new drugs or drugs unapproved for their applied use

In 1997 (PL 105-85) Congress and President Clinton added 10 USC 1107, "Notice of use of investigational new drugs or drugs unapproved for their applied use," pertaining to use of unapproved drugs on military personnel.

Congress authorized the Secretary of Defense to use "investigational new drugs" or "a drug unapproved for its applied use" on members of the armed forces, on condition that the Defense Secretary provide the member with "notice" and also provide information to health care providers administering investigational new drugs or unapproved drugs. 10 USC 1107(a)

Congress required the notice to be provided before administration "if practicable" or within 30 days after administration. 10 USC 1107(b)

Congress required the notice to service members to be in writing, "unless the Secretary of Defense determines that the use of written notice is impractical" because of the number of members receiving the drug, time constraints or "similar reasons." If notice in other than written form is used, Congress directed the Defense Secretary to report on the "alternative method" of notice and reasons it was used. 10 USC 1107(c)

Congress required the notice to include "clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use; the reasons why the investigational new drug or drug unapproved for its applied use is being administered; information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug; such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed." 10 USC 1107(d)

Congress required the Secretary of Defense to ensure that service member medical records accurately document the member's receipt of any investigational new drug or drug unapproved for its applied use; and the required notice. 10 USC 1107(e)

Congress defined the term ‘investigational new drug’ to mean a drug covered by FDCA 505(i) [21 USC 355(i), *New drugs, Exemptions*] and therefore exempt from new drug application procedures.

Congress defined the term ‘drug unapproved for its applied use’ to mean a drug administered for a use not described in the approved labeling of the drug under FDCA 505 [21 USC 355, *New drugs*].

1997 - 21 USC 360bbb
Title 21: Food and Drugs
General Provisions Relating to Drugs and Devices,
Expanded access to unapproved therapies

In 1997 (PL 105-115, FDA Modernization Act/FDAMA), Congress authorized the "expanded access to unapproved therapies" program, codified at 21 USC 360bbb.

This was the legal platform to which the "emergency use authorization" program was added in 2003, codified at 21 USC 360bbb-3

Through FDAMA, Congress authorized the HHS Secretary to authorize shipment of "investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations," under conditions to be determined by the HHS Secretary. 21 USC 360bbb(a)

Congress authorized any person, acting through a licensed physician, to request investigational drugs and devices from manufacturers, if the physician decided there were no comparable or satisfactory alternative therapies available, and that the "probable risk to the patient from the drug or device...is not greater than the probable risk from the disease or condition;" if the HHS Secretary determined that there is "sufficient evidence of safety and effectiveness" and that use of the drug or device will not interfere with clinical investigations to support marketing approval; and if the sponsor (manufacturer or investigator) submits a clinical protocol for use of the drug or device in a single patient or small group of patients. 21 USC 360bbb(b)

Congress directed sponsors or physicians to submit "expanded access protocols" and directed the HHS Secretary to permit shipping of the drugs or devices if the HHS Secretary determines that the drug or device was intended for use in diagnosis, monitoring or treatment of a serious or immediately life-threatening disease or condition; no comparable alternatives are available; non-interference with ongoing clinical trials; the drug or device is under investigation in a controlled clinical trial or trials had been completed, and the sponsor is pursuing marketing approval; there is "sufficient evidence of safety and effectiveness" to support use for "serious diseases;" and, for "immediately life-threatening diseases" if "the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury." 21 USC 360bbb(c)

Congress authorized HHS Secretary to terminate "expanded access" if the requirements are no longer met. 21 USC 360bbb(d)

Congress authorized the HHS Secretary to provide definitions for ‘investigational drug,’ ‘investigational device,’ ‘treatment investigational new drug application,’ and ‘treatment investigational device exemption’ through regulations. 21 USC 360bbb(e)

Congress directed the HHS Secretary to establish, by regulation, procedures for sponsors or manufacturers to request reviews of "scientific controversy" between HHS and sponsors, including reviews by scientific advisory panels or committees. 21 USC 360bbb-1

Congress directed applicants (sponsors, manufacturers) to submit requests about whether to classify the product as a "drug, biological product, device or combination product" including a recommendation for how the product should be classified. Congress gave the HHS Secretary 60 days to determine the classification, and provide a written statement, and provided that, if the HHS Secretary failed to act within the 60-day period, the applicants' classification recommendation would be considered to be a final determination by the HHS Secretary. 21 USC 360bbb-2.

1997 - 21 USC 355(i) [FDCA 505(i)]
Title 21: Food and Drugs
New drugs
Exemptions of drugs for research

In 1997 (PL 105-115), Congress amended exemptions provisions of the 1938 FDCA (PL 75-717, PL 87-781, summarized above) pertaining to exemptions for investigational drugs, by renumbering the existing provisions, and adding three new paragraphs.

Congress authorized manufacturers or sponsors to begin clinical investigation of a new drug 30 days after submitting information to the HHS Secretary about the drug and the clinical investigation, including "information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies." 21 USC 355(i)(2) as of 1997

Congress authorized the HHS Secretary to prohibit the sponsor from conducting the investigation (place a 'clinical hold') if he determines (and specifies informational basis in writing) that "the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment" of PL 105-115, Food and Drug Administration Modernization Act of 1997. Congress authorized sponsors to request that a clinical hold be removed, and required the HHS Secretary to provide a written response within 30 days. 21 USC 355(i)(3) as of 1997

Congress directed the HHS Secretary to prescribe regulations conditioning exemptions "upon the manufacturer, or the sponsor...requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." 21 USC 355(i)(4) as of 1997

1997 - 42 USC 262
Title 42: Public Health and Welfare
Regulation of biological products

In 1997 (PL 105-115), Congress amended and reorganized the law governing regulation of biological products.

Congress moved the section providing for issuance of licenses to establishments bottling vaccines and other biological products from 42 USC 262(d) to 42 USC 262(a).

Congress changed the term to denote the license held by each company to a 'biologics license' rather than a 'license.' The application process that had, prior to 1997, included an 'establishment license application,' a 'product license application' or both, was designated as a 'biologics license application' or BLA.

Congress carried forward the basic provisions of the 1902 Virus-Toxin law and 1944 Public Health Service Act. As of 1997, the law provided:

> "(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—
>
> (A) a biologics license is in effect for the biological product; and
>
> (B) each package of the biological product is plainly marked with—
>
> (i) the proper name of the biological product contained in the package;
>
> (ii) the name, address, and applicable license number of the manufacturer of the biological product; and
>
> (iii) the expiration date of the biological product." 42 USC 262(a)(1)

Congress directed the HHS Secretary to "establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses" and stated that the Secretary "shall approve" a BLA "on the basis of a demonstration that (I) the biological product that is the subject of the application is safe, pure, and potent; and (II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and if the applicant...consents to the inspection of the facility that is the subject of the application." 42 USC 262(a)(2)

Congress directed the HHS Secretary to "prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1)." 42 USC 262(a)(3)

Congress moved the list of articles categorized as "biological products" from its former location at 42 USC 262(a) to a new section: 42 USC 262(i), defining biological product to mean: "a virus,

therapeutic serum, toxin, anti- toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 USC 262(i)

Congress maintained provisions prohibiting false labeling and authorizing facility inspections. 42 USC 262(b) and 42 USC 262(c).

Congress maintained the provision that had been added in 1986 to authorize HHS Secretary recall of products "upon a determination that...a product...presents an imminent or substantial hazard to the public health." 42 USC 262(d).

Congress maintained a provision authorizing imposition of penalties up to $500 or imprisonment up to one year for offenses. 42 USC 262(f)

Congress maintained a provision generally exempting biological product establishments licensed under the Public Health Service Act from regulatory controls under the Food Drug and Cosmetic Act. 42 USC 262(g)

Congress added a provision exempting biological products bottled at establishments holding biologics licenses under the Public Health Service Act from new drug application (NDA) requirements under the Food Drug and Cosmetic Act. 42 USC 262(j).

Congress directed the HHS Secretary to "take measures to minimize differences in the review and approval of products required to have approved biologics license applications" under the PHSA and "products required to have approved new drug applications" under the FDCA. This provision was codified as a note under 21 USC 355, *New Drugs*.

Discussion

When amending the biological product licensing section in 1997, Congress did not direct the HHS Secretary to establish physical standards for product identity, safety, purity and potency.

Congress did not add requirements that applicants or regulators identify analytical tests capable of identifying product components, or tests capable of measuring product safety, purity and potency.

Congress did not add requirements that applicants or regulators submit product specimens to any inspections or analytical tests capable of identifying components or measuring safety, purity and potency for compliance with standards.

Congress did not add requirements that package labels contain specific, verifiable information about the physical composition, purity, stability or potency of the matter contained in the package.

Congress did not require federal officers to collect and test product specimens, or report non-

compliant specimens to a prosecutor, did not assign a duty to investigate and prosecute violations to any state or federal prosecutors, did not provide a standard of evidence, and did not designate a court to review evidence and impose penalties.

Congress thus maintained the practical, theoretical and legal infeasibility of any biological product being found or deemed unsafe, impure, ineffective, adulterated, contaminated, misbranded or an "imminent or substantial hazard to the public health."

Since 1997

Since 1997, Congress has amended the provisions of 42 USC 262 several times.

The most significant amendment was the addition, in 2010 (PL 111-148), of subsection (k) provisions authorizing the introduction into interstate commerce of biological products as 'biosimilar' or 'interchangeable:' products deemed "similar" to or "interchangeable" with "reference products" for which there exist no design or manufacturing standards.

1997 - 18 USC 2441
Title 18: Crimes and Criminal Procedures
War crimes

In 1997 (PL 105-118), Congress amended the law providing penalties for commission of war crimes under the Geneva Conventions.

Congress struck "grave breach of the Geneva Conventions," and the word "breach" and replaced both with "war crime." 18 USC 2441(a) and (b)

Congress defined war crime to mean "any conduct defined as a grave breach" in any of the 1949 Geneva Conventions, or any "protocol to such convention to which the United States is a party;" any conduct prohibited by Article 23, 25, 27, or 28 of the Annex to the 1907 Hague Convention IV, Respecting the Laws and Customs of War on Land; any conduct "which constitutes a violation of common Article 3" of the 1949 Geneva Conventions, "or any protocol to such convention to which the United States is a party and which deals with non-international armed conflict;" or any conduct "of a person who, in relation to an armed conflict and contrary to the provisions of the Protocol on Prohibitions or Restrictions on the Use of Mines, Booby-Traps and Other Devices as amended at Geneva on 3 May 1996 (Protocol II as amended on 3 May 1996), when the United States is a party to such Protocol, willfully kills or causes serious injury to civilians." 18 USC 2441(c)

1907 Hague Convention IV:

> Article 23. In addition to the prohibitions provided by special Conventions, it is especially forbidden -
>
> To employ poison or poisoned weapons;
>
> To kill or wound treacherously individuals belonging to the hostile nation or army;
>
> To kill or wound an enemy who, having laid down his arms, or having no longer means of defence, has surrendered at discretion; To declare that no quarter will be given;
>
> To employ arms, projectiles, or material calculated to cause unnecessary suffering;
>
> To make improper use of a flag of truce, of the national flag or of the military insignia and uniform of the enemy, as well as the distinctive badges of the Geneva Convention;
>
> To destroy or seize the enemy's property, unless such destruction or seizure be imperatively demanded by the necessities of war;
>
> To declare abolished, suspended, or inadmissible in a court of law the rights and actions of the nationals of the hostile party. A belligerent is likewise forbidden to compel the nationals of the hostile party to take part in the operations of war directed against their

own country, even if they were in the belligerent's service before the commencement of the war.

Article 25 - The attack or bombardment, by whatever means, of towns, villages, dwellings, or buildings which are undefended is prohibited.

Article 27 - In sieges and bombardments all necessary steps must be taken to spare, as far as possible, buildings dedicated to religion, art, science, or charitable purposes, historic monuments, hospitals, and places where the sick and wounded are collected, provided they are not being used at the time for military purposes.

It is the duty of the besieged to indicate the presence of such buildings or places by distinctive and visible signs, which shall be notified to the enemy beforehand.

Article 28 - The pillage of a town or place, even when taken by assault, is prohibited.

1949 Geneva Conventions

First Geneva Convention, Article 50, grave breaches

Article 50 — Grave breaches to which the preceding Article relates shall be those involving any of the following acts, if committed against persons or property protected by the Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, and extensive destruction and appropriation of property, not justified by military necessity and carried out unlawfully and wantonly.

Second Geneva Convention, Article 51, grave breaches

Article 51 — Grave breaches to which the preceding Article relates shall be those involving any of the following acts, if committed against persons or property protected by the Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, and extensive destruction and appropriation of property, not justified by military necessity and carried out unlawfully and wantonly.

Third Geneva Convention, Article 130, grave breaches

Article 130 — Grave breaches to which the preceding Article relates shall be those involving any of the following acts, if committed against persons or property protected by the Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, compelling a prisoner of war to serve in the forces of the hostile Power, or wilfully depriving a prisoner of war of the rights of fair and regular trial prescribed in this Convention.

Fourth Geneva Convention, (regarding civilian persons) Article 147, grave breaches

> Article 147 — Grave breaches to which the preceding Article relates shall be those involving any of the following acts, if committed against persons or property protected by the present Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, unlawful deportation or transfer or unlawful confinement of a protected person, compelling a protected person to serve in the forces of a hostile Power, or wilfully depriving a protected person of the rights of fair and regular trial prescribed in the present Convention, taking of hostages and extensive destruction and appropriation of property, not justified by military necessity and carried out unlawfully and wantonly.

1998 - 10 USC 1107
Title 10: Armed Forces
Medical and dental care
Notice of use of an unapproved drug or a drug unapproved for its applied use.

In 1998 (PL 105-261), Congress amended 10 USC 1107, which Congress had passed in 1997 (PL 105-85, summarized above).

In 1998, Congress struck out the phrase "if practicable, but in no case later than 30 days after the drug is first administered to the member" in section (b).

The amended provision read: "The notice required to be provided...shall be provided before the investigational new drug or drug unapproved for its applied use is first administered to the member." 10 USC 1107(b) as of 1998.

In 1998, Congress struck out the phrase, in subsection (c), "unless the Secretary of Defense determines that the use of written notice is impractical because of the number of members receiving the investigational new drug or drug unapproved for its applied use, time constraints, or similar reasons. If the Secretary provides notice...in a form other than in writing, the Secretary shall submit to Congress a report describing the notification method used and the reasons for the use of the alternative method."

The amended provision read: "The notice required...shall be provided in writing." 10 USC 1107(c) as of 1998.

In 1998, Congress redesignated the former subsection (f), providing definitions of terms, as subsection (g), and inserted a new subsection (f).

Congress authorized the President (only the President) to waive the requirement, under FDCA 505(i)(4) [21 USC 355(i)(4)[14]] that members of the armed forces provide prior consent to receive investigational new drugs or drugs unapproved for their applied uses. Congress authorized the President to grant such waivers "only if the President determines, in writing, that obtaining consent is not feasible; is contrary to the best interests of the member; or is not in the interests of national security." 10 USC 1107(f)(1)

Congress directed the President to "apply the standards and criteria that are set forth in the relevant FDA regulations for a waiver of the prior consent requirement on that ground," in making a determination to waive the prior consent requirement on a ground that "obtaining consent is not feasible" or that obtaining consent "is contrary to the best interest of the member." 10 USC 1107(f)(2)

[14] 21 USC 355(i)(4), *New drugs, Exemptions*. Use of investigational drugs conditioned on informing human beings administered such drugs, that the drugs are being used for investigational purposes, and on obtaining their consent except where it is not feasible or it is contrary to the best interests of such human beings.

Congress authorized the Defense Secretary to request the President to waive the prior consent requirement for investigational new drugs or drugs unapproved for their applied use, for members of the armed forces "in connection with the member's participation in a particular military operation" and held that the Defense Secretary could not delegate the authority to make such requests, and that if the President granted the waiver, the Defense Secretary should submit notifications, the Secretary's justification for the request, and the President's written determination, to congressional defense committees. 10 USC 1107(f)(3)

Congress defined the term "relevant FDA regulations" to mean regulations under FDCA 505(i) [21 USC 355(i), governing "Exemptions of drugs for research" under the law prohibiting introduction of new drugs into interstate commerce without an approved new drug application in effect.] 10 USC 1107(f)(4)(A)

Congress defined the term "prior consent requirement" to mean consent requirements under FDCA 505(i)(4) [21 U.S.C. 355(i)(4)] requiring manufacturers and sponsors of investigational drugs to inform human beings to whom such drugs are administered that the drugs are investigational, and to obtain consent, "except where it is not feasible or it is contrary to the best interests of such human beings." 10 USC 1107(f)(4)(B)

1998 - 18 USC 229 et seq
Title 42: Crimes and Criminal Procedures
Chemical Weapons

In 1998 (PL 105-277) Congress and President Clinton added Chapter 11B to Title 18, Crimes and Criminal Procedure, providing penalties for crimes involving chemical weapons, codified at 18 USC 229 et seq.

> 18 USC 229. Prohibited activities
>
> (a) Unlawful conduct.—Except as provided in subsection (b), it shall be unlawful for any person knowingly—
>
> > (1) to develop, produce, otherwise acquire, transfer directly or indirectly, receive, stockpile, retain, own, possess, or use, or threaten to use, any chemical weapon; or
> >
> > (2) to assist or induce, in any way, any person to violate paragraph (1), or to attempt or conspire to violate paragraph (1). 18 USC 229(a)

Congress exempted the retention, ownership, possession, transfer, or receipt of a chemical weapon by a department, agency, or other entity of the United States, or by a person (member of the Armed Forces...authorized ... to retain, own, possess, transfer, or receive the chemical weapon; or in an emergency situation, any otherwise nonculpable person if the person is attempting to destroy or seize the weapon) pending destruction of the weapon. 18 USC 229(b).

Congress provided for criminal and civil penalties including fines, imprisonment and the death penalty "for any person...by whose action the death of another person is the result." 18 USC 229A

Congress defined 'chemical weapon' to mean:

> "...together or separately:
>
> (A) A toxic chemical and its precursors, <u>except where intended for a purpose not prohibited under this chapter</u> as long as the type and quantity is consistent with such a purpose.
>
> (B) A munition or device, specifically designed to cause death or other harm through toxic properties of those toxic chemicals specified in subparagraph (A), which would be released as a result of the employment of such munition or device.
>
> (C) Any equipment specifically designed for use directly in connection with the employment of munitions or devices specified in subparagraph (B). 18 USC 229F(1)

Congress defined 'precursor' to mean

> any chemical reactant which takes part at any stage in the production by whatever method of a toxic chemical. The term includes any key component of a binary or multicomponent chemical system.18 USC 229F(6)

Congress defined 'purposes not prohibited:'

> (A) Peaceful purposes.—Any peaceful purpose related to an industrial, agricultural, research, medical, or pharmaceutical activity or other activity.
>
> (B) Protective purposes.—Any purpose directly related to protection against toxic chemicals and to protection against chemical weapons.
>
> (C) Unrelated military purposes.—Any military purpose of the United States that is not connected with the use of a chemical weapon and that is not dependent on the use of the toxic or poisonous properties of the chemical weapon to cause death or other harm.
>
> (D) Law enforcement purpose.—Any law enforcement purpose, including any domestic riot control purpose and including imposition of capital punishment. 18 USC 229F(7)

Congress defined 'toxic chemical:'

> any chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. The term includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere. 18 USC 229F(8)

1998 - 18 USC 2332a; 18 USC 2332c
Title 18: Crimes and Criminal Procedure
Terrorism, Weapons of mass destruction, Chemical weapons

In 1998 (PL 105-277), Congress repealed 18 USC 2332c, the previous law providing criminal penalties for use of chemical weapons of mass destruction which had been added in 1996 (PL 104-132), because it had been replaced by 18 USC 229 et seq.

Congress also revised the heading for 18 USC 2332a from "use of weapons of mass destruction" to "use of certain weapons of mass destruction," and added the phrase "other than a chemical weapon as that term is defined in section 229F" after the phrase "weapon of mass destruction."

1998 - 22 USC 6701 et seq
Title 22: Foreign Relations and Intercourse
Chemical Weapons Convention Implementation

In 1998 (PL 105-277), Congress and President Clinton added Chapter 75, Chemical Weapons Convention Implementation, under Title 22, Foreign Relations and Intercourse, codified at 22 USC 6701-6771.

Congress defined 'toxic chemical':

> any chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. The term includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere." 22 USC 6701(13)(A)

Congress defined 'purposes not prohibited by this chapter':

> (A) Peaceful purposes—Any peaceful purpose related to an industrial, agricultural, research, medical, or pharmaceutical activity or other activity.
>
> (B) Protective purposes—Any purpose directly related to protection against toxic chemicals and to protection against
> chemical weapons.
>
> (C) Unrelated military purposes—Any military purpose of the United States that is not connected with the use of a chemical weapon or that is not dependent on the use of the toxic or poisonous properties of the chemical weapon to cause death or other harm.
>
> (D) Law enforcement purposes—Any law enforcement purpose, including any domestic riot control purpose and including imposition of capital punishment. 22 USC 6701(8)

Congress addressed "use of human subjects for testing of chemical or biological agents"

> Prohibition.
>
> (a) In general.—Neither the Secretary of Defense nor any other officer or employee of the United States may, directly or by contract—
>
> > (1) conduct any test or experiment involving the use of any chemical or biological agent on a civilian population; or
> >
> > (2) use human subjects for the testing of chemical or biological agents. 22 USC 6771(a)

Congress added a rule of construction, exempting "actions carried out for purposes not prohibited" from application of the prohibition:

> Nothing in subsection (a) may be construed to prohibit actions carried out for purposes not prohibited by this Act as defined in [22 USC 6701(8)]. 22 USC 6771(b)

Congress defined 'biological agent,' using the definition established in 1997 under 50 USC 1520a

> In this section, the term ‘‘biological agent’’ means any micro-organism (including bacteria, viruses, fungi, rickettsiae or protozoa), pathogen, or infectious substance, or any naturally occurring, bio-engineered or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, capable of causing—
>
> > (1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
> >
> > (2) deterioration of food, water, equipment, supplies, or materials of any kind; or
> >
> > (3) deleterious alteration of the environment. 22 USC 6771(c)

Congress inserted exemptions under the UN Chemical Weapons Convention, for "unscheduled discrete organic chemicals," into the US law implementing the UN convention.

Congress defined 'unscheduled discrete organic chemical' to mean "any chemical not listed on any schedule contained in the Annex on Chemicals of the Convention that belongs to the class of chemical compounds consisting of all compounds of carbon, except for its oxides, sulfides, and metal carbonates." 22 USC 6701(15).

Congress provided that "notwithstanding any other provision of this chapter, no person located in the United States shall be required to report on, or to submit to, any routine inspection conducted for the purpose of verifying the production, possession, consumption, exportation, importation, or proposed production, possession, consumption, exportation, or importation of any substance that is— (1) an unscheduled discrete organic chemical; and (2) a coincidental byproduct of a manufacturing or production process that is not isolated or captured for use or sale during the process and is routed to, or escapes, from the waste stream of a stack, incinerator, or wastewater treatment system or any other waste stream." 22 USC 6743

1998 - 50 USC 1520
Title 50: War and National Defense
Chemical and Biological Warfare
Use of human subjects for testing of chemical or biological agents

In 1998 (PL 105-277), Congress repealed (for the second time) 50 USC 1520 (Section 808 of the 1978 Defense Appropriation Authorization Act, PL 95-79, summarized above), relating to the use of human subjects for the testing of chemical or biological agents.

Congress repealed the 1978 law twice because Congress had replaced the 1978 law with two laws: the 1997 law (50 USC 1520a, *Restrictions on the use of human subjects for testing of chemical and biological agents*) and the 1998 law (22 USC 6771, *Use of human subjects for testing of chemical or biological agents*.)

1998 - Pharmaceutical and vaccine stockpiling activities at CDC

In 1998 (PL 105-277), under the section Department of Health and Human Services Appropriations Act for FY1999, Congress designated $51,000,000 to the Public Health and Social Services Emergency Fund..."for pharmaceutical and vaccine stockpiling activities at the Centers for Disease Control and Prevention."

Discussion

This collection of products and product supply contracts was originally called the National Pharmaceutical Stockpile and was later codified at 42 USC 300hh-12 and renamed Strategic National Stockpile in 2002 and then moved, in 2004, to 42 USC 247d-6b.

1999 - 10 USC 382 (renumbered 10 USC 282 in 2016)
Title 10: Armed Forces
Emergency situations involving chemical or biological weapons of mass destruction

In 1999 (PL 106-65), Congress added a note to 10 USC 382, *Emergency situations involving chemical or biological weapons of mass destruction*, which Congress had added in 1996.

The note was titled: Military assistance to civil authorities to respond to act or threat of terrorism.

Congress authorized the Secretary of Defense, upon the request of the Attorney General, to "provide assistance to civil authorities in responding to an act of terrorism or threat of an act of terrorism, including an act of terrorism or threat of an act of terrorism that involves a weapon of mass destruction, within the United States, if the Secretary determines that (1) special capabilities and expertise of the Department of Defense are necessary and critical to respond to the act of terrorism or the threat of an act of terrorism; and (2) the provision of such assistance will not adversely affect the military preparedness of the Armed Forces." PL 106-65, Sec. 1023(a)

Congress authorized forms of assistance to include "deployment of Department of Defense personnel and the use of any Department of Defense resources to the extent and for such period as the Secretary of Defense determines necessary to prepare for, prevent, or respond to an act or threat of an act of terrorism," listing actions including "the prepositioning of Department of Defense personnel, equipment, and supplies." PL 106-65, Sec. 1023(b)

Congress required civil authorities to reimburse the DoD for "incremental costs incurred" in providing assistance. Congress authorized the Secretary of Defense to waive the reimbursement requirement in "extraordinary circumstances," if he determines that a waiver is in the "national security interests" of the United States and submits notification to Congress. Congress authorized the Department of Justice to cover the costs for civil authorities, if DOJ had been appropriated funds for responding to acts of terrorism or threats of acts of terrorism, using the DOJ funds. PL 106-65, Sec. 1023(c).

Congress limited annual funding for the program to up to $10 million per year. PL 106-65, Sec. 1023(d)

Congress restricted members of Army, Navy, Air Force or Marine Corps from directly participating in a search, seizure, arrest, or other similar activity or collecting intelligence for law enforcement purposes...unless otherwise authorized by law. PL 106-65, Sec. 1023(e)

Congress prohibited the Secretary of Defense from delegating the authority to make determinations and authorize military assistance to civil authorities, and prohibited the Attorney General from delegating authority to make requests for assistance. PL 106-65, Sec. 1023(f)

Congress stated that the authorities provided in the note were "in addition to any other authority available to the Secretary of Defense," and should not be construed to restrict authority regarding

use of members of the Armed Forces or equipment in effect prior to the law. PL 106-65, Sec. 1023(g)

Congress defined "threat of an act of terrorism" as "includes any circumstance providing a basis for reasonably anticipating an act of terrorism, as determined by the Secretary of Defense in consultation with the Attorney General and the Secretary of the Treasury."

Congress defined 'weapon of mass destruction' with reference to the definition under 50 USC 2302(1) as of 1996:

> any weapon or device that is intended, or has the capability, to cause death or serious bodily injury to a significant number of people through the release, dissemination, or impact of --
>
> (A) toxic or poisonous chemicals or their precursors;
>
> (B) a disease organism; or
>
> (C) radiation or radioactivity. PL 106-65, Sec. 1023(h)

Congress established the duration of the authority provided by the note as from Oct. 1, 1999 to Sept. 30, 2004. PL 106-65, Sec. 1023(i).

In 2016 (PL 114-328), Congress renumbered Title 10, Armed Forces, Chapter 18, "Military Support for Civilian Law Enforcement Agencies," to Chapter 15, and renumbered the subsections (formerly 10 USC 371 to 383) as 10 USC 271 to 284. As of 2025, provisions authorizing domestic deployment of US military personnel during "emergency situations involving weapons of mass destruction" have been codified at 10 USC 282.

2000 - 42 USC 247d et seq
Title 42: Public Health and Welfare
Public health emergencies

In 2000 (PL 106-505), Congress struck the "public health emergencies" section of the Public Health Service Act [PHSA 319], that Congress had first added in 1983 (PL 98-49, see above) and codified at 42 USC 247d.

Congress replaced the 1983 version of PHSA 319 with an expanded version, codified at 42 USC 247d through 42 USC 247d-7.

Congress incorporated core provisions of the 1983 law into the 2000 law and added new programs as PHSA 319A to 319G of the Public Health Service Act, codified at 42 USC 247d-1 through 42 USC 247d-7.

42 USC 247d [PHSA 319] - Public health emergencies

As it had in 1983, Congress authorized the Secretary of Health and Human Services to "determine, after consultation with such public health officials as may be necessary" that "a disease or disorder presents a public health emergency or a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks otherwise exists," and, if he so determined, Congress authorized the HHS Secretary to "take such action as may be appropriate to respond," including making grants, entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder. 42 USC 247d(a)

As it had in 1983, Congress established a "Public Health Emergency Fund in the Treasury to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection, and authorized appropriations of such sums as may be necessary."

Congress directed the HHS Secretary to submit annual reports to House and Senate committees within 90 days after the end of each fiscal year, describing expenditures and "each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency." 42 USC 247d(b)

42 USC 247d-1 [PHSA 319A] - National Needs to Combat Threats to Public Health

In 2000 (PL 106-505), Congress directed the HHS Secretary to "establish reasonable capacities that are appropriate for national, State, and local public health systems and the personnel or work forces of such systems" to "improve, enhance or expand the capacity of... public health agencies to detect and respond effectively to significant public health threats, including major outbreaks of infectious disease, pathogens resistant to anti- microbial agents and acts of bioterrorism."

Congress specified the capacities to include capacities to:

> (A) recognize the clinical signs and epidemiological characteristic of significant outbreaks of infectious disease;
>
> (B) identify disease-causing pathogens rapidly and accurately;
>
> (C) develop and implement plans to provide medical care for persons infected with disease-causing agents and to provide preventive care as needed for individuals likely to be exposed to disease-causing agents;
>
> (D) communicate information relevant to significant public health threats rapidly to local, State and national health agencies, and health care providers; or
>
> (E) develop or implement policies to prevent the spread of infectious disease or antimicrobial resistance.

Congress authorized $4 million for fiscal year 2001, and "such sums as may be necessary for each subsequent fiscal year through 2006."

42 USC 247d-2 [PHSA 319B] - Assessment of Public Health Needs

Congress directed the HHS Secretary to award grants to States and political subdivisions to evaluate "the extent to which the States or local public health agencies can achieve the capacities" listed in the previous section, and to provide technical assistance.

Congress authorized the States to contract with outside entities to conduct evaluations, directed the States to use methods that would enable state to state comparisons, and directed the States to submit reports about the evaluations to the HHS Secretary.

Congress authorized $45 million for fiscal year 2001, and "such sums as may be necessary" for subsequent years through 2003.

42 USC 247d-3 [PHSA 319C] - Grants to Improve State and Local Public Health Agencies

Congress authorized the HHS Secretary to award competitive grants to address core public health capacity needs, "with a particular focus on building capacity to identify, detect, monitor, and respond to threats to public health."

To be eligible for grants, States and political subdivisions had to have completed the evaluations under 42 USC 247d-2.

Congress authorized grant recipients to use funds for four program areas, to (1) train public health personnel; (2) improve "participation in an electronic network by which disease detection and public health related information can be rapidly shared among national, regional, State, and local public health agencies and health care providers;" (3) develop a plan for responding to

public health emergencies, including significant outbreaks of infectious diseases or bioterrorism attacks, which is coordinated with the capacities of applicable national, State, and local health agencies and health care providers;" and (4) enhance laboratory capacity and facilities.

Congress authorized $50 million for fiscal year 2001, and "such sums as may be necessary" for subsequent years through 2006.

42 USC 247d-4 [PHSA 319D] - Revitalizing the CDC

Congress stated, as "findings," that the Centers for Disease Control and Prevention "have an essential role in defending and combatting public health threats of the 21st century and requires secure and modern facilities."

Congress authorized $180 million for fiscal year 2001 to support construction and renovation of facilities, including "laboratories, laboratory support buildings, health communication facilities," and "such sums as may be necessary" for subsequent years through 2010.

42 USC 247d-5 [PHSA 319E] - Combating Antimicrobial Resistance

Congress directed the HHS Secretary to establish an "Antimicrobial Resistance Task Force" to provide advice and recommendations, to include representatives of federal agencies, and to seek input from public health, manufacturing, veterinary and medical professionals.

Congress directed the task force to consider "public health factors contributing to increasing antimicrobial resistance; public health needs to detect and monitor antimicrobial resistance; detection, prevention and control strategies for resistant pathogens; the need for improved information and data collection; the assessment of the risk imposed by pathogens presenting a threat to the public health" and any other issues determined by the HHS Secretary to be relevant.

Congress directed the HHS Secretary to work with the task force and State and local public health officials to improve "participation in a surveillance plan to detect and monitor emerging antimicrobial resistance" and improve "participation in an integrated information system...to exchange...data between public health departments."

Congress directed the HHS Secretary and the director of USDA Agricultural Research Services, to support research related to: development of new therapeutics, including vaccines and antimicrobials, against resistant pathogens; development of medical diagnostics to detect pathogens resistant to antimicrobials; epidemiology, mechanisms, and pathogenesis of antimicrobial resistance; sequencing of genomes of "priority pathogens" as determined by the NIH Director in consultation with the task force established under subsection, and other relevant research areas.

Congress directed the HHS Secretary and other federal public health officers to develop educational programs to increase general public awareness of the public health threat of antimicrobial resistance and the appropriate use of antibiotics; instruct health care professionals

in prudent use of antibiotics; and train laboratory personnel in the recognition or identification of resistance in pathogens.

Congress authorized the HHS Secretary to award competitive grants to States or local public health agencies, Indian tribes or other public or private nonprofit entities. Congress authorized funds to be used to train people to identify patterns of resistance, improve participation in information systems, and develop policies to control the spread of antimicrobial resistance. Congress authorized grants for demonstration programs to promote "judicious" use of antimicrobial drugs, eligible entities to include hospitals, clinics, long-term care facilities and professional medical societies. Congress directed the HHS Secretary to provide technical assistance, and authorized $40 million for fiscal year 2001, and "such sums as may be necessary" for subsequent years through 2006.

42 USC 247d-6 [PHSA 319F] - Public health countermeasures to a bioterrorist attack

Congress directed the HHS Secretary and Secretary of Defense to establish an "interdepartmental working group on preparedness...for the medical and public health effects of a bioterrorist attack on the civilian population." Congress directed the Working Group on Preparedness for Acts of Bioterrorism to coordinate research on pathogens likely to be used, therapies to treat such pathogens, equipment to detect pathogens and protect against infection, and to develop procedures for the release of strategic reserves of vaccines, drugs, and medical supplies "which may be needed rapidly after a bioterrorist attack." 42 USC 247d-6(a)

Congress directed the HHS Secretary, FEMA Director, Attorney General and Secretary of Agriculture to set up another working group to address the Public Health and Medical Consequences of Bioterrorism. Congress directed the Working Group on Public Health and Medical Consequences of Bioterrorism to improve the preparedness of public health institutions, providers of medical care and emergency service personnel to "detect, diagnose and respond" to a bioterrorist attack, and to assure the quality of joint planning and training programs for firefighters, ambulance personnel, police and other emergency responders, hospitals, primary care facilities and public health agencies. 42 USC 247d-6(b)

Congress authorized the HHS Secretary to award competitive grants and enter cooperative agreements to increase capacity to detect, diagnose and respond to acts of terrorism. Congress authorized grant recipients to use funds to train health care professionals "to recognize the symptoms and epidemiological characteristics of exposure to a potential bioweapon," identify potential bioweapons, coordinate medical care for exposed individuals, and coordinate "rapid communication of data generated from a bioterrorist attack between national, State, and local health agencies, and health care providers." Congress directed the HHS Secretary to notify the Director of the DOJ Office of Justice Programs and Director of the National Domestic Preparedness Office each year about grants awarded, and coordinate with grants awarded with the Office of Emergency Preparedness and the CDC. 42 USC 247d-6(c)

Congress directed the HHS Secretary to provide HHS assistance to State and local health agencies. 42 USC 247d-6(d)

Congress directed the HHS Secretary and the Working Group on Public Health and Medical Consequences of Bioterrorism to develop educational programs to instruct public health officials, medical professionals and other health care workers "in the recognition and care of victims of a bioterrorist attack" and to train laboratory workers "in the recognition and identification of a potential bioweapon." 42 USC 247d-6(e)

Congress directed the HHS Secretary and the Working Group on Preparedness for Acts of Bioterrorism to conduct research related to "the epidemiology and pathogenesis of potential bioweapons, the development of new vaccines or other therapeutics against pathogens likely to be used in a bioterrorist attack, the development of medical diagnostics to detect potential bioweapons," and other relevant research, under a section titled "future resource development." 42 USC 247d-6(f).

Congress directed the Comptroller General to prepare a General Accounting Office (GAO) report for House and Senate committees describing federal research on, preparedness for and management of the public health and medical consequences of a bioterrorist attack against the civilian population, coordination and funding of those federal activities, and the effectiveness of such programs. 42 USC 247d-6(g)

Congress directed that funds appropriated under the new section shall "supplement and not supplant" other funds, and authorized $215 million for fiscal year 2001, and "such sums as may be necessary" through 2006. 42 USC 247d-6(h) and (i).

42 USC 247d-7 [PHSA 319G] - Demonstration program to enhance bioterrorism training, coordination, and readiness

Congress authorized the HHS Secretary to make grants to up to three entities for demonstration programs to improve "detection of pathogens," development of response plans, and training programs. Congress designated, as eligible grant recipients, States, political subdivisions of States, and public or private non-profit organizations. 42 USC 247d-7(a) and (b)

Congress established, as criteria for grant awards, the applicant's proximity to a major research university "with expertise in scientific training, identification of biological agents, medicine, and life sciences," proximity to a laboratory with expertise in identification of biological agents, demonstrated support from State and local governments and research institutions, proximity to an academic medical center, and any other factors deemed appropriate by the HHS Secretary. 42 USC 247d-7(c)

Congress directed the Comptroller General to prepare a GAO report for House and Senate committees describing "the ability of grantees...to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel." 42 USC 247d-7(f)

Congress authorized $6 million for fiscal year 2001, and such "sums as may be necessary" through 2006. 42 USC 247d-7(g)

2001 - 10 USC 2370a et seq.
Title 10: Armed Forces
Medical countermeasures against biowarfare threats
Acceleration of research, development, and production of medical countermeasures for defense against biological warfare agents

In 2001 (PL 107-107), Congress added a note under 10 USC 2370a, *Medical countermeasures against biowarfare threats*, which had been enacted in 1993 (PL 103-160, summarized above).

Congress directed the Secretary of Defense to "carry out a program to aggressively accelerate the research, development, testing and licensure of new medical countermeasures for defense against the biological warfare agents that are the highest threat." Congress directed the Secretary to prioritize countermeasures for anthrax and to leverage ideas and technologies from the biological technology industry. 10 USC 2370a note at (a)

Congress directed the Secretary to contract with the Institute of Medicine and National Research Council to study "the review and approval process for new medical countermeasures" to identify new approaches for accelerating such process and "definitive and reasonable measures for assuring the agencies responsible for regulating such countermeasures will be effective in preventing disease in humans or in providing safe and effective therapy against such agents." 10 USC 2370a note at (b)

Congress authorized the Secretary of Defense to design and construct a facility on a DoD installation "for the production of vaccines...to prevent or mitigate the physiological effects of exposure to biological warfare agents;" to operate the facility and "qualify and validate" the facility for the production of vaccines in accordance with FDA requirements; and to contract with a private-sector source for the production of vaccines in the facility. USC 2370a note at (c)

Congress directed the Secretary to develop a long-range plan for production and acquisition of vaccines, including an evaluation of the need for one or more vaccine production facilities specifically dedicated to meeting DoD requirements and other national interests; evaluation of production means (including use of public facilities, private facilities, or a combination, management and operation of facilities by the Federal Government, private persons, or a combination); and the Secretary's determination of the means most appropriate. Congress directed the Secretary to "ensure that the plan is consistent with the requirement for safe and effective vaccines approved by the FDA." USC 2370a note at (d)

Congress directed the Secretary to submit a report on the plan to Congress, and authorized $10 million for the program. 10 USC 2370a note at (e) and (f).

Congress repealed 10 USC 2370a in 2004 (PL 108-375).

2001 - 18 USC 175 et seq
Title 18: Crimes and Criminal Procedure
Biological Weapons

In 2001, (PL 107-56, PATRIOT Act), Congress amended the law enacted in 1990 (PL 101-298) and amended in 1996 (PL 104-132), providing for criminal penalties for development, production, stockpiling, transfer, acquisition, retention, or possession of "any biological agent, toxin or delivery system for use as a weapon."

Congress added a new "additional offense" section.

> Additional Offense. --- Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both. In this subsection, the terms "biological agent" and "toxin" do not encompass any biological agent or toxin that is in its naturally occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source. 18 USC 175(b) as of 2001.

Congress amended the definition of 'for use as a weapon' that had been in effect from 1990 when Congress first enacted the biological weapons law until 2001:

> Definition.-- The term 'for use as a weapon' does not include the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for prophylactic, protective, or other peaceful purposes. 18 USC 175(b), 1990 to 2001

In 2001, Congress moved the definition to 18 USC 175(c) and changed it to read:

> "Definition.--The term 'for use as a weapon' includes the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for other than prophylactic, protective[,] bona fide research, or other peaceful purposes." 18 USC 175(c) as of 2001

Summarizing, in 2001, Congress shifted the definition from "does not include...production...of any biological agent...for prophylactic...purposes" to "includes...production...of any biological agent...for other than prophylactic...purposes," and Congress added, as one of the purportedly non-weapon uses, "bona fide research." [Congress added the comma between 'protective' and 'bona fide research' through a technical amendment in 2002]. Congress did not provide physical standards for determining a user's purpose or whether a purpose or use is "prophylactic, protective, bona fide research or peaceful," and did not direct the HHS Secretary to establish, by regulation, such physical standards. Congress did not establish any standard of evidence against which imputed "prophylactic, protective" or other "peaceful" purposes could be assessed, and did not establish judicial or other evidentiary review procedures for testing of claims as to purpose.

2001 - 18 USC 175b
Title 18: Crimes and Criminal Procedure
Biological weapons, possession by restricted persons

In 1996 (PL 104-132, summarized above), Congress had enacted, as a note under 42 USC 262, "Enhanced penalties and control of biological agents," introducing the "select agents" program. Congress had directed the HHS Secretary to establish and maintain a list of "each biological agent that has the potential to pose a severe threat to public health and safety." Congress had defined "biological agent" by incorporating the definition at 18 USC 178, biological weapons, and HHS officers had implemented the "enhanced control of biological agents" provisions through agency regulations published in October 1996, (61 FR 55190) and codified at 42 CFR 72.

42 CFR 72 had been used since 1980 to regulate "interstate shipment of etiologic agents." The 1980 regulations defined "etiologic agent" as "a viable microorganism or its toxin which causes, or may cause, human disease," including diagnostic specimens and biological products, but excluded from shipping restrictions "biological products" containing etiologic agents denoted as "measles virus," "mumps virus," "rotaviruses--all types" and dozens of other agents purportedly stabilized, identifiable, and contained in vaccine containers.

In 2001 (PL 107-56) Congress further implemented the "select agents" program, adding a section 18 USC 175b, *Possession by restricted persons*, after 18 USC 175a, *Requests for military assistance to enforce prohibition in certain emergencies,* which Congress had added in 1996 (PL 104-201, see above).

Through the 2001 law, Congress provided that "no restricted person...shall ship or transport interstate or foreign commerce, or possess in or affecting commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent" in 42 CFR 72.6(j) (pursuant to PL 104–132), "and is not exempted under" 42 CFR 72.6 (h) or Appendix A of 42 CFR 72. 18 USC 175b(a).

Congress provided that the term select agent "does not include any such biological agent or toxin that is in its naturally-occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source." 18 USC 175b(b)(1)

Congress defined a 'restricted person' to mean an individual who is under indictment or has been convicted of a crime punishable by imprisonment for a term exceeding 1 year; ...a fugitive from justice; ...an unlawful user of any controlled substance [21 U.S.C. 802]; ...an alien illegally or unlawfully in the United States;...has been adjudicated as a mental defective or has been committed to any mental institution;...is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State...has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism;...or has been discharged from the Armed Services of the United States under dishonorable conditions. 18 USC 175b(b)(2).

Congress provided for knowing violators of the prohibition on shipping, transport and possession of select agents by restricted persons, to be fined, imprisoned not more than 10 years, or both, but rendered the prohibition inapplicable "with respect to any duly authorized United States governmental activity." 18 USC 175b(c)

Biological agents and toxins (select agents) exempted from restrictions on shipping, transport and possession, under 42 CFR 72.6(h) included

> (h) Exemptions.
>
> (1) Exemptions for certain select agents: Select agents otherwise covered by this part are exempt from its provisions if:
>
> > (i) The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes...;
> >
> > (ii) The agent is a toxin having an LD50 for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or
> >
> > (iii) The agent(s) is an exempted strain specified in Appendix A of this part and/or CDC Form EA–101." 42 CFR 72.6(h) (61 FR 55198, Oct. 24, 1996)

Biological agents and toxins (select agents) were also exempted from restrictions on shipping, transport and possession, under Appendix A of 42 CFR 72.6.

Appendix A listed select agents categorized as viruses, bacteria, rickettsia, fungi, toxins and "recombinant organisms/molecules" ("1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease and 2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.")

Under the list of viruses, Appendix A exempted "vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP–12, Venezuelan Equine encephalitis virus strain TC–83, Yellow fever virus strain 17–D."

Under the list of bacteria, Appendix A exempted "vaccine strains as described in 9 CFR 78.1" [referring to USDA-APHIS regulations addressing brucellosis].

Under the list of toxins, Appendix A exempted "toxins for medical use, inactivated for use as vaccines, or toxin preparation for biomedical research use at an LD50 for vertebrates of more

than 100 nanograms per kilogram body weight" and "national standard toxins required for biologic potency testing as described in 9 CFR 113 [veterinary biological products]."

Under "Additional Exemptions," Appendix A exempted "products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 et seq) [pesticides] and the Toxic Substances Control Act (15 U.S.C. 2601 et seq). 42 CFR 72, Appendix A (61 FR 55199, Oct. 24, 1996)

The Toxic Substances Control Act of 1976 addressed EPA control of 'chemical substances,' defined as

> any organic or inorganic substance of a particular molecular identity, including—
>
> > (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
> >
> > (ii) any element or uncombined radical
> >
> > but excluding
> >
> > (i) any 'mixture' ("any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined");
> >
> > (ii) any pesticide;...and
> >
> > (iv) any food, food additive, drug, cosmetic, or device. 15 USC 2602.

2001 - 18 USC 2331 et seq
Title 18: Crimes and Criminal Procedure
Terrorism

In 2001 (PL 107-56, PATRIOT Act), Congress revised the law authorizing prosecution of "international terrorism" acts occurring "primarily outside the territorial jurisdiction of the United States," or transcending national boundaries, as added in 1986 (PL 99-399) and amended in 1992 (PL 102-571) and 1996 (PL 104-132).

Congress revised the definition of 'international terrorism' to add the term 'mass destruction,' to the section that had previously defined terrorism as activities that "appear to be intended" to intimidate or coerce civilian populations, influence government policy by intimidation, or affect the conduct of a government by assassination or kidnapping, such that the law read: "...affect the conduct of a government by mass destruction, assassination or kidnapping." 18 USC 2331(1)(B)(iii).

Congress added a provision authorizing prosecution of 'domestic terrorism,' defining domestic terrorism as the same activities (dangerous to human life, violation of the criminal laws of the United States or of any State, appear to be intended to intimidate or coerce a civilian population, influence the policy of a government by intimidation or coercion; or affect the conduct of a government by mass destruction, assassination, or kidnapping) that occur primarily within the territorial jurisdiction of the United States.

2002 - 42 USC 262a
Title 42: Public Health and Welfare
Regulation of biological products
Enhanced control of dangerous agents and toxins

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress expanded and revised many of the laws relevant to communicable disease control, biological weapons and vaccination, including addition of a new section to the Public Health Service Act Section 351 (Regulation of biological products), codified at 42 USC 262 since 1944.

The new section, PHSA Section 351A, Enhanced control of dangerous biological agents and toxins, was codified at 42 USC 262a, consolidating and amending provisions of the 1996 "select agent" law codified as a note to 42 USC 262 (PL 104-132) and in regulations (61 FR 55190), and the 2001 law prohibiting "possession by restricted persons" law codified at 18 USC 175b (PL 107-56).

In 2002, enacting 42 USC 262a, Congress directed the HHS Secretary to "establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety." 42 USC 262a(a)(1)(A)

Congress directed the HHS to consider criteria including "the effect on human health of exposure to the agent or toxin;...the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;...the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and...any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate" and to "consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise." 42 USC 262(a)(1)(B).

Congress directed the HHS Secretary to enact regulations governing "transfers" and "possession" of listed agents and toxins, including "safety procedures...proper training...of individuals involved in handling...proper laboratory facilities to contain and dispose of such agents and toxins...security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose...procedures to protect the public safety in the event of a transfer...in violation of the safety and security measures...and appropriate availability of biological agents and toxins for research, education and other legitimate purposes." 42 USC 262a(b) and 42 USC 262a(c).

Congress provided for several exemptions for laboratories, products and persons. 42 USC 262a(g)

Congress exempted, from "enhanced control" of transfer and possession, "clinical or diagnostic laboratories and other persons who possess, use or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification or proficiency testing." 42 USC 262a(g)(1)

Congress exempted, from limits on transfer and possession, five categories of products.

Congress provided that

> regulations...shall exempt products that are, bear or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the acts specified...unless the Secretary determines that applying additional regulation...to a specific product is necessary to protect public health and safety. 42 USC 262a(g)(2)(A)

Four Congressional acts were specified:

- Federal Food Drug and Cosmetic Act (FDCA) governing manufacturing and labeling of drugs, based on the 1906 Pure Food and Drug Act and codified at 21 USC 300-399 since 1938;
- Public Health Service Act (PHSA) Sec. 351, governing manufacturing and labeling of biological products intended for use on human beings, including vaccines, based on the 1902 virus-toxin law and codified at 42 USC 262 since 1944;
- Virus-Serum-Toxin Act of 1913, governing manufacturing and labeling of biological products intended for use on animals, codified at 21 USC 151-159;
- Federal Insecticide, Fungicide, and Rodenticide Act, governing manufacturing and labeling of pesticides and plant desiccants, based on the Insecticides Act of 1910 and codified at 7 USC 136 et seq since 1947. 42 USC 262a(g)(2)(B)

Congress authorized the HHS Secretary to exempt a fifth category of products from enhanced control of transfer and possession:

> an investigational product that is, bears, or contains a listed agent or toxin...when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation...to such product is not necessary to protect public health and safety. 42 USC 262a(g)(2)(C)

Congress authorized the HHS Secretary to exempt persons and entities (such as research departments) from "enhanced control" of transfer and possession of allegedly dangerous biological agents and toxins, "to provide for the timely participation of the person in a response to a domestic or foreign public health emergency...or agricultural emergency..." 42 USC 262(g)(3)

The HHS Secretary implemented the 2002 select agent law through regulations published in March 2005 (70 FR 13316) and codified at 42 CFR 73.

Discussion

Congress did not direct the HHS Secretary to collect or produce physical evidence in support of "select agent" and "toxin" classifications, or to establish or enforce physical standards of evidence against which claims of "potential to pose a severe threat to public health and safety" could be assessed, or to submit to a fact-finding, evidentiary review procedure.

Congress categorically exempted five categories of products from classification and enhanced control as select agents and toxins, regardless of their physical compositions' equivalence or similarity with listed select agents and toxins, and the similar unpredictability and toxicity of their physiological effects, but solely on the basis of their legal status, the manufacturing regulations under which they are produced, and the labels affixed to their containers.

The five categories include pesticides (insecticides, rodenticides, fungicides, desiccants, defoliants); biological products including vaccines for use on animals; biological products including vaccines for use on humans; chemical drugs intended for use on human targets; and investigational products.

2002 - 18 USC 175-178
Title 18: Crimes and Criminal Procedure
Biological Weapons

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress expanded and revised many of the laws relevant to communicable disease control, biological weapons and vaccination, including revision of several sections of the biological weapons law.

18 USC 175b - Possession by restricted persons

In 2001 (PL 107-56), Congress implemented the "select agents" program established in 1996 (PL 104-132). As of 2001, Congress provided that "no restricted person...shall ship or transport interstate or foreign commerce, or possess in or affecting commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent" in 42 CFR 72.6(j) pursuant to PL 104–132), "and is not exempted under" 42 CFR 72.6 (h) or Appendix A of 42 CFR 72. Congress provided for knowing violators of the prohibition on shipping, transporting and possessing by restricted persons, to be fined, imprisoned not more than 10 years, or both, but rendered the prohibition inapplicable "with respect to any duly authorized United States governmental activity."

In 2002 (PL 107-188), Congress moved and renumbered the section setting criminal penalties, and exempting "duly authorized United States government activity," to 18 USC 175b(a)(2).

Congress added a provision setting criminal penalties for "transfer" to or "possession" of select agents by an "unregistered person," including fines and imprisonment up to 5 years or both. 18 USC 175b(b)(1) and 18 USC 175(c)(1)

Congress added a provision setting criminal penalties for "transfer" to or possession of "other biological agents and toxins," by an "unregistered person" referring to plant and animal agents and toxins listed under the Agricultural Bioterrorism Protection Act of 2002 (also enacted through PL 107-188). 18 USC 175b(b)(2) and 18 USC 175(c)(2).

Congress amended the definition of "select agent," adding the qualifying phrase "a biological agent or toxin to which subsection (a) applies," so that the definition read: "the term "select agent" means a biological agent or toxin to which subsection (a) applies. Such term (including for purposes of subsection (a)) does not include any such biological agent or toxin that is in its naturally-occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source."

18 USC 175 - Prohibitions with respect to biological weapons

In 2002 (PL 107-188), as a technical correction to the 2001 addition of 'bona fide research' to the list of allegedly peaceful purposes, Congress inserted a comma between 'protective' and 'bona fide research' in the definition of 'for use as a weapon,' so that it read: "...for other than prophylactic, protective, bona fide research, or other peaceful purposes."

18 USC 176 - Seizure, forfeiture and destruction

Through the original 1990 biological weapons law (PL 101-298), Congress provided for the Attorney General to seek warrants to seize "any biological agent, toxin, or delivery system that exists by reason of conduct prohibited...or is of a type or in a quantity that under the circumstances has no apparent justification for prophylactic, protective, or other peaceful purposes" Congress placed the burden of proof on the Government, to prove by a preponderance of the evidence, that the biological agent "exists" by reason of prohibited conduct or in a type or quantity with no apparent peaceful purpose. Congress authorized the affirmative defense of asserting that "such biological agent, toxin, or delivery system is for a prophylactic, protective, or other peaceful purpose; and such biological agent, toxin, or delivery system, is of a type and quantity reasonable for that purpose." Congress authorized the Attorney General, "in exigent circumstances" to seize and destroy prohibited biological agents, toxins and delivery systems upon probable cause but without a warrant. 18 USC 176.

In 2002 (PL 107-188), Congress struck "exists by reason of" and replaced it with "pertains to," so that the US Government, in seeking a warrant, was required to demonstrate by a preponderance of the evidence that "any biological agent, toxin, or delivery system...pertains to conduct prohibited...or is of a type or in a quantity that under the circumstances has no apparent justification for prophylactic, protective, or other peaceful purposes." 18 USC 176(a)(1)(A)

18 USC 178 - Definitions

In 2002 (PL 107-188), Congress changed the definitions for 'biological agent,' 'toxin' and 'vector' that had been enacted in 1990 (PL 101-298) and amended in 1996 (PL 104-132).

As of 1996, Congress defined 'biological agent' to mean

> any micro-organism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, capable of causing—
>
> > (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
> >
> > (B) deterioration of food, water, equipment, supplies, or material of any kind; or
> >
> > (C) deleterious alteration of the environment. 18 USC 178(1) as of 1996

In 2002, Congress defined 'biological agent' to mean

> 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—

> (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
>
> (B) deterioration of food, water, equipment, supplies, or material of any kind; or
>
> (C) deleterious alteration of the environment. 18 USC 178(1) as of 2002

As of 1996, Congress defined 'toxin' to mean

> the toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including—
>
> (A) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or
>
> (B) any poisonous isomer or biological product, homolog, or derivative of such a substance. 18 USC 178(2) as of 1996

In 2002, Congress defined 'toxin' to mean

> the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes—
>
> (A) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or
>
> (B) any poisonous isomer or biological product, homolog, or derivative of such a substance. 18 USC 178(2) as of 2002

As of 1996, Congress defined 'vector' to mean:

> a living organism, or molecule, including a recombinant molecule, or biological product that may be engineered as a result of biotechnology, capable of carrying a biological agent or toxin to a host. 18 USC 178(4) as of 1996

In 2002, Congress defined 'vector' to mean:

> a living organism, or molecule, including a recombinant or synthesized molecule, capable of carrying a biological agent or toxin to a host. 18 USC 178(2) as of 2002

2002 - 18 USC 2331 to 2339

Title 18: Crimes and Criminal Procedure
Terrorism, Weapons of mass destruction

In 2002 (PL 107-188) Congress amended the law governing criminal prosecution of acts of terrorism involving weapons of mass destruction.

As of 1994 (PL 103-322), Congress had defined "weapon of mass destruction" to include, at 18 USC 2332a(c)(2)(C)

> ...(C) any weapon involving a disease organism.

In 2002, Congress struck the term "a disease organism" and replaced it with

> ...(C) a biological agent, toxin or vector (as those terms are defined in section 178 of this title)

Congress incorporated by reference the definitions Congress had amended in 2002 (PL 107-188) at 18 USC 178, summarized above.

2002 - 42 USC 247d
Title 42: Public Health and Welfare
Public health emergencies

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress expanded and revised many of the laws relevant to communicable disease control, biological weapons and vaccination, including programs under the public health emergencies section of the Public Health Service Act [PHSA 319] that Congress had enacted in 1983 (PL 98-49) and significantly expanded in 2000 (PL 106-505).

42 USC 247d(a) [PHSA 319(a)] - Public health emergencies

As of 2000 (PL 106-505), Congress provided that: "If the [HHS] Secretary determines, after consultation with [NIH Director, ADAMHA Administrator, FDA Commissioner or CDC Director] that— (1) a disease or disorder presents a public health emergency, or (2) a public health emergency otherwise exists and the Secretary has the authority to take action with respect to such emergency, the Secretary, acting through such Director, Administrator, or Commissioner, may take such action as may be appropriate to respond to the public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder described in paragraph (1)."

In 2002 (PL 107-188), Congress added provisions appearing to establish conditions for termination of an HHS Secretary's public health emergency determination 90 days after the date of issuance, but authorizing unlimited renewals:

> "Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination."

Congress also added a provision authorizing the HHS Secretary to grant extensions to reporting deadlines and waive sanctions otherwise applicable, "in any case in which the Secretary determines that, wholly or partially as a result of a public health emergency...individuals or public or private entities are unable to comply with deadlines." Congress directed the HHS Secretary to notify the Congress and publish notices in Federal Register before or shortly after granting extensions or waivers. 42 U.S.C. 247d(d)

42 USC 247d-3a [PHSA 319C-1] - Grants to improve state, local and hospital preparedness for and response to bioterrorism and other public health emergencies

In 2002 (PL 107-188), Congress added a new section under 42 USC 247d-3 [PHSA 319C, *Grants to improve state and local public health agencies*, enacted 2000], authorizing the HHS Secretary to make grants or enter into cooperative agreements with eligible entities to draft Statewide plans and community-wide plans for responding to bioterrorism and other public health emergencies, including a required Bioterrorism and Other Public Health Emergency Preparedness and Response Plan. 42 USC 247d-3a(a)

Congress directed the State and community recipients of funds to use the money to draft plans "that are coordinated with the capacities of applicable national, State, and local health agencies and health care providers, including poison control centers;" to address deficiencies identified in preparedness assessments [conducted under 42 USC 247d-2/PHSA 319B since enactment in 2000]; to buy or upgrade equipment, including communications equipment, supplies, pharmaceuticals or other priority countermeasures; to conduct exercises testing capabilities; to set up trauma care and burn center care components of State emergency medical services plans; to train public health laboratory employees; to train public health and health care personnel "to detect, provide accurate identification of, and recognize the symptoms and epidemiological characteristics of exposure to a biological agent that may cause a public health emergency" and provide treatment; to improve systems and equipment for disease detection and rapid communication among national, State, and local health agencies, emergency response personnel, and health care providers and facilities; to enhance communication to the public, including through the use of 2–1–1 call centers; to address the health security needs of children and other vulnerable populations; to train for and enhance safety of workers and workplaces; to plan for contamination prevention efforts; to plan for triage and transport management; to train health care professionals to recognize and treat mental health consequences; to train health care professionals to assist in providing appropriate health care for large numbers of exposed individuals; to plan for protecting the health and safety of personnel responding to a biological attack, including health care professionals; to train personnel in surveillance, detection, and response activities, including early warning and surveillance networks that use advanced information technology; and to improve existing telemedicine programs to provide health care information and advice as part of the emergency public health response. 42 USC 247d-3(d)

Congress required entities receiving an award to draft a Bioterrorism and Other Public Health Emergency Preparedness and Response Plan within 60 days of receiving the award, and to submit the plan to the HHS Secretary. Congress required States and communities to describe their plans to address deficiencies identified in assessments conducted under 42 USC 247d-2 [PHSA 319B]. 42 USC 247d-3a(c)

Congress designated 'eligible entities' to include States that submitted applications confirming that the State had completed a "needs assessment" study under the grant program funded in 2000; had prepared, or would have completed within 60 days of award receipt, a "Bioterrorism and Other Public Health Emergency Preparedness and Response Plan" in compliance with 42 USC 247d-3a(c); or a political subdivision of a State or consortium of two or more subdivisions that submitted applications in coordination with their State's statewide plan. 42 USC 247d-3a(b)

Congress set as priorities, activities to address, in priority order, "bioterrorism or acute outbreaks of infectious diseases" and then "other public health threats and emergencies." Congress authorized the HHS Secretary to determine and modify the degree of priority, based on "the extent to which eligible entities are adequately prepared for responding to "bioterrorism or acute outbreaks of infectious diseases" or if "there has been a significant change in the assessment of risks to the public health posed by...other public health threats and emergencies." Congress authorized the HHS Secretary to "determine areas of emphasis" among "bioterrorism or acute outbreaks of infectious diseases." 42 USC 247d-3a(e).

Congress directed the HHS Secretary to prioritize activities that include State or local government financial commitments; seek to incorporate multiple public health and safety services or diagnostic databases into an integrated public health entity; and cover geographic areas lacking advanced diagnostic and laboratory capabilities. 42 USC 247d-3a(f)

Congress directed grant recipients to coordinate activities with local Metropolitan Medical Response Systems [MMRS grant program established in 1995 by HHS, authorized in general as "domestic preparedness programs" through PL 104-201, placed under DHS control in 2003 through PL 107-296, and authorized specifically in 2006 through PL 109-295]. 42 USC 247d-3a(g)

Congress directed the HHS Secretary to annually notify the FEMA Director, DOJ Office of Justice Director, and Director of the National Domestic Preparedness Office, about grant award amounts, activities and status, and coordinate grant awards with other HHS bioterrorism and public health emergency preparedness programs. 42 USC 247d-3a(h)

Congress authorized funding for the HHS State and local bioterrorism preparedness programs, including for "enhancing the preparedness of hospitals (including children's hospitals), clinics, health centers, and primary care facilities." 42 USC 247d-3a(j)

42 USC 247d-3b [PHSA 319C-2] - Partnerships for community and hospital preparedness

In 2002 (PL 107-188), Congress added another new section under 42 USC 247d-3 [PHSA 319C, *Grants to improve state and local public health agencies*, enacted 2000] to make grants or enter into cooperative agreements to "improve community and hospital preparedness for bioterrorism and other public health emergencies." 42 USC 247d-3b(a)

Congress designated eligible entities as partnerships of one or more hospitals (including children's hospitals), clinics, health centers, or primary care facilities and one or more political subdivisions of States; or partnerships of States and political subdivisions of States, who prepare applications to HHS, in consultation with the State governor or Chief Executive Officer of the political subdivision in which the hospital or clinic located. 42 USC 247d-3b(b)

Congress directed the HHS Secretary to give preference to applications that, "in the determination of the Secretary" will enhance regional coordination among different entities and

serve the needs of a defined geographic area. 42 USC 247d-3b(c)

Congress directed award recipients to use the funds consistent with the applicable State Bioterrorism and Other Public Health Emergency Preparedness and Response Plan. 42 USC 247d-3b(d)

Congress authorized recipients to use the funds for activities including planning for and administering an award; preparing triage and transport management plans; training health care professionals to recognize symptoms of exposure to a potential bioweapon, diagnose and provide treatment; train health care professionals to recognize and treat mental health consequences of bioterrorism or other public health emergencies; train health care professionals to provide health care for large numbers of exposed individuals; train and plan to protect the health and safety of personnel involved in biological attack response; develop trauma care and burn center care components of the State emergency medical services plans; or conduct activities described under the Statewide grant program for hospitals, children's hospitals, clinics, health centers, or primary care facilities. 42 USC 247d-3b(e)

Congress set, as priority "hazard" categories, in priority order: "bioterrorism or acute outbreaks of infectious diseases" and then "other public health threats and emergencies;" authorized the HHS Secretary to modify priority classifications and determine areas of emphasis within the two categories; and directed eligible entities to coordinate activities with local Metropolitan Medical Response Systems. 42 USC 247d-3b(g) and (h)

42 USC 247d-4 [PHSA 319D] - Revitalizing the Centers for Disease Control and Prevention

In 2002 (PL 107-188) Congress amended the provisions of 42 USC 247d-4 on CDC revitalization Congress had added in 2000 (PL 106-505).

Congress maintained its 2000 "findings" that the CDC "has an essential role in defending against and combatting public health threats and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies. 42 USC 247d-4(a)(1)

Congress authorized the CDC Director to "design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities" and enter in to contracts for such projects. 42 USC 247d-4(a)(2)

Congress directed the HHS Secretary to "expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies," including activities such as training personnel; improving communications facilities and networks, including delivery of information to rural areas; improving public health surveillance and reporting activities, including an "integrated system of public health alert communications and surveillance

networks"; and improving laboratory facilities and the security of such facilities. 42 USC 247d-4(a)(3)

Congress directed the HHS Secretary, under a provision titled "National Communications and Surveillance Networks" to establish an "integrated system...of public health alert communications and surveillance networks...among Federal, State, and local public health officials; public and private health-related laboratories, hospitals, and other health care facilities...and any other entities determined appropriate by the Secretary." Congress authorized the HHS Secretary to set up the system directly or through grants, contracts and cooperative agreements and directed the HHS Secretary to ensure that the networks "allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency." Congress directed the HHS Secretary to establish technical and reporting standards, including standards for "interoperability" and provided funding for set-up of the network and improvement of CDC facilities. 42 USC 247d-4(b) and (c)

42 USC 247d-5 [PHSA 319E] - Antimicrobial resistance

In 2002 (PL 107-188) Congress amended provisions of 42 USC 247d-5, on "antimicrobial resistance" added in 2000 (PL 106-505)

In 2000, Congress had authorized and directed the HHS Secretary and USDA Director of Agricultural Research Services, to "conduct and support research...related to the development of new therapeutics, including vaccines and antimicrobials, against resistant pathogens; the development or testing of medical diagnostics to detect pathogens resistant to antimicrobials; and the epidemiology, mechanisms, and pathogenesis of antimicrobial resistance; and the sequencing of the genomes of priority pathogens as determined by the [NIH] Director..."

In 2002, Congress replaced "conduct and support" with "directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of" research related to development of vaccines and other products against "resistant pathogens."

In 2002, Congress replaced the fourth category of research with "the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens" as determined by the NIH Director in collaboration and coordination with "activities of the Department of Defense and the Joint Genome Institute of the Department of Energy."

In 2002, Congress authorized additional entities to be eligible for federal grants under the program. As of 2000, eligible entities included "hospitals, clinics, institutions of long-term care, professional medical societies, or other public or private nonprofit entities." In 2002, Congress added, "schools or programs that train medical laboratory personnel."

42 USC 247d-6 [PHSA 319F] - Public health countermeasures to a bioterrorist attack

In 2002 (PL 107-188), Congress reorganized, amended and expanded the "public health countermeasures to a bioterrorist attack" section Congress had added in 2000 (PL 106-505).

As of 2000 (PL 106-505), Congress had directed the HHS Secretary and Secretary of Defense to establish a Working Group on Preparedness for Acts of Bioterrorism to coordinate biomedical research and product release from strategic reserves [42 USC 247d-6(a)/PHSA 319F(a)]; directed the HHS Secretary, FEMA Director, Attorney General and Secretary of Agriculture to set up a Working Group on Public Health and Medical Consequences of Bioterrorism to prepare public health institutions, providers of medical care and emergency service personnel to "detect, diagnose and respond" to a bioterrorist attack [42 USC 247d-6(b)/PHSA 319F(b)]; authorized the HHS Secretary to award competitive grants and enter cooperative agreements to increase capacity to detect, diagnose and respond to acts of terrorism and coordinate "rapid communication of data" among national, State, and local health officers [42 USC 247d-6(c)/PHSA 319F(c)]; directed the HHS Secretary to provide HHS assistance to State and local health agencies [42 USC 247d-6(d)/PHSA 319F(d)]; directed the HHS Secretary and the Working Group on Public Health and Medical Consequences of Bioterrorism to develop educational programs to instruct health care workers to recognize "victims of a bioterrorist attack" and to train laboratory workers to recognize and identify "a potential bioweapon" [42 USC 247d-6(e)/PHSA 319F(e)]; directed the HHS Secretary and the Working Group on Preparedness for Acts of Bioterrorism to conduct research related to "epidemiology and pathogenesis of potential bioweapons... development of new vaccines...[and] development of medical diagnostics to detect potential bioweapons" [42 USC 247d-6(f)/PHSA 319F(f)]; directed the Comptroller General to prepare a GAO report describing federal preparedness for bioterrorist attacks [42 USC 247d-6(g)/PHSA 319F(g)]; directed that funds appropriated under the new section shall "supplement and not supplant" other funds [42 USC 247d-6(h)/PHSA 319F(h)]; and authorized $215 million for the programs for FY2001, and "such sums as may be necessary" through 2006 [42 USC 247d-6(i)/PHSA 319F(i)].

In 2002, Congress made several significant changes to these provisions.

42 USC 247d-6(a) [PHSA 319F(a)]- Working Group on Bioterrorism and Other Public Health Emergencies

In 2002 (Pl 107-188), Congress merged and expanded the responsibilities of two working groups on Preparedness for Acts of Bioterrorism and Public Health and Medical Consequences of Bioterrorism that had been set up in 2000 (PL 106-505).

Congress directed the HHS Secretary to coordinate with the Secretary of Agriculture (USDA), Attorney General (DOJ), Director of Central Intelligence, Secretary of Defense, Secretary of Energy, Administrator of the Environmental Protection Agency (EPA), Director of the Federal Emergency Management Agency (FEMA), Secretary of Labor, Secretary of Veterans Affairs (VA), and other similar Federal officials as determined appropriate, to form a working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies. 42 USC 247d-6(a)(1).

Congress directed the expanded/merged working group to meet, consult and make recommendations on responding to a bioterrorist attack, including training and protective measures for medical, emergency service, and other personnel; prioritizing countermeasures required to treat, prevent, or identify exposure to a biological agent or toxin pursuant to [PHSA 351A/42 USC 262a, *Enhanced control of dangerous biological agents and toxins*]; award grants, contracts, or cooperative agreements for the development, manufacture, distribution, supply-chain management, and purchase of priority countermeasures; research on pathogens likely to be used in a biological threat or attack on the civilian population; development of shared standards for equipment to detect and to protect against biological agents and toxins; priorities for preparedness of public health institutions, providers of medical care, and other emergency service personnel (including firefighters) to detect, diagnose, and respond (including mental health response) to a biological threat or attack; enhancement of the quality of joint planning and training programs that address the public health and medical consequences of a biological threat or attack on the civilian population between—local firefighters, ambulance personnel, police and public security officers, other emergency response personnel (including private response contractors) and hospitals, primary care facilities, and public health agencies; strategies for Federal, State, and local agencies to communicate information to the public regarding biological threats or attacks; the health security needs of children and other vulnerable populations; strategies for decontaminating facilities contaminated as a result of a biological attack; clarifying the responsibilities among Federal officials for the investigation of suspicious outbreaks of disease and other potential public health emergencies, and for related revisions of the interagency plan known as the Federal response plan; and (in consultation with the National Highway Traffic Safety Administration and the U.S. Fire Administration) coordination among Federal agencies involved with State, local, and community based emergency medical services, including issuing a report that identifies needs of community-based emergency medical services and ways to streamline Federal agency support for community-based emergency medical services. 42 USC 247d-6(a)(1)(A) through (L)

Congress directed the working group to consult with the pharmaceutical, biotechnology, and medical device industries, and other appropriate experts. 42 USC 247d-6(a)(2)

Congress provided that "determinations" made by the working group are "matters committed to agency discretion for purposes of 5 USC 701(a), [thus precluding judicial review.] 42 USC 247d-6(a)(4)

42 USC 247d-6(b) [PHSA 319F(b)] - Advice to the Federal Government

In 2002 (PL 107-188), Congress directed the HHS Secretary to establish two new advisory committees, both to serve one year and then terminate.

Congress tasked the National Advisory Committee on Children and Terrorism to make recommendations on the preparedness of the health care system (including mental health) to respond to bioterrorism as it relates to children; on health care system changes needed to meet the special needs of children; and on changes needed for the Strategic National Stockpile. Congress directed the committee to include Federal officials and experts in child health,

infectious disease, environmental health, toxicology, and other relevant professional disciplines. 42 USC 247d-6(b)(2)

In 2002 (PL 107-188), Congress directed the HHS Secretary to establish an Emergency Public Information and Communications Advisory Committee [EPIC Advisory Committee] to make recommendations on ways to communicate public health information on bioterrorism and other public health emergencies to the public, to be composed of ""experts in public health, medicine, communications, behavioral psychology, and other areas determined appropriate by the Secretary." Congress directed the HHS Secretary to review the recommendations of the EPIC committee "and ensure that appropriate information is disseminated to the public." 42 USC 247d-6(b)(3)

In 2013 (PL 113-5), Congress directed the HHS Secretary to establish a National Committee on Children and Disasters, codified at 42 USC 300hh-10a with a sunset clause that Congress later extended. The committee is still authorized as of 2025, now codified at 42 USC 300hh-10b. In 2019, (PL 116-22) Congress directed the HHS Secretary to establish a National Advisory Committee on Seniors and Disasters and National Advisory Committee on Individuals with Disabilities and Disasters, codified at 42 USC 300hh-10c and 10d, both still in operation as of 2025.

42 USC 247d-6(c) [PHSA 319F(c)] - Strategy for Communication of Information Regarding Bioterrorism and Other Public Health Emergencies.

In 2002 (PL 107-188), Congress directed the HHS Secretary to develop a strategy (directly or through grants, contracts, or cooperative agreements) for communicating information regarding bioterrorism and other public health emergencies, and means by which to communicate such information. 42 USC 247d-6(c)

42 USC 247d-6(d) [PHSA 319F(d)] - Recommendation of Congress regarding official Federal internet site on bioterrorism.

In 2002 (PL 107-188), Congress recommended that an official Federal Internet site on bioterrorism should be established, either directly or through provision of a grant to an entity that has expertise in bioterrorism and the development of websites. Congress recommended that the website include information relevant to diverse populations (including messages directed at the general public, medical personnel, public safety workers, and agricultural workers) and links to State and local government sites. 42 USC 247d-6(d)

42 USC 247d-6(e) [PHSA 319F(e)] - Grants

In 2002 (PL 107-188), Congress amended a provision enacted in 2000 (PL 106-505) to provide grants to eligible entities to "increase their capacity to detect, diagnose, and respond to acts of bioterrorism." In 2000, the provision was codified at 42 USC 247d-6(c) and designated eligible entities to include "a State, political subdivision of a State, a consortium of two or more States or political subdivisions of States, or a hospital, clinic, or primary care facility."

In 2002 (PL 107-188), Congress renumbered the section as 42 USC 247d-6(e), and added more entities eligible to receive grants, including any "professional organization or society, school or program that trains medical laboratory personnel, private accrediting organization, or other nonprofit private institution or entity meeting criteria established by the [HHS] Secretary." 42 USC 247d-6(e)

42 USC 247d-6(g) - [PHSA 319(e)] - Education; training regarding pediatric issues

In 2002 (PL 107-188), Congress amended a provision added in 2000 (PL 106-505) to "develop educational programs to instruct public health officials, medical professionals, and other personnel working in health care facilities in the recognition and care of victims of a bioterrorist attack; and develop and implement programs to train laboratory personnel in the recognition and identification of a potential bioweapon." In 2000, the education provision was codified at 42 USC 247d-6(e).

In 2002 (PL 107-188), Congress renumbered the section as 42 USC 247d-6(g) and expanded the provisions.

Congress directed the HHS Secretary to work with the Working Group on Bioterrorism and Other Public Health Emergencies and professional organizations to develop a "core curriculum" and materials for teaching public health officials, medical professionals, emergency physicians and other emergency department staff, laboratory personnel, and other health care personnel (including poison control centers) the "recognition and identification of potential bioweapons and other agents that may create a public health emergency," and for the care of victims of such emergencies, including special needs of children and other vulnerable populations. 42 USC 247d-6(g)(1)(A)

Congress directed the HHS Secretary to develop core curricula and materials for community-wide planning by State and local governments, hospitals and other health care facilities, emergency response units, and appropriate public and private sector entities to respond to a bioterrorist attack or other public health emergency. 42 USC 247d-6(g)(1)(B)

Congress directed the HHS Secretary to develop materials for proficiency testing of laboratory workers and other public health personnel "for the recognition and identification of potential bioweapons and other agents that may create a public health emergency." 42 USC 247d-6(g)(1)(C)

Congress directed the HHS Secretary to "provide for dissemination and teaching of the materials" through telemedicine, long-distance learning, or other means. 42 USC 247d-6(g)(1)(D)

Congress designated entities eligible to carry out these education and training activities to include Public Health Preparedness Centers, the Public Health Service's Noble Training Center, the Emerging Infections Program, the CDC Epidemic Intelligence Service (EIS), the Public Health Leadership Institute, multi-State, multi-institutional consortia, other appropriate educational entities, professional organizations and societies, private accrediting organizations,

and other nonprofit institutions or entities meeting criteria established by the Secretary. 42 USC 247d-6(g)(2)

Congress authorized the HHS Secretary to conduct the education programs directly; through the award of grants and contracts; and through interagency cooperative agreements with other Federal agencies. 42 USC 247d-6(g)(3)

Congress authorized the HHS Secretary to provide technical assistance to the Attorney General and FEMA Director, about health-related aspects of emergency response personnel training programs carried out by the Department of Justice and FEMA. 42 USC 247d-6(g)(4)

42 USC 247d-6(h) [PHSA 319F(h)] - Accelerated research and development on priority pathogens and countermeasures

In 2002 (PL 107-188), Congress added provisions for "accelerated research and development on priority pathogens and countermeasures."

Congress authorized and directed the HHS Secretary to conduct, and award grants, contracts, or cooperative agreements for research, investigations, experiments, demonstrations, and studies in the health sciences, "with respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency" in several forms: "epidemiology and pathogenesis" of such pathogens; sequencing of genomes, or other DNA analysis, or other comparative analysis, of "priority pathogens;" development of "priority countermeasures;" and other relevant areas of research. 42 USC 247d-6(h)(1)(A) through (D)

Congress authorized the NIH Director to "determine" priority pathogens, working with the Working Group on Bioterrorism, the Department of Defense and the Joint Genome Institute of the Department of Energy, and directed the HHS Secretary to give consideration to the needs of children and other vulnerable populations. 42 USC 247d-6(h)(1)(B).

Congress directed the HHS Secretary to give priority to funding research related to priority countermeasures. 42 USC 247d-6(h)(2)

Congress directed the HHS Secretary to consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with VA affiliations with health-professions universities, and authorized the HHS Secretary to enter into cooperative agreements with the VA Secretary. 42 USC 247d-6(h)(3)

Congress defined the term ‘priority countermeasure’ to mean "a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to [42 USC 262a/PHSA 351A], or harm from any other agent that may cause a public health emergency; or a priority to diagnose conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A)." 42 USC 247d-6(h)(4)

Discussion

Congress defined "priority countermeasures" in relation to the list of "biological select agents and toxins" determined unilaterally by the HHS Secretary under 42 USC 262a, the BSAT program authorized and codified through other sections of the 2002 Congressional act (PL 107-188). Congress further defined "priority countermeasures" to include products to be used to diagnose conditions caused by priority countermeasures themselves and resulting in adverse health consequences or death.

As of 2025, due to renumbering, "accelerated countermeasure research and development" provisions under the Public Health Service Act are codified at 42 USC 247d-6(e).

42 USC 247d-6, statutory note - Other reports

In 2002 (PL 107-188), Congress directed the HHS Secretary to submit a report to Congressional committees addressing the findings of the National Advisory Committee on Children and Terrorism, the Emergency Public Information and Communications [EPIC] Advisory Committee, characteristics of rural communities and "medically underserved" communities rendering them "uniquely vulnerable to a biological attack," additional legislative authorities the Secretary "determines" necessary to strengthen those communities, and the "need for and benefits of a National Disaster Response Medical Volunteer Service."

Congress directed the HHS Secretary to conduct a study on "local emergency response methods" addressing services provided by private response contractors and government volunteers, and to submit a report to Congressional committees describing the findings. 42 USC 247d-6, statutory note.

42 USC 247d-6, statutory note - Study regarding communications abilities of public health agencies

In 2002, Congress directed the HHS Secretary to consult with the Federal Communications Commission, the National Telecommunications and Information Administration, and other appropriate Federal agencies, to conduct a study to determine whether local public health entities have the ability to maintain communications in the event of a bioterrorist attack or other public health emergency, including "whether redundancies are required in the telecommunications system, particularly with respect to mobile communications, for public health entities to maintain systems operability and connectivity during such emergencies" and "recommendations to industry and public health entities about how to implement such redundancies if necessary."

42 USC 247d-7a [PHSA 319H] - Grants for training health care personnel

In 2002 (PL 107-188), Congress added a provision authorizing the HHS Secretary to award grants and cooperative agreements to public and nonprofit private health or educational entities, including health professions schools and programs, to provide low-interest loans, scholarships and other financial support for education and training of individuals in any category of health professions "for which there is a shortage that the Secretary determines should be alleviated in order to prepare for or respond effectively to bioterrorism and other public health emergencies." 42 USC 247d–7a(a)

42 USC 247d-7b [PHSA 319I] - Emergency system for advance registration of health profession volunteers

In 2002, (PL 107-188) Congress added a provision directing the HHS Secretary to directly, or through the awarding of grants, contracts or cooperative agreements, set up a system for the advance registration of health professionals for the purpose of verifying "credentials, licenses, accreditations, or hospital privileges" when, during public health emergencies, health care professionals volunteer to provide health services, and to provide for an electronic database. 42 USC 247d-7b(a).

Congress directed the HHS Secretary to establish criteria for prompt, efficient collecting, storage, updating and disseminating the information in the database; authorized the HHS Secretary to make grants and provide technical assistance to States and other public or nonprofit private entities for credential verification activities; authorized the HHS Secretary to "encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide such health services in the State [recognize credentials across State borders]. 42 USC 247d-7b(b) through (d).

Congress established, as a rule of construction, that the section "may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges." 42 USC 247d-7b(e)

42 USC 247d-7c [PHSA 319J] - Supplies and services in lieu of award funds

In 2002 (PL 107-188), Congress added a provision authorizing the HHS Secretary to provide "supplies, equipment and services" and to detail "any officer or employee" of HHS, in lieu of award funds to recipients of grants for any program under the public health emergencies sections, upon the request of the recipient. 42 USC 247d-7c(a)

Congress authorized the HHS Secretary, in response to a request for personnel and supplies, equipment and services in lieu of funds, to reduce the amount of payments under the grants awarded by the "costs of detailing personnel and the fair market value of any supplies, equipment, or services." 42 USC 247d-7c(b)

42 USC 247d-7d [PHSA 319K] - Security for countermeasure development and production

In 2002, (PL 107-188) Congress directed the HHS Secretary to consultation with the Attorney General and Secretary of Defense and authorized him to "provide technical or other assistance to provide security to persons or facilities that conduct development, production, distribution, or storage of priority countermeasures." 42 USC 247d-7d(a)

Congress authorized the HHS Secretary to provide guidelines for facilities to receive assistance to secure facilities against potential terrorist attack. 42 USC 247d-7d(b)

2002 - 42 USC 262 [PHSA 351] and 21 USC 355 [FDCA 505] -
Title 42: Public Health and Wefare and Food and Drugs
New drugs and biological products
Issuance of Rule on Animal Trials

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress ordered the HHS Secretary to issue a final rule authorizing approval of new drugs under 21 CFR 314 and biological products under 21 CFR 601, with reference only to animal studies, for products to be used against lethal or permanently disabling toxic substances, "when efficacy studies in humans ethically cannot be conducted," within 90 days of enactment of PL 107-188 (June 12, 2002)

HHS had published a request for public comment (62 FR 40996, July 31, 1997) and a proposed rule (64 FR 53960, Oct. 5, 1999) on what became known as the Animal Rule.

Through the FDA Commissioner, the HHS Secretary had already issued the final rule May 31, 2002: *New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible* (67 FR 37988, May 31, 2002).

2002 - 21 USC 356-1
Title 21: Food and Drugs
Accelerated approval of priority countermeasures

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress established a program for "accelerated approval of priority countermeasures" by the Food and Drug Administration, citing the definition of 'priority countermeasure' under 42 USC 247d-6d(h)(4).

Congress authorized the HHS Secretary to designate a priority countermeasure as a "fast-track product" under 21 USC 356 [FDCA 506, *Expedited approval of drugs for serious or life-threatening diseases or conditions,* added in 1997 (PL 105-115)], or as a device granted review priority under 21 USC 360e(d)(5) [FDCA 515(d)(5), *Action on application for premarket approval, review priority for devices for treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions,* added in 1997 (PL 105-115)]. 21 USC 356-1(a)

Congress authorized the HHS Secretary to designate products for "fast-track" approval before a sponsor or applicant submitted a request for such designation, or an application for investigational use under 21 USC 355(i) [FDCA 505(i), *New drugs, Exemptions of drugs for research*] or 42 USC 262(a)(3) [PHSA 351(a)(3), *Regulation of biological products, biologics license, exemptions for biological products undergoing investigation*.] 21 USC 356-1(a)

Congress construed the provision as maintaining the right of a product sponsor to decline a fast-track" designation. 21 USC 356-1(a)

Congress authorized the HHS Secretary to designate products submitted for approval under 21 USC 355(b) [FDCA 505(b), *New drugs, filing application*] or 42 USC 262 [PHSA 351, *Regulation of biological products*], as fast-track "on the basis of evidence of effectiveness that is derived from animal studies" under the "Animal Rule" proposed by the FDA in 1999 as "New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted"[...] because they would necessarily expose healthy subjects to a potentially lethal or permanently disabling substance..." (64 FR 53960)]. 21 USC 356-1(b)

Congress designated priority countermeasures that are a drug or biological product as a "priority" drug or biological product for purposes of "performance goals" for priority drugs or biological products agreed to by the FDA Commissioner. 21 USC 356-1(c)

Congress defined 'priority countermeasure' by citing the definition under 42 USC 247d-6(h)(4):

> "a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the [HHS] Secretary determines to be—

> (A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to [42 USC 262a/PHSA 351A], or harm from any other agent that may cause a public health emergency; or
>
> (B) a priority to diagnose conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A)."

Congress defined the term 'priority drugs or biological products' to mean

> a drug or biological product that is the subject of a drug or biologics application referred to" in [PL 105-115, FDAMA, Sec. 101(4), citing "letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record."]

2002 - Sense of Congress
Support for university biodefense research

In 2002 (PL 107-188) Congress noted, in support of HHS grants to university biodefense research: "It is the sense of the Congress that—(1) many excellent university-based programs are already functioning and developing important biodefense products and solutions... accelerating the crucial work done at university centers and laboratories will contribute significantly to the United States capacity to defend against any biological threat or attack...maximizing the effectiveness of, and extending the mission of, established university programs would be one appropriate use of the additional resources provided for in this Act and the amendments made by this Act..."

2002 - 42 USC 7257d
Title 42: Public Health and Welfare
Department of Energy
Expanded research by Secretary of Energy

In 2002 (PL 107-188), Congress directed the Secretary of Energy and the Administrator of the National Nuclear Security Administration to expand research relevant to the rapid detection and identification of pathogens likely to be used in a bioterrorism attack or other agents that may cause a public health emergency, including, as authorized activities, improving methods for detecting biological agents or toxins of potential use in a biological attack and testing such methods under variable conditions; improvement or pursuit of methods for testing, verifying, and calibrating new detection and surveillance tools and techniques; and other relevant research, in cooperation with the Working Group on Bioterrorism and Other Public Health Emergencies. The provision was codified at 42 USC 7257d.

2002 - 42 USC 264
Title 42: Public Health and Welfare
Quarantine and inspection, regulations to control communicable diseases

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress introduced the terms 'qualifying stage,' 'precommunicable stage' and 'likely to cause a public health emergency' as legal predicates authorizing apprehension and detention of individuals.

As of 1944 (PL 78-410, summarized above), Congress directed that regulations for communicable disease control:

> shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General. 42 USC 264(b), 1944 to 2002.

In 2002 (PL 107-188), Congress eliminated the putative function of the National Advisory Health Council, substituting "Executive orders of the President upon the recommendation of the [Health and Human Services] Secretary, in consultation with the Surgeon General." 42 USC 264(b) as of 2002.

As of 1944 (PL 78-410), Congress authorized the Surgeon General to prescribe regulations to "provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage" and either "moving or about to move from a State to another State" or "a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State." Congress authorized the Surgeon General to make such regulations "on recommendation of the National Advisory Health Council," and authorized the regulations to provide that "if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary." 42 USC 264(d).

In 2002 (PL 107-188), Congress eliminated the putative function of the National Advisory Health Council, substituted "in a qualifying stage" for "in a communicable stage," and added a definition for "qualifying stage," including a "precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals."

The revised section read:

> 42 USC 264(d) Apprehension and examination of persons reasonably believed to be infected
>
> (1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and

(A) to be moving or about to move from a State to another State; or

(B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State.

Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term "qualifying stage", with respect to a communicable disease, means that such disease-

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

In 2002 (PL 107-188), Congress added a preemption clause, providing that "nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a [State] provision conflicts with an exercise of Federal authority under this section or [42 USC 266/PHSA Sec. 363, special quarantine powers in time of war] of this title." 42 USC 264(e), added 2002.

Discussion

Congress did not cite physical evidence to support the premise that diseases are caused by communicable or transmissible pathogens in a one-to-one, cause-and-effect relationship.

Congress did not provide physical definitions for communicable diseases, 'in a communicable stage,' or 'in a precommunicable stage.' Congress did not direct the HHS Secretary or President to cite physical evidence or establish physical definitions when recommending diseases for inclusion in executive orders, or when issuing executive orders listing communicable diseases.

Congress did not direct the HHS Secretary to establish, by regulation, physical definitions for communicable diseases, 'communicable stage' or 'precommunicable stage.'

Congress did not establish standards of evidence against which claimed communicable diseases or communicable or precommunicable stages could be assessed, did not direct the HHS Secretary to establish such standards by regulation, and did not provide any process for evidentiary review of Presidential or HHS Secretary determinations.

2002 - 42 USC 300hh et seq
Title 42: Public Health and Welfare
National all-hazards preparedness and response planning, coordinating and reporting

In 2002 (PL 107-188, Public Health and Bioterrorism Preparedness and Response Act), Congress established a new framework for "national preparedness" planning and response, codified at 42 USC 300hh et seq/PHSA 2801 et seq.

When Congress enacted these provisions, there were four main sections:

- National Preparedness Plan (42 USC 300hh), including a statutory note directing the Comptroller General to draft a GAO report on federal preparedness;
- Coordination of preparedness for and response to bioterrorism and other public health emergencies, including establishment of a National Disaster Medical System (42 USC 300hh-11);
- Strategic National Stockpile (42 USC 300hh-12) along with a statutory note addressing stockpiling of potassium iodide tablets for populations within 20 miles of nuclear power plants; and
- Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies (42 USC 300hh-13).

Since 2002, this part of the Public Health Service Act (Chapter 6A, Public Health Service, Subchapter 26, National All-Hazards Preparedness for Public Health Emergencies) has been amended, reorganized and expanded from the original four provisions. As of 2025, the subchapter contains 23 provisions.

The original four provisions are described below.

<u>42 USC 300hh - National Preparedness Plan</u>

In 2002 (PL 107-188), Congress directed the HHS Secretary to "further develop and implement a coordinated strategy" building on the "core public health capabilities" that Congress had directed the Secretary to coordinate and direct in 2000 (PL 106-505) when expanding the Secretary's authority to determine, prepare for and respond to bioterrorism and other public health emergencies. Congress directed the Secretary to draft a National Preparedness Plan. 42 USC 300hh(a)(1)

Congress directed the Secretary to collaborate with the States to ensure that national activities would be coordinated with State and local activities. 42 USC 300hh(a)(2).

Congress directed the Secretary to set benchmarks for evaluating the progress of the federal, State and local governments, toward achieving the goals of the plan. 42 USC 300hh(a)(3).

Congress directed the Secretary to include provisions in the National Preparedness Plan addressing: assistance to State and local governments; ensuring that State and local governments

have "appropriate capacity to detect and respond effectively," (including surveillance and reporting mechanisms at the State and local levels; laboratory readiness; trained and equipped emergency response; public health and medical personnel; preparation of public health agencies to coordinate services; participation in communication networks to disseminate information to public and private entities and to the public). 42 USC 300hh(b)(1) and (2)

Congress directed the Secretary's plan to include provisions for "developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies." 42 USC 300hh(b)(3)

Congress directed the Secretary's plan to ensure coordination and minimize duplication of Federal, State and local planning, "including during the investigation of a suspicious disease outbreak or other potential public health emergency" and to "enhance the readiness of hospitals and other health care facilities." 42 USC 300hh(b)(4) and (5).

Congress directed the Secretary to submit biennial reports to Congressional committees, including "progress toward achieving the goals" listed in the prior section, and recommendations concerning "any additional legislative authority that the Secretary determines is necessary" for fully implementing the National Preparedness Plan and "to protect the public health in the event of an emergency" described in 42 USC 247d (the public health emergencies program). 42 USC 300hh(c).

Through this section, asking the HHS Secretary to recommend "additional legislative authority," Congress prepared to make subsequent amendments to Title 10, Armed Forces, Title 21, Food and Drugs, Title 42, Public Health and Welfare, and other titles, enacted in 2003 (PL 108-136), 2004 (PL 108-276), and 2005 (PL 109-148) addressing research and development of defense biomedical countermeasures, expedited procurement authority, authorization for medical products for use in emergencies, targeted liability protections for pandemic and epidemic products and security countermeasures, and related provisions.

42 USC 300hh, statutory Note - General Accounting Office Report

In 2002 (PL 107-188), Congress directed the Comptroller General to draft and submit to Congressional committees a report on federal activities related to research on, preparedness for and management of public health and medical consequences of a bioterrorist attack against the civilian population; coordination of those activities; effectiveness of those efforts in preparing national State and local authorities; activities and costs of Civil Support Teams of the National Guard; activities of the Working Group on Preparedness for Acts of Bioterrorism (established in 2000, PL 106-505) and "the ability of private sector contractors to enhance governmental responses to biological threats or attacks."

42 USC 300hh-11 - Coordination of preparedness for and response to bioterrorism and other public health emergencies

In 2002 (PL 107-188), Congress established a new position within the HHS Department: Assistant Secretary for Public Health Emergency Preparedness, to be appointed by the President and report to the HHS Secretary, and directed the HHS Secretary and Assistant Secretary to set up and run a National Disaster Medical System.

Since 2002, the Assistant Secretary position has been renamed the Assistant Secretary for Preparedness and Response and the office in which he works has been upgraded to the Administration for Strategic Preparedness and Response.

Congress directed the Assistant Secretary for Public Health Emergency Preparedness to carry out duties "with respect to bioterrorism and other public health emergencies" including coordinating interagency "interfaces" with other federal departments, agencies and offices, and with State and local emergency preparedness entities; coordinating operations of the National Disaster Medical System; and coordinating HHS efforts to "bolster" State and local emergency preparedness and evaluate their progress in meeting the benchmarks established through the National Preparedness Plan. 42 USC 300hh-11(a)

Congress directed the HHS Secretary to set up and operate a National Disaster Medical System, to be led by the Assistant Secretary for Public Health Emergency Preparedness. 42 USC 300hh-11(b)(1)

Congress described the NDMS as " a coordinated effort" by federal agencies including HHS, Federal Emergency Management Agency (FEMA), Department of Defense and Department of Veterans Affairs, in collaboration with States and other public or private entities, to carry out several purposes. 42 USC 300hh-11(b)(2)

Congress described the purpose of the NDMS as being "to provide health services, health-related social services...and auxiliary services...to respond to the needs of victims of a public health emergency (whether or not determined to be a public health emergency under section 319" [42 USC 247d] or "to be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified." 42 USC 300hh-11(b)(3)(A)

Congress authorized the NDMS to carry out "ongoing activities as may be necessary to provide for" the emergency services during emergencies. 42 USC 300hh-11(b)(3)(B)

Congress directed the HHS Secretary to "conduct an exercise to test the capability and timeliness" of the NDMS "to mobilize and otherwise respond effectively to a bioterrorist attack or other public health emergency that affects two or more geographic locations concurrently" within a year of the Congressional act's enactment (June 2002) and to conduct similar exercises thereafter. 42 USC 300hh-11(b)(3)(C)

Congress directed the HHS Secretary to "establish criteria for the operation" of the NDMS, but provided no further detail or physical definitions or standards to be required for activation and operation of the system. 42 USC 300hh-11(c)(1)

Congress directed the HHS Secretary to "establish criteria regarding the participation of States and private entities" in the NDMS, including criteria for agreements for such participation, to include provisions addressing custody and use of Federal personal property "on a reimbursable basis" and provisions addressing priorities in circumstances when an individual or entity has agreements with the NDMS and another entity for emergency services. 42 USC 300hh-(c)(2)

Congress authorized the HHS Secretary to appoint "intermittent disaster-response personnel" to operate the NDMS; directed that such personnel be "considered to be an employee of the Public Health Service performing medical, surgical, dental or related functions" under 42 USC 233 (civil claims against PHS officers or employees) and the Federal Tort Claims Act; and addressed other employment issues for intermittent appointees and PHS commissioned officers of the Regular or Reserve Corps assigned to serve with the NDMS. 42 USC 300hh-11(d) to (f).

Congress defined "auxiliary services" to include mortuary services, veterinary services and other services determined by the HHS Secretary to be appropriate for operating the National Disaster Medical System. 42 USC 300hh-11(g)

Congress authorized "such sums as may be necessary" for fiscal years 2002 through 2006, for the Assistant Secretary for Public Health Emergency Preparedness to set up and run the NDMS, and added as a "sense of Congress" note that the HHS Secretary should provide "sufficient resources...for reimbursement of expenses, operations, purchase and maintenance of equipment, training and other funds expended in furtherance of the National Disaster Medical System." 42 USC 300hh-11(h)

42 USC 300hh-12 - Strategic National Stockpile

In 1998 (PL 105-277, summarized above), had Congress had authorized $51,000,000 for the Public Health and Social Services Emergency Fund, to be used "for pharmaceutical and vaccine stockpiling activities at the Centers for Disease Control and Prevention." This collection of products was originally called the National Pharmaceutical Stockpile.

In 2002 (PL 107-188) Congress developed the stockpile program further, naming it the Strategic National Stockpile, and directing the HHS Secretary to coordinate with the Secretary of Veterans Affairs to "maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency." 42 USC 300hh-12(a)(1).

Congress defined the term "stockpile" to include " a physical accumulation (at one or more locations)" of supplies (drugs, vaccines and other biological products, medical devices and other supplies) or "a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary" such supplies. 42 USC 300hh-12(d).

Congress directed the HHS Secretary to manage the stockpile, including consulting with the Working Group on Preparedness for Acts of Bioterrorism [established in 2000, PL 106-505; codified at 42 USC 247d-6(a)/PHSA Section 319F(a)]; manage inventory and ensure physical security; consult with Federal, State and local officials about the "timing and location of special events;" review and revise the contents of the stockpile "to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;" and plan for supply chain management in consultation with Federal, State and local agencies and "the public and private health care infrastructure." 42 USC 300hh-12(a)(2)

Congress directed the HHS Secretary to award contracts and enter into cooperative agreements to ensure that the stockpile includes "an amount of vaccine against smallpox as determined by the Secretary to be sufficient to meet the health security needs of the United States." 42 USC 300hh-12(b)

Congress prohibited Federal agencies from disclosing "any information identifying the locations at which materials in the [Strategic National Stockpile] are stored." 42 USC 300hh-12(c)

Congress authorized $640 million for the Strategic National Stockpile for FY2002; $509 million for smallpox vaccine development for FY 2002; and "such sums as may be necessary" for each of the two programs for 2003 through 2006. 42 USC 300hh-12(e)

Later in 2002 (PL 107-296), when establishing the Department of Homeland Security, Congress transferred the "functions, personnel, assets and liabilities" of several entities to the DHS Secretary, including transferring the Strategic National Stockpile from HHS to DHS. Homeland Security Act Sec. 503, codified at 6 USC 313.

In 2004, Congress numbered the Strategic National Stockpile to PHSA Section 319F-2, moved it, within the US Code, from 42 USC 300hh-12 to 42 USC 247d-6b, and directed the HHS Secretary to manage the stockpile in coordination with the Secretary of the Department of Homeland Security.

In 2006, Congress struck the provision (Homeland Security Act Sec. 503/6 USC 313) assigning Strategic National Stockpile management and control to DHS (PL 109-295).

42 USC 300hh-13 - Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies

In 2002 (PL 107-188), Congress directed the HHS Secretary to "carry out a program to periodically evaluate new and emerging technologies that, in the determination of the Secretary, are designed to improve or enhance the ability of public health or safety officials to conduct public health surveillance activities relating to a bioterrorist attack or other public health emergency." 42 USC 300hh-13(a)

Congress directed the HHS Secretary to "survey" existing federally-funded technology programs for potentially useful technologies; issue requests for information from non-Federal public and private entities; develop criteria for evaluation; and evaluate the technologies in consultation with the Working Group on Preparedness for Acts of Bioterrorism [established in 2000, PL 106-505; codified at 42 USC 247d-6(a)/PHSA Section 319F(a)] and other public, nonprofit and private entities. 42 USC 300hh-13(b) and (c)

Congress directed the HHS Secretary to submit reports to Congressional committees on the evaluation of technologies for public health surveillance. 42 USC 300hh-13(d)

Since 2002 - 42 USC 300hh et seq - Amendments and additions

In 2004, Congress moved and renumbered the Strategic National Stockpile provisions from 42 USC 300hh-12 to 42 USC 247d-6b.

In 2006, Congress amended and renumbered the 2002 section titled "coordination of preparedness for and response to bioterrorism and other public health emergencies" (42 USC 300hh-11 as of 2002) and retitled the section "Coordination of preparedness for and response to all-hazards public health emergencies" (42 USC 300hh-10 as of 2006).

In 2006, Congress also amended and renumbered the 2002 section establishing the National Disaster Medical System (42 USC 300hh-11(b) as of 2002 and retitled the section "National Disaster Medical System" (42 USC 300hh-11 as of 2006).

As of 2025, there are three parts to the National All-Hazards Preparedness for Public Health Emergencies (Part A covering "planning coordinating and reporting," Part B covering "preparedness and response," and Part C covering "public health surveillance systems") comprised of 23 sections, most of which have been amended and expanded several times since.

Sections added since 2002 under Part A include National Health Security Strategy (42 USC 300hh-1, added 2006); enhancing medical surge capacity (42 USC 300hh-2, added 2006); and Office of Pandemic Preparedness and Response Policy (42 USC 300hh-3, added 2022).

Sections added since 2002 under Part B include Public Health Emergency Medical Countermeasures Enterprise (42 USC 300-10a, added 2019), although the PHEMCE had been set up by HHS and operational since 2006 (71 FR 38403); National Advisory Committee on

Children and Disasters (42 USC 300hh-10a, added 2013); National Advisory Committee on Seniors and Disasters (42 USC 300hh-10b, added 2019); National Advisory Committee on Individuals with Disabilities and Disasters (42 USC 300hh-10c, added 2019); Advisory Committee Coordination (42 USC 300hh-10e, added 2019); protection of health and safety during disasters (42 USC 300hh-14, added 2006); Volunteer Medical Reserve Corps (42 USC 300hh-15, added 2006); At-risk individuals (42 USC 300hh-16, added 2006); and Emergency response coordination of primary care providers (42 USC 300hh-17, added 2008).

Sections added since 2002 under Part C include Epidemiology-laboratory capacity grants (42 USC 300hh-31, added 2010); Enhanced support to assist health departments in addressing vector-borne diseases (42 USC 300hh-32, added 2019); Public health data system modernization (42 USC 300hh-33, added 2020); Genomic sequencing, analytics, and public health surveillance of pathogens program (42 USC 300hh-34, added 2022); Epidemic forecasting and outbreak analytics (42 USC 300hh-35, added 2022); Leadership exchange pilot for public health and medical preparedness and response positions at the Department of Health and Human Services (42 USC 300hh-36, added 2022); One Health framework as related to "prevention, detection, control and response for zoonotic disease" and related programs (42 USC 300hh-37, added 2022)

2002 - 7 USC 8401 et seq
Title 7: Agriculture
Biological select agents and toxins; surveillance for zoonotic diseases; other

In 2002 (PL 107-171 and PL 107-188) Congress added or amended several other laws related to preparedness and response to bioterrorism and public health emergencies.

In 2002, through PL 107-188 and also through PL 107-171 — the Farm Security and Rural Investment Act of 2002 — Congress added or amended several other laws related to national preparedness and response to events presented as actual or potential infectious or communicable disease outbreaks, pandemics, bioterrorist attacks and public health emergencies, including US Department of Agriculture programs.

7 USC 8401 - Enhancing controls on dangerous biological agents and toxins.

Congress directed the USDA to establish an agricultural BSAT program listing select biological agents and toxins affecting plant and animal health, with exemptions for laboratories, for products (classified as exempt not on the basis of their physicochemical characteristics or physiological effects but only on the basis of licensing/authorization/approval/registration and derivative labeling) and for persons working under "agricultural emergencies."

The USDA BSAT program mirrors provisions of the HHS BSAT program [42 USC 262a] listing select agents and toxins affecting human health, with exemptions for laboratories, for products (classified as exempt not on the basis of their physicochemical characteristics or physiological effects but only on the basis of licensing/authorization/approval/registration and derivative labeling), and for persons working during "public health emergencies."

7 USC 8411 - Interagency coordination

Congress directed interagency coordination regarding "overlap agents and toxins" listed by both HHS and USDA.

7 USC 8301 et seq - Animal Health Protection program.

Congressional findings: "that the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect animal health, the health and welfare of the people of the United States; the economic interests of the livestock and related industries...; the environment of the United States; and interstate commerce and foreign commerce of the United States in animals and other articles; [and that] animal diseases and pests are primarily transmitted by animals and articles regulated under this chapter." [Ch. 109].

Congress defined the term "disease" as "has the meaning given the term by the Secretary [of Agriculture]." 7 USC 8302(3)

There is no definition of "disease" listed in Title 9 of the Code of Federal Regulations, Animals and Animal Products, Part 1.1, Definitions (9 CFR 1.1), as promulgated by the Secretary of Agriculture.

In 2020 (85 FR 18471), USDA published a proposed rule to be codified at 9 CFR 57, ‘Animal diseases, Reporting, and recordkeeping requirements,’ and 9 CFR 161, ‘Reporting and recordkeeping requirements, Veterinarians,’ proposing to establish a National List of Reportable Animal Diseases (NLRAD).

USDA published a revised proposed rule in 2023 (88 FR 58524) but has not as of 2025 published a Final Rule.

The proposed rule does not include a definition for 'disease,' but includes definitions for categories of diseases which contain the undefined term 'disease.'

'Monitored disease' is defined in the 2020 proposed rule as "a disease or condition where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence.”

'Notifiable disease' is defined in the 2020 proposed rule as “A disease or condition that requires immediate notification to Federal and State veterinary authorities. Notifiable diseases are: (1) Emergency incidents (foreign animal diseases, exotic vectors, and high priority diseases), emerging disease incidents (involving diseases, infections, or infestations with agents that are unknown, newly identified, or previously identified but epidemiologically changed), and regulated disease incidents (involving diseases for which Federal regulations already are in place).”

7 USC 8319 - Surveillance of zoonotic diseases

Congress authorized and directed federal coordination of surveillance of zoonotic diseases to be carried out by the HHS Secretary, FDA Commissioner, CDC Director and the Secretary of Agriculture.

7 USC 8320 - Expansion of Animal and Plant Health Inspection Service [APHIS] activities

Congress authorized and directed the Secretary of Agriculture to "increase the inspection capacity of the Service at international points of origin; improve surveillance at ports of entry and customs; enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists; develop new and improve existing strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism or from unintentional introduction..."

7 USC 3351 - Special authorization for biosecurity planning and response

Congress authorized appropriation of funding through agricultural research, education and extension programs at colleges and universities, “to reduce the vulnerability of the United States food and agricultural system to chemical or biological attack; … to continue partnerships with institutions of higher education and other institutions to help form stable, long-term programs to enhance the biosecurity of the United States, including the coordination of the development, implementation, and enhancement of diverse capabilities for addressing threats to the Nation’s agricultural economy and food supply with special emphasis on planning, training, outreach, and research activities related to vulnerability analyses, incident response, and detection and

prevention technologies;…to award competitive grants and cooperative agreements to universities and qualified research institutions for research on counterbioterrorism;…to counter or otherwise respond to chemical or biological attack;…[and] to coordinate the tactical science activities of the Research, Education, and Economics mission area of the Department that protect the integrity, reliability, sustainability, and profitability of the food and agricultural system of the United States against biosecurity threats from pests, diseases, contaminants, and disasters."

7 USC 3352 - Agriculture research facility expansion and security upgrades

Congress directed the Secretary of Agriculture to provide grants to colleges and universities "to enhance the security of agriculture in the United States against threats posed by bioterrorism."

7 USC 3353 - Agricultural biosecurity

Congress directed the Secretary of Agriculture to provide grants to universities, colleges and food producers, "to review security standards and practices at their facilities in order to protect against bioterrorist attacks."

7 USC 3354 - Agricultural bioterrorism research and development

Congress authorized the Secretary of Agriculture to conduct and support (with grants) "research activities to...enhance the capability...to respond in a timely manner to emerging or existing bioterrorist threats to the food and agricultural system...expand the involvement of the [Agriculture] Secretary with international organizations dealing with plant and animal disease control,... [and fund] research to develop rapid detection field test kits to detect biological threats to plants and animals and to provide such test kits to State and local agencies preparing for or responding to bioterrorism..."

Appropriations for USDA Agricultural Research Service facilities

Congress appropriated $180 million for FY 2002 for upgrades by Agricultural Research Service [ARS] at biosecurity research facilities at Plum Island, NY, (expansion of the Biosafety Level 3 laboratory and animal research facilities); Ames, IA (ARS/APHIS facility); Athens, GA (ARS biocontainment laboratory for poultry research) and Laramie, WY (Arthropod-Borne Animal Disease Laboratory).

2002 - 42 USC 300aa-1 et seq
Title 42: Public Health and Welfare
Vaccines

In 2002 (PL 108-296) Congress added a definition for 'vaccine' to the law authorizing the National Vaccine Program and National Vaccine Injury Compensation Program enacted in 1986 (PL 99-660) without Congress defining the terms 'vaccine,' 'adulterant' or 'contaminant.'

In 2002, Congress defined the term 'vaccine' to mean

> any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccine's product license application and product label." 42 USC 300aa-33(7), added 2002.

Congress made conforming amendments at two other definitions.

From 1986 to 2002, Congress had defined the term 'manufacturer' to mean

> any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of [42 USC 300aa-28, manufacturer recordkeeping], such term shall include the manufacturer of any other vaccine covered by that section. The term 'manufacture' means to manufacture, import, process, or distribute a vaccine. 42 USC 300aa-33(3)

In 2002, Congress defined the term 'manufacturer' to mean

> any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury table, <u>including any component or ingredient of any such vaccine</u>, except that, for purposes of [42 USC 300aa-28], such term shall include the manufacturer of any other vaccine covered by that section. The term 'manufacture' means to manufacture, import, process, or distribute a vaccine <u>including any component or ingredient of any such vaccine</u>. 42 USC 300aa-33(3)

From 1986 to 2002, Congress had defined the term 'vaccine-related injury or death' to mean

> an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine. 42 USC 300aa-33(5) as of 1986

In 2002, Congress defined the term 'vaccine-related injury or death' to mean

> an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine. For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label. 42 USC 300aa-33(5) as of 2002.

In February 2003 (PL 108-7), Congress repealed the provisions enacted in November 2002, including the definition for 'vaccine,' noting that the Public Health Service Act should be applied as if the November 2002 amendments had never been enacted.

Congressional acts to revise vaccine-related definitions between November 2002 and February 2003 were related to an autism case then moving through the VICP process (*Leroy v. Secretary of HHS,* Office of Special Master, No. 02–392V), in which petitioner parents of a brain-damaged child sought to classify thimerosal as an 'adulterant' or 'contaminant,' whose inclusion in vaccines would place their case outside the jurisdiction of the court reviewing their VICP eligibility and compensation claims. The court ruled against the parents, declining to classify thimerosal as an 'adulterant' or 'contaminant,' as intentionally added to vaccines to ostensibly serve as a preservative.

2002 - 6 USC 101 et seq
Title 6: Homeland Security
Science and technology in support of homeland security

In 2002 (PL 107-296, Homeland Security Act) Congress established the Department of Homeland Security.

Provisions of the Homeland Security Act set up new offices and programs or transferred existing programs from other federal departments to DHS; several of the new and transferred programs related to preparedness and response to chemical, biological, radiological, nuclear and related weapons.

6 USC 121 [HSA 201] - Directorate for Information Analysis and Infrastructure Protection

In 2002 (PL 107-296), Congress established, within the new Department of Homeland Security. a Directorate for Information Analysis and Infrastructure Protection to be headed by the Under Secretary for Information Analysis and Infrastructure Protection appointed by the President with advice and consent of the Senate.

Congress included, among responsibilities assigned to the Undersecretary for Information Analysis, "to access...and analyze law enforcement information, intelligence information, and other information from agencies of the Federal Government, State and local government agencies...and private sector entities...to identify...terrorist threats to the homeland...and understand such threats in light of actual and potential vulnerabilities of the homeland" and "to carry out comprehensive assessments of the vulnerabilities of the key resources and critical infrastructure of the United States, including...assessments to determine the risks posed by particular types of terrorist attacks within the United States (including an assessment of the probability of success of such attacks and the feasibility and potential efficacy of various countermeasures to such attacks)." 6 USC 121(d)(1) and (2)

6 USC 181-182 [HSA 301-302] - Directorate of Science and Technology

In 2002 (PL 107-296), Congress established, within the new DHS, a Directorate of Science and Technology to be headed by the Under Secretary for Science and Technology. 6 USC 181

Congress directed the Under Secretary for Science and Technology to advise the DHS Secretary regarding research and development efforts and priorities; develop national policy and strategic plans for identifying and developing countermeasures to chemical, biological, radiological, nuclear, and other emerging terrorist threats; support the Under Secretary for Information Analysis and Infrastructure Protection in assessing and testing homeland security vulnerabilities and possible threats; conduct basic and applied research, development, demonstration, testing, and evaluation activities through both intramural and extramural programs, "except that such responsibility does not extend to human health-related research and development activities;" direct, fund, and conduct national research, development, test and evaluation, and procurement

of technology and systems for preventing the importation of chemical, biological, radiological, nuclear, and related weapons and material, and for detecting, preventing, protecting against, and responding to terrorist attacks; establish systems for transferring homeland security developments or technologies to Federal, State, local government, and private sector entities; enter into contracts with the Department of Energy for use of national laboratories; collaborate with the Secretary of Agriculture and the Attorney General to carry out the plant and animal biological select agent and toxin program (7 USC 8401); and collaborate with the Secretary of Health and Human Services and the Attorney General "in determining any new biological agents and toxins to be listed as select agents" under the human biological select agents and toxins program (42 U.S.C. 262a). 6 USC 182

6 USC 183 [HSA 303] - Transfer of functions

In 2002 (PL 107-296), Congress transferred to the Secretary of the new Department of Homeland Security, the functions, personnel, assets, and liabilities of several departments, or authorized joint operations.

Transferred programs included Department of Energy chemical and biological national security and supporting programs and nuclear smuggling programs, nuclear assessment programs, "such life sciences activities of the biological and environmental research program related to microbial pathogens as may be designated by the President for transfer" to DHS, the Environmental Measurements Laboratory and the advanced scientific computing research program and activities at Lawrence Livermore National Laboratory; the DoD National Bio-Weapons Defense Analysis Center, and related functions of the Secretary of Defense. 6 USC 183

6 USC 184 [HSA 304] - Conduct of certain public health related activities

In 2002 (PL 107-296), Congress authorized and directed the HHS Secretary to collaborate with the DHS Secretary to set priorities and policies and develop a coordinated strategy "with respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats" to be carried out by HHS including the Public Health Service) "to ensure consistency with the national policy and strategic plan developed" under 6 USC 182. Congress directed the DHS Secretary and HHS Secretary to develop benchmarks and outcome measurements for evaluating progress toward achieving the priorities and goals. 6 USC 184

6 USC 188 [HSA 308] - Conduct of research, development, testing and evaluation

In 2002 (PL 107-296), Congress directed the Under Secretary for Science and Technology to carry out the DHS programs for "conducting basic and applied research, development, demonstration, testing, and evaluation activities...through both intramural and extramural programs," except for human health-related research and development activities. 6 USC 188(a)

Congress directed the Under Secretary to operate extramural research, development, demonstration, testing, and evaluation programs to ensure that colleges, universities, private research institutes, and companies (and consortia thereof) from as many areas of the United

States as practicable participate; ensure that the research funded is of high quality, as determined through merit review processes; and distribute funds through grants, cooperative agreements, and contracts. 6 USC 188(b)(1)

Congress directed the Under Secretary to establish university-based centers for homeland security, to set up a coordinated, university-based homeland security system. Congress directed the Under Secretary to select colleges or universities based on demonstrated expertise in the training of first responders; responding to incidents involving weapons of mass destruction and biological warfare; emergency medical services; chemical, biological, radiological, and nuclear countermeasures; strong affiliations with animal and plant diagnostic laboratories; expertise in food safety; affiliation with USDA labs or training centers; expertise in water and waste water operations, port and waterway security or multi-modal transportation; nationally recognized programs in information security or engineering; expertise in educational outreach and technical assistance, border transportation and security, or interdisciplinary public policy research and communication outreach regarding science, technology, and public policy. 6 USC 188(b)(2)

Congress directed the Under Secretary to draw upon the expertise of any laboratory of the Federal Government, whether operated by a contractor or the Government, to carry out his science and technology responsibilities. Congress authorized the Under Secretary to set up a DHS headquarters laboratory and additional laboratory units.

6 USC 190 [HSA 310] - Transfer of Plum Island Animal Disease Center, Department of Agriculture

In 2002 (PL 107-296), Congress directed the Secretary of Agriculture to transfer the Plum Island Animal Disease Center of the Department of Agriculture, including assets and liabilities, to the DHS, and to enter into an access agreement to ensure that the USDA "is able to carry out research, diagnostic, and other activities" and that the Agriculture Secretary would continue to direct research, diagnostic, and other activities. Congress directed the President to notify Congress at least 180 days before any change in the biosafety level at Plum Island. 6 USC 190

6 USC 238 [HSA 430] - Directorate of Border and Transportation Security, Office for Domestic Preparedness

In 2002 (PL 107-296), Congress established, within the new DHS, a Directorate of Border and Transportation Security, and under it, an Office for Domestic Preparedness.

Congress tasked the Director of the Office for Domestic Preparedness with primary responsibility within the executive branch for the preparedness of the United States for acts of terrorism, including coordinating preparedness efforts at the Federal level, and working with all State, local, tribal, parish, and private sector emergency response providers on all matters pertaining to combating terrorism, including training, exercises, and equipment support; coordinating communications systems relating to homeland security at all levels of government; supervising Federal terrorism preparedness grant programs of the Federal Government (other HHS programs) for all emergency response providers; providing training for DHS agents and analysts, other agencies, and State and local agencies and international entities; cooperating

closely FEMA for FEMA's primary responsibility of preparing for and mitigating effects of nonterrorist-related disasters; supporting the DHS Secretary in conducting risk analysis and risk management activities of State, local, and tribal governments; operating the elements of FEMA Office of National Preparedness relating to terrorism, consolidated under the DHS Office for Domestic Preparedness. 6 USC 238

6 USC 231 [HSA 421] - Directorate of Border and Transportation Security; transfer of USDA agricultural inspection functions

In 2002 (PL 107-296), Congress transferred to the DHS Undersecretary for Border and Transportation Security, functions relating to agricultural import and entry inspection activities under a list of animal and plant protection laws, excluding quarantine functions.

The laws included the 1913 Virus-Serum-Toxin Act (animal vaccines and biological products, 21 U.S.C. 151 et seq); Honeybee Act; Title III of the Federal Seed Act (7 U.S.C. 1581 et seq.); Plant Protection Act (7 U.S.C. 7701 et seq.); Animal Health Protection Act (7 U.S.C. 8301 et seq.); Lacey Act Amendments of 1981 (16 U.S.C. 3371 et seq.); (7) Section 11 of the Endangered Species Act of 1973 (16 U.S.C. 1540).

6 USC 311 [HSA 501] - Directorate of Emergency Preparedness and Response

In 2002 (PL 107-296), Congress established, within the new DHS, a Directorate of Emergency Preparedness and Response, headed by an Under Secretary of Emergency Preparedness and Response. 6 USC 311

Congress tasked the DHS Undersecretary for Emergency Preparedness and Response with helping to ensure the effectiveness of emergency response providers to terrorist attacks, major disasters, and other emergencies; supervising the work of the Nuclear Incident Response Team and providing funds to Department of Energy and EPA for homeland security planning, exercises and training, and equipment; providing the Federal Government’s response to terrorist attacks and major disasters, including managing such response; directing the Domestic Emergency Support Team, the Strategic National Stockpile, the National Disaster Medical System and Nuclear Incident Response Team; overseeing the Metropolitan Medical Response System; coordinating other Federal response resources; aiding the recovery from terrorist attacks and major disasters; building a comprehensive national incident management system [NIMS] with Federal, State, and local government personnel, agencies, and authorities; consolidating existing Federal Government emergency response plans into a single, coordinated national response plan; and developing interoperative communications technology, and ensuring emergency response providers acquire such technology. 6 USC 312

6 USC 313 [HSA 503] Functions transferred

In 2002 (PL 107-296), when establishing the Department of Homeland Security, Congress transferred the "functions, personnel, assets and liabilities" of several entities to the DHS Secretary, including FEMA; the Integrated Hazard Information System of the National Oceanic and Atmospheric Administration, renamed FIRESAT; the FBI National Domestic Preparedness

Office; the DOJ Domestic Emergency Support Teams; the HHS Office of Emergency Preparedness, National Disaster Medical System, and Metropolitan Medical Response System including related HHS Secretary and Assistant Secretary for Public Health Emergency Preparedness functions; and the HHS Strategic National Stockpile of the Department of Health and Human Services. Congress assigned the DHS Secretary primary control of the Strategic National Stockpile, "in coordination with" the HHS Secretary and VA Secretary. 6 USC 313; 42 USC 300hh-12.

6 USC 315 [HSA 505] - Conduct of certain public health-related activities

In 2001 (PL 107-188), Congress directed the HHS Secretary to set priorities and preparedness goals for all public health-related, HHS-operated activities to improve State, local, and hospital preparedness and response to chemical, biological, radiological, and nuclear and other emerging terrorist threats, and to develop a coordinated strategy in collaboration with the DHS Secretary. Congress directed the HHS Secretary and DHS Secretary to develop benchmarks and outcome measurements for evaluating progress toward achieving the priorities and goals. 6 USC 315

6 USC 318 [HSA 508] - Use of national private sector networks in emergency response

In 2002 (PL 107-296), Congress directed the DHS Secretary to use national private sector networks and infrastructure for emergency response to chemical, biological, radiological, nuclear, or explosive disasters, and other major disasters. 6 USC 318

6 USC 422 [HSA 852] - Procurements for defense against or recovery from terrorism or nuclear, biological, chemical or radiological attack

In 2002 (PL 107-296), Congress authorized the DHS Secretary to use "streamlined acquisition thresholds" and other expedited contracting procedures for "any procurement of property or services by or for an executive agency that, as determined by the head of the executive agency, are to be used to facilitate defense against or recovery from terrorism or nuclear, biological, chemical, or radiological attack," provided a solicitation of offers for the procurement issued within one year after the enactment date of the Homeland Security Act (November 25, 2002). 6 USC 422

6 USC 428 [HSA 858] - Identification of new entrants into the federal marketplace

In 2002 (PL 107-296), Congress directed the head of each executive agency to "conduct market research...to identify effectively the capabilities, including the capabilities of small businesses and new entrants into Federal contracting, that are available in the marketplace...in furtherance of defense against or recovery from terrorism or nuclear, biological, chemical, or radiological attack." 6 USC 428

2002 - 42 USC 233
Title 42: Public Health and Welfare
Civil actions or proceedings against commissioned officers or employees, Administration of smallpox countermeasures by health professionals

In 2002 (PL 107-296, Homeland Security Act), Congress amended a 1970 law [42 USC 233] relating to civil remedies for individuals injured or killed by PHS officers or employees, to address injuries and deaths caused by smallpox "countermeasures."

In 1970 (PL 91-623, summarized above) Congress enacted 42 USC 233, *Defense of certain malpractice and negligence suits*, providing an exclusive remedy under provisions of the 1946 Federal Tort Claims Act and 1948 Judicial Code and Judiciary act [28 USC 1346(b)[15] and 28 USC 2672[16]] for "damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment" and providing for the Attorney General to defend any such action brought in any court against any commissioned officer or employee of the Public Health Service. 42 USC 233(a) through (f)

In 2002 (PL 107-296) Congress enacted an early form of the PREP Act that Congress passed in December 2005, adding the exclusive remedy provisions as a subsection under 42 USC 233 [PHSA 224], governing civil actions against commissioned Public Health Service officers or employees for injuries and deaths resulting from "administration of countermeasures against smallpox."

Congress provided that "a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary" under the following paragraph. 42 USC 233(p)(1)

Congress authorized the HHS Secretary to issue a declaration, "concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered counter measure to a category or categories of individuals;" specifying "the substance or substances that shall be considered covered counter-measures," as defined under 42 USC 233(p)(8)(A); specifying the beginning and ending dates of the effective period of the declaration (amendments to extend the end date authorized); and publishing each declaration and amendment in the Federal Register. 42 USC 233(p)(2)(A)

Congress limited liability of the United States, for claims arising out of administration of "covered countermeasure" to an individual, to cases in which the countermeasure was administered by a "qualified person," for a "purpose" specified in 42 USC 233(7)(A)(i), during the effective period of an HH Secretary declaration, to an individual "within a category of

[15] 28 USC 1346(b) - Judiciary and Judicial Procedure; district courts, jurisdiction; US as a defendant
[16] 28 USC 2672 - Tort Claims Procedure, Administrative adjustment of claims

individuals covered by the declaration" or if the qualified person "had reasonable grounds to believe that such individual was within such category." 42 USC 233(p)(2)(B)

Congress established rebuttable presumptions in case of "accidental vaccinia inoculation," deeming an individual to have a valid claim for compensation (unless rebutted), if he contracted "vaccinia" even though the "vaccinia vaccine" was not administered to him, during a period of time in which he resided with someone to whom the "vaccinia vaccine" was administered, and if an HHS declaration was in effect for "vaccinia vaccine" at the time, on the presumption that he "contracted vaccinia" from the person to whom the vaccine was administered. 42 USC 233(p)(2)(C)

Congress provided that the remedy "shall be exclusive of any other civil action or proceeding," and that the Attorney General's certification, removing the action from a State court to a Federal District Court, "that the action...is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure...shall conclusively establish such facts for purposes of jurisdiction." 42 USC 233(p)(3) and (4)

Congress directed defendants to cooperate with the United States, in defenses against claims based on the "alleged acts or omissions of such person," and authorized courts to substitute individual defendants for the United States, remand cases to other courts, and release the Attorney General from his obligation to defend, if defendants failed to cooperate. 42 USC 233(p)(5)

Congress authorized the United States to recover any damages awarded, plus interest and litigation costs, for damages "resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person." 42 USC 233(p)(6)

Congress defined the term ‘covered countermeasure’ or ‘covered countermeasure against smallpox’ to mean "a substance that is used to prevent or treat smallpox (including the vaccinia or another vaccine); or vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and specified in a declaration" issued by the HHS Secretary. 42 USC 233(p)(7)(A)

Congress defined the term ‘covered person’ when used with respect to the administration of a covered countermeasure, to include "any person who is a manufacturer or distributor of such counter measure; a health care entity under whose auspices such countermeasure was administered; a qualified person who administered such countermeasure; or an official, agent, or employee of a person described." 42 USC 233(p)(7)(B)

Congress defined the term ‘qualified person,’ when used with respect to the administration of a covered countermeasure, to mean "a licensed health professional or other individual who is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered." 42 USC 233(p)(7)(C)

2002
Role of Department of Defense in supporting homeland security

In 2002, (PL 107-314, Sec. 1404, 116 Stat. 2676), Congress directed the Secretary of Defense to provide a report to Congressional defense committees, "on DoD responsibilities, mission and plans for military support of homeland security...including providing military support to civil authorities, managing the consequences of terrorist attacks, and homeland defense;... the current capability of the DoD to respond to terrorist attacks employing chemical, biological, radiological, nuclear, high explosive or cyberterrorism weapons...current deficiencies in that capability, the resources required to achieve that capability, and a long-term plan to reach that capability;...a discussion of how the DoD biological defense research program supports its homeland security mission... An assessment of the need for and feasibility of developing and fielding DoD regional chemical-biological incident response teams across the US, including options for providing the resources and personnel necessary for developing and fielding any such teams...[and] the resource constraints and legal impediments to implementing any of the activities discussed."

The section was not codified.

Congress (PL 107-314, Sec. 1405) provided a "sense of Congress" note to 10 USC 12310, "that the Secretary of Defense should, to the extent the Secretary considers appropriate and feasible, provide assistance, in accordance with otherwise applicable provisions of law, to entities that are local first responders for domestic terrorist incidents in order to assist those entities in improving their capabilities to respond to such incidents."

2003 - 42 USC 300aa-1 et seq
Title 42: Public Health and Welfare
Vaccines

In February 2003 (PL 108-7), Congress repealed provisions enacted in November 2002 (PL 108-296, summarized above), including a definition for 'vaccine' at 42 USC 300aa-33(7)

Congress noted that the Public Health Service Act "shall be applied and administered as if the sections repealed by subsection (a) had never been enacted."

In repealing the definition of vaccine, Congress provided a "sense of Congress" note:

> It is the sense of the Congress that—
>
> (1) the Nation's ability to produce and develop new and effective vaccines faces significant challenges, and important steps are needed to revitalize our immunization efforts in order to ensure an adequate supply of vaccines and to encourage the development of new vaccines;
>
> (2) these steps include ensuring that patients who have suffered vaccine-related injuries have the opportunity to seek fair and timely redress, and that vaccine manufacturers, manufacturers of components or ingredients of vaccines, and physicians and other administrators of vaccines have adequate protections;
>
> (3) prompt action is particularly critical given that vaccines are a front line of defense against common childhood and adult diseases, as well as against current and future biological threats; and
>
> (4) not later than 6 months after the date of enactment of this Act, the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives should report a bill addressing the issues described in paragraphs (1) through (3).

2003
Appropriations to HHS and DOJ for counterterrorism programs

In 2003 (PL 108-7, Consolidated Appropriations Resolution) Congress appropriated $2,246,680,000 to the HHS Public Health and Social Services Emergency Fund for activities related to countering potential biological, disease and chemical threats to civilian populations, including $1,543,440,000 for Centers for Disease Control and Prevention, ($300 million for the National Pharmaceutical Stockpile); Office of the Secretary, $152,240,000; Health Resources and Services Administration; $546,000,000; and the Agency for Healthcare Research and Quality, $5,000,000.

Congress appropriated $1 billion to the Department of Justice, Office of Justice Programs, Office for Domestic Preparedness, for "grants, cooperative agreements, and other assistance authorized [1996, PL 104-132] for...counterterrorism programs, including training, exercises and equipment for fire, emergency medical, hazmat, law enforcement, and other first responders to prevent and respond to acts of terrorism, including incidents involving weapons of mass destruction or chemical or biological weapons."

Congress appropriated $3,730,973,000 to HHS National Institutes of Health, National Institute of Allergy and Infectious Diseases, providing that $100 million "may be made available to International Assistance Programs, Global Fund to Fight HIV/ AIDS, Malaria, and Tuberculosis and that up to $375 million "shall be for extramural facilities construction grants to enhance the Nation’s capability to do research on biological and other agents."

2003 - 6 USC 188
Title 6: Homeland Security
Science and Technology in Support of Homeland Security,
Conduct of research, development, demonstration, testing and evaluation

In 2003 (PL 108-7), Congress revised provisions authorizing "extramural research" conducted at colleges, universities, private research institutes and companies under the Homeland Security Act

Congress directed the Homeland Security Secretary, acting through the Under Secretary for Science and Technology, to "operate extramural research, development, demonstration, testing, and evaluation programs so as to "ensure that colleges, universities, private research institutes, and companies (and consortia thereof) from as many areas of the United States as practicable participate; ensure that the research funded is of high quality, as determined through merit review processes... and distribute funds through grants, cooperative agreements, and contracts." 6 USC 188(a), 6 USC 188(b)(1)

Congress directed the DHS Under Secretary for Science and Technology to designate university-based centers for homeland security "to establish a coordinated, university-based system to enhance the Nation's homeland security," and provided for criteria to include "demonstrated expertise" in training of first responders; responding to incidents involving weapons of mass destruction and biological warfare; emergency and diagnostic medical services; chemical, biological, radiological, and nuclear countermeasures or detection; animal and plant health and diagnostics; food safety; water and wastewater operations; port and waterway security; multi-modal transportation; information security and information engineering; engineering; educational outreach and technical assistance; border transportation and security; and public policy implications and public dissemination of homeland security related research and development. 6 USC 188(b)(2)

2003 - 42 USC 233 [PHSA 224] and 42 USC 239-239h [PHSA 261-269],
Title 42: Public Health and Welfare
Civil actions or proceedings against commissioned officers or employees
Smallpox Emergency Personnel Protection

In 2002 (PL 107-296), Congress added subsection (p) to 42 USC 233 (section added 1970, PL 91-623), authorizing the HHS Secretary to issue a declaration, "concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered counter measure to a category or categories of individuals;" specifying "the substance or substances that shall be considered covered counter-measures..."; specifying the beginning and ending dates of the effective period of the declaration; and publishing each declaration and amendment in the Federal Register. 42 USC 233(p)(2)(A)

In January 2003 (68 FR 4212), HHS Secretary Tommy Thompson issued a notice of declaration under 42 USC 233(p)(2)(A), effective through Jan. 23, 2004, declaring: "that a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified in this declaration for prevention or treatment of smallpox or control or treatment of adverse events related to smallpox vaccination, to categories of individuals named in this declaration. The countermeasures set forth below shall be considered to be administered pursuant to this declaration when used for prevention or treatment of smallpox, or to control or treat the adverse effects of smallpox vaccination." The notice listed "vaccinia (smallpox) vaccines, including the Dryvax vaccine; Cidofivir and derivatives thereof; and vaccinia immune globulin (VIG)" as "covered countermeasures."

The Federal Register notice of declaration listed, among "policy determinations," that "liability protections for manufacturers and distributors of smallpox countermeasures and the hospitals, health care facilities, and health care workers who will receive them and treat potentially infected smallpox cases are integral to ensuring maximum participation in the vaccination program."

The notice listed, as individuals covered, ("individuals to whom it is advisable to administer the covered countermeasures") health care workers, "any person who is a member of a smallpox response team," public safety personnel and personnel associated with certain US Government facilities abroad.

The notice defined "administration of a covered countermeasure," "health care entity under whose auspices such countermeasure was administered," and "official, agent or employee" for purposes of claims brought against the United States under the Federal Tort Claims Act procedures authorized by Congress under 42 USC 233 in 2002.

In April 2003 (PL 108-20), Congress enacted a claim review and compensation scheme for claims of smallpox countermeasure injuries.

42 USC 239 [PHSA 261] - General Provisions

Congress defined the term 'covered countermeasure' to mean "a covered countermeasure as specified in a Declaration made pursuant to [42 USC 233(p)]. 42 USC 239(a)(1)

Congress defined the term 'covered individual' as to mean

> an individual who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialities; who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan (as defined in [42 USC 239(a)(7)]) approved by the [HHS] Secretary; who has volunteered and been selected to be a member of a smallpox emergency response plan [] prior to the time at which the [HHS] Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States; and to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before the enactment of [42 USC 239, April 30, 2003]. 42 USC 239(a)(2)

Congress defined the term 'covered injury' to mean

> an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under [42 USC 239a], to have been sustained by an individual as the direct result of
>
> (A) administration to the individual of a covered countermeasure during the effective period of the Declaration; or
>
> (B) accidental vaccinia inoculation of the individual in circumstances in which—
>
> > (i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period;
> >
> > (ii) smallpox vaccine has not been administered to the individual; and
> >
> > (iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual. 42 USC 239(a)(3)(A) and (B)

Congress defined the term 'Declaration' to mean "the Declaration Regarding Administration of Smallpox Countermeasures issued by the [HHS] Secretary on January 24, 2003, and published in the Federal Register on January 28, 2003," and the term 'effective period of the declaration' to mean the period specified in the Jan. 28, 2003 declaration, or the end date specified in an extension published by the HHS Secretary. 42 USC 239(a)(4) and (5)

Congress defined the term 'eligible individual' to mean

> an individual who is (as determined [under 42 USC 239a])—
>
> (A) a covered individual who sustains a covered injury in the manner described in [42 USC 239(a)(3)(A)]; or
>
> (B) an individual who sustains a covered injury in the manner described in [42 USC 239(a)(3)(B)]. 42 USC 239(a)(6)

Congress defined the term 'smallpox emergency response plan' to mean "a response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States."

Congress directed the HHS Secretary to "ensure that a State, local, or Department of Health and Human Services plan to vaccinate individuals that is approved by the [HHS] Secretary establishes procedures to ensure, consistent with the Declaration and any applicable guidelines of the Centers for Disease Control and Prevention, that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part; there is voluntary screening provided to potential participants that can identify health conditions relevant to contraindications; and there is appropriate post-inoculation medical surveillance that includes an evaluation of adverse health effects that may reasonably appear to be due to such vaccine and prompt referral of, or the provision of appropriate information to, any individual requiring health care as a result of such adverse health event." 42 USC 239(b)

<u>42 USC 239a [PHSA 262] - Determination of Eligibility and Benefits</u>

Congress directed the HHS Secretary to establish procedures for determining "whether the individual is an eligible individual; whether an eligible individual has sustained a covered injury or injuries for which medical benefits or compensation may be available" [under 42 USC 239c and 42 USC 239d], "and the amount of such benefits or compensation; and whether the covered injury or injuries of an eligible individual caused the individual’s death for purposes of benefits" [under 42 USC 239e]. 42 USC 269a(a)

Congress authorized the HHS Secretary to accept a certification, provided by a Federal State or local government entity or private health care entity, that an individual is a "covered individual." 42 USC 239a(b)

Congress directed the HHS Secretary to apply criteria for determining reimbursement eligibility, for two categories of injuries: injuries the result of presumed causation under a vaccine injury table, and injuries not listed on the vaccine injury table whose causation meets a preponderance of the evidence standard.

For any case "where an injury or other adverse effective specified in the [Smallpox Vaccine Injury Table] established under [42 USC 239b] as a known effect of vaccine manifests in an

individual within the time period specified...such injury or other effect shall be presumed to have resulted from administration of such vaccine." 42 USC 239b(c)(1)

For any case other than those listed on the vaccine injury table, "in making determinations [] as to the causation or severity of an injury, the HHS Secretary shall employ a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts." 42 USC 239b(c)(2)

Congress set, as deadlines for initial requests for benefits, not later than one year after the date of administration of the vaccine for individuals to whom vaccines were administered, and not later than two years after the date of first symptom or manifestation of onset of the adverse effect, for individuals subject to "accidental vaccinia inoculation" by proximity to a vaccinated individual. 42 USC 239a(d)

Congress authorized the HHS Secretary to make lump-sum payments, purchase annuities or medical insurance policies, or execute an appropriate structured settlement agreement for medical benefits, lost income compensation or death benefits, at his discretion, in any case in which there was a reasonable likelihood that compensation would be required for more than one year. 42 USC 239a(e)

Congress authorized the HHS Secretary to review HHS determinations on his own motion or on application, and authorized him to affirm, vacate or modify such determinations "in any manner the [HHS] Secretary deems appropriate." 42 USC 239a(f)(1)

Congress prohibited Federal and State judicial review and administrative review other than the HHS Secretary's review of HHS agency determinations:

> No court of the United States, or of any State, District, territory or possession thereof, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the [HHS] Secretary under this section. No officer or employee of the United States shall review any action by the Secretary under this section (unless the President specifically directs otherwise). 42 USC 239a(f)(2)

<u>42 USC 239b, PHSA 263, Smallpox Vaccine Injury Table</u>

Congress directed the HHS Secretary to establish a table "identifying adverse effects (including injuries, disabilities, illnesses, conditions, and deaths) that shall be presumed to result from the administration of (or exposure to) a smallpox vaccine, and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply" by interim final regulation. Congress authorized the HHS Secretary to amend the Smallpox Vaccine Injury Table by regulation, with amendments to take effect on the date of promulgation, and apply retroactively for individuals who met filing deadlines after becoming eligible under the amended table. 42 USC 239b

42 USC 239c, PHS 264, Medical Benefits

Congress directed the HHS Secretary to make payment or reimbursement for "medical items and services as reasonable and necessary to treat a covered injury of an eligible individual, including the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation." Congress provided for payments under the smallpox countermeasures compensation program to be secondary to other payment obligations of the United States or third parties (such as insurance carriers, employers or State or local governments) under other provisions of law or contracts. 42 USC 239c

42 USC 239d [PHSA 265] - Compensation for Lost Income

Congress directed the HHS Secretary to pay compensation for loss of employment income "incurred as the result of a covered injury," and provided formulas for determining the amount based on lost income and whether the individual had dependents, subject to limitations (such as smallpox compensation payments secondary to payments through other compensation schemes and termination of lost income compensation payments to survivors of the dead following death benefits payment). Congress capped total compensation at $50,000 for any year per individual, and at the death benefit amount over the lifetime of the individual, and for termination of lost income compensation when the individual reached age 65. Congress provided for the limitations to be inapplicable for an individual suffering "permanent and total disability" as defined under the Social Security Act [42 USC 416(i)]. 42 USC 239d

42 USC 239e [PHSA 266] = Payment for Death

Congress directed the HHS Secretary to pay a death benefit to the survivor of an individual "whose death is determined to have resulted from a covered injury or injuries," calculating the amount using formulas under the Public Safety Officers' Benefits Program [42 USC 3796 et seq], reducing the amount by the amount of lost income compensation paid prior to death, and providing for dependents under the age of 18 at the time of the decedent's death. Congress provided for death benefits to be secondary to other compensation obligations (disability, retirement, life insurance) to survivors of employers, insurance carriers, governmental entities, etc. 42 USC 239e

42 USC 239f [PHSA 267] - Administration

Congress authorized the HHS Secretary to administer the smallpox vaccine compensation program through memoranda of agreement with the heads of any appropriate Federal agency, and directed such agency heads to promulgate "such implementing regulations as may be necessary." 42 USC 239f

42 USC 239g [PHSA 268] - Authorization of Appropriations

Congress authorized "such sums as may be necessary" for FY2003-2007, and subjected the HHS Secretary's payment of any benefit "to the availability of appropriations." 42 USC 239g

42 USC 239h [PHSA 269] - Relationship to other laws

Congress provided, "except as explicitly provided herein, nothing in this part shall be construed to override or limit any rights an individual may have to seek compensation, benefits, or redress under any other provision of Federal or State law." 42 USC 239h

Discussion:

Congress did not require the HHS Secretary to "take into consideration all relevant medical and scientific evidence presented" in making declarations or determinations specifying threats and countermeasures and invoking the liability immunity authorities and provisions.

Congress did not require the HHS Secretary to employ a preponderance of the evidence standard, or any other evidentiary standard, in making declarations or determinations specifying threats and countermeasures, and invoking the liability immunity authorities and provisions.

Congress precluded judicial review of agency acts including declarations and determinations specifying threats and countermeasures.

2003
Advance appropriation for Project BioShield

In 2003 (PL 108-90, Department of Homeland Security Appropriations Act, 2004), Congress appropriated $484 million for "public health programs - for necessary expenses for countering potential biological, disease, and chemical threats to civilian populations," including $400 million for the Strategic National Stockpile.

Congress appropriated as an advance appropriation Project BioShield, $5.593 billion for "biodefense countermeasures...for securing medical countermeasures against biological terror attacks" through Sept. 2013, authorizing up to $890 million to be obligated during fiscal year 2004 and up to $3.418 billion to be obligated during fiscal years 2004 through 2008.

HHS Office of Public Health Emergency Preparedness, Office of Public Health Emergency Medical Countermeasures, referred to the fund as the "Special Reserve Fund" in a 2006 report to Congress on the first two years of Project Bioshield, authorized in 2004 (PL 108-276). HHS defined "obligation" as "the promising of the money through a contract as opposed to the spending of the money, which would occur upon delivery of the countermeasures at some later date."

2003 - 21 USC 360bbb-3 [FDCA 564]
Title 21: Food and Drugs
Authorization for medical products for use in emergencies

In 1997 (PL 105-115, summarized above), Congress authorized the "expanded access to unapproved therapies" program, codified at 21 USC 360bbb to 360bbb-2.

In 2003 (PL 108-136, NDAA) Congress added a new provision: "authorization for medical products for use in emergencies," codified at 21 USC 360bbb-3.

Congress authorized the HHS Secretary to "authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an 'emergency use')...notwithstanding" other legal provisions governing interstate commerce in drugs, devices and biological products including FDCA 505, [21 USC 355, *New Drugs*], FDCA 510(k) [21 USC 360(k), *Report preceding introduction of devices into interstate commerce*], FDCA 515 [21 USC 360e, *Premarket approval of devices*] and PHSA 351 [42 USC 262, *Regulation of biological products*]. 21 USC 360bbb-3(a)(1)

Congress provided that, through an "emergency use" authorization, the HHS Secretary could authorize use of two categories of products:

> (2) Approval status of product.—An authorization under paragraph (1) may authorize an emergency use of a product that—
>
> > (A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an 'unapproved product'); or
> >
> > (B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an 'unapproved use of an approved product'). 21 USC 360bbb-3(a)(2)

Congress provided that an "emergency use" would be in addition to any other, authorized use. 21 USC 360bbb-3(a)(3)

Congress defined the term 'biological product' by reference the definition at 42 USC 262(i) [PHSA 351(i)] as of 1997 (PL 105-115):

> The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Congress defined the term 'product' to mean "a drug, device, or biological product," and defined the terms ‘emergency use,’ ‘unapproved product’ and ‘unapproved use of an approved product’ by reference to the first paragraph. 21 USC 360bbb-3(a)(4)

Congress authorized the HHS Secretary to "declare an emergency justifying the [emergency use] authorization...for a product on the basis of a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents." 21 USC 360bbb-3(b)(1)

Congress provided for termination of an emergency use authorization declaration to occur upon the earlier of two events: "a determination" by the HHS Secretary in consultation with the Secretary of Defense "that the circumstances [military emergency] have ceased to exist; or "the expiration of the one-year period beginning on the date on which the [HHS Secretary's emergency justifying use authorization] declaration is made." 21 USC 360bbb-3(b)(2)(A)

Congress authorized the HHS Secretary to renew a declaration at his discretion. 21 USC 360bbb-3(b)(2)(B)

Congress provided for the HHS Secretary to consult with product manufacturers for disposing of products whose distribution and use in interstate commerce would become unauthorized if the authorization terminated. 21 USC 360bbb-3(b)(2)(C)

Congress directed the HHS Secretary to give advance notice that a declaration was to be terminated, so that users and manufacturers could make arrangements for product returns, disposition of labeling and other informational records, and other disposition. 21 USC 360bbb-3(b)(3)

Congress directed the HHS Secretary to publish "each declaration, determination, advance notice of termination, and renewal" in the Federal Register. 21 USC 360bbb-3(b)(4)

Congress provided "criteria" for issuance of emergency use authorization declarations:

> (c) Criteria for issuance of authorization.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes—
>
> > (1) that an agent specified in a declaration under sub- section (b) can cause a serious or life-threatening disease or condition;
> >
> > (2) that, based on the totality of scientific evidence avail- able to the Secretary, including data from adequate and well- controlled clinical trials, if available, it is reasonable to believe that—
> >
> > > (A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this Act [FDCA], or licensed under section 351 of the Public Health Service Act [42 USC 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

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

(4) that such other criteria as the Secretary may by regulation prescribe are satisfied. 21 USC 360bbb-3(c)

Congress, under "scope of authorization" provisions, directed the HHS Secretary to state in his "emergency use" authorization declarations, "each disease or condition that the product may be used to diagnose, prevent, or treat;...the Secretary's conclusions...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; and the Secretary's conclusions... concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence." 21 USC 360bbb-3(d)

Congress, under "conditions of authorization" provisions, directed the HHS Secretary to "establish such conditions....as the Secretary finds necessary or appropriate to protect the public health," for emergency use of unapproved products, "to the extent practicable given the circumstances of the emergency," for "a person who carries out any activity for which the authorization is issued." 21 USC 360bbb-3(e)(1)(A)

Congress directed the HHS Secretary to establish "appropriate conditions" for health care professionals administering unapproved products, ensuring that they are informed that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and of the alternatives to the product that are available, and of their benefits and risks. 21 USC 360bbb-3(e)(1)(A)(i)

Congress directed the HHS Secretary to establish "appropriate conditions" for "individuals to whom [unapproved products are] administered," ensuring that they are informed that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and "of the option to accept or refuse administration of the product, of the

consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 USC 360bbb-3(e)(1)(A)(ii)

Congress directed the HHS Secretary to establish "appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product." 21 USC 360bbbb-3(e)(1)(A)(iii)

Congress directed the HHS Secretary to establish "appropriate conditions" for manufacturers of unapproved product, concerning recordkeeping and reporting, including records access by the Secretary. 21 USC 360bbb-3(e)(1)(A)(iv)

Congress authorized the HHS Secretary to establish "such conditions...as [he] finds necessary or appropriate to protect the public health," for persons who carry out other activities, such as which entities may distribute the [EUA] product...including limitation to distribution by government entities and...how distribution is to be performed…who may administer the product...and...the categories of individuals to whom, and the circumstances under which, the product may be administered...; conditions with respect to the collection and analysis of information...concerning the safety and effectiveness of the [EUA] product; and (for persons other than manufacturers), conditions concerning record-keeping and reporting, including records access by the Secretary. 21 USC 360bbb-3(e)(1)(B)

Congress directed and authorized much the same conditions for "unapproved use of an approved product" emergency use authorizations, "to the extent practicable given the circumstances of the emergency." 21 USC 360bbb-3(e)(2)(A)

Congress withheld authority for distributors or anyone else to "alter or obscure the labeling provided by the manufacturer" in the event the "emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change." 21 USC 360bbb-3(e)(2)(B)(i)

Congress authorized persons who are not manufacturers, in such circumstances (manufacturer refusal to change labeling) and who "choose to act under this clause" to "provide appropriate information with respect to such product in addition to the manufacturer's labeling, as long as he does not "alter or obscure" the manufacturer's labeling.

Congress noted that "such additional information shall not be considered labeling for purposes of [FDCA] section 502[17]." 21 USC 360bbb-3(e)(2)(B)(ii)

Congress prohibited the HHS Secretary from establishing, with respect to the distribution and administration of an EUA product for unapproved uses, conditions more restrictive than those for distribution and administration of the product for its approved uses. 21 USC 360bbb-3(e)(2)(C).

Congress authorized the HHS Secretary to waive or limit, "to the extent appropriate given the circumstances of the emergency," requirements regarding current good manufacturing practice

[17] 21 USC 352 [FCDA 502] prohibits "misbranding" of drugs and devices and deems a drug or device to be misbranded "if its labeling is false or misleading in any particular."

[cGMP] otherwise applicable to the manufacture, processing, packing, or holding of products, including requirements under FDCA Section 501 [21 USC 351[18]]. 21 USC 360bbb-3(e)(3)

Congress authorized the HHS Secretary to "establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of an EUA product including, with respect to drugs and biological products, requirements applicable to required contents of advertising for prescription drugs pursuant to FDCA 502(n) [21 USC 352(n)[19], or, with respect to devices, requirements under FDCA 502(r) [21 USC 352(r)[20]].

Congress provided for the "duration" of an emergency use authorization to be effective "until the earlier of the termination of the [HHS Secretary's emergency] declaration...or a revocation" and provided that, "notwithstanding" the termination of a declaration under subsection (b) or a revocation under subsection (g), an authorization "shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom it was administered during the [emergency declaration's period in effect], to the extent found necessary by such patient's attending physician." 21 USC 360bbb-3(f)

Congress directed the HHS Secretary periodically review the circumstances and the appropriateness of an authorization, and authorized the HHS Secretary to revoke an authorization "if the criteria...are no longer met or other circumstances make such revocation appropriate to protect the public health or safety." 21 USC 360bbb-3(g)

Congress directed the HHS Secretary to publish, in the Federal Register, notice of each authorization, and each termination or revocation of an authorization, and "an explanation of the reasons therefor (which may include a summary of data or information that has been submitted

[18] 21 USC 351 [FDCA Section 501 prohibits interstate commerce in "adulterated drugs and devices," and deems a drug or device to be adulterated (among other findings) "if it consists in whole or in part of any filthy, putrid, or decomposed substance; if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 USC 351(a)

[19] 21 USC 352(n) [FDCA Section 502(n)] provides that a prescription drug shall be deemed to be misbranded... "unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e)57, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e)57, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness..."

[20] 21 USC 352(r) [FDCA Section 502(r)] provides that a device shall be deemed to be misbranded "...unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device..."

in an application [for approval] even if such summary may indirectly reveal the existence of such application." 21 USC 360bbb-3(h)(1)

Congress affirmed the applicability of 18 USC 1905, prohibiting public disclosure by US government officers and employees of confidential information, and affirmed the applicability of an exemption provision of the Freedom of Information Act allowing federal officers to withhold "trade secrets and commercial or financial information obtained from a person and privileged or confidential" from public disclosure under 5 USC 552(b)(4). 21 USC 360bbb-3(h)(2)

Congress provided that "actions under the authority of this section by the [HHS] Secretary or by the Secretary of Defense are committed to agency discretion" and therefore beyond the reach of judicial review under the Administrative Procedure Act at 5 USC 701. 21 USC 360bbb-3(i)

Congress provided, as "rules of construction," that nothing in the "emergency use" authorization law "impairs the authority of the President as Commander in Chief of the Armed Forces" under the US Constitution;...impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law, or ...impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in [the Strategic National Stockpile])." 21 USC 360bbb-3(j)

Congress provided a categorical exclusion, for "emergency use" of products, from laws governing conduct of clinical investigations, by providing: "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" FDCA 505(i), FDCA 520(g), any other FDCA provision or PHSA 351. 21 USC 360bbb-3(k)

Congress provided for persons asked to carry out activities under the "emergency use" authorization law to have the "option to carry out authorized activities," but withheld from the HHS Secretary "any authority to require any person to carry out any activity that becomes lawful pursuant to an [emergency use] authorization." Congress provided that "no person is required to inform the Secretary that the person will not be carrying out such activity," with one exception. Congress required "a manufacturer of a sole-source unapproved product authorized for emergency use" to report to the HHS Secretary "if such manufacturer does not intend to carry out any activity under the authorization." 21 USC 360bbb-3(l)

Congress provided that the "option to carry out authorized activities" would only have legal effect on a person who carries out an activity for which an authorization under this section is issued, and provided that "nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an [emergency use] authorization." 21 USC 360bbb-3(l)

2003 - 10 USC 2370 et seq
Title 10: Armed Forces
Research and Development
Medical countermeasures against biowarfare threats

In 2003 (PL 108-136), Congress added a statutory note to 10 USC 2370a, which Congress had added in 1993 (PL 103-160) as 'Medical countermeasures against biowarfare threats: allocation of funding between near-term and other threats' and amended in 2001 (PL 107-107) by adding a statutory note on 'Acceleration of research, development, and production of medical countermeasures for defense against biological warfare agents.'

In 2003 (PL 108-236), Congress authorized and directed the Secretary of Defense to carry out a program for research and development of "defense biomedical countermeasures."

Congress authorized and directed the Secretary of Defense to "carry out a program to accelerate the research, development and procurement of biomedical countermeasures, including but not limited to therapeutics and vaccines, for the protection of the Armed Forces from attack by one or more biological, chemical, radiological, or nuclear agents." 10 USC 2370a Note, PL 108-236, Section 1601(a)

Congress authorized and directed the Defense Secretary to "enter into interagency agreements and other collaborative undertakings with other Federal agencies," and to ensure that DoD activities are coordinated with HHS and DHS activities, "through regular, structured, and close consultation" with the HHS Secretary and DHS Secretary. 10 USC 2370a Note, PL 108-236, Section 1601(b)

Congress authorized the Defense Secretary to use "expedited procurement authority" to procure property or services for use "performing, administering, or supporting biomedical counter-measures research and development," citing "streamlined acquisition procedures and other expedited procurement procedures" as authorized by [41 USC 428a, Special Emergency Procurement Authority, added to the Office of Federal Procurement Policy Act through PL 108-136, to be used "in support of a contingency operation; or to facilitate the defense against or recovery from nuclear, biological, chemical, or radiological attack"]; 10 USC 2371 [Research projects: transactions other than contracts and grants, added in 1989, PL 101-189, amended thereafter and renumbered to 10 USC 4021 et seq in 2021, PL 117-81] and a statutory note added to 10 USC 2371 in 1993, PL 103-160, authorizing the Director of the Advanced Research Projects Agency [ARPA, also known as Defense Advanced Research Projects Agency or DARPA] to "carry out prototype projects that are directly relevant to weapons or weapon systems proposed to be acquired or developed by the Department of Defense." 10 USC 2370a Note, PL 108-236, Section 1601(c)

Congress authorized the Defense Secretary to use expedited procurement procedures to "acquire, lease, construct or improve laboratories [and] research facilities," if the Secretary "determines that it is necessary" to carry out the biomedical countermeasures research and development program. 10 USC 2370a Note, PL 108-236, Section 1601(d)(1)

Congress directed the Defense Secretary to use "existing construction authorities," unless he "determines" using such construction authorities would prevent DoD from meeting a specific facility requirement, in which case he was directed to submit notification to congressional defense committees, and the facility project "may be carried out...after the end of the 21-day period beginning on the date the notification is received by the congressional defense committees," or the Defense Secretary may obligate funds first and notify the congressional committees within seven days after obligation, if he "determines that the facility is vital to national security or to the protection of health, safety, or the quality of the environment; and the requirement for the facility is so urgent that the advance notification...would threaten the life, health, or safety of personnel, or would otherwise jeopardize national security." 10 USC 2370a Note, PL 108-236, Section 1601(d)(2) through (4).

Congress authorized the Defense Secretary to use "personal services contracts" [under 10 USC 1091] to carry out health care responsibilities in DoD medical treatment facilities, provided that "the services to be procured are urgent or unique; and it would not be practicable for the DoD to obtain such services by other measures." 10 USC 2370a Note, PL 108-236, Section 1601(e)

Congress authorized the Defense Secretary to "appoint highly qualified experts, including scientific and technical personnel, to carry out research and development" under streamlined personnel authority provisions "upon a determination by the Secretary that use of such authority is necessary to accelerate the research and development under the program." 10 USC 2370a Note, PL 108-236, Section 1601(f)

Congress repealed 10 USC 2370a in 2004 (PL 108-375).

2003 - 10 USC 2302, note
Title 10: Armed Forces
Procurement, Procurement of Defense Biomedical Countermeasures

In 2003 (PL 108-136), Congress added a statutory note to 10 USC 2302 (a provision for military procurement definitions), titled "Procurement of Defense Biomedical Countermeasures."

Congress provided for "determination of material threats," authorizing and directing the Secretary of Defense to assess current and emerging threats of use of biological, chemical, radiological, and nuclear agents; to identify, on the basis of such assessment, those agents that present a material risk of use against the Armed Forces; to assess the potential consequences to the health of members of the Armed forces of use of the agents identified; and to identify...those agents for which countermeasures are necessary to protect the health of members of the Armed Forces. 10 USC 2302 Note, PL 108-136, Section 1602(a)

Congress directed the Defense Secretary to assess the availability and appropriateness of specific countermeasures to address specific threats. 10 USC 2302 Note, PL 108-136, Section 1602(b)

Congress directed the Defense Secretary to "identify specific countermeasures that the Secretary determines to be appropriate for procurement" for the DoD stockpile of biomedical countermeasures. 10 USC 2302 Note, PL 108-0136, Section 1602(c)(1)

Congress directed the Defense Secretary to not identify a specific countermeasure unless he determines that "the countermeasure is a qualified countermeasure;" and "it is reasonable to expect that producing and delivering, within 5 years, the quantity of that countermeasure required to meet the needs of the Department (as determined by the Secretary) is feasible." 10 USC 2302 Note, PL 108-136, Section 1602(c)(2)

Congress directed the Defense Secretary to carry out his activities "in regular, structured, and close consultation and coordination with" the DHS Secretary and HHS Secretary, and to enter into interagency agreements with DHS and HHS "to provide for acquisition" by DoD, of biomedical countermeasures procured for the Strategic National Stockpile by HHS, for use by the Armed Forces. Congress authorized the Defense Secretary to transfer funds to HHS as necessary, and authorized the HHS Secretary to use the funds to procure countermeasures for use by the Armed Forces, or to replenish the stockpile. 10 USC 2302 Note, PL 108-136, Section 1602(d)

Congress defined the term 'biomedical countermeasure' to mean a drug [FDCA 201(g)(1); 21 U.S.C. 321(g)(1)], device [FDCA 201(h); 21 U.S.C. 321(h)], or biological product [PHSA 351(i); 42 U.S.C. 262(i)] that is "used to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a military health emergency affecting the Armed Forces; or used to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug or biological product" that is so used. 10 USC 2302 Note, PL 108-136, Section 1602(e)(2)

Congress defined the term 'qualified countermeasure' to mean a biomedical countermeasure "approved" under FDCA 505(a) [21 U.S.C. 355, *New drugs*] or "licensed" under PHSA 351 [42 USC 262, *Regulation of biological products*], "approved" under FDCA 515 [21 USC 360e, *Premarket approval of devices*] or "cleared" under FDCA 510(k) [21 USC 360(k), *Report preceding introduction of devices into interstate commerce*] "for use as such a countermeasure to a biological, chemical, radiological, or nuclear agent identified as a material threat under the first paragraph" with respect to which the HHS Secretary "makes a determination that sufficient and satisfactory clinical experience or research data (including data, if available, from preclinical and clinical trials) exists to support a reasonable conclusion that the product will qualify for such approval or licensing for use as such a countermeasure." 10 USC 2302 Note, PL 108-136, Section 1602(e)(1)

Congress authorized "such sums as may be necessary" for procurement costs for fiscal year 2004 and each year thereafter. 10 USC 2302 Note, PL 108-136, Section 1602(f)

2003 - 10 USC 1107a
Title 10: Armed Forces
Medical and dental care
Emergency use products

In 2003 (PL 108-136), Congress added a provision authorizing the President to waive the condition that the HHS Secretary "ensure" members of the armed forces be informed of "an option to accept or refuse administration" of an emergency use authorization product, as required by the EUA law at 21 USC 360bbb-3(e), when administering EUA products.

The authorization for the President to waive the "option to accept or refuse administration" of "unapproved products" and "unapproved uses of approved products" was codified at 10 USC 1107a.

Congress authorized only the President to waive the condition, and "only if the President determines, in writing, that complying with such requirement is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security." 10 USC 1107a(a)

Congress directed that if the President waived the condition, and if the Defense Secretary, in consultation with the HHS Secretary, "makes a determination that it is not feasible based on time limitations" to give the recipients of the product information otherwise required to be given (that the HHS Secretary has "authorized the emergency use of the product" and "of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown") before administration of the product, then the information should be provided to the member of the armed forces or next-of-kin, in the case of the death, to whom the product was administered, as soon as possible, but not later than 30 days, after such administration.

Congress directed that the authority to withhold information until after administration because "not feasible based on time limitations" could not be delegated by the Defense Secretary, and that information about administration of the product was to be recorded in the medical records of product recipients. 10 USC 1107a(b).

In 1997 (PL 105-85, summarized above) Congress enacted 10 USC 1107(a) through (f), directing the Defense Secretary to provide notice of use of investigational new drugs or drugs unapproved for their applied use to members of the armed forces, written and before administration "if practicable" or unwritten and within 30 days after administration if not.]

In 2003 (PL 108-136), Congress provided that the provisions of 10 USC 1107(a) through (f), would be inapplicable for administration of EUA products authorized by the HHS Secretary based on a determination by the Defense Secretary that "there is a military emergency, or a significant potential for a military emergency, involving a heightened risk...of attack with a specified biological, chemical, radiological or nuclear agent or agents." 10 USC 1107a(c)

2004 - 21 USC 360bbb-3 [FDCA 564]
Title 21: Food and Drugs
Authorization for medical products for use in emergencies

In 2004 (PL 108-276, Project Bioshield Act), Congress amended provisions for "authorization for medical products for use in emergencies" which Congress had enacted in 2003 (PL 108-136) and which had been codified at 21 USC 360bbb-3.

When first enacted in 2003 (PL 108-236), the law authorized the HHS Secretary to declare an emergency justifying the authorization of emergency use of products "on the basis of a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents." This predicate was codified at 21 USC 360bbb-3(b)(1) in 2003 and renumbered to 21 USC 360bbb-3(b)(1)(B) as of 2004.

In 2004 (PL 108-276), Congress provided two additional predicates authorizing the [HHS] Secretary to "declare an emergency justifying the authorization" for emergency use of products.

In 2004, Congress authorized the HHS Secretary to declare an emergency on the basis of "a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents" 21 USC 360bbb-3(b)(1)(A) as of 2004.

In 2004, Congress authorized the HHS Secretary to declare an emergency on the basis of his own determination: "a determination by the [HHS] Secretary of a public health emergency under [PHSA] section 319 [42 USC 247d] that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents." 21 USC 360bbb-3(b)(1)(C) as of 2004.

In 2004, Congress amended the "termination of declaration" provision, such that the HHS Secretary's declaration (of an emergency justifying authorization for emergency use of products) terminates upon the earlier of a determination by the HHS Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances (military emergency, domestic emergency, public health emergency, or significant potential for such emergencies) have "ceased to exist" or the expiration of the one-year period from the date on which the HHS declaration was made. 21 USC 360bbb-3(b)(2)(A) as of 2004

Congress maintained the HHS Secretary's authority to renew any such declaration in his sole discretion. 21 USC 360bbb-3(b)(2)(B)

In 2004, Congress amended the "actions committed to agency discretion" provision precluding judicial review, to cover the actions of the HHS Secretary, Secretary of Defense (covered by the 2003 version) and cover the actions of the Secretary of Homeland Security. 21 USC 360bbb-3(i) as of 2004

Since 2004 - Amendments to 21 USC 360bbb et seq

Congress has amended and expanded the provisions of 21 USC 360bbb many times since 2004.

Two such amendments are summarized below.

In 2013 (PL 113-5) Congress added to 360bbb-3, another predicate authorizing the HHS Secretary to issue emergency use authorization declarations upon "the identification of a material threat pursuant to [PHSA] section 319F–2 [42 U.S.C. 247d–6b]...sufficient to affect national security or the health and security of United States citizens living abroad." 21 USC 360bbb-3(b)(1)(D) as of 2013.

In 2017 (PL 115-92), Congress added provisions for "expedited development and review of medical products for emergency uses" codified at 21 USC 360bbb-3c.

Congress authorized the Secretary of Defense to request that the HHS Secretary, acting through the FDA Commissioner, take actions to expedite the development of a medical product, review of investigational new drug applications, review of investigational device exemptions, and review of applications for approval and clearance of medical products, including applications for licensing of vaccines or blood as biological products, or applications for review of regenerative medicine advanced therapy products, "if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk." 21 USC 360bbb-3c(1).

Congress directed the HHS Secretary and FDA Commissioner to respond to a request by the Defense Secretary for expedited development and review, by holding meetings with the sponsor and the review team throughout the development of the medical product; providing timely advice to, and interactive communication with, the sponsor regarding the development of the medical product to ensure that the development program to gather the nonclinical and clinical data necessary for approval or clearance is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; applying any applicable FDA program intended to expedite the development and review of a medical product; and in appropriate circumstances, permitting expanded access to the medical product during the investigational phase, in accordance with applicable requirements of the Food and Drug Administration. 21 USC 360bbb-3c(2)

To facilitate enhanced collaboration and communication with respect to the most current priorities of the Department of Defense, Congress directed the FDA to meet with the DoD and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority [BARDA] on a semi-annual basis for the purposes of conducting a full

review of the relevant products in the DoD portfolio; and directed the Director of the Center for Biologics Evaluation and Research [FDA-CBER] to meet quarterly with the DoD to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the DoD (which may include freeze dried plasma products and platelet alternatives), unless the Secretary of Defense determines that any such meetings are not necessary. 21 USC 360bbb-3c(3)

2004 - 42 USC 247d-6
Public Health and Welfare
Public health emergencies
Public health countermeasures to a bioterrorist attack

2004 - 42 USC 300hh
Public Health and Welfare
Strategic National Stockpile

In 2004 (PL 108-276, Project Bioshield Act), Congress amended 42 USC 247d-6 [PHSA 319F] to expand the category of products subject to "priority" designation, and to add research and development [42 USC 247d-6a/PHSA 319F-1], procurement [42 USC 247d-6b/PHSA 319F-2] and reporting provisions.

This summary does not include detailed information about the procurement methods authorized by the act, but does summarize provisions defining terms and authorizing Presidents and Cabinet secretaries to invoke the procurement authorities.

42 USC 247d-6(a) - Working Group on Bioterrorism and Other Public Health Emergencies

In 2004 (PL 108-276), Congress added the Secretary of the Department of Homeland Security, as a member of the Working Group on Bioterrorism and Other Public Health Emergencies established in 2002 (PL 107-188).

42 USC 247d-6(h) - Accelerated research and development on priority pathogens and countermeasures

In 2002 (PL 107-188), Congress had added provisions directing the HHS Secretary to conduct and supervise research on "priority pathogens" and "countermeasures." Congress, as of 2002, defined "priority countermeasure" to mean two types of products:

> (A) a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to [42 USC 262a/PHSA 351A], or harm from any other agent that may cause a public health emergency; or
>
> (B) a priority to diagnose conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority... 42 USC 247d-6(h)(4)(A) and (B) as of 2002.

In 2004 (PL 108-276), Congress struck "to diagnose conditions" from subsection (B) and replaced the phrase with "to treat, identify or prevent conditions," so that the section authorized priority designation for drugs, biological products, devices, etc., to "treat, identify and prevent conditions...that may be caused by administering priority countermeasures."

42 USC 247d-6a [PHSA 319F-1] - Authority for use of certain procedures regarding qualified countermeasure research and development activities

In 2004 (PL 108-276), Congress authorized the HHS Secretary to consult with the NIH Director and conduct "qualified countermeasures" research and development activities as part of the NIH National Institute of Allergy and Infectious Diseases (NIAID) conduct of "research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases" under 42 USC 285f [PHSA 446]. 42 USC 247d-6(a)(1)

Congress defined 'qualified countermeasure' to mean

> a drug[21]...biological product[22]...or device[23] that the [HHS] Secretary determines to be a priority (consistent with sections 302(2)[24] and 304(a)[25] of the Homeland Security Act of 2002) to
>
> (A) treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or
>
> (B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A). 42 USC 247d-6a(a)(2)

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[21] *Drug*, as defined by FDCA 201(g)(1) [21 U.S.C. 321(g)(1)] "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)..."

[22] *Biological product*, as defined by PHSA 351(i) [42 U.S.C. 262(i)] " a virus, therapeutic serum, toxin, anti- toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic com- pound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."

[23] *Device*, as defined by FDCA 201(h) [21 U.S.C. 321(h)] - "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." [Exceptions distinguish this use from use of the word 'device' to denote labeling components similar to 'statements," 'designs' and 'words.']

[24] Homeland Security Act of 2002, Sec. 302 [6 USC 181] - Congress established Directorate of Science and Technology within DHS, authorized to develop national policy and strategic plans for identifying and developing countermeasures to chemical, biological, radiological, nuclear, and other emerging terrorist threats.

[25] Homeland Security Act of 2004, Sec. 304 [6 USC 184] - Congress authorized and directed the HHS Secretary to collaborate with the DHS Secretary to "set priorities...and policies and develop a coordinated strategy "with respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats."

Congress authorized the HHS Secretary to enter into interagency agreements with other federal agencies, and directed that biocontainment laboratories and related specialized research facilities covered by such agreements be "available as needed...to respond to public health emergencies affecting national security" whenever the Secretary determines such facility use is "necessary for the purpose of performing, administering, or sup- porting qualified countermeasure research and development." 42 USC 247d-6a(a)(3) and (4).

Congress authorized the HHS Secretary to use expedited procurement authority, including an increased simplified acquisition threshold for procurement of property or services "for use (as determined by the Secretary) in performing, administering or supporting qualified countermeasure research or development activities that the Secretary determines necessary;" authority to limit competition whenever the Secretary "determines that the mission of the BioShield Program...would be seriously impaired" without such limits on competition; authority to expedite peer review; authority to "obtain by...personal services contracts...the services of experts or consultants who have scientific or other professional qualifications;" authority to deem such consultants to be an HHS employee for purposes of the Federal Tort Claims Act governing claims for "money damages for personal injury, including death, resulting from performance of functions under such contract;" deemed such HHS determinations to be "final and binding on the [HHS] Secretary and the Attorney General and other parties to any civil action or proceeding," and authorized the US government to recover, from contractors, portions of damages paid as a result of a contractor's "failure to carry out any obligation or responsibility...or from any grossly negligent or reckless conduct or intentional or willful misconduct." 42 USC 247d-6a(b) through (e)

Congress committed all actions by the HHS Secretary to expedite qualified countermeasure research and development to agency discretion, thus precluding judicial review. 42 USC 247d-6a(f)

42 USC 287 [PHSA 481] - National Center for Research Resources

Congress made technical amendments to 42 USC 287 [PHSA 481] Division of Research Resources]. Congress established the Division of Research Resources within NIH in 1985 (PL 99-158), "to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources." Congress renamed the division as National Center for Research Resources in 1993 (PL 103-43), and authorized the NIH Director, acting through the Director of the Center, "to make grants to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, under a program titled Biomedical and behavioral research facilities."

In 2004 (PL 108-276), Congress added authority for the Director of the National Institute of Allergy and Infectious Diseases [NIAID] to review grant applications and waive otherwise applicable limitations.

42 USC 247d-6b [PHSA 319F-2] - Strategic National Stockpile

In 2004 (PL 108-276), Congress moved provisions governing the Strategic National Stockpile, within the US Code, from 42 USC 300hh-12 (codification under Public Health Security and Bioterrorism Preparedness and Response Act of 2002, PL 107-188) to 42 USC 247d-6b, and designated the provision as Section 319F-2 of the Public Health Service Act.

In 2004 (PL 108-276), Congress directed the HHS Secretary, in coordination with the DHS Secretary, to "maintain stockpiles...of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency." 42 USC 247d-6b(a)(1)

Congress directed the HHS Secretary to consult with the Working Group on Bioterrorism and Other Public Health Emergencies; to manage the stockpile inventory and ensure its physical security; to review the contents to ensure that "emerging threats, advanced technologies, and new countermeasures are adequately considered;" to deploy the stockpile "as required by the Secretary of Homeland Security to respond to an actual or potential emergency;" to deploy the stockpile at his own [HHS] "discretion...to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety." 42 USC 247d-6b(a)(2)

Congress directed the HHS Secretary to award contracts and cooperative agreements to ensure that the stockpile includes "an amount of vaccine against smallpox...sufficient to meet the health security needs of the United States," as determined by the HHS Secretary. 42 USC 247d-6b(b)

Congress provided the HHS Secretary with "additional authority regarding procurement of certain biomedical countermeasures" and set up a "special reserve fund" to be used for procurement. 42 USC 247d-6b(c)

Congress defined the term 'security countermeasure' to mean "a drug,[26]...biological product[27]...or

[26] *Drug*, as defined by FDCA 201(g)(1) [21 U.S.C. 321(g)(1)] "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)..."

[27] *Biological product*, as defined by PHSA 351(i) [42 U.S.C. 262(i)] - " a virus, therapeutic serum, toxin, anti- toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic com- pound), applicable to the prevention, treatment, or cure of a disease or condition of human beings"

device[28] that the [HHS] Secretary determines to be a priority [consistent with HSA 302(2)[29] and HSA 304(a)[30]] to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat[31]...or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; [which product] the Secretary determines...to be a necessary countermeasure[32]; and is approved or cleared under [FDCA 505/21 USC 255 et seq, *New drugs*] or licensed under [PHSA 351/42 USC 262, *Regulation of biological products*]; or is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination[33]...; or is authorized for emergency use under [FDCA 564/21 USC 360bbb-3, *Authorization for medical products for use in emergencies*]. 42 USC 247d-6b(c)(1)(B)

Congress authorized and directed the DHS Secretary, on an ongoing basis, in consultation with the HHS Secretary and other agency heads as appropriate, to "assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and determine which of such agents present a material threat against the United States population sufficient to affect national security." 42 USC 247d-6b(c)(2)(A)

Congress authorized and directed the HHS Secretary, on an ongoing basis, to "assess the potential public health consequences for the United States population of exposure to agents identified [by the DHS Secretary as material threats]; and determine, on the basis of such assessment, the agents identified [by the DHS Secretary as material threats] for which countermeasures are necessary to protect the public health." 42 USC 247d-6b(c)(2)(B)

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[28] *Device*, as defined by FDCA 201(h) [21 U.S.C. 321(h)] - "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." [Exceptions distinguish this use from use of the word 'device' to denote labeling components similar to 'statements," 'designs' and 'words,']

[29] Homeland Security Act of 2002, Sec. 302 [6 USC 181] - Congress established Directorate of Science and Technology within DHS, authorized to develop national policy and strategic plans for identifying and developing countermeasures to chemical, biological, radiological, nuclear, and other emerging terrorist threats.

[30] Homeland Security Act of 2004, Sec. 304 [6 USC 184] - Congress authorized and directed the HHS Secretary to collaborate with the DHS Secretary to "set priorities...and policies and develop a coordinated strategy "with respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats."

[31] *Material threat*, as defined under PHSA 319F-2(2)(A)(ii)/42 USC 247d-6b(2)(A)(ii)

[32] *Necessary countermeasure*, as defined under PHSA 319F-2(2)(B)(ii)/42 USC 247d-6b(2)(B)(ii)

[33] *Determination of Countermeasures Appropriate for Funding from Special Reserve Fund,* as defined under PHSA 319F-2(5)/42 USC 247d-6b(5)

Congress directed the HHS Secretary and DHS Secretary to notify designated congressional committees that a "determination of material threat" and/or a "determination of necessary countermeasure" has been made. 42 USC 247d-6b(c)(2)(C)

Congress directed the DHS Secretary, in making "material threat determinations" to use all relevant information relating to "current and emerging threats of chemical, biological, radiological, and nuclear agents," collected by the DHS Directorate for Information Analysis and Infrastructure established in 2002 (PL 107-296) and codified at 6 USC 122. 42 USC 247d-6b(c)(2)(D)

Congress directed the DHS Secretary and HHS Secretary, on an ongoing basis, to assess "the availability and appropriateness of specific countermeasures to address specific [determined material] threats.

Congress authorized the DHS Secretary and HHS Secretary to submit proposals to the President to issue calls for development of countermeasures determined to be appropriate, but currently unavailable, and to make commitments for procurement, and to recommend use of the "special reserve fund" to procure the countermeasures. Congress directed the DHS and HHS secretaries, "to the extent practicable," to include in the proposals, countermeasure specifications, including "estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of the dosage form; necessary measures of minimum safety and effectiveness; estimated price [per dose]; and other information that may be necessary to encourage and facilitate research, development and manufacture of the countermeasure..." Congress authorized the DHS and HHS secretaries to inform potential vendors if a proposal made to the President has been approved by the President. 42 USC 247d-6b(c)(4)

Congress authorized the HHS Secretary, in consultation with DHS Secretary, to "identify specific security countermeasures that the Secretary determines...to be appropriate for inclusion in the [Strategic National] stockpile...pursuant to" procurements using the Special Reserve Fund. Congress directed the HHS Secretary to include, in a determination of "appropriate countermeasures" the quantities needed, the feasibility of production and deliver within eight years of such quantities, and "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-6b(c)(5)

Congress established procedures for recommendations to be made to the President; for Presidential approval; for notice to congressional committees; for HHS Secretary determinations as to subsequent specific countermeasures, and for such determinations to be "committed to agency discretion," precluding judicial review. 42 USC 247d-6b(c)(6)

Congress established procurement procedures including interagency agreements; negotiation of terms (quantities, production schedules, prices); payment conditioned on delivery unless advance payments determined necessary by HHS Secretary; discounted prices per unit of a product "that is not licensed, cleared or approved;" additional payments per unit "if the product becomes so licensed, cleared or approved;" contract duration; storage of product by vendor; contract requirements that vendors "seek product approval, clearance or licensing from the Secretary" and

authorization for HHS Secretary to waive such requirements "on request of the vendor or on the initiative of the Secretary;" availability of simplified acquisition procedures; authority to limit competition if the HHS Secretary "determines that the mission of the BioShield Program...would be seriously impaired" without such limits on competition; unreviewable authority for the HHS Secretary to award "premium" payments for vendors who prioritize "production and delivery" of an "increment" of the total quantity required; and "unreviewable" authority for HHS Secretary to extend closing dates for receipt of proposals ("committed to agency discretion"). 42 USC 247d-6b(7).

Congress defined Special Reserve Fund with reference to the 2002 Homeland Security Act, Sec. 510, as enacted through the same 2004 law (PL 108-276). 42 USC 247d-6b(10)

Congress prohibited Federal agencies from disclosing (under FOIA), any information identifying the location at which materials in the Strategic National Stockpile are stored. 42 USC 247d-6b(d)

Congress defined the term 'stockpile' as "a physical accumulation (at one or more locations) of the supplies [drugs, biological products and devices] or a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies." 42 USC 247d-6b(e)

Restating text from the 2002 Public Health Security and Bioterrorism Response and Preparedness Act of 2002 (PL 107-188), Congress authorized appropriation of $640 million for maintenance of the Strategic National Stockpile for FY2002, and "such sums as may be necessary" FY2003-2006, in addition to amounts in the special reserve fund established under the Homeland Security Act and codified at 6 USC 320 and Congress authorized appropriation of $509 million for "smallpox vaccine development" for FY2002, and "such sums as may be necessary" for FY2003-2006. 42 USC 247d-6b(f)

42 USC 247-6b, Note - Stockpile functions transferred

Congress transferred, from the DHS Secretary to the HHS Secretary, "the functions, personnel, assets, unexpended balances, and liabilities of the Strategic National Stockpile, including the functions of the Secretary of Homeland Security relating thereto," except for functions explicitly assigned to the DHS Security under the Project Bioshield Act.

42 USC 247d-6c - Reports regarding authorities under Project Bioshield Act

In 2004 (PL 108-276), Congress directed the HHS Secretary to submit annual reports on "particular exercises of authority," including use of increased simplified acquisition threshold, procedures other than full and open competition, expedited peer review procedures and premium provisions in multiple-award contracts, for research and development projects and for procurement.

Congress directed the HHS Secretary to submit annual reports on emergency uses of certain drugs and devices, declarations of an emergency, and conditions on authorization under 21 USC 360bbb-3.

Congress directed the HHS Secretary to submit an annual report summarizing "the particular actions that were taken under the authorities...including...the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used; the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities; the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and (for President-approved procurements) whether a contract was entered into within one year after such approval by the President.

Congress directed the HHS Secretary to submit annual reports summarizing use of increased micropurchase threshold, authority for personal services contracts and streamlined personnel authority.

Congress directed the HHS Secretary and DHS to report, within one year after enactment of the Project Bioshield Act (PL 108-276, July 21, 2004), to congressional committees "any potential barriers to the procurement of security countermeasures that have not been addressed by this Act."

Congress directed the Comptroller General, four years after date of enactment, to initiate a GAO study reviewing the HHS Secretary's use of the authorities granted for simplified acquisition procedures, procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel authority, and the purchase of security countermeasures under the special reserve fund; and to make recommendations to improve the use or effectiveness of such authorities; to review use of the authority "to authorize an emergency use of a biomedical countermeasure, including the means by which the Secretary determines whether and under what conditions any such authorizations should be granted and the benefits and adverse impacts, if any, resulting from the use of such authority;" to make recommendations to improve the use of such authority and to enhance protection of the public health; to identify any purchases or procurements that would not have been made or would have been delayed without the granted authorities; to determine whether and to what extent activities undertaken pursuant to the biomedical countermeasure research and development authorities have enhanced the development of biomedical countermeasures affecting national security; and to make recommendations to improve the ability of the Secretary to carry out these activities in the future.

Congress directed the GAO review to provide assessments of the current availability of biomedical countermeasures to address threats identified by the DHS Secretary; the extent to which Project Bioshield programs will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and threats to national security that are posed by technology that will enable [between 2004 and 2014] "the development of antibiotic resistant, mutated, or bioengineered strains of biological agents;" and to recommend short-term and long-term governmental strategies for addressing such threats, including recommendations for Federal

policies regarding research priorities, the development of countermeasures, and investments in technology.

Congress directed the HHS Secretary and DHS Secretary (within four months of Project Bioshield Act enactment), to report to the designated congressional committees "whether there is a lack of adequate large-scale bio- containment facilities necessary for the testing of security counter- measures in accordance with Food and Drug Administration requirements."

Congress designated congressional committees to whom reports were to be submitted as House Committee on Energy and Commerce, Committee on Appropriations, Committee on Government Reform, and Select Committee on Homeland Security (or any successor to the Select Committee) and in the Senate, "the appropriate committees."

Discussion

Congress did not require collection or presentation of physico-chemical evidence in support of unilateral determinations, by the DHS Secretary and HHS Secretary, as to "material threats," "necessary countermeasures" or "countermeasures appropriate for funding from Special Reserve Fund."

Congress did not establish standards of evidence, and did not provide procedures for evidentiary review.

2004 - 6 USC 320
Title 6: Homeland Security
Procurement of Security Countermeasures for Strategic National Stockpile
[Special Reserve Fund]

In 2004 (PL 108-276), Congress added a provision to the Homeland Security Act of 2002 (PL 107-296), establishing a "special reserve fund" for biodefense procurements.

Mirroring text from 2003 (PL 108-90), Congress authorized appropriation of $5.593 billion for "the procurement of security countermeasures," for FY2004 through September 2013, including up to $890 million to be obligated during fiscal year 2004 and up to $3.418 billion to be obligated during FY2004-2008. 6 USC 320(a)

Congress defined the term "special reserve fund" to mean "the 'Biodefense Countermeasures' appropriations account or any other appropriation" under 6 USC 320(a). 6 USC 320(b)

Congress provided for Presidential approval, for use of the special reserve fund, of proposals submitted by the HHS Secretary and DHS Secretary under 42 USC 247d-6b. 6 USC 320(c)

Congress authorized "such sums as may be necessary" for FY2004-2006, for hiring analysts to work in the DHS Directorate for Information Analysis and Infrastructure Protection, "responsible for chemical, biological, radiological, and nuclear threat assessment (including but not limited to analysis of chemical, biological, radiological, and nuclear agents, the means by which such agents could be weaponized or used in a terrorist attack, and the capabilities, plans, and intentions of terrorists and other non-state actors who may have or acquire such agents)." 6 USC 320(d)(1)

Congress authorized funds for the DHS Secretary to acquire and deploy "secure facilities (including information technology and physical infrastructure, whether mobile and temporary, or permanent)" to enable the DHS Secretary to receive "classified information and products to which the Under Secretary for Information Analysis and Infrastructure is entitled" 6 USC 320(d)(2)

2004 - 10 USC 2370a
Title 10: Armed Forces
Biological defense research program
Medical countermeasures against biowarfare threats

In 2004 (PL 108-375) Congress repealed 10 USC 2370a, providing for research and development of medical countermeasures, which Congress had enacted in 1993 (PL 103-160) as 'Medical countermeasures against biowarfare threats: allocation of funding between near-term and other threats'; amended in 2001 (PL 107-107) by adding a statutory note on 'Acceleration of research, development, and production of medical countermeasures for defense against biological warfare agents;' and amended in 2003 (PL 108-236), to authorize and direct the Secretary of Defense to carry out a program for research and development of "defense biomedical countermeasures."

See also: biological defense research reporting requirement Congress established in 1990 at 10 USC 2370 (PL 101-510) and repealed in 1996 (PL 104-106).

Congress repealed 10 USC 2370a, because the core provisions had been moved to Title 42, Public Health and Welfare in 2002, when Congress established the "accelerated countermeasures research and development" program codified at 42 USC 247d-6d (2002, PL 107-188),

2004 - 10 USC 1107, 10 USC 1107a
Title 10: Armed Forces
Notice of use of investigational new drugs or drugs unapproved for their applied use; Emergency use products

10 USC 1107 - Notice of use of investigational new drugs or drugs unapproved for their applied use

In 1997 (PL 105-85, summarized above) Congress and President Clinton added 10 USC 1107, "Notice of use of investigational new drugs or drugs unapproved for their applied use," pertaining to use of unapproved drugs on military personnel.

In 1998 (PL 105-261, summarized above), Congress amended 10 USC 1107 to add a new subsection (f). Congress authorized the President to waive the requirement, under FDCA 505(i)(4) [21 USC 355(i)(4)], that members of the armed forces provide prior consent to receive investigational new drugs or drugs unapproved for their applied uses, "only if the President determines, in writing, that obtaining consent (A) is not feasible; (B) is contrary to the best interests of the member; or (C) is not in the interests of national security." 10 USC 1107(f)(1) as of 1998. Congress provided: "In making a determination to waive the prior consent requirement on a ground [that obtaining consent is not feasible or is contrary to the best interests of the member], the President shall apply the standards and criteria that are set forth in the relevant FDA regulations for a waiver of the prior consent requirement on that ground." 10 USC 1107(f)(2) as of 1998.

In 2004 (PL 108–375), Congress amended provisions of 10 USC 1107(f) and 10 USC 1107a.

Congress struck the phrase "obtaining consent (A) is not feasible; (B) is contrary to the best interests of the member; or (C)" from the paragraph (f)(1) list of grounds for Presidential waivers of prior consent requirements. After the amendment, the provision authorized the President to waive requirements for prior consent "only if the President determines, in writing, that obtaining consent is not in the interests of national security." 10 USC 1107(f)(1) as of 2004.

Congress struck the 1998 paragraph (f)(2) and inserted a new paragraph (f)(2):

> "The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which prior consent for administration of a particular drug is required by reason of a determination by the Secretary of Health and Human Services that such drug is subject to the investigational new drug requirements of section 505(i) of the Federal Food, Drug, and Cosmetic Act." 10 USC 1107(f)(2) as of 2004.

Discussion

Under 1938 FDCA 505(i) exemption provisions and 1962 (PL 87-781) amendments thereto, Congress authorized administration of investigational drugs without informed or prior consent where experts using such drugs "deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings," rendering consent to be not "required."

2004 - 10 USC 1107a - Emergency use products

In 2003 (PL 108-136, summarized above) Congress added 10 USC 1107a, a provision authorizing the President to waive the condition that the HHS Secretary "ensure" members of the armed forces be informed of "an option to accept or refuse administration" of products authorized for emergency use under 21 USC 360bbb-3 [FDCA 564].

> 10 USC 1107a(a) Waiver by the President—
>
> (1) In the case of the administration of a product authorized for emergency use under [21 USC 360bbb-3] to members of the armed forces, the condition described in [21 USC 360bbb-3(e)(1)(A)(ii)(III)[34] of such Act and required under 21 USC 360bbb-3(e)(1)(A)[35] or (2)(A)[36]] designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security. 10 USC 1107a(a)(1) as of 2003

In 2004 (PL 108-375), Congress redesignated the subparagraph as (a)(1)(A) and struck the phrase "is not feasible, is contrary to the best interests of the members affected, or" from the paragraph, leaving the grounds for Presidential waiver as "is not in the interests of national security." 10 USC 1107a(a)(1)(A) as of 2004

In 2004, Congress added a new subparagraph (a)(1)(B):

> (B) The waiver authority provided in subparagraph (A) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under [FDCA] 564 [21 USC 360bbb-3]. 10 USC 1107a(a)(1)(B) as of 2004

Since 2004, 10 USC 1107a has been amended. In 2006 (PL 109-364), Congress redesignated (renumbered) the subparagraphs. In 2017 (PL 115-91), Congress added a subparagraph (d), pertaining to "additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war," and repealed subparagraph (d) the same day (PL 115-92), when adding a provision for "expedited development and review of medical products for emergency uses" codified at 21 USC 360bbb-3c.

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[34] 21 USC 360bbb-3(e)(1)(A)(ii)(III) Conditions of Authorization, Unapproved product, Required Conditions, With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the circumstances of the emergency, shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following...(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed— (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

[35] 21 USC 360bbb-3(e)(1)(A) - Conditions of authorization, unapproved product, required conditions

[36] 21 USC 360bbb-3(e)(2)(A) - Conditions of authorization, unapproved use of an approved product, required conditions

2004 - 18 USC 2332a et seq
Title 18: Crimes and Criminal Procedure
Terrorism, Use of weapons of mass destruction

In 1994 (PL 103-322, summarized above), Congress and President Clinton added a "weapon of mass destruction" section to the federal law on terrorism (18 USC 2331 et seq) establishing as a crime, the acts of "a person who uses, threatens, or attempts or conspires to use, a weapon of mass destruction" against US nationals abroad and/or against persons or property within the United States; through or affecting interstate or foreign commerce. 18 USC 2332a(a).

In 1996 (PL 104-132, summarized above), Congress and President Clinton amended the law criminalizing use of weapons of mass destruction.

In 1998 (PL 105-277, summarized above), Congress repealed 18 USC 2332c, the previous law providing criminal penalties for use of chemical weapons of mass destruction which had been added in 1996 (PL 104-132), because it had been replaced by 18 USC 229 et seq. Congress also revised the heading for 18 USC 2332a from "use of weapons of mass destruction" to "use of certain weapons of mass destruction," and added the phrase "other than a chemical weapon as that term is defined in section 229F" after the phrase "weapon of mass destruction."

In 2004 (PL 108-458), Congress struck the word "certain" and the phrase "other than a chemical weapons as that term is defined in section 229F" to restore the applicability of 18 USC 2332a to use of chemical weapons.

Congress amended the jurisdictional bases and scope provisions, providing that:

> (a) Offense Against a National of the United States or Within the United States.
>
> A person who, without lawful authority, uses, threatens, or attempts or conspires to use, a weapon of mass destruction-
>
> > (1) against a national of the United States while such national is outside of the United States;
> >
> > (2) against any person or property within the United States, and
> >
> > > (A) the mail or any facility of interstate or foreign commerce is used in furtherance of the offense;
> > >
> > > (B) such property is used in interstate or foreign commerce or in an activity that affects interstate or foreign commerce;
> > >
> > > (C) any perpetrator travels in or causes another to travel in interstate or foreign commerce in furtherance of the offense; or

(D) the offense, or the results of the offense, affect interstate or foreign commerce, or, in the case of a threat, attempt, or conspiracy, would have affected interstate or foreign commerce;

(3) against any property that is owned, leased or used by the United States or by any department or agency of the United States, whether the property is within or outside of the United States; or

(4) against any property within the United States that is owned, leased, or used by a foreign government,

shall be imprisoned for any term of years or for life, and if death results, shall be punished by death or imprisoned for any term of years or for life. 18 USC 2332a(a) as of 2004

Congress also added a definition for the term 'property,' to mean "includes all real and personal property." 18 USC 2332a(c)(3) as of 2004.

2004 - 18 USC 175b
Title 18: Crimes and Criminal Procedure
Biological weapons, possession by restricted person

In 1996 (PL 104-132, summarized above), Congress enacted, as a note under 42 USC 262, "Enhanced penalties and control of biological agents," introducing the "select agents" program.

In 2001 (PL 107-56) Congress further implemented the "select agents" program, codified at 18 USC 175b under the heading "possession by restricted persons."

In 2002 (PL 107-188) Congress revised, reorganized and renumbered several sections of the biological weapons law, including 18 USC 175b

In 2004 (PL 108-458), Congress expanded the categories of restricted persons, to add, to the category "is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State...has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism" a person who "acts for or on behalf of, or operates subject to the direction or control of, a government or official of a country described in this subparagraph." 18 USC 175b(d)(2)(G) as of 2004.

In 2004 (PL 108-458), Congress also made conforming amendments to align the statute with redesignated HHS regulations (formerly 42 CFR 72 and Appendix A) pertaining to control of select biological agents and toxins, to designate agents and toxins as covered by the program if "the biological agent or toxin is listed as a non-overlap or overlap select biological agent or toxin in sections 73.4 and 73.5 of title 42, Code of Federal Regulations, pursuant to section 351A of the Public Health Service Act, and is not excluded under sections 73.4 and 73.5 or exempted under section 73.6 of title 42, Code of Federal Regulations."

Congress provided for the conforming amendment to "take effect at the same time" that 42 CFR 73.4, 73.5 and 73.6 became effective. By Federal Register notice (70 FR 13294, March 18, 2005), new select agent and toxins regulations at 42 CFR 73 took effect April 18, 2005.

In 2004, (PL 108-458), under Subtitle J, Prevention of Terrorist Access to Destructive Weapons Act, Congress added a new provision, 18 USC 175c, "Variola virus," and a statutory note.

Under findings, Congress stated: "Variola virus is the causative agent of smallpox, an extremely serious, contagious, and sometimes fatal disease. Variola virus is classified as a Category A agent by the Centers for Disease Control and Prevention, meaning that it is believed to pose the greatest potential threat for adverse public health impact and has a moderate to high potential for large-scale dissemination. The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977. Although smallpox has been officially eradicated after a successful worldwide vaccination program, there remain two official repositories of the variola virus for research purposes. Because it is so dangerous, the variola virus may appeal to terrorists."

Congress provided:

> Except as provided in paragraph (2), it shall be unlawful for any person to knowingly produce, engineer, synthesize, acquire, transfer directly or indirectly, receive, possess, import, export, or use, or possess and threaten to use, variola virus. 18 USC 175c(a)(1)

Paragraph (2):

> This subsection does not apply to conduct by, or under the authority of, the Secretary of Health and Human Services. 18 USC 175c(a)(2)

Congress established US jurisdiction to prosecute conduct prohibited by subsection (a) "if the offense occurs in or affects interstate or foreign commerce; the offense occurs outside of the United States and is committed by a national of the United States; the offense is committed against a national of the United States while the national is outside the United States; the offense is committed against any property that is owned, leased, or used by the United States or by any department or agency of the United States, whether the property is within or outside the United States; or an offender aids or abets any person over whom jurisdiction exists under this subsection in committing an offense under this section or conspires with any person over whom jurisdiction exists under this subsection to commit an offense under this section." 18 USC 175c(b)

Congress established criminal penalties:

> (1) Any person who violates, or attempts or conspires to violate, subsection (a) shall be fined not more than $2,000,000 and shall be sentenced to a term of imprisonment not less than 25 years or to imprisonment for life.
>
> (2) Other circumstances.—Any person who, in the course of a violation of subsection (a), uses, attempts or conspires to use, or possesses and threatens to use, any item or items described in subsection (a), shall be fined not more than $2,000,000 and imprisoned for not less than 30 years or imprisoned for life.
>
> (3) Special circumstances.—If the death of another results from a person's violation of subsection (a), the person shall be fined not more than $2,000,000 and punished by imprisonment for life. 18 USC 175c(c)

Congress defined the term 'variola virus' to mean "a virus that can cause human smallpox or any derivative of the variola major virus that contains more than 85 percent of the gene sequence of the variola major virus or the variola minor virus." 18 USC 175c(d)

2004 - 18 USC 1961
Title 18: Racketeer Influenced and Corrupt Organizations [RICO]
Definitions

In 2004 (PL 108-458), Congress added, to the definition of racketeering activity under 18 USC 1961(1)(B): "any act which is indictable under any of the following provisions of title 18, United States Code," the phrase: "sections 175–178[37] (relating to biological weapons), sections 229–229F[38] (relating to chemical weapons), section 831 (relating to nuclear materials)."

[37] 18 USC 175-178, Biological weapons
[38] 18 USC 229-229F, Chemical weapons

2005 - 42 USC 247d-6d [PHSA 319F-3] and 42 USC 247d-6e [PHSA 319F-4]
Title 42: Public Health and Welfare
Public health emergencies
Targeted liability protections for pandemic and epidemic products and security countermeasures; Covered countermeasure process

In 2005 (PL 109-148), Congress enacted the PREP (Public Readiness and Emergency Preparedness) Act, providing "targeted liability protections for pandemic and epidemic products and security countermeasures," and a "covered countermeasure process" under 42 USC 247d-6 [PHSA 319F], *Public health countermeasures to a bioterrorist attack,* which Congress had added in 2000 (PL 106-505).

Congress added the "targeted liability protections" provisions at 42 USC 246d-6d [PHSA 319F-3] and the covered countermeasure process provisions at 42 USC 247d-6e [PHSA 319F-4].

42 USC 246d-6d [PHSA 319F-3] - Targeted liability protections for pandemic and epidemic products

42 USC 247d-6d(a) - Liability Protections

In 2005 (PL 109-148), Congress provided immunity from suit and liability under Federal and State law, for any "covered person...with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 USC 247d-6d(a)(1)

Congress authorized the HHS Secretary to put the liability immunity provisions into effect for covered countermeasures as manufactured, distributed or used by "covered persons," by making two unilateral decisions: a "determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency" and a "declaration...recommending... the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." 42 USC 247d-6d(b)(1)

Congress defined the term 'loss' to mean "any type of loss, including death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss...without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause." 42 USC 247d-6d(a)(2)(A)

Congress provided for liability immunity to apply to "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." 42 USC 247d-6d(a)(2)(B)

Congress provided for liability immunity for a covered person with respect to a covered countermeasure to apply, "only if the countermeasure was administered or used during the effective period of the declaration [issued by the HHS Secretary]... the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration [issued by the HHS Secretary]; and...in the case of a covered person who is a program planner or qualified person...the countermeasure was administered to or used by an individual who was in a population specified by the declaration; and was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration." 42 USC 247d-6d(a)(3)

Congress provided for liability immunity to apply to a manufacturer or distributor of the covered countermeasure, "without regard to whether such countermeasure was administered to or used by an individual in accordance with the [population and geographic area]. 42 USC 247d-6d(a)(4)(A)

Congress provided for liability immunity to apply to program planner or qualified person use of a covered countermeasure including in "circumstances in which the...covered person reasonably could have believed that the countermeasure was administered or used in accordance with the [population and geographic] conditions [specified in the HHS Secretary declaration]. 42 USC 247d-6d(a)(4)(B)

Congress provided for liability immunity to apply "regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that...the declaration [by the HHS Secretary] provides that liability immunity applies only to covered countermeasures obtained through a particular means of distribution. 42 USC 247d-6d(a)(5)

Congress established, as a rebuttable presumption, that "any administration or use, during the effective period of the emergency declaration by the Secretary...of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued." 42 USC 247d-6d(a)(7)

42 USC 247d-6d(b) - Declaration by the Secretary

Congress authorized the HHS Secretary to make two unilateral decisions.

Congress authorized the HHS Secretary to make "a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." 42 USC 247d-6d(b)(1)

Congress authorized the HHS Secretary, on the basis of his own "determination that a disease...constitutes a public health emergency," to then make "a declaration...recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) [liability immunity] is in effect with respect to the activities so recommended." 42 USC 247d-6d(b)(1)

Congress directed the HHS Secretary to make such a declaration recommending manufacture, testing, development, distribution, administration or use" of countermeasures, by publishing the declaration in the Federal Register. 42 USC 247d-6d(b)(1)

Congress directed the HHS Secretary, in such declarations, to "identify, for each covered countermeasure specified...the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure; the period... during which [the liability immunity declaration] is in effect...designated by dates, or by milestones or other description of events...the...populations of individuals for which [the liability immunity declaration] is in effect...which may be a specification that such [liability immunity] applies without geographic limitation to all individuals;...the geographic...areas for which [the liability immunity declaration] is in effect including...a specification, as determined...by the Secretary, of whether the [liability immunity] declaration applies only to individuals physically present in such areas or [also] to individuals who have a connection to such areas...described in the declaration; and whether [the liability immunity declaration] is effective only to a particular means of distribution...and if so, the particular means." 42 USC 247d-6d(b)(2)

Congress authorized the HHS Secretary, in his discretion, to specify different periods [of duration of effect for liability immunity] for different covered persons to address different logistical, practical or other differences in responsibilities. 42 USC 247d-6d(b)(3)(A)

Congress directed the HHS Secretary to consult with the manufacturer of each covered countermeasure as needed, to "specify a date that is after the ending date [for the effective period of the liability immunity declaration]...that allows what the Secretary determines is a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure." 42 USC 247d-6d(b)(3)(B)

Congress directed that the effective period of a liability immunity declaration for covered countermeasures obtained for the Strategic National Stockpile during an active liability immunity declaration include the period of time when the product was administered or used after distribution or release from the stockpile. 42 USC 247d-6d(b)(3)(C)

Congress authorized the HHS Secretary to amend any portion of a liability immunity declaration, by publishing the amendment in the Federal Register, and prohibited amendments to retroactively limit the applicability of liability immunity. 42 USC 247d-6d(b)(4)

Congress authorized the HHS Secretary to withhold, from Federal Register publication, information exempted from disclosure under the Freedom of Information Act (FOIA), 5 USC 552(b).[39] 42 USC 247d-6d(b)(5)

[39] 5 USC 552(b) exempts from disclosure classified national defense or foreign policy information; records related solely to internal personnel rules and practices of an agency; exempted from disclosure by other statutes; trade secrets and commercial or financial information and privileged or confidential; interagency or intraagency memos; personnel and medical files (invasion of personal privacy; records compiled for law enforcement purposes; records pertaining to regulation of financial institutions; or geological and geophysical information and data concerning wells.

Congress directed the HHS Secretary, in deciding to issue a liability immunity declaration, to "consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure." 42 USC 247d-6d(b)(6)

Congress barred all courts of the United States (federal courts) and all States, from "subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary" pertaining to liability immunity determinations and declarations. 42 USC 247d-6d(b)(7)

Congress denied to every State and every political subdivision of a State, authority to "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any [liability immunity declaration] requirement [that] relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under" the Public Health Service Act or the Federal Food, Drug, and Cosmetic Act. 42 USC 247d-6d(b)(8)

Congress directed the HHS Secretary to notify Congressional committees within 30 days after making a liability immunity declaration, or an amendment to a declaration, by submitting a report explaining the reasons for issuing the declaration and the reasons underlying his determinations about the "categories of diseases," period of effect, populations, geographic areas and distribution means. 42 USC 247d-6d(b)(9)

42 USC 247d-6d(c) Definition of willful misconduct

For the purposes of setting a standard of liability for civil claims brought under 42 USC 247d-6d(d), Congress defined the term 'willful misconduct' to "denote an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." 42 USC 247d-6d(c)(1)(A)

Congress established, as a rule of construction, that the definition for 'willful misconduct,' establishes "a standard for liability that is more stringent than a standard of negligence in any form or recklessness." 42 USC 247d-6d(c)(1)(B)

Congress authorized and directed the HHS Secretary, in consultation with the Attorney General, to promulgate regulations, through interim final rules, "that further restrict the scope of actions or omissions by a covered person that may qualify as ‘willful misconduct.’" 42 USC 247d-6d(c)(2)(A)

Congress directed the HHS Secretary and Attorney General to "consider the need to define the scope of permissible civil actions...in a way that will not adversely affect the public health." 42 USC 247d-6d(c)(2)(B)

Congress authorized the HHS Secretary and AG to prescribe regulations that "specify the temporal effect that they shall be given." 42 USC 247d-6d(c)(2)(C)

Congress directed the HHS Secretary and AG to begin and complete an initial rulemaking process further restricting the scope of 'willful misconduct' standard of liability within 180 days after enactment[40] of the PREP Act (Dec. 30, 2005). 42 USC 247d-6d(c)(2)(D)

Congress placed the burden of proof on the plaintiff bringing any action under 42 USC 247d-6d(d), and established the standard of evidence as "clear and convincing evidence" of "willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury." 42 USC 247d-6d(c)(3)

Congress established, as an affirmative defense "notwithstanding any other provision of law," that "a program planner or qualified person shall not have engaged in ‘willful misconduct’ as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the [liability immunity] declaration." Congress provided, as a condition, that "either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff’s alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person." 42 USC 247d-6d(c)(4)

Congress established an "exclusion for regulated activity of manufacturer or distributor." Congress provided that "if an act or omission by a manufacturer or distributor with respect to a covered countermeasure," alleged under the procedure for a plaintiff to bring a claim based on "willful misconduct," is subject to regulation under the PHSA or the FDCA, then "such act or omission shall not constitute ‘willful misconduct’ if neither the HHS Secretary nor the AG had "initiated an enforcement action with respect to such act or omission; or such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy." 42 USC 247d-6d(c)(5)(A)

Congress established that any action brought by a plaintiff against a manufacturer or distributor, if an HHS or AG enforcement action were in process, would be "stayed during the pendency of such an enforcement action." 42 USC 247d-6d(c)(5)(A)

Congress defined the term ‘enforcement action’ to mean "a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under [FDCA 505(i), for drugs or FDCA 520(g), for devices], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under [FDCA 564/21 USC 360bbb-3, emergency use], or a suspension or withdrawal, based on willful misconduct, of an approval or

[40] To the author's knowledge, this rulemaking has not occurred and the "willful misconduct" definition as defined by Congress is the standard applicable to claims brought under 42 USC 247d-6d(d)

clearance under [FDCA 501 et seq/21 USC 351 et seq, for drugs and devices] or of a licensure under [PHSA 351/42 USC 262, for biological products]. 42 USC 247d-6d(c)(5)(B)(i)

Congress defined the term ‘covered remedy’ to mean "an outcome that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under [FDCA 505(i) or FDCA 520(g)], a debarment, an investigator disqualification, a revocation of an authorization under [FDCA 564/21 USC 360bbb-3, emergency use], or a suspension or withdrawal of an approval or clearance under [FDCA 501 et seq/21 USC 351 et seq, for drugs and devices] or of a licensure under [PHSA 351/42 USC 262, for biological products] and that results from a final determination by a court or from a final agency action." 42 USC 247d-6d(c)(5)(B)(ii)

Congress defined the terms ‘final’ and ‘finally’ to mean: "with respect to a court determination, or to a final resolution of an enforcement action that is a court determination...a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and with respect to an agency action, or to a final resolution of an enforcement action that is an agency action...an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal." 42 USC 247d-6d(c)(5)(B)(iii)

Congress established, as rules of construction, that nothing in the section on "willful misconduct" should be construed "to affect the interpretation of any provision of the [FDCA], of [the PHSA], or of any other applicable statute or regulation; or to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the [HHS] Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this Act, under the [FDCA], under title 18 of the United States Code, [Crimes and Criminal Procedure] or under any other applicable statute or regulation." 42 USC 247d-6d(c)(5)(C)(i)

Congress provided that a "mandatory recall called for in the [liability immunity] declaration [published in the Federal Register by the HHS Secretary] is not a Food and Drug Administration enforcement action." 42 USC 247d-6d(c)(5)(C)(ii)

42 USC 247d-6d(d) - Exception to immunity for covered persons

Congress provided that the "sole exception to the immunity from suit and liability of covered persons...shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct...[as defined in the preceding section] by such covered person," and referred to paragraph (f), affirming the sovereign immunity and defenses available to the United States and its employees as government officers. 42 USC 247d-6d(d)(1)

Congress provided that, for purposes of 28 USC 2679(b)(2)(B) [Federal Tort Claims Act] a cause of action for death or serious physical injury alleged to be "proximately caused by willful misconduct by a covered person, is not "an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized." 42 USC 247d-6d(d)(1)

Congress provided standing to sue for "wrongful death or serious physical injury" for "any person who suffers such injury or by any representative of such a person." 42 USC 247d-6d(d)(2)

42 USC 247d-6(e) Procedures for Suit

Congress required any action brought based on claims of willful misconduct by a covered person proximate to serious injury or death involving a covered countermeasure to be "filed and maintained only in the United States District Court for the District of Columbia," providing exclusive federal jurisdiction and limiting jurisdiction to only one Federal District Court. 42 USC 247d-6d(e)(1)

Congress provided that "the substantive law for decision" in willful misconduct action "shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section." 42 USC 247d-6d(e)(2)

As noted above, through the PREP Act, Congress denied to every State and every political subdivision of a State, authority to "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any [liability immunity declaration] requirement [that] relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure."

Congress required the plaintiff's complaint to "plead with particularity each element of the plaintiff's claim, including each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used...; facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury." 42 USC 247d-6d(e)(3)

Congress required the plaintiff to verify the complaint (state under oath by affidavit that the pleading is true to the knowledge of the deponent [person who gives testimony], except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true), and file it with supporting medical records. 42 USC 247d-6d(e)(4)

Congress established that any "matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff." 42 USC 247d-6d(e)(4)

If a complaint failed to comply with the verification requirement and the medical records requirement, Congress directed the court to refuse to accept it for filing, and to leave the running of the statute of limitations in effect. 42 USC 247d-6d(e)(4)(A)

Congress required the plaintiff to file "an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and certified medical records documenting such injury or death and such proximate causal connection." 42 USC 247d-6d(e)(4)(C)

Congress directed that an action be assigned initially to a panel of three judges of the US District Court for the District of Columbia, to have jurisdiction for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. 42 USC 247d-6d(e)(5)

Congress directed that after the three-judge panel had denied such motions, or if the time for filing such motions has expired, the panel would refer the action to the chief judge for assignment for further proceedings, including any trial. 42 USC 247d-6d(e)(5)

Congress provided that 28 USC 1253 [authorizing direct appeals to the Supreme Court from an order granting or denying...an interlocutory or permanent injunction in any civil action...which Congress has required to be heard and determined by a district court of three judges] and 28 USC 2284(b)(3) [directing convening of a three-judge district court panel "when otherwise required by Act of Congress, or when an action is filed challenging...constitutionality of...apportionment of congressional districts or...apportionment of any statewide legislative body"] "shall not apply." 42 USC 247d-6d(e)(5)

Congress provided, "no discovery shall be allowed before each covered person sued has had a reasonable opportunity to file a motion to dismiss; in the event such a motion is filed, before the court has ruled on such motion; and in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal." 42 USC 247d-6d(e)(6)(A)

For discovery after the close of the period for motions to dismiss and appeals from denials of motions to dismiss, Congress provided that the court should restrict discovery to be conducted "only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response." 42 USC 247d-6d(e)(6)(B)

Congress provided that, if a plaintiff obtained an award of damages, it should be reduced by the amount of "collateral source benefits" and that providers of collateral source benefits should not be entitled to recover any amount from the plaintiff or receive any lien or credit against the plaintiff's award of damages, or be equitably or legally subrogated to the right of the plaintiff (in other words, to be reimbursed for payments they made to plaintiff, from the damages paid to the plaintiff as a result of a willful misconduct case). 42 USC 247d-6d(e)(7)

Congress defined the term ‘collateral source benefit’ to mean "any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to any State or Federal health, sickness, income-disability, accident, or workers’ compensation law; any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage; any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or any other publicly or privately funded program." 42 USC 247d-6d(e)(7)(C)

Congress provided for proportional awards: "in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff" for "noneconomic damages." Congress defined "noneconomic damages" as "damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses." 42 USC 247d-6d(e)(8)

Congress provided for penalties (payments to other parties), for violations of Rule 11, Federal Rules of Civil Procedure, which requires all pleadings and motions to be signed by an attorney or the plaintiff himself if unrepresented, and to certify under oath that the papers are not being filed for improper purposes (such as harassment, delay); that the claims are supported by existing law or "nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law;" that the factual contentions have evidentiary support or will have evidentiary support after discovery; and that denials of factual contentions are warranted on the evidence. 42 USC 247d-6d(e)(9)

Congress assigned jurisdiction for interlocutory appeals by a "covered person" to the US Court of Appeals for the District of Columbia Circuit, with such appeals to be filed within 30 days, appealing district court orders denying a defendant's motion to dismiss or motion for summary judgment (based on the covered person's immunity) or, for a manufacturer or distributor, based on the preclusion [under 42 USC 247d-6d(c)(5)] of a manufacturer or distributor's acts being deemed "willful misconduct" provided neither the HHS Secretary or Attorney General had initiated an enforcement action, or, if an enforcement action had been initiated, if the action terminated without a covered remedy. 42 USC 247d-6d(e)(10)

42 USC 247d-6d(f) - Actions by and against the United States

Congress provided that "nothing in this section" [authorizing the HHS Secretary to provide liability immunity for covered persons manufacturing, distributing or using covered countermeasures by declaration] "shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of [the Federal Tort Claims Act, procedures for civil claims brought against government officers]. 42 USC 247d-6d(f)

42 USC 247d-6d(g) - Severability

Congress included a severability clause, that "if any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby."

42 USC 247d-6d(h) - Rule of construction concerning National Vaccine Injury Compensation Program (VICP)

Congress provided that nothing in the PREP Act should be construed to affect the National Vaccine Injury Compensation Program (VICP).

42 USC 247d-6d(i) - Definitions

Congress defined 'covered countermeasure' to mean

> a qualified pandemic or epidemic product[41]; or a security countermeasure[42]; or a drug[43], biological product[44], or device [45] that is authorized for emergency use.[46] 42 USC 247d-6d(i)(1)

Congress defined the term 'covered person,' "when used with respect to the administration or use of a covered countermeasure" to mean

> the United States; or a person or entity that is a manufacturer of such countermeasure; a distributor of such countermeasure; a program planner of such countermeasure; a qualified person who prescribed, administered, or dispensed such countermeasure; or an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv) [manufacturer, distributor, program planner or qualified person]. 42 USC 247d-6d(i)(2)

Congress defined 'distributor' to mean

> a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; ware- houses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies. 42 USC 247d-6d(i)(3)

[41] Qualified pandemic or epidemic product as defined in PHSA 319F-3(i)(7) [42 USC 247d-6d(i)(7)]
[42] Security countermeasure as defined in PHSA 319F–2(c)(1)(B) [42 USC 247d-6b(c)(1)(B)]
[43] Drug as defined in FDCA 201(g)(1) [21 USC 321(g)(1)]
[44] Biological product as defined in PHSA 351(i) [42 USC 262(i)]
[45] Device as defined in FDCA 201(h) [21 USC 321(h)]
[46] Authorized for emergency use in accordance with FDCA 564 [21 USC 360bbb-3] *Authorization for medical products for use in emergencies*]

Congress defined manufacturer to include

> a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer. 42 USC 247d-6d(i)(4)

Congress defined the term ‘person’ to include "an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department." 42 USC 247d-6d(i)(5)

Congress defined the term ‘program planner’ to mean

> a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [liability immunity] declaration. 42 USC 247d-6d(i)(6)

Congress defined the term ‘qualified pandemic or epidemic product’ to mean

> a drug...biological product...or device...
>
> that is a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause;
>
> or a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in [the preceding clause]; and
>
> approved or cleared under [FDCA 505/21 USC 355, *New drugs*] or licensed under [PHSA 351/42 USC 262, *Regulation of biological products*];
>
> the object of research for possible use [to address a pandemic or epidemic or to limit the harm caused by a product used to address a pandemic or epidemic] and is the subject of an exemption under [FDCA 505(i)/21 USC 355(i), *New drugs, Exemptions of drugs for research* or FDCA 520(g)/21 USC 360(g), *Registration of producers of drugs or devices, Exclusions*; or
>
> authorized for emergency use in accordance with [FDCA 564/21 USC 360bbb-3, *Authorization for medical products for use in emergencies*] 42 USC 247d-6d (i)(7)

Congress defined the term 'qualified person' "when used with respect to the administration or use of a covered countermeasure" to mean

> a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons so identified [as 'qualified persons'] in a [liability immunity] declaration by the Secretary under subsection (b). 42 USC 247d-6d (i)(8)

Congress defined the term 'security countermeasure' [42 USC 247d-6d (i)(9)] by citing 42 USC 247d-6b(c)(1)(B) [PHSA 319F–2(c)(1)(B), enacted in 2004 (PL 108-276)]:

> a drug,[47]...biological product[48]...or device[49] that the [HHS] Secretary determines to be a priority [consistent with HSA 302(2)[50] and HSA 304(a)[51]] to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat[52]...or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; [which product] the Secretary determines...to be a necessary countermeasure[53]; and is approved or cleared under [FDCA 505/21 USC 255 et seq, *New drugs*] or licensed under [PHSA 351/42 USC 262, *Regulation of biological*

[47] *Drug*, as defined by FDCA 201(g)(1) [21 U.S.C. 321(g)(1)] "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)..."

[48] *Biological product*, as defined by PHSA 351(i) [42 U.S.C. 262(i)] - " a virus, therapeutic serum, toxin, anti- toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic com- pound), applicable to the prevention, treatment, or cure of a disease or condition of human beings"

[49] *Device*, as defined by FDCA 201(h) [21 U.S.C. 321(h)] - "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." [Exceptions distinguish this use from use of the word 'device' to denote labeling components similar to 'statements," 'designs' and 'words,']

[50] Homeland Security Act of 2002, Sec. 302 [6 USC 181] - Congress established Directorate of Science and Technology within DHS, authorized to develop national policy and strategic plans for identifying and developing countermeasures to chemical, biological, radiological, nuclear, and other emerging terrorist threats.

[51] Homeland Security Act of 2004, Sec. 304 [6 USC 184] - Congress authorized and directed the HHS Secretary to collaborate with the DHS Secretary to "set priorities...and policies and develop a coordinated strategy "with respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats."

[52] *Material threat*, as defined under PHSA 319F-2(2)(A)(ii)/42 USC 247d-6b(2)(A)(ii)

[53] *Necessary countermeasure*, as defined under PHSA 319F-2(2)(B)(ii)/42 USC 247d-6b(2)(B)(ii)

> *products*]; or is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination[54]...; or is authorized for emergency use under [FDCA 564/21 USC 360bbb-3, *Authorization for medical products for use in emergencies*]. 42 USC 247d-6b(c)(1)(B)

Congress defined 'serious physical injury' to mean

> an injury that is life threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. 42 USC 247d-6d(i)(10)

42 USC 247d-6e [PHSA 319F-4] - Covered countermeasure process

In 2005 (PL 109-148), Congress provided that when the HHS Secretary issued a liability immunity declaration, an emergency 'Covered Countermeasure Process Fund, would be established in the Treasury, "for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." Congress provided for the fund to include emergency appropriations under H. Con. Res 95 of 109th Congress, Sec. 402, to remain in effect through Oct. 1, 2006. 42 USC 247d-6e(a)

Congress authorized and directed the HHS Secretary to "provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to" a liability immunity declaration. 42 USC 247d-6e(b)(1)

Congress provided for the same elements, and in the same amounts, as amounts prescribed in 2003 (PL 108-20) for individuals injured as a result of smallpox countermeasures under PHSA 264, *Medical benefits*, PHSA 265, *Compensation for lost employment income*, and PHSA 266, *Payment for Death* [42 USC 239 et seq] except that PHSA 266(a)(2)(B), *Reduction of death benefit by the amount paid for lost employment income*, "shall not apply." 42 USC 247d-6e(b)(2)

Congress provided, as a rule of construction, that "neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by [PHSA] 266." 42 USC 247d-6e(b)(3)

Congress provided for "determination of eligibility for compensation" (whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under the CICP program, and the amount of such compensation) to be conducted by procedures established in PHSA 262 [42 USC 239a] and related regulations, and other regulations prescribed by the HHS Secretary.

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[54] *Determination of Countermeasures Appropriate for Funding from Special Reserve Fund*, as defined under PHSA 319F-2(5)/42 USC 247d-6b(5)

Congress authorized the HHS Secretary to make determinations, (other than those about injuries "presumed to be directly caused" by a covered countermeasure under the Covered Countermeasure Injury Table) as to the direct causation of a covered injury, only based on "compelling, reliable, valid, medical and scientific evidence." 42 USC 247d-6e(b)(4)

Congress directed the HHS Secretary to, by regulation, "establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply."

Congress authorized the HHS Secretary to identify such covered injuries only "where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury." 42 USC 247d-6e(b)(5)(A)

Congress authorized the HHS Secretary to make amendments to the Covered Injury Compensation Table. 42 USC 247d-6e(b)(5)(B)

Congress prohibited judicial review of any action by the HHS Secretary to identify covered injuries for the covered countermeasure injury table:

> "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph." 42 USC 247d-6e(b)(5)(C)

Congress held that, in applying the provisions of the Smallpox Emergency Personnel Protection Act, for purposes of countermeasures generally the terms ‘vaccine’ and ‘smallpox vaccine’ "shall be deemed to mean a covered countermeasure." 42 USC 247d-6e(b)(6)

Congress directed the HHS Secretary to ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any liability immunity declaration "and any applicable guidelines of the Centers for Disease Control and Prevention," and that recipients of countermeasures "are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part." 42 USC 247d-6e(c)

Congress precluded any "covered individual" from bringing a civil action alleging willful misconduct under 42 USC 247d-6d(d), against a "covered person" unless he or she had exhausted CICP administrative remedies, with two exceptions: if funds have not been appropriated for the CICP fund, or if the HHS Secretary failed to make a final determination on compensation claim within 240 days after such request was filed. 42 USC 247d-6e(d)(1)

Congress provided that the time limit (statute of limitations) for filing a civil action alleging willful misconduct under 42 USC 247d-6d(d) for an injury or death to be tolled (paused) while a submitted CICP administrative claim is under review. 42 USC 247d-6e(d)(2)

Congress provided, as a rule of construction, that the countermeasures injury compensation program would not supersede or otherwise affect the application of a requirement, under 28 USC 171 [Tort Claims Procedure], to exhaust administrative remedies. 42 USC 247d-6e(d)(3)

Congress provided for the countermeasures injury compensation process to be the exclusive remedy (precluding any other civil action or proceeding), except for a willful misconduct proceeding under 42 USC 247d-6d. 42 USC 247d-6e(d)(4)

Congress authorized individuals for whom the HHS Secretary determined that they are a covered individual who qualifies for compensation under the CICP, to elect to accept the compensation, or to bring an action under 42 USC 247d-6d(d), and barred anyone who elected to accept the CICP compensation, from bringing an action under 42 USC 247d-6d(d).

Congress defined the term ‘covered countermeasure’ by reference to 42 USC 247d-6d: "a qualified pandemic or epidemic product; or a security countermeasure; or a drug, biological product, or device that is authorized for emergency use. 42 USC 247d-6e(e)(1)

Congress defined the term ‘covered individual’ to mean

> an individual—
>
> (A) who is in a population specified in [a liability immunity] declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or
>
> (B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A). 42 USC 247d-6e(e)(2)

Congress defined the term ‘covered injury’ to mean "serious physical injury or death." 42 USC 247d-6e(e)(3)

Congress defined the term ‘declaration’ to mean a liability immunity declaration issued by the HHS Secretary under 42 USC 247d-6d(b). 42 USC 247d-6e(e)(4)

Congress defined the term ‘eligible individual’ to mean "an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury." 42 USC 247d-6e(e)(5)

2005 - 42 CFR 73
Title 42: Public Health
Select agents and toxins
[Regulations promulgated under 42 USC 262a]

In 2005 (70 FR 13316), the HHS Secretary published a final rule prescribing regulations implementing the "select agent and toxins" program Congress authorized in 2002 (PL 107-188).

This report does not summarize provisions of the regulations in detail, but does summarize the core provisions which enable products containing biological agents and toxins possessing the capacity to cause biological malfunction, disease and death, to enter interstate and international commerce without legal impediment, by exempting such products from restrictions on possession, use and transfer, not on the basis of their physical identity, but on the basis of their classification by the HHS Secretary and labeling by manufacturers.

Under the rule, "products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under" any of the following laws, are categorically "exempt from the provisions of this part insofar as their use meets the requirements of such laws"..."unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety."

The laws invoked include the Federal Food, Drug, and Cosmetic Act [21 USC 301 et seq.], PHSA Sec. 351 [42 USC 262, *Regulation of biological products*], the Virus-Serum-Toxin Act [21 U.S.C. 151– 159, biological products for use on domestic animals], and the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]. 42 CFR 73.5(c) *Exemptions for HHS select agents and toxins*, and 42 CFR 73.6(c), *Exemptions for overlap select agents and toxins*.

The regulation authorized the HHS Secretary to "exempt from the requirements of this part an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety." 42 CFR 73.5(d) *Exemptions for HHS select agents and toxins*, and 42 CFR 73.6(d), *Exemptions for overlap select agents and toxins*.

2006 - 50 USC 1511-1528
Title 50: War and National Defense
Biological and chemical defense; reporting to Congress

In 1993 (PL 103-160) Congress directed the Defense Secretary to "carry out the chemical and biological defense program of the United States," and to report on chemical and biological warfare defense programs, inventories, and other elements in his annual report to Congress under 10 USC 113(c). 50 USC 1522 and 1523. Congress specified eight subject areas for reporting: quantities, characteristics, and capabilities of fielded chemical and biological defense equipment; status of research, development and acquisition programs, including assessment of DoD and industrial base capacities; status of training and readiness; measures taken to improve coordination; problems encountered, recommended solutions; and implementation of the Chemical Weapons Convention. 50 USC 1523(b)(1) through (8) as of 1993.

In 1997 (PL 105-85), Congress added a ninth subject area, requiring the annual general DoD report, in the section on chemical and biological warfare defense, to provide "A description of any program involving the testing of biological or chemical agents on human subjects..." 50 USC 1523(b)(9) as of 1997.

In 2006 (PL 109-364), Congress added a Paragraph (10), requiring Defense Secretary annual reports to Congress to include information about DARPA programs:

> (10) A description of the coordination and integration of the program of the Defense Advanced Research Projects Agency (DARPA) on basic and applied research and advanced technology development on chemical and biological warfare defense technologies and systems...with the overall program of the Department of Defense on chemical and biological warfare defense, including an assessment of the degree to which the DARPA program is coordinated and integrated with, and supports the objectives and requirements of, the overall program of the Department of Defense; and the means by which the Department determines the level of such coordination and support." 50 U.S.C. 1523(b)(10) as of 2006

Congress eliminated the reporting requirements under 50 USC 1523 in 2016 (PL 114-328), effective Dec. 31, 2021.

2006 - 18 USC 2441
Title 18:Crimes and Criminal Procedure
War Crimes

2006 - 10 USC 948 et seq
Title 10: Armed Forces
Military Commissions

In 2006 (PL 109-366), Congress added Chapter 47A under Title 10, Armed Forces, establishing military commissions for prosecution of war crimes. 10 USC 948a et seq

Congress defined, as offenses triable by military commission, murder of protected persons, attacking civilians, attacking civilian objects, attacking protected property, pillaging, denying quarter, taking hostages, employing poison or similar weapons, using protected persons as a shield, using protected property as a shield, torture, cruel or inhuman treatment, intentionally causing serious bodily injury, mutilating or maiming, murder in violation of the law of war, destruction of property in violation of the law of war, using treachery or perfidy, improperly using a flag of truce, improperly using a distinctive emblem, intentionally mistreating a dead body, rape, sexual assault or abuse, hijacking or hazarding a vessel or aircraft, terrorism, providing material support for terrorism, wrongfully aiding the enemy, spying and conspiracy. 10 USC 950v(b)(1) through (28).

The list of offenses was renamed, revised and renumbered 10 USC 950t(b)(1) through (31) in 2009 (PL 111-84).

Through the 2006 Military Commissions Act, Congress defined 'employing poison or similar weapons:'

> any person subject to this chapter who intentionally, as a method of warfare, employs a substance or weapon that releases a substance that causes death or serious and lasting damage to health in the ordinary course of events, through its asphyxiating, bacteriological, or toxic properties, shall be punished, if death results to one or more of the victims, by death or such other punishment as a military commission under this chapter may direct, and, if death does not result to any of the victims, by such punishment, other than death, as a military commission under this chapter may direct." 10 USC 950v(b)(8)

Congress defined 'mutilating or maiming:'

> any person subject to this chapter who intentionally injures one or more protected persons by disfiguring the person or persons by any mutilation of the person or persons, or by permanently disabling any member, limb, or organ of the body of the person or persons, without any legitimate medical or dental purpose, shall be punished, if death results to one or more of the victims, by death or such other punishment as a military commission under this chapter may direct, and, if death does not result to any of the victims, by such punishment, other than death, as a military commission under this chapter may direct. 10 USC 950v(b)(14)

Through the same act, (PL 109-366), Congress amended the war crimes law to add definitions for listed "grave breaches," by adding a new section at 18 USC 2441(d).

Congress defined under "prohibited conduct," the term ‘grave breach of common Article 3’ to mean:

> (A) Torture.—The act of a person who commits, or conspires or attempts to commit, an act specifically intended to inflict severe physical or mental pain or suffering (other than pain or suffering incidental to lawful sanctions) upon another person within his custody or physical control for the purpose of obtaining information or a confession, punishment, intimidation, coercion, or any reason based on discrimination of any kind.
>
> (B) Cruel or Inhuman Treatment.—The act of a person who commits, or conspires or attempts to commit, an act intended to inflict severe or serious physical or mental pain or suffering (other than pain or suffering incidental to lawful sanctions), including serious physical abuse, upon another within his custody or control.
>
> (C) Performing Biological Experiments.—The act of a person who subjects, or conspires or attempts to subject, one or more persons within his custody or physical control to biological experiments without a legitimate medical or dental purpose and in so doing endangers the body or health of such person or persons.
>
> (D) Murder.—The act of a person who intentionally kills, or conspires or attempts to kill, or kills whether intentionally or unintentionally in the course of committing any other offense under this subsection, one or more per- sons taking no active part in the hostilities, including those placed out of combat by sickness, wounds, detention, or any other cause.
>
> (E) Mutilation or Maiming.—The act of a person who intentionally injures, or conspires or attempts to injure, or injures whether intentionally or unintentionally in the course of committing any other offense under this subsection, one or more persons taking no active part in the hostilities, including those placed out of combat by sickness, wounds, detention, or any other cause, by disfiguring the person or persons by any mutilation thereof or by permanently disabling any member, limb, or organ of his body, without any legitimate medical or dental purpose.

> (F) Intentionally Causing Serious Bodily Injury.— The act of a person who intentionally causes, or conspires or attempts to cause, serious bodily injury to one or more persons, including lawful combatants, in violation of the law of war.
>
> (G) Rape.—The act of a person who forcibly or with coercion or threat of force wrongfully invades, or conspires or attempts to invade, the body of a person by penetrating, however slightly, the anal or genital opening of the victim with any part of the body of the accused, or with any foreign object.
>
> (H) Sexual Assault or Abuse.—The act of a person who forcibly or with coercion or threat of force engages, or conspires or attempts to engage, in sexual contact with one or more persons, or causes, or conspires or attempts to cause, one or more persons to engage in sexual contact.
>
> (I) Taking Hostages.—The act of a person who, having knowingly seized or detained one or more persons, threatens to kill, injure, or continue to detain such person or persons with the intent of compelling any nation, person other than the hostage, or group of persons to act or refrain from acting as an explicit or implicit condition for the safety or release of such person or persons. 18 USC 2442(d)(1)

Congress further defined 'severe mental pain or suffering' with reference to 18 USC 2340(2) [definitions under law prohibiting torture]; 'serious bodily injury' with reference to 18 USC 113(b)(2) [definitions under law prohibiting assaults within maritime and territorial jurisdiction]; 'sexual contact' with reference to 18 USC 2246(3) [definitions under law prohibiting sexual abuse]. 18 USC 2441(d)(2)(A), (B) and (C).

Congress directed that the term 'serious physical pain or suffering' be applied as meaning

> bodily injury that involves—
>
> (i) a substantial risk of death;
>
> (ii) extreme physical pain;
>
> (iii) a burn or physical disfigurement of a serious nature (other than cuts, abrasions, or bruises); or
>
> (iv) significant loss or impairment of the function of a bodily member, organ, or mental faculty. 18 USC 2441(d)(2)(D)

Congress defined ‘serious mental pain or suffering’ with reference to 18 USC 2340(2) [definitions under law prohibiting torture] substituting 'serious" for ‘severe’ in the torture law definitions, substituting ‘serious and non-transitory mental harm (which need not be prolonged)’ for the term ‘prolonged mental harm.’

Congress precluded prosecution of acts of murder, mutilation or maiming and intentionally causing serious bodily injury with respect to "collateral damage" or "death, damage, or injury incident to a lawful attack."

Congress made most of the provisions retroactive to November 26, 1997, as if they had been enacted with PL 105-118, except the provision, defining ‘serious mental pain or suffering' as effective with the enactment of the Military Commissions Act of 2006.

Congress further prohibited cruel, inhuman or degrading treatment or punishment of individuals "in the custody or under the physical control of the United States Government, regardless of nationality or physical location," and defined "cruel, inhuman, or degrading treatment or punishment" to mean

> cruel, unusual, and inhumane treatment or punishment prohibited by the Fifth, Eighth, and Fourteenth Amendments to the Constitution of the United States, as defined in the United States Reservations, Declarations and Understandings" to the 1984 UN Convention Against Torture and Other Forms of Cruel, Inhuman or Degrading Treatment or Punishment done at New York, December 10, 1984.

Discussion

Congress did not define standards for assessing the legitimacy of claimed medical or dental purposes.

Section 4
International Law of War

International Law, Wikipedia:

> "International humanitarian law (IHL), also referred to as the laws of armed conflict or the laws of war, is the law that regulates the conduct of war...It is a branch of international law that seeks to limit the effects of armed conflict by protecting persons who are not participating in hostilities and by restricting and regulating the means and methods of warfare available to combatants."

International Criminal Court, Wikipedia

> The International Criminal Court (ICC) is an intergovernmental organization and international tribunal seated in The Hague, Netherlands. It is the first and only permanent international court with jurisdiction to prosecute individuals for the international crimes of genocide, crimes against humanity, war crimes, and the crime of aggression. The ICC is distinct from the International Court of Justice, an organ of the United Nations that hears disputes between states. [The ICC was] established in 2002 pursuant to the multilateral Rome Statute...

1907 - Hague Convention IV
Respecting the Laws and Customs of War on Land
Annex - Section II, Hostilities,
Chapter I, Means of Injuring the Enemy, Sieges, and bombardments

Article 23.

In addition to the prohibitions provided by special Conventions, it is especially forbidden-

To employ poison or poisoned weapons;

To kill or wound treacherously individuals belonging to the hostile nation or army;

To kill or wound an enemy who, having laid down his arms, or having no longer means of defence, has surrendered at discretion; To declare that no quarter will be given;

To employ arms, projectiles, or material calculated to cause unnecessary suffering;

To make improper use of a flag of truce, of the national flag or of the military insignia and uniform of the enemy, as well as the distinctive badges of the Geneva Convention;

To destroy or seize the enemy's property, unless such destruction or seizure be imperatively demanded by the necessities of war;

To declare abolished, suspended, or inadmissible in a court of law the rights and actions of the nationals of the hostile party. A belligerent is likewise forbidden to compel the nationals of the hostile party to take part in the operations of war directed against their own country, even if they were in the belligerent's service before the commencement of the war.

1925 - Geneva Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare

Wikipedia:

> The Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, usually called the Geneva Protocol, is a treaty prohibiting the use of chemical and biological weapons in international armed conflicts. It was signed at Geneva on 17 June 1925 and entered into force on 8 February 1928. It was registered in *League of Nations Treaty Series* on 7 September 1929.
>
> The Geneva Protocol is a protocol to the Convention for the Supervision of the International Trade in Arms and Ammunition and in Implements of War signed on the same date, and followed the Hague Conventions of 1899 and 1907. It prohibits the use of "asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices" and "bacteriological methods of warfare." This is now understood to be a general prohibition on chemical weapons and biological weapons, but has nothing to say about production, storage or transfer. Later treaties did cover these aspects – the 1972 Biological Weapons Convention (BWC) and the 1993 Chemical Weapons Convention (CWC).

Geneva Protocol, relevant text

> ...Whereas the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices, has been justly condemned by the general opinion of the civilized world; and
>
> Whereas the prohibition of such use has been declared in Treaties to which the majority of Powers of the world are Parties; and
>
> To the end that this prohibition shall be universally accepted as a part of International Law, binding alike the conscience and the practice of nations;
>
> Declare: That the High Contracting Parties, so far as they are not already Parties to Treaties prohibiting such use, accept this prohibition, agree to extend this prohibition to the use of bacteriological methods of warfare and agree to be bound as between themselves according to the terms of this declaration...

Discussion

The Geneva Protocol addressed use of chemical and bacteriological materials in "war" only. The Geneva Protocol was silent on the use of chemical and bacteriological materials in medical research, experimentation and treatment, scientific experimentation and research, agriculture, industry, and for law enforcement and military purposes not deemed elements of warfare.

1949 Geneva Conventions

Wikipedia:

> The Geneva Conventions are international humanitarian laws consisting of four treaties and three additional protocols that establish international legal standards for humanitarian treatment in war. The singular term *Geneva Convention* colloquially denotes the agreements of 1949, negotiated in the aftermath of the Second World War (1939–1945), which updated the terms of the two 1929 treaties and added two new conventions.
>
> The Geneva Conventions extensively define the basic rights of wartime prisoners, civilians and military personnel; establish protections for the wounded and sick; and provide protections for the civilians in and around a war-zone. The Geneva Conventions define the rights and protections afforded to those non-combatants who fulfill the criteria of being 'protected persons.' The treaties of 1949 were ratified, in their entirety or with reservations, by 196 countries. The Geneva Conventions concern only protected non-combatants in war.
>
> The use of wartime conventional weapons is addressed by the Hague Conventions of 1899 and 1907 and the 1980 Convention on Certain Conventional Weapons, while the biological and chemical warfare in international armed conflicts is addressed by the 1925 Geneva Protocol.

The First Geneva Convention provided "for the amelioration of the condition of the wounded and sick in armed forces in the field." The Second Geneva Conventions provided "for the amelioration of the condition of wounded, sick and shipwrecked members of armed forces at sea." The Third Geneva Convention addressed acts and omissions "relative to the treatment of prisoners of war." The Fourth Geneva Convention addressed acts and omissions "relative to the protection of civilian persons."

Several articles are included in each of the four Geneva Conventions, called "common articles."

Provisions relevant to use of poisonous substances include the following.

> Common Article 3. —
>
> In the case of armed conflict not of an international character occurring in the territory of one of the High Contracting Parties, each Party to the conflict shall be bound to apply, as a minimum, the following provisions:
>
> > 1) Persons taking no active part in the hostilities, including members of armed forces who have laid down their arms and those placed *hors de combat* [out of action] by sickness, wounds, detention, or any other cause, shall in all circumstances be treated humanely, without any adverse distinction founded on race, colour, religion or faith, sex, birth or wealth, or any other similar criteria.

> To this end, the following acts are and shall remain prohibited at any time and in any place whatsoever with respect to the above-mentioned persons:
>
> > *a)* violence to life and person, in particular murder of all kinds, mutilation, cruel treatment and torture;
> >
> > *b)* taking of hostages;
> >
> > *c)* outrages upon personal dignity, in particular humiliating and degrading treatment;
> >
> > *d)* the passing of sentences and the carrying out of executions without previous judgment pronounced by a regularly constituted court, affording all the judicial guarantees which are recognized as indispensable by civilized peoples.

First Geneva Convention (regarding members of armed forces in the field), Article 12 - Wounded and sick, protection and care

> Article 12 — Members of the armed forces and other persons mentioned in the following Article, who are wounded or sick, shall be respected and protected in all circumstances.
>
> They shall be treated humanely and cared for by the Party to the conflict in whose power they may be, without any adverse distinction founded on sex, race, nationality, religion, political opinions, or any other similar criteria. Any attempts upon their lives, or violence to their persons, shall be strictly prohibited; in particular, they shall not be murdered or exterminated, subjected to torture or to biological experiments; they shall not wilfully be left without medical assistance and care, nor shall conditions exposing them to contagion or infection be created...

First Geneva Convention, Article 50 - Repression of Abuses and Infractions; Grave breaches

> Article 50 — Grave breaches to which the preceding Article [Article 49, penal sanctions] relates shall be those involving any of the following acts, if committed against persons or property protected by the Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, and extensive destruction and appropriation of property, not justified by military necessity and carried out unlawfully and wantonly.

Second Geneva Convention (regarding members of armed forces at sea), Article 12 - Wounded, sick and shipwrecked, protection and care

> Article 12 — Members of the armed forces and other persons mentioned in the following Article, who are at sea and who are wounded, sick or shipwrecked, shall be respected and

> protected in all circumstances, it being understood that the term “shipwreck” means shipwreck from any cause and includes forced landings at sea by or from aircraft.
>
> Such persons shall be treated humanely and cared for by the Parties to the conflict in whose power they may be, without any adverse distinction founded on sex, race, nationality, religion, political opinions, or any other similar criteria. Any attempts upon their lives, or violence to their persons, shall be strictly prohibited; in particular, they shall not be murdered or exterminated, subjected to torture or to biological experiments; they shall not wilfully be left without medical assistance and care, nor shall conditions exposing them to contagion or infection be created...

Second Geneva Convention, Article 51 - Repression of Abuses and Infractions; penal sanctions; grave breaches

> Article 51 — Grave breaches to which the preceding Article [Article 50, penal sanctions] relates shall be those involving any of the following acts, if committed against persons or property protected by the Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, and extensive destruction and appropriation of property, not justified by military necessity and carried out unlawfully and wantonly.

Third Geneva Convention, (regarding prisoners of war), Article 13 - Humane treatment of prisoners

> Article 13 — Prisoners of war must at all times be humanely treated. Any unlawful act or omission by the Detaining Power causing death or seriously endangering the health of a prisoner of war in its custody is prohibited, and will be regarded as a serious breach of the present Convention. In particular, no prisoner of war may be subjected to physical mutilation or to medical or scientific experiments of any kind which are not justified by the medical, dental or hospital treatment of the prisoner concerned and carried out in his interest. Likewise, prisoners of war must at all times be protected, particularly against acts of violence or intimidation and against insults and public curiosity. Measures of reprisal against prisoners of war are prohibited.

Third Geneva Convention, Article 130, grave breaches

> Article 130 — Grave breaches to which the preceding Article [Article 129, penal sanctions] relates shall be those involving any of the following acts, if committed against persons or property protected by the Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, compelling a prisoner of war to serve in the forces of the hostile Power, or wilfully depriving a prisoner of war of the rights of fair and regular trial prescribed in this Convention.

Fourth Geneva Convention, (regarding civilian persons) Article 32 - Prohibition on corporal punishment, torture, etc.

> Article 32 — The High Contracting Parties specifically agree that each of them is prohibited from taking any measure of such a character as to cause the physical suffering or extermination of protected persons in their hands. This prohibition applies not only to murder, torture, corporal punishment, mutilation and medical or scientific experiments not necessitated by the medical treatment of a protected person, but also to any other measures of brutality whether applied by civilian or military agents.

Fourth Geneva Convention, Article 146. — Execution of the Convention; Penal sanctions

> Article 146 - The High Contracting Parties undertake to enact any legislation necessary to provide effective penal sanctions for persons committing, or ordering to be committed, any of the grave breaches of the present Convention defined in the following Article.
>
> Each High Contracting Party shall be under the obligation to search for persons alleged to have committed, or to have ordered to be committed, such grave breaches, and shall bring such persons, regardless of their nationality, before its own courts. It may also, if it prefers, and in accordance with the provisions of its own legislation, hand such persons over for trial to another High Contracting Party concerned, provided such High Contracting Party has made out a *prima facie* case.
>
> Each High Contracting Party shall take measures necessary for the suppression of all acts contrary to the provisions of the present Convention other than the grave breaches defined in the following Article.
>
> In all circumstances, the accused persons shall benefit by safeguards of proper trial and defence, which shall not be less favourable than those provided by Article 105 and those following of the Geneva Convention relative to the Treatment of Prisoners of War of August 12, 1949.

Fourth Geneva Convention, Article 147. — Execution of the Convention; grave breaches

> Article 147 — Grave breaches
>
> Grave breaches to which the preceding Article relates shall be those involving any of the following acts, if committed against persons or property protected by the present Convention: wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health, unlawful deportation or transfer or unlawful confinement of a protected person, compelling a protected person to serve in the forces of a hostile Power, or wilfully depriving a protected person of the rights of fair and regular trial prescribed in the present Convention, taking of hostages and extensive destruction and appropriation of property, not justified by military necessity and carried out unlawfully and wantonly.

1970
WHO, Health Aspects of Chemical and Biological Weapons

In 1970, the World Health Organization published a report titled "Health Aspects of Chemical and Biological Weapons.

At p. 12, the authors provided working definitions.

WHO defined chemical agents of warfare as "all substances employed for their toxic effects on man, animals, or plants," but excluding "chemicals now employed in warfare such as high explosives, smoke, and incendiary substances (e.g., napalm, magnesium, and white phosphorus) that exert their primary effects through physical force, fire, air-deprivation or reduced visibility."

WHO defined 'biological agents' as including "those that depend for their effects on multiplication within the target organism, and are intended for use in war to cause disease or death in man, animals or plants," and excluding "toxins elaborated by some microbes (e.g., botulinal toxin and staphylococcal enterotoxin) when they are preformed outside the target organism" noting "in some discussions of chemical and biological weapons, such toxins are classified as biological agents because the technology of their production resembles that of biological agents rather than that of chemical agents."

WHO defined a 'lethal agent' as "one intended to cause death when man is exposed to concentrations well within the capability of delivery for military purposes," noting "in lower doses, such agents can cause severe and sustained disability and certain of them may act predominantly in this way when employed in combat."

WHO defined an 'incapacitating agent' as "one intended to cause temporary disease or to induce temporary mental or physical disability, the duration of which greatly exceeds the period of exposure," noting

> No sharp line of demarcation can be drawn between lethal and incapacitating agents used in chemical and biological warfare, because incapacitating agents can be lethal or permanently disabling under certain circumstances (e.g., in the presence of malnutrition or pre-existing disease; in infants or the aged; or when there is exposure to unusually high doses, as in enclosed spaces or in close proximity to functioning chemical or biological weapons). For similar reasons, no sharp demarcation line can be drawn between harassing agents and other anti-personnel chemical agents; furthermore, harassing agents may be used in war in conjunction with high-explosive, fragmentation or other weapons to increase the lethal effectiveness of the latter-as distinct from their employment in riot control in order to reduce injuries and to save lives.

WHO defined a 'harassing agent (or short term incapacitant)' as "one capable of causing a rapid disablement that lasts for little longer than the period of exposure" and referred again to the note about "no sharp line of demarcation."

WHO defined 'casualties' as "deaths or disabilities."

1972-1975:
UN Convention on Bacteriological (Biological) and Toxin Weapons

The UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, opened for signatures 1972 and entered into force in 1975.

> Article I.
>
> Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
>
> 1. microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
>
> 2. weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict...
>
> Article II.
>
> Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, which are in its possession or under its jurisdiction or control.
>
> Article X.
>
> 1. The State Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also co-operate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes.
>
> 2. This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international co-operation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

Discussion

The 1972 UN Convention did not prohibit use of biological and toxin weapons, only development, production, stockpiling, acquisition and retention.

The 1972 UN convention on biological, bacteriological and toxin weapons did not prohibit all biological agents, only those "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes."

The convention only prohibited weapons, equipment or delivery systems related to using biological agents or toxins "for hostile purposes or in armed conflict."

The 1972 UN Convention explicitly ratified exchange of "equipment, materials and scientific and technological information" for purposes deemed to be peaceful, such as "prevention of disease."

The 1972 UN Convention did not define the terms prophylactic, protective or peaceful purposes, and did not provide for physical evidence, evidentiary standards or fact-finding procedures or venues to establish or disprove claims that the purpose of any given biological agent was peaceful, prophylactic, protective or capable of contributing to prevention of disease.

1976 UN International Covenant on Civil and Political Rights

Article 7 - No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

1977 Additional Protocols to the Geneva Conventions

Additional Protocol I, "relating to the protection of victims of international armed conflicts."

Additional Protocol II, "relating to the protection of victims of non-international armed conflicts."

Additional Protocol I, Article 11

> Article 11
>
> 1. The physical or mental health and integrity of persons who are in the power of the adverse Party or who are interned, detained or otherwise deprived of liberty as a result of a situation referred to in Article 1 shall not be endangered by any unjustified act or omission. Accordingly, it is prohibited to subject the persons described in this Article to any medical procedure which is not indicated by the state of health of the person concerned and which is not consistent with generally accepted medical standards which would be applied under similar medical circumstances to persons who are nationals of the Party conducting the procedure and who are in no way deprived of liberty.
>
> 2. It is, in particular, prohibited to carry out on such persons, even with their consent:
>
> *a)* physical mutilations;
> *b)* medical or scientific experiments;
> *c)* removal of tissue or organs for transplantation,
>
> except where these acts are justified in conformity with the conditions provided for in paragraph 1...
>
> 4. Any wilful act or omission which seriously endangers the physical or mental health or integrity of any person who is in the power of a Party other than the one on which he depends and which either violates any of the prohibitions in paragraphs 1 and 2 or fails to comply with the requirements of paragraph 3 shall be a grave breach of this Protocol.

Additional Protocol I, Article 75

> Article 75 - Fundamental guarantees...
>
> 2. The following acts are and shall remain prohibited at any time and in any place whatsoever, whether committed by civilian or by military agents:
>
> a) violence to the life, health, or physical or mental well-being of persons, in particular:
>
> > i) murder;
> > ii) torture of all kinds, whether physical or mental;
> > iii) corporal punishment; and
> > iv) mutilation...

Additional Protocol II, Article 4 - Fundamental guarantees

> 4(2) Without prejudice to the generality of the foregoing, the following acts against the persons referred to in paragraph 1 are and shall remain prohibited at any time and in any place whatsoever:
>
> *a)* violence to the life, health and physical or mental well-being of persons, in particular murder as well as cruel treatment such as torture, mutilation or any form of corporal punishment;

Additional Protocol II, Article 5 - Persons whose liberty has been restricted

> Article 5(2) Those who are responsible for the internment or detention of the persons referred to in paragraph 1 shall also, within the limits of their capabilities, respect the following provisions relating to such persons:...
>
> > (e) their physical or mental health and integrity shall not been dangered by any unjustified act or omission. Accordingly, it is prohibited to subject the persons described in this Article to any medical procedure which is not indicated by the state of health of the person concerned, and which is not consistent with the generally accepted medical standards applied to free persons under similar medical circumstances.

1984-1987 UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment

The UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment opened for signature in1984 and entered into force in 1987.
entry into force 26 June 1987

Article 1

1. For the purposes of this Convention, the term "torture" means any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions.

2. This article is without prejudice to any international instrument or national legislation which does or may contain provisions of wider application.

Article 2

1. Each State Party shall take effective legislative, administrative, judicial or other measures to prevent acts of torture in any territory under its jurisdiction.

2. No exceptional circumstances whatsoever, whether a state of war or a threat of war, internal political instability or any other public emergency, may be invoked as a justification of torture.

3. An order from a superior officer or a public authority may not be invoked as a justification of torture...

Article 4

1. Each State Party shall ensure that all acts of torture are offences under its criminal law. The same shall apply to an attempt to commit torture and to an act by any person which constitutes complicity or participation in torture. 2. Each State Party shall make these offences punishable by appropriate penalties which take into account their grave nature.

Article 8

1. The offences referred to in article 4 shall be deemed to be included as extraditable offences in any extradition treaty existing between States Parties. States Parties undertake to include such offences as extraditable offences in every extradition treaty to be concluded between them.

1988 - UN Body of Principles for the Protection of All Persons under Detention or Imprisonment

Principle 22 - No detained or imprisoned person shall, even with his consent, be subjected to any medical or scientific experimentation which may be detrimental to his health.

1993-1997 - UN Chemical Weapons Convention

UN Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction opened for signatures in 1993 and entered into force in 1997.

Article I, General Obligations

1. Each State Party to this Convention undertakes never under any circumstances:

(a) To develop, produce, otherwise acquire, stockpile or retain chemical weapons, or transfer, directly or indirectly, chemical weapons to anyone;
(b) To use chemical weapons;
(c) To engage in any military preparations to use chemical weapons;
(d) To assist, encourage or induce, in any way, anyone to engage in any activity prohibited to a State Party under this Convention.

2. Each State Party undertakes to destroy chemical weapons it owns or possesses, or that are located in any place under its jurisdiction or control, in accordance with the provisions of this Convention.

3. Each State Party undertakes to destroy all chemical weapons it abandoned on the territory of another State Party, in accordance with the provisions of this Convention.

4. Each State Party undertakes to destroy any chemical weapons production facilities it owns or possesses, or that are located in any place under its jurisdiction or control, in accordance with the provisions of this Convention.

5. Each State Party undertakes not to use riot control agents as a method of warfare.

Article II, Definitions and Criteria

For the purposes of this Convention:

1. "Chemical Weapons" means the following, together or separately:

(a) Toxic chemicals and their precursors, except where intended for purposes not prohibited under this Convention, as long as the types and quantities are consistent with such purposes;

(b) Munitions and devices, specifically designed to cause death or other harm through the toxic properties of those toxic chemicals specified in subparagraph (a), which would be released as a result of the employment of such munitions and devices;

(c) Any equipment specifically designed for use directly in connection with the employment of munitions and devices specified in subparagraph (b).

2. "Toxic Chemical" means:

Any chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. This includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere.

(For the purpose of implementing this Convention, toxic chemicals which have been identified for the application of verification measures are listed in Schedules contained in the Annex on Chemicals.)

3. "Precursor" means:

Any chemical reactant which takes part at any stage in the production by whatever method of a toxic chemical. This includes any key component of a binary or multicomponent chemical system.

(For the purpose of implementing this Convention, precursors which have been identified for the application of verification measures are listed in Schedules contained in the Annex on Chemicals.)

9. "Purposes Not Prohibited Under this Convention" means:

(a) Industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes;

(b) Protective purposes, namely those purposes directly related to protection against toxic chemicals and to protection against chemical weapons;

(c) Military purposes not connected with the use of chemical weapons and not dependent on the use of the toxic properties of chemicals as a method of warfare;

(d) Law enforcement including domestic riot control purposes.

Discussion

The terms of the UN Chemical Weapons Convention protected the right of each party "to develop, produce, otherwise acquire, retain, transfer and use toxic chemicals and their precursors for purposes not prohibited under this Convention."

The terms of the convention required each State Party to "make an initial declaration on relevant chemicals and facilities in accordance with the Verification Annex." Article VI(7)

The Annex on Chemicals included guidelines for classification of chemical compounds as Schedule 1, Schedule 2 or Schedule 3, followed by lists of chemicals under each schedule heading.

The Verification Annex to the UN Chemical Weapons Convention defined "discrete organic chemical" to mean "any chemical belonging to the class of chemical compounds consisting of all compounds of carbon except for its oxides, sulfides and metal carbonates, identifiable by chemical name, by structural formula, if known, and by Chemical Abstracts Service registry number, if assigned." Verification Annex

Under a part titled "activities not prohibited under this convention in accordance with Article VI," the Verification Annex required that the initial declaration made by each State Party listing "relevant chemicals and facilities" include

> "a list of all plant sites that: (a) Produced by synthesis during the previous calendar year more than 200 tonnes of unscheduled discrete organic chemicals; or (b) Comprise one or more plants which produced by synthesis during the previous calendar year more than 30 tonnes of an unscheduled discrete organic chemical containing the elements phosphorus, sulfur or fluorine (hereinafter referred to as "PSF-plants" and "PSF-chemical"). Verification Annex, Part IX.

Through a May 16, 1997 decision by the Convention of State Parties, the parties expressed the "understanding" that the requirement for declaring all plant sites producing "unscheduled discrete organic chemical" does not "cover" plants producing "unscheduled discrete organic chemicals" in the form of "oligomers and polymers, whether or not containing phosphorus, sulfur or fluorine" nor plants producing "chemicals only containing carbon and metal." UN-OPCW C-I/DEC.39

Oligomers and polymers, as "discrete organic chemicals" exempt from plant disclosures and production prohibitions under the UN Chemical Weapons Convention, include proteins, nucleic acids, and other biological macromolecules formed by living organisms through cell and tissue culture, propagation and fermentation methods used in vaccine production.

1998 - Rome Statutes of the International Criminal Court

Article 8. War crimes

1. The Court shall have jurisdiction in respect of war crimes in particular when committed as part of a plan or policy or as part of a large-scale commission of such crimes.

2. For the purpose of this Statute, "war crimes" means:

(a) Grave breaches of the Geneva Conventions of 12 August 1949, namely, any of the following acts against persons or property protected under the provisions of the relevant Geneva Convention:

(i) Wilful killing;
(ii) Torture or inhuman treatment, including biological experiments;
(iii) Wilfully causing great suffering, or serious injury to body or health;...

(b) Other serious violations of the laws and customs applicable in international armed conflict, within the established framework of international law, namely, any of the following acts:

(iii) Intentionally directing attacks against personnel, installations, material, units or vehicles involved in a humanitarian assistance or peacekeeping mission in accordance with the Charter of the United Nations, as long as they are entitled to the protection given to civilians or civilian objects under the international law of armed conflict;

(x) Subjecting persons who are in the power of an adverse party to physical mutilation or to medical or scientific experiments of any kind which are neither justified by the medical, dental or hospital treatment of the person concerned nor carried out in his or her interest, and which cause death to or seriously endanger the health of such person or persons;

(xvii) Employing poison or poisoned weapons; [inserted Dec. 14, 2017]

(xviii) Employing asphyxiating, poisonous or other gases, and all analogous liquids, materials or devices; [inserted Dec. 14, 2017]

(xxvii) Employing weapons, which use microbial or other biological agents, or toxins, whatever their origin or method of production. [inserted Dec. 14, 2017]

2.(e) Other serious violations of the laws and customs applicable in armed conflicts not of an international character, within the established framework of international law, namely, any of the following acts:...

(xi) Subjecting persons who are in the power of another party to the conflict to physical mutilation or to medical or scientific experiments of any kind which are neither justified by the medical, dental or hospital treatment of the person concerned nor carried out in his

or her interest, and which cause death to or seriously endanger the health of such person or persons;

(xiii) Employing poison or poisoned weapons; [inserted June 11, 2010]

(xiv) Employing asphyxiating, poisonous or other gases, and all analogous liquids, materials or devices;... [inserted June 11, 2010]

(xvi) Employing weapons, which use microbial or other biological agents, or toxins, whatever their origin or method of production. [inserted Dec. 14, 2017]

The United States signed the Rome Statute of the International Criminal Court in 1998 but withdrew its signature in 2002.

2005 - International Committee of the Red Cross
Customary Rules of International Humanitarian Law

Weapons - General Principles on the Use of Weapons

Rule 70. The use of means and methods of warfare which are of a nature to cause superfluous injury or unnecessary suffering is prohibited. [International Armed Conflicts and Non-International Armed Conflicts]

Rule 71. The use of weapons which are by nature indiscriminate is prohibited. [IAC/NIAC]

Rule 72 - The use of poison or poisoned weapons is prohibited. [IAC/NIAC]

Rule 73 - Biological weapons - The use of biological weapons is prohibited. [IAC/NIAC]

Rule 74. Chemical weapons - The use of chemical weapons is prohibited. [IAC/NIAC]

Rule 75. Chemical weapons - The use of riot-control agents as a method of warfare is prohibited. [IAC/NIAC]

Rule 76. Chemical weapons - The use of herbicides as a method of warfare is prohibited if they:

(a) are of a nature to be prohibited chemical weapons;
(b) are of a nature to be prohibited biological weapons;
(c) are aimed at vegetation that is not a military objective;
(d) would cause incidental loss of civilian life, injury to civilians, damage to civilian objects, or a combination thereof, which may be expected to be excessive in relation to the concrete and direct military advantage anticipated; or
(e) would cause widespread, long-term and severe damage to the natural environment. [IAC/NIAC]

Treatment of Civilians and Persons Hors de Combat - Fundamental guarantees

Rule 92. Mutilation, medical or scientific experiments or any other medical procedure not indicated by the state of health of the person concerned and not consistent with generally accepted medical standards are prohibited. [IAC/NIAC]

Appendix

Further evidence supporting the findings and conclusions contained herein may be found in the following documents. These are a small subset of the available documentary evidence.

2012 to present, specific to Covid-19 events and Covid-19 vaccines

US-HHS Secretary, public health emergency determinations and declarations
US-HHS Secretary, PREP Act liability immunity declarations
Jackson v. Pfizer, court case documents
Contracts - Pfizer/BioNTech/ATI/DOD
Contracts - Pfizer/ purchasing countries
Contract - Emergent Manufacturing Operations (June 2012)
US-FDA Form 483, Rentschler (2022), FDA inspectors "observed the simulated fill process"
Pfizer/BioNTech application, emergency use authorization (EUA)
US-FDA EUA Review memo, etc.
Federal Register notices/EUA approval, multiple products
BioNTech BLA application and CMC submissions
US-FDA BLA CMC Review, redacted
US-FDA BLA approval letter, redacted
Pfizer/BioNTech Comirnaty labels - US License No. 2229
Pfizer-BioNTech Comirnaty fact sheets
US-HHS Office of General Counsel opinions re: PREP Act
US-DOJ Office of General Counsel opinion re: EUA product mandates
Bridges v. Houston Methodist Hospitals, court case documents

Communicable disease control, vaccine manufacturing and vaccination generally

1903-present - US federal agency regulations (Code of Federal Regulations and precursor regulations prescribed under 1902 Virus-Toxin law), implementing statutes, especially pertaining to establishment standards, inspections, samples, characterization, labeling, purity tests, potency tests, sterility tests, general safety tests, lot release, biomarkers, surrogate endpoints, inactivation procedures, viability testing protocols, sample retention, and records retention, including clauses on exemptions, exclusions, waivers and alternatives.

US Pharmacopeia and National Formulary records "not intended to convey requirements enforceable by regulatory agencies," especially pertaining to, vaccines, gene therapies, biological assays, sterility, stability, bacterial endotoxins, residual host cell proteins, etc.

1998-present - Mutual Recognition Agreements, international harmonisation documents.

1910 - Report, *Vaccine Virus* (Milton J. Rosenau, Director, 1899-1909, US-PHS Hygienic Laboratory, precursor to NIH, Journal of American Medical Association)

> Vaccine virus is the specific principle in the material obtained from the skin eruption of calves having a disease known as vaccinia [cowpox]…
>
> both the pulp and the lymph are mixtures containing epithelial cells, serum, blood, leucocytes, products of inflammation, debris, bacteria, etc., in varying proportions."
>
> the specific principle of vaccinia [cowpox] is unknown...
>
> it is impossible to obtain vaccine virus free from the bacteria of the skin...
>
> the fact that a serum or vaccine is granted a license does not mean that it is a valuable curative or prophylactic; in fact, it may have little or no therapeutic value...
>
> it is evidently the province of the medical profession to determine for itself whether a certain substance has therapeutic value or not. The chief concern of the government is to protect the practitioner against sophistications, impurities, faults or mislabeling...

On resistance from US Pharmacopeia officials to adding *vaccine virus* to the US Pharmacopeia, Rosenau wrote:

> The objection, that vaccine virus is an indefinite substance, the ‘active principle’ of which is not known, is no longer valid, for the Pharmacopeia contains many such substances, including the ferments, against which similar objection holds.
>
> The objection that vaccine virus cannot be “assayed” by the average druggist also lacks force when we recall that the potency and purity of vaccine virus in interstate traffic is cared for by the federal government under the law of July 1, 1902, which relieves the pharmacist of this responsibility…

1910 - Report, *The Federal Control of Serums, Vaccines, Etc*. (Milton J. Rosenau, Director,

1899-1909, US-PHS Hygienic Laboratory [precursor to NIH], Journal of American Medical Association)

> "The government does not guarantee that each vaccine point or each package of antitoxin will produce its full therapeutic effect and be free from all danger. This would be impracticable with the extent and variety of the business in biologic products now carried on in this country and abroad..."

1913, book and lecture, *Anaphylaxis* (Charles Richet, Nobel Prize Lecture)

> *Phylaxis*, a word seldom used, stands in the Greek for protection. *Anaphylaxis* will thus stand for the opposite. Anaphylaxis, from its Greek etymological source, therefore means that state of an organism in which it is rendered hypersensitive, instead of being protected.
>
> To make this plain, we will consider the example of a subject that has received a poison.
>
> Let us suppose the dosage to be moderate and that after a few days the subject is, or at least appears to be, normal. If, at this point, a further injection is given of the same dosage of the same poison, what will happen?
>
> There are three possibilities.
>
> The first and simplest is that there has been no change in the organism and that in receiving the same dosage as one month previously, exactly the same phenomena will result, in exactly the same conditions. Naturally this is what happens most of the time. Specialists and doctors work on this assumption when they repeat the intoxication at one month intervals.
>
> The second possibility is that the subject has become less sensitive. In other words, the preceding intoxication has produced a certain condition of tolerance or non-sensitivity. This will mean that a stronger dose is necessary at the second injection to give the same results. This is the case of (relative) immunization or, as it is some8mes called, of *mithridatism*. The most remarkable case of this tolerance is to be seen when opium or morphine are used...
>
> These two cases, of unchanged sensitivity or *stability*, and of diminished sensitivity or *habituation*, have been known since long. Now I have shown that there is a third possibility, frequently to be observed in certain conditions which I have specified: this is of heightened sensitivity. The first injection, instead of protecting the organism, renders it more fragile and more susceptible. This is anaphylaxis...
>
> ...In 1903 Arthus, in Lausanne, showed that a first intravenous injection of serum on a

> rabbit causes anaphylaxis, i.e. three weeks after the first injection the rabbit is hypersensitive to the second injection. The phenomenon of anaphylaxis was becoming of general application. Instead of applying only to toxins and toxalbumins, it held good for all proteins, whether toxic at the first injection or not.
>
> Two years later Rosenau and Anderson, two American physiologists, demonstrated in a noteworthy piece of work that the phenomenon of anaphylaxis occurs after every injection of serum, even when the injection is minute, for example of 0.00001 ml which is an infinitely small amount but nevertheless sufficient to anaphylactize an animal.
>
> They quoted examples of anaphylaxis from all organic liquids: milk, serum, egg, muscle extract. They specified the reaction and clearly showed that of all the subjects, the guinea-pig appeared the most sensitive in anaphylactic terms....

1924-present, Congressional hearing transcripts, Congressional Record of Congressional proceedings.

> The law regulating the sale of these serums and toxins for human beings makes but one requirement, and that is that this stuff, whether dirt or dung, or whatever it is, shall be put up in a laboratory which is hygienically conducted. An inspector can go in and say that the methods are clean, and on that basis alone they are regulated… (1924, Rathbone hearings)

1944-present - Presidential executive orders, Presidential Decision Directives, Homeland Security Presidential Directives, Presidential Emergency Action Documents, and executive memoranda (i.e. National Security Decision Memoranda, National Science and Technology Council reports)

1947-present, World Health Organization (WHO), Expert Committee on Biological Standardization, reports (Technical Report Series/TRS, etc.)

1953 - Report, Public Health Aspects of the New Insecticides, Morton S. Biskind, American Journal of Digestive Diseases, re: physiological effects of chlorinated cyclic hydrocarbons and organic phosphorous compounds, "closely related to the 'nerve gases' of chemical warfare, and lethal for man in minute doses."

1935-present, Congressional funding of research, development, vaccination and liability indemnification programs through States, foreign assistance and Medicaid/CHIP programs

- Social Security Act of 1935 (PL 74-271), Title V, *Maternal and Child Health*;
- Social Security Amendments Act of 1965 (PL 89-97, *Grants to states for medical assistance programs*)
- Social Security Amendments of 1967 (PL 90-248, barring State compulsion for medical treatment over religious objections for "any purpose...other than for the purpose of discovering and preventing the spread of infection or contagious disease...," 42 USC 1396f);

- NIH Revitalization Act of 1993 (PL 103-43, *Children's Vaccine Initiative,* 42 USC 283d)
- Omnibus Budget Reconciliation Act of 1993 (PL 103-66, *Program for Distribution of Pediatric Vaccines,* 42 USC 1396s)
- Foreign Assistance Act of 1973 (PL 93-189, *Population planning and health,* 22 USC 2151b) as amended by International Security and Development Cooperation Act of 1985 (PL 99-83, *Promotion of immunization* of infants, children and expectant mothers in low-income countries, 22 USC 2151b(c)); and National Defense Authorization Act for FY2023 (PL 117-263, *Global Health Security and International Pandemic Prevention, Preparedness and Response Act*, "strengthening vaccine readiness; reducing vaccine hesitancy; delivering and administering vaccines.." 22 USC 2151b, note)

See also, Drug Export Amendments Act of 1986, (PL 99-660, *Export of certain unapproved products* to specified European counties, Canada, Australia, New Zealand, covered in 1986 section on 42 USC 262 in Section 3 of this report.

1955 - Report, *Technical Report on Poliomyelitis Vaccine,* (Public Health Service staff, Public Health Reports)

1955 - Report, *Effects of Routine Immunization of Children with Triple Vaccine: Diphtheria-Tetanus-Pertussis*. (Johannes Ipsen and Harry E. Bowen, American Journal of Public Health, re: "serologic epidemiology.")

1958 - Report, *Federal Regulation of Biologicals Applicable to the Disease of Man*, Parke M. Banta, General Counsel, Dept. of Health, Education and Welfare, Food, Drug, Cosmetic Law Journal)

> "[T]here has not been since the enactment of the statute in 1902 any litigation directly involving its application or interpretation; no one has been penalized for its violation nor, so far as I know, charged under its any penalty provisions with any violation of any of its provisions. Moreover, I am informed that no license has been suspended or revoked over the protest of the licensee."

1963, 1968, 1975 - Book editions, *Clinical Aspects of Immunology,* 'Classification of allergic reactions responsible for clinical hypersensitivity and disease,' Philip Gell, R.R.A. Coombs, and P.J. Lachmann, eds.)

1965 Restatement (Second) of Torts, Section 402A, comment k re: "unavoidably unsafe products"

1972 - Report series, *Division of Biologics Standards: In the Matter of J. Anthony Morris*; *Division of Biologics Standards: Scientific Management Questioned*; *DBS: Officials Confused over Powers*; *Division of Biologics Standards: The Boat That Never Rocked*; *DBS: Agency Contravenes Its Own Regulations* (Nicholas Wade, *Science*) re: internal memo by Joseph Smadel, Sept. 18, 1962, ordering Morris to pass vaccines on the basis of manufacturers' tests alone. Memo: "The manufacturer will provide full data on the potency assay of his lots which are submitted for release. Furthermore, release by the DBS will be on the basis of data submitted by the manufacturer and not on the basis of results obtained in this institution."

1972 - Report, *Problems involving the effectiveness of Vaccines* (US-General Accounting Office/GAO, Comptroller General)

1976, 1988 - Federal "emergency" law enacted by Congress other than the federal "public health emergency" law (42 USC 247d) and invoked for "Covid-19," including National Emergencies Act 1976 (PL 94-412, 50 USC Ch. 34) and Stafford Act of 1988 (PL 100-707, 42 USC Ch. 68)

1978 - Report, *Swine Flu Chronology January 1976—March 1977* from *The Swine Flu Affair: Decision-Making on a Slippery Disease* (RE Neustadt, HV Fineberg, National Academies Press)

1980 - Report, *Answers to Questions on Selected FDA Bureau of Biologics' Regulation Activities* (US General Accounting Office/GAO, Comptroller General)

1985 to present - US-FDA Points to Consider and Guidance for Industry documents, non-binding, especially pertaining to manufacturing and labeling of biological products.

1985 - Book, *Vaccine Supply and Innovation* (National Academy of Sciences)

1988 - 5th Cir. Court of Appeals: *Hurley v. Lederle*, 863 F.2d 1173 (1988), US-FDA as "passive agency."

1992 - Book, Biologic Markers in Immunotoxicology (National Academy of Sciences)

> …This document presents a brief history and review of immunology, immunotoxicology, and biologic markers (Chapters 1 and 2). The effects of toxicants on the immune system can be expressed in two ways. Excessive stimulation can result in hypersensitivity or autoimmunity; suppression can result in the increased susceptibility of the host to infectious and neoplastic agents...
>
> Hypersensitivity (Chapter 3) has become an important human health problem in industrialized societies. Inhalation of a variety of chemicals can cause asthma, rhinitis, pneumonitis, or chronic granulomatous pulmonary disorders. Hypersensitivity is an immunologically based host response to a compound or its metabolic products...
>
> Autoimmune disease occurs when an immune system attacks the body's own tissues or organs, resulting in functional impairment, inflammation, and occasionally, permanent tissue damage (Chapter 4). Some xenobiotics are known to induce autoimmunity…
>
> ...Immunotoxicology formally emerged as a distinct discipline within toxicology during the 1970s (Descotes, 1988), prompted by animal studies that demonstrated the researcher's ability to measure the effects of chemicals on the immune system (Koller, 1980; Vos, 1980; Dean et al., 1982; Luster et al., 1982).
>
> ... Mechanisms of Chemically Induced Immune Disease

> Exposure to immunotoxicants can cause immunologic suppression, resulting in altered host resistance. The outcome of immune suppression is influenced by the dose and mechanism of action of the immunotoxicant along with concomitant exposure to other agents, such as bacteria, viruses, parasites, or chemicals at levels so low they might normally be innocuous...
>
> Xenobiotics also can act as sensitizers to stimulate the immune system as antigens by provoking a substantial immune response that leads to hypersensitivity...
>
> Diseases that are immune-reaction mediated include rheumatoid arthritis, some types of diabetes, and myasthenia gravis...
>
> An older classification of immune reactions, developed by Gell and Coombs (Gell et al., 1975), is noted in Table 2-1 for comparison."

1994 - Book, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* (National Academy of Sciences)

> ...A classification of immunologic reactions that can cause disease has been proposed by Coombs and Gell (1968). Four reactions make up the classification: type I, immediate hypersensitivity, the most serious clinical manifestation of which is anaphylaxis; type II, reaction of antibody with tissue antigens; type III, Arthus- type reaction, caused by deposition of antigen- antibody complexes in tissues, leading to the tissue-damaging effects of complement and leukocytes; and type IV, delayed-type hypersensitivity, which is mediated largely by T lymphocytes and macrophages.
>
> In clinical reactions to foreign antigens, these categories frequently overlap.
>
> These reactions are a by-product of the body's capacity to reject foreign invasion, particularly by microorganisms...

1995 - Policy documents, *National Performance Review: Reinventing Regulation of Drugs and Medical Devices*; *National Performance Review: Reinventing the Regulation of Drugs Made from Biotechnology* (President William Clinton and Vice-President Al Gore)

2001 - State "public health emergency" law; Model State Emergency Health Powers Act (Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, US-HHS CDC), provisions enacted before and since 2001 by state legislatures and executives.

2006-present - Reports by US-DOJ, US-HHS-CDC, US-DHS, US-DHS-FEMA, US-DoD, including *Role of Law Enforcement in Public Health Emergencies* (2006); *A Framework for Improving Cross-Sector Coordination for Emergency Preparedness and Response* (2008) and other reports.

2010 - Book, *Sequence Based Classification of Select Agents: A Brighter Line* (Committee on Scientific Milestones for the Development of a Gene Sequence-Based Classification System for the Oversight of Select Agents, National Academies of Sciences, Engineering and Medicine)

> A sequence-based prediction system for oversight of Select Agents is not possible now and will not be possible in the usefully near future.
>
> - Select Agent is not a biological term; rather it is a regulatory designation. Some properties historically considered in assigning an organism to the Select Agent list are not biological properties, and therefore, can never be determined from the organism's genome sequence.
> - High-level biological phenotypes—such as pathogenicity, transmissibility, and environmental stability—cannot plausibly be predicted with the degree of certainty required for regulatory purposes, either now or in the foreseeable future.
> - Reliable prediction of the hazardous properties of pathogens from their genome sequence alone will require an extraordinarily detailed understanding of host, pathogen, and environment interactions integrated at the systems, organism, population, and ecosystem levels. It is a prediction problem of the greatest complexity.
> - Biology is not binary. Microorganisms are not either "potential weap- ons of mass destruction" or "of no concern." No single characteristic makes a microorganism a pathogen, and no clear-cut boundaries that separate a pathogen from a non-pathogen. Pathogenic microorganisms are not defined by taxonomy; it is common for a given microbial species to have both pathogenic and non-pathogenic representatives. An agent has multiple biological attributes, and the degree to which these are expressed fall along a spectrum for each biological characteristic;1 consequently, agents present varying degrees of risk.

2010 - Report, *Seeking Biosecurity Without Verification: The New U.S. Strategy on Biothreats* (Jonathan B. Tucker, Arms Control Association)

2011 - Court case, *Bruesewitz v. Wyeth*, 562 U.S. 223 (SCOTUS, 2011)

> "[T]he FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use."

2011 - WHO manual for the establishment of national and other secondary standards for vaccines

> "*Biologicals* are substances which cannot be fully characterized by physico-chemical means alone, and which therefore require the use of some form of *bioassay*...a laboratory procedure for the estimation of the nature or potency of a material by means of the reaction that follows its application to some elements of a living system (examples include animals, tissues, cells, receptors and enzymes)..."

2012 - *Parker v. St. Lawrence,* 102 A.D.3d 140, (Appellate Division of Supreme Court of New York, 2012)

> Considering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent...

2014-present - US federal agency, interagency memorandums of understanding (MOUs) and MOUs between US federal agencies and non-government organizations (incl. BMGF), re: countermeasures development, select agent classification, "regulatory science" and related.

2014 - Report, *Convergence of Chemistry and Biology* (Organisation for the Prohibition of Chemical Weapons [OPCW] Scientific Advisory Board)

2015 - Report, *Verification* (OPCW Scientific Advisory Board)

> A discrete organic chemical (DOC) is a molecule comprising a definite number of atoms bonded together by chemical bonds and weak intermolecular forces. A DOC can exist in a pure form or in either a mixture or a solution. The word “discrete” in the Convention definition does not imply that DOCs are produced in pure form.
>
> The Convention defines the term discrete organic chemical as “any chemical belonging to the class of chemical compounds consisting of all compounds of carbon except for its oxides, sulfides and metal carbonates, identifiable by chemical name, by structural formula, if known, and by Chemical Abstracts Service (CAS) registry number, if assigned”.
>
> In this respect, the Convention defines “unscheduled discrete organic chemicals containing the elements phosphorus, sulfur or fluorine” as PSF chemicals...
>
> Bio-mediated production of chemicals has been available for decades and commercialised for products ranging from antibiotics to amino acids and peptides. The volume and number of chemicals being produced by bio-mediated synthesis continues to increase. Many of these chemicals meet the definition of a DOC.
>
> Currently, there is a lack of consistency in how States Parties declare plant sites which produce DOCs. One inconsistency applies to the declaration of chemical mixtures containing DOCs, another applies to how States Parties declare plant sites that produce DOCs via bio-mediated production methods.

2016 - Report, *Early Developments in the Regulation of Biologics* (Terry S. Coleman, Food and Drug Law Journal)

> Although the archives have been purged of PHS documents related to the legislation [1902 Virus-Toxin law], the circumstantial evidence that the bill was a joint undertaking

> of the industry and PHS is overwhelming. The Republican-controlled Fifty-Seventh Congress was conservative, allied with big business, and hostile to governmental regulation of business.
>
> Nevertheless, the bill flew through Congress with amazing speed and almost invisibly—there were no committee hearings, no request for a report from the Administration, no "active steps" by PHS to further its adoption, no public statements or speeches about the bill, no floor debate, and no recorded votes, and both Houses passed the bill in the closing days of the session in June 1902.

2017 - Report, *Recalibrating Vaccination Laws* (Efthimios Parasidis, Boston University Law Review)

> [T]the [National Childhood] Vaccine [Injury] Act [of 1986] does not mandate that data integral to evaluating causation be collected by manufacturers, submitted to regulators, or made available to the public.

2018 - Court case, *Dean* v. *HHS,* No. 16–1245V, 2018 WL 3104388, at * 9 (Fed. Cl. Spec. Mstr. May 29, 2018), defining ''vaccine'' as ''any substance designed to be administered to a human being for the prevention of 1 or more diseases'') (quoting 26 U.S.C. 4132(a)(2)).

2018 - *Informed Consent Action Network (ICAN) v. US-HHS*, (USDC, Southern District New York, 18-cv-03215), stipulation: "The [Department]'s searches for records did not locate any records responsive to your request" for records of safety monitoring for the national childhood vaccination program, under the 1986 NCVIA law, between 1986 and 2017.

2025 - Book, *Legal history of non-regulation of biological products*[55] (Katherine Watt and Lydia Hazel)

See also:

Biomedical science: anaphylaxis. Work by Ignaz Semmelweis, Francois Magendie, Maurice Arthus, Charles Richet, Milton Rosenau, Clemens von Pirquet, Bela Schick, P. Coombs, R.R.A. Gell, and others on induction of anaphylaxis, allergies, blood disorders, organ damage and death by injection of foreign biological and chemical matter into the blood through natural and artificial wounds.

Biomedical science: bacteriology, pathology, virology, epidemiology, preventive medicine. Work by Louis Pasteur, Robert Koch, John Enders, Stefan Lanka and Jamie Andrews on infeasible scientific methods for isolation, propagation and confirmation of etiologic (causative) agents.

Biomedical statistics: ICD, classification of disease (case diagnosis and causation mis-attribution) and cause-of-death misattribution (mortality)

[55] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/04/2025.04.02-subject-series-book-1-biological-product-non-regulation-no-identity-no-standards-no-compliance-no-enforcement.pdf