Understanding vaccination as legalized, willful use of intentionally harmful chemical and biological agents.

Part 2 of series.

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I had hoped to do this series in two parts, but have decided to make it a three-part series because of the lengthiness of the content.

Part 2 is below, covering relevant Congressional acts passed between 1983 and 1998. I plan to assemble the material into a PDF memo after I finish writing the last part.

Part 1:

- May 9, 2025 - Are vaccines biological and chemical weapons? By physical composition and physiological effects, yes. Under deceitful American and international law, no. - "...It's useful to think of vaccines, gene therapies and biosimilars (and analogous biological products which go by many different names) as binary or two-step weapons systems. Enabling laws and their

embedded exemptions and misleading labels comprise parts of the initial step: defeating the cognitive defenses of human targets by deceiving them into believing contents of containers are stable, specific (identifiable, pure, unmixed, uncontaminated, unadulterated) and capable of mitigating or protecting from disease. Containers (vials), refrigeration, syringes, hypodermic needles and human vaccinators comprise parts of the second step: defeating physical defenses of human targets by preventing natural decomposition and harmless dispersal of biological matter, and by crossing barriers presented by skin, mucous membranes, and digestive tract. Key to understanding deceptions derived from communicable disease and biological poison frauds is understanding why there are exemptions in the UN conventions and US federal laws for biological agents and chemical toxins claimed to be produced and used for purposes claimed to be defensive or peaceful. Deceivers need people to believe two sets of lies: lies about threats against which defense or protection can be presented as necessary ("something is spreading") and lies about poisons which can be camouflaged as protection-from-threats. Deceivers have made legal instruments to serve as theatrical props in support of both sets of projected illusions…"

Development of relevant international legal instruments:

- July 10, 2025 - International legal instruments supporting the conclusion that each vaccination is a willful act of war, willfully cloaked as an act of medical care.

Part 2: Understanding vaccination as legalized, willful use of intentionally harmful chemical and biological agents.

1983 - 42 USC 247d - 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 provision 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 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)

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 HHS Secretary determinations 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."

1986 - 42 USC 300aa-1 et seq - Vaccines

[This section was previously published as a standalone post:

- July 1, 2025 - 1986 National Childhood Vaccine Injury Act, National Vaccine Program, and National Vaccine Injury Compensation Program]

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

Through PL 99-660, Congress

1. established the National Vaccine Program and National Vaccine Injury Compensation Program/VICP (National Childhood Vaccine Injury Act/NCVIA);
2. amended biological product manufacturing regulation law (42 USC 262) to authorize exports of "partially processed biological products" and set up an ostensible recall system for biological products presenting "an imminent or substantial hazard to public health;" and
3. established a National Commission to Prevent Infant Mortality whose tasks included assessing "adequacy of biostatistics registration systems for collecting and reporting on infant health statistics."

The NCVIA passed by Congress had two main parts, establishing the National Vaccine Program and the National Vaccine Injury Compensation Program.

National Vaccine 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) and appoint a Director 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
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), 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 (42 USC 300aa-3) and to submit annual reports about the implementation of the National Vaccine Program to Congressional committees (42 USC 300aa-4).

Congress established a National Vaccine Advisory Committee (NVAC) 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).

[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).]

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)

National Vaccine Injury Compensation Program

The second part of the NCVIA passed by Congress in 1986 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 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.

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.

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42 USC 300aa - Definitions

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 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) 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; Advisory Commission on Childhood Vaccines 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

42 USC 300aa-25 - Adverse event reporting by health care providers

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

42 USC 300aa-26 - Information materials

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

42 USC 300aa-27 - Task force; "mandate for safer childhood vaccines."

Through the NCVIA, Congress established a so-called "mandate for safer childhood 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).

42 USC 300aa-28 - Record-keeping and reporting by manufacturers

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.

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 the products after the containers leave the bottling facilities.

Congress did not define the term "imminent or substantial public health hazard" or any of its constituent words, 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.”

1986 - 42 USC 262 - Regulation of biological products; recall authority; export of partially processed biological products

In 1986, through the same NCVIA, Congress revised two sections of 42 USC 262.

42 USC 262(d)(2) - Recall

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); 21 USC 382 - Export of partially processed biological 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).

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."

1993 - 50 USC 1511 et seq - War and National Defense, Chemical and Biological Warfare

Expanding somewhat on a section described in Part 1 of this series, in 1993 (PL 103-160), Congress directed the Secretary of Defense to "carry out the chemical and biological defense program."

Congress directed the Defense Secretary to assign responsibility for "coordination and integration of the chemical and biological warfare defense program and biological medical defense program to a single office...to ensure "close and continuous coordination" between the two programs, and to exercise oversight through the Defense Acquisition Board process.

Congress directed the Defense Secretary to designate the Army as executive agent to "coordinate and integrate research, development, test and evaluation, and acquisition" requirements for military departments; to submit budget requests for chemical and biological defense as a separate account and to review the management structure of the program, including research, development, test, and evaluation; procurement; doctrine development; policy; training; development of requirements; readiness and risk assessment; and to submit a report to Congress about how to improve joint coordination and oversight. 50 USC 1522.

1996 - 42 USC 262 - Regulation of 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

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.

Under the system of legalized biological product non-regulation/regulatory simulation in place since 1902, there had never been 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 - 18 USC 2441 - 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 or 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 either 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 mean "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.

1949 Geneva Conventions

> First Geneva Convention, 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 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 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, 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.

1996 - 50 USC 1522 - 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 - 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; 18 USC 175a; 18 USC 2332c/18 USC 229F - Armed Forces, military assistance to civilian law enforcement in emergency situations

In 1996 through the same act, (PL 104-201) Congress and President Clinton added a new section to Title 10, Armed Forces chapter governing "military support for civilian law enforcement agencies" (Chapter 18 at the time), 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 jointly "determine that an emergency situation exists;" and the Defense Secretary determines that providing assistance will not adversely affect military preparedness. 10 USC 382(a)

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. 10 USC 382(b)

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. 10 USC 382(c) and (d).

Congress added conforming provisions at the biological weapons law, 18 USC 175a, and chemical weapons law, 18 USC 2332c as of 1996, 18 USC 229 et seq as of 1998, authorizing the Attorney General to request military assistance in emergency situations involving biological and chemical agents.

Congress renumbered 10 USC 382 in December 2016 (PL 114-328) to 10 USC 282, where it is located as of 2025.

1997 - UN Chemical Weapons Convention

The 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 on April 29, 1997.

Relevant provisions of the UN chemical weapons convention were summarized in Part 1 of this series.

The United States is a party to the treaty; 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."

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." Article VI(1)

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

In October 1998 (PL 105-277) Congress inserted the same exemptions into the US implementing law, defining "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) and providing 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

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.

1997 - 50 USC 1511 et seq. - Chemical and Biological Warfare; use of human subjects; reporting to Congress

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.

1997 - 50 USC 1520a - Restrictions on the use of human subjects for testing of chemical and biological agents.

In 1997, (PL 105-85) Congress prohibited the 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)

Congress excluded from 50 USC 1520a, acknowledgement that there are no feasible methods to obtain or disclose information about the contents of unstable mixtures of biological and chemical matter (informed consent); no laws or regulations requiring biological product bottlers to provide accurate, complete information about contents on container labels or other printed matter; that Congress, government regulators (FDA), and third-party quality control organizations (such as USP-NF) have not and cannot set physical standards of purity, stability, or non-toxicity or designate analytical tests capable of assessing compliance; and that 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 function in living recipients of chemical and biological agents.

1997 - 50 USC 1523 - Annual report on chemical and biological warfare defense

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

Recall, in 1993 (103-160), Congress had 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.

1997 - 50 USC 1520 - Use 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.

1997 - 10 USC 1107 - Armed Forces; Notice of use of investigational new drugs or drugs unapproved for their applied use

In 1997 (PL 105-85) Congress and President Clinton added to a chapter on medical and dental care (Title 10, Armed Forces, Chapter 55), a new provision on "Notice of use of investigational new drugs or drugs unapproved for their applied use," pertaining to use of unapproved drugs on military personnel. 10 USC 1107

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 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)] 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].

1997 - 21 USC 360bbb, 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 upon which the "emergency use authorization" or EUA 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 determined 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 were 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 - 42 USC 262 - Regulation of biological products

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

Congress eliminated the section providing for issuance of licenses to establishments bottling vaccines and other biological products at 42 USC 262(d) and established new provisions at 42 USC 262(a).

Congress designated the license held by each company as a "biologics 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, providing that

> (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" prohibitions

on and requirements for introduction into interstate commerce under 42 USC 262(a)(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.

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

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 to identify components or measure 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. Congress 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 pure, impure, safe, unsafe, potent, ineffective, adulterated, contaminated, misbranded, falsely labeled, or an "imminent or substantial hazard to the public health."

1997 - 18 USC 2441 - War crimes

In 1997 (PL 105-118), Congress amended the law (first enacted in 1996) 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

> 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.

See also, above at 1996 section on 18 USC 2441, First Geneva Convention, Article 50; Second Geneva Convention, Article 51; Third Geneva Convention, Article 130; and Fourth Geneva Convention, Article 147, each prohibiting grave breaches including "wilful killing, torture or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health..."

1998 - 18 USC 229 et seq - 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 et seq replaced the previous law providing criminal penalties for prohibited use of chemical weapons, under the terrorism chapter (Chapter 113B) 18 USC 2332c.

Congress prohibited any person knowingly to "develop, produce, otherwise acquire, transfer directly or indirectly, receive, stockpile, retain, own, possess, or

use, or threaten to use," any chemical weapons; or to assist or induce someone else to develop or use chemical weapons. 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:"

> ...together or separately:
>
> (A) A toxic chemical and its precursors, except where intended for a purpose not prohibited under this chapter 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 "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)

Congress defined "precursor:"

> 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)

1998 - 18 USC 2331 et seq, Crimes and Criminal Procedure, Terrorism, Weapons of mass destruction

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, Foreign Relations and Intercourse, Chemical Weapons Convention Implementation

In 1998 (PL 105-277), to implement the UN Chemical Weapons Convention that had entered into force in 1997, 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 provided a rule of construction: "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 1511 et seq, War and National Defense, Chemical and Biological Warfare

In 1998 (PL 105-277), Congress repealed (for the second time) 50 USC 1520 (enacted in 1977 and amended in 1982), relating to the use of human subjects for the testing of chemical or biological agents and reporting to Congress on use of human subjects for the testing of chemical or biological agents.

Congress repealed the 1977 law twice because Congress had replaced 50 USC 1520 law with two laws: one enacted in 1997 at 50 USC 1520a, “restrictions on the use of human subjects for testing of chemical and biological agents,” and the other

enacted in 1998 at 22 USC 6771, “use of human subjects for testing of chemical or biological agents.”

1998 - Appropriations for pharmaceutical and vaccine stockpiling activities at CDC

In 1998 (PL 105-277), under the Department of Health and Human Services Appropriations Act for FY1999, Congress designated $51,000,000 to the Public Health and Social Services Emergency Fund [revised name of the Public Health Emergencies Fund established in 1983] ..."for pharmaceutical and vaccine stockpiling activities at the Centers for Disease Control and Prevention."

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

Related:

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