

# Exhibit 528

## Legal History – American Domestic Bioterrorism Program

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## LEGAL HISTORY - AMERICAN DOMESTIC BIOTERRORISM PROGRAM

*Enabling statutes, regulations, executive orders, guidance documents and budget allocations.*

At least six Congressionally-authorized statutory frameworks and related budget appropriations, reinforced through Presidential Executive Orders and related executive branch declarations,<sup>1</sup> and implemented through hundreds of regulatory amendments,<sup>2</sup> mostly promulgated through the Federal Register since 1969, authorized and funded a coordinated US Government attack (actors), on the American people (targets), using toxic biological and chemical material (bioagents/biochemical weapons) distributed across state borders labelled as "Covid-19 vaccines."<sup>3</sup>

These biochemical weapons have been fraudulently marketed by the US Government and pharmaceutical weapons manufacturers including Pfizer, Moderna, Johnson & Johnson and their manufacturing subcontractors as "safe and effective vaccines," following the transfer of the US Government's Chemical and Biological Warfare Program, formerly housed in the Department of Defense (DOD), to the Public Health Emergency (PHE) Emergency Use Authorization (EUA) Medical Countermeasures (MCM) program.

The American chemical and biological warfare program is now housed in the Department of Health and Human Services (HHS) and jointly operated by DOD, HHS, Department of Homeland Security, Department of State, most other federal agencies and their subordinate departments, divisions, offices, authorities, enterprises, committees, advisory boards and employees.

Six of the enabling statutes, in chronological order of Congressional enactment:

- 1969 - Title 50, War and National Defense, Chapter 32, §1511 et seq. **Chemical and Biological Warfare**, enacted Nov. 19, 1969 (PL 91-121).
- 1983 - Title 42, Public Health Service, §247d et seq. **Public health emergencies**, established July 13, 1983 (PL 98-49).
- 1986 - Title 42 - Public Health Service, §300aa-1 et seq. **National Vaccine Program and Vaccine Injury Compensation Program**, established Nov. 14, 1986 (PL 99-660).
- 1997 - Title 21 - Federal Food and Drugs Act, §360bbb et seq, **Expanded access to unapproved therapies and diagnostics**, adopted Nov. 21, 1997 (PL 105-115).
- 2002 - Title 42 - Public Health Service, §300hh et seq, **National All-Hazards Preparedness for Public Health Emergencies**, adopted June 12, 2002 (PL 107-188).
- 2015 - Title 10 - Armed Forces, §4021 et seq., **Research projects: transactions other than contracts and grants**. Originally adopted July 29, 1958 (PL 85-568) for NASA, expanded for DOD use for "prototype" contracting on Nov. 25, 2015 (PL 114-92).

## EXECUTIVE SUMMARY

### *1969 - Chemical and Biological Warfare Program*

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

Subsequent amendments, often passed through annual National Defense Authorization Acts (NDAAs),<sup>4</sup> expanded components of the Chemical and Biological Warfare Program; redefined bioweapons as "medical countermeasures;" transferred many components to statutory frameworks governing Health and Human Services programs under "public health emergency" conditions; and reduced or eliminated most Congressional reporting requirements relating to DOD Chemical and Biological Warfare, Biological Defense Research and related programs.

Key provisions of the Chemical and Biological Warfare program as of December 2022.<sup>5</sup>

### *1983 - Public Health Emergency Program*

A key turning point occurred in 1983, with Congressional passage of the Public Health Service Act Amendment, codified at 42 USC 247d to create a sweeping **Public Health Emergency Program** under the direction of the Secretary of Health and Human Services. The Public Health Emergency program at 42 USC 247d falls under Title 42, Public Health and Welfare, Chapter 6A, Public Health Service, Subchapter II, Powers and Duties, Part B, **Federal-State Cooperation**.

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

Public health emergencies joined wars, natural disasters and other emergency circumstances capable of subordinating or federalizing state, local and tribal government authorities, codified by the 1973 War Powers Resolution, 1976 National Emergencies Act, 1988 Robert T. Stafford Disaster Relief and Emergency Act of 1988, 2001 Authorization for Use of Military Force, 2001 PATRIOT Act, 2002 Homeland Security Act and related provisions.<sup>6</sup>

Through the 1983 act and subsequent amendments,<sup>7</sup> Congress authorized concentration of federal governing power in the hands of the Secretary of Health and Human Services during any "public health emergency" as determined and extended by the HHS Secretary at his or her sole discretion.

Key provisions of Public Health Emergencies program as of December 2022.<sup>8</sup>

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

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

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

In 2005, Congress replicated the VICP model through the Countermeasures Injury Compensation Program (CICP), established through the PREP Act in 2005. The CICP framework authorizes "covered persons" to produce, distribute and use biochemical weapons to murder people, with legal impunity, provided the weapons are classified by the HHS Secretary as "medical countermeasures" and used during a declared "public health emergency."<sup>9</sup>

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

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

Through the pioneering work of the Informed Consent Action Network (ICAN) and Children's Health Defense (CHD), culminating in a July 9, 2018 stipulation,<sup>10</sup> Americans have learned that those oversight functions have never been performed by US Government officials, and none of the currently-available "vaccines" produced by or for American pharmaceutical companies and administered to children and adults in the United States and around the world, can be conclusively demonstrated to be safe or effective. It is now more widely understood that federally-directed production and use of the biochemical weapons known as "vaccines" to injure, sicken and kill Americans, and provide liability exemption for sponsors, pharmaceutical manufacturers and vaccinators, has been domestic and international policy and practice since at least 1986.

Key provisions of National Vaccine Program as of December 2022.<sup>11</sup>

Key provisions of National Vaccine Injury Compensation Program as of December 2022.<sup>12</sup>

### *1997 - Emergency Use Authorization Program*

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

The 2004 Project Bioshield Act amendments codified at 21 USC 360bbb-3, Authorization for medical products for use in emergencies, commonly known as the **Emergency Use Authorization (EUA) program**, represent the key expansion that enabled the Covid-19 biochemical weapons attack on the American people.

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

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

In a related Congressional act in 1998 (PL 105-277), Congress converted the status of the DOD's chemical and biological weapons stockpile – which was illegal under the terms of the UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, as codified in a different section of the same Congressional act – into a pseudo-legal "National Pharmaceutical Stockpile," later renamed the Strategic National Stockpile. The 1998 Congressional act also transferred management of the products, now called "medical countermeasures," to the CDC operating under HHS direction.

Key provisions of 21 USC 360bbb, Expanded access to unapproved therapies and diagnostics, as of December 2022.<sup>14</sup>

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

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

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

Coordinating committees comprised of representatives of these federal offices are authorized to meet and establish supervisory procedures to direct, control and fund public health emergency response programs at the federal, state, local and tribal levels. These coordinating committees include but are not limited to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), established by HHS in 2006 and authorized by Congress in 2019,<sup>15</sup> and other public, private, hybrid and quasi-governmental entities, including the FDA Medical Countermeasures Initiative (MCMi); HHS Biomedical Advanced Research and Development Authority (BARDA); and the Medical Chemical, Biological, Radiological, Nuclear [CBRN] Defense Consortium (MCDC).

Key provisions of 42 USC 300hh, National All-Hazards Preparedness for Public Health Emergencies program as of December 2022.<sup>16</sup>

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

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

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

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

DOD used this authority to contract for development, production and distribution of Covid-19 biochemical weapons in 2020. The contracts covered "large scale manufacturing demonstrations," but not clinical trials, and were carried out by Medical CBRN [Chemical Biological Radiological Nuclear] Defense Consortium (MCDC) program members, coordinated by Advanced Technology International (ATI) and other weapons-procurement corporations.

Key provisions of 10 USC 4022, Research projects: transactions other than contracts and grants, as of December, 2022, at footnote.<sup>18</sup>

## COVID-19 'VACCINES' AS CASE STUDY

21 USC 360bbb-3(k) is a crucial provision at the intersection of the six primary statutory pillars.

This law provides that "use" of EUA-covered medical countermeasure (MCM) products including masks, diagnostic tests, bioagent injections, and other drugs, devices and biologics, once so classified by the HHS Secretary and his/her delegees, "shall not be considered to constitute a clinical investigation."

Jan. 27, 2020 was the effective date of US Secretary of Health and Human Services Alex Azar's *Determination that a Public Health Emergency Exists*, signed Jan. 31, 2020, retroactive to Jan. 27, 2020.<sup>19</sup> It has been extended continuously since, most recently by HHS Secretary Xavier Becerra on March 15, 2023. (88 Federal Register 16644)

Effective Feb. 04, 2020, HHS Secretary Azar issued Notice of *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*.<sup>20</sup>

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

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

Recipients of such products are not legally recognized as experimental subjects or patients receiving experimental, authorized or approved products, because "use" of the products "shall not constitute clinical investigation." There is no stopping condition, because there is no legally-relevant "clinical investigation" to be stopped.

On the basis of a self-declared "public health emergency" and self-declared classification of products as "emergency use medical countermeasures," including an unreviewable determination as to the relative risks posed by a communicable pathogen as compared to "medical countermeasure" products, the Secretary of Health and Human Services can suspend informed consent obligations and rights, on behalf of the entire American population.

"Vaccinators" are thereby authorized by the HHS Secretary to withhold information about product ingredients; vial contents; potential individual risks and benefits based on individual health conditions; treatment alternatives; and the option to accept or refuse the products.

*Provisions include:*

- 10 USC 4022: DOD is authorized to contract with pharmaceutical corporations to produce and distribute ‘prototype’ products for use on the general public. *See also* Defense Production Act of 1950, 50 USC 4501 et seq.
- 21 USC 360bbb-3(c)(2)(A): The only required product **efficacy** standard authorizing "use" of such products is that "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that — the product **may be effective** in diagnosing, treating, or preventing—(i) such disease or condition [SARS-CoV-2]; or (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent," with all risk and benefit assessments reserved to HHS Secretary alone, no data required and no data or decisional review by Congress, courts or individual recipients authorized.
- 21 USC 360bbb-3(c)(2)(B): There are no **safety** standards required prior to "use" of medical countermeasures, which are authorized for production and use "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that... the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration," with all risk and benefit assessments reserved to HHS Secretary alone, no data required and no data or decisional review by Congress, courts or individual recipients authorized.
- 21 USC 360bbb-3(e)(1)(A)(ii): Authorizes HHS Secretary blanket waiver of informed consent for entire American population for "unapproved products."
- 21 USC 360bbb-3(e)(2)(A): Authorizes HHS Secretary blanket waiver of informed consent for entire American population for "unapproved use of an approved product."
- 21 USC 360bbb-3(k): "Relation to other provisions. If a product is the subject of an authorization under this section, the **use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation** for purposes of section 355(i), 360b(j), or 360j(g) of this title or any other provision of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262]."
- 21 USC 360bbb-3a(c); 21 USC 360bbb-3a(d); 21 USC 360bbb-3(e)(2)(B)(ii): EUA medical countermeasures “shall not be deemed adulterated or misbranded” even if noncompliant with regulations governing clinical research, manufacturing, testing, purity, quality, batch and lot variability, adulteration, expiration dates, labeling, serialization, marketing, branding, dispensing and prescriptions.
- 21 USC 355g: Authorizes use of "real world evidence" (mass administration of products to general public prior to or in parallel with standard nonclinical, preclinical and clinical safety and efficacy studies) followed by collection of private/proprietary information about the effects, from health insurance systems, government databases (Medicare, Medicaid, Defense Medical Epidemiology Database, Veterans Health Administration) for the purposes of FDA regulatory action.



- 21 USC 355(i)(4): Authorizes HHS Secretary blanket waiver of informed consent for entire American population, for products classified by HHS as "minimal risk drugs."
- 21 USC 360j(g)(3)(D)(i) - Authorizes HHS Secretary blanket waiver of informed consent for entire American population, for products classified by HHS as "minimal risk devices."
- 42 USC 247d-6a(d)(2)(A): Manufacturers, as contractors, are considered HHS employees for purposes of legal immunity under Federal Tort Claims Act.
- 42 USC 247d-6b(c)(5)(B)(iii): One of the factors to be considered by HHS secretary in making determinations about EUA products (qualified security countermeasures) and use of Special Reserve Fund/Strategic National Stockpile appropriations for procurement is "whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure."
- 42 USC 247d-6d(b)(7): Blocks access to courts for judicial review of the facts or law relating to HHS Secretary public health emergency declarations and medical countermeasures product classifications.
- 42 USC 247d-6d(b)(8): Preempts authority of state, local and tribal governments and individuals to manage public health emergency and medical countermeasures classification and regulation outside of HHS/DOD control.
- 42 USC 247d-6d(b)(9): Narrowly limits obligation for HHS to report to Congress on public health emergency status and medical countermeasures classifications, and no authorization for Congress to override HHS declarations, determination, and decisions.
- 42 USC 247d-6d(c)(4): Authorizes "just following orders" defense for defendants.
- 42 USC 247d-6d(c)(5): Blocks access for plaintiffs, to civil courts for judicial review, and no entity to whom civil liability can attach, for injuries and deaths caused by covered medical countermeasures, unless and until HHS and/or Attorney General/DOJ first file enforcement action against manufacturers and prove willful misconduct proximate to injury or death.
- 50 USC 4558(j) and 50 USC 4558(o): Military contractors producing and distributing biochemical weapons under "voluntary agreements" during "emergencies" are exempt from contract law and anti-trust law.

## DISCUSSION

The interlocking corruption of federal emergency management, public health and drug safety laws, for the purpose of mounting a covert biochemical weapons attack by the US Government on the American people under the fraudulent characterization of weapons as "Covid-19 vaccines," was deployed fully starting Jan. 27, 2020 and continues to be fully operational at the present time, more than three years later.

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

These nurses and other "vaccinators" are authorized to injure and murder patients with legal impunity using procedures and products (including withholding of effective non-EUA products as treatments; restraints, starvation, dehydration, isolation, sedatives, Remdesivir/Veklury, ventilators), to drive public panic and acceptance of the lethal injections colloquially known as "Covid-19 vaccines."

The same conclusions may be reached from observations of acts taken and not taken by American drug safety regulators since the Covid-19 biochemical weapons were first used on human targets between March and November 2020 during fraudulent "clinical trials," and then entered mass distribution in mid-December 2020.

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

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

The products are biochemical weapons deployed by actors within the US Government and pharmaceutical/bioweapons industry manufacturing contractors, intended to injure and kill American people as targets, and exported to other countries' governments to injure and kill their people. The killing is intentional; killing is what weapons are designed and intended to do.

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

Instead, third party access to and testing of vial contents is prohibited under the terms of the DOD-mediated supply and distribution contracts between purchasing governments, manufacturing corporations and "vaccination" sites, on penalty of federal "criminal or civil prosecution."<sup>21</sup>

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<sup>1</sup> 1983-present, relevant Presidential Executive Orders, proclamations and related acts, partial list: Executive Order 12452, 1983 (expanded list of communicable diseases subjecting citizens to forcible apprehension and detention under HHS Secretary quarantine authority); EO 13139, 1999 (forced experimental, unapproved 'vaccines' on armed forces without informed consent); Proclamation 7463, 2001 (Declaration of National Emergency by Reason of Certain Terrorist Attacks, renewed annually since); EO 13295, 2003 (added **symptomatic SARS** to quarantinable

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communicable diseases); EO 13375, 2005 (added **symptomatic influenza** to quarantinable communicable diseases; National Security Presidential Directive 51, 2007; EO 13527, 2009 (*Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack*); EO 13601, 2012 (*National Defense Resources Preparedness*); EO 13674, 2014 (added **asymptomatic, suspected SARS** to quarantinable communicable diseases); EO 13747, 2016 (*Advancing the **Global Health Security Agenda** to Achieve a World Safe and Secure from Infectious Disease Threats*); EO 13887, 2019 (*Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health*; directed **rapid-deployment mRNA/DNA/LNP/nanotech drugs and devices**); Proclamation 9994, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak, renewed annually since); EO 13909, 2020 (*Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID–19*); EO 13910, 2020 (*Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID–19*); EO 13911, 2020 (*Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources To Respond to the Spread of COVID–19*); EO 14047, 2021 (added **measles** to the list of quarantinable communicable diseases); EO 14081, 2022 (*Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*).

<sup>2</sup> 1981-present, relevant HHS Proposed Rules, Final Rules, Notices, and Guidance for Industry, partial list: HHS-Food and Drug Administration Final Rule Protections for Human Subjects; Prisoners Used as Subjects in Research (1981); HHS-FDA Final Rule Protection of Human Subjects; Informed Consent (1981); HHS Interim Final Rule: Informed Consent for Human Drugs and Biologics; Determination that Informed Consent is Not Feasible (1990); 1991 Common Rule (1991); HHS-FDA Guidance for Human Somatic Cell Therapy and Gene Therapy (1998); HHS Interim Final Rule - Human Drugs and Biologics; Determination That Informed Consent Is NOT Feasible or Is Contrary to the Best Interests of Recipients; Revocation of 1990 Interim Final Rule; Establishment of New Interim Final Rule (1999); HHS-FDA Draft Guidance Re: Emergency Use Authorization of Medical Products (2005); HHS-FDA Interim Final Rule, Medical Devices; Exception From General Requirements for Informed Consent (2006) HHS-FDA Guidance: Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Effects (2006); HHS-FDA Guidance - Emergency Use Authorization of Medical Products (2007); HHS Interim Final Rule - FDA Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile. (2007); HHS-FDA Final Rule: Medical Devices; Exception From General Requirements for Informed Consent (2011); HHS-FDA Guidance: Potency Tests for Cellular and Gene Therapy Products (2011); HHS-FDA Preclinical Assessment of Investigational Cellular and Gene Therapy Products (2013); HHS-FDA Guidance: Decisions for Investigational Device Exemption Clinical Investigations (2014); HHS-FDA Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products (2015); HHS-FDA Guidance: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products (2015); HHS Final Rule - HHS Clinical Trials Registration and Results (2016); HHS Workshop Summary - The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile (2016); HHS-FDA Guidance: Emergency Use Authorization of Medical Products and Related Authorities (2017); HHS Final Rule - Federal Policy for the Protection of Human Subjects (2017); HHS Final Rule - Control of Communicable Diseases (2017); HHS-FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects (2017); HHS-FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (2017); HHS Final Rule - Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period (2018); HHS-FDA Guidance: Development and Licensure of Vaccines to Prevent COVID-19 (2020); HHS-FDA Guidance: Emergency Use Authorization for Vaccines to Prevent COVID-19 (2020); HHS-FDA Guidance: Real-World Data - Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products (2021); HHS-FDA Guidance: Real-World Data - Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products (2021); HHS Interim Final Rule - Possession, Use, and Transfer of Select Agents and Toxins—Addition of SARS–CoV/SARS–CoV–2 Chimeric Viruses Resulting From Any Deliberate Manipulation of SARS–CoV–2 To Incorporate Nucleic Acids Coding for SARS–CoV Virulence Factors to the HHS List of Select Agents and Toxins (2021); HHS Final Rule - National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table (2022); HHS-FDA Proposed Rules: Protection of Human Subjects and Institutional Review Boards (2022)

<sup>3</sup>2018: "Agent or **bioagent** is used broadly to refer to any product created using biological components that may be intended to cause harm. In the context of synthetic biology, an agent could be a pathogen, a toxin, or even a biological component, such as a genetic construct or a biochemical pathway, that may be developed with the intent to harm a

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human target; **Actor** is used to refer to individuals or groups who may seek to effect an attack; **Target** is typically used to refer to the human beings harmed (or intended to be harmed) in an attack. In the context of manipulation of biological components, target may be used to refer to the intended outcomes of those manipulations." *Biodefense in the Age of Synthetic Biology*, National Academy of Sciences (2018).

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

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

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

<sup>7</sup> 1983-present, relevant Congressional acts regarding establishment and expansion of **Public Health Emergencies Program**, partial list. **Public Health Service Act Amendment** of 1983 (PL 98-49); Health Omnibus Programs Extension Act of 1988 (PL 100-607); National Institutes of Health Revitalization Act of 1993 (PL 103-43); Food and Drug Administration Modernization Act of 1997 (PL 105-115); Omnibus Consolidated and Emergency Supplemental Appropriations of 1998, for FY1999 (PL 105-277); **Public Health Improvement Act** of 2000 (PL 106-505); **Public Health Security and Bioterrorism Preparedness and Response Act** of 2002 (PL 107-188); **NDAA for FY2004** (PL 108-136) [Added 21 USC 360bbb-3, "Authorization for Medical Products for Use in Emergencies" under Federal

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Food Drug and Cosmetics Act, 21 USC 360bbb added in 1997, “*Expanded Access to Unapproved Diagnostics and Therapies.*” Added 10 USC 1107a, *Emergency Use Products*, authorizing US President to waive informed consent rights of military personnel during declared emergencies and redefining the meaning of the right to be “informed of an option to accept or refuse administration of a product.”]; **Project Bioshield Act** of 2004 (PL 108-276); DOD Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2005, including **Public Readiness and Emergency Preparedness (PREP) Act** (PL 109-148); **Pandemic and All-Hazards Preparedness Act** of 2006 (PL 109-417); National Institute of Health Reform Act of 2007 (PL 109-482); Food and Drug Administration Amendments Act of 2007 (PL 110-85); Patient Protection and Affordable Care Act of 2010 (ObamaCare) including Biologics Price Competition and Innovation Act of 2009 (PL 111-148); Food and Drug Administration Safety and Innovation Act of 2012 (PL 112-144); **Pandemic and All-Hazards Preparedness Reauthorization Act** of 2013 (PL 113-5); Medicare Access and CHIP Reauthorization (MACRA) Act of 2014 (PL 114-10); **21st Century Cures Act** of 2016 (PL 114-255); FDA Reauthorization Act of 2017 (PL 115-52); NDAA for FY 2018 (PL 115-91); **Act to amend FDCA EUA statute**, 21 USC 360bbb-3, of 2017 (PL 115-92); **Pandemic and All-Hazards Preparedness and Advancing Innovation Act** of 2019 (PL 116-22); Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (PL 116-123); Families First Coronavirus Response Act of 2020 (PL 116-127); Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 (PL 116-136); Paycheck Protection Program and Health Care Enhancement Act of 2020 (PL 116-139); Consolidated Appropriations Act of 2020 (PL 116-260); American Rescue Plan/Consolidated Appropriations Act of 2021 (PL 117-2); NDAA for FY2022 (PL 117-81); Consolidated Appropriations Act of 2022 (PL 117-103).

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

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

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

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

<sup>12</sup> 42 USC §300aa–10 et seq. **National Vaccine Injury Compensation Program** §300aa–10. Establishment of program; §300aa–11. Petitions for compensation; §300aa–12. Court jurisdiction; §300aa–13. Determination of

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eligibility and compensation; §300aa-14. Vaccine Injury Table; §300aa-15. Compensation; §300aa-16. Limitations of actions; §300aa-17. Subrogation; §300aa-18. Repealed.; §300aa-19. Advisory Commission on Childhood Vaccines; §300aa-21. Authority to bring actions; §300aa-22. Standards of responsibility; §300aa-23. Trial; §300aa-25. Recording and reporting of information; §300aa-26. Vaccine information; §300aa-27. Mandate for safer childhood vaccines; §300aa-28. Manufacturer recordkeeping and reporting; §300aa-31. Citizen's actions; §300aa-32. Judicial review; §300aa-33. Definitions; §300aa-34. Termination of program

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

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

<sup>15</sup> 42 USC 300hh-10a. **Public Health Emergency Medical Countermeasures Enterprise** membership shall include: (1) The [HHS] Assistant Secretary for Preparedness and Response; (2) The Director of the Centers for Disease Control and Prevention; (3) The Director of the National Institutes of Health; (4) The Commissioner of Food and Drugs; (5) The Secretary of Defense; (6) The Secretary of Homeland Security; (7) The Secretary of Agriculture; (8) The Secretary of Veterans Affairs; (9) The Director of National Intelligence; (10) Representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases, and the Director of the Office of Public Health Preparedness and Response, as the [HHS] Secretary determines appropriate.

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

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

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<sup>18</sup> 10 USC §4021. **Research projects: transactions other than contracts and grants**; § 4022. **Authority of the Department of Defense to carry out certain prototype projects**; §4023. Procurement for experimental purposes; §4024. Merit-based award of grants for research and development; §4025. Prizes for advanced technology achievements; §4026. Cooperative research and development agreements under Stevenson-Wydler Technology Innovation Act of 1980; [§4027. Disclosure requirements for recipients of research and development funds]

<sup>19</sup> Notice of **Determination that a Public Health Emergency Exists, effective Jan. 27, 2020**. 85 Federal Register 7316, Feb. 07, 2020.

<sup>20</sup> Notice of **Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, effective Feb. 04, 2020**. 85 Federal Register 15198, March 17, 2020.

<sup>21</sup> 2021: CDC *COVID-19 Vaccination Program Provider Requirements and Support*, <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html#provider-agreement> (updated 06/11/2021). **Diversion of COVID-19 Vaccines Prohibited:** "At this time, all COVID-19 vaccine in the United States has been purchased by the United States Government for administration exclusively through the CDC COVID-19 Vaccination Program. The vaccine and all related ancillary supplies, including the COVID-19 Vaccination Cards, remains U.S. government property until vaccine is administered to the recipient...COVID-19 vaccination providers are prohibited from selling USG-purchased COVID-19 vaccine (and ancillary materials purchased by the USG for use in the Vaccination Program), soliciting or receiving any inducement, whether direct or indirect, for vaccinating (or providing COVID-19 vaccine to be used for vaccinating) any individual who is not currently eligible to receive COVID-19 vaccine as a member of a group currently authorized under prioritization specified by HHS/CDC /ACIP, the state/territory's governor or other relevant public health authority, or otherwise diverting COVID-19 vaccine from the CDC COVID-19 Vaccination Program. Such use constitutes fraud and is a violation of the terms of the provider agreement. It shall be cause for immediate termination from the CDC COVID-19 Vaccination Program and criminal or civil prosecution for violation of 18 U.S.C. §1001 or other relevant federal statutes.