

American Domestic Bioterrorism Program. Building the case to prosecute members of Congress, presidents and HHS secretaries for treason under 18 USC 2381.

Research and organizing tool first posted April 28, 2022, subject to ongoing revision as new information comes to light. Last updated May 6, 2022.

I started looking closely at the legal architecture supporting the Covid national prison panopticon¹ on Jan. 30, 2022, **after hearing Attorney Todd Callender's interview²**, which provided information about the American domestic legal framework; how it fit with the oddly-coordinated pandemic story told by governments worldwide; and how it relates to the World Health Organization International Health Regulations of 2005 at the center.

I wrote up the interview:

- Legal Walls - Short Version³
- Legal Walls of the Covid-19 Kill Box⁴

Prior to that day, I'd spent a lot of time, with increasing confusion and alarm and despair, trying to figure out why the U.S. Constitutional legal system hadn't put a stop to the nonsense as its nonsensicality became obvious to so many people.

Why did it continue, with no end in sight, and not even a glimpse of a path to the end?

In the three months since then, as I've dug into Callender's analysis following the supporting paper trails, I've learned why, and how.

A whole lot of things that once were federal and state crimes and civil rights violations have been legalized by Congress through legislative, statutory revisions to the United States Code, signed by US Presidents, and implemented at the administrative, regulatory level by the Department of Health and Human Services through the Code of Federal Regulations.

I've reported on those findings in small bits and pieces, connecting the laws to court cases, executive orders, guidance documents for researchers, academic papers, intellectual property patents, regulatory amendments, psychological manipulation programs, geopolitical developments and other facts as they've floated across my field of view.

I think the critical decay began around 1983, when the 'public health emergencies' section was added to the 1944 Public Health Service Act, although the 1944 PHSA itself represented an additional militarization of human medicine in the United States.

¹ <https://www.ucl.ac.uk/bentham-project/who-was-jeremy-bentham/panopticon>

² <https://www.americaoutloud.com/compulsory-vaccination-and-forced-quarantine-camps-in-arizona/>

³ <https://bailiwicknews.substack.com/p/legal-walls-short-version?s=w>

⁴ <https://bailiwicknews.substack.com/p/legal-walls-of-the-covid-19-kill?s=w>

Most of the worst laws have been passed since 2000 — just before 9/11 and the US Department of Defense false flag anthrax attacks.

They are listed below, with links to the full text of each law, and a short summary of what I understand about how each one fits into the overall scheme.

The basic goal of the architects, which has been achieved, was to set up legal conditions in which all governing power in the United States could be automatically transferred from the citizens and the three Constitutional branches into the two hands of the Health and Human Services Secretary, effective at the moment the HHS Secretary himself declared a public health emergency, legally transforming free citizens into enslaved subjects.

That happened on Jan. 31, 2020, in effect as of Jan. 27, 2020⁵ through the present day.

In other words: **Congress legalized and funded the overthrow of the U.S. Constitution, the U.S. government and the American people, through a massive domestic bioterrorism program relabeled as a public health program, conducted by the HHS Secretary on behalf of the World Health Organization and its financial backers.**

Below is the current list of statutes, subject to change as I learn more.

ENABLING STATUTES

- 1935 Social Security Act - PL 74-271. 49 Stat. 620. [Added to list on May 1, 2022.] Social Security Act is the law governing Medicare and Medicaid, which are among the authorization and funding pathways through which ‘breakthrough’ devices and drugs, fast-track products, products eligible for accelerated approval and other FDA- classified products are developed, manufactured and used on humans. Amendments to SSA since 1983 and pending, have expanded/will further expand the novel drug and device/bioweapon classes eligible for fast-tracked federal research and deployment funding within the Medicare/Medicaid programs.
- 1938 Federal Food Drug and Cosmetic Act⁶ - PL 75-717. 52 Stat. 1040. (21 pages.) 21 USC 9 et seq. Original law passed “to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.”
- 1944 Public Health Service Act⁷ - PL 78-410. 58 Stat. 682. (39 pages.) 42 USC 201 et seq. Consolidated, centralized and militarized the American public health system that had developed within several agencies since the Revolution.
- 1983 Public Health Service Act Amendment⁸ - PL 98-49, 97 Stat. 245. (2 pages.) Amended Public Health Service Act (at 42 USC 247d) to add Section 319, ‘Public Health Emergencies’ granting new powers to Health and Human Services Secretary and establishing a \$30 million slush fund called the Public Health Emergencies Fund. Summary posted April 20, 2022⁹.
- 1986 State Comprehensive Mental Health Services Plan Act¹⁰ - PL 99-660 (73 pages). Title III - National Childhood Vaccine Injury Act. 100 Stat. 3755. Amended Public Health Service Act (42 USC 201 et seq) to add Title XXI, 42 USC 300aa et seq, including Subtitle 1, establishing and funding a National Vaccine Program, and Subtitle 2, granting vaccine manufactures legal immunity for injuries and deaths caused by

⁵ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

⁶ <https://govtrackus.s3.amazonaws.com/legislink/pdf/stat/52/STATUTE-52-Pg1040a.pdf>

⁷ <https://uscode.house.gov/statviewer.htm?volume=58&page=682>

⁸ <https://uscode.house.gov/statutes/pl/98/49.pdf>

⁹ <https://bailiwicknews.substack.com/p/1983?s=w>

¹⁰ <https://www.congress.gov/99/statute/STATUTE-100/STATUTE-100-Pg3743.pdf>

their products, and establishing and funding a tax revenue/public debt-funded National Vaccine Injury Compensation Program.

- 1988 Health Omnibus Programs Extension Act¹¹ - PL 100-607. 102 Stat. 3048. (126 pages.) Established National Center for Biotechnology Information under Public Health Service Act; outlined and funded HIV-AIDS research under direction of NIH/NIAID/Fauci; increased funding for the Public Health Emergencies Fund to \$45 million.
- 1992 Alcohol, Drug Abuse, Mental Health Administration (ADAMHA) Restructuring Act¹² - PL 102-321, 106 Stat. 323. (120 pages). Expanded drug abuse prevention and treatment programs; reorganized HHS subdivisions.
- 1992 Preventative Health Amendments¹³ - PL 102-531. 106 Stat. 3504. (40 pages.) Changed name from Centers for Disease Control to Centers for Disease Control and Prevention.
- 1997 Food and Drug Administration Modernization Act¹⁴ - PL 105-115, 11 Stat. 2296. (86 pages). Added new section to Federal Food Drug and Cosmetics Act (21 USC 9) to expand access to investigational drugs and devices during emergency situations (21 USC 360bbb). This was the beginning of the Emergency Use Authorization framework that culminated in the federal government’s psychological, social and economic coercion program aimed at universal injection of all American citizens with products marketed as Covid-19 vaccines, operational from mid-2020 to the present.
- 1998 Omnibus Consolidated and Emergency Supplemental Appropriations for FY1999¹⁵ - PL 105-277. (920 pages). 112 Stat. 2681- 358: Established the National Pharmaceutical Stockpile, later renamed the Strategic National Stockpile. Appropriated \$51,000,000, “to remain available until expended...for pharmaceutical and vaccine stockpiling activities at the Centers for Disease Control and Prevention.”
- 2000 Public Health Improvement Act¹⁶ - PL 106-505, 114 Stat. 2314. (38 pages). Title I, Public Health Threats and Emergencies Act, reworked and expanded Section 319 of Public Health Service Act, 42 USC 247d (the Public Health Emergencies section first added in 1983). Appropriated funding and established a working group on bioterrorism ‘countermeasures’ research and development.
- 2001 Authorization for Use of Military Force¹⁷ (PL 107-40; 115 Stat. 224) Passed under the 1973 War Powers Act, 50 U.S. Code § 1541, and construed as putting the United States in a permanent state of war (Global War on Terror) with no limitations in time or geographically.
- 2002 Public Health Security and Bioterrorism Preparedness and Response Act¹⁸ - PL 107-188, 116 Stat. 594 (105 pages). Major amendments to Public Health Service Act (42 USC 201) and Federal Food Drug and Cosmetics Act (21 USC 9). This law fully constructed and expanded funding for the federal government’s domestic bioterrorism apparatus headquartered at the CDC, disguising it as a program to protect Americans from non-state actors. Sections included National Preparedness and Response Planning, Coordinating, and Reporting; Strategic National Stockpile; Development of Priority Countermeasures (i.e. fast-tracking approval of drugs and devices without standard safety testing, efficacy testing, and regulatory compliance); Improving State, Local, and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies; Emergency Authorities (i.e. federal quarantine power); Controls on Dangerous Biological Agents and Toxins; Safety and Security of Food and Drug Supply; Drinking Water Security and Safety. Coincidentally also in 2002, HHS-NIH-funded (grant no. AI23946-08) University of North Carolina researcher and Fauci colleague Ralph Baric filed a US patent

¹¹ <https://www.congress.gov/100/statute/STATUTE-102/STATUTE-102-Pg3048.pdf>

¹² <https://www.congress.gov/102/statute/STATUTE-106/STATUTE-106-Pg323.pdf>

¹³ <https://www.congress.gov/102/statute/STATUTE-106/STATUTE-106-Pg3469.pdf>

¹⁴ <https://www.congress.gov/105/plaws/publ115/PLAW-105publ115.pdf>

¹⁵ <https://www.congress.gov/105/plaws/publ277/PLAW-105publ277.pdf>

¹⁶ <https://uscode.house.gov/statutes/pl/106/505.pdf>

¹⁷ <https://www.congress.gov/107/plaws/publ40/PLAW-107publ40.pdf>

¹⁸ <https://www.congress.gov/107/plaws/publ188/PLAW-107publ188.pdf>

(7,279,372¹⁹) on methods to make bat coronaviruses more lethal to humans, noting that “the US government has certain rights to this invention.” More on that²⁰.

- 2002 Homeland Security Act²¹ - PL 107-296, 116 Stat. 2135. (187 pages.) Established Department of Homeland Security as a cabinet-level administrative arm of the executive branch. Expanded militarization of domestic surveillance and law enforcement. Title V: established a Directorate of Emergency Preparedness and Response within Department of Homeland Security, headed by an Undersecretary. Strengthened crosslinks between DHS and other federal agencies: Health and Human Services, Federal Emergency Management Agency (FEMA), Department of Defense, Department of Justice and Department of Agriculture, to build and operate a public-health-predicated martial law system.
- 2004 Project Bioshield Act²² - PL 108-276, 118 Stat. 835. (30 pages.) Amendments to Public Health Service Act (42 USC 201) and Federal Food Drug and Cosmetics Act (21 USC 9). Amended and expanded 21 USC 360bbb (first adopted in PL 105-115 in 1997), relating to authorization for investigational drugs and devices to be used in emergencies (Emergency Use Authorization). Established program for ‘qualified countermeasure’ research, procurement, contracting, manufacture, use and liability exemptions. Expanded authority of NIAID Director (Fauci). Appropriated \$640,000,000 for the Strategic National Stockpile for FY2002, \$590,000,000 for smallpox vaccine development for FY2002, and \$5,593,000,000 for “procurement of security countermeasures.” Expanded HHS power to subject citizens to involuntary relocation and indefinite detention on communicable disease predicates. Expanded coordination among Secretary of Health and Human Services, Secretary of Defense and Secretary of Homeland Security.
- 2005 Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act²³ - PL 109-148. (154 pages). 119 Stat. 2818, Division C at last 14 pages: Public Readiness and Emergency Preparedness (PREP) Act. Amended Public Health Service Act (42 USC 201). Established power of Secretary of Health and Human Services, during self-declared public health emergency under Section 319, to unilaterally issue declarations recommending “manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures.” 42 USC 247d-6d(b). Added more detail on liability shields for pandemic and epidemic products and security countermeasures. Set pre-suit hurdle requiring HHS to first bring claims against defendants, and bar private claims until after HHS claims resolved, if and only if defendant found liable. Set liability standard at willful misconduct, “establishing a standard...more stringent than negligence in any form or recklessness,” requiring proof defendant 1) intentionally engaged in misconduct 2) proximate to victim’s injury or death. Established just-following-orders defense for vaccinators and others in the chain of distribution. Established court-alternative, tax-and-debt-funded Covered Countermeasure Process Fund, similar to Vaccine Injury Compensation Fund established in 1986 for products on childhood vaccine schedule. Another provision of the DOD Supplemental Emergency Appropriation funded the Public Health and Social Service Emergency Fund (PHSSEF), a slush fund under the control of the Secretary of Health and Human Services, with \$3.3 billion to start.
- 2006 Pandemic and All-Hazards Preparedness Act²⁴. PL 109-417, 120 Stat. 2878. (51 pages). Fulfilled many of the requirements of the World Health Organization International Health Regulations of 2005²⁵, by further consolidating and centralizing power in federal Health and Human Services Secretary’s hands. Created new HHS department, led by new Assistant Secretary for Preparedness and Response (counterpart to the DHS Director of Emergency Preparedness and Response position created in 2002). Established rules for coordination among HHS, Secretary of Defense, Secretary of Veterans Affairs, Secretary of Transportation and “any other relevant federal agency.” Established national framework

¹⁹ <https://patents.justia.com/patent/7279327>

²⁰ <https://www.eyenews.com/the-fauci-covid-19-dossier-investigation-into-possible-illegal-patent-claims-resulting-in-millions-of-in-commercial-benefits/>

²¹ <https://www.congress.gov/107/plaws/publ296/PLAW-107publ296.pdf>

²² <https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf>

²³ <https://uscode.house.gov/statutes/pl/109/148.pdf>

²⁴ <https://www.congress.gov/109/plaws/publ417/PLAW-109publ417.pdf>

²⁵ <https://www.who.int/publications/i/item/9789241580496>

subordinating state, county, tribal and local public health and law enforcement systems to federal agencies. Expanded surveillance programs. Clarified definitions of qualified countermeasure, security countermeasure, and infectious disease for purposes of 2004 Project Bioshield Act. Established Biomedical Advanced Research and Development Authority (BARDA) division under HHS, “to facilitate a broad-based approach to emergency medical countermeasure-related activities,” including \$1,070,000,000 appropriation. Tools included HHS authority to limit competition among manufacturers of pandemic products as defined under 2004 Project Bioshield Act.

- 2007 John Warner Defense Authorization Act²⁶ - PL 109-364, 120 Stat. 2095. (439 pages). Section 1076 amended 1807 Insurrection Act²⁷, (10 USC 333, renumbered as 10 USC 253), providing exemptions to 1878 Posse Comitatus Act²⁸, to expand the authority of federal government to deploy 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 the following year.
- 2007 National Institute of Health Reform Act²⁹ - PL 109-482, 120 Stat. 3675. (29 pages). Reorganization, consolidation of power and funding.
- 2008 National Defense Authorization Act³⁰ - PL 110-181. (602 pages). 122 Stat. 325: Section 1068 repealed 2007 amendments to Insurrection Act which had expanded exemptions to 1878 Posse Comitatus Act limits on US Presidents’ power to deploy the military domestically.
- 2012 National Defense Authorization Act³¹ - PL 112-81, Section 1021. Codified authority for US President to order military arrest and indefinite detention of American civilians without charge or trial under 10 USC 801 et seq. (Uniform Code of Military Justice), to the extent the 2001 Authorization for Use of Military Force (PL 107-40; 115 Stat. 224, passed under the 1973 War Powers Act, 50 U.S. Code § 1541) is construed as putting the United States in a permanent state of war (Global War on Terror).
- 2012 Food and Drug Administration Safety and Innovation Act³² - PL 112-144, 126 Stat. 993. (140 pages). Amendments to Federal Food, Drug, and Cosmetic Act (21 USC 9) regarding user-fee programs for prescription drugs and medical devices, generic drugs and biosimilars, and for other purposes. *See* August 2014 FDA Decisions for Investigational Device Exemption: Clinical Investigations Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and FDA Staff³³; January 2017 Emergency Use Authorization of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders³⁴; and July 2021 Department of Justice Opinion: Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization³⁵, for federal government’s position on legal status and regulatory control differences between Emergency Use Authorization (EUA) products, Investigational New Drugs (IND) and Investigational Device Exemptions (IDE).
- 2013 Pandemic and All-Hazards Preparedness Reauthorization Act³⁶ - PL 113-5, 127 Stat. 161. (37 pages). Renewed and updated 2006 Pandemic and All-Hazards Preparedness Act, with amendments to Public Health Service Act (42 USC 201) and Federal Food Drug and Cosmetics Act (21 USC 9). Added sections 564A and 564B to the FDCA to further authorize emergency use of approved products in emergencies and products held for emergency use. Amended definitions of covered countermeasures and qualified pandemic and epidemic products in Section 319F-3 of PHS Act (2005 PREP Act provisions). Extended

²⁶ <https://www.congress.gov/109/plaws/publ364/PLAW-109publ364.pdf>

²⁷ <https://uscode.house.gov/statviewer.htm?volume=12&page=281>

²⁸ <https://uscode.house.gov/statviewer.htm?volume=12&page=281>

²⁹ <https://www.govinfo.gov/content/pkg/STATUTE-120/pdf/STATUTE-120-Pg3675.pdf#page=11>

³⁰ <https://www.congress.gov/110/plaws/publ181/PLAW-110publ181.pdf>

³¹ <https://www.congress.gov/112/plaws/publ81/PLAW-112publ81.pdf>

³² <https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf>

³³ <https://www.fda.gov/media/81792/download>

³⁴ <https://www.fda.gov/media/97321/download>

³⁵ <https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf>

³⁶ <https://www.congress.gov/113/plaws/publ5/PLAW-113publ5.pdf>

definitions to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

- 2016 21st Century Cures Act³⁷ (Cures Act 1.0) - PL 114-255, 130 Stat. 1033 (312 pages). Updated and expanded Public Health Service Act, 42 USC 201, “to accelerate the discovery, development, and delivery of 21st century cures.” Provided — at Section 3023 and 3024 — broad authority for HHS Secretary to waive or alter human subject protections and informed consent requirements for participants in clinical trials, by transferring the individual human subject’s risk assessment authority to the HHS Secretary, who can preemptively decide, for all subjects, without knowledge of individual health conditions, and without the subjects’ knowledge or consent, that the risk is minimal.
- 2017 National Defense Authorization Act³⁸ - PL114-328, 130 Stat. 2509. Established DOD Defense Security Cooperation Agency (DSCA) and Director of DSCA, with authority to coordinate and synchronize US military with foreign military forces, and conduct domestic military campaigns in violation of the 1878 Posse Comitatus Act. 10 USC 382. *See* 01/23/2017 Department of Homeland Security Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans³⁹ at p. 78, stating that 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.”
- 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act⁴⁰ - PL 116-22, 133 Stat. 905 (61 pages). Amended Public Health Service Act (42 U.S.C. 201), further consolidating federal power in HHS Secretary’s hands during public health emergencies, further merging public health and law enforcement systems, and further subordinating state, tribal, county and municipal governments and American civilians to direct federal control.
- 2020 US Secretary of Health and Human Services Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19.⁴¹ 85 Federal Register 15198 (6 pages). Issued March 10, 2020, effective Feb. 4, 2020. Deployment of the domestic bioterrorism program against all American citizens under Covid-19 pretext.
- 2020 Coronavirus Preparedness and Response Supplemental Appropriations Act⁴² - PL 116-123, 134 Stat. 146 (12 pages). \$8.3 billion to Health and Human Services, Centers for Disease Control and Prevention, National Institute of Health, National Institute of Allergy and Infectious Diseases, Food and Drug Administration, Small Business Administration, Department of State and US Agency for International Development, for research and development of vaccines, therapeutics and diagnostics and other Covid programs.
- 2020 Families First Coronavirus Response Act⁴³ - PL 116-127, 134 Stat. 178. (43 pages). \$3.5 billion for Covid mass testing, supplemental nutrition (Department of Agriculture), sick leave, family medical leave, and unemployment compensation (Department of Labor) programs.
- 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act⁴⁴ - PL 116-136, 134 Stat. 281. (335 pages) 15 USC 9001. \$2.2 trillion in corporate and small business loans, household support and unemployment insurance, tax deferrals, aid to state and local governments, aid to universities and colleges, aid to K-12 schools, aid to hospitals and veterans programs, airline loans and grants, and \$10 billion for “Operation Warp Speed.”

³⁷ <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>

³⁸ <https://www.congress.gov/114/plaws/publ328/PLAW-114publ328.pdf>

³⁹ https://www.fema.gov/sites/default/files/2020-07/fema_incident-annex_biological.pdf

⁴⁰ <https://www.congress.gov/116/plaws/publ22/PLAW-116publ22.pdf>

⁴¹ <https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf>

⁴² <https://www.congress.gov/116/plaws/publ123/PLAW-116publ123.pdf>

⁴³ <https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf>

⁴⁴ <https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf>

- 2020 Consolidated Appropriations Act⁴⁵ - PL 116-260, 134 Stat. 1182 (5,593 pages). \$2.3 trillion spending bill, including \$900 billion for Covid programs.
- 2021 Orange Book Transparency Act⁴⁶ - PL 116-290, 134 Stat. 4889. (5 pages) Amendments to patent law under Federal Food Drug and Cosmetics Act, (21 USC 9)
- 2022 Consolidated Appropriations Act⁴⁷ - PL 117-103. Passed Congress March 15, 2022. \$1,274,678,000 for the Public Health and Social Services Emergency Fund (first funded in 2005). \$780,000,000 for new domestic bioweapons production, classified as ‘security countermeasures’ under the Public Health Service Act as amended by 2004 Project Bioshield Act, 42 USC 247d-6b(c)(1)(B)⁴⁸; \$845,000,000 to stock the Strategic National Stockpile, established 1998, controlled by the CDC within HHS 42 USC 247d-6b(a); \$300,000,000 “to prepare for or respond to an influenza pandemic,” including federally-funded construction or renovation of privately-owned pharmaceutical manufacturing facilities, if the Secretary of Health and Human Services finds such construction or renovation necessary; \$1,000,000,000 to establish ARPA-H: Advanced Research Program Agency - Health, to conduct research and development of bioweapons misbranded as public health measures; \$3,880,000,000 to US Agency for International Development (US-AID) for programs mislabeled as ‘Global Health Programs,’ including immunization programs, HIV/AIDS programs, The GAVI Alliance [population-control zealot Bill Gates’ Global Alliance for Vaccines and Immunization] and a multilateral vaccine development partnership, for, among other projects, “experimental contraceptive drugs, devices and medical procedures.”
- 2022 Covid Supplemental Appropriations Act⁴⁹ - Pending, HR7007. Authorizes \$10.6 billion for Covid bioweapon development and deployment, including “up to \$9,850,000,000 to Biomedical Advanced Research and Development Authority [BARDA, established 2006] for advanced research and development, manufacturing, production, and purchase, at the discretion of the Secretary of Health and Human Services, of vaccines, therapeutics, diagnostics, and supplies.”
- 2022 Research Investment to Spark the Economy (RISE) Act⁵⁰ - Pending, S.289. Senate counterpart to Cures 2.0 Act/HR6000, Title V, Section 502. Authorizes billions in funding for the Departments of Agriculture, Commerce, Defense, Education, Energy, the Interior, Health and Human Services, and Transportation, National Aeronautics and Space Administration (NASA), National Science Foundation, and Environmental Protection Agency to provide support for research regarding COVID-19 (i.e., coronavirus disease 2019) or research disrupted by the COVID-19 pandemic. Support may be used to provide supplemental funding to extend the duration of a grant...that was awarded prior to enactment, or to expand the purposes of such a grant; issue awards to research the effects of the current pandemic and potential future pandemics; and provide flexibility on awards to account for facility closures or other limitations during the COVID-19 public health emergency.
- 2022 PASTEUR Act⁵¹ - Pending, HR3832. (41 pages). Pioneering Anti-microbial Subscriptions To End Upsurging Resistance Act. Would create subscription-based procurement contracts between the US government and pharmaceutical corporations for ongoing, open-ended development, purchase and deployment of drugs alleged to treat antibiotic-resistant infections. Program to be developed by committee comprised of National Institute of Allergy and Infectious Diseases, Centers for Disease Control and Prevention, Biomedical Advanced Research and Development Authority, Food and Drug Administration, Centers for Medicare & Medicaid Services, Veterans Health Administration, and Department of Defense.
- 2022 Cures 2.0 Act⁵² - Pending, HR6000. (173 pages.) Would legally establish Covid-infection injury and Covid-19 bioweapon injection injury as “long Covid,” (erasing injection-caused injury as a separate

⁴⁵ <https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf>

⁴⁶ <https://www.congress.gov/116/plaws/publ290/PLAW-116publ290.pdf>

⁴⁷ <https://www.congress.gov/117/bills/hr2471/BILLS-117hr2471enr.pdf>

⁴⁸ <https://www.law.cornell.edu/uscode/text/42/247d-6b>

⁴⁹ <https://www.congress.gov/bill/117th-congress/house-bill/7007>

⁵⁰ <https://www.congress.gov/bill/117th-congress/senate-bill/289/text>

⁵¹ <https://www.congress.gov/117/bills/hr3932/BILLS-117hr3932ih.pdf>

⁵² <https://www.congress.gov/117/bills/hr6000/BILLS-117hr6000ih.pdf>

diagnostic classification) and appropriate research and treatment funding; would establish genomic testing program for children and teens (corroborating evidence that government developed the bioweapons to cause listed harms and anticipates observing those effects in the population); would establish pharmacogenetic consulting and other programs. Title V, Section 502 is House counterpart to S.289, RISE Act (see above), to authorize billions in funding for the Departments of Agriculture, Commerce, Defense, Education, Energy, the Interior, Health and Human Services, and Transportation, National Aeronautics and Space Administration (NASA), National Science Foundation, and Environmental Protection Agency to provide support for research regarding COVID-19 (i.e., coronavirus disease 2019) or research disrupted by the COVID-19 pandemic.

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ENABLING REGULATIONS, RULES & GUIDANCE DOCUMENTS

[Section added May 5, 2022]

- 2014/08/19 - FDA Guidance: Decisions for Investigational Device Exemption Clinical Investigations⁵³ (19 pages)
- 2015/08 - FDA Guidance: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products.⁵⁴ (19 pages)
- 2016/06/21 - HHS Clinical Trials Registration and Results Final Rule.⁵⁵ 81 FR 64981 (177 pages)
- 2017/01/19 - Federal Policy for the Protection of Human Subjects Final Rule⁵⁶. 82 FR 7149. (126 pages) Joint rule by 16 federal agencies, subsequently adopted by other agencies. Revised 1991 Common Rule⁵⁷, which had been developed based on 1947 Nuremberg Code⁵⁸ and 1978 Belmont Report⁵⁹.
- 2017/01/19 HHS Control of Communicable Diseases Final Rule⁶⁰. 82 FR 6890. (89 pages)
- 2017/01 - FDA Guidance: Emergency Use Authorization of Medical Products and Related Authorities⁶¹. (49 pages)
- 2017/07 - FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects⁶². (8 pages)
- 2017/08 - FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices⁶³. (17 pages)
- 2018/06/19 - 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 Final Rule⁶⁴. 83 FR 28497 (24 pages)
- 2021/04/02 - Congressional Research Service Opinion: State and Federal Authority to Mandate COVID-19 Vaccination⁶⁵ (14 pages)

⁵³ <https://www.fda.gov/media/81792/download>

⁵⁴ <https://www.fda.gov/media/89036/download>

⁵⁵ <https://www.govinfo.gov/content/pkg/FR-2016-09-21/pdf/2016-22129.pdf>

⁵⁶ <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf>

⁵⁷ <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

⁵⁸ <http://www.cirp.org/library/ethics/nuremberg/>

⁵⁹ https://www.videocast.nih.gov/pdf/ohrp_belmont_report.pdf

⁶⁰ <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-00615.pdf>

⁶¹ <https://www.fda.gov/media/97321/download>

⁶² https://www.fda.gov/files/about_fda/published/IRB-Waiver-or-Alteration-of-Informed-Consent-for-Clinical-Investigations-Involving-No-More-Than-Minimal-Risk-to-Human-Subjects---Printer-Friendly.pdf

⁶³ <https://www.fda.gov/media/99447/download>

⁶⁴ <https://www.govinfo.gov/content/pkg/FR-2018-06-19/pdf/2018-13187.pdf>

⁶⁵ <https://crsreports.congress.gov/product/pdf/R/R46745/3>

- 2021/07/06 - DOJ Opinion: Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization⁶⁶ (18 pages)
- 2021/09 - FDA Guidance: Real-World Data - Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products⁶⁷ (39 pages)
- 2021/11 - FDA Guidance: Real-World Data - Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products⁶⁸ (17 pages)
- 2021/11/17 - HHS - 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. Interim Final Rule⁶⁹. 86 FR 64075 (7 pages)
- 2022/02/07 - Congressional Research Service Opinion: State and Federal Authority to Mandate COVID-19 Vaccination⁷⁰. Update to 4/2/21 version. (46 pages)

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Specific to the deadly products marketed as Covid-19 vaccines, Congressional enabling seems to converge on one provision of the Food Drug and Cosmetics Act: the Emergency Use Authorization law: 21 USC 360bbb et seq⁷¹, which was adopted in 1997 as part of the Food and Drug Administration Modernization Act.

EUA-covered medical countermeasure (MCM) products, once designated as such by HHS (March 10, 2020, retroactive to February 4, 2020⁷²) are legally not part of any “clinical investigation,” no matter how untested, unmonitored, unsafe, or ineffective they may be.

Many other legal facts derive from this, and I’m in the process of tracking down the specific citation(s) in statute and regulation, for each one:

1. The use of the EUA products marketed as Covid-19 vaccines “shall not be considered to constitute a clinical investigation,” and the products are exempt from laws regulating use of investigational, experimental drugs or devices on human beings. Federal Food Drug and Cosmetics Act, 21 USC 360bbb-3(k). 1997, 2004, 2005, 2013.
2. There are no required standards for product safety, and only one standard for efficacy: a declaration by the HHS Secretary that a product “may be effective.” Federal Food Drug and Cosmetics Act, 21 USC 360bbb-3(c)(2)(A). 1997, 2004.
3. There are no human subjects or patients receiving the products marketed as Covid-19 vaccines. [Note to self: track statutory history authorizing 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, 45 CFR 46A re: definition of human subjects, and protections for human subjects as amended 01/27/1981 to present.]
4. There are no informed consent duties for those who administer the products (to provide risk and benefit information and obtain consent) or rights for those who receive the products (to receive risk and benefit information and give consent). 21 USC 355(i)(4), for drugs, and 21 USC 360j(g)(3), for devices. 2016.
5. There are no clinical investigators studying the effects of products marketed as Covid-19 vaccines on human subjects; there are no doctors, nurses, or other treatment providers providing experimental

⁶⁶ <https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf>

⁶⁷ <https://www.fda.gov/media/152503/download>

⁶⁸ <https://www.fda.gov/media/154449/download>

⁶⁹ <https://www.govinfo.gov/content/pkg/FR-2021-11-17/pdf/2021-25204.pdf>

⁷⁰ <https://crsreports.congress.gov/product/pdf/R/R46745>

⁷¹ <https://www.law.cornell.edu/uscode/text/21/360bbb>

⁷² <https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf>

treatment to their patients using products marketed as Covid-19 vaccines or subject to the Hippocratic Oath; and there is no legal requirement for medical supervision during product administration, or recipient monitoring after injection.

6. There are no coordinated, public federal data collection or analysis programs, because there are no clinical investigations, there are no human subjects or patients, and there is no administration of an investigational or experimental drug.
7. There are no requirements for individual prescriptions to be written prior to dispensing products marketed as Covid-19 vaccines, and products dispensed without prescriptions “shall not be deemed adulterated or misbranded.” Federal Food Drug and Cosmetics Act, 21 USC 360bbb-3a(d). 2013.
8. There are no Institutional Review Boards supervising administration of products marketed as Covid-19 vaccines for the protection of human subjects. [Note to self: track statutory history authorizing 21 CFR 56.101 et seq. re: Institutional Review Boards as amended 01/27/1981 to present.]
9. Manufacturers, as contractors, are considered HHS employees for purposes of sovereign immunity under Federal Tort Claims Act. 42 USC 247d-6a(d)(2)(A).
10. There is no treatment group and no control group, because there are no clinical investigations and no investigational products.
11. There are no required standards for quality-control in manufacturing; no inspections of manufacturing procedures; no prohibition on wide variability among lots; no prohibition on adulteration; and no required compliance with Current Good Manufacturing Practices. EUA products, even though unregulated and non-standardized, “shall not be deemed adulterated or misbranded.” Federal Food Drug and Cosmetics Act, 21 USC 360bbb-3a(c). 2013.
12. There are no labeling requirements regarding the contents or ingredients in the products marketed as Covid-19 vaccines.
13. There is no limitation of administration of products past their expiration dates.
14. There is no stopping condition, because there is no clinical investigation to stop, no party responsible for the wellbeing of recipients, no coordinated monitoring of recipients after receiving the products for adverse effects and deaths, and no coordinated data collection or analysis.
15. There cannot be clinical trial fraud, because there are no clinical investigations, no investigational drugs, no investigators and no human subjects.
16. There are no marketing standards.
17. There is no consumer fraud, because the only legal parties to the financial transactions are the government as buyer — and the entity that legally authorized the EUA exemptions from laws that otherwise apply to investigational drugs and devices — and the pharmaceutical corporations as sellers, contracted to develop and manufacture the products. There are no commercial pharmaceutical products, and no consumers.
18. There is no access to courts for judicial review of the facts or law relating to HHS Secretary declarations of covered countermeasures. Public Health Service Act, 42 USC 247d-6d(b)(7). 2005.
19. There is no civil or criminal liability and no entity to whom civil or criminal liability can attach, for injuries and deaths caused by declared covered countermeasures, because Congress set enormous barriers to suit. Public Health Service Act, 42 USC 247d-6d. 2005.
20. Even if there were access to courts for judicial review, and a fact-finder found evidence of harms caused by administration of products to recipients, and even evidence that those who caused the harms, by administering the products to the recipients, knew their actions were harmful, “just following orders” is an authorized, legal defense. Public Health Service Act, 42 USC 247d-6d(c)(4). 2005.

21. Summary: there are no actions that can be legally classified as crimes or civil torts; there are no medical battery or homicide victims, or plaintiffs; and there are no medical batterers or murderers. Because legally, nothing has been done, and no one has done anything, to anyone else.
22. The recursive loop can be infinite, as covered countermeasures are developed, authorized and deployed, through HHS Secretary EUA declarations, as treatments for complications from prior countermeasures.