Flight into Egypt. Bartolome Esteban Murillo

PREP Act, public health emergency, and EUA countermeasure law

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October 2025 Introduction

This volume contains writing about the PREP Act (Public Readiness and Emergency Preparedness Act), public health emergency (PHE) law, and emergency use authorization (EUA) law published by the authors at Bailiwick News and at Due Diligence and Art on Substack from 2022 to 2025. It is an expanded, revised version of an edition published in April 2025.

In 2020, as I began observing events and studying communicable disease control law and biological product law, I believed it was physically possible (feasible) for stable, disease-causing particles of biological matter to exist in stable, pathogenic (disease-causing), transmissible form; for transmission of such disease-causative matter to occur through casual physical contact (such as by airborne droplets); and that it might be feasible for disease-causing, transmissible particles to be artificially modified to increase their disease-causing capacity and/or transmissibility.

I believed the infection-control effectiveness of closure and occupancy restrictions in schools, businesses and churches, masking and 6-foot-spacing was overstated by public authorities. I believed the accuracy of diagnostic tests was overstated by public authorities. I believed the novelty of the allegedly-stable, allegedly-circulating biological particles and the severity of the allegedly-particle-caused illness (risks of permanent disability and death) were overstated by public authorities.

But I accepted claims by public authorities that an illness (named by authorities as Covid-19) afflicted human beings, and was caused by a stable, transmissible substance (classified as a 'virus' and named by authorities as SARS-CoV-2).

I have learned that claims and premises as to the stability, pathogenicity and transmissibility of particles of biological matter were and are not true, and have concluded that there are no sound scientific or medical reasons to justify communicable disease control, pandemic preparedness and response, biodefense and vaccination policies, programs, spending, industries or products.

Some of the reports collected in this volume were written before I understood the falsity of scientific premises and methods surrounding viruses, diagnostic testing, disease-causation attribution, pathology, epidemiology, vaccine manufacturing and vaccination; before I understood how long false premises and methods have been used to deceive people into taking vaccines and vaccinating babies and children; and before I understood that many information sources I once regarded as trustworthy, are more prudently regarded as untrustworthy. I've made minor edits for clarity and inserted a few update paragraphs, and advise readers to use discernment.

For additional material, please see American Domestic Bioterrorism Program (timeline); Legal history of biological product non-regulation (records back to 1798); St. Benedict Memo (summaries of relevant US federal laws passed between 1938 and 2006 and related material), and general collections of Bailiwick News, 2022-2025.

About the Authors

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Lydia Hazel holds degrees in Latin (BA) and linguistics (MA), with minors and concentrations in mathematics, phonetics/phonology, and philology. Hazel's professional background is teaching English as a Second Language.

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- Jan. 2, 2023 - Bioweapon prototype deployments, informed consent, targeted enemies, state of war, doctrine of necessity.
- Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation."
- March 22, 2023 - War criminal Xavier Becerra extends the public health emergency, effective March 15, 2023, using slightly-different wording.
- April 11, 2023 - Biden rescinding Trump-Biden Proclamation 9994 under 1976 National Emergencies Act does not terminate Azar-Becerra's Public Health Emergency authorities under 1983 PHE amendment to the 1944 PHSA.
- July 1, 2023 - Another sign that tide of covert war is turning will be pharmacies that refuse to take delivery of DoD biochemical weapons and pharmacists who refuse to use them on targets.
- Aug. 18, 2023 - Bridges v. Houston Methodist Hospital Court decisions supporting the conclusion that vaxx recipients are military targets, enemy combatants, chattel slaves or similar legal status in which consent is moot.
- Aug. 28, 2023 - March 15, 2023 and May 11, 2023 HHS Dictator-Secretary determinations and declarations.
- Oct. 17, 2023 - Texas and Oklahoma v. US Department of Health and Human Services and Xavier Becerra: case documents
- Oct 18, 2023 - There is never going to be another "deadly global pandemic." There have not been any in the past.
- Oct. 23, 2023 - On civil suits against Pfizer for "contamination" of Covid-19 biochemical weapons.
- Oct. 26, 2023 - 21 USC 360bbb-3(e)(3) and 360bbb-3a(c): federal law authorizing HHS Secretary to waive current Good Manufacturing Practices (cGMP) for EUA products. Relevant to public discussion of whether growing body of sequencing evidence of "adulteration" of Pfizer, Moderna and other mRNA platform technology products, opens new opportunities for litigation.
- Nov. 4, 2023 - Do C-19 Vax Manufacturers Violate cGxP? (Sasha Latypova)
- Nov. 14, 2023 - Separation of powers, reservation of powers (federalism), and the PREP Act.
- Dec. 1, 2023 - On 'mandates,' and the irrelevance of informed consent principles in the EUA countermeasures use context.
- Dec. 2, 2023 - EUA Countermeasures are neither investigational nor experimental. (Sasha Latypova)
- Dec. 6, 2023 - More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.
- Dec. 6, 2023 - Litigation proposals for state Attorneys General.
- Dec. 20, 2023 - Ending National Suicide Act. Draft bill for 118th Congress

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- Jan. 10, 2024 - On international and US legal instruments governing "adjustment of domestic legislative and administrative arrangements" and exercise of political authority during declared public health emergencies. (Jan. 10, 2024)
- Jan. 26, 2024 - Memo Re EUA Countermeasures to send to your doctor, pharmacist, employer, school, sheriff, county commissioner and state lawmakers (Sasha Latypova)
- Feb. 14, 2024 - Medical Countermeasures Awareness Bill (Tools for illuminating, defying and dismantling kill-box anti-laws)
- Feb. 23, 2024 - What section of the US Code did the Global Health Security and International Pandemic Prevention, Preparedness and Response Act enter after enactment Dec. 22, 2022? 22 USC 2151b, Population planning and health programs, as a statutory note.
- April 17, 2024 - Globalist misleaders focus public attention on WHO International Health Regulations to distract people from understanding and repealing federal and state public health emergency law.
- April 19, 2024 - Current Congress members have legal authority and moral agency to stop vaccine-mediated mutilation and killing programs worldwide.
- May 7, 2024 - Pandemics are fake. Federal and state public health emergency kill box laws can be repealed and nullified.
- May 7, 2024 - Bits and pieces about 10 USC 1107a(a) consent waivers, EUA products, BLA products, legalized FDA non-regulation of pharmaceutical manufacturing, and related things.
- May 15, 2024 - Global pandemic preparedness and response provisions already in US domestic law.
- May 17, 2024 - Global Catastrophic Risk Management Act, enacted by Congress and Biden Dec. 2022, codified at 6 USC 821-825.
- May 21, 2024 - There is no legal limit to the amount of so-called contamination that can legally be included in vaccines or any other biological products.
- May 23, 2024 - Top 10 US federal laws Congress should repeal to end worldwide vaccination, mutilation and killing programs.
- June 24, 2024 - On misconstruction of EUA countermeasures and vaccines as medicinal products, rather than weapons and poisons, and on legal-judicial system role in sustaining public ignorance and submission.
- June 27, 2024 - Intentional infliction of harm is not a legitimate government purpose; enabling it is not a permissible legislative object.
- July 2, 2024 - On reading PREP Act declarations as declarations of war issued by treasonous, seditious agents acting in unofficial, personal capacities.
- July 12, 2024 - Preliminary analysis of Loper v. Raimondo. Congress legalized military and civil administrators overriding US Constitution under self-declared emergency conditions, and Congress can repeal the enabling acts.
- Sept. 20, 2024 - Federal and state poison-legalizing laws and quarantine laws matter more than the UN, WHO and the IHR. Congress and state legislatures have the political authority to repeal poison-legalizing laws and quarantine laws.

- March 15, 2025 - Congressional elimination of judicial review and preemption of state law to enable interstate trafficking in intentionally harmful 'covered countermeasures.' 42 USC 247d-6d(b)(7) and 42 USC 247d-6d(b)(8)
- March 17, 2025 - Erwin Chemerinsky letter to Senate, Dec. 20, 2005, on unconstitutional PREP Act.
- March 17, 2025 - Senators Kennedy, Biden, Clinton, Byrd, denouncing PREP Act on Dec. 21, 2005, and then committing treason by voting for it the same day. (March 17, 2025)
- March 19, 2025 - On the absence of legal and scientific standards of evidence for public health emergency and emergency countermeasure determinations and declarations by HHS Secretary.
- April 4, 2025 - Repealing PREP Act and terminating HHS Secretary determinations and declarations issued under PREP Act are two different things.
- April 7, 2025 - No one can be found in legal violation of a rule they were never required to comply with, nor can anyone be found to have failed to meet an evidentiary standard they were never required to meet.
- April 21, 2025 - PREP Act Brief: "License to Kill" must be repealed. (Sasha Latypova)
- April 24, 2025 - PREP Act, An act of treason, video discussion. Stephanie Weidle, Sasha Latypova, Katherine Watt. (Transcript)
- June 2, 2025 - There cannot be product liability exposure for manufacturers of products for which no physical, objective standards exist.
- June 6, 2025 - On whether 'public health emergency of international concern' declarations by WHO Director-General are required to be supported by physical evidence, or subject to fact-finding and evidentiary review
- June 9, 2025 - On whether US-HHS Secretary Alex Azar needed UN-WHO declaration of "public health emergency of international concern" to issue determination that "public health emergency exists" in January 2020.
- June 17, 2025 - No HHS or FDA authority or competency to standardize or regulate vaccine-bottling processes or products; notes on "recall" authority.
- Aug. 19, 2025 - Common law, statutory law and administrative law preclusion of judicial review of government acts allegedly undertaken for disease surveillance and control.
- Sept. 10, 2025 - 42 USC 247d et seq, Public health emergencies, enacted by US Congress through Public Health Improvement Act (2000)
- Sept. 10, 2025 - 21 USC 360bbb-3 [FDCA 564], Authorization for medical products for use in emergencies, enacted by US Congress through NDAA (2003) and Project Bioshield Act (2004)
- Sept. 10, 2025 - 42 USC 247d-6d [PHSA 319F-3] and 42 USC 247d-6e [PHSA 319F-4], Targeted liability protections for pandemic and epidemic products and security countermeasures; Covered countermeasure process, enacted by Congress through PREP Act (2005)

Oct. 11, 2024 - Learning Curve

The US Department of Health and Human Services (1979-present), previously Health, Education and Welfare (1953-1979), previously Federal Security Agency (1939-1953), with military and corporate partners, has now mass-poisoned four generations of children with vaccines: Boomers (born roughly between 1946-1964), Gen-X (1965-1980), Millennials (1981-1996) and Gen Z (1997-2010).

They've mass-poisoned most of Gen-Alpha (2011-present) and are coming for the rest.

Stop taking vaccines. Stop vaccinating babies and children.

For readers who are also somewhere on this learning curve, below is a summary of how I got from what I believed in January 2020, to what I understand now.

1. In January 2020, I believed the government stories about infectious diseases and vaccines.

2. By March or April 2020, after learning about the symptoms (in most cases similar to seasonal, mild, brief upper respiratory illness) allegedly caused by the allegedly novel pathogen, I was questioning government responses — "lockdowns" and occupancy restrictions, church, school and business closures, mask mandates and more — as disproportionate, abusive and unconstitutional.

3. I learned that federal courts had been knocked out of commission and were unable to engage in fact-finding or apply legal standards of evidence to review of government policies. (Sept.-Oct. 2020)

4. I learned that a person with knowledge of drug research and development and nothing to gain by speaking out (Mike Yeadon), found vaccine development projects as publicly described by government officers and pharmaceutical company officials to be deeply disturbing, and predicted that the product, as described in official publications, would be extremely toxic. (Oct.-Dec. 2020).

5. I watched the Covid vaccination campaign, injuries and deaths unfold and continued studying legal and scientific issues. (Dec. 2020-Jan. 2022)

6. Between January and May 2022, I learned about the World Health Organization International Health Regulations and about US domestic public health emergency laws implementing WHO-IHR provisions. I learned about the non-existence of scientific or legal standards of evidence to support government officer claims about pathogens, emergencies and products. I learned HHS Secretary pronouncements are legally unilateral, unreviewable and require no validated scientific support. I learned about government officers', product fake-regulators' (FDA) and pharmaceutical officials' knowledge of the non-existence of applicable scientific or legal standards of evidence, and about military contracts for vaccine procurement and distribution, through Brook Jackson's case.

7. During 2022 and 2023, I met Sasha Latypova (July 2022) and deepened my understanding that public health emergency/biodefense programs are drawn from a playbook[1] that had been used several times already in recent decades (SARS, MERS, H1N1). I realized that playbooks are written to be used repeatedly and the PHE/biodefense playbook would be used again, and therefore people should be warned not to use or take any emergency "medical countermeasures" (isolation and social-distancing advice, masks, diagnostic tests, vaccines, medications).

8. I also learned that government and pharmaceutical officers would incorporate the same alleged new substances and manufacturing processes allegedly used to make Covid vaccines, into all emergency and routine vaccines henceforth, and that government officers had reduced or eliminated even the purported scientific evidentiary standards used to authorize use of the emergency Covid vaccines, which standards I knew to be non-existent, pretextual, inapplicable, unenforceable, and unenforced. I understood that people should be urged not to accept or use any vaccines at all, routine or emergency, on babies, children or adults.

9. I learned (in December 2023) the phrase "Direct Final Rule" as describing federal administrative agency regulations published in the Federal Register that go into effect on an expedited schedule. Direct Final Rules can be contrasted with standard Notice of Proposed Rulemaking, comment period, and Final Rule sequences, which are also useless for stopping bad laws from taking effect but allow for the compilation of public records of public objections. Direct Final Rule procedures are available for agency decisions deemed, by the agency, to be "non-controversial." For example, if no one files a "significant adverse comment" within 30 days of a Direct Final Rule notice, the rule itself goes into effect 60 days from the date the Direct Final Rule notice was published. I learned the Direct Final Rule process was used from Dec. 2012 to Feb. 2013 to revise HHS-CDC interstate and foreign quarantine rules by adopting new definitions, including a definition for the term "quarantinable communicable disease."

10. In Dec. 2023, I also learned that FDA attempted to use the Direct Final Rule process in January 2018 to eliminate biological product establishment inspection duties for FDA inspectors. I learned that the Direct Final Rule had been withdrawn and the new Final Rule issued April 2019, effective May 2019. I knew (by Dec. 2023) that even if inspectors had entered vaccine manufacturing facilities in 2020, or in the years following 2020, FDA had never developed or promulgated any scientific evidentiary standards for vaccines, so the inspectors would have had no scientific evidentiary standards available to apply to the procedures and products being manufactured in the factories anyway.

11. I began to understand that the non-existence of scientific and legal evidentiary standards pre-dated Covid, and that the standards that don't exist for emergency and non-emergency products manufactured during and since Covid, also didn't exist for vaccines and other biological products manufactured before Covid. I wanted to find out when and how the evidentiary standards — and the legal forums for evidence review and substantive decisions (regulatory agencies, courts) — had been eliminated, or whether they had ever existed at all.

[1] https://bailiwicknews.substack.com/p/playbook-for-poisoning-populations

12. I learned (March 2024) about the 1995 Clinton-Gore policy document *Reinventing the Regulation of Drugs Made from Biotechnology*, and then found dozens of regulatory amendments made between 1995 and 2019 (and ongoing) to carry out the deregulation program laid out in the 1995 document and related Congressional statutes and Presidential executive orders.

13. I learned about the 1955 nationwide polio vaccination campaign targeting children and expectant mothers, and the "Cutter incident;" 1968-1969 influenza pandemic; 1971-1972 Congressional GAO study of NIH Division of Biologics Standards' (non-)regulation of "ineffective" influenza vaccines; 1972 transfer of biological product (non-)regulation from NIH to FDA; and 1976-1977 swine flu vaccine program, injuries and government payouts.

14. I learned about how each event was handled by Congress with show hearings and fake-investigations but no vaccination program shutdowns or statutory repeals, and how they were handled by regulatory agencies with program transfers, reorganizations and renaming but no vaccination program shutdowns or substantive scientific standards or enforcement. I learned that Congress and the fake-regulators work only to protect and expand vaccination/mass-poisoning programs, suppress vaccine hostility and maintain vaccine confidence, and how the events following the 1955 polio campaign led to the 1986 National Childhood Vaccine Injury Act.

15. I learned more about the 1944 Public Health Service Act provisions governing biological product non-regulation, and more about the development of biological product non-regulation from the 1902 Virus-Toxin law that was incorporated into the 1944 Public Health Service Act, and more about the development of scientific fraud in virology, immunology, and related fields from 1798 and throughout the 1800s.

* * *

2022

John the Baptist preaching. Pieter Bruegel the Elder

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2022

- Feb. 2, 2022 - January 19, 2017 Federal Register. US Health and Human Services final rulemaking, WHO International Health Regulations, and human liberty.
- March 23, 2022 - Why Pfizer and Moderna and FDA are working toward government authorization to inject babies and small children.
- March 24, 2022 - Project Bioshield Act of 2004 and PREP Act of 2005. Legal immunity for Pfizer, Moderna, hospitals, nursing homes, pharmacies, clinics, nurses, doctors, pharmacists.
- March 30, 2022 - Sharp, prophetic reporting from 2009 by Stephen Lendman
- April 7, 2022 - Responding to Steve Kirsch, James Roguski and others. World War Biochemistry has been underway for decades, key battle won by World Health Organization silently in January 2020.
- April 7, 2022 - Re: "judicially-unreviewable."
- April 8, 2022 - Note to Attorney Aaron Siri re: US statutes nullifying US Constitution.
- April 25, 2022 - The investigational drugs that weren't.
- April 28, 2022 - American Domestic Bioterrorism Program. Building the case to prosecute members of Congress, presidents, HHS and DOD secretaries and federal judges for treason under 18 USC 2381, excerpt from introduction.
- May 11, 2022 - On legal strategies and cases already filed. Griner v. Biden (Utah), Ealy v. Redfield (Oregon) and PREP Act immunity provisions.
- June 9, 2022 - COVID-19 injectable bioweapons as case study in legalized, government-operated domestic bioterrorism.
- June 14, 2022 - April 4, 2003 - Rep. Henry Waxman questioning FDA Commissioner Mark McClellan about informed consent waivers authorized through Project Bioshield Act.
- July 4, 2022 - Possibilities for proving intent. The work product of attorneys Susan E. Sherman, Wen W. Shen, Dawn Johnsen and the July 6, 2021 Department of Justice legal opinion, excerpts.
- Sept. 27, 2022 - On why Biden's comment that 'the pandemic is over' doesn't lift the bioterrorist police state jackboot off our necks.
- Oct. 4, 2022 - Notes for state Attorneys General considering filing challenges to protect the people in their states.
- Oct. 21, 2022 - Legal horror movie pitch: The World According to Darp. 'Shouting fire in a crowded theater' meets 'When did you stop beating your wife?' Starring US Government as Darpon Fink, serial-killer/arsonist. Section discussing PREP, insert excerpt.
- Dec. 13, 2022 - Excerpt from transcript, Nov. 2, 2022 Latypova-Watt discussion, public health emergencies, PREP Act, EUA countermeasures
- Dec. 13, 2022 - Intent to Harm (by Sasha Latypova)

Feb. 2, 2022 - January 19, 2017 Federal Register. US Health and Human Services final rulemaking, WHO International Health Regulations, and human liberty.

I'm working on writing up my notes from Attorney Todd Callender's interview by Dr. Elizabeth Lee Vliet[2], and doing some research to correct timeline errors and review cited documents.

Among other key events, Callender pointed to the 2005 adoption, through the World Health Organization, of a set of International Health Regulations.[3]

The WHO description accompanying publication of the second edition (emphasis added):

> "In response to the exponential increase in international travel and trade, and emergence and reemergence of international disease threats and other health risks, 196 countries across the globe have agreed to implement the International Health Regulations (2005) (IHR)."
>
> This binding instrument of international law entered into force on 15 June 2007.
>
> The stated purpose and scope of the IHR are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."
>
> Because the IHR are not limited to specific diseases, but are applicable to health risks, irrespective of their origin or source, they will follow the evolution of diseases and the factors affecting their emergence and transmission.
>
> The IHR also require States to strengthen core surveillance and response capacities at the primary, intermediate and national level, as well as at designated international ports, airports and ground crossings. They further introduce a series of health documents, including ship sanitation certificates and an international certificate of vaccination or prophylaxis for travelers...

The 2005 International Health Regulations required each signatory nation-state to adopt implementing legislation, which the United States government did, through revisions to 42 CFR Parts 70 and 71, governing interstate and foreign quarantine during any "public health emergency of international concern" as declared by the director of the Centers for Disease Control and the director of the World Health Organization.

The most recent major, highly-relevant revisions of 42 CFR Parts 70 and 71 occurred through a "final rulemaking" by the Department of Health and Human Services, published in the Federal Register on January 19, 2017 (6890 Federal Register/Vol. 82, No. 12[4]) and effective Feb. 17, 2017.

[2] https://www.americaoutloud.com/compulsory-vaccination-and-forced-quarantine-camps-in-arizona/
[3] https://www.who.int/publications/i/item/9789241580410
[4] https://www.federalregister.gov/documents/2017/01/19/2017-00615/control-of-communicable-diseases

The revisions were put in place just as Donald Trump was taking office as US President after a surprising electoral win.

Excerpts from Federal Register, 82 FR 6890:

> [p. 81] *Public health emergency* as used in this part means:
>
> (1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or
>
> (2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or
>
> (3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or
>
> (4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or
>
> (5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

Health and Human Services/CDC officials responded to public comments expressing concern.

> [pp. 16-17] One commenter also requested clarification concerning whether the World Health Organization's (WHO) declaration of a Public Health Emergency of International Concern (PHEIC) could continue to serve as the basis for a ''public health emergency'' if the President or HHS Secretary disagreed with the declaration of a PHEIC on legal, epidemiologic, or policy grounds.
>
> In response, HHS/CDC notes that the scenario proposed by the commenter is unlikely, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.
>
> HHS/CDC also received a comment objecting to referencing the WHO's declaration of a Public Health Emergency of International Concern (PHEIC) in the definition of ''public health emergency'' because this ostensibly relinquishes U.S. sovereignty.

HHS/CDC disagrees. By including references to a PHEIC, HHS/CDC is not constraining its actions or makings its actions subject to the dictates of the WHO. Rather, the declaration or notification of a PHEIC is only one way for HHS/CDC to define when the precommunicable stage of a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals.

While HHS/CDC will give consideration to the WHO's declaration of a PHEIC or the circumstances under which a PHEIC may be notified to the WHO, HHS/CDC will continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. Thus, HHS/CDC disagrees that referencing the WHO determination of a PHEIC results in any relinquishment of U.S. sovereignty.

The International Health Regulations are an international legal instrument that sets out the roles of WHO and State parties in identifying, responding to, and sharing information about public health emergencies of international concern. HHS/CDC believes that it would be unlikely for the United States to formally object to the WHO's declaration of a PHEIC, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

Also regarding the definition of ''public health emergency,'' one public health association expressed concern that *any* disease considered to be a public health emergency may qualify it as quarantinable. Another commenter noted that some PHEICs ''most certainly do not qualify as public health emergencies'' under the proposed definition. HHS/CDC appreciates the opportunity to clarify. Only those communicable diseases listed by Executive Order of the President may qualify as quarantinable communicable diseases. For example, Zika virus infection, which although the current epidemic was declared a PHEIC by WHO, is not a quarantinable communicable disease. The definition of *Public health emergency* is finalized as proposed."

As we all now know, the HHS/CDC blandishments — about scenarios in which the United States government would subordinate its national sovereignty to the World Health Organization being "unlikely" — were lies, told with full knowledge of their falsehood by the HHS/CDC liars.

March 23, 2022 - Why Pfizer and Moderna and FDA are working toward government authorization to inject babies and small children.

[March 27, 2025 Note - Information gathered since March 2022 about biological product non-regulation support the conclusion that all vaccines have been exempt from liability throughout all vaccination campaigns since 1902, because no valid standards for biological product identity or manufacturing quality exist, none can exist, no regulatory compliance is enforced, and none can be enforced. The swine flu act of 1976, 1986 National Childhood Vaccine Injury Act (NCVIA), 2004 Project Bioshield Act, 2005 PREP Act, and inclusion on the childhood immunization schedule offer manufacturers layers of civil and criminal liability immunity *in addition to* the basic immunities afforded by the manufacturers' participation in intentional, government-run mutilation and murder programs using biological and chemical weapons labeled as vaccines.]

Alex Berenson's latest: Moderna wants to sell mRNA shots for children that barely lowered Covid infections and caused 15 percent of kids to spike fevers[5] joins Toby Rogers' recent: Urgent call to action! We have 26 days to convince the FDA to reject the Pfizer mRNA shot in kids under 5. Let's go![6]

What's driving Pfizer, Moderna and the FDA? It's about getting the injections on the childhood vaccine schedule, so that the manufacturers and all the people who have administered the toxic pharmaceutical products marketed by the US government, Pfizer and Moderna as "Covid-19 vaccines" can have liability immunity permanently.

Robert F. Kennedy Jr.[7]:

> "They are never going to market a vaccine, allow people access to a vaccine, an approved vaccine without getting liability protection. Now the emergency use authorization vaccines have liability protection under the PREP Act and under the CARES Act.
>
> So as long as you take an emergency use vaccine, you can't sue them. Once they get approved, now you can sue them, unless they can get it recommended for children. Because all vaccines that are recommended, officially recommended for children get liability protection, even if an adult gets that vaccine.
>
> That's why they are going after the kids. They know this is going to kill and injure a huge number of children, but they need to do it for the liability protection."

*

[5] https://alexberenson.substack.com/p/moderna-wants-to-sell-mrna-shots?
[6] https://tobyrogers.substack.com/p/urgent-call-to-action-we-have-30?
[7] https://wsau.com/2021/12/31/robert-f-kennedy-jr-explains-why-fauci-is-going-after-children/

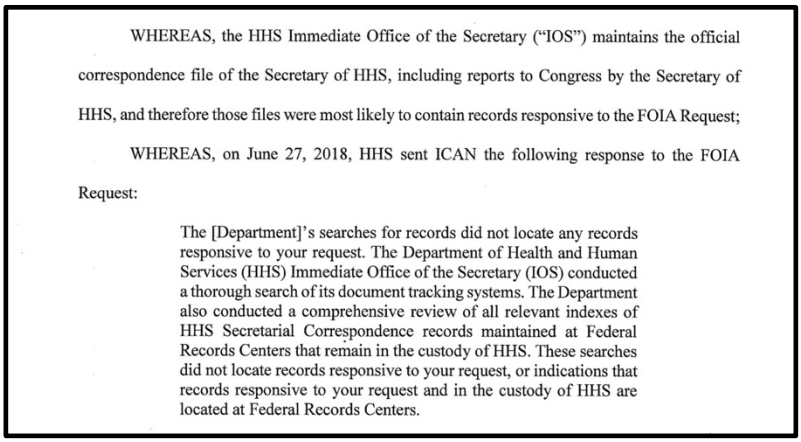
The legislative trail:

1986 National Childhood Vaccine Injury Act gave manufacturers immunity for liability for injuries and deaths caused by vaccines listed on the government-recommended childhood immunization schedule.

The argument used to exempt manufacturers from liability was that the government, through the Department of Health and Human Services, would monitor the childhood vaccination program, collect safety data, and report it to Congress to provide oversight and take harmful vaccines off the market.

However, the HHS and Congressional oversight required by the 1986 law didn't occur.

See Informed Consent Action Network v. US-HHS[8], 1:18-cv-03215-JMF, which ended with a July 9, 2018 stipulation[9] by the U.S. government that HHS had no records of any safety monitoring or public reporting of the childhood vaccination program, under the 1986 law, between 1986 and 2018.



WHEREAS, the HHS Immediate Office of the Secretary ("IOS") maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

> The [Department]'s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

Later two reports were located, filed on 5/4/88[10] and 7/21/89.[11] Since 1989: nothing. No evidence that the childhood vaccination schedule was safe at that time, nor any evidence that the injections added to the childhood schedule since 1986, alone or cumulatively, are safe.

*

2005 PREP Act, Public Readiness and Emergency Preparedness Act, gave manufacturers immunity from liability for injuries and deaths caused by vaccines under Emergency Use Authorization.

This legislation coincided with World Health Organization International Health Regulations and Presidential Executive Orders[12] signed by President Bush in 2003 and 2005, adding the common cold and influenza to the list of communicable diseases that could be declared public emergencies by the US-HHS Secretary, triggering cascading effects, including emergency use authorizations for pharmaceutical products and full manufacturer liability.

[8] https://www.icandecide.org/ican-vs-hhs-the-great-vaccine-debate/
[9] https://www.icandecide.org/wp-content/uploads/2019/09/Stipulated-Order-copy.pdf
[10] https://www.documentcloud.org/documents/5835885-Report-1.html
[11] https://www.documentcloud.org/documents/5835886-Report-2.html
[12] https://bailiwicknews.substack.com/p/legal-walls-short-version?s=w

2020 CARES Act, Coronavirus Aid, Relief, and Economic Security Act, March 27, 2020, expanded PREP Act provisions, by (among other things) expanding the number of people allowed to administer injections without facing liability for injuries and deaths caused by vaccines under EUA.

US-HHS Secretary Alex Azar declared Covid-19 a public health emergency on Jan. 31, 2020 (effective Jan. 27, 2020) and then issued a PREP Act declaration for Covid-19 March 10, 2020, retroactive to Feb. 4, 2020, followed by a series of amendments expanding its reach. (Synopsis of original and ten amendments adopted through Jan. 7, 2022) at Federal Register[13] (Vol. 87, No. 5, p. 982).

US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response web page[14]:

> To expand the workforce available and authorized to administer COVID-19 vaccines, the Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity to qualified individuals.
>
> When Immunity from Liability Applies
>
> When the Secretary determines that a threat or condition constitutes a present or credible risk of a future public health emergency, the Secretary may issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of covered countermeasures to diseases, threats and conditions identified in the declaration.
>
> Professionals and Entities Covered by Immunity
>
> PREP Act immunity applies to:
>
> - licensed health professionals authorized to administer covered medical countermeasures under the law of the state where the countermeasure is administered, and
> - other individuals identified in the declaration by the Secretary of Health and Human Services (HHS) to prescribe, dispense, or administer covered countermeasures, including the COVID-19 vaccine
>
> Qualified Persons
>
> In March 2020, the Secretary issued a PREP Act Declaration covering COVID-19 tests, drugs and vaccines providing liability protections to manufacturers, distributors, states, localities, licensed healthcare professionals, and others identified by the Secretary

[13] https://www.govinfo.gov/content/pkg/FR-2022-01-07/pdf/2022-00151.pdf
[14] https://www.phe.gov/emergency/events/COVID19/COVIDvaccinators/Pages/PREP-Act-Immunity-from-Liability-for-COVID-19-Vaccinators.aspx

(qualified persons) who administer COVID-19 countermeasures. The Declaration has been amended several times to expand liability protections, including prior amendments to cover licensed healthcare professionals who cross state borders and federal response teams.

Under the PREP Act, a qualified person is a covered person. Except for willful misconduct, a covered person is immune from lawsuits and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure, such as a COVID-19 vaccine, if they meet criteria stated in a declaration under the PREP Act issued for the health emergency or threat and covered countermeasure.

The seventh PREP Act amendment expands the list of professionals who are qualified to administer vaccines and are protected from liability as follows:

- Non-Traditional Licensed or Certified Health Professionals: Listed healthcare providers who are licensed or certified prescribe, dispense and/or administer COVID-19 vaccines.
- Previously Active and Recently Retired Professionals: Any retired professional whose license or certification expired within the past five years to prescribe, dispense and/or administer COVID-19 vaccines in any state or U.S. territory so long as the license or certification was active and in good standing prior to the date it went inactive.
- Healthcare Students: Any student who has proper training in administering vaccine from their school or training program and are under supervision by a currently practicing healthcare professional experienced in intramuscular injections.

Impacts on State, Local, Tribal, and Territorial Health Agencies

The PREP Act Declaration amendments preempt requirements that would result in a qualified person being unable to prescribe, dispense, or administer vaccines as authorized by the state or U.S. territory. Licensing laws that are less restrictive than those in the Declaration amendments are not preempted. States and U.S. territories determine authorized vaccinators in their jurisdiction.

March 24, 2022 - Project Bioshield Act of 2004 and PREP Act of 2005. Legal immunity for Pfizer, Moderna, hospitals, nursing homes, pharmacies, clinics, nurses, doctors, pharmacists.

Looking today at Project Bioshield Act of 2004, PL-108-276, and the PREP Act of 2005, PL-109-148, 42 U.S.C. 247d-6d et. seq. which together made a lot amendments to the Public Health Service Act of 1944, 42 USC 247(d), and paved the road we're traveling on now.

The Project Bioshield Act[15] (30 pages) was passed by Congress and signed by President George W. Bush on July 21, 2004.

The PREP Act[16] was passed by Congress and signed into law on Dec. 30, 2005. It was tagged on as the last 14 pages of a 154-page Department of Defense supplemental appropriations and Hurricane Katrina relief bill.

Together, these two laws changed a lot of federal laws related to bioterrorism, pandemics, drug development, appropriations, contracting, procurement, and product liability.

Project Bioshield[17] was

> "established to help incentivize private industry to develop vitally needed medical countermeasures by providing multi-year funding to support advanced research, clinical development, manufacture and procurement. Without this secure source of funding, companies do not have the incentive needed to develop the medical countermeasures that are critical to national security."

Together with several other laws[18], the Project Bioshield Act and PREP Act appear to be the source of the US Secretary of Health and Human Services' Emergency Use Authorization (EUA) power, through which HHS Secretary Alex Azar first declared Covid-19 a public health emergency a public health emergency on Jan. 31, 2020 (the day after World Health Organization Director-General Tedros declared it a "public health emergency of international concern."

Azar then issued a "declaration for medical countermeasures" for Covid-19 effective February 4, 2020[19], followed by other declarations and amendments to the original declarations.

Azar's PREP Act declaration bestowed immunity for liability on developers, manufacturers, distributors and vaccinators, for injuries and deaths caused by vaccines developed, manufactured, distributed and administered under Emergency Use Authorization.

[15] https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf
[16] https://www.congress.gov/109/plaws/publ148/PLAW-109publ148.pdf#page=140
[17] https://www.phe.gov/about/barda/Pages/Project-Bioshield.aspx
[18] https://www.phe.gov/Preparedness/legal/Pages/default.aspx
[19] https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

The only exception is for "willful misconduct," which might apply to Pfizer and Moderna if the clinical trial fraud alleged by whistleblower Brook Jackson[20] can be proved — as Edward Dowd and others are working toward. But it would probably not apply to distributors and injectors who can credibly claim they had no knowledge of the clinical trial fraud.

HHS Secretary Azar's declaration also rendered contractors like Pfizer, Moderna, nurses and pharmacists, as classifiable, in legal terms, as government employees of the Department of Health and Human Services for purposes of the Federal Tort Claims Act and related laws: 28 USC 1346(b) and 28 USC 2672.

The HHS PREP Act declaration has been amended several times since March 2020, each time expanding its reach, most recently on Jan. 7, 2022 (10th amendment[21]).

The Project Bioshield Act of 2004 includes provisions specifically addressing how EUAs are to be declared, maintained and terminated, at 42 USC 360bbb-3[22], relating to use of "unapproved products" or "unapproved uses of approved products."

The effect of Azar's PREP Act declaration, through the Project Bioshield Act of 2004, was to authorize government-funded development, marketing, distribution and deployment, by the contractors (Pfizer, Moderna, hospitals, nursing homes, clinics, pharmacies, nurses, pharmacists, etc.) of the pharmaceutical products marketed as "Covid-19 vaccines."

Crucially, the EUA could only be initiated and maintained by denying that safe, effective medications such as hydroxychloroquine, Ivermectin, anti-inflammatory drugs, anti-coagulants, antivirals and vitamins, existed for the treatment of the symptoms of Covid-19. This was the reason the US government and propaganda apparatus viciously attacked doctors and nurses who successfully treated patient symptoms with existing medications targeting those symptoms (inflammation, clotting, etc.) and then tried to share their successful treatments with other doctors, nurses and the general public.

That's why the EUA provisions at 360bbb were challenged by a petition to federal court filed in Alabama on July 19, 2021 by America's Frontline Doctors against Secretary of Health and Human Services Xavier Becerra, Fauci, Woodcock, HHS, FDA, CDC, NIH, NIAID, et al, 2:21-cv-00702-CLM. Which has been slowly working its way through the court system.

*

[20] https://s3.documentcloud.org/documents/21206071/brook-jackson-lawsuit.pdf
[21] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx
[22] https://www.govinfo.gov/content/pkg/USCODE-2019-title21/pdf/USCODE-2019-title21-chap9-subchapV-partE-sec360bbb-3.pdf

Today at Coffee and Covid[23], Jeff Childers addressed the Moderna application for EUA approval[24] for injections for babies and young children, asking the question:

> "If emergency use authorization only applies during an emergency, how are the EUA vaccines still viable? It's been over two years. Everybody agrees the pandemic is over, and we are learning to "live with Covid." When do these EUA licenses expire?"

It's not true that "everybody agrees the pandemic is over."

The World Health Organization Director-General declaration of the "public health emergency of international concern," originally issued Jan. 30, 2020, is still in full force.

The US Secretary of Health and Human Services PREP Act emergency declaration and related declarations, that began Jan. 31, 2020, are still in full force, temporary 'rollbacks' and 'pauses' and 'updated guidance' notwithstanding.

On Feb. 18, 2022, President Biden indefinitely extended the original national state of emergency declared by President Trump on March 13, 2020.

Under the circumstances, the EUA status still applies, and there's no legal liability for any injuries or deaths caused by manufacturers and vaccinators.

21 USC 360bbb-3(b)(2) addresses "Termination" of an EUA:

> (A) In general, A declaration under this subsection shall terminate upon the earlier of—
>
> (i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or
>
> (ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

EUA seems to expire when the HHS Secretary says so, or when the EUA products get full approval, whichever comes first.

The PREP Act has been interpreted by at least one court (Supreme Court of New York) to even shield manufacturers and vaccinators from liability for injury and death when the treatment was given without consent, relating to H1N1 'vaccines.'

See *Parker v. St. Lawrence*, 102 A.D.3d 140 (2012):

> Liability protections for pandemic countermeasures taken by certain "covered persons" in response to a declaration of a public health emergency by the Secretary are specifically provided for in the PREP Act (*see* 42 USC § 247d-6d [a], [b]). It provides that "a covered person *shall* be immune from suit and liability under Federal and *State law* with respect to *all* claims for loss caused by, arising out of, relating to, or resulting from the administration to ... an individual of a covered countermeasure" pursuant to a declaration of, among other things, a public health emergency (42 USC § 247d-6d [a] [1] [emphasis added]).
>
> The statute broadly defines "loss" as "any type of loss, including... physical, mental, or emotional injury" or fear thereof (42 USC § 247d-6d [a] [2] [A] [ii]-[iii]), and provides that its immunity provision applies to "*any claim* for loss that has a causal relationship with the administration to ... an individual of a covered countermeasure," including, among other things, "dispensing [and] administration" (42 USC § 247d-6d [a] [2] [B] [emphasis added]). The "sole exception" to immunity from suit and liability is a federal action for "death or serious physical injury proximately caused by willful misconduct" (42 USC § 247d-6d [d] [1]).[4]
>
> Considering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent (*see Bruesewitz v Wyeth LLC,* 562 US ___, ___, 131 S Ct 1068, 1088 [2011]).
>
> Notably, Congress created an alternative administrative remedy — the Countermeasures Injury Compensation Program — for covered injuries stemming from countermeasures taken in response to the declaration of a public health emergency (*see* 42 USC § 247d-6e [a]; 74 Fed Reg at 51154),[5] as well as a separate federal cause of action for wrongful death or serious physical injury caused by the willful misconduct of covered individuals or entities (*see* 42 USC § 247d-6d [d]). The provision of these exclusive federal remedies further supports our finding of preemption.
>
> We are unpersuaded by plaintiff's assertion that immunity pursuant to the PREP Act does not extend to qualified persons who administer a covered countermeasure to an individual without consent. The immunity provisions of the PREP Act are triggered where, as here, the vaccines are purchased pursuant to a federal contract or agreement (*see* 75 Fed Reg 63656, 63658 [2010]) and, despite plaintiff's assertions to the contrary, Executive Order No. 29 neither defines nor otherwise places limitations upon the scope or applicability of such immunity.[6]

> Plaintiff also asserts that Congress could not have intended to immunize such "radical measures" as administering a vaccination without consent. It is not our role, however, to speculate upon congressional judgments. Rather, we must presume that Congress fully understood that errors in administering a vaccination program may have physical as well as emotional consequences, and determined that such potential tort liability must give way to the need to promptly and efficiently respond to a pandemic or other public health emergency.

*

Aggregated, the new laws, amendments to existing laws, HHS regulations and declarations put into place since the mid-2000s, and now cited by the US-HHS Assistant Secretary for Preparedness and Response[25] as the source of authority for the Covid-19 project, are the laws that the United States government was forced to adopt and implement upon becoming a member party to the 2005 World Health Organization International Health Regulations. List of US government Covid-19 declarations[26]: government rule by unilateral, unreviewable, unappealable proclamation made by unelected technocrats. Interestingly, the Feb. 4, 2020 medical countermeasures declaration doesn't appear in the timeline created by Congressional Research Service through June 2021.

[25] https://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx
[26] https://crsreports.congress.gov/product/pdf/R/R46809

March 30, 2022 - Sharp, prophetic reporting from 2009 by Stephen Lendman

2009 report[27] by Stephen Lendman,[28] summarizing provisions of three US laws passed by Congress and signed by President Bush to embed World Health Organization International Health Regulations of 2005 into American federal statutes and regulations[29]:

> At least three US federal laws should concern all Americans and suggest what may be coming - mandatory vaccinations for hyped, non-existent threats, like H1N1 (Swine Flu). Vaccines and drugs like Tamiflu endanger human health but are hugely profitable to drug company manufacturers.
>
> The Project BioShield Act of 2004 (S. 15) became law on July 21, 2004 "to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures."
>
> In other words, the FDA may now recklessly approve inadequately tested, potentially dangerous vaccines and other drugs if ever the Secretaries of Health and Human Services (HHS) or Defense (DOD) declare a national emergency, whether or not one exists and regardless of whether treatments available are safe and effective. Around $6 billion or more will be spent to develop, produce, and stockpile vaccines and other drugs to counteract claimed bioterror agents.
>
> The Public Readiness and Emergency Preparedness (PREP) Act of 2005 slipped under the radar when George Bush signed it into law as part of the 2006 Defense Appropriations Act (HR 2863). It lets the HHS Secretary declare any disease an epidemic or national emergency requiring mandatory vaccinations. Nothing in the Act lists criteria that warrant a threat. Also potential penalties aren't specified for those who balk, but very likely they'd include quarantine and possible fines.
>
> The HHS web site also says the Secretary may "issue a declaration...that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of (vaccine or other pharmaceutical) countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency...."
>
> The industry-run US Food and Drug Administration (FDA) notoriously rushes inadequately tested drugs to market, putting their efficacy and safety into question, and turning those who use them into lab rats. It includes everyone if a mass vaccination is ordered on the mere claim of a public emergency - no proof required.

[27] https://web.archive.org/web/20090612165816/http:/www.globalresearch.ca/index.php?context=va&aid=13925
[28] https://stephenlendman.org
[29] https://bailiwicknews.substack.com/p/legal-walls-short-version?s=w

The Pandemic and All-Hazards Preparedness Act of 2006 (S. 3678) is the other worrisome law, effective December 19, 2006. It amended "the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes." Even its supporters worry about issues of privacy, liability, and putting profits over public health. Critics express greater concerns about dangerous remedies for exaggerated or non-existent threats as well as mass hysteria created for political purposes.

At least one other measure is also worrisome - The Model State Emergency Health Powers Act (MSEHPA)…

April 7, 2022 - Responding to Steve Kirsch, James Roguski and others. World War Biochemistry has been underway for decades, key battle won by World Health Organization silently in January 2020.

(Excerpts)

Steve Kirsch posted yesterday about the latest round of negotiations to expand the World Health Organization's power to strip citizens and nation-states around the world of our sovereignty, physical freedom and Nuremberg-enshrined human rights, and operate as a one-world government accountable to no one and legally authorized to continue committing global genocide. He linked to a series of excellent posts by James Roguski.

Both are rightly raising the alarm, and I agree with them: people should get involved now, if not sooner, in trying to fight off the latest power grab by the World Health Organization, its demonic, anti-human financial backers and World War Biochemistry profiteers (the Rothschild-Rockefeller cabal), and its quislings in the United States Congressional-military-industrial-pharmaceutical complex.

One way to take action, advocated by former WHO scientist Astrid Stuckelberger, is posted here...

It's also important for people to understand that the one-world government led by WHO is already in place, and operational at the federal, state, county and municipal level in every country, including America, through the legal merger of the public health and law enforcement systems.

The WHO already declared a "public health emergency of international concern," and it therefore automatically, silently took control of the US government, through the US Secretary of Health and Human Services, who already declared a public health emergency, in full subordination and compliance with WHO orders.

The US-HHS Secretary (first Azar, now Becerra) is already functioning as an unelected, unannounced dictator and has been in full power since January 2020.

Xavier Becerra already has Congressionally-legislated and funded, President-ratified, judicially-unreviewable power to domestically deploy the US military and local law enforcement to try to round up and imprison dissidents, aka people who can be alleged are asymptomatic carriers of colds and flus, and/or insurrectionists disturbing civil order by objecting to Covid-related government policies and programs, or election fraud, or any other pretext.

They haven't used that power yet, for at least two reasons:

1. They'd rather conduct the genocide so it looks voluntary, committed by people who go to hospitals, nursing homes, pharmacies and clinics and get the toxic injections under their own steam, without resistance, than try to go door-to-door hauling people out of our homes, shipping us to medical facilities or detention camps, and injecting us by force.
2. Americans are armed at the household level, thanks to the Constitutional framers' incredible wisdom and foresight in enshrining the Second Amendment right of the citizens to keep and bear arms to protect ourselves from what we now face: government tyranny. Our government is actively working, on behalf of hostile enemies fronted by the WHO, to enslave and kill the People.

To repeat: It's a good idea to try to stop WHO from expanding and strengthening its one-world-government powers, which is what the current round of negotiations is about. They want it to also be deployable in any future natural disaster (floods, hurricanes, droughts) and any man-made disaster (wars, famines, supply chain disruptions, currency collapses), not just to communicable diseases.

The legal framework is already in place, through the 2005 International Health Regulations as implemented through US statutes and regulations, which all flowed from the anthrax attacks just after 9/11, which were deployed by the US military itself, to create the population-level mass fear predicates for Congressional adoption of the Patriot Acts and the related public health martial laws.

Some of the pieces were put into place between 1944 and 2000, especially in 1983, when Section 319 was added to 42 USC 247d to cover "public health emergencies" and set up a Public Health Emergency Fund and 1986, when the Childhood Vaccine Compensation Act stripped US citizens of access to federal and state courts for wrongful death and injury claims caused by pharmaceutical homicide products marketed as vaccines.

But most have been put into place since 2000, alongside hundreds of implementing regulations adopted by the Department of Homeland Security (including FEMA); the Department of Health and Human Services (including the CDC, FDA, NIH, NIAID); the Department of Justice; the Department of Defense (including the Army and National Guard) and other federal agencies.

And they've been tested to see how they work, to psychologically condition the population to interpret government interference and oppression as government protection, and to strengthen them, through the 2001 anthrax attacks, the 2003 SARS outbreak, 2005 Hurricane Katrina and Hurricane Rita disaster management programs, 2005 H5N1 outbreak, 2009 H1N1 outbreak, 2014 Ebola outbreak, 2019 SARS-CoV-2 outbreak, November 2020 election theft, and January 6, 2021 protests in Washington DC, with subsequent political imprisonment of non-violent trespassers and wholesale criminalization of public or private dissent from and criticism of government-by-executive-decree.

Below are the main statutes passed between 2000 and the present, setting the frameworks in place.

These are the illegitimate U.S. laws that must be openly, deliberately resisted and violated by individual citizens, families and communities, and repealed by Congress, if America is to move forward in history as a Constitutional republic, with sovereign self-governance and protection of God-given natural human rights, just as the United States must withdraw from its membership in the anti-human World Health Organization:

- 2000 Public Health Improvement Act (expanded authorities granted to Secretary of Health and Human Services under Section 319, Public Health Emergencies);
- 2002 Public Health Security and Bioterrorism Preparedness and Response Act;
- 2002 Homeland Security Act;
- 2004 Project Bioshield Act;
- 2005 Public Readiness and Emergency Preparedness Act;
- 2006 Pandemic and All-Hazards Preparedness Act;
- 2007 John Warner Defense Authorization Act (amended 10 USC 333 re: “insurrection.”);
- 2012 National Defense Authorization Act (authorized indefinite detention of US citizens without charge or trial);
- 2013 Pandemic and All-Hazards Preparedness Reauthorization Act;
- 2016 21st Century Cures Act;
- 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act;
- 2020 Coronavirus Aid, Relief, and Economic Security Act

April 7, 2022 - Re: "judicially-unreviewable."

Commenter to previous post[30] wrote:

> "judicially-unreviewable power"
>
> Having a hard time reconciling this with the 10th Amendment. Either the Constitution is supreme or revolutionary war will come.
>
> Are you saying SCOTUS would try to enforce the treaties? Are treaties supreme to national laws?
>
> Someone needs to explain how this is law just because legislation was passed. Unconstitutional laws pass and get rejected. States refuse to prosecute laws. How is this different?

My response:

More likely, SCOTUS will simply kick out all cases brought on Constitutional and civil liberties grounds, which is what they've done to date, acting as if those issues are moot.

So far, (as far as I know) all of their rulings — even the ones that benefit workers by lifting alleged mandates — have been on procedural and regulatory grounds, and SCOTUS Chief Justice Roberts, in a May 2020 case *South Bay United Pentecostal v. Newsom*, explicitly said that federal judges should not even attempt to review or second-guess emergency actions taken by executive and legislative branches.

> "The precise question of when restrictions on particular social activities should be lifted during the pandemic is a dynamic and fact-intensive matter subject to reasonable disagreement.
>
> Our Constitution principally entrusts "[t]he safety and the health of the people" to the politically accountable officials of the States "to guard and protect." Jacobson v. Massachusetts, 197 U. S. 11, 38 (1905).
>
> When those officials "undertake[ ] to act in areas fraught with medical and scientific uncertainties," their latitude "must be especially broad." Marshall v. United States, 414 U. S. 417, 427 (1974).
>
> Where those broad limits are not exceeded, they should not be subject to second-guessing by an "unelected federal judiciary," which lacks the background, competence, and expertise to assess public health and is not accountable to the people. See Garcia v. San Antonio Metropolitan Transit Authority, 469 U. S. 528, 545 (1985)."

[30] https://bailiwicknews.substack.com/p/responding-to-steve-kirsch-james?s=w

So far, most federal courts have abided by Justice Roberts' implicit directive to steer clear of Constitutional review.

Also, Congress put provisions into the statutes that authorize a variety of court workarounds, mostly related to the principle of "committed to agency discretion."

Once the HHS Secretary has declared a public emergency, he or she has emergency powers that courts cannot review. 42 USC 247d-6d(b)(7).

And once he or she has designated a product as an EUA "countermeasure," use of the product, and all the people involved in developing, manufacturing, distributing and administering the product are almost completely immune from accountability for their actions.

People who have claims are barred from using state or federal courts for civil cases; the sole remedy is the Congressionally authorized Countermeasures Injury Compensation scheme (CICP).

No court can review compensation payouts made under that program. 42 USC 247d-6e(b)(5)(C).

Congress legalized the "just following orders" defense for nurses and other vaccinators. 42 USC 247d-6d(c)(4).
Procurement contracts (i.e. with Pfizer) can only be reviewed by the contracting agency (HHS/FDA/CDC) or by the Comptroller General.

Contractors are, for legal purposes, considered HHS employees, so they get government immunities.

Burden of proof is on plaintiffs to prove willful misconduct proximate to injury and/or death, stricter standard than negligence.

The only federal court authorized to hear claims is the US District Court for District of Columbia (home court) and they are required to use a three-judge panel, and their rulings are specifically not appealable to US Supreme Court. 42 USC 247d-6d(e)(5)

I'm working on detailed summaries and analysis of the U.S. laws passed between 2000 and 2022, to post here over the next few weeks/months, so some of those specific citations might be wrong, and will be corrected in the full posts.

In the meantime, the main statutes to look at, to confirm or refute my analysis so far, are the 2004 Project Bioshield Act, PL 108-276, passed July 21, 2004, and the 2005 PREP Act, PL 109-148, passed Dec. 30, 2005.

April 8, 2022 - Note to Attorney Aaron Siri re: US statutes nullifying US Constitution.

(Sent by email at the suggestion of a reader.)

I'm a paralegal and independent investigative reporter, and I write a Substack about Covid-times law, geopolitics, etc. called Bailiwick News. Since late January, after I heard Attorney Todd Callender's interview on Truth4Health with Elizabeth Lee Vliet, I've been researching and writing about Callender's findings about the legal frameworks put in place to implement the WHO 2005 International Health Regulations in the United States. I wrote a long-read piece, posted on Feb. 26, and have done several other smaller pieces and a summary version:

As I continue digging, I've found the series of Congressional statutes passed and signed by presidents between 2000 and the present, including the two mentioned in the subject line: Project Bioshield Act of 2004 and PREP Act of 2005. Full list of the statutes I've found so far is below.

I've been reading them and preparing to write a series of synopsis/analysis posts about them.

Yesterday, in response to more coverage about the current round of World Health Organization "pandemic treaty" negotiations, I posted another piece highlighting that the theft of sovereignty isn't at some point in the future, if the new round of WHO negotiations concludes with a new pandemic treaty.

The theft of sovereignty is complete already, and has been operational since January 2020, with WHO Director-General Tedros' Jan. 30, 2020 declaration of "public health emergency of international concern" (PHEIC) followed by US Health and Human Services Secretary Alex Azar's Jan. 31, 2020 declaration of public health emergency in America.

Combined, those two acts functioned under the WHO Constitution and the implementing statutes already in place in the US, to silently and automatically transfer all federal governing power in the United States from the three branches working within the US Constitution, into the HHS Secretary's hands, with the Secretary serving as a subordinate to Tedros, to implement WHO policies in the U.S. under the WHO Constitution.

The only missing piece is that the silent, automatic overthrow of the US government by WHO hasn't been announced to the population yet.

In response to the post, a commenter asked me why I used the phrase "judicially unreviewable" to describe the hostile takeover, given the 10th Amendment to the US Constitution, so I posted a quickly-assembled list of some of the provisions I've found so far in reading and taking margin notes on the 2004 Project Bioshield Act and the 2005 PREP Act.

A commenter on that piece asked about "willful malfeasance" as a way for plaintiffs to get around the liability protections for the products (vaxxes) and the people involved in developing, manufacturing, distributing and administering them.

I wrote back:

> "My understanding is that the people who wrote the statutes — probably pharma lobbyists and WHO technocrats on behalf of financial elites — wrote them carefully to split apart the people who knew how deadly the shots are (the corporate executives, attorneys and researchers) from the people who would actually administer them (the nurses, pharmacists and doctors). So they wrote in two prongs plaintiffs must prove for defendants to be culpable: "willful misconduct" (knowingly engaging in bad behavior like clinical trial fraud or adding toxic ingredients to vials) and "proximate" to injury and death (being near in time and space to the victim.
>
> The corporate executives and researchers knew but weren't proximate, because they didn't personally inject victims. The nurses and pharmacists were proximate to the injuries (delivered the injections) but didn't know about the clinical trial fraud and adulterated contents of the vials."

The commenter asked me to forward that analysis to you, and ask you "how bulletproof that scheme is."

I've also forwarded the information to Attorney Todd Callender, lead attorney on a Department of Defense case of military personnel against Secretary Austin, who filed an appellate brief in 10th Circuit Court of Appeals on March 28. (22-1032).

Thank you for your tremendous work with Public Health and Medical Professionals for Transparency[31] and other cases.

[October 2025 Note - Siri did not respond; a colleague of his responded briefly on April 8, 2022.]

[31] https://phmpt.org/court-documents/

April 25, 2022 - The investigational drugs that weren't.

...Arkmedic posted a comment on Steve Bannon/Naomi Wolf links:

> They are missing the important bit. That is, that 97% of the patients are missing from the Clinical Record Forms (CRFs) files released in the first document dump. This is the clincher. So many people don't understand what it means but you have to.
>
> There are only 10-15 patients in the clinical record forms (CRFs) for each of the four sites' forms released as part of the court orders [in *Public Health and Medical Professionals for Transparency v. FDA*]. Each site should have around 300 patients, because that is the number in the recruitment log.
>
> They are NOT in a later dump because the court order was for the four biggest sites CRFs to be released first, which they did.

My response to Arkmedic:

...I'm working on a synopsis of the many legal frameworks constructed to make the government-corporation Covid plan work, and they all seem to converge on one provision of EUA law: 21 USC 360bbb-3(k), such that EUA covered countermeasure products, once designated as such by HHS (March 10, 2020, retroactive to February 4, 2020, which was the same day that WHO provided the Pierre Gsell "list of candidate vaccines" to governments and researchers) are legally not part of any "clinical investigation," despite the fact that the so-called Phase 3 clinical trials will not be finished for two years at the earliest.

Many other legal facts derive from this: there are no clinical trials, no investigational drugs or experimental treatments, no human subjects or patients, no informed consent requirements, no supervising doctors, no data collection and analysis, no prescriptions, no doctor-patient relationships subject to Hippocratic Oath, no Institutional Review Boards, no civil or criminal liability, no safety or efficacy benchmarks, no stopping conditions, no quality control or manufacturing standards or inspections, no product labeling requirements, no marketing standards, no clinical trial fraud, no requirement to produce a pure/unadulterated product.

At the end of the day, under legal definitions, nothing has been done, and no one has done anything, to anyone.

And the recursive loop can be infinite, as covered countermeasures are developed and deployed, and authorized, through EUA, as [alleged] treatments for complications from previously developed and deployed covered countermeasures...

April 28, 2022 - American Domestic Bioterrorism Program. Building the case to prosecute members of Congress, presidents, HHS and DOD secretaries and federal judges for treason under 18 USC 2381.

Excerpt from introduction

…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 and Department of Defense through the Code of Federal Regulations…

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...

Congress and US Presidents 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 and Secretary of Defense on behalf of the World Health Organization and its financial backers…

May 11, 2022 - On legal strategies and cases already filed. Griner v. Biden (Utah), Ealy v. Redfield (Oregon) and PREP Act immunity provisions.

(Excerpts)

Back in April, I sent an email to Attorney Aaron Siri's firm, at the suggestion of a reader. Siri is the attorney who filed the successful Freedom of Information Act case, *Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, which has led to the tranches of Pfizer documents released since November 2021 and under public review by citizen investigators and legal analysts coordinated by Naomi Wolf at DailyClout, and many others.

The same reader followed up today, to ask if I heard back from Siri's firm and whether it's worth trying to mount a crowdfunded campaign to get Siri to file a case.

I got a response from an attorney on Siri's staff, who didn't want to be cited by name, who provided this legal opinion:

> "The "willful misconduct" exception (for claims that can be brought) only applies to manufacturers and distributors. Further, no claim can be brought even for misconduct unless the government (HHS or AG) first brings a claim for the same conduct. So the DOJ would need to bring claims against, say, Pfizer for willful misconduct for a particular action(s) and only after there is a resolution there could someone else potentially bring a claim for willful misconduct."

Siri's associate was citing to a section of the 1944 Public Health Service Act as amended by the 2005 PREP Act: *See* 42 USC 247d-6d(c)(5).

In my review of the PREP Act and liability immunity, I think it covers manufacturers and distributors, but also developers at the R&D end, and vaccinators at the point of injection.

But I think the main point Siri's associate made is right: that before *any* civil lawsuits by individual plaintiffs can be filed, first the Health and Human Services Secretary or the Attorney General has to file a criminal prosecution, mandatory recall or other enforcement action against the defendant(s), and has to win that case, as a baseline to establish willful misconduct for use in subsequent civil suits. *See* 42 USC 247d-6d(c)(5)(B)(i).

Health and Human Services employees are immune from suit under sovereign, government immunity.

HHS and the Attorney General are both in on the criminal treason/establishment of the public heath police state.

Manufacturers and other contractors working through HHS procurement are also covered by sovereign government immunity because they've been reclassified as HHS employees for the purpose of fulfilling the contracts. *See* 42 USC 247d-6a(d)(2)(A), passed by Congress in the 2004 Project Bioshield Act.

So HHS and AG, at least until a major changing of the guard, will not pursue enforcement actions against their co-conspirators Pfizer etc.

Which means the first barrier to private lawsuits will not be overcome.

I don't know if private attorneys like Aaron Siri, Tom Renz, Todd Callender, George Wentz, Jeff Childers, etc., can initiate criminal treason prosecutions.

I think Republican state attorneys general are a better target for grassroots organizing campaigns, since many of them have already worked together to challenge some of the vaccine mandates and other federal acts.

I asked Siri's associate about their views on the bigger picture question,

> "That it appears the US Congress and President, in 2004 and 2005, adopted American laws to automatically suspend the American federal government (President and Congress), the US Constitution, and US federal and state courts, and silently place the country under the control of the World Health Organization and the WHO Constitution, upon the trigger of the WHO Director-General declaring a "public health emergency of international concern," operational through regulations adopted in early 2017 to authorize the domestic actions of the US Secretary of Health and Human Services, Attorney General, and Department of Defense Secretary that we've seen over the past two years?"

They said they hadn't looked at that issue yet...

June 9, 2022 - COVID-19 injectable bioweapons as case study in legalized, government-operated domestic bioterrorism.

Or: why there won't be any civil suits, or compensatory damages for injured victims or survivors of dead victims.

Published June 9, 2022, last updated June 24, 2022.

This is a reworking of information posted previously, including at the bottom of the American Domestic Bioterrorism Program[32] post.

Since first realizing the implications of the many Congressional statutes and Health and Human Services regulations adopted to create and operate the bioterrorism program, mostly between 1997 and the present, I've been intermittently finding the specific citations for each statement while researching related issues.

Some statements are simply logical deductions from the first premise, corroborated by the observable actions and inactions of Food and Drug Administration officials as the observable injuries and deaths mount up in the American people.

Others are specifically written into the laws, but I don't yet have the citations because I've prioritized my research time investigating other issues related to the bioterrorism program.

I'm posting the information as I understand it today, despite those limitations, in case it's useful for readers who also follow FDA Vaccine and Related Biological Products Advisory Committee (VRBPAC) reporting by Toby Rogers, Igor Chudov, Steve Kirsch, Jessica Rose, and others.

They continue to rightly raise public awareness and alarm about FDA's ongoing failure to protect the public from the Emergency Use Authorized (EUA) products.

But they don't address the main reason why FDA is acting as it is.

FDA is not pulling the EUA products from the market or stopping the 'vaccination' campaign because Health and Human Services Secretary Xavier Becerra and FDA Commissioner Robert Califf are running the US government's bioterrorism program jointly with Defense Secretary Lloyd Austin, Department of Justice Attorney General Merrick Garland, Department of Homeland Security Secretary Alejandro Majorkas, Pfizer CEO Albert Bourla, Moderna CEO Stephane Bancel, and World Health Organization Director-General Tedros Adhanom Ghebreyesus.

[32] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program?s=w

Main Premise

Use of EUA-covered medical countermeasure (MCM) products including masks, PCR tests, mRNA and DNA injections, and other drugs, devices and biologics, once designated as such by the Secretary of Health and Human Services (March 10, 2020, retroactive to February 4, 2020) "shall not be considered to constitute a clinical investigation." 21 USC 360bbb-3(k). EUA law, adopted 1997 and amended 2003, 2004, 2005, 2013, 2017.

This is true no matter how untested, unmonitored, unsafe, or ineffective they are, no matter whether their harmfulness to human health and uselessness for infection-control are known before use, or discovered afterward.

Legal implications derived from the main premise:

- There is no stopping condition.
- EUA products are exempt from laws regulating researcher use of investigational, experimental drugs, devices and biologics on human beings.
- EUA products are exempt from laws regulating physician use of approved drugs, devices and biologics as medical treatments for patients.
- There are no manufacturers of experimental products (EUA products are not part of any clinical investigation, and therefore not experimental.)
- There are no government or private contracts for purchase of experimental products; there are only contracts for 'large scale vaccine manufacturing demonstrations.'
- There is no act of administration of any experimental products.
- There are no nurses or pharmacists administering experimental products.
- There are no human subjects (of experiments) or patients (of physicians providing treatment) receiving experimental products: no victims.
- There is no party responsible for the wellbeing of recipients after administration of EUA products.
- There is no treatment group and no control group.
- Human beings administering EUA products have no informed consent obligations to provide information about ingredients, risks, benefits, alternatives, or the option to accept or refuse the products. *See* 21 USC 360bbb-3(e)(1)(A)(ii)) waiving informed consent for unapproved products (2004); 21 USC 360bbb-3(e)(2)(A) waiving informed consent for unapproved use of an approved product (2004); 21 USC 355(i)(4) waiving informed consent for experimental products classified by HHS as 'minimal risk' drugs (2016); 21 USC 360j(g)(3) waiving informed consent for experimental 'minimal risk' devices (2016).
- Human beings receiving EUA products have no informed consent rights to receive information about ingredients, risks, benefits, alternatives, or the option to accept or refuse the products. *See* citations, bullet point above.
- There are no Institutional Review Boards supervising administration of the experimental products.
- There are no safety standards for EUA products.
- There are no efficacy standard for EUA products. *See* 21 USC 360bbb-3(c)(2)(A), 1997, 2004, re: 'may be effective'
- There are no clinical investigators studying the effects of EUA products on human subjects.

- There are no doctors, nurses, or other treatment providers providing experimental treatment to their patients subject to the Hippocratic Oath ("first do no harm") using EUA products.
- There is no coordinated, public, federal government monitoring of recipients after receiving the products for adverse effects and deaths.
- There is no coordinated, public, federal government data collection or analysis.
- There is no legal requirement for medical supervision during product administration.
- There is no legal requirement for recipient monitoring after product administration.
- 'Real world evidence' — mass administration of products to general public, 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) and other private databases — is authorized for the purposes of FDA regulatory decisions. *See* 21 USC 355g. 2016.
- There is no requirement for individual prescriptions to be written prior to dispensing EUA products, and products dispensed without prescriptions "shall not be deemed adulterated or misbranded." *See* 21 USC 360bbb-3a(d). 2013.
- Manufacturers, as contractors, are considered HHS employees for purposes of legal immunity under Federal Tort Claims Act. *See* 42 USC 247d-6a(d)(2)(A).
- DOD is authorized to contract with pharmaceutical corporations to conduct 'prototype' experiments on the general public, and under such contracts, is exempt from legal obligation to comply with Good Clinical Practices or other FDA regulations. *See* 10 USC 2371b (2015), renumbered 10 USC 4022 (Jan. 1, 2021, effective Jan. 1, 2022)
- 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 to procure them 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." *See* 42 USC 247d-6b (c)(5)(B)(iii)
- 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." *See* 21 USC 360bbb-3a(c). 2013.
- There are no labeling requirements regarding the contents or ingredients in EUA products. 21 USC 360bbb-3(e)(2)(B)(ii). 2004.
- There is no limitation of administration of EUA products past their expiration dates.
- There cannot be clinical trial fraud, because there are no clinical investigations, no investigational drugs, no investigators and no human subjects.
- There are no marketing standards.
- There cannot be consumer fraud, because the only legal parties to the financial transactions are the US government (DOD) as buyer; the US government (HHS) as regulator authorizing exemptions from consumer protection laws that otherwise apply to medical products; and the pharmaceutical corporations as sellers, contracted to develop and manufacture the products. There are no commercial pharmaceutical products, no commercial marketplace, and no commercial market consumers.
- There is no access to courts for judicial review of the facts or law relating to HHS Secretary declarations of EUA products, which are committed to agency discretion. *See* 42 USC 247d-6d(b)(7). 2005.

- There is no access for plaintiffs, to civil courts for judicial review, and no entity to whom civil liability can attach, for injuries and deaths caused by declared covered countermeasures, unless and until FDA/HHS and/or Attorney General/DOJ file enforcement action against manufacturers and prove willful misconduct proximate to injury or death, but HHS and DOJ have operated the EUA product program together with the manufacturers since inception, and will not prosecute their co-conspirators. *See* 42 USC 247d-6d. 2005.
- 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 developing, manufacturing, distributing and/or administering the EUA products, knew the EUA products were toxic and knew their own actions were harmful, "just following orders" is an authorized, legal defense. *See* 42 USC 247d-6d(c)(4). 2005.

June 14, 2022 - April 4, 2003 - Rep. Henry Waxman questioning FDA Commissioner Mark McClellan about informed consent waivers authorized through Project Bioshield Act.

Today I did a search on my hard drive for "known and potential" risks and benefits, which is the language that appears in Health and Human Services Secretary declarations and FDA authorizations, and the phrase "informed consent."

The "informed consent" phrase appeared in a transcript of a Congressional hearing held April 4, 2003, chaired by Rep. Henry Waxman (D-California, 1975-2015), and titled: Project Bioshield: Contracting for the Health and Security of the American Public[33].

The earliest hit on the "known and potential" phrase in documents on my hard drive is the 1997 Emergency Use Authorization (EUA) law in the FDA Modernization Act[34] (Section 402 et seq.)

It's the phrase that purportedly voids the principle of informed consent for medical treatment, by taking risk-benefit assessment acts away from each man or woman receiving an EUA product, and giving it to the HHS Secretary and FDA Commissioner.

See 21 USC 360bbb-3(e)(1)(A)(ii) waiving informed consent for unapproved products (2004); 21 USC 360bbb-3(e)(2)(A) waiving informed consent for unapproved use of an approved product (2004). *See* also 21 USC 355 (i)(4) waiving informed consent for experimental products classified by HHS as 'minimal risk' drugs (2016); 21 USC 360j(g)(3) waiving informed consent for experimental 'minimal risk' devices (2016).

The statutes include language that HHS Secretary may set conditions on EUAs that recipients be informed "of the option to accept or refuse administration of the product, [and] of the consequences, if any, of refusing administration of the product," which appears to protect a meaningful option to refuse, thus upholding the principle of informed consent as framed by the Nuremberg Code.

However, the Department of Justice[35] and at least one federal judge[36] [case: *Bridges v. Houston Methodist Hospital*] have interpreted the "consequences of refusal" to mean that recipients may be told by the person demanding that they accept the product, that if they refuse, they will be disciplined, fired or lose their place at school, thus legalizing coercive medical treatment in violation of the Nuremberg Code.

The bait-and-switch maneuver is similar to how the 1997 FDA Modernization Act, read in conjunction with the NDAA passed three days earlier[37] (Section 1078), transferred the US government's chemical and biological weapons development and testing program from the Department of Defense to the Department of Health and Human Services.

[33] https://www.govinfo.gov/content/pkg/CHRG-108hhrg87141/pdf/CHRG-108hhrg87141.pdf
[34] https://www.congress.gov/105/plaws/publ115/PLAW-105publ115.pdf
[35] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf
[36] https://casetext.com/case/bridges-v-hous-methodist-hosp
[37] https://www.congress.gov/105/plaws/publ85/PLAW-105publ85.pdf

The "known and potential" phrase can be found in several — perhaps all — of the Covid-19 EUA Letters of Authorization issued by HHS since February 2020, for things like masks, PCR tests and mRNA/DNA injections, including the Pfizer/BioNTech letter first issued by FDA Dec. 11, 2020, reissued Dec. 23, 2020, Feb. 25, 2021 and May 10, 2021[38].

The EUA law has been amended several times since first Congressional adoption in 1997, including in 2004 through the Project Bioshield Act[39]; in 2005 through the PREP Act[40] (Division C at 119 Stat. 2818); and in 2013 through the Pandemic and All-Hazards Preparedness Reauthorization Act[41].

As far as I know, the Project Bioshield Act was passed as drafted, despite Rep. Waxman's expressed concerns about waivers of informed consent and other consumer protections, and prohibitions on judicial review. I think the 2005 and 2013 amendments expanded FDA authority and manufacturer indemnity further, while reducing consumer protection and judicial oversight even more, but will need to confirm those conclusions through further research.

In the meantime, below is the text of the informed consent comments and questions raised by Rep. Waxman on April 4, 2003 during a hearing held by the House Committee on Government Reform.

Speakers included NIAID Director Anthony Fauci; FDA Commissioner Mark McClellan; Michael "Heck-of-a-Job-Brownie" Brown, Department of Homeland Security Under Secretary for Emergency Preparedness and Response; and Dale Klein, Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs, along with representatives from Aventis Pasteur; Pharmaceutical Research and Manufacturers of America; Avant Immunotherapeutics, Inc.; Alexion Antibody Technologies; and Infectious Diseases Society of America.

*

REP. WAXMAN, opening the hearing:

We are holding a hearing on a proposal by the [George W. Bush] administration which I think all of us would support in its intent. We want to accomplish what the proposal would seek to have us accomplish, but our responsibility as Members of Congress is to scrutinize it carefully, to try to think about the unintended consequences, and to make sure that the job is done right.

The development of effective countermeasures to bioterrorism is certainly vital to our natural security. The Project BioShield represents a proposal to encourage the development of these products. We all support trying to do that, but we have a responsibility to look closely at the provisions of the legislation, and some of those provisions give me some cause for concern.

[38] https://www.fda.gov/media/144412/download
[39] https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf
[40] https://uscode.house.gov/statutes/pl/109/148.pdf
[41] https://www.congress.gov/113/plaws/publ5/PLAW-113publ5.pdf

For example, the proposal removes important protections against waste and abuse that are standard for government contracts. I understand the concern that these protections, in an emergency situation, could impede the development of necessary products. However, any exceptions should be made only when necessary and should be subject to review.

This proposal would make it nearly impossible for the courts, for Congress and even the executive branch to rein in abuses. The provision eliminating the government's access rights to contractors' books and records is particularly trou- bling.

Another provision permits products to be distributed without FDA approval. Here again, I recognize there may be unusual circumstances that would require this step in case of a dire emergency. However, the proposal's language is overly broad and could be used to support products that are simply not safe enough for FDA approval. This provision could also permit widespread distribution of unapproved drugs without informed consent, record-keeping or reporting of adverse events.

The BioShield proposal also provides for unlimited guaranteed spending for procurement of vaccines and other countermeasures with little congressional guidance or limits on how much to spend.

This is a blank check approach. It could be looked at as an abdication of congressional responsibility. We should work to improve this proposal in such a way as to preserve oversight and recognize that, in order for BioShield to work, we need to assure that commitments made will be honored.

In this regard, it is ironic that the administration does not support a similar approach of assuring that commitments will be honored in the case of a smallpox vaccine compensation program. Here, the argument for mandatory spending is strong, because nurses, firefighters and other first responders deserve to know that they and their families will be supported in the case of severe injury or death. Yet in the case of smallpox vaccination compensation, the administration has proposed limiting compensation to the amount appropriated each year, explicitly refusing to guarantee its commitment to those Americans on the front lines of a bioterrorist attack. This inexplicable failure to assure funding is one of the reasons that the House voted down the administration's legislation on smallpox vaccines compensation last Monday.

I raised this issue last week in the Commerce Committee to point out the inconsistencies. At the time I did that, many people raised the point, why should we allow automatic spending in this area? They argued we shouldn't allow automatic spending in any area.

But Secretary Thompson made the case last week that we want to assure that funding will be there so that the companies that are taking the financial risk of developing these products know that they will be able to count on those funds.

I thought that was a strong argument to make. But, equally strong is to make the assurances clear that if a first responder gets immunized for smallpox that they are going to be able to count on funding should there be, in rare circumstances, but nevertheless in some circumstances, an adverse event.

Let me conclude by pointing out that the BioShield proposal includes provisions for public health emergencies, not just bioterrorism threats. The idea of including public health emergencies in a BioShield makes sense, because infectious diseases that occur in nature can claim many lives, can even become bioterrorist agents if intentionally spread.
What justifies government intervention to support countermeasures is that the market fails to encourage their development on its own. This rationale also applies to the development of treatments for potential public health emergencies.

In 2002, not a single new antimicrobial drug was approved by FDA; and apparently only a handful are in development by major pharmaceutical companies. One reason may be that the market for the few cases of multidrug-resistant bacteria is currently quite small. That leads to a market failure. And yet the need for such treatments is enormous.

Just yesterday, the New England Journal of Medicine carried the first report of a common bacteria that is extremely resistant to an antibiotic that is usually the last line of defense.

If properly designed, then, BioShield can serve valuable purposes, improving our preparedness against bioterrorist attacks and natural epidemics.

I look forward to hearing from the witnesses today to help us understand this proposal and find ways to improve it. We need to work together collaboratively for what is certainly a shared goal that we all have…

Rep. WAXMAN questioning FDA Commissioner Mark McClellan:

Dr. McClellan, the BioShield proposal would allow the Secretary of Health and Human Services to waive virtually all of the consumer protections in the Federal Food and Drug Cosmetic Act in case of an emergency. Moreover, the proposal would then severely curtail judicial review of the Secretary's decision. What is the rationale for allowing informed consent, recordkeeping, adverse event reporting, and other key requirements to be waived; and what is the rationale for severely limiting oversight of these extraordinary powers?

Dr. MCCLELLAN. The rationale for the emergency use authorization is to provide the most potentially effective treatments to Americans in emergency situations. This is a limited authority program that only applies when the Secretary and others have determined there is a national emergency because of a bioterrorism threat or another type of public health emergency, and it only involves agents where there are not effective approved treatments already available but where there may be treatments in the pipeline where the potential benefits outweigh the potential risks. We have a few now that are marching as quickly as possible toward approval and toward a full demonstration of safety and effectiveness. That remains our goal.

I would highlight that we are going to have even better incentives for that under the BioShield program. You don't get full payment for development of a countermeasure under BioShield unless it is approved and licensed, fully licensed, fully shown to be safe and effective by the FDA. That is a strong incentive for getting to the finish line that doesn't exist today and would move us out of the world we are in now, where there are a lot of products that may be of use, but no companies, as I talked about before, are willing to make the investments and come up with the good ideas needed to translate proof of concept into a truly effective treatment.

Mr. WAXMAN. I understand that. That is an important part of why this bill is necessary. But in creating this balance we let the Secretary waive all of these consumer protections, and it looks to me like this authority is quite broad to waive FDA approval standards. Will that give incentives that are needed to conduct the kinds of safety and efficacy trials that are needed, or are some of these companies going to figure they can get around that?

Dr. MCCLELLAN. I agree we need more incentives to conduct the needed safety and effectiveness trials. That is the main reason for the procurement authority for BioShield that only makes payment on delivery of — a full payment for an approved product.

The emergency use authorization does include a number of protections to make sure that in the limited circumstances of the emergency we do as much as possible to limit distribution, limit who can administer, require studies, require recordkeeping and access to records. All of those are elements of the BioShield proposal, and the Secretary would specifically design its use with our recommendations and those of others to do as much of all of those activities as possible.
Mr. WAXMAN. You are giving me assurances that we are not going to pay these companies unless they do what they are required to do, but I am concerned about the broad authority to waive some of the consumer protections like informed consent or making sure we know about the adverse events and other aspects, where right now the law is set up to not just make sure the company does what it needs to do to get paid but the consumers and adverse consequences—the consumers are monitored with and dealt with adequately.

Dr. MCCLELLAN. Right. We want to get to approved treatments as quickly as possible. But with these products in development there may be a number that have been shown to have potential benefits for conditions where there are no effective treatments approved. Under those circumstances, we think it is appropriate, with all of these restrictions in place, to do as much recordkeeping as possible, as much monitoring and standards for production as possible, as much mandatory reporting of adverse events, and informing the consumer, informing the public as possible about appropriate use as can be done under the circumstances. I would be happy to continue to work with your staff to make sure that we tailor that language appropriately.

We think the bill does a pretty good job now of getting as much done as possible on informing consumers, on collecting adverse event data and the like. We think that is very important in the emergency use process. But it is an emergency, and it is a very special limited use condition that requires some special considerations.

July 4, 2022 - Possibilities for proving intent. The work product of attorneys Susan E. Sherman, Wen W. Shen, Dawn Johnsen and the July 6, 2021 Department of Justice legal opinion.

Two pieces of work in progress. I'm finishing another post on ultra vires[42], looking at federal cases that have already cited the principle in challenging federal government acts that go beyond constitutionally-legitimate authority, and expanding on their approach. Planning to post later this week.

I'm also starting a piece on the sequence of legal steps taken by the US government to destroy the principle of informed consent, which was — before its destruction — the single most-effective legal barrier to the depopulation-by-coerced-lethal-injection program.

Dismantling informed consent was the start of the cover-up for the government's Covid-19 crimes, and the dismantling process predated Covid-19, providing evidence of intent.

The primary document is the July 6, 2021 slip opinion[43] written by Deputy Attorney General Dawn Johnsen, which defines the legal question as: Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization.

Attorney Johnsen did not address the question of whether any public or private entity is ever authorized to suspend informed consent rights and engage in coerced bodily trespass.

She addressed instead whether any Congressional law specifically prohibited suspension of informed consent, and finding none in her review, concluded that Congress permitted entities to use coercion to violate bodily integrity through mandated medical treatment.

Attorney Johnsen's opinion laid out the legal basis for the vaccine mandates imposed by the Biden Administration, state and local governments, public and private schools, and private employers, including:

- 2021/08/24 - Department of Defense order from Secretary of Defense Lloyd Austin on military personnel in Army, Navy, Air Force, Marines and Coast Guard.
- 2021/09/09 - Biden Executive Order 14042 on federal contractors.
- 2021/09/09 - Biden Executive Order 14043 on federal employees
- 2021/09/09 - Biden directive to Department of Labor Occupational Safety and Health Administration (OSHA) on private employers with more than 100 employees.
- 2021/11/05 - Biden directive to Department of Health and Human Services Center for Medicare and Medicaid Services (CMS) on health care workers at hospitals, nursing homes and other federally-funded facilities.

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42 https://bailiwicknews.substack.com/p/smart-v-kemp

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

The topic of proving intent came up this morning in a Gab thread discussing Paul Alexander's recent Substack post Warning: coming many Americans, many people will die because of these COVID injections, many healthy children WILL die due to these shots; FDA, CDC, NIH, Moderna, & Pfizer secretly told me this.[44]

> …I was told by these officials (FDA, CDC, NIH, Moderna, & Pfizer), in confidential secret discussions, that in about 6 to 6.5 years from roll-out, in those who take the injections, they feared mass auto-immune disease and deaths, they feared viral immune escape and very problematic variants, and they anticipated constant deaths from the injections but a major number of deaths to emerge. I could not even understand exactly what they did for it was so haphazard, but these were officials. And they wanted to talk to me. To tell me 'their truths'.
>
> They said based on all they knew, that the COVID injections could never work, especially the mRNA platform. It never worked in the animal model and was pathological. They told me that in about 6 to 6.5 years, there will be a surge in deaths in persons who take the injections (then about 1 year ago). This was their projection. They advised me they nor their families will never (especially their children) take any of the COVID injections.

DoorlessCarp posted on Gab:

> The rest of us had to work this out by trawling through preprints & clinical reports and added[45]: "6 to 6.5 years from rollout" is very specific. I believe they are working on the same 5 year post exposure data I posted last week for heart disease & cancer symptomology, now autoimmune disorders too, then allowed for 12-18 months or 3-4 boosters on top of that. They obviously know the LD_{50} is 3-4 doses for the bell curve to peak then."

NehmingNehms replied:

> LD_{50}, for those who don't know, is the lethal dose that kills half of those to whom it's administered. Not to put too fine a point on it, Big Health was worried about mass casualties, but not worried enough to prevent them from reeling in massive profits. We really need to start calling this what it is: intentional mass murder.

ManDownUnder replied:

> The tough part is going to be proving the "intentional" aspect. The "mass murder" aspect? That will become obvious. But, being realistic, how do you prove intent with this? Negligence? Recklessness? Corporate greed? Sure, that part will be easy. But intent? That's going to be a tough nut to crack, short of someone giving themselves up and rolling on others...

44 https://palexander.substack.com/p/warning-coming-many-americans-many

45 https://gab.com/kgwatt/posts/108589256957352364

I replied:

I think we can prove the intentional part, through proving the deliberate, premeditated legal process of eliminating informed consent via statutes, regulations and guidance documents.

I'm currently focusing on the acts, arguments and documents produced by two people: Attorney Susan E. Sherman of the Office of General Counsel for HHS, and Attorney Dawn Johnsen, Deputy Attorney General at DOJ, through the July 6, 2021 Slip 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 Authorization*[46] — and the authorities cited by Johnsen in that opinion, which was used to back the federal and private employer 'mandates.'

Sherman's key contribution (that I've found so far) shows up around 2009/2010 with H1N1, EUAs and the Strategic National Stockpile — the US government's bioweapons depot.

2009/11/18 HHS FDA Workshop Summary - Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model at p. 26

> "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.' "

Sherman's bio from a 2016 workshop report on The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile:

> Susan E. Sherman, J.D., M.S., is a senior attorney with the Office of the General Counsel, HHS. She provides legal advice to the HHS Assistant Secretary for Preparedness and Response, advising on a wide variety of legal issues related to federal public health emergency preparedness and response. Earlier in her career at HHS, she advised the National Institutes of Health on legal issues related to biomedical research grants administration, human subjects protection, and laboratory animal welfare. Prior to working at HHS, she worked at the Institute of Medicine on studies leading to publications, including The Future of Public Health and Quality of Care in Nursing Homes. She holds a law degree from the George Washington University National Law Center and a master's degree in health science from the Johns Hopkins Bloomberg School of Public Health.

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

List of events and documents in the paper trail leading to the Johnsen Slip Opinion

- 2003/04/04 - Congressional hearing on Project Bioshield: Contracting for the Health and Security of the American Public. Congress members discussed authorizing HHS to waive informed consent during declared emergencies. (06/14/2022 Bailiwick post.)
- 2003/04/04 - President George W. Bush Executive Order 13295 added symptomatic SARS to list of quarantinable communicable diseases, authorizing HHS to order apprehension and indefinite detention of Americans for contracting common respiratory illnesses. 42 USC 264, 42 CFR 70.6.
- 2003/11/24 - National Defense Authorization Act (NDAA). PL 108-136, 117 Stat. 1392.
- At Section 1603(a) of the NDAA, Congress created 21 USC 360bbb-3 - "Section 564 - Authorization for Medical Products for Use in Emergencies" under the EUA part of the Federal Food Drug and Cosmetics Act as amended in 1997 to add 21 USC 360bbb "Expanded Access to Unapproved Diagnostics and Therapies."
- At Section 1603(b)(1) of the NDAA, Congress added Section 1107a to the military code after 10 USC 1107, authorizing the 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."
- 2003/12/22 - Doe v. Rumsfeld, 297 F Supp. 2d 119 (DDC 2003), addressing Presidential waivers of informed consent in the anthrax vaccination campaign context
- 2004/07/21 - 2004 Project Bioshield Act - PL 108-276, 118 Stat. 835. Amendments to Public Health Service Act and Federal Food Drug and Cosmetics Act. Nullified informed consent principles under US law; amended, expanded and funded 'Emergency Use Authorization' bioweapons research, development, procurement, contracting, manufacture, marketing and distribution program.
- 2005/07/05 - HHS FDA Draft Guidance Re: Emergency Use Authorization of Medical Products. 70 FR 38689
- 2007/05/04 - President George W. Bush National Security Presidential Directive 51.
- 2007/07/01 - HHS FDA Guidance - Emergency Use Authorization of Medical Products. 71 FR 41083. Finalized draft guidance published in Federal Register July 5, 2005 (70 FR 38689).
- 2007/12/28 - HHS FDA Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile. 72 FR 73589.
- 2009/11/18 - HHS FDA Workshop - Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model
- 2010/03/23 - Biologics Price Competition and Innovation Act of 2009. Related to the legal, approval/authorization, labelling and marketing differences among 'biosimilars,' BLA (Biologics License Application) products, and EUA products.
- 2014/07/31 - President Barack Obama Executive Order 13674, adding asymptomatic, suspected SARS to list of quarantinable communicable diseases.
- 2016/10/24 - US Government Workshop: The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile

- 2017/01/13 - HHS FDA Guidance: Emergency Use Authorization of Medical Products and Related Authorities. (Update/revision to 07/01/2007 version)
- 2017/01/19 - HHS Final Rule - Federal Policy for the Protection of Human Subjects. 82 FR 7149. Joint rule by 16 federal agencies, subsequently adopted by other agencies. Revised 1991 Common Rule, which had been developed based on 1947 Nuremberg Code and 1978 Belmont Report.
- 2017/01/19 HHS Final Rule - Control of Communicable Diseases Final Rule. 82 FR 6890
- 2017/07/25 - HHS FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects.
- 2017/12/12 - Act to amend FDCA EUA statute, 21 USC 360bbb-3. PL 115-92, 131 Stat. 2023. (3 pages). Provided for "Additional Emergency Uses for Medical Products to Reduce Deaths and Severity of Injuries Caused by Agents of War"
- 2019/05/22 - Congressional Research Service Opinion: An Overview of State and Federal Authority to Impose Vaccination Requirements by Wen W. Shen
- 2020/05/19 - Advisory Opinion on the PREP Act and the March 10, 2020 Declaration Under the Act, April 17, 2020, as modified on May 19, 2020, by Robert P. Charrow of HHS Office of General Counsel. Legal opinion on statutory liability shields.
- 2020/08/26 - HHS CDC Advisory Committee on Immunization Practices Meeting Summary Report. At p. 56 - "Dr. Cohn reminded everyone that under an EUA, vaccines are not allowed to be mandatory. Therefore, early in the vaccination phase individuals will have to be consented and cannot be mandated to be vaccinated." [Attorney Johnsen cited this interpretation of Section 564 in a footnote on p. 7 of her slip opinion, immediately citing the judge's June 12, 2021 order in Bridges v. Houston Methodist as "summarily rejecting" the argument.]
- 2021/04/02 - Congressional Research Service Opinion: State and Federal Authority to Mandate COVID-19 Vaccination by Wen W. Shen
- 2021/06/12 - Bridges v. Houston Methodist Hospital, 543 F. Supp. 3d 525[47] (S.D. Tex. 2021). Federal judge ruled that informed consent doesn't apply to hospital workers, because the injections are government-authorized under FDA Emergency Use Authorization, therefore not part of experimental clinical trials or ordinary medical treatments, therefore hospital employees cannot be legally construed as human subjects or ordinary patients, therefore they have no individual, Constitutional liberties; rights to privacy and against government violation of bodily integrity; or rights to be secure in their persons against warrantless search and seizure.
- 2021/06/25 - FDA EUA Pfizer Fact Sheet[48] addressing "option to accept or refuse." This is only one of many versions issued between December 2020 and present; it's the one cited by Attorney Johnsen in her legal opinion.
- 2021/07/06 - Dawn Johnsen, Deputy Attorney General at DOJ Slip 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 Authorization.

47 https://casetext.com/case/bridges-v-hous-methodist-hosp

48 https://www.drrandywalker.com/wp-content/uploads/2021/08/pfizer-consent-english.pdf

Sept. 27, 2022 - On why Biden's comment that 'the pandemic is over' doesn't lift the bioterrorist police state jackboot off our necks.

Email from an attorney

> As to the PREP Act, I am curious why we are not insisting that when Biden declared Covid as over, the PREP Act is over too.

My reply:

There are at least three Covid-related state of emergency declarations still in force.

Biden saying that the pandemic is over in a press conference doesn't officially revoke the presidential declarations and proclamations of a national emergency due to Covid, issued under the National Emergencies Act of 1976 and the Stafford Act of 1988.

These were first issued by Trump on March 13, 2020 (NEA; Stafford) and have been renewed annually by Biden in early 2021 and early 2022.

President Biden's press conference comments also don't revoke the 'public health emergency' declaration issued by HHS Alex Azar on Jan. 31, 2020 (retroactive to Jan. 27, 2020) under Section 319 of the Public Health Service Act, as added in 1983 and amended by the 2005 PREP Act to put the power to declare public health emergencies into HHS secretary's unilateral hands.

All three of these Covid-era emergency declarations have been extended repeatedly by Trump, Biden, Azar and Becerra.

The HHS Secretary public health emergency declaration was most recently extended on July 15, 2022, with the next extension expected before the current one expires Oct. 13.

In addition, the state of national emergency proclaimed by President Bush on Sept. 14, 2001 in response to 'terrorism' under the 1976 law is still in force. It has been renewed every year since by Bush, Obama, Trump and Biden.

All four of these declarations and proclamations triggered expanded federal government authorities and limits to state, local and individual power, at least until a federal court finds that the proclamations — and the 1976, 1988, 2005 and related statutes under which they've been issued — are unconstitutional, null and void.

Or until Congress repeals the enabling statutes.

Or until the People of one or more states, working independent of the federal government through their own legislatures, governors, courts and state constitutions, block the effect of these federal power grabs within their own state borders as unconstitutional, null and void violations of the Tenth Amendment to the US Constitution.

Several members of Congress, led by Senator Roger Marshall of Kansas, have attempted to pass legislation to terminate the emergency declarations, without success. Marshall's bill passed the Senate in March 2022, but the House refused to take it up, and Biden promised to veto it.

Even if such a bill got through Congress with a veto-proof majority, the biomedical police state laws on the books specifically exclude Congressional and court review of HHS declarations and actions. (*See*, for example, 42 USC 247d-6d(b)(7), as amended in 2005 by PREP Act, blocking court review.)

Again, the beatings will continue until morale improves a federal court finds the enabling statutes including the 2005 PREP Act, the 1988 Stafford Act, and the 1976 National Emergencies Act are now and have always been unconstitutional. Or until Congress repeals those laws with veto-proof majorities. Or until individual states take steps to block the effect of those federal laws within their own state borders.

The legal conditions for suspending all conflicting laws and constitutional rights are still firmly in place, for so long as the federal courts, Congress and each state government allows the federal executive usurpation under emergency declarations and proclamations, and the statutes authorizing those executive proclamations, to remain in force.

Oct. 4, 2022 - Notes for state Attorneys General considering filing challenges to protect the people in their states.

I got an email today about efforts to get state Attorneys General (state prosecutors) to take action, through legal challenges including product adulteration claims. The question was about what powers states might have to audit the pharmaceutical manufacturing or regulatory process, or to force investigations, vaxx campaign suspension, or product recalls on provably adulterated, mislabeled, toxic products.

Many, many people have been trying to mobilize state AGs for a very long time now. And we have to keep trying, until they understand the fraud-based mass murder that's happening and understand their authority to interpose to help bring it to an end.

The PREP Act (42 USC 247d-6d), for as long as it stands without Congressional repeal or court invalidation of it, and for as long as state AGs, governors and legislatures defer to it, appears to block states from engaging in independent vaxx campaign blockades or vaxx recalls or adulteration challenges.

The section is 42 USC 247d-6d(b)(8)

> Preemption of State law. During the effective period of a declaration under subsection (b) [that a public health emergency exists], or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

In talking to state AGs, it's important to be very clear and open about the incredible usurpation of state authority for public health and safety that Congress and President George W. Bush enacted with the PREP Act, especially through this provision.

It's also important to immediately emphasize that state AGs are among the best-positioned prosecutors to challenge the preemption directly, by filing cases in federal court asking the federal courts to review the PREP Act for constitutionality, find that it violates the 10th Amendment (among many others) and declare it null and void.

Product labeling, adulteration and recall issues are clearly related to that. AGs could easily make the argument that the federal government is killing the people that the state government has a duty to protect from toxic or adulterated products (such as fentanyl, opioids, etc.). [Set aside for the moment that the Covid-19 injections are actually bioweapons, any use of which is an international and federal crime.]

But state prosecutors can't make that labeling, adulteration and recall argument without also confronting the PREP Act pre-emptions head-on and confronting them hard.

They need to understand that as quickly as possible or they will either give up before they get started (not file labeling/adulteration/recall actions at all) or they'll file something and spin their wheels until the courts dismiss the cases by citing to the PREP Act pre-emptions.

The ideal scenario, in my opinion, is for a state AG or several state AGs working together, to start attacking the enabling statutes, on grounds that the federal government never had the authority to adopt those laws in the first place.
They may run into statutes of limitations. In many cases, these horrible laws had final severability paragraphs acknowledging that they might be found unconstitutional, but setting a time limit on the time during which actions challenging their constitutionality could be brought. (Interestingly, the 1986 National Vaccine Program had a non-severability section, saying that if any part of it was found unconstitutional, the whole thing would be unconstitutional too.)

I think the argument the state Attorney Generals need to make is that even though the PREP Act was passed in 2005, the full scale of the effect of nullifying all consumer product/bioweapon victim protections at the state level did not become clear until the federal government actually used it during Covid.

So the clock for filing a constitutional challenge should be started from the date of the Pfizer EUA, for example, (Dec. 11, 2020) or some other, similar date, as the "constructive notice" that the AGs finally got about the impact and clear unconstitutionality of the 2005 law.

It would also be good to let the AGs know that if they go after the PREP Act, they'll need to go after the related laws, because the laws are interlocking and mutually-reinforcing.

But the PREP Act should be their primary target, because it's the one that purported to strip the state governments of their authority and simultaneously suspend Congressional oversight, the federal courts and the US Constitution.

Oct. 21, 2022 - Legal horror movie pitch: The World According to Darp. 'Shouting fire in a crowded theater' meets 'When did you stop beating your wife?' Starring US Government as Darpon Fink, serial-killer/arsonist

(Excerpts)

In an email thread yesterday, I was casting about for more ways to think about, understand and deal with the complex crimes committed by the fiends who have infiltrated the US Government, overthrown the US Constitution and sickened and killed a lot of people.

Covertly since 1969 and somewhat more openly since January 2020.

I hit upon a film pitch about the collision of two legal tropes. “Shouting fire in a crowded theater” is an analogy used by Supreme Court Justice Oliver Wendell Holmes in Schenck v. U.S.,[49] 247 US 47 (1919), to illustrate potential limits to the First Amendment right of free speech. The Supreme Court later repudiated[50] that particular analogy and upheld broader speech rights. But the phrase remains deeply embedded in American popular culture.

“When did you stop beating your wife?” is shorthand for a cross-examination technique in which the question is structured such that any answer given by the defendant results in an admission of the implied wrongdoing.

*

Here’s the movie pitch.

The villain is Darpon Fink, an ugly, awkward, reclusive middle-aged serial killer/arsonist. Darpon gets a job as a building inspector in a mid-sized American city.

His first day on the job, he repeals all the building safety codes. His second day on the job, he lobotomizes city council members, police officers, firefighters, prosecutors and judges, and then gasses them with paralytics. They sit in their usual chairs, at their usual desks in their City Hall offices.

But they can’t move or speak.

His third day on the job — the day a popular musician is scheduled to perform in the city’s largest theater — Darp removes the smoke detectors and sprinklers in the theater and barricades from the outside all but one door.

He positions hired snipers in adjacent buildings, ordering them to shoot on-sight anyone trying to leave the building, and anyone approaching the building from outside to help the people inside.

49 https://scholar.google.com/scholar_case?case=8474153321909160293&q=schenck+v+united+states&hl=en&as_sdt=2006

50 https://abovethelaw.com/2021/10/why-falsely-claiming-its-illegal-to-shout-fire-in-a-crowded-theater-distorts-any-conversation-about-online-speech/

A half-hour before showtime, the audience arrives and begins to take their seats. When everyone is seated, Darp shouts “FIRE!”, barricades the entrance door from the outside, and sets the building ablaze.

The building burns to the ground and everyone trapped inside is trampled, burned to death or killed by smoke inhalation. Passersby who notice the fire and rush to the barricaded doors to try to get in and help trapped victims, are killed by the snipers.

The next day, Darp hosts a press conference. He stands in front of the blackened rubble of the incinerated theater filled with charred bodies, and the piles of bullet-ridden bodies at the perimeter.

To the assembled media, Darp congratulates himself for this pilot demonstration of successful urban renewal. The media agrees.

One reporter asks: “When will you bring this excellent program to other communities? Especially, for the sake of equity, to black, indigenous and persons of color (BIPOC) communities in America, and the people of other countries?”

Darp responds that — thanks to a World Arson Organization training program — the same urban renewal demonstration has already been conducted in every other city in the world in the previous week, with equal success.

A few people at the edge of the press conference are confused. Their family and friends died in the fire or were shot dead trying to rescue people.

One of them shouts: “This isn’t urban renewal! This is mass murder and arson! You should be punished! Where are the police and arson investigators and prosecutors and judges?”

And Darpon Fink replies, “It’s not a crime. There are no longer any laws prohibiting mass murder by entrapment in urban renewal fires.”

*

Same issue came up in a recent reader comment:

> I have not had time to read all your postings so if I have missed something forgive me. You mention "laws" passed in 2020, which if they violate the Constitution cannot actually be law. To prosecute these people, provided a court could be found, would not the U.S. Code criminal and civil penalties for acting under color of law[51] apply?

My reply, revised and expanded:

The key phrase there is "provided a court could be found."

If/when such courts can be found, then yes, color of law challenges could be successfully brought.

A massive amount of unconstitutional law has been passed since around the 2001 PATRIOT Act, and Congress continues to pass unconstitutional laws to the present.

But because of the declared national emergencies[52] (re: terrorism in 2001, renewed every year since and re: Covid-19 in Jan. 2020, extended several times since), all the constitutional provisions for checks and balances between the three branches, particularly judicial review of legislation and executive orders for constitutional muster, have also been putatively suspended.

As have the checks and balances between the federal government and the respective 50 state governments.

Almost all the federal courts have gone along with these pretenses. They have refused to openly declare the constitutional crisis that began around 2000 and became much more visible to the People in January 2020. They have refused to address it or take action to resolve it.

The key piece you've not yet seen (and I know the material here is voluminous) through which Covid gave us a window into the covert overthrow of the US Constitution by domestic enemies within US Government, is where Congress pretended to pass a law stripping itself of oversight powers it would otherwise have over the executive branch, and also stripping the federal judiciary of oversight powers it would otherwise have over the executive and legislative branches.

If it weren't so diabolical and destructive, it could be regarded as a beautifully complex work of perfect, recursive, silent self-destruction by a national government.

Two posts to start down the rabbit hole:

- April 7, 2022 - Responding to Steve Kirsch, James Roguski and others.
- April 8, 2022 - Re: judicially unreviewable.

51 https://www.justice.gov/crt/deprivation-rights-under-color-law

52 https://bailiwicknews.substack.com/p/on-why-bidens-comment-that-the-pandemic

Once the President has declared a national emergency under the National Emergencies Act of 1976 (50 USC 1601[53] et seq), there are only two ways to terminate it. The President can declare the emergency over or Congress can pass a joint resolution. 50 USC 1622.[54] President Biden/his handlers hold the position that the President can and would veto a joint resolution.[55] They issued that response after the Senate narrowly passed a resolution in March[56] that the House later refused to take up. Sen. Roger Marshall of Kansas introduced the bill again on Sept. 22.[57]

Once the President has declared a national emergency under the Stafford Act of 1988 (42 U.S.C. 5121[58] et seq), as far as I can tell, the only thing that ends it is when the state or tribe that requested federal assistance from FEMA decides it doesn't want that assistance anymore. It may exist, but I haven't yet found any information on terminating a Stafford Act declaration.

Once the HHS Secretary has declared a public health emergency under the 2005 PREP Act provisions, he has emergency powers that only end when he stops extending the declaration. Becerra recently extended his own unreviewable emergency powers[59] for another 90 days, on October 13.

So long as federal courts construe the PREP Act and related laws as constitutionally-sound, federal judges can't review or terminate the HHS declaration. 42 USC 247d-6d(b)(7).

So long as states regard the PREP Act and related laws as constitutionally-sound, they can't ignore HHS declarations and manage emergencies independently, 42 USC 247d-6d(b)(8).

So long as Congress construes the PREP Act and related laws as constitutionally-sound, the HHS secretary's only subordinate obligation to Congress is to provide reports.

See Public Readiness and Emergency Preparedness Act (PREP Act), 12/30/2005, 119 Stat. 2818.

> 42 USC 247d-6d - Targeted liability protections for pandemic and epidemic products and security countermeasures…
>
> 42 USC 247d-6d(b)(7) - Judicial review - No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.
>
> 42 USC 247d-6d(b)(8) - Preemption of State law - During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish,

53 https://uscode.house.gov/view.xhtml?path=/prelim@title50/chapter34&edition=prelim

54 https://www.law.cornell.edu/uscode/text/50/1622

55 https://www.whitehouse.gov/wp-content/uploads/2022/03/SJRes-38-SAP.pdf

56 https://www.politico.com/news/2022/03/03/senate-votes-to-end-covid-19-emergency-declaration-biden-threatens-veto-00013946

57 https://www.marshall.senate.gov/newsroom/press-releases/wsj-sen-marshall-to-force-vote-on-ending-covid-19-emergency-declaration/

58 https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-2012-title42-chapter68&saved=%7CZ3JhbnVsZWlkOlVTQy0yMDEyLXRpdGxlNDItc2VjdGlvbjUxMjE%3D%7C%7C%7C0%7Cfalse%7C2012&edition=2012

59 https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx

> enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that— (A) is different from, or is in conflict with, any requirement applicable under this section...
>
> 42 USC 247d-6d(b)(9) - Report to Congress. Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

*

Interesting July 2020 Congressional Research Service report[60] on all the changes that the three active emergency declarations — 1976 National Emergencies Act, 1988 Stafford Act and 2005 PREP Act — triggered throughout the American legal system starting in January 2020...

60 https://sgp.fas.org/crs/natsec/R46379.pdf

Dec. 13, 2022 - Transcript of Nov. 2, 2022 Latypova-Watt discussion, excerpts on public health emergencies, PREP Act, EUA countermeasures

(Excerpts. Full transcript available in July to December 2022 collection)

...Sasha Latypova: I also was stunned by the long history of this. What was the earliest relevant piece of law that you can trace that was changed in particular for this plandemic to occur?

Katherine Watt: I think the earliest one was the 1983 establishment[61] of the Public Health Emergencies Program under the rubric of the Public Health Services Act, which was a 1944 law.[62] But when Reagan and the Congress at the time put in the Public Health Emergencies section, that was the beginning of concentrating much, much more power in the hands of the Health and Human Services Secretary, whenever a public health emergency has been declared by the HHS Secretary. So it's a completely closed loop of once they declare it, they have all the power, and they are the only one who can suspend their power because of the way they wrote the laws, to the extent—let's say—to the extent that federal judges and Congress accept the premise that the executive branch can shut them out of everything after the announcement has been made.

SL: So this unconstitutional, I would say, law was put in place in the eighties... saying that this branch of government can usurp power...pretty much at their own discretion. So what is a public health emergency and how—does it have to have some sort of concrete set of rules, data, any threshold that needs to be reached for a public health emergency to be declared? Or is it just something that they describe as one?

KW: So far? I think it's just one that they describe as one. There may have been at the beginning—no, it just said, public health emergencies is a thing. It's basically like a parallel version of a national emergency. So if they declare a national emergency because of a war or because of a natural disaster, that has all these cascade effects on other laws and other constitutional rights. This just added another version of that to be public health emergencies as part of medicalizing it. And I think probably as part of making it harder for people to see that it was a government usurpation or a government tyranny effort because people think, 'Oh, it's about public health. It's about protecting us...'

SL: For no reason whatsoever. So that's what I want people to clearly understand. The second question I had is about this other transactional authority...

KW: Right. I came across it because of Brook Jackson's case.[63] Brook Jackson is the whistleblower who was working for Ventavia, who was a subcontracted to Pfizer under the contract Pfizer had with the Department of the Defense to produce a hundred million doses of what they call a vaccine and distribute it through the DOD to all the people in the United States. Brook Jackson, as soon as she got to her trial site—she had three—in Texas, she noticed there were terrible problems with the clinical trials. She reported it first to her bosses at Ventavia, then to people at Pfizer. Then she

[61] https://bailiwicknews.substack.com/p/22-worst-congressional-bioterrorism
[62] https://uscode.house.gov/statviewer.htm?volume=58&page=682
[63] https://www.covidlawcast.com/p/brook-jackson-pfizer-whistleblower

tried to file, I think an anonymous hotline report, to the FDA and within hours of the FDA report, she was fired. Then she filed a False Claims Act case because her theory at that time was that Pfizer was defrauding the U.S. government by falsely saying they were doing good clinical trials, and that the U.S. government would want to know this because they would want to not spend money on a fraudulently produced product.

It turned out that that is not the case. The U.S. government was in on the fraudulent clinical trials and in on the whole fraud entirely. That came out in Pfizer's April 2022 motion to dismiss.[64] Because Brook, when she filed her False Claims Act, she attached the Statement of Work, which was a contract that was supposed to govern how the clinical trials were done. And in its motion to dismiss Pfizer attached another contract called an Other Transaction Authority[65]—OTA contract—saying in effect, no, we had no obligation to conduct valid clinical trials because the only goods and services we were providing to the U.S. government, according to this contract are a large scale manufacturing demonstration for a prototype. So they split off the clinical trials from the manufacturing and production side. I looked at that contract and had already come to the conclusion that it was a joint fraud between Pfizer and the DOD. And this corroborated that in Pfizer's own words.

So the OTA is a separate contracting, purchasing framework that U.S. government agencies can enter into with private companies. And the report that I sent you is from KEI. The title of it is Other Transaction Agreements: Government Contracts that Eliminate Protections for the Public on Pricing, Access and Competition, Including in Connection with COVID 19 Vaccines and Treatments[66] [KEI Briefing Note 2020: 3 Other Transaction Agreements: Government Contracts that May Eliminate Protections for the Public on Pricing, Access and Competition, Including in Connection with COVID-19;[67] local PDF[68]].

It started in 1958, according to that report through NASA. But it's since been expanded to, I think they said, 11 agencies have it now, have this special authority that Congress has given them to enter into these contracts. And it suspends all kinds of oversight.

That's the bottom line of what an OTA does. In my view, Pfizer is probably correct that under the terms of the OTA, they had no obligation to ever conduct a valid clinical trial. They could make the entire thing a fraud. They could make the entire thing seem to be real and said that actual data, but it didn't have to be good data. It didn't have to be in compliance with any of the regulations that otherwise govern clinical trials. That's why in the one piece I've done on it, I compared it to the Emergency Use Authorization because OTA did for the financial contracting side, what EUA did to the drug regulation side: they both just took them out of the normal.

[64] https://bailiwicknews.substack.com/p/pfizers-motion-to-dismiss-the-brook
[65] https://bailiwicknews.substack.com/p/other-transactional-authority-ota
[66] https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf
[67] https://www.keionline.org/bn-2020-3
[68] https://ratical.org/PandemicParallaxView/KEI-Briefing-OTA-29june2020.pdf

SL: So this is a structure by which the government can essentially waive for themselves all the normal rules and regulations for development approval of otherwise regulated products such as pharmaceuticals.... And order that thing that now has no regulations attached to it.... From the private manufacturer who otherwise would be regulated by those rules...

SL: I've been talking a lot about the fact that the DOD ordered all these prototypes and all these countermeasures.

KW: And that they control it from, from the very beginning of the ...

SL: Yes. That's why a lot of people ask me what is the proof that DOD controls it? How would you answer that question? What does need to exist to show people the proof? Well—other than the documents that we're all pointing out to—but really, how do they control this whole production?

KW: I mean, I think they control it because they control the—well, there's the things that you've pointed out in the contract about that DOD has to be a participant on every single phone call, every single email, every single meeting that happens between Pfizer or its subcontractors or any of the pharmaceutical subcontractors and the FDA regulators. Which means that DOD is in there directly controlling the decisions that FDA makes and the announcements that FDA makes, and the material that FDA is allowed to review or not review. That plays into another piece of the puzzle that showed up through Brook Jackson's case,[69] which is under the law, the HHS secretary is supposed to make his or her decisions about EUA products, about medical countermeasures, about security countermeasures, all these terms they came up with, which basically just mean bioweapons. But bioweapons packaged so that they look like medicine.[70]

They're supposed to make it on the basis of scientific data and evidence, "if available". And that *if available* is very, very important because the DOD was in a position to make sure that no valid data would ever be made available to the FDA regulators. And to ensure that even without it, they would produce the authorizations and the approvals that the DOD required under the terms of the contract with Pfizer in order to go ahead with the manufacturing and the contracts and the hundreds of millions of dollars that they funneled to these companies. So the availability of data is a key part of how DOD controls not just the product itself, but also the information available to the regulators and to the HHS secretary. I don't think that gets them off the hook morally because I think that the FDA and HHS officials were willing and knowing participants in it. And I think that can be shown. But it does explain the mechanism by which it was done—is done.

SL: So yes. We need to spend a little more time on this. So the decision to—what is it legally called? Is it authorization, licensing or is it just deployment of the countermeasures?—is up to the sole authority of HHS secretary who under Trump was Alex Azar, and now it's Xavier Becerra. So those two individuals, sequentially, made decisions about deployment of these counter measures, prototypes, bioweapons, to the American public and the world. And that decision was based on available data, *if available*.

[69] https://totalityofevidence.com/brook-jackson-pfizer-whistleblower/

[70] https://bailiwicknews.substack.com/p/congress-appropriated-billions-more

KW: Yes. It was based on available data about the products. And it was also based on available data about the known and potential risks of the actual thing that they were deploying the product against. So they got to decide, unilaterally, basically as dictators, what is the level of threat that this SARS-CoV-2 poses to the population, and what are the acceptable risks and benefits calculations of the countermeasure deployed against that first SARS-CoV-2 thing. It was, it is multilayered.

SL: The enormity of this, I just, I can't emphasize enough, is one person, Alex Azar or Xavier Becerra, decides for 300 million people in the United States, unilaterally, how much threat Covid poses to them today and in the future... And how safe, efficacious this product is for them, specifically individual and for their children, their babies, their elderly, now and in the future... How insane that is, it just blows my mind. But it is written in the U.S. law.

KW: Right. It's massive and it's very hard to wrap your head around how massive it is.

SL: Yes. And I will put citations that Katherine provided under this video as well, so that people can check for themselves and read that language that we just cited. Another question I had, before we go into the information management of this. Let's just play back the scenario. Alex Azar is HHS. This thing starts unfolding. They're claiming it's super lethal, next plague. Okay. He decides—somebody shoves these things in front of him and says they're okay. Pfizer said so. FDA said so. DOD says so. He thinks, Okay, they may be effective and so let's deploy them... But that's early, let's say early 2020. Now, two years later, we have two years worth of data on both the transmission, local transmission of Covid, which is near zero everywhere.

KW: Effective other treatments is another thing.

SL: Effective other treatments. The deadliness of the injections. There's a lot of adverse events. And now they're even admitting officially myocarditis is a thing. A bunch of states such as Florida said that we're not going to recommend it to children. Is this the available information that now Xavier Becerra has to take into account? Or is it just, he can pretend he never heard these things?

KW: I think he can pretend he never heard these things. He can definitely pretend he never heard these things because he's been pretending that for two years now. And that's where it gets into the amazing structural features Congress built into these things where Congress not only put all the power into the HHS secretary's hand. They also eliminated their own oversight power. They eliminated, or they claimed to—this is written in the laws—they claimed that they have no power to overrule or review his emergency declarations about their existing emergency. They can't overrule his EUA declarations. They also put provisions that no federal judge can review those declarations. Once they're made, they're considered solely within agency discretion. So there's no judicial review and eliminated states power to take any course of action different from what the HHS secretary has said that they should do, which is called preemption.

There's sections in these laws—I have it in my head, but I can't think of the name of it [42 USC 247d-6d(b)(7), 42 USC 247d-6d(b)(8) and 42 USC 247d-6d(b)(9)[71]]—that make it so that there is no state authority to overrule HHS secretary, there is no congressional authority to overrule HHS secretary, and there is no judicial authority. And Congress did that. Which raises the interesting, super interesting philosophical question of — with horrible implications — how did they give away a power that they didn't have the power to give away? Congress does not have the power to dissolve itself. Congress does not have the power to dissolve the federal judiciary under the U.S. Constitution. But they did it to the extent that the federal judges are deferring to them. And Congress is deferring to the HHS secretary. And the states, for the most part, with exceptions like Florida, are deferring and not challenging these things. They're just saying, Whoop, that happened.

SL: I guess, well, you know, you gave our power away --

KW: I guess the Constitution's gone now, so whatever.

SL: So whatever. We'll just continue collecting pensions and have a nice life and, hope it will blow over. Right?

KW: I don't know if they hope it'll blow over. I think they're planning to make it more of them doing less and more of—I mean, because I think their goal is to turn it all over to the World Health Organization and [] stuff. That's the game that they're playing, but if they never had—you can't give away a power that wasn't yours to give away to begin with. And the power in our country is supposed to be in the Constitution, the supreme law of the land. There's supposed to be nobody that's above it. So to have Congress say, Well, you know, never mind, is just super bizarre.

SL: It's absolutely, it's absolutely incredible. And I hope more people see this and understand what's happened. But before we go into, what's the next steps, this just puts into perspective all the information warfare that was associated with this. Because again, the key thing is available information *if available* to one person.

KW: And if that person doesn't want to look at it, it's not available to him...

SL: ...let's come back a little bit to the clinical trials, documentations, manufacturing documentation, any documentation that so far has been produced through FOIA. I know some firms have been very successful in doing that, like Aaron Siri's ICAN. They've produced a lot of materials and especially the Pfizer clinical trial documents that I have been reviewing with a number of colleagues myself. How do we think about it? If they never had to produce them or produce them to quality of the clinical trial—if it's not even a clinical trial, what do we think of them as?

KW: I think of them as a performance art. They had to do them only insofar as they had to make people believe that real ones were happening. And they only had to make people believe that—if they had been as successful as they wanted to be, they would've done this short, sharp, panic campaign, which is what they did in early 2020. They would've done these clinical trials in the

[71] https://www.law.cornell.edu/uscode/text/42/247d-6d

shoddy, fraudulent way that they did them. But a lot of the people I think, like at the level of Brook Jackson and down, did not know that what they were participating in was fake. They actually were getting injections. They actually were having symptoms or not having symptoms. They actually were reporting some of them to the clinical trial sites. The clinical trial sites were actually reporting some of the things that happened to the collection, like, the sponsors. Because they needed to maintain that part of the fraud too.

If people had known very early on, Well, there's not really clinical trials at all, then many more people would not have taken it. The problem for them is that a lot of people didn't take it anyway, because a lot of people thought—first of all, people figured out, some of them, that the actual underlying SARS-CoV-2 was not as big of a threat as what they wanted everybody to believe. A lot of people had it or what they believed it was. And then they were like, I have natural immunity. So then they had to knock down, Well there is no such thing as natural immunity anymore. There's no such thing as herd immunity anymore. A vaccine doesn't have to prevent you from getting something anymore. They had to change all of these definitions and keep the thing going.

And the longer they tried to do that, the more evidence came out through like you said these other alternative media channels or people just knowing people who got sicker after they took it or whatever. But yeah, I think the whole point of it that, and I don't—I say that partially because that's how I understand the framework, but also I do think there's useful data in those things. It's just not complete. It's not up to the standards that it would need to be, to actually like, you know far better than I do. It doesn't meet any of the things that a normal pharmaceutical regulatory process would have done. But it still is data. And that's why people like Naomi Wolf and Aaron Siri and Del Bigtree are able to have these crowdsourced analysis of the data and come up with information about what these things cause. Which then helps other people try to reverse engineer what's actually in them to be causing this enormous range of neurological and reproductive and respiratory [injury] and all of the things that the injections cause. But yeah, the overarching purpose of them was to make it look like a valid pharmaceutical regulatory process had taken place when it had not.

SL: By law, do they have an obligation to people to disclose, if you are issuing authorization for emergency use of the product, and you are issuing it under this Other Transaction Authority, under Public Health Emergency, where it's a declaration by Alex Azar, do they have legal obligation to tell people that? Or is it okay under the law to lie and pretend that clinical trials are required for this?

KW: I think that they've set it up so that it's okay because they've split them apart. They've split it apart as this is a prototype, this is not a clinical trial. And then they said in the contracts, the clinical trials are actually being done by—they're not taxpayer funded—they're done by Pfizer itself as the sponsor. I don't know where—I think there are other contracts that would cover that. I have not seen them.

SL: I haven't seen them either. I don't think they actually exist from the government.

KW: I don't think they actually exist from the government either. And I don't know where they would exist. But I don't think they have—because they folded it under the EUA, because they folded it under the Other Transaction Authority, I don't think they have any obligation to do anything as far as—

SL: Exactly. So now that you said that it became even clearer in my head that I've seen those contracts and it was very puzzling—I've seen the DOD contracts—and it was a very puzzling way that they have carved out the clinical trial and anything that has to do with regulatory process from the money that was being paid, ostensibly for the large-scale demonstration. And now it makes full sense because, literally they're saying this clinical trial stuff and regulatory theater, this is a voluntary activity by Pfizer and FDA. They're just playing, play acting together because they feel like it.

KW: Yes.

SL: [What] we're paying for is this other thing: other transactional authority, prototype, military prototype. So I think that that's how they actually separated it. So that now these guys are performing theater here...

Dec. 13, 2022 - Intent to Harm - "mRNA Vaccine Approval" was a farce. Deaths and injuries are real and intentional.

By Sasha Latypova

Note: video presentation of this material is here.[72] I am publishing this as a written piece since many people asked.

Totality of evidence to date points to the intentional harm by Covid-19 injections as well as all other "covid countermeasures". I am not going to spend much time demonstrating this in this article but will link extensive documented[73] evidence sources.

The shots as well as other "countermeasures" like lockdowns, suppression of effective early treatments, overuse of opioids behind the closed doors of hospitals and nursing homes, overuse of ineffective and harmful (but very profitable) remdesivir, finishing patients off on a ventilator, or simply starving them to death locked in the hospital "covid unit" are all nonsensical in the context of public health and are toxic by design.

The mechanisms of injury are designed into C-19 injections. In layman terms, it simply trains your cells to attack and destroy themselves. It is only a matter of exposure – how much of this instruction is delivered where and in what amounts in your body, that determines whether you will drop dead from a heart attack or stroke within days to months or will deteriorate in slower and more painful (but profitable!) ways from cancer, neurodegeneration, autoimmune conditions, or other forms of chronic demise.

There is no safety nor efficacy in these products, instead we observe a horrific death and injury toll (VAERS, vSAFE, Eudravigilance, Yellow Card, etc. contain millions of reports). Negative efficacy, i.e. propensity to cause covid illness has been documented as well.

Then there is VERY bad manufacturing[74]: Highly variable production, non-compliant with cGMP accompanied by no enforcement of cGMP by any agency anywhere. I will be republishing my extensive research on this topic on this substack in the coming weeks.

Finally, all of this is maintained by a deeply malignant policy worldwide: government lies, cover-up, gaslighting of the injured, prosecution of dissent and whistleblowers, collusion with media, and massive perverse financing of the above.

If you do not see any of this by now, God help you, and I mean this with compassion.

If you DO see it, you are probably screaming at this point "I know!!! Why hasn't anything been done about this? Why are all regulators acting this way?" Here is why.

[72] https://www.bitchute.com/video/8ftbShzrkjl9/
[73] https://grandsolarminimum.com/2022/12/01/covid-19-vaccine-harm-evidence/
[74] https://www.bitchute.com/video/BGIqC6ufcyjF/

Key Legal Facts (read Katherine Watt's Bailiwick News if you want to survive this time in history): April 28, 2022 - American Domestic Bioterrorism Program[75]

Congressional amendments to the 1938 FD&C Act and the 1944 PHS Act over decades had eliminated federal regulatory standards for production and use of products designated by the FDA for "emergency use" during an HHS-declared, HHS-maintained "public health emergency."

Specifically, 21 USC 360bbb-3(c) "Criteria for Issuance of Authorization": the law provides that the HHS Secretary may issue emergency use authorizations if he/she concludes:

- 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—
- (A) the product may be effective in diagnosing, treating, or preventing—
- (i) such disease or condition; or
- (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this 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; and
- (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

Note that the authority issuing emergency use authorizations is the HHS Secretary him/herself. There is also no applicable regulatory standard for issuing it other than the sole discretion of the HHS Secretary to make the determination of "may-be" efficacy.

The scientific evidence does not need to be available to support this decision, and there are no hard scientific standards for assessing risks or benefits, "potential" is a sufficient standard here.

There are also no stopping criteria or any process that would update/amend the decision of the HHS Secretary if and when new scientific data becomes available. What happens if more rigorous scientific data, for example larger datasets, collected over longer period become available and the findings contradict the decision made by the HHS Secretary based on small, hastily collected ones? There is no legal process defined to revise those decisions.

[75] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program?utm_source=substack&utm_campaign=post_embed&utm_medium=web

Of particular interest is a special category of products designated by the Department of Defense (DOD) as “prototype countermeasures”.

- 10 USC 4022(a)(1) - “[T]he Director of [] (DARPA), the Secretary of a military department, or any other official designated by the Secretary of Defense may, under the authority of section 4021 of this title, carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces.”

The language above is a lot of words that do not describe anything specific. These are simply “things that DOD needs”. You don’t need to know what they are. Because you already know what they are – they are weapons. Those are the things the DOD needs most of the time.

Final Piece of Legal Puzzle:

21 USC 360bbb-3(k): use of EUA-covered medical countermeasure (MCM) products, once designated as such by the Secretary of Health and Human Services (March 10, 2020, retroactive to February 4, 2020) “shall not be considered to constitute a clinical investigation.” 21 USC 360bbb-3(k). EUA law, adopted 1997 and amended 2003, 2004, 2005, 2013, 2017.

Countermeasures are legally NOT pharmaceutical products.

The FDA has no authority over them and cannot enforce any regulations. They only pretend that they do. This answers the question WHY the regulators are acting this way. They are acting. As in “theater acting”...

2023

Christ in the Storm on the Sea of Galilee. Rembrandt van Rijn

Work published at Substack, 2022-2025. October 2025 version.
Katherine Watt - PO Box 1142 - State College PA 16804

2023

- Jan. 2, 2023 - Bioweapon prototype deployments, informed consent, targeted enemies, state of war, doctrine of necessity.
- Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation."
- March 22, 2023 - War criminal Xavier Becerra extends the public health emergency, effective March 15, 2023, using slightly-different wording.
- April 11, 2023 - Biden rescinding Trump-Biden Proclamation 9994 under 1976 National Emergencies Act does not terminate Azar-Becerra's Public Health Emergency authorities under 1983 PHE amendment to the 1944 PHSA.
- July 1, 2023 - Another sign that tide of covert war is turning will be pharmacies that refuse to take delivery of DoD biochemical weapons and pharmacists who refuse to use them on targets.
- Aug. 18, 2023 - Bridges v. Houston Methodist Hospital Court decisions supporting the conclusion that vaxx recipients are military targets, enemy combatants, chattel slaves or similar legal status in which consent is moot.
- Aug. 28, 2023 - March 15, 2023 and May 11, 2023 HHS Dictator-Secretary determinations and declarations.
- Oct. 17, 2023 - Texas and Oklahoma v. US Department of Health and Human Services and Xavier Becerra: case documents
- Oct 18, 2023 - There is never going to be another "deadly global pandemic." There have not been any in the past.
- Oct. 23, 2023 - On civil suits against Pfizer for "contamination" of Covid-19 biochemical weapons.
- Oct. 26, 2023 - 21 USC 360bbb-3(e)(3) and 360bbb-3a(c): federal law authorizing HHS Secretary to waive current Good Manufacturing Practices (cGMP) for EUA products. Relevant to public discussion of whether growing body of sequencing evidence of "adulteration" of Pfizer, Moderna and other mRNA platform technology products, opens new opportunities for litigation.
- Nov. 4, 2023 - Do C-19 Vax Manufacturers Violate cGxP? (Sasha Latypova)
- Nov. 14, 2023 - Separation of powers, reservation of powers (federalism), and the PREP Act.
- Dec. 1, 2023 - On 'mandates,' and the irrelevance of informed consent principles in the EUA countermeasures use context.
- Dec. 2, 2023 - EUA Countermeasures are neither investigational nor experimental. (Sasha Latypova)
- Dec. 6, 2023 - More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.
- Dec. 6, 2023 - Litigation proposals for state Attorneys General.
- Dec. 20, 2023 - Ending National Suicide Act. Draft bill for 118th Congress

Jan. 2, 2023 - Bioweapon prototype deployments, informed consent, targeted enemies, state of war, doctrine of necessity.

(Excerpts)

An email correspondent recently asked me if I had read Deputy Attorney General Dawn Johnsen's July 6, 2021 opinion on the legal implications of the Emergency Use Authorization (EUA) laws, in which Johnsen offered the Department of Justice position on the question (posed by President Biden's Deputy Counsel, who was seeking DOJ cover for Biden's executive orders and agency 'vaccine' mandates): "Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization?"

…The DOJ attorney [Dawn Johnsen] concluded that no legal impediment to 'vaccine' mandates by public and private entities exists…

In light of what I've learned in the last few months, I'm convinced that the whole project, as a bioweapons prototype deployment project, falls exclusively under 50 USC Ch. 32 - Chemical and Biological Warfare.

There are some notice and consent provisions in 50 USC Ch. 32. But 50 USC 1515 authorizes the President to waive any part of the Chemical and Biological Warfare laws, under emergency powers during a declared emergency.

There may be a publicly-available document recording the date on which President Trump and/or President Biden invoked or extended 50 USC 1515 to suspend all prohibitions on use of chemical and biological weapons on American people and people in other countries. But it may be classified and non-public as a national security document.

If that document exists — and the observable evidence of how the vaxx campaign has unfolded suggests it does — Trump and Biden waived all rights to resist/refuse administration for all potential targets (military and civilian) because under a state of war, state of national emergency, and/or state of public health emergency, all resisters are classified as enemy insurgents or enemy aliens.

Johnsen's (and many other federal officials') invoking of 21 USC 360bbb and 42 USC 247d in opinions, declarations and determinations, were, in my view, simply red herrings. Those legal frameworks were cited only to increase the persuasiveness and distract the targets from the core illusion: that biological and chemical weapons — primarily packaged as vaccines and in use for many decades — are medicinal products...

Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation."

Last week I got an email requesting clarification about the significance of 21 USC 360bbb-3(k) for the planning, execution and continuance of the Covid-19 global pharmaweapon mass murder campaign.

> 21 USC 360bbb-3[76] Authorization for medical products for use in emergencies
>
> …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].

My reply

The shortest version is that — like the current Good Manufacturing Practice, current Good Laboratory Practice, current Good Distribution Practice and labeling and dispensing laws that Sasha Latypova has investigated so thoroughly[77] (and found that none of the standards that FDA applied to drug, vaccine and biologics development prior to 2020, were applied by FDA to the products produced after the 2020 PREP Act declarations about Covid-19 EUA countermeasures) — so also none of the current Good Clinical Practices were followed either.

Brook Jackson identified these blatant violations in the human clinical "trials" in August and September 2020, collected supporting evidence, and described the violations in detail, with supporting documentation and photos, in her reports to Ventavia, Pfizer and FDA.

Ventavia, Pfizer and FDA ignored the evidence; continued attacking unwitting victims with lethal injections while telling those victims they were participants in an FDA-regulated clinical trial; and arranged for Jackson to be fired.

Jackson included the same information and evidence in her whistleblower complaint[78] at p. 8

> …"[Brook Jackson] observed:
>
> - fabrication and falsification of blood draw information, vital signs, signatures and other essential clinical trial data;
> - enrollment and injection of ineligible clinical trial participants, including Ventavia employees' family members;

[76] https://www.law.cornell.edu/uscode/text/21/360bbb-3
[77] https://sashalatypova.substack.com/p/my-talk-from-lakarupropet-conference
[78] https://bailiwicknewsarchives.files.wordpress.com/2022/10/2022.02.22-jackson-amended-complaint.pdf

- failure to timely remove ineligible patients' data from the trial;
- failure to maintain temperature control for the vaccine at issue;
- failure to monitor patients after injection as required by the trial protocol;
- principal investigator oversight failures;
- use of unqualified and untrained personnel as vaccinators and laboratory personnel;
- failure to maintain the "blind" as required, which is essential to the credibility and validity of the observer-blinded clinical trial;
- ethical violations, such as failure to secure informed consent and giving patients unapproved compensation;
- improper injection of the vaccine (i.e., by over-diluting vaccine concentrate or using the wrong needle size);
- failure to ensure that trial site staff were properly trained as required by good clinical practices;
- safety and confidentiality issues, including HIPAA violations; and
- other violations of the clinical trial protocol, FDA regulations, and Federal Acquisition Regulations and their DoD supplements.

Ventavia failed to report the majority of its clinical trial protocol and regulatory violations to Pfizer or the external Institutional Review Board. Issues were improperly documented or hidden away in "notes to the file," and not corrected…"

*

If *any* FDA regulations had been legally operative, then the whole project would have been stopped by FDA long before human sham-trials could even begin.

Red flag stopping points showed up in the very earliest animal studies, one of which was conducted between July 16, 2020 and Sept. 24, 2020, concurrent with the sham human trials, and eventually provided by Pfizer/Acuitas/DOD to FDA in November 2020.[79]

Another version was provided to Japanese regulators[80] by February 2021, after mass rollout worldwide began in December 2020. It was subsequently translated into English and discussed by Byram Bridle in May 2021 reports and on Bret Weinstein's June 2021 Darkhorse podcast, highlighting that the data showed the lipid nanoparticles (payloads unidentified) accumulate in rat organs, among other toxicity evidence.

[79] https://bailiwicknewsarchives.files.wordpress.com/2022/09/2020.11.09-pfizer-wistar-study-77-p..pdf

[80] https://bailiwicknewsarchives.files.wordpress.com/2021/12/2021-japan-study-translation-lnp-in-ovaries.pdf

See Sept. 19, 2022 - In Nov. 2020, Pfizer told FDA reviewers, led by Marion Gruber, that safety studies were neither needed nor conducted. In making that argument, Pfizer cited WHO guidance written in 2002 by a team led by Marion Gruber.[81]

> …At this point in early Summer 2021, four facts became more widely understood among the community of people trying to understand the biotechnology, risks and benefits of the products marketed as 'Covid-19 vaccines.'
>
> 1. The inflammatory lipid nanoparticles and their payloads collect in the ovaries and other key organs, are not rapidly cleared from the human body and are toxic.
> 2. Pfizer scientists knew this before seeking EUA approval from the FDA through the 11/20/2020 EUA application.
> 3. FDA scientists led by Marion Gruber knew this when authorizing the product for emergency use on 12/11/2020.
> 4. Pfizer, FDA and Gruber withheld this information from the public and knowingly lied each time they described the products as "safe and effective…"

The Pfizer-DOD death machine submitted the Wistar rat data to the fake FDA reviewers as part of the EUA package, including a document called "Phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity and efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals."[82]

In that sham "clinical trial" protocol at p. 72, Pfizer-DOD flatly stated that the "study" had not and would not assess pharmacokinetics, pharmacodynamics, biomarkers or genetics.

The aggregate evidence for the intent and function of 21 USC 360bbb-3(k) as a blanket waiver of the American drug regulation system to facilitate and pre-cover-up a covert, criminal bioweapons production and deployment program — can be summed up as "the dog that didn't bark."[83]

Reinforcing evidence is the establishment of "real world evidence"[84] — "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials" — as a basis for fake FDA regulatory decisions, a monstrosity Congress passed and Obama signed through the 2016 21st Century Cures Act[85] at Section 3022. More reinforcing evidence: the government-coordinated, fraud-based suppression of all the alternative treatments for Covid-19, any one of which would have been enough to block the EUA, which depends on there being no available alternative treatments.

[81] https://bailiwicknews.substack.com/p/in-nov-2020-pfizer-told-fda-reviewers
[82] https://bailiwicknewsarchives.files.wordpress.com/2021/12/2020.11-pfizer-biontech-c4591001-clinical-protocol.pdf
[83] https://en.wikipedia.org/wiki/The_Adventure_of_Silver_Blaze
[84] https://bailiwicknews.substack.com/p/faked-clinical-trials-and-real-world
[85] https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf

Another way to think about 21 USC 360bbb-3(k): It's the provision that quietly nullified every substantive way in which FDA regulatory functions would have been fulfilled, rendering the entire FDA performance a sham intended only to shield from public view, that the operation was and is actually run under 50 USC Ch. 32, the Chemical and Biological Warfare Program.

As I keep researching, I find more evidence that FDA officials fully understood how outside-the-FDA-law the EUA program is, and they've understood it for a very long time.

Especially FDA lawyers running the "legal preparedness" apparatus.

See, for example, Susan Sherman's part in a 2009 workshop[86] (*Medical Countermeasures Dispensing Emergency Use Authorization and the Postal Model*, at p. 26) and an August 2020 presentation by Elizabeth Sadove,[87] summarizing the simultaneous cover-up/crime in a table at p. 18:

Comparison of Access Mechanisms

Consideration	Clinical Trial	Expanded Access (IND/IDE)	EUA
Ability to inform effectiveness	Yes – designed to provide evidence of safety and effectiveness	Not likely; possibly anecdotal information with larger population size	Not likely
Ability to inform safety	Yes – designed to provide evidence of safety and effectiveness	Safety signals might be identified	Safety signals might be identified
Ability to obtain useful information to benefit future patients	Yes - designed and intended to benefit future patients – randomized/blinded	Not likely; with larger sized populations, possibly some safety data in patient subgroups that could inform broader labeling	Not likely
Availability of findings	Eventually published in medical journals. If part of a regulatory approval, FDA makes reviews public.	Individual medical records are not released to the general public. Case reports might be published in medical journals.	Generally there is no systematic data collection. Retrospectives studies may be conducted and published.
Informed consent required?	Yes	Yes	No, but requires informing the volunteer of 1) right to refuse and 2) that product is unapproved/available under an EUA
Institutional review board (IRB) required?	Yes	Yes, but no prior approval needed for individual patient access	No
Level of access to investigational product	Depends on trial design P1 typically 20 – 100 P2 typically several 100 P3 typically 300 – 3,000	Depends on type of expanded access, which ranges from individual patient (e-IND/IDE) to large (e.g., 100-1,000) populations	Can enable access to a large number of patients

That table makes clear that "Clinical Trial" products, "Expanded Access (IND/IDE)" products and "EUA" products are three completely different legal frameworks.

Under "Clinical Trials," the use will provide evidence of safety and effectiveness; will produce useful information to benefit future patients; will eventually be published in medical journals and possibly published FDA reviews; that informed consent is required; that Institutional Review Boards are required; and that a limited number of people will have access to the product.

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[86] https://www.ncbi.nlm.nih.gov/books/NBK53126/pdf/Bookshelf_NBK53126.pdf

[87] https://bailiwicknewsarchives.files.wordpress.com/2023/02/2020.08.25-fda-cdc-regulatory-updates-use-of-mcms-table-p.-18.pdf

Under EUA, product use is "not likely" to provide evidence of efficacy; "might" provide safety signals; is "not likely" to provide useful information to benefit future patients; "generally there is no systematic data collection" although retrospective studies "may" be conducted and published; informed consent is not required; IRB review is not required; and the access pool is "a large number of patients."

The primary purpose of all the statutory, regulatory changes and guidance document revisions year after year, page after page, is to keep people from, first, understanding the war crimes as war crimes, and — if people do figure it out — keep them chasing their tails trying to find the FDA loophole that the war criminals somehow failed to close, through which somebody might someday be able to get them to stop killing us.

In the meantime, they just keep killing, and we don't find loopholes, because the complexity of the web is impenetrable, and the program is not an FDA-regulated medical treatment program anyway: it's a military-operated global genocide.

I try to maintain attention and expand understanding of demonstrable fact sets and the moral judgments that follow once those acts are accurately perceived: "What they are doing is intentional killing, and intentionally killing people is wrong."

And I try to participate in the global struggle to stop the killing by helping to mobilize political and social pressure on lawmakers to use international and federal criminal laws to stop the cull and bring the killers to justice; repeal the enabling laws and put in place new laws that better protect people from socially- and economically- coerced submission to mass murderers pretending to be everything other than what they are.

March 22, 2023 - War criminal Xavier Becerra extends the public health emergency, effective March 15, 2023, using slightly-different wording.

...Yesterday, someone sent me a March 20, 2023 Federal Register notice[88] on the extension of the Public Health Emergency (PHE) and Emergency Use Authorization (EUA) declarations and determinations.

The sender asked me "whether that EUA amendment I sent you made substantive changes, or was this just a regular extension?"

I replied that there are enough redundancies built in throughout the PHE and EUA declaration and determination procedures, and they're both unreviewable by Congress and courts anyway, that the wording of any particular one isn't worth spending a lot of time to parse in detail.

[Note: when criminal prosecutions are eventually brought against specific war criminals, these documents will be part of the evidence incriminating the signatories. At that point, parsing the documents in detail will be extremely important, to tie the dates, circumstances and effects of specific acts taken in furtherance of the war crimes, to the people who committed those acts.]

The latest iteration slightly alters the original, false claims.

In the original determination of public health emergency, effective Feb. 4, 2020,[89] a war criminal impersonating the US-HHS Secretary (Alex Azar) claimed that "there *is* a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad" and that the emergency "involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, China."

In the latest amendment to the determination of public health emergency, effective March 15, 2023,[90] a war criminal impersonating the US-HHS Secretary (Xavier Becerra) claimed that the nCoV outbreak has already infected and killed millions of people, and that there are now variations circulating, such that "there is a public health emergency, *or a significant potential for a public health emergency,* that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad."

The two forms of PHE "determination" are used interchangeably, to provide pseudo-legal pretexts for COVID–19 Emergency Use Authorization/EUA declarations (which are, more accurately, military orders to deploy bioweapons labeled as 'vaccines' to injure and kill recipients) and amendments thereto.

[88] https://www.govinfo.gov/content/pkg/FR-2023-03-20/pdf/2023-05609.pdf
[89] https://www.govinfo.gov/content/pkg/FR-2020-02-07/pdf/2020-02496.pdf
[90] https://www.govinfo.gov/content/pkg/FR-2023-03-20/pdf/2023-05609.pdf

For emphasis, Becerra added to the latest notice:

> …The four previously-issued section 564 declarations that refer to the February 4, 2020 determination have not been terminated by the Secretary because, among other things, the circumstances described in section 564(b)(1) continue to exist — i.e., COVID–19, a disease attributable to SARS–CoV–2, continues to present a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad…

As with all effective lies, there are kernels of truth within most HHS Secretary notices, declarations and determinations.

The emergency that existed in January 2020, and still exists, is a group of war criminals, coordinating with each other worldwide, as participants in a criminal enterprise that "involves" the novel coronavirus pretext as a pseudo-legal mechanism to suspend lawful government functions; instill fear; suppress critical thinking, public debate, alternative treatments, comparative assessment of threats, biomedical ethics obligations and rights, and self-preservation instincts; and induce peaceful compliance with lethal injection programs labeled as 'vaccine' programs.

For the purpose of making it easier for mass murderers to get away with mass murder...

One other purpose of the new, March 15, 2023 determination, is to *de facto* void the Jan. 30, 2023 announcement[91] that the public health emergency would end effective May 11, 2023.

Biden, on behalf of his central banker handlers, made that announcement to:

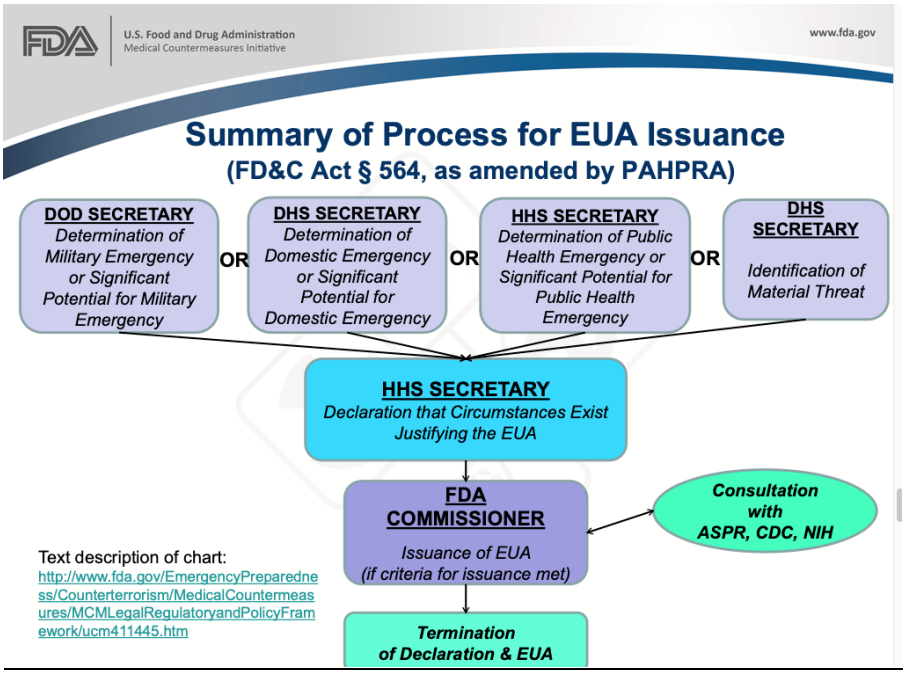
1. undercut then-pending Congressional action (H.R. 382,[92] approved by House Jan. 31, 2023, 220 to 210, and H.J. Res. 7,[93] approved by House Feb. 1, 2023, 229 to 197), without actually relinquishing emergency executive powers; and
2. prevent any further consideration of the termination bills by Congress, because Congressional debate would make the Constitutional crisis triggered by the Covid-19 control-and-kill program through the enabling statutes and regulations, much more visible to the American people.

[91] https://apnews.com/article/biden-united-states-government-district-of-columbia-covid-public-health-2a80b547f6d55706a6986debc343b9fe

[92] https://www.congress.gov/bill/118th-congress/house-bill/382

[93] https://www.congress.gov/bill/118th-congress/house-joint-resolution/7

FDA offers a slide from an April 2015 FDA slide deck outlining changes to EUA law effected by 2013 Congressional passage of the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).



The chart shows how many different ways mass murdering war criminals pretending to be US government officials can declare and maintain "emergency" powers to kill people using bioweapons fake-named as EUA 'vaccines' and other countermeasures, including events for which there may not even be fake evidence of a threat, but for which the war criminals claim there is "significant potential" of a future threat.

It's very similar to the gradual addition of "asymptomatic" and "precommunicable" stages of disease, to the original "symptomatic" stage, authorizing the HHS Secretary to order the military and local law enforcement[94] to arrest and detain civilians indefinitely under 42 USC 264 and related regulations and executive orders.

These war criminal assessments, like all the other determination and declaration procedures rendered visible through the Covid-19 global crime, are assessments placed by Congress and US Presidents, solely in Cabinet secretary hands, and — for so long as they remain unchallenged by Congress members and judges, three years and counting — not subject to Congressional or judicial review or termination.

Many paths. Same herd-culling destination. The death machine will keep running until some combination — of Congress, courts, state governments, the People and/or some other political force TBD — cuts off the statutory fuel and the funding.

[94] https://bailiwicknews.substack.com/p/january-17-2017-federal-register

April 11, 2023 - Biden rescinding Trump-Biden Proclamation 9994 under 1976 National Emergencies Act does not terminate Azar-Becerra's Public Health Emergency authorities under 1983 PHE amendment to the 1944 PHSA.

Becerra and his successors will extend the PHE until they no longer need it to kill people with pseudo-legal impunity. Or until Congress, federal judges or states repeal or nullify the enabling acts.

A reader emailed today, linking to a Feb. 9, 2023 Health and Human Services Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap[95] and asking questions about the legal effects of Biden's recent signature on House Joint Resolution 7.

> HJR 7[96] - Relating to a national emergency declared by the President on March 13, 2020. *Resolved by the Senate and House of Representatives of the United States of America in Congress assembled,* That, pursuant to section 202 of the National Emergencies Act (50 U.S.C. 1622), the national emergency declared by the finding of the President on March 13, 2020, in Proclamation 9994 (85 Fed. Reg. 15337) is hereby terminated.

April 10, 2023 - Biden Signs Measure Ending COVID-19 National Emergency[97] (Jeff Louderback, *Epoch Times*)

> President Joe Biden on April 10 signed a measure that immediately ended the COVID-19 national emergency more than three years after it was enacted, the White House announced.
>
> HJ Res 7 passed through the Senate on March 29 by a 68-23 margin, with 21 Democrats joining 47 Republicans to support the measure.
>
> Four Republicans and five Democrats did not cast a vote—and 23 Democrats voted against the short resolution—which was introduced by Rep. Paul Gosar (R-Ariz.) last month and passed by the House 229-197 on Feb. 1.

The reader asked:

> Does the PHE actually expire? It appears that they are extending most of the PHE provisions with other mechanisms, [including] free vaccine and PREP Act protection. Can you tell whether the HHS Secretary "Tyranny Powers" are being released on May 11?

No, the HHS Secretary PHE powers are not terminated on May 11. There are at least three interlocking frameworks for the consolidation of power in executive hands during declared emergencies: the 1976 National Emergencies Act, the 1988 Stafford Act, and the 1944 Public Health Service Act as amended in 1983 to add the Public Health Emergencies (PHE) program.

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[95] https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html
[96] https://www.congress.gov/bill/118th-congress/house-joint-resolution/7/text
[97] https://www.theepochtimes.com/biden-signs-measure-ending-covid-19-national-emergency_5185150.html?

Congress and Biden have rescinded the emergency proclamation issued under the 1976 National Emergencies Act, but the Public Health Emergency declaration issued by then-HHS Secretary Alex Azar on Jan. 31, 2020, effective Jan. 27, 2020, remains in force, along with the Stafford Act determination Trump issued on March 13, 2020.

The National Emergencies Act Proclamation 7463 *Declaration of National Emergency by Reason of Certain Terrorist Attacks*, issued by President Bush in September 2001 and renewed annually since then, also remains in force, along with the 2001 Authorization for Use of Military Force passed under the 1973 War Powers Act, and any secret orders that may exist without Congressional or public knowledge, such as PEADs[98] (Presidential Emergency Action Documents) and Continuity of Government (COG) orders.

The emergency authorities held by the Health and Human Services Secretary under the Public Health Emergency (PHE) program of the 1944 Public Health Service Act, as established by Congress and President Reagan in 1983 and expanded by Congress and Presidents Bush I, Clinton, Bush II, Obama, Trump and Biden since then, will not expire in May.

Current HHS Secretary Xavier Becerra recently — very quietly — extended his Public Health Emergency authority and derivative Emergency Use Authorization power, using slightly different wording, through a Federal Register notice effective March 15, 2023.[99]

The HHS Secretary him or herself (Becerra or a successor) is the only person authorized to end the PHE and terminate his own emergency powers, unless and until Congress repeals the enabling acts, federal judges nullify the enabling acts, and/or state governments nullify the enabling acts to block the illegitimate exercise of federal authority at their own state borders.

How did these extraordinary powers get into Becerra's hands?

Congress and US Presidents unlawfully and unconstitutionally (*de facto* but not *de jure*[100]) transferred Congress's own power, the power of the federal courts, and the power of the states, into the HHS Secretary's unilateral, unreviewable control, through amendments to the 1944 Public Health Service Act codified at 42 USC 247d-6d, Targeted liability protections for pandemic and epidemic products and security countermeasures[101] and related statutes, executive orders and regulations.

- 42 USC 247d-6d(b)(7): No 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.

[98] https://bailiwicknews.substack.com/p/peads-presidential-emergency-action
[99] https://www.govinfo.gov/content/pkg/FR-2023-03-20/pdf/2023-05609.pdf
[100] https://onlinelaw.wustl.edu/blog/legal-english-de-factode-jure/
[101] https://www.law.cornell.edu/uscode/text/42/247d-6d

- 42 USC 247d-6d(b)(9): Extremely limited obligation for HHS to report to Congress on public health emergency status and EUA medical countermeasures classifications, and no authorization for Congress to override HHS declarations, determination, and decisions.

National Emergencies Act Proclamation 9994[102] issued by President Trump and extended by President Biden might expire in May — that's what Biden's signature on HRJ 7 means.

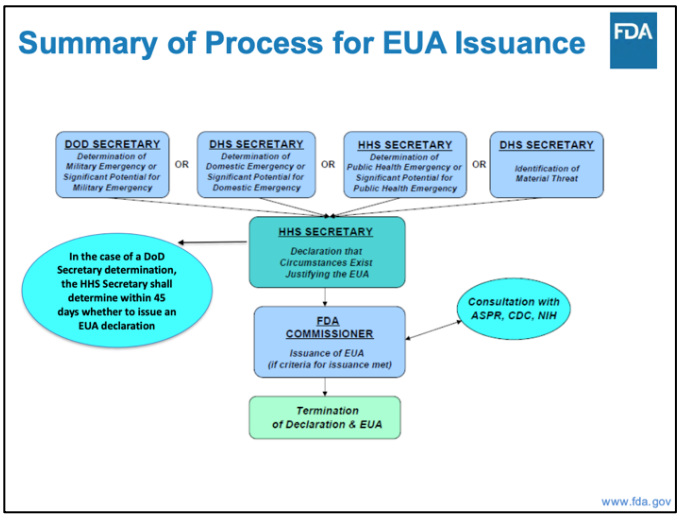
But the termination of the NEA proclamation isn't enough to bring the Constitutional disaster to a close, because the HHS secretary's Public Health Emergency powers are exercised independent of the NEA declaration.

[102] https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/

July 1, 2023 - Another sign that tide of covert war is turning will be pharmacies that refuse to take delivery of DoD biochemical weapons and pharmacists who refuse to use them on targets.

HHS Secretary declarations under the Public Readiness and Emergency Preparedness (PREP) Act…[are] basically…declarations of war, with sections laying out the HHS-DoD-DHS designated

- Threats (Section VIII, Category of Disease, Health Condition or Threat);
- Geographic terrain (Section XI, Geographic Area);
- Duration (Section XII, Effective Time Period and Section XIII, Additional Time Period of Coverage);
- Deployed personnel (Section V, Covered Persons);
- Weapon classes (Section VI, Covered Countermeasures);
- Rules of combat engagement with targeted enemies (Section IX, Administration of Covered Countermeasures); and
- Enemy-civilian targets (Section X, Population).



Source: Feb. 13, 2018 FDA Slide Deck.

The most recent, eleventh amendment to the original PREP Act declaration was issued effective May 11, 2023.[103] Relevant PREP Act documents are linked at Footnote 1 [of online version] and FDA legal preparedness slide decks explaining the anti-law mechanisms through which covert, biomedicalized mass murder has been rendered non-criminal are linked at Footnote 2 [online version].

[103] https://bailiwicknewsarchives.files.wordpress.com/2023/05/2023.05.11-hhs-prep-act-amendment-11-distribution-limitations-time-qualified-persons-category-of-threat-burden-of-seasonal-influenza-88-fr-30769.pdf

Readers interested in reading, who only have time to read one document, are encouraged to read the May 11, 2023 one, because it includes a handy recap of the intervening declarations and amendments, with footnotes citing legal advisory opinions and guidance documents.

I haven't had time to write a detailed anatomy-of-a-PREP-Act-declaration post, but Sasha's BARDA post reminded me of one important component of the PREP Act declarations and amendments that's useful to highlight: the US government's use of retail pharmacies[104] as primary locations to which DoD biochemical weapons known as 'vaccines' are delivered, and classification of pharmacists and pharmacy technicians as "covered persons" and "qualified persons" ordered to inject enemy targets with the weapons, through the Federal Retail Pharmacy Program for COVID-19 Vaccination.[105]

Adding pharmacies and pharmacy technicians to the PREP Act "covered persons" and "qualified persons" lists was an important part of PREP Act declarations and amendments.

It's another example of the bait-and-switch, hidden in plain sight crimes.

Retail pharmacies are not medical facilities regulated the way hospitals, clinics and doctors' offices are.

Pharmacists aren't trained, supervised and regulated the same way doctors and nurses are, and pharmacists don't have any professional ethical obligations to protect individual patient health and safety, such as the classic Hippocratic Oath, whose main precept is often paraphrased as "first do no harm."

> …I will offer those who suffer all my attention, my science and my love. Never will I betray them or risk their well-being to satisfy my vanity. I will not hurt my fellow or put a knife to his flesh if I don't know how, or give him an herb to soothe his pain, even if he begs for it in anguish, if it might take away his breath.
>
> I will never harm my suffering friend, because life is sacred, from the tender fruit that he once was in his mother's womb to that first sigh he gave out between her legs when he opened his eyes to the world…

In contrast, for example, the current version of the American Association of Colleges of Pharmacy and American Pharmacists' Association Oath of a Pharmacist[106] calls upon pharmacists only to "consider the welfare of humanity and relief of suffering" as primary concerns.

Even though the Hippocratic Oath is not emphasized in medical education anymore and has been eviscerated of its prohibition against intentional killing through 1964 revisions[107] that cleared a path for doctors to murder for social and economic reasons, the original Hippocratic Oath still has a slight hold over the public imagination and restrains some doctors' and nurses' behaviors.

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[104] https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/participating-pharmacies.html
[105] https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/
[106] https://www.aacp.org/sites/default/files/2021-12/oath-of-a-pharmacist-pdf-2021.pdf
[107] https://en.wikipedia.org/wiki/Hippocratic_Oath#Modern_versions_and_relevance

A January 2023 HHS Office of Inspector General report, *Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19*,[108] stated that as of December 2022, DoD had injected 7.5 million biochemical weapon doses, VA had injected 7.4 million doses, and Indian Health Services (IHS) had injected 2.2 million doses, while neighborhood pharmacists had injected 234.9 million doses.

> …The number of these Federal agency and pharmacy partners providing vaccinations biochemical weapons varies amongst immunization biochemical warfare programs' jurisdictions, but they are widespread and represent a substantial portion of the data that immunization programs need.
>
> For example, while all jurisdictions may not have DoD facilities, VA is present in all States. Combined, these two agencies have administered over 14 million doses to veterans, active military, and other beneficiaries. All State and local immunization programs utilize the Federal retail pharmacy program to help administer vaccinations in their areas.
>
> There are 21 pharmacy partners, representing 41,000 locations. In addition to including large chain pharmacies (e.g., Walgreens, CVS) the program includes partners with a small number of stores and those which serve rural areas.
>
> As of March 2022, pharmacy partners receiving vaccines directly from CDC[-DoD] were responsible for 40 percent of all administered doses of COVID-19 vaccines…

Other dispensers of DoD biochemical weapons include corporate health care "providers" offices, paid off with escalating bounties for hitting percentage benchmarks[109] in their patient populations, and pop-up tent or drive-through clinics located in parking lots, at businesses and at schools.

As of June 8, 2023, according to CDC, 303.7 million doses had been administered at those 41,000 retail pharmacy locations,[110] out of a total of 676.7 million doses CDC claims had been administered by May 10, 2023.[111]

The big picture reasons for the dysfunctional reporting systems covered by the January 2023 HHS-OIG report[112] are at least two-fold: 1) to hide the DoD-HHS-CDC-FDA-WHO biowarfare programs' injury and death toll from public databases and public understanding, and 2) to create the pretext for nationally and globally centralized data collection and storage.

*

[108] https://oig.hhs.gov/oei/reports/OEI-05-22-00010.pdf
[109] https://providernews.anthem.com/kentucky/articles/covid-19-vaccine-provider-incentive-program
[110] https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/
[111] https://covid.cdc.gov/covid-data-tracker/#vaccination-states-jurisdictions
[112] https://oig.hhs.gov/oei/reports/OEI-05-22-00010.pdf

In the PREP Act declarations and amendments and legal interpretations preempting narrower state "scope-of-practice" laws for pharmacists, the authorization of pharmacists to use DoD biochemical weapons on enemy-civilians with legal impunity is loosely correlated with a 20-hour training course, to include hands-on injection technique, that may or may not be completed.[113]

Excerpt from OGC Advisory Opinion 20-03:

> …The Third Amendment preempts narrower state scope-of-practice laws for pharmacists and pharmacy interns who meet the requirements set forth in the Third Amendment. But the Third Amendment does not affect broader state scope-of-practice laws. The preamble to the Third Amendment specifies that "nothing herein shall preempt State laws that permit additional individuals to administer vaccines that ACIP recommends to persons age 18 or younger according to ACIP's standard immunization schedule."
> For example, the Third Amendment requires the licensed pharmacist seeking PREP Act coverage to "complete a practical training program of at least 20 hours."
>
> Some states require less than 20 hours of such training for a licensed pharmacist to order and administer vaccinations to individuals ages 3 to 18. The Third Amendment does not affect such less-stringent, state-law requirements.
>
> So a pharmacist who seeks PREP Act coverage under § 247d-6d(i)(8)(B) and the Third Amendment—e.g., because the pharmacist is not authorized to vaccinate under the state scope-of- practice law—must satisfy the 20-hour requirement. But a pharmacist in a state that requires less than 20 hours may still vaccinate under state law even if the pharmacist does not complete 20 hours of training as required under the Third Amendment. And as explained above, such a pharmacist would be a "qualified person" under § 247d-6d(i)(8)(A), and therefore eligible for PREP Act coverage if the pharmacist satisfies those other requirements of the PREP Act and Declaration not associated with being a "qualified person."

[113] *See,* for example, Aug. 24, 2020 - HHS Secretary PREP Act Declaration, Amendment 3; Sept. 3, 2020 - HHS Office of the Assistant Secretary for Health (OASH) Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act; Oct. 20, 2020 - HHS-OASH Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing; Oct. 23, 2020 - HHS-Office of General Counsel (OGC) Advisory Opinion 20-03 on the PREP Act and the Secretary's Declaration Under the Act.

The training and requirements allegedly imposed by the declarations, like the requirements allegedly imposed by all the statutes, regulations and contracts Sasha and I have analyzed so far, include a mixture of legally enforceable/enforced provisions, and legally unenforceable/unenforced provisions.

The only way to tell which is which, is to observe — over elapsed time — which provisions are actually carried out during the covert biochemical warfare, which are not carried out, and whether any enforcement action follows non-compliance.

If law enforcement agencies prosecute a violator for a violation, then that provision was enforceable.

If the law enforcement agencies refuse to investigate or prosecute, then the provision was never going to be enforced; those provisions were added only to serve as legally irrelevant fluff for misdirection and manipulation purposes.

Aug 18, 2023 - Bridges v. Houston Methodist Hospital. Court decisions supporting the conclusion that vaxx recipients are military targets, enemy combatants, chattel slaves or similar legal status in which consent is moot.

Introduction

Below are lightly-edited email exchanges from the last couple of weeks, about *Bridges v. Houston Methodist Hospital* as a primary indicator that the legal status of each recipient of unidentified, unregulated, injectable biochemical products has been something other than a 'human subject' or 'clinical trial subject' (in relation to a clinical investigator) or 'patient' (in relation to a physician).

This has been true since January 2020 when then-HHS-Secretary Alex Azar established 'public health emergency' conditions on American soil, which remain in effect to the present and will remain in effect until Congress repeals 42 USC 247d, 21 USC 360bbb, and all their related statutory tentacles, through which Congress has transferred — to the HHS Secretary — unilateral, unreviewable power to declare and maintain public health emergency status and direct biochemical attacks on the American people camouflaged as 'vaccination' programs.

From the June 12, 2021 order by USDJ Lynn N. Hughes, dismissing the case:

> On April 1, 2021, Houston Methodist Hospital announced a policy requiring employees be vaccinated against COVID-19 by June 7, 2021, starting with the leadership and then inoculating the remaining workers, all at its expense.
>
> Jennifer Bridges and 116 other employees sued to block the injection requirement and the terminations. She argued that Methodist is unlawfully forcing its employees to be injected with one of the currently-available vaccines or be fired. The hospital has moved to dismiss this case.
>
> Bridges dedicates the bulk of her pleadings to arguing that the currently-available COVID-19 vaccines are experimental and dangerous. This claim is false, and it is also irrelevant. Bridges argues that, if she is fired for refusing to be injected with a vaccine, she will be wrongfully terminated. Vaccine safety and efficacy are not considered in adjudicating this issue.
>
> Texas law only protects employees from being terminated for refusing to commit an act carrying criminal penalties to the worker. To succeed on a wrongful termination claim, Bridges must show that (a) she was required to commit an illegal act – one carrying criminal penalties, (b) she refused to engage in the illegality, (c) she was discharged, and (d) the only reason for the discharge was the refusal to commit an unlawful act…

Worth noting, Judge Hughes declared Bridges' assertion that the 'vaccines' are experimental and dangerous to be "false," *without allowing discovery or conducting evidentiary review*.

Bridges v. Houston Methodist Hospital case documents, and a related US Department of Justice slip opinion:

- 2021.06.04 Bridges v. Houston Methodist Motion for Temporary Restraining Order[114]
- 2021.06.12 Bridges v. Houston Methodist District Court Opinion denying TRO[115] Alternate version: 2021.06.12 Bridges v. Houston Methodist District Court Opinion denying TRO[116]
- 2021.07.06 DOJ Dawn Johnsen Slip opinion re mandating vaxxes[117]
- 2021.11.15 Bridges Appellant Brief to Fifth Circuit[118]
- 2022.01.28 Fifth Circuit Bridges Appellees Brief[119]
- 2022.06.13 Bridges v. Houston Methodist Fifth Circuit Affirmed District Court[120]

Email 1 from reader:

> …looking for a document or memo you wrote mentioning the pseudo-legal frameworks that characterize civilians as enemy combatants for the purposes of deployment of countermeasures frameworks that characterize civilians as enemy combatants for the purposes of deployment of countermeasures.

My reply to email 1:

One of the posts where I addressed that is this one:

- Jan. 19, 2023 - Repost - Pharmaco-military genocide, enabling laws Congress should repeal and courts should nullify...

Blurring the line between combatants and non-combatants and using bioweapons as political tools also comes up in the PNAC Rebuilding America's Defenses[121] report:

- Aug. 26, 2022 - Project for a New American Century - Rebuilding America's Defenses, Sept. 2000...

[114] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2021.06.04-bridges-v.-houston-methodist-motion-for-temporary-restraining-order.pdf
[115] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2021.06.12-bridges-v.-houston-methodist-district-court-opinion.pdf
[116] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2021.06.12-bridges-v.-houston-methodist-district-court-opinion-denying-tro.pdf
[117] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2021.07.06-doj-dawn-johnsen-slip-opinion-re-mandating-vaxxes.pdf
[118] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2021.11.15-bridges-appellant-brief.pdf
[119] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2022.01.28-fifth-circuit-bridges-appellees-brief.pdf
[120] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2022.06.13-bridges-v.-houston-methodistl-fifth-circuit-affirmed.pdf
[121] https://archive.org/details/RebuildingAmericasDefenses/mode/2up

Otherwise, the designation of victims as some form of enemy target or combatant is implied by the fact that the products are weapons and informed consent is moot, meaning that use on non-consenting human beings is deemed legal, which translates to attack on a military target.

The two key documents for that are the July 2021 DOJ opinion[122] combined with the June 2021 court decision in Bridges v. Houston Methodist Hospital.

- June 12, 2021 - Bridges v. Houston Methodist Hospital,[123] 543 F. Supp. 3d 525 (S.D. Tex. 2021). Federal judge ruled that informed consent doesn't apply to hospital workers, because the injections are government-authorized under FDA Emergency Use Authorization, therefore not part of experimental clinical trials or ordinary medical treatments, therefore hospital employees cannot be legally construed as human subjects or ordinary patients, therefore they have no individual, Constitutional liberties; rights to privacy and against government violation of bodily integrity; or rights to be secure in their persons against warrantless search and seizure.

I've written about it in these posts:

- July 5, 2022 - Possibilities for proving intent. The work product of attorneys Susan E. Sherman, Wen W. Shen, Dawn Johnsen and the July 6, 2021 Department of Justice legal opinion....
- Jan. 2, 2023 - Bioweapon prototype deployments, informed consent, targeted enemies, state of war, doctrine of necessity.

A lot of other cases have since cited Bridges v. Houston Methodist.[124]

[122] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf
[123] https://casetext.com/case/bridges-v-hous-methodist-hosp
[124] https://casetext.com/case/bridges-v-hous-methodist-hosp/how-cited?citingPage=1&sort=relevance

Email 2 — from another reader who was on the thread for Email 1:

> What specific law outlines us as "enemy combatants" and allows for "countermeasures" including "bio-weapons" against a domestic population? You addressed this previously in an email. If you have something really succinct in a paragraph or so form, that would be great though.

My reply:

I don't have a more succinct version of the enemy combatants framing right now. It's very similar to the vaccine/bioweapon structure, in that the laws and court cases don't directly state that all civilians are enemy combatants.

The laws and court cases simply deny — with lots of obscuring language in orders dismissing cases — that any of the rights (such as informed consent and rights against assault and homicide) normally held by non-combatants, apply to targets of EUA products during Public Health Emergency conditions.

In the same way that none of the rules that normally apply to pharmaceutical manufacturing, distribution and dispensing, apply to EUA products during Public Health Emergency conditions.

Setting aside for now the 2001 Authorization for Use of Military Force, PATRIOT Act and other mechanisms, the main documents through which this bait and switch type maneuver has been done are the July 2021 DOJ opinion,[125] combined with the June 2021 ruling in Bridges v. Houston Methodist,[126] which was affirmed by the Fifth Circuit Court of Appeals in June 2022.[127]

Key paragraphs in Bridges v. Houston Methodist ruling by USDJ Lynn N. Hughes, US District Court, Southern District of Texas:

> "…Bridges does not specify what illegal act she has refused to perform, but in the press-release style of the complaint, she says that she refuses to be a "human guinea pig." Receiving a COVID-19 vaccination is not an illegal act, and it carries no criminal penalties. She is refusing to accept inoculation that, in the hospital's judgment, will make it safer for their workers and the patients in Methodist's care...
>
> She also argues that injection requirement violates federal law governing the protection of "human subjects." She says that the injection requirement is forcing its employees to participate in a human trial because no currently-available vaccine has been fully approved by the Food and Drug Administration. Federal law requires participants give legal, effective, and informed consent before participating in a human trial; this consent cannot

[125] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf
[126] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2021.06.12-bridges-v.-houston-methodist-district-court-opinion.pdf
[127] https://bailiwicknewsarchives.files.wordpress.com/2023/08/2022.06.13-bridges-v.-houston-methodistl-fifth-circuit-affirmed.pdf

> be obtained through coercion or undue influence. Bridges says the threat of termination violates the law...
>
> Bridges has again misconstrued this provision, and she has now also misrepresented the facts. The hospital's employees are not participants in a human trial. They are licensed doctors, nurses, medical technicians, and staff members. The hospital has not applied to test the COVID-19 vaccines on its employees, it has not been approved by an institutional review board, and it has not been certified to proceed with clinical trials. Bridges's claim that the injection requirement violates 45 C.F.R. § 46.116 also fails.
>
> She also says that the injection requirement is invalid because it violates the Nuremberg Code, and she likens the threat of termination in this case to forced medical experimentation during the Holocaust. The Nuremberg Code does not apply because Methodist is a private employer, not a government. Equating the injection requirement to medical experimentation in concentration camps is reprehensible. Nazi doctors conducted medical experiments on victims that caused pain, mutilation, permanent disability, and in many cases, death.
>
> Although her claims fail as a matter of law, it is also necessary to clarify that Bridges has not been coerced. Bridges says that she is being forced to be injected with a vaccine or be fired. This is not coercion. Methodist is trying to do their business of saving lives without giving them the COVID-19 virus. It is a choice made to keep staff, patients, and their families safer. Bridges can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else."

Again worth noting: Judge Hughes ruled it improper to equate injection of 'Covid-19 vaccines' with Nazi medical experimentation in concentration camps, by describing the Nazi program as "causing pain, mutilation, permanent disability, and in many cases death."

But he *did not allow discovery or conduct evidentiary review* through which the court could have assessed the data that 'Covid-19 vaccines' also cause pain, mutilation, permanent disability and death. That data was available to the manufacturers and FDA reviewers no later than Sept. 25, 2020,[128] to DoD officials no later than Dec. 14, 2020,[129] and even more conclusively to manufacturers, FDA and DoD by April 2021.[130]

April 2021 was the point at which private employers like Houston Methodist Hospital — in response to federal coercion and bribes through Medicare and Medicaid funding programs — were imposing mandates on employees by offering prizes for compliance and threatening termination for refusal.

[128] https://bailiwicknewsarchives.files.wordpress.com/2022/10/2022.04.22-pfizer-mtd-exh-c.pdf
[129] https://bailiwicknewsarchives.files.wordpress.com/2022/10/2022.04.22-pfizer-mtd-exh-e.pdf
[130] https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

I underlined the key sentence in Judge Lynn's ruling, because it lists what hospital employees are "not," according to the judge, including that they are not clinical trial subjects in a clinical trial, with any attendant rights as subjects of experimentation. He cites to the cornerstone EUA law: 21 USC 360bbb.

But in describing what hospital employees are, he does not say patients, citizens, individual human beings with inherent personhood or civilians with rights to informed consent, bodily integrity or due process.

He simply says they're doctors, nurses and other hospital employees, defining them exclusively in relationship to their employers. And because he goes on to find that therefore, the hospital can do what it wants to them, or else they have to find work elsewhere, he implicitly recognizes them as slaves or enemy combatants, who have no claim to control over their own bodies or preservation of their own lives.

My view is that Dawn Johnsen in the DOJ coordinated with the judge, and he coordinated with her, so that his June 2021 ruling would align with what she would argue in her July 2021 legal opinion, citing for support his ruling as precedential case law.

The deception, obscuring of truth and misdirection are extremely well-coordinated and well-executed. This is just another example of it.

Aug. 28, 2023 - March 15, 2023 and May 11, 2023 HHS Dictator-Secretary determinations and declarations.

Reader comment:

> I am trying to track the actual cite that shows that through HHS Secretary continuing authority, the CV emergency has not truly been lifted. Any help would be appreciated.

Key premises:

The US Health and Human Services Secretary (first Alex Azar, now Xavier Becerra), by Congressional authorization under Congressionally-repealable statutes (42 USC 247d/Public Health Service Act Section 319, 21 USC 360bbb/Food Drug and Cosmetics Act Section 564 and related) has been the *de facto* administrative dictator of America, directing a covert mass murder campaign, since January 2020.

Azar and Becerra's lethal power has been consolidated under the many mutually-reinforcing Covid-19 "public health emergency" lies, deceptions and illusions promulgated by government and government media outlets.

From time to time, the HHS Secretary issues new unilateral, unreviewable administrative decrees to reinforce and expand his covert ongoing dictatorship.

The most recent (that I'm aware of, I haven't checked recently for updates) — are these two, issued by unindicted war criminal Xavier Becerra effective March 15, 2023 and May 11, 2023:

- 2023.03.15 HHS PREP Act EUA Delegation of Authority and EUA Amendment, signed 2023.03.20, 88 FR 16645[131]
- 2023.05.11 HHS PREP Act Amendment 11, distribution limitations, time, qualified persons, category of threat burden of seasonal influenza 88 FR 30769[132]

There is a lot more information in those two administrative decrees, and their many precursors, than the parts I've excerpted below...

The underlined paragraph below, promulgated as decree by the HHS Secretary, is a series of false statements, commonly known as lies. Because of the legal structures established and not yet repealed by Congress, there is currently no process for Congress to hold meaningful hearings to review evidence that would establish the truth or falsity of the HHS Secretary claims and legislatively override his decrees [42 USC 247d-6d(b)(9)] and there is currently no access to federal courts to review evidence that would establish the truth or falsity of the HHS Secretary claims and judicially nullify or void his decrees. [42 USC 247d-6d(b)(7).]

[131] https://bailiwicknewsarchives.files.wordpress.com/2023/05/2023.03.15-hhs-prep-act-eua-delegation-of-authority-and-eua-amendment-signed-2023.03.20-88-fr-16645.pdf

[132] https://bailiwicknewsarchives.files.wordpress.com/2023/05/2023.05.11-hhs-prep-act-amendment-11-distribution-limitations-time-qualified-persons-category-of-threat-burden-of-seasonal-influenza-88-fr-30769.pdf

The only move available to Congress is repeal of the enabling laws, to strip the HHS Secretary of the power he currently holds, with which he can and is lying to Congress, and lying to, torturing and killing the American people, with legal impunity.

Excerpts from March 15, 2023 determination and declaration decrees:

> Section II: Determination by the Secretary of Health and Human Services
>
> On February 4, 2020, pursuant to his authority under section 564 of the FD&C Act, [21 USC 360bbb] the Secretary of HHS determined that the circumstances in section 564(b)(1) exist because ''there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV).'' 85 FR 7316…

[KW note: The following paragraph promulgated as decree by the HHS Secretary is a series of false statements, commonly known as lies. Because of the legal structures established and not yet repealed by Congress, there is currently no process for Congress to hold meaningful hearings to review evidence that would establish the truth or falsity of the HHS Secretary claims and legislatively override his decrees [42 USC 247d-6d(b)(9)] and there is currently no access to federal courts to review evidence that would establish the truth or falsity of the HHS Secretary claims and judicially nullify or void his decrees. [42 USC 247d-6d(b)(7).] The only move available to Congress is repeal of the enabling laws, to strip the HHS Secretary of the power he currently holds, with which he can and is lying to Congress, and lying to, torturing and killing the American people, with legal impunity.]

> …It is now well established that SARS– CoV–2 is constantly evolving and continues to be an ongoing challenge. As of January 30, 2023, SARS–CoV–2 has led to over 753 million cases of COVID–19, including 6.8 million deaths worldwide. This is due, in part, to variations in the virus that may allow it to spread more easily or make it resistant to treatments or decreased vaccine effectiveness. There is also a risk that eventually a variant will emerge that will escape the protection provided by the current generation of vaccines against severe disease. For example, the SARS–CoV–2 Omicron variant has continued to evolve into sublineages with additional mutations in the spike glycoprotein and the receptor binding domain. Evolution of the virus also raises similar concerns about the continued efficacy of certain categories of therapeutics, such as monoclonal antibodies. The distribution of Omicron sublineages varies at different points in time in different regions of the world. The large number of mutations in the Omicron variant sublineages and the ongoing evolution of the virus remain a concern for potential evasion of vaccine immunity.
>
> In light of this, I have now amended the February 4, 2020 determination to recognize the fact that there is ''a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad'' and that involves a biological agent, namely the novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV, or SARS–CoV–2).

If the current conditions change such that there is no longer a ''public health emergency'' within the meaning of section 564, the section 564(b)(1)(C) determination would remain in place because I have determined that there is also a ''significant potential for a public health emergency'' under that section.

This avoids the need to issue a new determination under section 564 when there is no longer a ''public health emergency,'' but there is still a ''significant potential for a public health emergency'' involving SARS–CoV–2.

The four previously-issued section 564 declarations that refer to the February 4, 2020 determination have not been terminated by the Secretary because, among other things, the circumstances described in section 564(b)(1) continue to exist—i.e., COVID–19, a disease attributable to SARS–CoV–2, continues to present a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad. Consistent with section 564(f), the currently-in-effect Emergency Use Authorizations (EUAs) issued under those section 564 declarations remain in effect until the earlier of the termination of relevant section 564 declarations under section 564(b), or revocation the EUAs. Therefore, these EUAs continue in effect…"

Section III. Declarations of the Secretary of Health and Human Services; EUAs Issued Under the Declarations

Based on the February 4, 2020 determination, in February and March 2020, the Secretary of HHS, pursuant to section 564 of the FD&C Act and subject to the terms of any authorization issued under that section, declared that circumstances exist justifying the authorization of emergency use of: (1) in vitro diagnostics for detection and/or diagnosis of this novel coronavirus, 85 FR 7316; (2) personal respiratory protective devices, 85 FR 13907; (3) other medical devices including alternative products used as medical devices, 85 FR 17335; and (4) drugs and biological products, 85 FR 18250.

These section 564 declarations continue in effect. Specifically, under section 564(b)(2)(A), a declaration made under section 564 will not terminate unless the Secretary determines that ''the circumstances described in [section 564(b)(1)] have ceased to exist,'' or there is ''a change in the approval status of the [authorized] product such that the circumstances described in subsection (a)(2) have ceased to exist.'' Section 564(b)(2)(A) of the FD&C Act.

The first basis for termination is not met because the circumstances described in section 564(b)(1) have not ceased to exist; to the contrary, as described above, I have determined that the circumstances described in section 564(b)(1)(C) continue to exist.

The second basis for termination is not met because each declaration covers many products, or emergency uses of products, at least some of which remain ''unapproved'' within the meaning of section 564(a)(2).

> Consistent with section 564(f), the EUAs issued under these declarations remain in effect until the earlier of the termination of relevant section 564 declarations or revocation of the EUAs. Accordingly, the currently-in-effect EUAs issued under the section 564 determination/declarations for COVID– 19 also continue in effect…
>
> *

Excerpts from May 11, 2023 Eleventh Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 decrees:

> Summary: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act [42 USC 247d] to update the determination of a public health emergency and clarify the disease threat…
>
> Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID–19
>
> To the extent any term previously in the Declaration, including its amendments, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling. This Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this Declaration. This Declaration is a ''requirement'' under the PREP Act.
>
> Section I. Determination of Public Health Emergency, 42 U.S.C. 247d–6d(b)(1)
>
> I have determined that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a credible risk of a future public health emergency.
>
> I further determine that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency that former Secretary Azar declared on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the response of the nation's healthcare community to the COVID-19 outbreak.
>
> Section II. Factors Considered, 42 U.S.C. 247d–6d(b)(6)
>
> I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures…
>
> Section VIII. Category of Disease, Health Condition, or Threat, 42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is not only COVID–19 caused by SARS–CoV– 2, or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS–CoV–2, or a virus mutating therefrom, including the threat of increased burden on the healthcare system due to seasonal influenza infections occurring at the same time as COVID–19 infections, which will lead to an increase in the rate of infectious diseases…"

Oct. 17, 2023 - Texas and Oklahoma v. US Department of Health and Human Services and Xavier Becerra: case documents

This is an important case, dismissed by US District Judge Terry R. Means of the USDC for the Northern District of Texas, Fort Worth Division, by order dated Aug. 18, 2023.

My understanding is that the plaintiffs (Texas and Oklahoma) had 60 days to file an appeal to the Fifth Circuit Court of Appeals because the parties include a US Government agency and a US Government official.

The 60-day clock expires today, and to my knowledge (through PACER database), neither Texas nor Oklahoma has filed a notice of appeal.

The original petition for rulemaking was filed with HHS in July 2022 by the attorneys general of 15 American states: Oklahoma, Alabama, Arizona, Arkansas, Florida, Georgia, Indiana, Louisiana, Mississippi, Missouri, Montana, Nebraska, South Carolina, Texas, and Utah.

Only Oklahoma and Texas filed the federal case in US District Court in January 2023.

The states petitioned HHS to repeal three subsections of 42 CFR 70.1, through which HHS defined "public health emergency" conditions on US soil as potentially triggered by the actions of World Health Organization member nations (predicate 3) or the actions of the World Health Organization's Director-General (predicates 4 and 5).

42 CFR 70.1 - General Definitions[133]

> *Public health emergency* as used in this part means:
>
> (1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or
>
> (2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)); or
>
> (3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or
>
> (4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or

[133] https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-70/section-70.1

> (5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

Judge Means dismissed the case without prejudice, meaning state plaintiffs can re-file a new complaint.

It would be good if some state AGs filed a new complaint, challenging the first two definitions of a "public health emergency" as promulgated by HHS by regulatory notice on Jan. 19, 2017,[134] in addition to the latter three definitions the states have already challenged during this first litigation.

The states should challenge HHS to provide any factual, evidentiary basis for the claim that a "public health emergency" is different from the mere fact that human beings sometimes get sick, sometimes recover (with or without treatment), and eventually, inevitably die.

This would help expose other fraud-based elements of the global criminal enterprise, including mass-testing of populations to present pseudo-diagnostic data to the public, fraudulently characterized as evidence that a pandemic is occurring.

To pursue this legal strategy, state AGs will need to reject the foundational lie they have swallowed hook, line and sinker to date: that a pandemic happened.

They will need to understand the Covid-19 fraud in its entirety — from the centuries of propaganda-based preparation (fear-mongering and pharmaceutical idolatry) that created the conditions for the present-day crimes to occur, right through to the intentional misrepresentation of illegal US DoD biochemical weapons as FDA-regulated "Covid-19 vaccines" and the injury and death toll caused by the intentional military attacks as conducted within each state.

They will also need to reckon with the role that their own states' disease surveillance, detention, quarantine and forced treatment laws1 play in 1) maintaining many mutually-reinforcing public fictions and 2) rendering their state populations vulnerable to State-sponsored mass theft, mass torture and mass murder conducted under public health law pretexts.

To the extent a federal court allowed the case to proceed, HHS would be challenged to prove that a "public health emergency" has ever existed, exists during the so-called Covid-19 outbreak, or ever can exist, as a set of circumstances morally and legally distinct from living creatures' intrinsic, God-given susceptibility to illness and God-given capacity for endurance of suffering and for recovery of health.

The fraud of "public health emergencies" has been used to morally and legally justify exercise of government police powers to control and restrict citizen use and enjoyment of God-given rights to life, liberty and property: to justify State-orchestrated torture, murder and theft.

[134] https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-00615.pdf

The actual exercise of these expansive government police powers was triggered upon the actual HHS PHE declaration of Jan. 31, 2020 (effective Jan. 27, 2020) in coordination with the actual WHO PHEIC declaration of Jan. 30, 2020.

These illegitimate, fraudulent legal predicates have actually been used to injure and deprive citizens of life, liberty and property; and they remain in effect at the present time under a slightly modified form.

Through the case whose documents are provided below, HHS officials have clearly stated their plan to continue using false "public health emergencies" and collaboration with the World Health Organization and its legal instruments, to illegitimately concentrate even more power in the future: to torture more people, to kill more people and to rob more people.

HHS officials have also clearly indicated (albeit in a footnote) their understanding — along with the judge — that if the three alleged WHO-based predicates to action are vulnerable to challenge by US states (as violations of the states' quasi-sovereign authority to protect, among other things, "the health and well-being—both physical and economic—of [state] residents in general") then so are the two predicates allegedly based on US statutory authority.

See March 27, 2023 Defendant HHS brief in support of motion to dismiss, FN 3 at p. 6 and Aug. 18, 2023 Opinion and Order Granting Motion to Dismiss at FN 3, p. 11 and FN 4, p. 12.

Texas, Oklahoma v. HHS, Becerra documents

- 2022.07.18 Petition for Rulemaking Texas Oklahoma v. HHS[135]
- 2022.10.31 HHS refuse Oklahoma petition for rulemaking Texas Oklahoma v. HHS[136]
- 2023.01.18 Texas Oklahoma v HHS Becerra WHO PHE[137]
- 2023.03.27 Texas Oklahoma v. HHS Defendants Brief MtD[138]
- 2023.05.01 Texas Oklahoma v. HHS Plaintiffs Opposition to MtD[139]
- 2023.05.15 Texas Oklahoma v. HHS Defendants Reply in further support MtD[140]
- 2023.08.18 Texas Oklahoma v. HHS Order Dismissal Lack of Standing[141]

[135] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2022.07.18-petition-for-rulemaking-texas-oklahoma-v.-hhs.pdf
[136] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2022.10.31-hhs-refuse-oklahoma-petition-for-rulemaking-texas-oklahoma-v.-hhs.pdf
[137] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.01.18-texas-oklahoma-v-hhs-becerra-who-phe.pdf
[138] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.03.27-texas-oklahoma-v.-hhs-defendants-brief-mtd.pdf
[139] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.05.01-texas-oklahoma-v.-hhs-plaintiffs-opposition-to-mtd.pdf
[140] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.05.15-texas-oklahoma-v.-hhs-defendants-reply-in-further-support-mtd.pdf
[141] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.08.18-texas-oklahoma-v.-hhs-order-dismissal-lack-of-standing.pdf

Oct. 18, 2023 - There is never going to be another "deadly global pandemic." There have not been any in the past. The Monster has only devised means to produce the illusion of deadly global pandemics. And that's all he will ever be able to do.

[October 2025 Note: In light of what I later learned about biology, pathology, epidemiology and related biomedical and scientific subjects, I do not find claims or predictions about the stability, identity, homogeneity, pathogenicity (disease-causative agency), and casual-contact transmissibility of biological matter to be credible.]

Notes on the 2017 addition of "public health emergency" definitions to 42 CFR 70.1.

Incessant prattling of lobbyists for State-sponsored bioterrorism (code name "biodefense") notwithstanding, there hasn't ever been a deadly global pandemic, or a pathogen with the potential to circulate around the whole world and kill millions or billions of people.

So there can't be another one, or a next one, or any other future one for which the lessons of Covid must be learned; new treaties and laws must be drafted, signed and enforced; new surveillance and control programs developed; and billions of preparatory dollars spent.

There was a first theatrical production of the illusion of a deadly global pandemic: the 1918 Spanish flu.

And now there has been a second theatrical production of the illusion of a deadly global pandemic: Covid-19.

There are going to be more attempts to produce the same illusion under different titles; the producers routinely announce and demand funding for their road shows.

Human men and women are the audience.

Individual human minds are the private theaters into which the shows are projected.

*

I'm not going to go into a lot of detail on the microbiology, immunology, epidemiology and actuarial evidence that supports the proposition that there has never been a deadly global pandemic, and there will never be one.

The short version is that — once the legal definitions, laws, governing institutions and methods of information distribution are set up properly — a very realistic impression of a deadly global pandemic can be formed in the minds of individual human beings, by combining the legal and informational scenery with several props:

1. intentional, localized dispersal of synthetic, weaponized toxins (aerosols, food additives, medications, and 'vaccines')

2. background circulating vectors that contribute to the common human experience of mild, short-duration illnesses known as colds and flus.
3. social isolation policies
4. masking and physical distancing customs
5. mass false-positive-generating diagnostic testing programs

Other writers are far better equipped than I am to explain the biological mechanisms of action; tradeoffs between transmissibility and virulence that infectious disease vectors experience in their quest to propagate themselves without killing their hosts; the history of Rockefeller medicine; uses and limitations of PCR and lateral flow tests; how psychological pressure works on the human mind and in human social groups; and statistical data demonstrating that differences between pre-Covid mortality and "deadly global pandemic" mortality are fully attributable — not to any communicable disease — but to the intentional lethality of interventions (economic disruption and unemployment, social isolation, masks, and synthetic toxins) whose premeditated deployment was pseudo-authorized on grounds that a "public health emergency exists."

Most Bailiwick readers are already up to speed those subjects and how they fit into the big puzzle that close observers of anomalies and inconsistencies have been piecing together since January 2020, day by day as events have unfolded.

*

I'm hoping to spend a lot of time the next few weeks on the Texas and Oklahoma v. HHS and Becerra case documents, because it's a rich mine of information about elements of the giant lie variously known as one world health, global health security, pandemic preparedness, pathogens of pandemic potential, biodefense strategy and dozens of other non-sense, sub-rational phrases.

- 2016.08.15 HHS Notice of Proposed Rulemaking 81 FR 54230 Communicable Disease Control Public Health Emergency[142]
- 2017.01.19 HHS Federal Register Final Rule Communicable Disease Control Public Health Emergency 82 FR 6890[143]
- 2022.07.18 Petition for Rulemaking Texas Oklahoma v. HHS[144]
- 2022.10.31 HHS refuse Oklahoma petition for rulemaking Texas Oklahoma v. HHS[145]
- 2023.01.18 Texas Oklahoma v HHS Becerra WHO PHE[146]
- 2023.03.27 Texas Oklahoma v. HHS Defendants Brief MtD[147]
- 2023.05.01 Texas Oklahoma v. HHS Plaintiffs Opposition to MtD[148]

[142] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2016.08.15-81-fr-54230-notice-of-proposed-rulemaking-public-health-emergency-incorrectly-cited-as-81-fr-53240-in-texas-oklahoma-v.-hhs-becerra.pdf
[143] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2017.01.19-hhs-federal-register-communicable-disease-control-82-fr-6890.pdf
[144] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2022.07.18-petition-for-rulemaking-texas-oklahoma-v.-hhs.pdf
[145] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2022.10.31-hhs-refuse-oklahoma-petition-for-rulemaking-texas-oklahoma-v.-hhs.pdf
[146] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.01.18-texas-oklahoma-v-hhs-becerra-who-phe.pdf
[147] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.03.27-texas-oklahoma-v.-hhs-defendants-brief-mtd.pdf
[148] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.05.01-texas-oklahoma-v.-hhs-plaintiffs-opposition-to-mtd.pdf

- 2023.05.15 Texas Oklahoma v. HHS Defendants Reply in further support MtD[149]
- 2023.08.18 Texas Oklahoma v. HHS Order Dismissal Lack of Standing[150]

When I read legal documents, I look for phrases and arguments that seem odd or off-tone.

Public health and emergency preparedness law documents are full of such phrases, embedded into contorted sentences and paragraphs to obscure or shade or corrupt their meanings.

Example terms and phrases include precommunicable, asymptomatic, qualifying stage of a disease, existing circumstance, predicate to action, independent decision, "desirability of encouraging," "data, if available," "not feasible," and medical countermeasures.

The phrase that jumped out at me in reading the Texas v. HHS documents is "inform the public."

It's not a strange phrase in itself. It's strange for how it's used.

It's used as a code word for cognitive and behavioral training.

*

In their original petition in July 2022, the attorneys general for Oklahoma, Texas and 13 other states asked HHS to revise 42 CFR 70.1 to remove three of the five definitions of "public health emergency" that authorize HHS officials to exercise and delegate federal police power to detain individuals suspected of carrying disease.

The AGs presented three arguments.

First, the petitioners argued that the WHO-based definitions of "public health emergency" promulgated in January 2017 "exceed HHS's authority," as granted by Congress.

Second, the petitioners argued that the listing of World Health Organization acts as predicates for "public health emergency" declarations is unlawful "because WHO is not a trustworthy agency for public health information."

This argument was derived from the petitioners' erroneous belief that Covid-19 was a deadly global pandemic, in response to which WHO officials provided poor global leadership.

In truth, Covid-19 was merely a theatrical production of a deadly global pandemic and WHO officials have been serving as producers and directors for the performance.

[149] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.05.15-texas-oklahoma-v.-hhs-defendants-reply-in-further-support-mtd.pdf
[150] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2023.08.18-texas-oklahoma-v.-hhs-order-dismissal-lack-of-standing.pdf

Third, they argued that since the HHS had conceded that "it does not intend to use" the WHO-predicates for public health emergency declarations, the three WHO predicates are unnecessary and could be removed without harm to the agency.
The petitioners wrote:

> "In the Federal Register notice issuing the definition of public health emergency, HHS indicated that it would make independent decisions regarding public health emergencies. 82 Fed. Reg. 6890, 6906. Those independent decisions would continue to be cognizable under definitions (1) and (2) were this Petition granted. Accordingly, HHS would suffer no harm from granting the petition."

The petitioners concluded:

> "The only potential reason to retain unlawful rules that HHS does not believe it needs is to permit a future HHS to change its mind in later years...
>
> By including the additional definitions deferring to the WHO, HHS is facilitating complete deferral to the WHO in the future even if it professes no intent to defer to WHO now...
>
> [I]f we believe its protestations in the Federal Register, the existing HHS does not believe it needs definitions (3), (4), and (5) to manage public health emergencies, [so] it should repeal them as unnecessary even if it does not want to address the legality issues and WHO concerns raised..."

*

In October 2022, Marvin Figueroa, HHS Director of Intergovernmental and External Affairs, responded to the petitioners, denying their request to remove the "public health emergency" definitions predicated on the acts of WHO member nations and the WHO Director-General.

In addressing petitioners' second argument, Figueroa cited the need to "inform the public" as driving the definitional rule-making.

Figueroa wrote, at p. 4:

> "Although we acknowledge the concerns noted in the petition regarding purported political influence on WHO decision-making, they do not support removing references to that organization. Rather, HHS/CDC considers it important to include references to WHO in the definition of "public health emergency" to inform the public of the circumstances that HHS/CDC may consider when determining whether a public health emergency exists using its own independent judgment.
>
> Furthermore, we are committed to strengthening WHO...to prepare for and respond to COVID-19 and the next pandemic. These efforts include strengthening the IHR (2005)..."

In his final paragraph on p. 6, he repeated the phrase:

> "Lastly, your assertion that HHS/CDC would not be harmed by deleting definitions 3, 4, and 5 of "public health emergency" as used in 42 CFR 70.1, even if accurate, does not justify the expenditure of agency resources to amend the regulations.
>
> Also, as explained in the 2017 Final Rule, HHS/CDC considered it important to include references to WHO in the definition of "public health emergency" to inform the public of the circumstances that HHS/CDC may consider when making such a determination using its own independent judgment."

Petitioner states filed a federal complaint in January 2023, and the phrase "inform the public" shows up in each document as the two sides argued the point.

See Jan. 18, 2023 Complaint at p. 8; March 27, 2023 Defendants' Brief in Support of Motion to Dismiss at p. 10 and 19; May 1, 2023 Plaintiffs Response in Opposition to Motion to Dismiss at p. 4; May 15, 2023 Defendants' Reply to Plaintiff's Response to Defendants' Motion to Dismiss at p. 2; and Aug. 18, 2023 Opinion and Order Granting Motion to Dismiss at p. 4.

*

This odd HHS focus on "informing the public" is telling.

I think the state AG petitioners are correct that HHS wants to keep the WHO-based predicates for "public health emergency" declarations so that they can be used to create more illusions of "deadly global pandemics" in future.

I also think that the treaties and statutes are already written with enough interlacing between international and domestic law, that the WHO-HHS International Health Regulations Public Health Emergency of International Concern-Public Health Emergency automatic trigger system is already fully functional, even as the Monster works to make the treaties and statutes even more disordered in relation to natural and divine law.

But I think the "inform the public" rationale is mostly about manipulating individuals.

The globalist Monster has an intense desire to instill into human minds the fiction that the phrase "world health" corresponds to something in material, temporal reality; the Monster wants to justify the existence of a global organization to surveil and control, to coordinate field operations through subordinate organizations within member countries' governments.

In truth, there is only individual human health, corresponding with things in both material, temporal reality and in spiritual, eternal reality.

Individual well-being is organized by God in co-operation with the human creatures to whom He gives bodily, material form at conception, within the temporal human societies we build and

arrange so that we can love, live, work, raise children, and conform our souls to the will of God in the hope of eternal salvation for ourselves and our neighbors.

The Monster wants to substitute — inside human bodies, minds, and souls — the fiction of "world health" defined in secular, materialist terms as the ultimate end of human life and the ultimate purpose of human society, for the truth that God created mankind as material and spiritual beings.

The Monster wants to cut us off from the knowledge that we are beings for whom temporal existence is a brief opportunity to know, love and serve God: directly through prayer and worship, and indirectly by knowing, loving and serving our neighbors as ourselves, in our human societies, vocations and stations in life.

Above all else, the Monster wants to cut us off from the knowledge that we are beings for whom spiritual existence is eternal: eternal happiness with God in heaven or eternal torment separated from God, in hell.

That's why it was so important, in 2016 and 2017, for the Monster to add the last few legal props ahead of the sequel to Spanish flu, the theatrical performance "Deadly Global Pandemic: Covid-19."

It was to further build up the cognitive and behaviorally-compliant connection between the phrases *public health emergency* and *World Health Organization,* and from there, to HHS authority to use police power to arrest, detain, torture and murder anyone, anywhere, at any time, on suspicion of carrying communicable disease.

One reason why the Texas federal judge dismissed the petitioner states' case against Xavier Becerra and the Department of Health and Human Services is that the judge didn't think the states presented any evidence of actual harm, concrete injury or threatened imminent injury to the people living in the states.

HHS argued, and the judge agreed, that the harm from the WHO-based definitions of "public health emergency" were speculative, hypothetical, conjectural, and therefore the states lacked standing.

Soon, the next "deadly global pandemic" performance will begin.

If and when state AGs file new cases to protect state residents from “public health emergency”-predicated arrest, detention, torture and murder, it will be very important that they incorporate the information that has so painfully been brought into the light these last few years.

They must lay out the evidence that "deadly global pandemic" stories are fiction.

They must incorporate the facts about the injuries and deaths caused in each state by use of products known as "Covid-19 vaccines" under Emergency Use Authorization status: the actual harms and concrete injuries.

They must lay out how deployment of EUA products, as covert biochemical weapons, is directly connected to HHS declarations that a "public health emergency exists."

And they must lay out how HHS declarations that a "public health emergency exists" are directly connected to all five of the legal definitions inserted into American regulatory law through the January 19, 2017 edition of the Federal Register, and connected to the whole system of treaties and laws built to enable State-sponsored mass murder,[151] which grows more ripe for dismantling with every passing day.

Related

- Feb. 2, 2022 - January 19, 2017 Federal Register. US Health and Human Services final rulemaking, WHO International Health Regulations, and human liberty.
- May 11, 2022 - On the relationship between the World Health Organization and the US government.
- Oct. 17, 2023 - Texas and Oklahoma v. US Department of Health and Human Services and Xavier Becerra: case documents

[151] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program

Oct. 23, 2023 - On civil suits against Pfizer for "contamination" of Covid-19 biochemical weapons.

A reader sent an email asking for my views on claims that Pfizer is newly vulnerable to civil suits, in the wake of 1) a Michigan state court ruling about the applicability of the PREP Act in cases involving "contaminated" pharmaceutical products and 2) the growing pile of sequencing studies replicating Kevin McKernan's identification[152] of plasmids, SV-40 promoters and other "contaminants" in the DoD biochemical weapons formerly known as "Covid-19 vaccines."

Brief recap of events since 2020

The alleged manufacturers (Pfizer, Moderna, etc.) did not disclose the ingredients now being found by independent researchers, to the alleged regulators (US-FDA, European Medicines Agency, Australian Therapeutic Goods Association, etc.) or to the public.

The alleged regulators did not demand disclosure of ingredients; did not independently evaluate the ingredient claims of the alleged manufacturers; and — even when they noted irregularities (see Latypova memo to Sen. Ron Johnson, Dec. 18, 2022, at p. 4/12[153], re: EMA Nov. 2020 "rolling review" of Pfizer's Chemical and Manufacturing (CMC) Controls documentation) — did not enforce purity and non-adulteration regulations.

Instead, the alleged regulators granted "approvals" and "authorizations," and instructed populations to submit to injection and shun anyone who wouldn't submit.

Together, the alleged manufacturers and alleged regulators withheld ingredient information and information about regulatory non-regulation, from victims of the DoD's biowarfare campaign formerly known as the "Covid-19 vaccination program."

My reply

…The Michigan case has to do with glass shards in remdesivir: Nowacki v. Gilead[154].

Yes, the whole thing is a coordinated red herring to pull attention and money away from attacks on DoD and WHO.

I need to think it through a bit more, but I think the goal (of the Monster-agents pushing for new "contamination" civil suits against Pfizer) is to make it somewhat clearer that PREP Act coverage not only gives killers a "just following orders" defense if they're challenged for doing the things HHS/CDC/DoD orders them to do (lethal injections, hospital homicides) but it also forces them to follow those orders by making the only circumstances under which they can be prosecuted, circumstances in which they don't follow HHS/CDC/DoD orders to the letter.

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[152] https://anandamide.substack.com/p/dna-fragments-detected-in-monovalent

[153] https://bailiwicknewsarchives.files.wordpress.com/2023/02/2022.12.18-latypova-memo-re-cgmp-intentional-noncompliance-12-p.pdf

[154] https://childrenshealthdefense.org/wp-content/uploads/Nowacki-v-Gilead-Complaint.pdf

So, for example, HHS/CDC/DoD orders hospitals and health care workers to use remdesivir, even though in its uncontaminated form, it's deadly.

Hospitals and health care workers that refuse to use remdesivir are the only ones who are liable under PREP.

That's why the ones who didn't want to be killers have all quit the "Covid wards," and the only ones left are happy to kill. [Excellent interview by Sasha Latypova on this subject, with interviewer Shannon Joy.[155]]

HHS/CDC/DoD also orders Gilead to produce Remdesivir, to specifications that don't include glass shards. Gilead is only liable to the extent that non-HHS-approved-toxins (ie glass shards) end up in the product.

Same deal with the Saldana v. Glenhaven[156] case.

PREP Act is a legal tunnel to trap health care workers and turn them into criminals.

The Pfizer cases will be slightly different. We know HHS/CDC/DoD has ordered Pfizer to produce a variety of different compounds, with various toxicity levels and mechanisms of action. We also know that they all planned to destroy Pfizer as a front organization, to channel the public anger when people started figuring it out.

If Pfizer just goes bankrupt, and the bankruptcy court starts allocating its assets to creditors, maybe Covid-19 shot victims will be somewhere at the bottom of the list of payees, but more likely not. The money all passed through Pfizer a long time ago, out the back door into the pockets of politicians and bankers. It's been a DoD front company/shell company for many years.

So the exercise that people calling for new civil suits against Pfizer are advocating is more about getting people to waste their time and money for the next 3-4 years than anything else.

However, if some of the civil cases are framed properly, to draw Pfizer into pointing to DoD as the source of the raw materials and contractual obligations to put "contaminants" like SV-40 promoters into the products and not disclose those ingredients to regulators or victims, then the civil cases could be useful to continuing to expose the whole criminal enterprise to the public and mobilize Congress to withdraw the US from WHO and the UN, and repeal PREP Act, the EUA laws and the rest of the "public health emergency" legal structure.

Pfizer may try to use PREP Act in its defenses to civil suits, but will probably lean harder on the Defense Production Act, 50 USC 4558, *Voluntary agreements and plans of action for preparedness programs and expansion of production capacity and supply*, especially sections (j) and (o)....

[155] https://sashalatypova.substack.com/p/highland-hospital-rochester-ny-attempted
[156] https://law.justia.com/cases/federal/appellate-courts/ca9/20-56194/20-56194-2022-02-22.html

Oct. 26, 2023 - 21 USC 360bbb-3(e)(3) and 360bbb-3a(c): federal law authorizing HHS Secretary to waive current Good Manufacturing Practices (cGMP) for EUA products.

Relevant to public discussion of whether growing body of sequencing evidence of "adulteration" of Pfizer, Moderna and other mRNA platform technology products, opens new opportunities for litigation.

21 USC 360bbb-3. Authorization for medical products for use in emergencies

> 21 USC 360bbb-3(e)(3). Conditions of authorization; Good manufacturing practice; Prescription
>
> With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the applicable circumstances described in subsection (b)(1)—
>
> > (A) requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including such requirements established under section 351 or 360j(f)(1) of this title, and including relevant conditions prescribed with respect to the product by an order under section 360j(f)(2) of this title;
> >
> > (B) requirements established under subsection (b) or (f) of section 353 of this title or under section 354 of this title; and
> >
> > (C) requirements established under section 360j(e) of this title.
>
> 21 USC 360bbb-3a(c) - Emergency use of medical products; Current good manufacturing practice
>
> (1) In general. The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including requirements under section 351 or 360j(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 360j(f)(2) of this title.
>
> (2) Effect. Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

I haven't yet located documents purporting to be HHS Secretary authorization of waivers, limitations or deviations from cGMP for the manufacture of the biochemical weapons injected into Americans and people around the world as "Covid-19 vaccines."

I have seen waiver documents pertaining to other EUA products, including ventilators:

- March 24, 2020 - FDA Letter of Authorization, EUA, ventilators, by HHS Rear Admiral Denise Hinton, FDA Chief Scientist.[157] (Section III at p. 7)

There are several possible reasons why I haven't found HHS waiver/limitation/deviation of cGMP documents for "Covid-19 vaccines."

One is that the documents are in the Federal Register somewhere, on an HHS website somewhere, or even in my research hard-drive with searchable keywords but I just haven't found them.

Another possibility is that the documents have been scanned into the Federal Register without being converted to OCR format (Optical Character Recognition), so keyword searches don't produce hits.

That's the non-searchable format in which the Dec. 11, 2020 (Pfizer) and Dec. 18, 2020 (Moderna) FDA Letters of Authorization were entered into the Federal Register, Jan. 19, 2021, 86 FR 5200.

A third possibility is that the HHS waiver/limit/deviation from cGMP documents are classified as national security records not subject to public disclosure.

I have seen provisions in the Dec. 11, 2020 (Pfizer) and Dec. 18, 2020 (Moderna) Federal Register notices[158] by Rear Admiral Denise Hinton, that could be construed as requiring cGMP compliance.

See Section III, Item I, Conditions of Authorization, at p. 8/20 for Pfizer Letter of Authorization, and Section III, Item I, Conditions of Authorization, at p. 17/20 for Moderna. The provisions look like this:

> I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

[157] https://bailiwicknewsarchives.files.wordpress.com/2023/10/2020.03.24-fda-ventilator-eua-letter-of-authorization-cgmp-waive-p.-7.pdf

[158] https://bailiwicknewsarchives.files.wordpress.com/2023/05/2020.12.11-hhs-fda-hinton-eua-pfizer-eff-2020.12.11-moderna-eff-2020.12.18-dated-2021.01.12-86-fr-5200.pdf

These provisions can only be construed as requiring cGMP compliance, if observers ignore the knowledge painfully gained from Brook Jackson's whistleblower case: that there are public-facing contracts and regulatory documents listing otherwise applicable terms and conditions, and also as-yet-undisclosed contracts, authorizations, notices and other regulatory documents that nullify, void, waive, limit or authorize deviation from the otherwise-applicable, otherwise-enforceable terms and conditions in the public-facing documents, rendering them inapplicable and unenforceable.

Update/clarification from Sasha Latypova:

> "Technical fine point -- the facility can be cGMP compliant, but that does not mean the specific product is cGMP compliant. The reference to "cGMP compliant facilities" is another set of words designed to deceive the reader. cGMP compliance for pharmaceutical product means the process of making that specific product, it's raw materials and all quality control steps are certified compliant.
>
> I believe that the DOD is sending "black box" components to be assembled by pharma in pharmaceutical manufacturing places but pharmas themselves (especially employees on the manufacturing line) probably do not have good idea or traceability of what those components are."

Three years into the covert biochemical warfare being waged by the US Government through the Department of Defense, Advanced Technologies Inc., Medical CBRN Defense Consortium, and contractors including Pfizer and Moderna, cGMP regulations remain observably unenforced.

New lawsuits filed on the basis of mounting evidence that the products have been throughout, and are still being "adulterated" should take these legal facts into account.

Plaintiffs should draft the complaints so as to give HHS Secretary Xavier Becerra and Attorney General Merrick Garland opportunities to cite 21 USC 360bbb-3(e)(3) and 21 USC 360bbb-3a(c) in their defenses, and produce the signed, dated, unredacted authorization documents through which former HHS Secretary Alex Azar and/or current HHS Secretary Becerra waived, limited or authorized deviation from cGMP regulations for manufacture of "Covid-19 vaccines."

County and state lawmakers considering action to protect and defend the people living in their political jurisdictions from further attacks — for example, by banning use of mRNA products, halting all "vaccination" programs, and seizing contraband vials stored at pharmacies and in transit across state borders — should also take 21 USC 360bbb-3(e)(3) and 21 USC 360bbb-3a(c) into account.

Nov. 4, 2023 - Do C-19 Vax Manufacturers Violate cGxP?

Master class in pharmaceutical regulations[159]: the difference between EAU and EUA that nobody on Earth has noticed in the past 3 years. Including me until yesterday afternoon.

By Sasha Latypova

Let's look at the clip[160] of recent JJ Couey's debunking the Debunk guy debunking Kevin McKernan. All of this centers around the CHD video "Intent to Deceive" where Kevin discussed his finding the SV40 promoter sequence in Pfizer's vials and the fact that someone inside Pfizer or inside its contractor or ultimately at the DOD (where all contracts originate) went into trouble of deleting that sequence so it does not show up in the documents that Pfizer submitted to the regulators like FDA, EMA, TGA, etc.

So there was an intent to deceive the regulators, vaccinators and the public about the presence of this well-known nuclear localizing, cancer-inducing piece of code in the injections.

Well, JJ Couey is not really debunking the Debunk guy, but rather using his line of argument to criticize Kevin and CHD... This article is not endorsing [Couey] in any way, I am using it for illustration only.

Both positions in the video are not correct IMO. Let's review.

The Debunk Bro is easy - he is a paid propagandist and simply repeats the FDA/CDC/HHS/DOD prescribed narrative. The narrative goes like this:

- Kevin got vials from who knows where, we don't know if they came from Pfizer and Moderna or maybe they are fake!
- Lengthy discussion of existing cGxP laws - every pharmaceutical must be in compliance, look at all the quality checks, and tests and quality control procedures that must be in place before approval, then all the batch-release testing for each batch, so many rules everyone must comply, yada, yada, therefore what Kevin says he found in the vials cannot happen! Because cGxP.

JJ Couey's position can be condensed to the following:

- Because cGxP, FDA will use the "contamination" finding to remove the product from the market and maybe superficially punish Pfizer.
- The mRNA poison will be cleaned up from SV40 and DNA plasmids and put it back on the market and continue.

[159] cGxP refers to current Good Manufacturing Practices, current Good Clinical Practices, current Good Laboratory Practices, current Good Distribution Practices, etc.
[160] Video clip available at https://sashalatypova.substack.com/p/do-fentanyl-dealers-violate-cgxp

- The mRNA is poison with or without SV40, because it is transfecting cells and nothing positive to health can happen that way. Only damage can result from this.

That last bullet I 100% agree with, and I don't believe Kevin McKernan or anyone involved in the vial testing activities disagrees with it either.

What's wrong about both positions - the highlighted part. Both rely on the assumption that covid jabs are pharmaceutical products subject to cGxP laws and FDA regulations, and therefore finding and proving a cGxP violation may result in recall or another pharmaceutical law enforcement action. That's the most profound lie on which this whole situation hinges...

Covid-19 poison marketed as "vaccine" is NOT a pharmaceutical product subject to cGxP laws and FDA enforcement powers under 21CFR 312.

Let's recall:

21 USC 360bbb-3(k): use of EUA-covered medical countermeasure (MCM) products, once designated as such by the Secretary of Health and Human Services "shall not be considered to constitute a clinical investigation."

The definition of clinical investigation from cGxP (21CFR part 312):

Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

There are 3 mutually exclusive categories of pharmaceuticals regulated by cGxP laws:

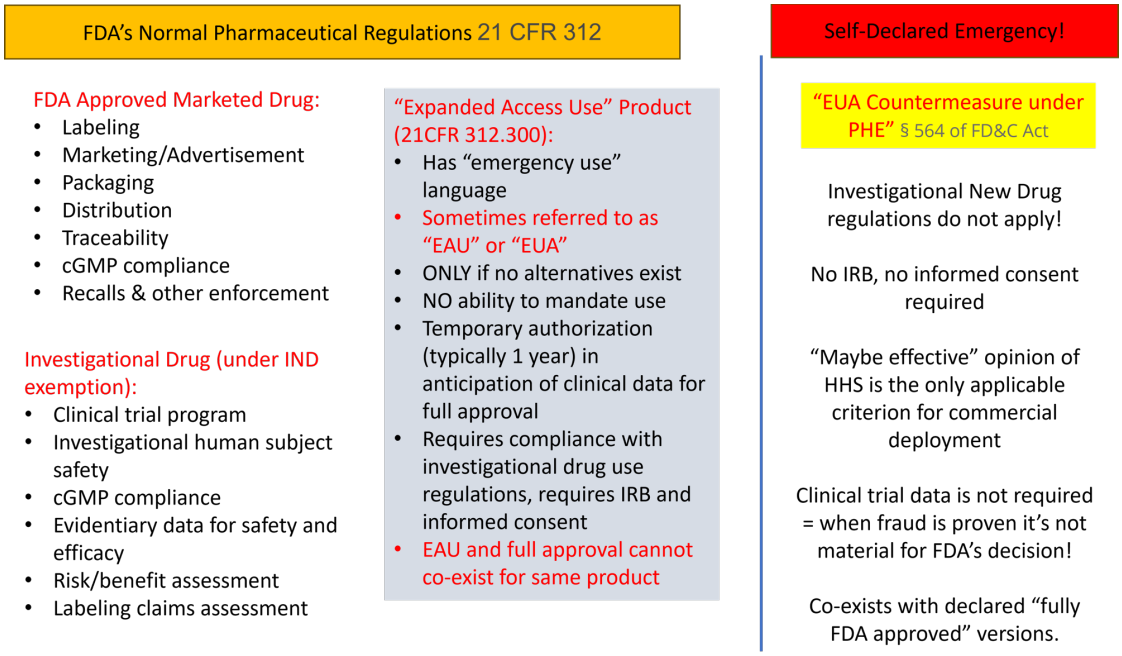
- FDA approved/marketed;
- In clinical trials under IND exemption;
- "Expanded Access Use" products *(EAU, colloquially referred to as "emergency use" or "EUA")*

There is a 4th category of things imagined and fabricated more recently (after 9/11) that is mutually exclusive with these 3 categories above, by way of legal magic and word confusion:

- EUA Countermeasure under Public Health Emergency which is regulated (sort of, but mostly just waved through with lots of panic and confusion) under para 564 of the Food, Drug and Cosmetics Act.

This "EUA" is not the same "EAU" (are you following this?) as it requires the situation of total global panic because of a few false-positive PCR tests primed with some code from a post-it note and about 40 Chinese murdered in Wuhan with remdesivir and ventilators under the supervision of Robert Malone's dear friend the CIA agent Dr. Michael Callahan.

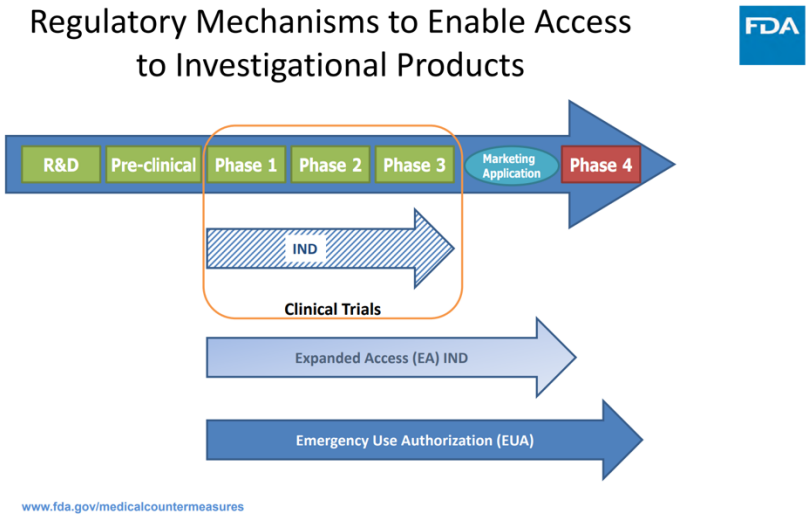
EUA exists when PHE and PREP Act declaration are in force:



Relevant post by Bailiwick News with more details about legal status of Countermeasures:

- Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation."

Here is a slide from "Legal Preparedness" deck of the FDA[161] from August 2020, discussing the same concept. EUA (no IND) is not EAU (which requires IND). In the same presentation the FDA lawyers state that "certain [pandemic] preparedness activities [without EUA + PREP Act shield] would otherwise violate the FD&C Act". "Legal preparedness" is exactly what it sounds - they write new illegal-laws that allow them to break all established laws. They fully plan to poison people and anticipate massive numbers of injured plaintiffs. And they know that they need to build many walls of their legal fortress so that no actual justice can occur.



Credit to David Wiseman for fishing out this absolute gem from a 400-page transcript of the VRBPAC meeting on October 22, 2020.[162] Here Doran Fink (then at FDA, currently enjoying his reward for the job well done at Moderna) explains why EUA and not EAU regulatory pathway was used for Poison-19 injections. Annotations and emphasis are mine:

P201/408 of transcript:

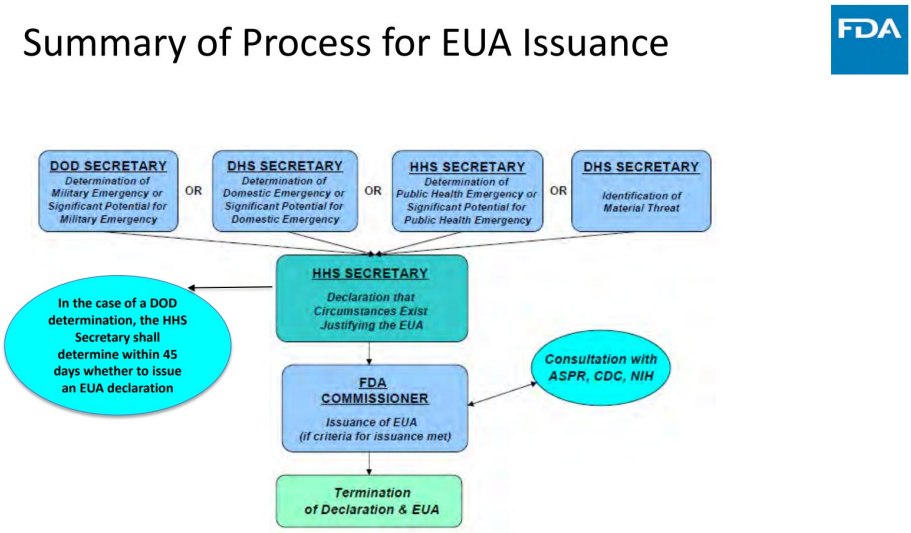
> "DR. KURILLA: And then for Doran [FINK], did you consider at all the possibility of an expanded access protocol for those specific groups that you would issue the indication for the EUA instead of an EUA?... [notice they are themselves confused between EAU and EUA!]
>
> Dr. FINK: Yeah. So to answer your question about an expanded access protocol [EAU or Expanded Access], that is another regulatory mechanism for providing access to investigational vaccine. I think if we were to consider an expanded access protocol of the same size and scope as what is being considered for an Emergency Use Authorization, then the benefit/risk considerations and the data to inform those benefit/risk considerations and allow that type of use would be highly similar. The differences between expanded access

[161] https://bailiwicknewsarchives.files.wordpress.com/2023/02/2020.08.25-fda-cdc-regulatory-updates-use-of-mcms-table-p.-18.pdf
[162] https://www.fda.gov/media/143982/download

> use and Emergency Use Authorization are that expanded access use is done -- or is carried out under FDA's investigational new drug regulations. So among many other things, those regulations require use of an institutional review board and also obtaining informed consent from recipients of the investigational vaccine according to regulations for clinical investigations -- research use of investigational vaccines. And so operationally speaking, an expanded access protocol would add some complexity, and that is why Emergency Use Authorization is being considered primarily as the mechanism for addressing the public health emergency that has been declared."

I think it's time to put the issues of the informed consent and the need to follow cGxP regs to rest, isn't it? The FDA officials clearly explained here that the reason they went with EUA is specifically NOT to follow any investigational drug rules or cGxP, and NOT to provide informed consent. And it is legal for them to do so for EUA under PHE!

This explains many, many things, but still does not explain the curious Schroedinger cat-like phenomenon of both EUA and the FDA's assertion of "full approval" co-existing for covid poisons, unless of course we realize that the "approval" is a fake. There cannot be an FDA approval per 21 CFR 312 if IND and clinical trials are not relevant to it.



From the same FDA lawyer presentation, observe the process of issuing EUA:

This process consists entirely of "determinations" (opinions of a bunch of bureaucrats) and declarations that "circumstances exist". Did you see a box on this chart that said "open IND and complete a clinical trial, it's ok to do it badly and break a bunch of rules, but you still need to do it"? Was there any box saying "safety/efficacy data review"? No? I don't see those either. Clinical trials were IMMATERIAL. Judge Truncale said so when dismissing Brook Jackson's case under allegations of serious fraud.

Let's not forget, that an extra precaution of PREP Act must be in place for this scheme of conducting illegal experiments without informed consent can take place. It is in fact so critical that it is prominently specified in the Emergent Biosolutions-DOD contract[163] for manufacturing Poison-19 injections (they were the manufacturer of AstraZeneca and Janssen poisons):

On page 49, you can read :

> "In the event the Contractor delivers vaccine under this contract which is not covered by the aforementioned declaration (PREP ACT) because of the expiration of the aforementioned declaration (PREP ACT) and any renewals or amendments thereof, the Government agrees that the medical countermeasure delivered by the Contractor under this contract will not be administered for use in humans."

They are fully aware that without the PREP Act the Medical Countermeasures cannot be used in humans. None of the real pharmaceutical products have this requirement.

Do fentanyl dealers violate cGxP? Rhetorical question.

If a substance cannot be subject to clinical investigation, the Investigational New Drug (IND) exemption for it is meaningless, and so are the clinical trials, and review and approval in compliance with cGxP. The best part of this: if you cannot really comply with cGxP, violations of cGxP cannot happen either!

Here is the thing about SV40 finding, it's not the only evidence of contamination, adulteration or violation of cGxP for these products. I can list perhaps hundreds of examples of severe violations of cGxP, many I have reported on since 2021, and many that were documented by dozens of people worldwide. Clear and undeniable violations of all laws that relate to consumer safety and pharmacy distribution in the US and other countries. That's because NONE of them apply to "EUA Countermeasure under PHE".

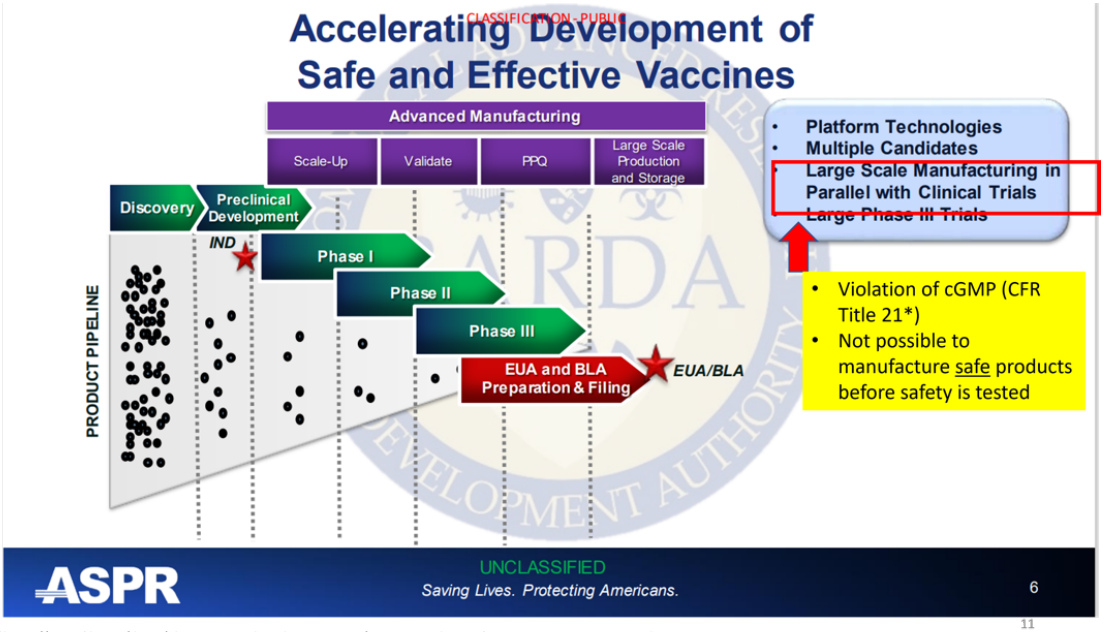
<u>Can cGxP violation/contamination argument still be used to remove this poison from the market?</u>

This theoretical possibility of this remains, as hope is the last one to die on this planet. However, I am pretty certain at this point that the FDA has dug themselves into a very deep hole via rigorously not noticing any severe cGxP violations that continue to exist in reality over the past 2-3 years. They use capricious methods to occasionally "notice" things that help them solidify their ability to further engage in this crime by creating useful case law - such as the case of them "noticing" glass shards in remdesivir and allowing the one injury lawsuit to proceed which will simply help the HHS/DOD to defend PREP Act legitimacy in the future. "See, the injured do have recourse! We regulate quality and cGxP applies!"

With SV40 it is not as simple as glass shards. The SV40 issue is much hotter for them as they cannot really acknowledge it as a problem without opening a larger can of worms pointing to premeditated mass poisoning, and lying about fake-"approving" this stuff to fool the public and especially to fool the professionals.

[163] https://www.keionline.org/misc-docs/HHS-BARDA-Emergent-Contract-HHSO100201200004I-15June2012.pdf

Let's recall the DOD-lead Operation Warp Speed and BARDA's own slides explaining how these stable geniuses were never planning to comply with cGxP in the first place (yellow box is my annotation):



*https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

The Debunk Bro is simply spewing the prescribed narrative of the criminal FDA-DOD-Pharma cartel describing all the regulations that exist (cGxP) "forgetting" to mention that they do not apply to the "EUA Countermeasures under PHE". In fairness, he probably doesn't know this, and that makes him sound more assured and convincing as a paid actor that he is.

Once the status of these illicit substances is understood, it is easy to debunk the Debunk Bro. They are illicit poisons which are trafficked the same way fentanyl or heroin are trafficked worldwide (and probably by the same main actors). Kevin's work is extremely important to stopping these shots by educating the public worldwide, and energizing the few legislators with remaining conscience. That is not to diminish the point that even in the "uncontaminated" form, the mRNA platform is a very dangerous poison and should not be used for any application.

Nov. 14, 2023 - Separation of powers, reservation of powers (federalism), and the PREP Act.

I've been reading Covid-times case law related to:

1) Constitutional separation of powers between the three distinct branches of the federal government — executive (President and administrative Cabinet secretaries and agencies); legislative (Congress); and judicial (federal district courts, circuit courts of appeals and Supreme Court); and

2) Constitutional federalism, or reservation of powers — powers "not delegated" by the States and the people to the federal government and powers not "prohibited by" the Constitution — to the States, under Amendment 10: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

*

There are two main ways that the monsters working in and through the United Nations World Health Organization preemptively hobbled the US Constitution as embodied in American governing institutions, that would have interfered with the Covid-19 sequence of orchestrated lies and stopped the ongoing mass murder program.

One mechanism for the kneecapping of the Constitution is through the laws passed by Congress and signed by US presidents. More on those statutory mechanisms below.

The other main mechanism is through federal court decisions that have interpreted the Constitution expansively with regard to exercise of federal power, and narrowly with regard to exercise of State power.

Through his May 29, 2020 opinion in *South Bay Pentecostal Church v. Gavin Newsom, et al*,[164] SCOTUS Chief Justice John Roberts issued a stand-down order to block all federal courts from reviewing federal and state exercise of executive and legislative power for constitutional soundness.

Justice Roberts cited a 1985 case, Garcia v. San Antonio Metropolitan Transit Authority et al,[165] to support his argument:

> …Where those broad limits [on latitude to act for "the safety and health of the people"] are not exceeded, they should not be subject to second-guessing by an "unelected federal judiciary," which lacks the background, competence, and expertise to assess public health and is not accountable to the people….

*

[164] https://www.supremecourt.gov/opinions/19pdf/19a1044_pok0.pdf
[165] https://tile.loc.gov/storage-services/service/ll/usrep/usrep469/usrep469528/usrep469528.pdf

On the statutory side, the Constitutional damage was mostly inflicted at 42 USC 247d-6d(b)(7), (8) and (9): provisions added to the Public Health Service Act of 1944 in 2005 through the PREP Act.

For background:

The "public health emergency" section (PHSA 319, 42 USC 247d) was added to the PHSA in July 1983. The 1983 Congressional act introduced the category of "public health emergency" to the collection of national circumstances (such as state of war) authorizing overrides of constitutional law, civil tort law and criminal law.

> 42 USC 247d = PHSA 319: Public Health Emergencies
>
> (a) Emergencies.—If the Secretary determines, after consultation with the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control, that—
>
> (1) a disease or disorder presents a public health emergency; or
>
> (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,
>
> the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder described in paragraph (1).

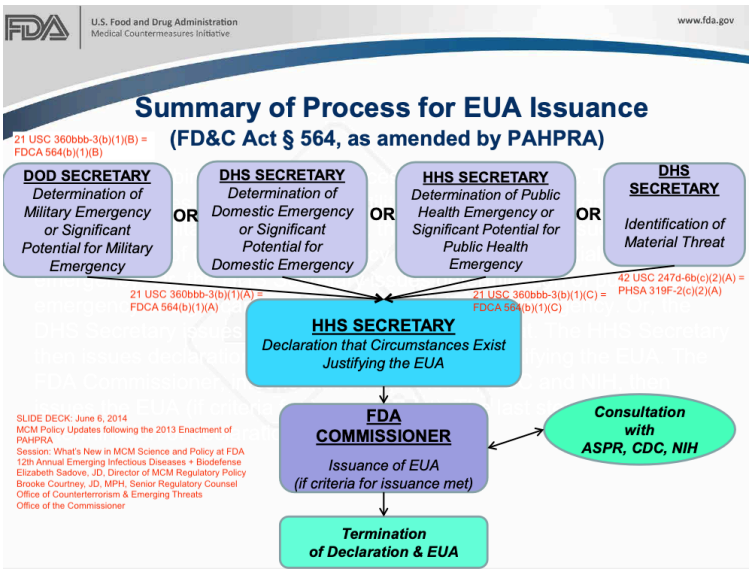
The act was very short, just over one page,[166] and the second part appropriated $30 million for a Public Health Emergencies Fund: the slush fund of money to support HHS Secretary "action."

The only oversight provision in the act was a requirement that the HHS Secretary provide annual, retrospective reports to the House Energy and Commerce Committee and the Senate Labor and Human Resources Committee. [The 1983 PHE section was repealed and replaced with another version, transferring more unilateral, unreviewable power into the hands of the HHS Secretary, in 2000. PL 106-505, Public Health Improvement Act, Public Health Threats and Emergencies Act]

[166] https://uscode.house.gov/statutes/pl/98/49.pdf

In 2013, the HHS Secretary authority to make a "determination" about the existence of a public health emergency was also added to the Food Drug and Cosmetics Act (FDCA Section 564 = 21 USC 360bbb-3) through the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA Act), to connect the *event* "determination" to the HHS power to deploy "Emergency Use Authorized" *products* and platforms:

> 21 USC 360bbb-3(b) = FDCA 564(b).
>
> Declaration of Emergency or Threat Justifying Emergency Authorized Use.--
>
> (1) In General.—The [HHS] Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—
>
> > (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;
> >
> > (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, United States Code, of attack with—
> >
> > > (i) a biological, chemical, radiological, or nuclear agent or agents; or
> > >
> > > (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;
> >
> > (C) a determination by the [HHS] Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or
> >
> > (D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act sufficient to affect national security or the health and security of United States citizens living abroad. [42 USC 247d-6b(c)(2)(A)]



Then-HHS Secretary Alex Azar invoked and exercised his power under 21 USC 360bbb-3(b)(1)(C), in his Feb. 4, 2020 Notice of Determination of Public Health Emergency and Declaration that "circumstances exist justifying the authorization of emergency use of in vitro diagnostics," a reference to PCR and other Covid-19 testing products. 85 FR 7316[167].

Also effective Feb. 4, 2020, (signed March 10, 2020, published March 17, 2020, 85 FR 15198[168]), as amended (signed June 4, 2020, published June 8, 2020, 85 FR 35100[169]) was Azar's Declaration Under the Public Readiness and Emergency Preparedness [PREP] Act for Medical Countermeasures Against Covid-19, invoking and exercising HHS Secretary power to exempt all the people involved in medical countermeasures [biochemical weapons] development, manufacture, distribution and use, from legal liability for their actions (PHSA 319F-3 = 42 USC 247d-6d), and to divert all injury and death claimants into the dead-end Countermeasures Injury Compensation Program (CICP), (PHSA 319F-4 = 42 USC 247d-6e.)

The PREP Act, signed on Dec. 30, 2005, is where Congress and President George W. Bush made more explicit, the intentional dismantling of the constitutional principles of both separation of powers and federalism (reservation of powers to the states).

Congress and President Bush stripped Congress of its authority to oversee or terminate emergency declarations and determinations made unilaterally by the HHS Secretary; stripped federal courts of their authority to review or nullify declarations and determinations; and stripped states, tribes, and municipalities (political subdivisions of states) of their authority to apply their own constitutions and laws to the declarations, determinations, products and uses directed by the HHS Secretary as part of the federal executive branch.

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167 https://www.govinfo.gov/content/pkg/FR-2020-02-07/pdf/2020-02496.pdf
168 https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf
169 https://bailiwicknewsarchives.files.wordpress.com/2023/05/2020.02.04-hhs-prep-act-amendment-2-qualified-pandemic-epidemic-products-limit-harm-otherwise-caused-signed-2020.06.04-85-fr-35100.pdf

42 USC 247d-6d(b)(1) = PHSA 319F-3(b)(1)

Declaration by Secretary. (1) Authority to Issue Declaration.

Subject to paragraph (2) [list of declaration contents], if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

42 USC 247d-6d(b)(7) = PHSA 319F-3(b)(7)

Judicial Review. No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

42 USC 247d-6d (b)(8) = PHSA 319F-3(b)(8)

Preemption of State Law. During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.

42 USC 247d-6d (b)(9) = PHSA 319F-3(b)(9)

Report to Congress. Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

Dec. 1, 2023 - On 'mandates' and the irrelevance of informed consent principles in the EUA countermeasures use context

Question posted at Rumble video, Nov. 25, 2023 - FDA flooded the market with illegal drugs.[170] (42 min, Sasha Latypova, Willem Engel.)

> So it's sounding like there was no real legal authority to mandate an EUA product (countermeasure) but there was also not a specific law prohibiting it? Or that's what Comirnaty was for right?

My reply

My current understanding is that bribery and coercion are legal under PREP Act, and the "mandates" were mechanisms to do those crimes and to cover up that those were the acts being committed.

For example, it was and is legal for federal and state governments to link payouts to schools and businesses, to reaching target percentages of vaxx uptake among their student and employee populations, and it was and is legal for schools and businesses to link access to education and jobs to individual vaxx uptake.

Same for linking hospital and nursing home payouts to use of Remdesivir/ventilators and uptake of vaxxes. And for government employers (DoD, for example).

Part of this is the substitution of "option to refuse or accept" for "informed consent" in a context in which informed consent is an incoherent principle, because no true information about the contents or effects of the product exists to be provided to targets; because the authorized consequences of refusal include firing and expulsion from school; and because targets are military targets whose consent is irrelevant, not clinical trial subjects (because no clinical trials are happening) and not patients (because no doctor-patient, diagnosis-treatment relationship exists).

I also think PREP Act and related laws legalize federal government to threaten federal contractor businesses and funding recipients (hospitals, nursing homes) that failure to reach vaxx uptake targets will result in loss of contracts and funding.

And PREP Act sets up conditions so that the only acts by 'covered persons,' 'program planners' and 'qualified planners' that don't enjoy full civil and criminal liability protection, are acts of resistance.

Bribery, coercion, assault and murder do have full liability exemption.

[170] https://rumble.com/v3xqd6s-fda-flooded-the-market-with-illegal-drugs.html

Refusal to commit bribery, to coerce other people, to assault other people and to kill them, will strip the PREP Act protections and expose the refusers to civil and criminal prosecution. [*See*, for example, USA v. Kirk Moore.[171]]

As for Comirnaty, Comirnaty's fake FDA "approval" wasn't needed for PREP Act coverage nor for the operation of the bribery-coercion funding system. Comirnaty was and is just another layer of the performance art. Possibly if the vaxx rates had gone high enough without the Comirnaty FDA charade, they wouldn't have bothered with it. But because vaxx rates were not going high enough in Spring/Summer 2021, they decided to add another layer of fraud, to deceive/persuade hold-outs, including institutional hold-outs that weren't bribing and coercing students and employees hard enough, and individuals.

Related

- June 14, 2022 - April 4, 2003 - Rep. Henry Waxman questioning FDA Commissioner Mark McClellan about informed consent waivers authorized through Project Bioshield Act.
- July 4, 2022 - Possibilities for proving intent. The work product of attorneys Susan E. Sherman, Wen W. Shen, Dawn Johnsen and the July 6, 2021 Department of Justice legal opinion.
- Jan. 2, 2023 - Bioweapon prototype deployments, informed consent, targeted enemies, state of war, doctrine of necessity.
- Jan. 31, 2023 - August 2020 - Elizabeth Sadove presentation to FDA-CDC: Regulatory Updates on Use of Medical Countermeasures.
- Aug. 18, 2023 - Bridges v. Houston Methodist Hospital. Court decisions supporting the conclusion that vaxx recipients are military targets, enemy combatants, chattel slaves or similar legal status in which consent is moot.

[171] https://bailiwicknews.substack.com/p/usa-v-dr-kirk-moore-et-al

Dec. 2, 2023 - EUA countermeasures are neither investigational nor experimental

By Sasha Latypova

"Judge, I was forced to take an experimental vaccine!"

Kaiser Permanente in CA is getting sued. [Horsely v. Kaiser Foundation Hospitals Inc. et all, USDC Northern District of California, Oakland Division, Oct. 31, 2023]

Here is another example - Roberts v Shriners. [Roberts v. Shriners Hospitals for Children, et al, USDC Eastern District of Washington, Spokane Division, Oct. 13, 2023].

The case cites correct law concerning EUA (360bbb). Then states that "FDA defines the drugs at issue as investigational":

That is what FDA *says* about these drugs to the public, it is not how they are defined in law. The FDA also *says* they are "fully approved" now - a legal impossibility for EUA substances. The FDA also *says* they are "safe and effective", and we know that's a lie, too.

Note that I am not a lawyer, and I am not asking you to hire me for this or any other case in any capacity, and I gave absolutely zero financial or any other interest to point this out. However, why do these lawyers not read the law?

An EUA drug under PHE and current PREP Act declarations is NOT an investigational drug! It is a legal impossibility for it to be investigational or experimental by definition of its status as EUA.

Bailiwick News Katherine Watt wrote about Bridges v Methodist case [Aug. 18, 2023].

Note that the case was dismissed in June 12, 2021 order by USDJ Lynn N. Hughes quoted below (emphasis mine):

> On April 1, 2021, Houston Methodist Hospital announced a policy requiring employees be vaccinated against COVID-19 by June 7, 2021, starting with the leadership and then inoculating the remaining workers, all at its expense.
>
> Jennifer Bridges and 116 other employees sued to block the injection requirement and the terminations. She argued that Methodist is unlawfully forcing its employees to be injected with one of the currently-available vaccines or be fired. The hospital has moved to dismiss this case.
>
> Bridges dedicates the bulk of her pleadings to arguing that the currently-available COVID-19 vaccines are experimental and dangerous**.** This claim is false, and it is also irrelevant. Bridges argues that, if she is fired for refusing to be injected with a vaccine, she will be wrongfully terminated. Vaccine safety and efficacy are not considered in adjudicating this issue.

Judge Hughes declared Bridges' assertion that the 'vaccines' are experimental and dangerous to be "false."

Turns out the judge is technically correct about the experimental part, while being morally deplorable, of course. Note that the "dangerous" part was never allowed to be argued in court and this is by design of the covid campaign and it's illegal-legal structure. This structure (aka "covid kill box") was designed carefully over the years to ensure that most professionals involved in it are either: fooled; or given plausible deniability to act as if they were fooled; or given lots of financial incentives to act as if they were fooled.

However, Bridges would have had a far better chance of getting to present the evidence of danger had she based her cased on the applicable current law. It is false to assert that EUA vaccines are medical experiments, because they are not, as I will explain further in this article.

Before I do that, here is another example of wide spread misunderstanding of the nature of the covid military campaign - the ubiquitous in the "health freedom" crowd narrative of "dolts botching shit" (credit Sage Hana).

Here is one such example: "Incompetent pharmas can't mass produce anything!"[172]

The claim therein is that for 3 whole years nobody in pharma manufacturing noticed that they are shipping poison laced with many other poisons, and that this is because utterly incompetent medical people just don't know how to manufacture things to pharmaceutical grade standards. If only car companies made vaccines!

My eyes are rolling so far back into my head, I am seeing the back of my skull and it's not pretty. Yeah... If only...

If this hypothesis is correct, then why all other drugs are shipped seemingly within manufacturing tolerances? How come pharmas seem to be able to mass produce those things? And when they are not, AG of Texas is suing manufacturer for product adulteration? Why hasn't fearless Ken Paxton filed this same lawsuit for covid vaccines?

Based on my knowledge of thousands of vials tested all over the world, not a single vial has been found in conformance with the allegedly "FDA approved" product label. It would be a slam dunk. And the fines he could have recovered would be OMG, eyewatering! Yet, he has filed a lawsuit v Pfizer for "deceptive marketing practices" and NOT manufacturing fraud. For some reason he is not suing Moderna, which engaged in the same deceptive marketing practices and media collusion.

Note - I will write a separate post about Paxton's lawsuit, which is better articulated than others, but commits the same fallacy with regard to the EUA. What is so special about covid vaxxes? Think! Think harder....Oh, I know.

[172] https://covidmythbuster.substack.com/p/mass-injection-protocols-should-be

Let's look what "EUA" regulatory status means. Do EUA countermeasures have to adhere to the current Good Manufacturing Practices? Let's consult US Code:

21 USC 360bbb-3a

With respect to whether or not the typical cGMP regulations in manufacturing apply to COVID shots:

- https://uscode.house.gov/view.xhtml?req=(title:21%20section:360bbb-3a%20edition:prelim)

(c) Current good manufacturing practice

(1) In general

The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including requirements under section 351 or 360j(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 360j(f)(2) of this title.

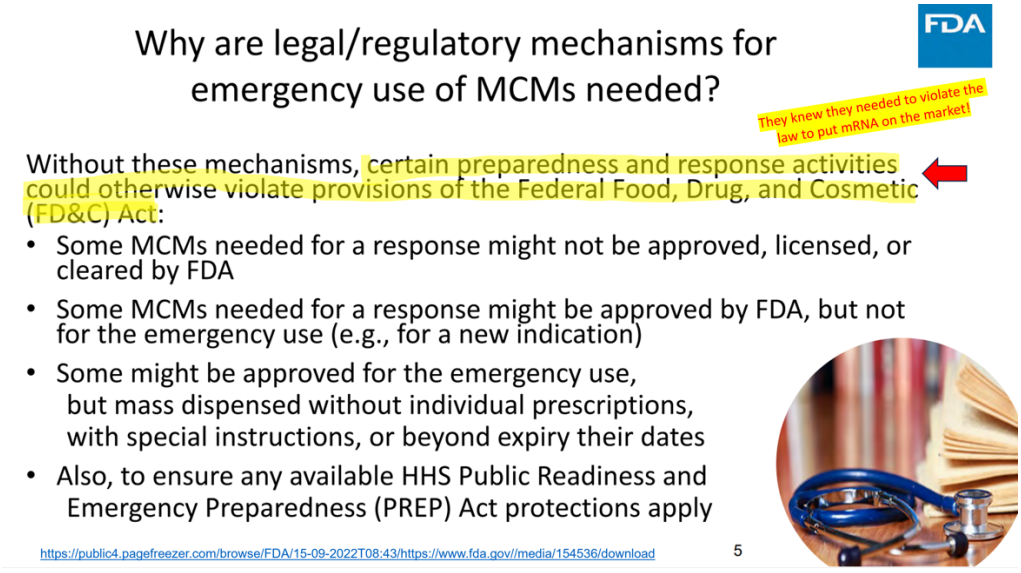
(2) Effect

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and **shall not be deemed adulterated or misbranded** under this chapter because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

=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." 21 USC 360bbb-3a(c). 2013.

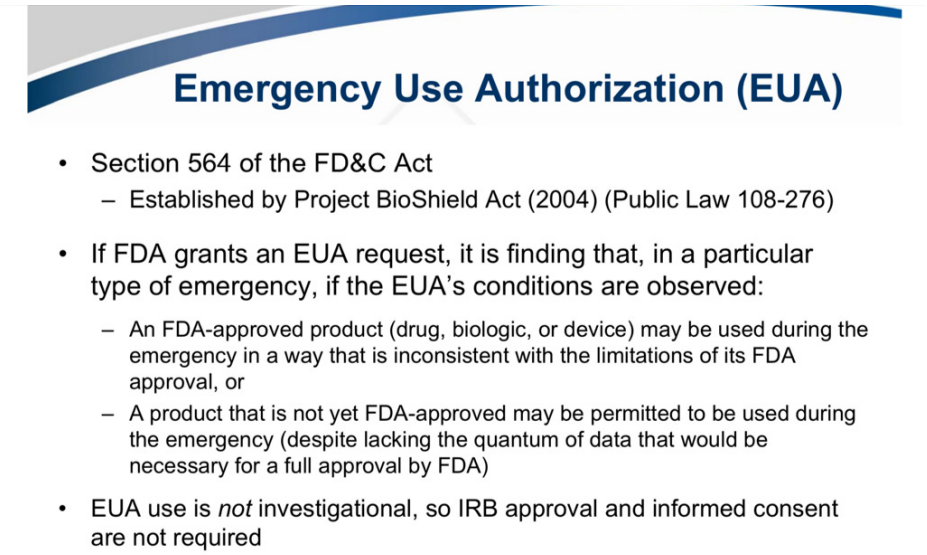
Looks like the answer is "no".

But what do I know? Maybe we should ask Ford Motor Company to opine. Maybe a better group of people to consult is the FDA lawyers. Here's what they say in their own "legal preparedness" [preparedness to break FD&C Act] powerpoint presentations:

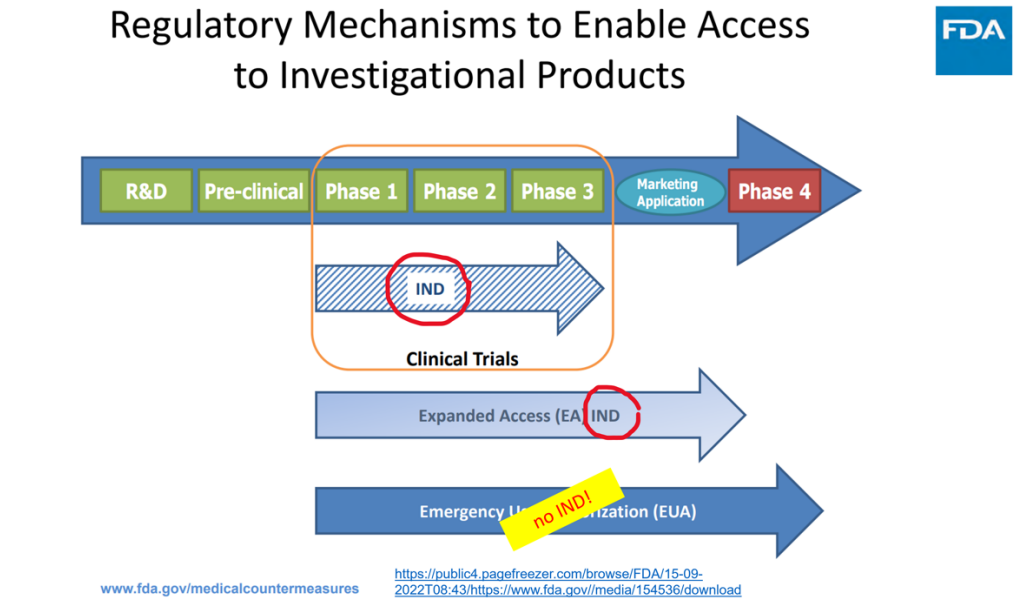


We know we need to break the law to put this poison on the market, so, we need to make a parallel universe where the illegal things are called legal and we are good. Let's call it EUA. Stroke of genius, I must admit.

On this page, they plainly state that "EUA use is *not* investigational, so IRB approval and informed consent are not required".



And for avoidance of any doubt - clinical trials (as legally defined human experiment) do not exist for EUA:



The FDA lawyers found a way to break the FD&C Act by creating a separate section in it (random number 564) and making up a new “regulatory” pathway that resides entirely outside of all pharmaceutical regulations: NO investigational review board, NO informed consent and NO cGMP compliance apply to things called “EUA countermeasures under Public Health Emergency”.

That’s why when Judge Hughes writes: "Bridges dedicates the bulk of her pleadings to arguing that the currently-available COVID-19 vaccines are experimental and dangerous. This claim is false, and it is also irrelevant," he is correct about “false and irrelevant”.

Let’s review how. Medical experiments, aka “clinical investigations” are defined in FDCA as:

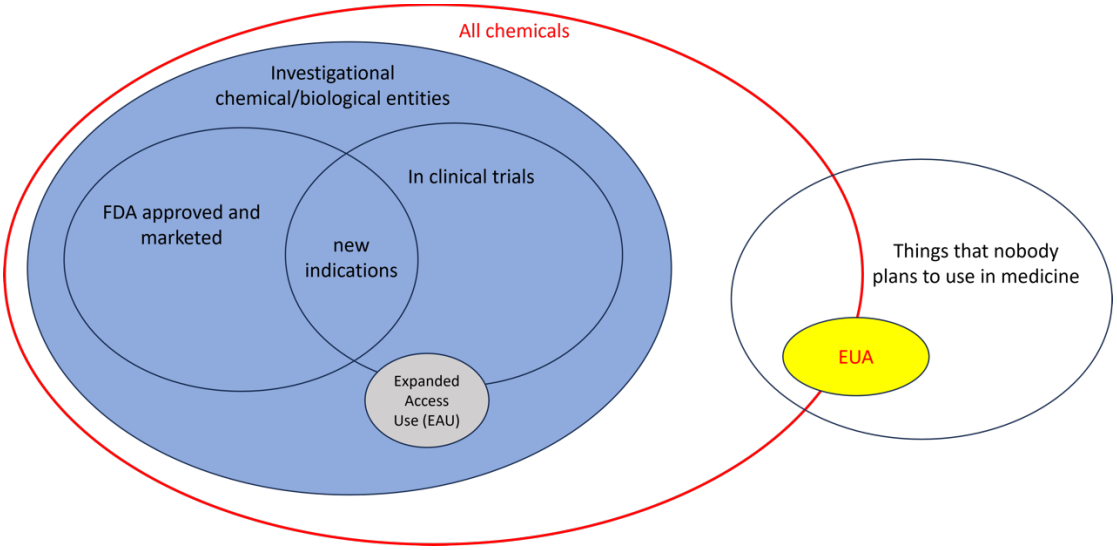
> *Clinical investigation* means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. [21 CFR 312.3]

However, another US law removes EUAs from the purview of FDCA (and FDA regulations), by creating a special “non-investigational” class:

> 21 USC 360bbb-3(k): 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].

Therefore, medical experiments are legally not possible for the EUA thingies by their “non-investigational” status. If a product cannot be investigational, there is no process for assembling the regulatory evidence of safety, efficacy and manufacturing control for purposes of compliance with Section 351(a) of the Public Health Service Act (PHS Act), (42 U.S.C. 262) and cGMP (section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) and 21 CFR Parts 210, 211, and 610).

By process of elimination, we arrive at this:



These injections are chemicals and biologics that are not suitable as medicine and nobody plans to use them as such, aka poisons. Please stop calling them experimental, investigational, medical or pharmaceutical products. They are neither of those things. They are illicit drugs and poisons trafficked by the US Government-Military and their contractors all over the world (video).

Judge Hughes is correct that it is “false and irrelevant” to call covid injections experimental and dangerous. It is false because EUA is not experimental and can never be. It is irrelevant because safety is irrelevant to EUA, which gets issued based on opinions and not approved based on data. There is no way to collect clinical trial data and collate it such that an assessment of risk benefit (as defined in FDCA) can be made.

Dec. 6, 2023 - More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.

At the request of a reader, I've been digging deeper into the complex, deceptive and misleading legal language used by unindicted war criminals, to extend the public health emergency-predicated killing spree on American soil, while they publicly claim that the public health emergency has been ended.

The machinations revolve around terms and phrases including *is*, *exists*, *constitutes*, *significant potential for-*, *credible risk of a future-*, and *category of disease, health condition, or threat*, and concurrent but distinct PHE determinations issued under the Public Health Service Act (PHSA) and the Food Drug and Cosmetics Act (FDCA).

One PHE determination, issued under Public Health Service Act (PHSA) Section 319(a) [42 USC 247d(a)] on Jan. 31, 2020, retroactive to Jan. 27, 2020, and extended every 90 days thereafter, was allowed to expire on May 11, 2023.

This series of PHSA PHE determinations was not, to my knowledge, promulgated through the Federal Register. Announcements simply appeared at the HHS-ASPR website,[173] most recently Feb. 9, 2023[174] (the 90-day renewal that expired May 11, 2023)

On May 11, 2023, another PHE determination under the PHSA, this time Section 319(b)(1) [42 USC 247d-6d(b)(1)] took effect, and was published in the Federal Register as part of a PREP Act declaration amendment.

> "SARS-CoV-2…*constitutes a credible risk of a future* public health emergency" replaced the original, Jan. 27, 2020 wording: "SARS-CoV-2…*constitutes* a public health emergency."

Meanwhile, four public health emergency determinations under the Food Drug and Cosmetics Act (FDCA) Section 564(b)(1)(C), [21 USC 360bbb-3(b)(1)(C)] have been in continuous legal force since the first one took effect on Feb. 4, 2020.

A fifth, amended FDCA public health emergency determination joined the first four, effective March 15, 2023.

The FDCA PHE determinations were promulgated through the Federal Register at 85 FR 7316, 85 FR 13907, 85 FR 17335, 85 FR 18250, and 88 FR 16644.

FDCA PHE determinations are issued without expiration dates; termination is solely at the discretion of the HHS secretary. FDCA 564(b)(2) [21 USC 360bbb-3(b)(2)].

[173] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx
[174] https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx

Meanwhile, the original PREP Act declaration issued under PHSA 319(b)(1) [42 USC 247d-6d(b)(1)], signed March 10, 2020, published in the Federal Register March 17, 2020, (85 FR 15198) retroactive to Feb. 4, 2020, and its 11 amendments promulgated between March 17, 2020 and May 11, 2023, had an original termination date of Oct. 1, 2024.

By amendment effective May 11, 2023 (88 FR 30769), the current termination date is Dec. 31, 2024, and the termination date can be pushed back further, also solely at the discretion of the HHS secretary.

Related

- Sept. 27, 2022 - On why Biden's comment that 'the pandemic is over' doesn't lift the bioterrorist police state jackboot off our necks.
- March 22, 2023 - On the utility, for inducing peaceful compliance with violent globalist control-and-kill programs, of presenting fake threats as real. Plus war criminal Xavier Becerra extends the public health emergency, effective March 15, 2023, using slightly-different wording.
- April 11, 2023 - Biden rescinding Trump-Biden Proclamation 9994 under 1976 National Emergencies Act does not terminate Azar-Becerra's Public Health Emergency authorities under 1983 PHE amendment to the 1944 PHSA. Becerra and his successors will extend the
- Aug. 28, 2023 - March 15, 2023 and May 11, 2023 HHS Dictator-Secretary determinations and declarations.

Dec. 6, 2023 - Litigation proposals for state Attorneys General.

...State Attorneys General should build on what has been learned through *Jackson v. Ventavia, Pfizer et a*[175]*l*; *Bridges v. Houston Methodist Hospital*,[176] and *Texas, Oklahoma et al v. US Department of Health and Human Services, Xavier Becerra et al*,[177] (4:23-cv-00066-Y).

They should file federal complaints against the US Congress and US presidents, at the Supreme Court, under SCOTUS original jurisdiction on constitutional matters (US Constitution, Art III.S2.C2.2), to have the *Public Health Emergencies* sections of the Public Health Service Act (42 USC 247d through 42 USC 247d-12) and the *Expanded access to unapproved therapies and diagnostics* sections of the Food Drug and Cosmetics Act (21 USC 360bbb through 21 USC 360bbb-8d) declared null and void *ab initio* (from the beginning)…

Because those laws were enacted unconstitutionally outside the power (*ultra vires*) of Congress and Presidents to draft and sign any laws that:

1. enable US government officials operating within the executive and administrative branches to plan and commit mass fraud and mass murder using EUA "countermeasure" poisons and frauds to sicken and kill American people under "public health emergency" decrees;
2. block the constitutional separation of powers authority of federal courts to review and halt such criminal acts by the federal executive branch [42 USC 247d-6d(b)(7)];
3. block the constitutional separation of powers authority of Congress to review and halt such criminal acts by the federal executive branch [42 USC 247d-6d(b)(9)];
4. block the constitutional (federalism) authority of state, tribal and local authorities to review and halt such criminal acts by the federal executive branch [42 USC 247d-6d(b)(8)];

The state AG litigation should challenge two key Congressional acts: the 2004 Project Bioshield Act, and the 2005 Public Readiness and Emergency Preparedness (PREP) Act.

Without Congress enacting and US presidents signing those two laws, the mass fraud and mass murder of the Covid events could not have happened.

But because of the corruption of law that those two Congressional acts in 2004 and 2005 — and their precedent and successor acts[178] — have wrought, the entire PHSA (first enacted 1944) and FDCA (first enacted 1938) should also be nullified and all executive branch public health agencies and programs should be judicially and/or legislatively dismantled.

They have been turned into criminal enterprises.

[175] https://bailiwicknews.substack.com/p/other-transactional-authority-ota
[176] https://bailiwicknews.substack.com/p/bridges-v-houston-methodist-hospital
[177] https://bailiwicknews.substack.com/p/texas-and-oklahoma-v-us-department
[178] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program

Dec. 20, 2023 - Ending National Suicide Act. Draft bill for 118th Congress

Published Dec. 20, 2023

Two PDF versions available - one with links from the Cornell University law database[179] and one without links.

- Ending National Suicide Act (with links, formatted)[180]
- Ending National Suicide Act (without links, formatted)[181]

Related PDF reports and summaries:

- 2 pages - Weaponization of Language and Law: US Government Bioterrorism Program from 1969 to Covid.[182] (January 2023, abstract)
- 14 pages - Legal History: American Domestic Bioterrorism Program.[183] Enabling statutes, regulations, executive orders, guidance documents, etc. (May 2023 version)

Interested Bailiwick readers can send the draft bill to members of the 118th Congress, with a personal letter explaining your understanding — gained through the Covid-19 events as they've unfolded since January 2020 — of how global financial creditors wielding the leverage of unpayable financial debts are using American laws, presidents and Cabinet secretaries to induce national self-destruction.

The current Congress holds the God-given authority to repeal the anti-laws that Congress has passed: anti-laws that illegitimately enable the subversion of constitutional rule of law, and illegitimately enable the bodily destruction of men, women and children, through the mechanisms of faked emergencies, consolidation of executive power, and deployment of biochemical weapons that sicken, sterilize and kill those on whom they are used.

Congress holds the God-given authority to tear down the walls of the public health emergency kill box.

Congress also holds the God-given authority to pursue morally-sound policies and programs, including restoration of constitutional rule of law; orderly debt default; and establishment of sound money operated outside the control of the corrupted and corrupting central banking system.

*

[179] https://www.law.cornell.edu/uscode/text
[180] https://bailiwicknewsarchives.files.wordpress.com/2023/12/ending-national-suicide-act-with-links-formatted.pdf
[181] https://bailiwicknewsarchives.files.wordpress.com/2023/12/ending-national-suicide-act-without-links-formatted.pdf
[182] https://bailiwicknewsarchives.files.wordpress.com/2023/06/2023.01.13-watt-k.-abstract-us-government-state-sponsored-bioterrorism.pdf
[183] https://bailiwicknewsarchives.files.wordpress.com/2023/05/2023.05.01-legal-history-american-domestic-bioterrorism-program.pdf

AN ACT To repeal Congressional authorizations for communicable disease control, quarantine and inspection programs; chemical and biological warfare programs; biological products and vaccine manufacturing programs; public health emergency programs; national vaccine and immunization programs; expanded access and emergency use authorization programs; public health and emergency preparedness and response programs; enhanced control of dangerous biological agents and toxins programs; and related statutes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REPEAL OF Title 42, The Public Health Service, Chapter 6A, Public Health Service, Subchapter II, General Powers and Duties, Part G, Quarantine and Inspection, § 264 to § 272, [PHSA §361 to §369]. Authorization for the quarantine and inspection program, (July 1, 1944, ch. 373, title III, 58 Stat. 703-706; as amended...is hereby repealed.

SEC. 2. REPEAL OF Title 50, War and National Defense, Chapter 32, Chemical and Biological Warfare Program, §1511-1528. Authorization for the Chemical and Biological Warfare Program, (Nov. 19, 1969, Pub. L. 91–121, title IV, § 409(a) to 409(e), 83 Stat. 209 - 210; as amended ...is hereby repealed.

SEC. 3 - REPEAL OF Title 42, The Public Health Service, Part F, Licensing of Biological Products and Clinical Laboratories, Subpart 1, biological products, 42 USC 262-263, [PHSA § 351-352]. Authorization for the biological products program, (July 1, 1944, ch. 373, title III, § 351, 352, 58 Stat. 702-703; as amended ...is hereby repealed.

SEC. 4 - REPEAL OF Title 42, The Public Health Service, Ch. 6A, Subchapter II, Part B, Federal-State Cooperation, § 247d to 247d-7g; 247d-11 to 247d-12, Public health emergencies [PHSA §319-319M.] Authorization for the public health emergencies program, (July 1, 1944, ch. 373, title III, § 319 as added Pub. L. 106–505, title I, § 102, Nov. 13, 2000, 114 Stat. 2315 - 2324 [repealing and replacing previous PHSA § 319 as added Pub. L. 98–49, July 13, 1983, 97 Stat. 245]; and amended ... is hereby repealed.

SEC. 5 - REPEAL OF Title 42, The Public Health Service, Chapter 6A, Public Health Service, Subchapter XIX, Vaccines, Part 1, National Vaccine Program, (§300aa-1 to 300aa-6); and Part 2, National Vaccine Injury Compensation Program, (§300aa-10 to 300aa-34). Authorization for the National Vaccine Program and National Vaccine Injury Compensation Program, (July 1, 1944, ch. 373, title XXI, § 2101-2133 as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3756-3778); and amended ...is hereby repealed.

SEC. 6 - REPEAL OF Title 21, Food and Drugs, Ch. 9, Federal Food Drug and Cosmetics Act, Subchapter V, Drugs and Devices, Part E, General Provisions Relating to Drugs and Devices, §360bbb to §360bbb-8d, Expanded access to unapproved therapies and diagnostics program [FDCA Ch. 675, §561 to 569D] Authorization for the Expanded access to unapproved therapies and diagnostics program, (June 25, 1938, ch. 675, §561 et seq, as added Pub. L. 105–115, title IV, § 402, Nov. 21, 1997, 111 Stat. 2365, and amended ...) is hereby repealed.

SEC. 7 - REPEAL OF Title 42, Public Health Service, Ch. 6A, Public Health Service, Subchapter XXVI, National All-Hazards Preparedness for Public Health Emergencies, Parts A-C, §300hh-1 to 300hh-37 [PHSA §2801-2826] Authorization for the National All-Hazards Preparedness for Public Health Emergencies program (July 1, 1944, ch. 373, title XXVIII, § 2801, as added Pub. L. 107–188, title I, § 101(a), June 12, 2002, 116 Stat. 596; and amended...is hereby repealed.

2024

Virgin of the grapes. Pierre Mignard.

Work published at Substack, 2022-2025. October 2025 version.
Katherine Watt - PO Box 1142 - State College PA 16804

2024

- Jan. 10, 2024 - On international and US legal instruments governing "adjustment of domestic legislative and administrative arrangements" and exercise of political authority during declared public health emergencies. (Jan. 10, 2024)
- Jan. 26, 2024 - Memo Re EUA Countermeasures to send to your doctor, pharmacist, employer, school, sheriff, county commissioner and state lawmakers (Sasha Latypova)
- Feb. 14, 2024 - Medical Countermeasures Awareness Bill (Tools for illuminating, defying and dismantling kill-box anti-laws)
- Feb. 23, 2024 - What section of the US Code did the Global Health Security and International Pandemic Prevention, Preparedness and Response Act enter after enactment Dec. 22, 2022? 22 USC 2151b, Population planning and health programs, as a statutory note.
- April 17, 2024 - Globalist misleaders focus public attention on WHO International Health Regulations to distract people from understanding and repealing federal and state public health emergency law.
- April 19, 2024 - Current Congress members have legal authority and moral agency to stop vaccine-mediated mutilation and killing programs worldwide.
- May 7, 2024 - Pandemics are fake. Federal and state public health emergency kill box laws can be repealed and nullified.
- May 7, 2024 - Bits and pieces about 10 USC 1107a(a) consent waivers, EUA products, BLA products, legalized FDA non-regulation of pharmaceutical manufacturing, and related things.
- May 15, 2024 - Global pandemic preparedness and response provisions already in US domestic law.
- May 21, 2024 - There is no legal limit to the amount of so-called contamination that can legally be included in vaccines or any other biological products.
- May 17, 2024 - Global Catastrophic Risk Management Act, enacted by Congress and Biden Dec. 2022, codified at 6 USC 821-825.
- May 23, 2024 - Top 10 US federal laws Congress should repeal to end worldwide vaccination, mutilation and killing programs.
- June 24, 2024 - On misconstruction of EUA countermeasures and vaccines as medicinal products, rather than weapons and poisons, and on legal-judicial system role in sustaining public ignorance and submission.
- June 27, 2024 - Intentional infliction of harm is not a legitimate government purpose; enabling it is not a permissible legislative object.
- July 2, 2024 - On reading PREP Act declarations as declarations of war issued by treasonous, seditious agents acting in unofficial, personal capacities.
- July 12, 2024 - Preliminary analysis of Loper v. Raimondo. Congress legalized military and civil administrators overriding US Constitution under self-declared emergency conditions, and Congress can repeal the enabling acts.
- Sept. 20, 2024 - Federal and state poison-legalizing laws and quarantine laws matter more than the UN, WHO and the IHR. Congress and state legislatures have the political authority to repeal poison-legalizing laws and quarantine laws.

Jan. 10, 2024 - On international and US legal instruments governing "adjustment of domestic legislative and administrative arrangements" and exercise of political authority during declared public health emergencies.

A reader asked me to provide my understanding of the legal instruments governing exercise of political authority during declared public health emergencies, and how the United Nations World Health Organization International Health Regulations (IHR, 2005); the current proposed amendments; and American statutes, regulations, executive orders and other domestic legal instruments, fit together within that legal framework.

Nutshell: My understanding is that all officers of US federal and state governments are subordinated to the US Secretary of Health and Human Services for the duration of any 'public health emergency,' as unilaterally declared by the HHS Secretary, using authority placed in his hands through domestic kill box laws enacted through the mechanisms of Congressional votes and presidential signatures.

And the HHS Secretary himself, and the US federal and state government officials he controls for the duration of any declared 'public health emergency,' are subordinated to the UN and WHO, under the terms of international agreements adopted and sustained by the mechanism of silence/inaction/non-rejection/non-withdrawal by Congress, presidents, federal and state courts, and state legislatures.

The HHS Secretary serves two functions: he's an administrator**,** tasked by his United Nations supervisors with implementing and directing UN-WHO military-public health policies and programs in the US, and he's a dictator in his relationship to other branches and officers of the US government, the governments of the 50 states, and the people.

I disagree with Meryl Nass, James Roguski, Bret Weinstein and others who focus public time and attention on current proposed IHR amendments and a proposed new pandemic treaty. I've briefly indicated my disagreement with Nass, Roguski and others in personal correspondence and also in public presentations. I haven't belabored it for two reasons.

First, I support the work they do to the extent it helps lawmakers and populations around the world better recognize that:

1. The WHO is a military branch of the United Nations;
2. The UN is engaged in a military attack on the world's people under 'public health emergency' pretexts, using totalitarian policies and programs (informational, surveillance, testing, masking, social distancing); military, law enforcement and public health proxies (DoD-directed biological weapons manufacturers, FDA officials, pharmacists, and nurses) and toxic products (poisons/weapons) that are falsely presented as medicinal treatments;
3. National governments legally can and prudently should withdraw from the United Nations and the World Health Organization, under their own domestic laws and Article 62 of the Vienna Convention on Treaties, due to the "fundamental change of circumstances:" public understanding of the two preceding facts gained through the Covid-19 events that have occurred since January 2020.

Sept. 24, 2023 - 51 Congress members co-sponsoring Rep. Andy Biggs HR-79, WHO Withdrawal Act. *See also* H.R. 6645 and S. 3428 (Disengaging Entirely from the United Nations Debacle Act of 2023).

*

Second, I don't want to fuel personal conflicts that distract readers from what I regard as the most effective forms of resistance to the ongoing mass murder programs and strengthening of the walls of the global kill box: Repeal and nullification of the domestic implementing laws, at the federal and state level, by Congress, state legislatures, and federal and state courts whose members understand that 'public health emergencies' are camouflaged power grabs...

*

I think US domestic law has already transferred sovereign government functions to the United Nations World Health Organization, such that current IHR amendments, (if the United States remains a UN and WHO member), and when they enter into force, will increase the speed, expand the scope and strengthen the force of the geopolitical coup that that has already taken place.

But they won't comprise a new theft of sovereignty.

The already-completed sovereignty transfer, or de facto UN coup, was enacted through a sequence of Congressional and presidential acts that began in 1944 with enactment of the Public Health Service Act and US Senate ratification (in 1945) of the United Nations Charter, followed by Congressional authorization given in 1948 to President Truman to accept membership in the WHO on behalf of the US government, followed by hundreds of other implementing statutes, executive orders, presidential directives, and agency regulations.

Further, I don't think there are any substantive political mechanisms to directly intervene or stop the adoption or amendment of international legal instruments, because there is no political nexus between ordinary people and global governing institutions. Treaties are contracts between nation-states, not between governments and those who are governed. The men and women coercing public submission to their edicts — through supranational institutions — have no political subjects or constituents. There is no hereditary line of succession, and there are no electoral, recall or impeachment procedures.

As Roguski has reported, the World Health Assembly adopts IHR amendments by “silence procedure,” consensus mechanisms; there is no recorded vote. IHR amendments then enter into force in member-states through non-rejection mechanisms, which are also silent. Unless the legislature and executive formally file notice of rejection or reservation with the WHO Director-General, before the end of the interval specified in Article 59 of the IHR (2005), the amendments enter into force at the end of another, short interval.

They are self-executing.

As also laid out in Article 59, member-states are obligated to "adjust domestic legislative and administrative arrangements fully" to align them with IHR provisions within that entry-into-force time interval, by adopting implementing statutes and regulations (kill box laws) that are triggered when trigger conditions are met.

For example, by the WHO Director-General declaring a PHEIC (public health emergency of international concern) and/or by the in-country health administrator (HHS Secretary in the US) declaring a public health emergency.

Article 56, Sections 1-3 of the IHR lay out procedures for state parties to resolve disputes about the "interpretation or application" of the regulations, including mechanisms for negotiation, mediation, conciliation, and compulsory arbitration.

As a June 2022 Congressional Research Service report noted, "To date, no WHO Member State has ever invoked the Article 56 process against another Member State."

None have needed to, because Article 56, Section 4 recognizes that WHO member-states, including the United States, are also controlled by the coercive power of other "international agreements and "intergovernmental organizations," such as the Bank for International Settlements and World Trade Organization, which are empowered to use financial mechanisms to enforce the terms of the WHO Constitution and the IHR on the US Government and the people of the United States.

To avoid or reduce the financially destructive wrath of the BIS, WTO and other supranational organizations, governments of sovereign countries have subordinated themselves to the United Nations: they have "adjusted domestic legislative and regulatory arrangements" to comply with the WHO-IHR.

Nutshell again:

The US federal and state government officials — for so long as they silently defer to illegitimate, unconstitutional international legal instruments and domestic, implementing kill box laws — are subordinate to the HHS Secretary during a public health emergency.

And the HHS Secretary and all other US federal and state government officials are subordinate to the UN-WHO — for so long as they silently defer to illegitimate, unconstitutional international legal instruments — under the terms of international treaties and other "binding instruments of international law..."

Jan. 26, 2024 - Memo Re EUA Countermeasures to send to your doctor, pharmacist, employer, school, sheriff, county commissioner and state lawmakers

By Sasha Latypova

Purpose: Clarify the legal status of EUA Medical Countermeasures (MCMs)

1. Pursuant to Section 564 of the FD&C Act, as amended by PAHPRA, 2013, and the Supremacy Clause of the United States Constitution (Article VI, Clause 2), EUA MCMs have potentially been exempted from testing using Good Laboratory Practices, Good Clinical Practice, including informed consent, and from being assessed to determine if Risk Evaluation and Mitigation Strategies (REMS) are necessary.

2. Safety regulations governing the manufacture, shipment, holding, dispensing, administration and labeling do not necessarily apply to MCMs, rather, they are subject to an opinion by FDA and HHS officials without proper Congressional or judicial review for the duration of HHS-declared emergency. The declaration of emergency is likewise without properly defined stopping criteria, nor Congressional or judicial review.

3. Under federal law, FDA must approve any new drug product prior to a manufacturer introducing it into interstate commerce. [1] This process requires manufacturer to open an Investigational New Drug application and obtain an exemption from the FDA for its use in regulated investigational clinical research (trials). This normal regulated process is therefore referred to as an "investigational" regulatory pathway. It requires a manufacturer to conduct regulated clinical research (trials) under the IND, obtaining Institutional Review Board's (IRB) approval for clinical trial protocols, independent safety monitoring oversight, and properly executed informed consent from clinical trial volunteers. In addition, manufacture of the drugs and biologics subject to the investigational status is regulated by the current Good Manufacturing practices (cGMP). [2]

4. EUA Medical Countermeasures are a radically different, defined in law as *non-investigational* drugs, biologics and devices deployed under FDA's authorization power known as the "Emergency Use Authorization" (EUA) process. [3]

5. The EUA process is used only when the United States Secretary of Health and Human Services declares an emergency. [4]

6. By law, the EUA process is non-investigational [5]: while the manufacturers may choose and FDA may ask to undertake some of the activities typically expected from an investigational clinical trial and manufacturing validation process, none of the typical regulatory standards are applicable in an enforceable way.

7. FDA has the discretion to issue an EUA if the applicant shows that its product "may be effective" in treating the relevant disease or condition [6]. It is important to emphasize the no other criteria for approval apply in an enforceable way.

8. FDA will approve EUA products on incomplete information so long as the applicant shows that the "known and potential benefit of the product" merely "outweigh[s] the known and potential risks" [7] and considers it unlikely that "comprehensive effectiveness data" will be available before an EUA grant. In contrast, for an investigational drug (under normal regulatory approval process) the FDA "shall" deny approval if the applicant "do[es] not show that such drug is safe." [8]

9. Therefore, the EUA status of an MCM precludes collection of the investigational (subject to IRB and informed consent) clinical trial data and thus precludes reliable, valid scientific knowledge of risks and benefits associated with the EUA Countermeasure.

10. The EUA process precludes meaningful informed consent from the recipients of the product: while Congress mandated that FDA directly inform health care professionals and product recipients of any "significant known and potential benefits and risks," [9] formal regulated clinical trials are neither required nor possible for a non-investigational EUA product. Thus, there is no reliable and scientifically valid information on risks and benefits of an EUA, especially for extremely novel technologies such as mRNA shots.

11. Furthermore, there are no required standards for quality-control in manufacturing; no inspections of manufacturing procedures; no lot-release testing and no prohibition on wide variability among lots; no prohibition on adulteration; and no required compliance with Current Good Manufacturing Practices (cGMP). EUA products, even though unregulated and non-standardized, "shall not be deemed adulterated or misbranded." [10]

In summary, the process through which the EUA products enter interstate commerce and claims about their safety, efficacy or contents are based solely on the HHS Secretary opinion, which requires no supporting scientific evidence. Misrepresentation of safety, efficacy or contents of EUA products is allowed by federal law. Thus, claims provided by the federal health authorities or manufacturers cannot be considered reliable sources of information.

<u>Key Enabling Statutes</u>

Six primary enabling statutes include:

- Title 21 – Federal Food and Drugs Act, at §360bbb et seq, "Expanded access to unapproved therapies and diagnostics," as established in 1997;
- Title 42 – Public Health Service Act, at §247d et seq, "Public health emergencies," as established in 1983;
- Title 42 – Public Health Service Act, at §300hh et seq, "National All-Hazards Preparedness for Public Health Emergencies," as established in 2002;
- Title 42 – Public Health Service Act, at §300aa-1 et seq, "Vaccines," as established in 1986;
- Title 10 – Armed Forces Act, at §4021 et seq, "Research projects: transactions other than contracts and grants," as established for DoD use for "prototype" contracting in 2015;
- Title 50, Chapter 32, §1511 et seq, "Chemical and Biological Warfare," as established in 1969.

References

[1] See, e.g., 21 U.S.C. § 355 (drugs); 42 U.S.C. § 262 (biologics).

[2] CFR Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799, and 800-1299.

[3] Section 564 FD&C Act. Note that the EUA pathway should not be confused with the "Expanded Access Use" regulatory pathway which is often colloquially referred to as an "emergency use". The expanded access is an investigational pathway and is regulated in the same manner as all normal drug approvals. (21 CFR 312.310-320)

[4] 21 U.S.C. § 360bbb-3(a)(1), (b).

[5] 21 USC 360bbb-3(k): 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].

[6] 21 U.S.C. § 360bbb-3(c)(2)(A)

[7] 21 U.S.C. § 360bbb3(c)(2)(B)

[8] 21 U.S.C. § 355(d)(2); See also 42 U.S.C. § 262(a)(2)(RB) (biologic approved only if it actually "is . . . safe").

[9] 21 U.S.C. § 360bbb-3(e)(1)(A)(II)

[10] 21 USC 360bbb-3a(c).

More references at online version.[184]

[184] https://sashalatypova.substack.com/p/memo-re-eua-countermeasures-to-send

Feb. 14, 2024 - Medical Countermeasures Awareness Bill (Tools for illuminating, defying and dismantling kill-box anti-laws)

Template legislation for introduction, deliberation and adoption by any governmental entity that levies and distributes taxes.

Notes:

An earlier version of the template bill posted below was drafted by Lydia Hazel[185] in October 2023, and she circulated it to state legislators in Illinois and to Congressman Thomas Massie the same month. Hazel forwarded her draft to me in December; I formatted and revised it and received Hazel's permission to publish the revised version for Bailiwick reader use.

The PDF includes references and bracketed sections that can be filled in with the names of specific EUA countermeasure products and manufacturers as needed.

For the text posted below, as an example, I filled in "Pfizer-BioNTech COVID-19 Vaccine/BNT162b2" for the product, and "Pfizer Inc. and BioNTech" for the manufacturer, and State of Illinois as the sample government entity adopting the bill.

To summarize the basis for the bill: the default position is that no compliance with any FDA regulation for drugs, devices or biological products is required of any EUA product manufacturer and/or enforced by FDA against any EUA product or product manufacturer, because by definition, under 21 USC 360bbb-3(k), once the product has the EUA classification, it cannot be the subject of valid clinical trials, Investigational New Drug (IND) applications, manufacturing standards, quality control testing, inspections of facilities where it's manufactured, or any other FDA product regulation pathway.

Further, since a May 2019 HHS-FDA rule change, the same non-regulation by default holds true for *all* biological products and biological products manufacturing facilities, whether they're making licensed, approved, unlicensed, unapproved, EUA, IND or any other class of products.

*

[185] Lydia Hazel holds degrees in Latin (BA) and linguistics (MA), with minors and concentrations in mathematics, phonetics/phonology, and philology. Her professional background is teaching English as a Second Language. She raised four children, unvaccinated since 1993, after Hazel investigated vaccines when Hepatitis B vaccines were added to the CDC-recommended childhood immunization schedule. She lives in Illinois. Email: lydiahazel@aol.com.

Medical Countermeasures Awareness Bill

Template legislation for introduction, deliberation and adoption by any governmental entity that levies and distributes taxes: city/town, school district, county, state and federal. (PDF[186])

Medical Countermeasures Awareness Bill

Every entity (public, private and/or public-private) receiving State of Illinois funds who makes any announcements, statements and/or declarations regarding any medical countermeasure, for example, statements about the medical countermeasure's availability, purpose, safety, efficacy, history of development, etc., shall simultaneously include the following notice to prospective users and recipients:

Pursuant to Section 564 of the Food Drug and Cosmetics Act, 21 USC 360bbb, governing use of "Emergency Use Authorization" (EUA) products, as amended by the Pandemic and All-Hazards Preparedness Act (PAHPRA) of 2013 and related federal legislation, and the Supremacy Clause of the United States Constitution (Article VI, Clause 2),

Pfizer-BioNTech COVID-19 Vaccine/BNT162b2, manufactured by Pfizer Inc. and BioNTech, has been exempted from testing using Good Laboratory Practices; from Good Clinical Practice, including informed consent; from Good Manufacturing Practice; and from being assessed to determine if Risk Evaluation and Mitigation Strategies (REMS) are necessary.

Safety regulations governing the manufacture, shipment, holding, dispensing, administration and labeling of Pfizer-BioNTech COVID-19 Vaccine/BNT162b2, manufactured by Pfizer Inc. and BioNTech do not apply to this product.

No Federal or State agency assures that the contents of the batch of Pfizer-BioNTech COVID-19 Vaccine/BNT162b2**,** manufactured by Pfizer Inc. and BioNTech, from which the dose you are about to receive was taken, has similar contents to any other batch of Pfizer-BioNTech COVID-19 Vaccine/BNT162b2**,** manufactured by Pfizer Inc. and BioNTech, making any practical determination of the safety of your dose of Pfizer-BioNTech COVID-19 Vaccine/BNT162b2**,** manufactured by Pfizer Inc. and BioNTech impossible.

Failure for any entity to comply will result in loss of all State of Illinois funding until compliance occurs.

* * *

186 https://bailiwicknewsarchives.files.wordpress.com/2024/02/medical-countermeasures-awareness-bill.pdf

Feb. 23, 2024 - What section of the US Code did the Global Health Security and International Pandemic Prevention, Preparedness and Response Act enter after enactment Dec. 22, 2022? 22 USC 2151b, Population planning and health programs, as a statutory note.

I've been updating the list of legal issues for further research a bit, to add in US Code citations for some of the laws in case readers want to research any of those issues.

The Global Health Security and International Pandemic Prevention, Preparedness and Response Act was formerly known as the Global Health Security Act.

The Global Health Security Act was first introduced during the 115th Congress, on Dec. 13, 2018.[187]

The 117th Congress enacted it — under its new name — as part of the NDAA for FY2023, President Biden signed it, and it became law Dec. 23, 2022.[188]

The Global Health Security and International Pandemic Prevention, Preparedness and Response Act was codified at 22 USC 2151b, as a statutory note.

I ran across 'statutory notes' as a category of law last summer — Richard J. McKinney, Assistant Law Librarian for the Board of Governors for the Federal Reserve Board, reported at a May 26, 2011 meeting:

> "In statutory research it is common to find that a provision of Federal law has been placed in the note area following a related section of the United States Code. The question then arises as to whether the provision in the note has as much authority as a section in the body of the U.S. Code and, if so, why the codifiers did not give the provision its own section or perhaps add it to the related section.
>
> The authority of statutes placed in a note area, although sometimes questioned, cannot be doubted — they do indeed have the same authority as statutes placed as U.S. Code sections. It may be more difficult to locate and distinguish these statutes from other matters in the note area or to cite to them, but it follows logically that if a U.S. statute is valid then it does not matter where it is placed in the Code…"

[187] https://www.congress.gov/search?q=%7B%22source%22%3A%22all%22%2C%22search%22%3A%22%5C%22Global+Health+Security+Act%5C%22%22%7D&pageSort=latestAction%3Aasc

[188] https://www.congress.gov/bill/117th-congress/house-bill/7776/text

22 USC 2151b is a section of the US Code under Title 22, Foreign Relations and Intercourse.

22 USC 2151b, Population planning and health programs, was enacted by Congress and President on Dec. 17, 1973 (PL 93-189, 87 Stat. 714), as an addition to the Foreign Assistance Act of 1961.

After about a dozen amendments, 22 USC 2151b now includes the provisions below and more, authorizing and funding global depopulation programs as US geopolitical policy.

To get the true sense of this law, and the programs it authorizes, it's important to translate as you read to replace the ostensible reasons — for example, "vaccines for immunizations" to reduce "incidence of communicable diseases among children, mothers, and infants," reduce "childhood mortality" and increase "child survival" — with the actual reasons: injection of sterilizing and disease-causing agents to reduce present fertility and life expectancy among mothers and fathers, and life expectancy and future fertility among children and infants. "Protection" should be translated as "sterilization" or "destruction."

It's also important to understand that the use of the term "voluntary" is deceptive, and legally irrelevant. The sterilize-and-kill programs are housed under the US State Department, US Agency for International Development (US-AID) and the Foreign Assistance program.

Message to countries: no sterilizing injection of your men, women and children, no public or private aid money.

22 USC 2151b(a) Congressional declaration of policy.

> The Congress recognizes that poor health conditions and uncontrolled population growth can vitiate otherwise successful development efforts. Large families in developing countries are the result of complex social and economic factors which change relatively slowly among the poor majority least affected by economic progress, as well as the result of a lack of effective birth control. Therefore, effective family planning depends upon economic and social change as well as the delivery of services and is often a matter of political and religious sensitivity. While every country has the right to determine its own policies with respect to population growth, voluntary population planning programs can make a substantial contribution to economic development, higher living standards, and improved health and nutrition. Good health conditions are a principal element in improved quality of life and contribute to the individual's capacity to participate in the development process, while poor health and debilitating disease can limit productivity.

22 USC 2151b(b) Assistance for voluntary population planning.

> In order to increase the opportunities and motivation for family planning and to reduce the rate of population growth, the President is authorized to furnish assistance, on such terms and conditions as he may determine, for voluntary population planning. In addition to the provision of family planning information and services, including also information and services which relate to and support natural family planning methods, and the conduct of directly relevant demographic research, population planning programs shall emphasize motivation for small families.

22 USC 2151b(c) Assistance for health programs; special health needs of children and mothers; Child Survival Fund; promotion of immunization and oral rehydration; control of AIDS and tuberculosis…

> 22 USC 2151b(c)(2)(A) In carrying out the purposes of this subsection, the President shall promote, encourage, and undertake activities designed to deal directly with the special health needs of children and mothers. Such activities should utilize simple, available technologies which can significantly reduce childhood mortality, such as improved and expanded immunization programs, oral rehydration to combat diarrhoeal diseases, and education programs aimed at improving nutrition and sanitation and at promoting child spacing...
>
> 22 USC 2151b(c)(3)…The promotion of vaccines for immunization…is an essential feature of the health assistance program. To this end, the Congress expects the agency primarily responsible for administering subchapter I of this chapter to set as a goal the protection of not less than 80 percent of all children, in those countries in which such agency has established development programs, from immunizable diseases by January 1, 1991…

The "Notes" section of 22 USC 2151b is where the lengthy Global Health Security and International Pandemic Preparedness and Response Act entered US law after Congress passed it in December 2022.

Readers who want to read it, go to the 22 USC 2151b page,[189] click on the blue "Notes" tab, and scroll down.

Congress enacted this law to comply — as it has in so many other instances in recent decades — with the dictates of the United Nations World Health Organization under the already-binding terms of the International Health Regulations, 2005...

[October 2025 Note - Text of Global Health Security and International Pandemic Preparedness and Response Act available in January to June 2024 collection at pp. 308-328.]

[189] https://www.law.cornell.edu/uscode/text/22/2151b

April 17, 2024 - Globalist misleaders focus public attention on WHO International Health Regulations to distract people from understanding and repealing federal and state public health emergency law.

A few weeks ago, I got an email asking for my views on international and US domestic law, as related to state bills attempting to protect state citizens from forced communicable disease surveillance, reporting, quarantine (apprehension and detention), and treatment, including vaccinations.

The email writer referred, as an example, to Louisiana Senate Bill 133,[190] "to disallow the exercise of jurisdiction by certain international organizations" including the World Health Organization, and similar proposed bills.[191]

I think it's a good idea for state lawmakers to draft, introduce and vote for bills that help each state lawmaker go on public record as denying that officials representing the United Nations, World Health Organization, and other supranational entities have legal jurisdiction over American citizens living in American states.

However, such laws are not enough to protect Americans from officials representing American state governments, and the US federal government, exercising domestic legal jurisdiction, under American federal and state law, to surveil, report, apprehend, detain and poison Americans under 'public health emergency' pretexts.

Louisiana citizens, for example, are currently subject to communicable disease surveillance, reporting, quarantine, and treatment, including vaccination, within their own state and country, under federal communicable disease control law (42 USC 264, 42 CFR 70, 42 CFR 71, and related statutes, regulations and executive orders) and under Louisiana state communicable disease control law and policy, enforceable by Louisiana public health and law enforcement officers.

See, for example: 29 LRS 764A(2)(e) and A(4)(c)[192] and related laws and communicable disease control program guidelines.[193]

Louisiana citizens are also currently subject to surveillance, reporting, quarantine and vaccination under existing law if they choose to travel abroad, under the federal laws as implemented by other countries' governments to execute the terms of the WHO International Health Regulations treaty.

[190] https://legiscan.com/LA/text/SB133/2024
[191] https://standforhealthfreedom.com/state-sovereignty-v-the-who/
[192] https://www.legis.la.gov/legis/Law.aspx?p=y&d=207680
[193] https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/sanitarycode.pdf

In my view, fights around the WHO pandemic treaty and WHO IHR amendments are distraction maneuvers to occupy the time and energy of people who might otherwise work on repealing or nullifying federal and state public health emergency and communicable disease control law.

Seven federal public health emergency, communicable disease control, biological product licensing and vaccination laws that should be repealed by Congress, and nullified by state legislatures:

1. Quarantine and Inspection, 42 USC §264 to 272 (in effect since 1944)
2. Chemical and Biological Warfare Program, 50 USC §1511 to 1528 (since 1969)
3. Licensing of Biological Products, 42 USC §262 to 263 (since 1944)
4. Public health emergencies, 42 USC § 247d to 247d-12 (since 1983)
5. National Vaccine Program and National Vaccine Injury Compensation Program, 42 USC §300aa-1 to 300aa-34 (since 1986)
6. Expanded access to unapproved therapies and diagnostics program, 21 USC §360bbb to 360bbb-8d (since 1997)
7. National All-Hazards Preparedness for Public Health Emergencies, 42 USC §300hh-1 to 300hh-37 (since 2002)

Tools Congress members and state lawmakers can use to repeal and nullify the federal laws, and the state versions of same: Ending National Suicide Act[194]; Repeal state public health emergency, emergency management, communicable disease control laws[195]

[194] https://bailiwicknewsarchives.files.wordpress.com/2023/12/ending-national-suicide-act-without-links-formatted.pdf
[195] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/04/2024.03-repeal-state-public-health-emergency-emergency-management-communicable-disease-control-laws.pdf

April 19, 2024 - Current Congress members have legal authority and moral agency to stop vaccine-mediated mutilation and killing programs worldwide.

That's why so many people work so hard to make it difficult for Congress members to understand the authority they hold in their hands, and to use it.

I received an email from a reader in response to this post: April 17, 2024 - Globalist misleaders focus public attention on WHO International Health Regulations to distract people from understanding and repealing federal and state public health emergency law.

The reader made two false claims:

- "The purpose of the WHO documents is to globalize the PREP Act and the other emergency bills."
- "It [focusing public attention on Congressional and state lawmaker authority to repeal bad federal and state laws] would allow our leaders to say they have no control and blame the WHO."

My reply:

Your two points are false.

First, the PREP Act and other emergency laws are already operationalized globally through the manufacturing, sales, supply and purchasing contracts.

See, for example, Section 11 (Other, PREP Act) of the DoD-ATI-Pfizer contract, July 21, 2020,[196] combined with Section 8 (Indemnification), Section 9.2 (Limits on Liability), Section 9.4 (Waiver of sovereign immunity), Section 9.5 (Conditions Precedent to Supply) and Section 12.2 (Arbitration) of the Pfizer "Manufacturing and Supply" agreements.

These purchasing agreements were signed by national governments, and are enforceable in US courts under international trade law and under the dispute resolution functions of the International Chamber of Commerce.

The same language is in all Pfizer contracts and term sheets worldwide, although section numbering differs among contracts and some sections are redacted in the publicly-available contracts.

[196] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2022/10/2020.07.21-dod-ati-pfizer-technical-direction-letter-ota-w15qkn-16-9-1002-35-p.pdf

Cut-and-paste from Pfizer-Albania contract, at section 9.5,[197] Conditions Precedent to Supply:

> Purchaser [Albania, all purchasing countries] represents that it has and will continue to have adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations and provide adequate protection to Pfizer and all Indemnitees from liability for claims and all Losses arising out of or in connection with the Vaccine or its use.
>
> Purchaser hereby covenants and acknowledges and agrees that a condition precedent for the supply of the Product hereunder requires that Purchaser shall implement and maintain in effect such statutory or regulatory requirements or funding appropriation sufficient to meet its obligations in this Agreement prior to supply of the Product by Pfizer and thereafter shall maintain such statutory and regulatory requirement and funding appropriation, each as applicable, for so long as necessary to meet all of Purchaser's obligations under this Agreement, including, without limitation, any such obligations that, pursuant to Section 6.5, survive expiration or termination of this Agreement.

For clarity, the sufficiency of such statutory or regulatory requirements or funding appropriation shall be in Pfizer's sole discretion…

Your second point is equally false.

It's non-productive to encourage Congress members to play-act at having influence within international organizations for which they are not appointed or elected, voting members.

Congress members actually do have legal authority and moral agency, as Congress members, to repeal bad US laws that they and their predecessors passed.

By repealing those laws, Congress will not only strip DoD, HHS and the other federal agencies of their legalized authority to mask, test, track, quarantine, mutilate, poison and kill Americans in conspiracy with pharmaceutical drug and vaccine manufacturers such as Pfizer, BioNTech, Moderna, Merck, Janssen, Gilead, and Sanofi-Pasteur.

The US Congress will also strip the US government of its ability to coerce —through predatory contracts — other countries' federal governments and agencies of their legalized authority to mask, test, track, quarantine, mutilate, poison and kill their people.

That's precisely why so much effort is expended to push Congress members and the public away from understanding, acknowledging and using Congress members' own legal authority and moral agency.

[197] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/04/2021-albania-contract-pfizer.pdf

Related

- Sept. 14, 2022 - Biotech idolatry: DOD-Pfizer contracts have replaced federal constitutions and laws. And the DOD-DOJ-HHS complex has replaced federal legislatures and courts.
- April 7, 2023 - On enforcement mechanisms wielded against non-compliant nation-states.
- Oct. 12, 2023 - On the moral agency of living human lawmakers.
- Dec. 20, 2023 - Ending National Suicide Act.
- Jan. 10, 2024 - On international and US legal instruments governing "adjustment of domestic legislative and administrative arrangements" and exercise of political authority during declared public health emergencies.
- March 8, 2024 - Regulatory simulations at home and abroad: Mutual Recognition Agreements. Part 1, series on legal links connecting domestic and international non-regulation of non-medicines.

May 7, 2024 - Pandemics are fake. Federal and state public health emergency kill box laws can be repealed and nullified.

Readers have asked recently about news that some US Senators and others are sending letters and things, expressing some grumpy indignation about the soon-to-be-in-force World Health Organization International Health Regulations amendments adopted by the World Health Assembly in May 2022,[198] other batches of proposed IHR amendments, and a proposed pandemic treaty.

My reply

I don't follow much news, even among the so-called medical freedom movement, because so much of it is false information...Given my overall views of the function the WHO fights have in the distraction and diversion system…*See* April 2, 2024 - Help state and federal lawmakers understand the legal predicaments created and maintained by international and domestic public health emergency law…

My guess is that these are just part of that campaign: to get people to be focused on WHO and ineffectual bloviating, and not thinking about or working to help people understand that pandemics are fake and to repeal and nullify the domestic laws that are used to create the simulations and to carry out very real thefts and bodily assaults under cover of those simulations, which were already demonstrated with Covid.

Since the World Health Assembly meeting is at the end of May, this month will be a peak time for the misdirection teams to make PR [public relations] waves.

[198] https://bailiwicknews.substack.com/p/government-by-silent-immobility-an

May 7, 2024 - Bits and pieces about 10 USC 1107a(a) consent waivers, EUA products, BLA products, legalized FDA non-regulation of pharmaceutical manufacturing, and related things.

Correspondence with Bill Marshall of Judicial Watch this morning. FOIA (Freedom of Information Act) officers with US Department of Defense responded to another request Marshall filed on Feb. 1, 2023, seeking:

> Signed, dated documents recording date on which Presidents Trump and/or Biden waived informed consent for military personnel under 10 USC 1107a(a) to receive injections for the stated or intended purpose of preventing infection by the SARS-CoV-2 virus and/or prevention of COVID-19 disease.

10 USC 1107a(a) is a law authorizing the US president to waive the fake informed consent provision of the Emergency Use Authorization law — "option to accept or refuse," 21 USC 360bbb-3(e)(1)(A)(ii) — "if the President determines, in writing, that complying with such requirement is not in the interests of national security."

Congress passed it as another move in the multi-decade tug-of-war between Presidents, Defense Secretaries and FDA lawyers who like to force-poison military personnel using vaccines and other inherently toxic biochemical agents, and the handful of Congress members and federal judges who sometimes feel a little uneasy about providing legislative and judicial cover for those poisoning programs and try to pin the culpability tail on the executive donkey.

See, for example, President Bill Clinton's Executive Order 13139[199] (Sept. 30, 1999) *Administration of Investigational New Drugs to Members of the Armed Forces;* DoD Directive 6200.2[200] (Aug. 1, 2000), *Use of Investigational New Drugs for Force Health Protection*; NDAA FY2004 (PL 108-136, Nov. 24, 2003) at 117 Stat. 1690, *Emergency use products, Waiver by the President; Doe v. Rumsfeld I-III* (2003-2005)*;* and FDA Office of Counterterrorism Policy and Planning, *Guidance: Emergency Use Authorization of Medical Product*s (July 2007):[201] "…informed consent under part 50 of FDA regulations (21 CFR part 50) is not required for administration of an EUA product [and] Congress authorized the President to waive, under certain circumstances, the option for members of the armed services to accept or refuse administration of an EUA product (10 U.S.C. 1107a)."

199 https://www.govinfo.gov/content/pkg/WCPD-1999-10-04/pdf/WCPD-1999-10-04-Pg1875.pdf

200 https://mrdc.health.mil/assets/docs/orp/irbo/11_DOD_6200.2_Use_of_INDs_for_FHP.PDF

201 https://www.fdanews.com/ext/resources/files/archives/e/Emergency-Use-Authorization.pdf

On May 7, 2024, a DoD FOIA officer responded to Marshall's FOIA request:

> …No records were located responsive to your request.
>
> Additionally, please note that the Office of the Under Secretary for Personnel and Readiness noted that on August 23, 2021, US-FDA approved the biologics license application [BLA] for the Pfizer vaccine, which had previously been released under an emergency use authorization (EUA).
>
> According to the Secretary of Defense memo, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," it states that "...Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the FDA...".
>
> 10 USC 1107a(a) requires a Presidential waiver only for products authorized for emergency use and no such waiver would have been necessary to mandate vaccination with a fully licensed vaccine.

Marshall asked for feedback.

My reply:

…DoD is probably correct that neither Trump nor Biden issued waivers under 10 USC 1107a(a).

The fake BLA process was probably conducted mostly to provide cover so that Trump and Biden wouldn't need to issue the waivers.

The dates of mandates, dates of injection, and vaxx lot identification (to identify EUA lots and BLA lots) are complicated.

The DOD Memorandum ordering vaccination was issued August 24, 2021. Some military personnel were injected before that date, and some after. Some believed that there was a physical difference between the EUA lots and the BLA lots, and some believed that there was a legal difference between the EUA lots and the BLA lots.

In truth, neither the EUA product nor the BLA product went through any real FDA manufacturing regulation process — both the EUA process and the BLA process were faked, by FDA, in collaboration with DoD and the manufacturers.

The fake-regulation is legal, under biological product licensing law and under public health emergency law. All biological product licensing and manufacturing in the US, as allegedly supervised by FDA, is faked, and the fake regulation is legal, and has been since before FDA took over biological product regulation from NIH in 1972. The rule-making paper trail is more readily available for the period since 1973.

I have not written much about the BLA process or its application to the Covid vaccines, because after I understood that the EUA was a completely separate track…

- Jan. 31, 2023 - August 2020 - Elizabeth Sadove presentation to FDA-CDC: Regulatory Updates on Use of Medical Countermeasures.
- Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation."

I saw the BLA process as solely a distraction/misdirection campaign, and because I lack the detailed experience with regulatory paperwork and terminology to be able to untangle it properly for general readers.

Sasha Latypova has done some reporting on this. As of June 2023, she regarded the BLA process as a real regulatory process, but not properly used — manipulated for improper, deceptive, "bait-and-switch" purposes.

- June 20, 2023 - Declaration of Peter "Pretzel" Marks[202]

By November 2023, she and I were discussing the fact that the BLA process is also fake, and one of the ways in which it was faked for the Covid-19 vaccines was by citing the alleged "clinical trials" conducted during the EUA process, as the basis for the BLA decision, when in truth, valid clinical trials were never and are never possible under the EUA legal framework, because by statute, use of EUA products "shall not constitute clinical investigation."

That's the legal mechanism that exempts use of EUA products from informed consent, Institutional Review Boards, prescriptions, labeling requirements, non-adulteration rules and all other protections for consumers of drugs, devices and biological products.

- Nov. 4, 2023 - Do C-19 Vax Manufacturers Violate cGxP?[203]
- Nov. 8, 2023 - FDA "Approval" for Covid-19 Vaccines Was Fake - based non-investigational use of a non-experimental unapproved substance (a poison) [204]

The DoD FOIA response would be a good hook for more reporters to do more writing about the FDA's fake regulation of EUA products (as a subcategory of biological products) and fake regulation of the whole class of biological products, to help more people understand the massive fraud under which they consume manufactured products that are presented as FDA-regulated.

202 https://sashalatypova.substack.com/p/declaration-of-peter-pretzel-marks

203 https://sashalatypova.substack.com/p/do-fentanyl-dealers-violate-cgxp

204 https://sashalatypova.substack.com/p/fda-approval-for-covid-19-vaccines

I've been working on a series about non-regulation of biological products for several months (since I realized in December 2023 that *all* biological products are legally regulation-exempt) and the intricacy of the lie structure built since 1973 is kicking my ass.

- Dec. 19, 2023 - Legalized FDA non-regulation of biological products effective May 2, 2019, by Federal Register Final Rule, signed by then-FDA Commissioner Scott Gottlieb
- Jan. 3, 2024 - On the continuing effort to fit a square peg (legalized manufacturing and use of biological weapons) into a round hole (FDA drug, device and biological product regulation).
- March 8, 2024 - Part 1: Mutual Recognition Agreements. First in series on legal links connecting domestic and international non-regulation of non-medicines
- March 12, 2024 - Part 2: Statutory and regulatory definitions for drugs, biological products, and biosimilars
- March 15, 2024 - Part 3: Deregulation of biological product manufacturing, mid-1990s to present
- March 20, 2024 - Part 4: Vaccines have always been heterogeneous mixtures of toxins used to intentionally sicken people and animals
- March 21, 2024 - Part 5: Vaccine and related biological product manufacturing as US government-licensed poison manufacturing Evidence from November 1986 'mandate for safer childhood vaccines' codified at 42 USC 300aa-27, and July 2018 stipulation by HHS.
- April 3, 2024 - Part 6: On why FDA revised written non-rules for non-regulation of biological products to make them more unintelligible, inapplicable and unenforceable since the 1990s.
- April 25, 2024 - Part 7: Terms, phrases and organizations involved in worldwide regulatory and manufacturing deception surrounding vaccines and other biological products.

Related, on “informed consent” and “option to accept or refuse”

- June 14, 2022 - April 4, 2003 - Rep. Henry Waxman questioning FDA Commissioner Mark McClellan about informed consent waivers authorized through Project Bioshield Act.
- July 4, 2022 - Possibilities for proving intent. The work product of attorneys Susan E. Sherman, Wen W. Shen, Dawn Johnsen and the July 6, 2021 Department of Justice legal opinion.
- Dec. 1, 2023 - On 'mandates,' and the irrelevance of informed consent principles in the EUA countermeasures use context.
- Jan. 2, 2023 - Bioweapon prototype deployments, informed consent, targeted enemies, state of war, doctrine of necessity.
- Jan. 31, 2023 - August 2020 - Elizabeth Sadove presentation to FDA-CDC: Regulatory Updates on Use of Medical Countermeasures.
- Aug. 18, 2023 - Bridges v. Houston Methodist Hospital.

May 15, 2024 - Global pandemic preparedness and response provisions already in US domestic law.

I had a phone conversation with a colleague a few days ago, about the absurdity of agitation about the World Health Organization International Health Regulations and proposed pandemic treaty, as expressed recently by US Senators (May 1, 2024 - Sen. Ron Johnson and 48 Republican co-signers' letter to President Biden re World Health Organization[205]) US state Attorneys General (May 8, 2024 - Montana Attorney General Austin Knudsen and 21 other AGs letter to President Biden re World Health Organization[206]) and fake-resistance misdirection agents of the seemingly non-governmental sort.

The agitation is absurd because the main source of World Health Organization IHR amendments, pandemic treaty texts and worldwide fake-pandemic alarmism, simulations, active military operations and behavioral programming is the US government, including the US delegation to the World Health Assembly:

> "….The United States delegation to WHO led the most recent round of amendments, which were submitted by HHS Assistant Secretary Loyce Pace to the United Nations/World Health Organization on Jan. 18, 2022[207]…On May 27, 2022,[208] the World Health Assembly "adopted" the resolution through the consensus process outlined above, which requires no recorded votes, simply the absence of formal objections…By default, any amendments passed by consensus at a WHA meeting become enforceable in all the member-states 24 months later…" (*See* Bailiwick News, April 4, 2023, Government by silent immobility: an effective ruling innovation developed by the globalists, capitalizing on natural human aversion to hard work, conflict and pain[209])

And because the US Congress and President Biden put a slew of global health security provisions into US law — with a $5,000,000,000 appropriation — effective December 2022 (PL 117-263, NDAA FY2023; Senate roll call vote 83-11-6, codified as a statutory note to 22 USC 2151b). *See* Bailiwick, Feb. 23, 2024, What section of the US Code did the Global Health Security and International Pandemic Prevention, Preparedness and Response Act enter after enactment Dec. 23, 2022?

Below is the text of the Global Health Security and International Pandemic Prevention, Preparedness and Response Act, currently in force and funded.

Almost all of the Senators who signed Sen. Ron Johnson's May 1, 2024 letter to President Biden, also voted to pass the Global Health Security and International Pandemic Prevention, Preparedness and Response Act in December 2022.

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[205] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2024.05-senator-letter-who.pdf
[206] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2024.05.08-state-ag-letter-montana-knudsen-to-biden-re-who-ihr-pandemic-treaty.pdf
[207] https://bailiwicknewsarchives.files.wordpress.com/2023/04/2022.01.18-us-loyce-pace-submit-us-proposed-ihr-amendments-to-who.pdf
[208] https://bailiwicknewsarchives.files.wordpress.com/2023/04/2022.05.27-wha-adopts-us-proposed-ihr-amendments.pdf
[209] https://bailiwicknews.substack.com/p/government-by-silent-immobility-an

To the extent Sen. Ron Johnson and his 48 co-signers understand how global and domestic atrocities are enabled by global and domestic pandemic preparedness and response programs and want to stop the atrocities, their time would be better spent introducing, debating, and voting on bills to withdraw the United States from the United Nations (HR 6645[210] and S 3428,[211] which should be amended[212] to include July 28, 1945, Executive F, Ratification of the United Nations Charter[213]) and bills to withdraw the US from the World Health Organization (HR 79,[214] introduced Jan. 2023 in House, stalled in Foreign Affairs committee, with no corresponding Senate bill introduced to date), and to repeal US federal implementing laws. (*See* Bailiwick, Dec. 20, 2023 - Ending National Suicide Act.[215] Draft.[216])

To the extent Attorneys General of American states understand how global and domestic atrocities are enabled by global and domestic pandemic preparedness and response programs and want to stop the atrocities, their time would be better spent repealing their own states' Model State Emergency Health Powers Act provisions, and nullifying US federal implementing laws. (*See* Bailiwick, March 28, 2024 - Repeal state public health emergency, emergency management, and communicable disease control laws.[217] Model act.[218]; Feb. 16, 2024 - State nullification procedure acts.[219]

It is prudent and just to assess the motives and integrity of US Senators, House members, Presidents, presidential candidates, Cabinet secretaries, governors, Attorneys General and state legislators by their observable acts and omissions.

Those who do not work to repeal, nullify and strip funding from pandemic preparedness and response laws and programs, are refusing to do that work because they support the continuing atrocities — faked pandemics, fraudulent diagnostic testing programs, and all-too-real lethal injection/vaccination programs — that are enabled by the laws...

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[210] https://www.congress.gov/bill/118th-congress/house-bill/6645/text
[211] https://www.congress.gov/bill/118th-congress/senate-bill/3428/text
[212] https://bailiwicknews.substack.com/p/on-the-omission-of-the-july-28-1945
[213] https://bailiwicknewsarchives.files.wordpress.com/2024/01/1945.07.28-senate-vote-ratify-un-charter-and-bretton-woods-executive-f.pdf
[214] https://www.congress.gov/bill/118th-congress/house-bill/79/cosponsors?s=4&r=1&q=%7B%22search%22%3A%5B%22HR79%22%5D%7D
[215] https://bailiwicknews.substack.com/p/ending-national-suicide-act
[216] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/12/ending-national-suicide-act-without-links-formatted.pdf
[217] https://bailiwicknews.substack.com/p/repeal-state-public-health-emergency
[218] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/04/2024.03-repeal-state-public-health-emergency-emergency-management-communicable-disease-control-laws.pdf
[219] https://bailiwicknews.substack.com/p/tools-for-illuminating-defying-and-d95

May 17, 2024 - Global Catastrophic Risk Management Act, enacted by Congress and Biden Dec. 2022, codified at 6 USC 821-825.

Following up on May 15, 2024 Bailiwick report, (Global pandemic preparedness and response provisions already in US domestic law) yesterday I was tracking the development of several statutes, while working on a model nullification act for state lawmakers to use to nullify bad federal laws.

I found several relevant provisions of Title 6, Homeland Security, including the Global Catastrophic Risk Management Act, passed as part of the same NDAA through which Congress and President Biden enacted the Global Health Security and International Pandemic Prevention, Preparedness and Response Act.

Before, during and after Hurricane Katrina in August 2005, civic disorder, fear, hunger, homelessness, illness, injury and death were exacerbated by the Department of Homeland Security (DHS) Federal Emergency Management Agency (FEMA) under the direction of President George W. Bush, DHS Secretary Michael Chertoff, and FEMA Administrator Michael Brown.

Congress and President Bush characterized the disaster as the result of not enough centralized power, and used Hurricane Katrina and its aftermath as predicates to establish — in October 2006 — new DHS-FEMA emergency preparedness and response laws, authorities and programs.

- 2006/10/04 - Congress and President Bush passed Department of Homeland Security Appropriations Act of 2007. PL 109-295, 120 Stat 1355.[220] Subtitle C, Sec. 641 established National Preparedness System, codified at 6 USC 741[221] et seq.

Problem-reaction-solution.

Orchestrated, faked or exacerbated, falsely-characterized problem.

Manipulated, society-disordering reaction.

Pre-loaded, geopolitical power-centralizing solution.

*

[220] https://www.congress.gov/109/plaws/publ295/PLAW-109publ295.pdf

[221] https://www.law.cornell.edu/uscode/text/6/chapter-2/subchapter-II/part-A

Title 6, Homeland Security, Chapter 2, National Emergency Management, Subchapter II, Comprehensive Preparedness System:

> Part A—National Preparedness System (§§ 741 – 754) ← Added Oct. 4, 2006
> Part B—Additional Preparedness (§§ 761 – 765) ← Added Oct. 4, 2006
> Part C—Miscellaneous Authorities (§§ 771 – 777) ← Added Oct. 4, 2006
> Part D—Prevention of Fraud, Waste, and Abuse (§§ 791 – 797) ← Added Oct. 4, 2006
> Part E—Authorization of Appropriations (§ 811) ← Added Oct. 4, 2006
> Part F—Global Catastrophic Risk Management (§§ 821 – 825) ← Added Dec. 23, 2022

The DHS Appropriations Act of 2007 (PL 102-295, Oct. 4, 2006) included the "Post-Katrina Emergency Management Reform Act," introducing new or updated legal terms and definitions.

> Catastrophic incident: any natural disaster, act of terrorism, or other man-made disaster that results in extraordinary levels of casualties or damage or disruption severely affecting the population (including mass evacuations), infrastructure, environment, economy, national morale, or government functions in an area.
>
> Emergency management: the governmental function that coordinates and integrates all activities necessary to build, sustain, and improve the capability to prepare for, protect against, respond to, recover from, or mitigate against threatened or actual natural disasters, acts of terrorism, or other man-made disasters

The definition section is followed by sections covering National Emergency Management (6 USC 311 et seq.); establishing a FEMA National Integration Center to centralize planning, chain-of-command, and response activity and to coordinate/subsume state and local authority (6 USC 319); further developing the FEMA National Infrastructure Simulation and Analysis Center set up by the PATRIOT Act in 2001 (6 USC 321); and more.

The DHS Appropriations Act of 2007 also set up a National Preparedness System (6 USC 741 et seq.), to include:

> (b) Components…
>
> > (1) Target capabilities and preparedness priorities;
> > (2) Equipment and training standards;
> > (3) Training and exercises;
> > (4) Comprehensive assessment system;
> > (5) Remedial action management program;
> > (6) Federal response capability inventory;
> > (7) Reporting requirements;
> > (8) Federal preparedness and
>
> (c) National Planning Scenarios, along with provisions establishing coordination of federal, state and local communications and an Emergency Communications Preparedness Center (6 USC 576).

National Planning Scenarios defined:

> …planning scenarios to reflect the relative risk requirements presented by all hazards, including natural disasters, acts of terrorism, and other man-made disasters, in order to provide the foundation for the flexible and adaptive development of target capabilities and the identification of target capability levels to meet the national preparedness goal.

And much more, now in US law from 6 USC 741 to 6 USC 811.

In December 2022, Congress and President Biden added a new Title 6, Homeland Security section — Part F, Global Catastrophic Risk Management[222] — through the Global Catastrophic Risk Management Act, to connect the national emergency management system further centralized in 2006, to an even more centralized global emergency management system.

See NDAA for FY2023.[223] PL 117-263, 136 Stat. 2395. Section 5559, Global Health Security and International Pandemic Prevention, Preparedness and Response Act of 2022 authorized, expanded and funded globalized military-health structure linking US military to global genocide apparatus operating under WHO frameworks, and was codified at 21 USC 2151b, Notes.[224] Section 7301, Global Catastrophic Risk Management Act of 2022, established global emergency management system, and was codified at 6 USC 821[225] et seq.

To be clear, the US Government — specifically the traitorous agents who currently control it through extortion and other financial crimes, and the subversive, disloyal US legislators (Congress) and military personnel (DOD-HHS-DHS) who serve those traitors instead of serving the nation — is a pivotal geopolitical entity preparing, programming, faking, causing and/or deliberately exacerbating sequential and concurrent global catastrophes and also running the global emergency responses.

US Government, United Nations, World Health Organization are three interpenetrating and overlapping public faces, divisions or front organizations serving an overarching, globalist, secular, materialist, technocratic, Satanic geopolitical force.

Foxes, hen-house style. Mob enforcers, protection-racket style. The bear is already in the house,[226] and has been for a very long time.

[222] https://www.law.cornell.edu/uscode/text/6/chapter-2/subchapter-II/part-F
[223] https://www.congress.gov/117/plaws/publ263/PLAW-117publ263.pdf
[224] https://www.law.cornell.edu/uscode/text/22/2151b
[225] https://www.law.cornell.edu/uscode/text/6/821#6
[226] https://naomiwolf.substack.com/p/facing-the-beast/comment/7802768

Full text of the Global Catastrophic Risk Management Act from PL 117-263 is [reprinted in Jan. to June 2024 Bailiwick collection at pp. 333-339.] Highlighting some of the new legal definitions passed into law in December 2022 by Congress and President Biden:

> The term "catastrophic incident"—
>
> (A) means any natural or man-made disaster that results in extraordinary levels of casualties or damage, mass evacuations, or disruption severely affecting the population, infrastructure, environment, economy, national morale, or government functions in an area; and
>
> (B) may include an incident—
>
> (i) with a sustained national impact over a prolonged period of time;
>
> (ii) that may rapidly exceed resources available to State and local government and private sector authorities in the impacted area; or
>
> (iii) that may significantly interrupt governmental operations and emergency services to such an extent that national security could be threatened.
>
> The term "existential risk" means the potential for an outcome that would result in human extinction.
>
> The term "global catastrophic risk" means the risk of events or incidents consequential enough to significantly harm or set back human civilization at the global scale.
>
> The term "global catastrophic and existential threats" means threats that with varying likelihood may produce consequences severe enough to result in systemic failure or destruction of critical infrastructure or significant harm to human civilization. Examples of global catastrophic and existential threats include severe global pandemics, nuclear war, asteroid and comet impacts, supervolcanoes, sudden and severe changes to the climate, and intentional or accidental threats arising from the use and development of emerging technologies.

To emphasize one other point, Global Catastrophic Risk Management annex updates are specifically directed to address:

> Developing international partnerships with allied nations for the provision of relief services and goods. [6 USC 824(a)(4)] and Efforts the Federal Government should undertake and agreements the Federal Government should seek with international allies to enhance the readiness of the United States to provide for the general welfare. [6 USC 824(b)(4)]

Those are Congressional endorsements for things like US-Government-directed UN-WHO International Health Regulations amendments and US-Government-directed UN-WHO pandemic treaties...

May 21, 2024 - There is no legal limit to the amount of so-called contamination that can legally be included in vaccines or any other biological products. Part 8 of series.

(Excerpt)

On Kevin McKernan's latest re contaminants found[227] (by McKernan's lab and other labs) in vaccines:

KW: There is no legal limit to the amount of so-called contamination that can legally be included in Covid-19 vaccines or any other vaccines or biological products. The FDA has no regulatory obligation to enforce compliance with any safety, efficacy or purity standards, and there are no defined safety, efficacy or purity standards to which FDA could enforce compliance, even if FDA inspectors were legally obligated to enforce compliance, which FDA is not obligated to do.

The entire FDA regulatory system pertaining to biological products, including vaccines, is fake: it's intended only to deceive the public into believing that unregulated poisons are regulated medicinal products.

Reply to a comment[228] at one of Sage Hana's recent posts,[229] about mRNA technology having been around since the 1970s, but not used "because of the regulations."

KW: From my findings about the non-regulation/pretend-regulation and non-definition of all biological products including vaccines, going back to 1902 and earlier, but better documented since the 1944 Public Health Service Act, 42 USC 262, and even better documented since the transfer of fake-regulatory functions from NIH to FDA in 1972, I think the statement that they've had the tech for about 50 years is also a mischaracterization. There is no "tech" in the sense of a predictable method to produce measurable, physically/ chemically/pharmacologically identifiable, standardized, pure biological products. All vaccines are heterogenous mixtures of immunotoxic nucleic acids, metals, lipids and other junk, and they're all inherently unstable and inherently destructive to the recipient organism.

The innovation of the post-2020 vaccines, I think, is slightly more effective lipid packaging to get the encased unstable junk into cells better and faster, to better bypass the functional parts of the immune system that can flag and destroy non-self genetic material (xenogeneic/different species, allogeneic/same species, different individual). Maybe they've known about the better lipid packaging since the 1970s, but also were playing the long con and then decided circa 2019 to put the pedal to the floor.

The statutes and regulations were never in the way of putting toxic junk into babies and children and adults. They were always written to make and keep clear the legal path for the junk to get injected, and to make it look to the public like there was a real regulatory process to monitor and control manufacturing and use for safety, efficacy and purity. Which there was not...

227 https://substack.com/@bailiwicknews/note/c-56854218

228 https://sagehana.substack.com/p/the-job-is-to-include-things-like/comment/56810869

229 https://sagehana.substack.com/p/the-job-is-to-include-things-like

May 23, 2024 - Top 10 US federal laws Congress should repeal to end worldwide vaccination, mutilation and killing programs.

Top 10 repealable American federal laws enacted by US Congress and US Presidents, between 1944 and the present, to embed worldwide vaccination, mutilation and killing programs in US domestic federal law, and, through international pharmaceutical-military-weapons-product sales contracts and international mutual recognition agreements pertaining to pharmaceutical non-regulation, to embed the same programs in the national governance and laws of other countries.

1. 42 USC 262 through 263-1 - Regulation of biological products; Enhanced control of dangerous biological agents and toxins; etc. (licensing of biological product manufacturing, including vaccines) ←Enacted by US Congress in 1944.
2. 42 USC 264 through 272 - Quarantine and inspection, regulations to control communicable diseases (foreign, domestic inspection and quarantine provisions; etc.) ←Enacted by US Congress in 1944
3. 50 USC 1511 through 1528 - Chemical and biological warfare program (authorization and funding for chemical and biological weapon research and use on human targets) ← Enacted by US Congress in 1969
4. 42 USC 243 through 247d-12 - Public health service, federal-state cooperation (public health emergencies; vaccination tracking and distribution; liability immunity for vaccine manufacturers and users under emergency declarations; etc.) ← Enacted by US Congress in 1983
5. 42 USC 300aa-1 through 300aa-34 - Vaccines (national vaccination programs; liability immunity for vaccine manufacturers and users under non-emergency conditions; etc.) ←Enacted by US Congress in 1986
6. 21 USC 360bbb through 360bbb-8d - General provisions relating to drugs and devices (emergency use authorization/EUA product manufacturing, distribution; medical countermeasures; etc.) ← Enacted by US Congress in 1997
7. 42 USC 300hh through 300hh-37 - National all-hazards preparedness for public health emergencies (national planning, coordination, chain-of-command, execution for military and medical personnel during declared public health emergencies; etc.) ← Enacted by US Congress 2002
8. 6 USC 104 through 106 - National biodefense strategy (national biodefense strategy; implementation plans; etc.) ← Enacted by US Congress 2016
9. 21 USC 2151b, statutory note, Sec. 5559 through 5566 - Population planning and health programs, international pandemic preparedness. ←Enacted by US Congress in 2022
10. 6 USC 741 through 825 - Comprehensive preparedness system; national preparedness system ←Enacted by US Congress in 2006; global catastrophic risk management. ←Enacted by US Congress in 2022

June 24, 2024 - On misconstruction of EUA countermeasures and vaccines as medicinal products, rather than weapons and poisons, and on legal-judicial system role in sustaining public ignorance and submission.

Some thoughts on lawsuits challenging the practices of administering remdesivir, sedatives, ventilators and other hospital homicide Emergency Use Authorization (EUA) countermeasure products and protocols without obtaining "informed consent" from patients as comprising medical malpractice not subject to PREP Act preemption and defenses (I read another of these complaints this morning.

I hold the view that none of the products classified as "countermeasures" and incorporated into NIH treatment guidelines are intended to help or heal patients.

The products are weapons intended to harm patients, and the people who use them on patients are military contractors engaged in intentional killing.

EUA countermeasures, and routine and EUA vaccines, are chemical and mechanical abortions to kill adults, adolescents, children and babies at any time after birth (and before birth, when given to pregnant women), and they're legalized, just as abortion was legalized nationwide in 1973 through *Roe v. Wade*, and (post-*Dobbs*, 2022) is still legalized in many US states.

So traditional legal principles and precedents about medical treatment, informed consent, medical malpractice and medical product liability are inapplicable.

I also hold the view that *Saldana v. Glenhaven*[230] (cited in many complaints claiming to challenge PREP Act) stands for the proposition that PREP Act is written to drive medical practitioners into criminal activity (intentional battery and homicide) by imposing liability exposure only on practitioners who do not use NIH-CDC-FDA-CMS directed products and protocols [weapons] as directed and incentivized by NIH-CDC-FDA-CMS and hospital administrators, for the purpose of intentionally harming and killing recipients, and PREP Act therefore offers "complete" preemption in the sense that the HHS-Office of General Counsel argues in its legal memos.

These cases may drag on for another 5-10 years, and can be seen as intentional legal-judicial system distractions to allow military-financial-Congressional biological products weapons-systems and covert military-financial-Congressional biological-product warfare to continue under the cover provided by being falsely presented to the public, and widely misconstrued by the public, as medicinal products forming components of health care practice.

I have not written a detailed analysis of *Saldana v. Glenhaven* yet. I mentioned the case in an Oct. 2023 post,[231] as another example of the pattern (legally funneling HCWs into committing otherwise criminal acts by providing indemnification only for the criminal acts HHS-DoD wants to induce them to commit) that also includes *Nowacki v. Gilead*.

[230] https://law.justia.com/cases/federal/appellate-courts/ca9/20-56194/20-56194-2022-02-22.html
[231] https://bailiwicknews.substack.com/p/on-civil-suits-against-pfizer-for

June 27, 2024 - Intentional infliction of harm is not a legitimate government purpose; enabling it is not a permissible legislative object.

New court decisions, new case filings, and other law-related records have come across my path in the last couple of weeks, and readers have requested my analysis of some of them. There are also many filings, decisions and other law-related documents that are not-so-recent...

Generally, I think most of the recently-filed cases are still misfires, because they continue to avoid acknowledging the intentionality of the harms caused by government-directed pandemic preparedness, pandemic response and vaccination programs, and they still include factual history and legal argument sections that reinforce the discernible lies government officials continue to tell.[232]

Government officials — from presidents, presidential candidates, cabinet secretaries, Congress members and federal lawyers and judges, down through state and county officials — are lying about pandemic pathogens, pandemics, pandemic-preparedness-and-response, and the purpose and effect of public health emergency laws. They're lying about diagnostic testing as predicates for medical isolation and treatment programs. They're lying about biological product and vaccine laws, regulations, development, manufacturing, safety and efficacy.

Among public officials, Congress members are best positioned to start cleaning up the corruption of law and public morals. The evil laws were born in the federal legislature, and then used as models for state and international laws and contracts. So Congress is the primary governing institution in which those enabling laws must be eliminated.

Instead, Congress members are conducting misleading investigative hearings and issuing misleading reports in a bid to cover up and evade earthly accountability for their personal participation in evil lawmaking acts, and the resulting ruination of human lives, bodies and souls.

When they're ready to turn things around, they'll introduce bills to repeal the PREP Act and all the other enabling acts, and they'll fight loud and hard for the enactment of those repeals.

Among private lawyers, some of the most prominent knew, long before I knew, about the complete non-validity of biological product and vaccination law. I'm therefore past the point of being able to attribute most of these lawyers' omissions, fact errors and legal argument errors as benign oversights motivated by good-faith efforts to work within a rigged judicial system, retain their law licenses and get some financial compensation for the injured and bereaved, although I understand why the assessments of others may differ from my own.

Whether by public officials or private lawyers, deliberate omissions of knowable and known truths, and deliberate repetition and reinforcement of factual and legal errors lead people astray. They mislead people. They lead individuals and societies into temporal occasions of sin, into commission of criminal acts of self-harm, harm of others, and murder. They lead people away from piety, charity, holiness and eternal salvation.

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[232] *See* Nov. 14, 2022 - Thought-stopping stage sets in legal pleadings

July 2, 2024 - On reading PREP Act declarations as declarations of war issued by treasonous, seditious agents acting in unofficial, personal capacities.

Jeff Childers' analysis of *Trump v. US* and other recent SCOTUS rulings relating to constitutional government, executive legislation, administrative state and presidential exposure to criminal prosecution: July 2, 2024 - Devastating[233]. Note - Linking to Childers' analysis does not equal endorsement of his views or concurrence in his analysis. Childers is addressing some issues that I also study, and therefore his work may be of interest to Bailiwick readers.

July 1, 2024 - SCOTUS decision in *Trump v. US*[234]

> "*Held:* Under our constitutional structure of separated powers, the nature of Presidential power entitles a former President to absolute immunity from criminal prosecution for actions within his conclusive and preclusive constitutional authority. And he is entitled to at least presumptive immunity from prosecution for all his official acts. There is no immunity for unofficial acts."

I'm posting some excerpts from some of my prior writing on these topics...I'm still not aware of any lawyers in the United States (or in any other countries) who are interested in using the legal research Sasha Latypova and I have compiled, or pursuing related legal strategies.

This information is being offered for use by Bailiwick readers making personal and family decisions about government-identified security threats and government-endorsed products and programs, to help more people understand that PREP Act declarations are war declarations that lay out who (public health mercenaries classified as "covered persons") can use which weapons ("covered countermeasures") on which targets under which geopolitical conditions ("category of disease, health condition or threats"), with full immunity from civil and criminal prosecution.

It's important to understand these things, because HHS Secretary Xavier Becerra and his successors, persuasively pretending to exercise federal executive authority in an official capacity to respond to "public health emergencies," will — in coming weeks and months — probably issue more PREP Act declaration extensions.

Under the Notice of [11th] Amendment issued May 11, 2023,[235] Covid PREP declarations are currently scheduled to expire Dec. 31, 2024 and will probably be extended again.

[233] https://www.coffeeandcovid.com/p/devastating-tuesday-july-2-2024-c
[234] https://www.supremecourt.gov/opinions/23pdf/23-939_e2pg.pdf
[235] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/05/2023.05.11-hhs-prep-act-amendment-11-distribution-limitations-time-qualified-persons-category-of-threat-burden-of-seasonal-influenza-88-fr-30769.pdf

HHS Secretary Becerra has already issued and extended PREP Act declarations, for other fake public health threats, including influenza, botulism, anthrax, Zika, nerve agents, and insecticides, all in place through Dec. 31, 2027. *See* Conspiracy Sarah, April 12, 2024 - H5N1 Bird Flu Jab: Accelerated Approval, Immune from Liability, & Already Purchased by US Government[236] *See* also, five Federal Register notices published Dec. 23, 2022, re: nerve agents and insecticides (87 FR 78975); Zika (87 FR 78976); influenza (87 FR 78978); anthrax (87 FR 78981); and botulism (87 FR 78983).

HHS Secretary delegates (FDA Commissioner; FDA Chief Scientist) will probably issue more related Emergency Use Authorization (EUA) Letters of Authorization (LOA), covering more covered countermeasure product classes and specific brand-name products.

Examples: Dec. 11, 2020 LOA for Pfizer; Dec. 18, 2020 LOA for Moderna, 86 FR 5200.[237]

An April 2024 slide deck[238] from a Biopharmaceutical Manufacturing Preparedness Consortium meeting indicates that the product classes currently sponsored, continuously manufactured, and deployed by US government officials and their private sector and academic co-conspirators include diagnostic devices, vaccines, delivery systems, sedatives, paralytics, and neuromuscular blockers.

PREP Act declarations and EUA Letters of Authorization are very helpful tools to quickly identify fake threats to ignore (as promulgated solely to deceive targets and elicit fear and compliance) and malign people and intentionally harmful products to avoid.

[236] https://conspiracysarah.substack.com/p/h5n1-bird-flu-jab-accelerated-approval
[237] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/05/2020.12.11-hhs-fda-hinton-eua-pfizer-eff-2020.12.11-moderna-eff-2020.12.18-dated-2021.01.12-86-fr-5200.pdf
[238] https://www.biomap-consortium.org/wp-content/uploads/2024/04/BioMaP-C-April-2024-Industry-Day-Slide-Final_040424.pdf

July 12, 2024 - Preliminary analysis of Loper v. Raimondo. Congress legalized military and civil administrators overriding US Constitution under self-declared emergency conditions, and Congress can repeal the enabling acts.

A few readers have asked for my views on the US Supreme Court's recent ruling in *Loper Bright Enterprises, et al, v. Raimondo, Secretary of Commerce, et al.*,[239] as overturning the *Chevron v. NRDC* (1984) framework (judicial deference to executive agency interpretation of ambiguous statutory law) and applying the Administrative Procedure Act (APA) of 1946 more fully to judicial review of federal executive agency acts.

From the *Loper* decision syllabus:

> *Held*: The Administrative Procedure Act requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, and courts may not defer to an agency interpretation of the law simply because a statute is ambiguous; *Chevron* is overruled.

Readers asked whether I think the *Loper* decision overturning *Chevron* deference will allow for challenges against agency interpretations of public health emergency laws such as the PREP Act.

I've replied by email to a few readers:

In my opinion (pending further review) the *Loper* decision doesn't help for PREP Act challenges, because *Chevron* and *Loper* are about cases in which Congressional legislative intent is arguably ambiguous. PREP Act and the other chemical and biological warfare enabling acts are clear and unequivocal (not ambiguous) expressions of Congressional intent to block judicial review, and preempt Congressional authority and state and local authority. Again, I need to read the *Loper* decision more carefully to confirm, but that's my initial response.

I have read the *Loper* synopsis but not the whole opinion, and I read the synopsis in the light cast by public health emergency laws enacted by Congress and US Presidents (2002 Public Health Security and Bioterrorism Preparedness and Response Act, 2004 Project Bioshield Act, 2005 PREP Act and many more[240]) and in the light cast by SCOTUS' May 2020 decision in *South Bay Pentecostal Church v. Newsom*, addressing judicial review of federal and state agency acts during declared public health and other national emergencies.

Within that legal context — Congressional acts signed by US presidents, and *South Bay Pentecostal v. Newsom* — I construe SCOTUS' decision in *Loper v. Raimondo* as yet another diversionary maneuver, to steer public scrutiny and legal challenges away from the deliberate complicity of Congress, US Presidents and federal judges in the overthrow of the US Constitution and handover of control of the American government to military and public health civil administrators working within the executive branch.

[239] https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

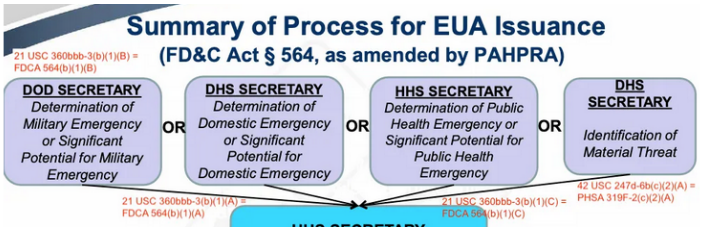
[240] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program

Those civil administrators, exemplified by HHS Secretary Xavier Becerra, Defense Secretary Lloyd Austin and Homeland Security Secretary Alejandro Majorkas (alongside all other cabinet secretaries, deputy secretaries and SES officials[241]) are working for central bankers, United Nations-World Health Organization and related supranational organizations, to conduct fraud-based informational, psychological, biological and chemical war.
Congress members, US Presidents and federal judges have emasculated themselves.

Helping more people understand how and why[242] they've done what they've done, is an important part of challenging Congress and US presidents to reverse the procedure (repeal the enabling acts[243]) and restore constitutional rule of law.

Through the public health emergency laws, Congress and US Presidents have created a legal platform from which, in January 2020, military and civil administrators carried out a coup and assumed semi-overt, semi-covert ruling power in the United States.

Laws enacted by Congress (legislative branch) and signed by US Presidents (executive branch), created triggering "emergency" conditions under which the US Constitution and separation of powers are nullified, and ruling power is automatically concentrated in the hands of the HHS Secretary, Defense Secretary and Homeland Security Secretary (executive branch, military and civil administrative component) upon those secretaries unilaterally and unreviewably declaring that a public health emergency, military emergency, domestic emergency or material threat exists, and extending such declarations in the same unreviewable way.



June 6, 2014 FDA slide deck - *What's new in medical countermeasures science and policy?* Red notes by KW

Key terms Congress and US Presidents have embedded into federal statutory law include "not reviewable" and "committed to agency discretion" which preclude judicial review of agency acts under APA exemptions 5 USC 701(a)(1) and (2).

> 5 USC 701 Application; definitions
>
> (a) This chapter applies, according to the provisions thereof, except to the extent that --
> (1) statutes preclude judicial review; or
> (2) agency action is committed to agency discretion by law.

[241] https://www.opm.gov/policy-data-oversight/senior-executive-service/
[242] https://sashalatypova.substack.com/p/since-1997-20-trillion-has-been-stolen
[243] https://bailiwicknews.substack.com/p/top-10-us-federal-laws-congress-should

Four examples

Congress placed all policy and program decisions about "Expanded access to unapproved therapies and diagnostics" — design, manufacturing, labeling, procurement, distribution and use of intentionally toxic 'medical countermeasures' to injure and kill recipients — under the unilateral, unreviewable control of the HHS Secretary and his or her delegates within HHS (FDA, CDC, NIH) in coordination with counterparts in DoD and DHS, through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

> 21 USC 360bbb-3(i) - Actions committed to agency discretion. Actions under the authority of this section by the Secretary [of Health and Human Services], by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

Congress blocked 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)(7) Judicial review. No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the [HHS] Secretary under this subsection.

Congress preempted all 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)(8) - Preemption of State law. During the effective period of a declaration under subsection (b) [unilateral, unreviewable HHS determination that a disease constitutes a 'public health emergency' combined with declaration recommending manufacture, testing, development, distribution, administration, or use of 'covered countermeasures'], or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act...

Congress narrowly limited obligation for HHS to report to Congress on public health emergency status and medical countermeasures classifications, and provided no authorization for Congress to override HHS declarations, determination, and decisions.

> 42 USC 247d-6d(b)(9), Report to Congress. Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

SCOTUS joined Congress and US Presidents, ratifying the emergency-predicated, military and civil administrators' coup, through its May 2020 decision in *South Bay Pentecostal v. Newsom*.[244]

[244] https://www.supremecourt.gov/opinions/19pdf/19a1044_pok0.pdf

Sept. 20, 2024 - Federal and state poison-legalizing laws and quarantine laws matter more than the UN, WHO and the IHR.

Congress and state legislatures have the political authority to repeal poison-legalizing laws and quarantine laws. Lawmakers choose not to acknowledge their authority and choose not to use it.

Reader questions received a few days ago, about efforts to get Congress to withdraw US from United Nations...

Whether the US government in 1945 validly ratified and signed the UN charter as a treaty, and whether or not Congress repeals one or more of the presumed ratification acts, my view is that the UN and UN-WHO directors (and their non-public handlers) have always been interested in creating redundancy by using international agreements — whether validly ratified or not — as the political basis for obtaining compliance from national lawmakers, and state-level lawmakers within each nation, to install enforceable versions of the terms of the international agreements.

The one-world atheist technocratic bankers' government has no visible law enforcement mechanisms, although they do use the US military through its personnel, weapons and bases all around the world; the Bank for International Settlements and national central banks, through their control of financial transactions and currencies; and the World Trade Organization, through its control of commercial contracts. Those three banker-controlled supranational entities (with a handful of others) enforce the terms of specific commercial contracts such as the Pfizer vaccine supply contracts with national governments around the world.

In other words, it doesn't matter what the UN, WHO or IHR texts say in themselves. They have already been used to generate military and economic momentum (see previous paragraph) and also political momentum for getting Congress and all 50 US states (and other countries' governments) to adopt federal and state laws that are enforceable, including all of the 'public health emergency' preparedness and response laws.

This is the main point on which my work differs from the social, political and economic organizing work of those who refuse to discuss the federal and state laws already on the books.

Their silence on the existing federal and state laws is the basis on which I assess their work as non-credible. They want to keep public attention on largely irrelevant, unenforceable international legal instruments, to keep it away from extremely relevant, enforceable, deceit-, mutilation- and murder-legalizing federal and state kill box statutes, fake-regulations, and case law.

2025

Adoration of the Shepherds. Bartolomé Esteban Murillo

Work published at Substack, 2022-2025. October 2025 version.
Katherine Watt - PO Box 1142 - State College PA 16804

2025

- March 15, 2025 - Congressional elimination of judicial review and preemption of state law to enable interstate trafficking in intentionally harmful 'covered countermeasures.' 42 USC 247d-6d(b)(7) and 42 USC 247d-6d(b)(8)
- March 17, 2025 - Erwin Chemerinsky letter to Senate, Dec. 20, 2005, on unconstitutional PREP Act.
- March 17, 2025 - Senators Kennedy, Biden, Clinton, Byrd, denouncing PREP Act on Dec. 21, 2005, and then committing treason by voting for it the same day. (March 17, 2025)
- March 19, 2025 - On the absence of legal and scientific standards of evidence for public health emergency and emergency countermeasure determinations and declarations by HHS Secretary.
- April 4, 2025 - Repealing PREP Act and terminating HHS Secretary determinations and declarations issued under PREP Act are two different things.
- April 7, 2025 - No one can be found in legal violation of a rule they were never required to comply with, nor can anyone be found to have failed to meet an evidentiary standard they were never required to meet.
- April 21, 2025 - PREP Act Brief: "License to Kill" must be repealed. (Sasha Latypova)
- April 24, 2025 - PREP Act, An act of treason, video discussion. Stephanie Weidle, Sasha Latypova, Katherine Watt. (Transcript excerpts)
- June 2, 2025 - There cannot be product liability exposure for manufacturers of products for which no physical, objective standards exist.
- June 6, 2025 - On whether 'public health emergency of international concern' declarations by WHO Director-General are required to be supported by physical evidence, or subject to fact-finding and evidentiary review
- June 9, 2025 - On whether US-HHS Secretary Alex Azar needed UN-WHO declaration of "public health emergency of international concern" to issue determination that "public health emergency exists" in January 2020.
- June 17, 2025 - No HHS or FDA authority or competency to standardize or regulate vaccine-bottling processes or products; notes on "recall" authority.
- Aug. 19, 2025 - Common law, statutory law and administrative law preclusion of judicial review of government acts allegedly undertaken for disease surveillance and control.
- Sept. 10, 2025 - 42 USC 247d et seq, Public health emergencies, enacted by US Congress through Public Health Improvement Act (2000)
- Sept. 10, 2025 - 21 USC 360bbb-3 [FDCA 564], Authorization for medical products for use in emergencies, enacted by US Congress through NDAA (2003) and Project Bioshield Act (2004)
- Sept. 10, 2025 - 42 USC 247d-6d [PHSA 319F-3] and 42 USC 247d-6e [PHSA 319F-4], Targeted liability protections for pandemic and epidemic products and security countermeasures; Covered countermeasure process, enacted by Congress through PREP Act (2005)

March 15, 2025 - Congressional elimination of judicial review and preemption of state law to enable interstate trafficking in intentionally harmful 'covered countermeasures.'

42 USC 247d-6d(b)(7) and 42 USC 247d-6d(b)(8)

Response I gave to a reader who sent me a link to Ray Flores' recent piece: Legal Opinion - PREP Allows for Two Different Causes of Action.[245]

I think Flores' interpretations of the text of 42 USC 247d-6d and suggested legal strategies are incorrect, false and misleading in several different ways.

My views are based on my reading of the federal PREP Act law and my reading of federal and state court decisions in cases interpreting and applying the PREP Act to covered countermeasure products and to acts of manufacture and use or non-use of such products as committed by manufacturers and health care workers.

For the time being, I'm limiting my comments to pointing again to 42 USC 247d-6d(b)(7) and (b)(8), which preempt all access to state and federal courts for review and overturning of HHS Secretary actions, and preempt all access to state law for review and overturning of any HHS Secretary action pertaining to a covered countermeasure.

> 42 USC 247d-6d(b)(7) - Judicial review. No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the [HHS] Secretary under this subsection.
>
> 42 USC 247d-6d(b)(8) - Preemption of State law. During the effective period of a declaration under subsection (b) [unilateral, unreviewable HHS determination that a disease constitutes a 'public health emergency' combined with declaration recommending manufacture, testing, development, distribution, administration, or use of 'covered countermeasures'], or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act...

[245] https://rayfloreslaw.substack.com/p/legal-opinion-prep-allows-for-two

Under these conditions, which have been in place without interruption since January 2020 for Covid-19 countermeasures and remain in place (current amendment extends these conditions through Dec. 31, 2029[246]), the only inquiries any state or federal court will make, upon receiving a civil or criminal case involving a *covered countermeasure* and manufacture or use of it by a *covered person* or *qualified person* or *program planner*, all classified as such by unilateral HHS Secretary action without any requirement for evidence or any opportunity for evidentiary review or overturning, are whether the item is or is not classified as a covered countermeasure; whether the person did or did not make or use the product; and whether the person is or is not classified as a covered person, qualified person or program planner, or reasonably believed him or herself to be a covered person or qualified person or program planner.

If the product is classified as a covered countermeasure and was made or used by a covered person, qualified person or program planner, then the inquiry stops there and the case is dismissed, because the state or federal court has no jurisdiction, because Congress stripped jurisdiction by statute.

There is no further evidentiary review as to the product's development, production and use, the harmfulness of its contents, or the knowledge, intent or culpability of the covered person or qualified person who made or used it.

It's just a legally-authorized kill product, used by a legally-authorized killer.

If it's not a covered countermeasure, then the case might proceed to further discovery or evidentiary review.

Under HHS Secretary PREP Act actions, all Covid products are covered countermeasures, and all the people who make and use them are qualified persons or covered persons.

The PREP Act and related laws are written to make a legal box in which legalized mutilation and killing can take place, by precluding all possibility of authentic, rigorous, adversarial, public evidentiary review in scientific and judicial venues, because the scientific and legal evidence supporting covered countermeasures, vaccines and vaccination programs cannot withstand any scrutiny at all without collapsing.

Upon scrutiny, the products are instantly exposed as intentionally harmful, their development and promotion instantly exposed as intentionally fraudulent, and the laws enabling their manufacture, trafficking and use are instantly exposed as immoral, treasonous and void from the beginning.

For as long as Congress, US Presidents, HHS secretaries, drug manufacturers, drug regulators, judges, lawyers, physicians, pharmacists and nurses can forestall evidentiary review, they can and will continue legally lying to legally induce homicidal and suicidal behavior, including acts of vaccine administration, and acts of submission to vaccination.

[246] https://www.govinfo.gov/content/pkg/FR-2024-12-11/pdf/2024-29108.pdf

March 17, 2025 - Erwin Chemerinsky letter to Senate, Dec. 20, 2005, on unconstitutional PREP Act.

Erwin Chemerinsky[247] submitted a letter, dated Dec. 20, 2005, to Senator Patrick Leahy, which was entered into the Congressional Record dated Dec. 21, 2005.

- 2005.12.21 Congressional Record PREP Act discussion S14233 to 14240[248]
- 2005.12.21 Congressional Record PREP Act discussion S14241 to 14254[249] Chemerinsky
- 2005.12.21 PREP Act Senate Roll Call[250]
- 2005.12.30 Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act - PL 109-148, 119 Stat. 2818. Synopsis from Bailiwick American Domestic Bioterrorism Program timeline: "…Division C at last 14 pages: Public Readiness and Emergency Preparedness (PREP) Act. Amended Public Health Service Act. 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." Codified at 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…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…"

Sen. Leahy voted later the same day (Dec. 21, 2005) with 92 other senators to commit treason and pass the military funding and hurricane recovery bill to which the PREP Act had been attached.

<u>Senator Leahy introducing Chemerinsky's letter</u>

Mr. LEAHY. Late Sunday night [Dec. 18, 2005], Republican leadership slipped language [PREP Act] into a lengthy appropriations conference report that will immunize drug companies against reckless misconduct and will impede our ability to protect our citizens from the threatened avian flu pandemic. This provision is a gift to the drug manufacturers and will likely have a devastating effect on our ability to protect our constituents.

[247] https://en.wikipedia.org/wiki/Erwin_Chemerinsky
[248] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/03/2005.12.21-congressional-record-prep-act-discussion-s14233-to-14240.pdf
[249] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/03/2005.12.21-congressional-record-prep-act-discussion-s14241-to-14254-chemerinsky.pdf
[250] https://bailiwicknewsarchives.wordpress.com/treason-evidence/

Under the guise of a threatened pandemic, this legislation goes far beyond the scope of vaccine preparedness and includes language that is far more sweeping than any language previously passed by the House or the Senate. Instead of focusing on protecting American families from avian flu or ensuring that victims of any untested vaccine will be compensated for their injuries, the provision simply shields drug companies from any culpability for injuries caused by its actions. The scope of this immunity is so expansive that once the Secretary of Health and Human Services has declared a public health emergency even for a future threat, drug companies would not be held accountable for any injuries or deaths caused by the drugs they manufacture, including drugs that are not specifically used in a pandemic context. This is disgraceful and will deter Americans from taking vaccines and drugs if we ever experience a health crisis.

The only exception to the broad immunity given to drug companies in this proposal is the possibility that a victim could prove that the company acted with ''willful misconduct.'' Knowingly committing health violations would not even suffice to state a claim. Knowing violations as well as gross negligence would be immunized from accountability. Even if the drug company acted with the intent to harm people, it would nevertheless be immune from criminal conduct unless the Attorney General or Secretary of Health and Human Services initiates an enforcement action against a drug company that is still pending at the time a personal claim is filed. That is unbelievable.

I question whether such a role for the Secretary of HHS is even constitutional. Since when do we in Congress allow a political appointee of the administration to determine when, and if, someone injured by willful misconduct can be compensated for their injuries?

Professor Erwin Chemerinsky sent a letter yesterday that outlines his concerns regarding the constitutionality of the provision and I ask that his letter be made part of the [Congressional] Record.

Chemerinsky's letter, recorded at S. 14247

I understand that the Congress is considering legislation that has been denominated as the ''Public Readiness and Emergency Preparedness Act.'' This legislation would give the Secretary of Health and Human Services extraordinary authority to designate a threat or potential threat to health as constituting a public health emergency and authorizing the design, development, and implementation of countermeasures, while providing total immunity for liability to all those involved in its development and administration.

In addition to according unfettered discretion to the Secretary to grant complete immunity from liability, the bill also deprives all courts of jurisdiction to review those decisions. Sec. [(b)(7).] I write to alert the Congress to the serious constitutional issues that the legislation raises.

First, the bill is of questionable constitutionality because of its broad, unfettered delegation of legislative power by Congress to the executive branch of government. Under the nondelegation doctrine, Congress may provide another branch of government with authority over a subject matter, but ''cannot delegate any part of its legislative power except under the limitation of a prescribed standard.'' *United States v. Chicago, M., St. P. & P.R. Co.,* 282 U.S. 311, 324 (1931).

Recently, the Supreme Court endorsed Chief Justice Taft's description of the doctrine: ''the Constitution permits only those delegations where Congress 'shall lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.''' *Clinton v. City of New York,* 524 U.S. 417, 484 (1998)(emphasis in original), quoting *J.W. Hampton, Jr., & Co. v. United States,* 276 U.S. 394, 409 (1928).

The breadth of authority granted the Secretary without workable guidelines from Congress appears to be the type of ''delegation running riot'' that grants the Secretary a ''roving commission to inquire into evils and upon discovery correct them'' of the type condemned by Justice Cardozo in *A.L.A. Schechter Poultry Corp. v. United States,* 295 U.S. 495, 553 (1935)(Cardozo, J., concurring).

Second, the bill raises important federalism issues because it sets up an odd form of federal preemption of state law. All relevant state laws are preempted. Sec. [(b)(8)]. However, for the extremely narrow instance of willful (knowing) misconduct by someone in the stream of commerce for a countermeasure, the bill establishes that the substantive law is the law of the state where the injury occurred, unless preempted. Sec. (e)(2).

The sponsors appear to be trying to have it both ways, which may not be constitutionally possible. The bill anticipates what is called express preemption, because the scope of any permissible lawsuits is changed from a state-based to a federally based cause of action. See *Beneficial Nat'l Bank v. Anderson,* 539 U.S. 1, 8 (2003).

Usually, that type of ''unusually 'powerful''' preemptive statute provides a remedy for any plaintiff's claim to the exclusion of state remedies. *Id.* at 7 (citation omitted). Here, rather than displace state law in such instances, the bill adopts the different individual laws of the various states, but amends them to include a willful misconduct standard that can only be invoked if the Secretary or Attorney General initiates an enforcement action against those involved in the countermeasure and that action is either pending at the time a claim is filed or concluded with some form of punishment ordered.

Such a provision raises two important constitutional concerns. One problem is that this hybrid form of preemption looks less like an attempt to create a federal cause of action than an direct attempt by Congress to amend state law in violation of *Erie Railroad Co.* v. *Tompkins*, 304 U.S. 64 (1938) and basic principles of federalism. Although Congress may preempt state law under the Supremacy Clause by creating a different and separate federal rule, see *Crosby* v. *Nat'l Foreign Trade Counc.*, 530 U.S. 363, 372 (2000), it may not directly alter, amend, or negate the content of state law as state law. That power, the Erie Court declared, ''reserved by the Constitution to the several States.'' 304 U.S. at 80.

It becomes clear that the bill attempts to amend state law, rather than preempt it with a federal alternative, when one realizes that States will retain the power to enact new applicable laws or amend existing ones with a federal overlay that such an action may only be commenced in light of a federal enforcement action and can only succeed when willful misconduct exists. The type of back and forth authority between the federal and state governments authorized by the bill fails to constitute a form of constitutionally authorized preemption.

The other problem with this provision is that the unfettered and unreviewable discretion accorded the Secretary or Attorney General to prosecute an enforcement action as a prerequisite for any action for willful misconduct violates the constitutional guarantee of access to justice, secured under both the First Amendment's Petition Clause and the Fifth Amendment's Due Process Clause. See *Christopher* v. *Harbury*, 536 U.S. 403, 415 n.12 (2002).

In fact, the Court has repeatedly recognized that ''the right of access to the courts is an aspect of the First Amendment right to petition the Government for redress of grievances.'' *Bill Johnson's Restaurants* v. *NLRB*, 461 U.S. 731, 741 (1983), citing *California Motor Transport Co*. v. *Trucking Unlimited*, 404 U.S. 508, 510 (1972).

First Amendment rights, the Supreme Court has said in a long line of precedent, cannot be dependent on the ''unbridled discretion'' of government officials or agencies. See, e.g., *City of Lakewood* v. *Plain Dealer Pub. Co*., 486 U.S. 750, 757 (1988). At the same time, the Due Process Clause guarantees a claimant an opportunity to be heard ''at a meaningful time and in a meaningful manner.'' *Armstrong* v. *Manzo*, 380 U.S. 545, 552 (1965).

The obstacles placed before a claimant, including the insuperable one of inaction by the Secretary or Attorney General, raise significant due process issues. The Supreme Court has recognized that official inaction cannot prevent a claimant from being able to go forth with a legitimate lawsuit. See *Logan* v. *Zimmerman Brush Co*., 455 U.S. 422 (1982). The proposed bill seems to reverse that constitutional imperative.

Third, the complete preclusion of judicial review raises serious constitutional issues. The Act, through Sec. 319F–3(b)(7), expressly abolishes judicial review of the Secretary's actions, ordaining that ''[n]o court of the United States, or of any State, shall have subject matter jurisdiction,'' i.e., the power, ''to review . . . any action of the Secretary regarding'' the declaration of emergencies, as well as the determination of which diseases or threats to health are covered, which individual citizens are protected, which geographic areas are covered, when an emergency begins, how long it lasts, which state laws shall be preempted, and when or if he shall report to Congress .

The United States Supreme Court has repeatedly stressed that the preclusion of all judicial review raises ''serious questions'' concerning separation of powers and due process of law. See, e.g., *Johnson* v. *Robison*, 415 U.S. 361 (1974); see also, *Oestereich* v. *Selective Service System Local Board No. 14*, 393 U.S. 233 (1968); *McNary* v. *Haitian Refugee Center, Inc*., 498 U.S. 479 (1991); *Reno* v. *Catholic Social Services*, 509 U.S. 43 (1993).

Judicial review of government actions has long regarded as ''an important part of our constitutional tradition'' and an indispensable feature of that system, *Lehnhausen* v. *Lake Shore Auto Parts Co*., 410 U.S. 356, 365 (1973).

The serious constitutional issues raised by this legislation deserve a full airing and counsels against any rush to judgment by the Congress. Whatever the merits of the bill's purposes, they may only be accomplished by consideration that assures its constitutionality.

March 17, 2025 - Senators Kennedy, Biden, Clinton, Byrd, denouncing PREP Act on Dec. 21, 2005, and then committing treason by voting for it the same day.

Senator Edward Kennedy:

…Over these last several months in the Senate we have addressed the issue of a potential epidemic, the pandemic flu. There have been two areas of leadership. One has been in our [Health, Education, Labor and Pensions] HELP Committee under the chairmanship of Senator Enzi and Senator Burr, where we have tried to work out a whole approach to deal with the area of epidemics and bioterrorist attacks, and another with the leadership of Senator Harkin, who had asked that we commit some $8 billion to be able to purchase vaccines and also antiviral drugs for influenza.

I attended the NIH announcement by the President of the United States when he actually requested $7.1 billion to prepare for a flu pandemic. Those funds were going to be used for public health, first of all, to be able to detect flu outbreaks overseas; secondly, to be able to detect them here at home; then to be able to build containment capacities, what we call ''surge'' capacity; and, also to have a generously funded vaccine program, and also an antiviral program.

That is really where we were before the Defense appropriations bill.

A number of us on the HELP Committee had a series of negotiations to try to make a bipartisan recommendation to the Senate. We did so on pensions, on higher education, on work-force, and on Head Start. We were able to do so in a number of different areas. And we were moving ahead toward making a recommendation in issues related to the purchase of vaccines and antivirals. There are two important issues to consider with the purchase of pandemic influenza vaccine and antivirals. One is the danger to an individual that is going to take those vaccines or antivirals; and the other is the risk those dangers raise for the companies that produce them. One is the compensation issue, and the other is the liability issue.

We have dealt with these issues on several occasions. We dealt with them with respect to the swine flu. We dealt with these issues with smallpox. We dealt with these issues for childhood vaccines.

One thing we know from experience is, if you do not have an adequate compensation program, no matter how much money you put in for the purchase of vaccines or of antivirals, the program is not going to work. There has to be an assurance that, if first responders and others are going to go out there and take their chance with these new vaccines or other drugs, that if they become grievously ill or sick or even die there will be some compensation for them and for their families for lost wages and medical costs and the like. And there has to be the assurance to the first responders and others that those vaccines are not going to be produced negligently. Otherwise, they will not take the risk of using the vaccines or drugs. That is the framework.

We have to ask ourselves, for the liability and compensation provisions that have been put in the Defense appropriations bill, how do they line up with what has been successful in the past, with bipartisan efforts? These provisions fail in every respect of the word.

First, there is a compensation program that is not funded. It is not funded. It will depend upon future appropriations. If you want to buy a pig in a poke, buy that particular provision. All you have to do is ask my friend from Utah, Senator Hatch, how we have funded the compensation program for the downwinders. Over a long period of time, we did not have the required payments for them, when we know, as a direct result of governmental action, we adversely affected tens, even hundreds, of thousands of downwinders in the State of Utah and in the West more broadly. We have not measured up to our responsibilities to them, and the compensation program before us now is no more adequate. And as a consequence, this compensation program is not going to work.

Not only that, what have we done with regard to the manufacturers? What kind of immunity have we given to them? It's really extraordinarily broad, effectively complete. What they call the ''bad actor'' provision describes the circumstances in which the immunity from liability fails. And it's really very narrow, because a company's actions have to meet a very narrow definition of willful misconduct.

Page 12 of this 40-page liability section says in order to have any kind of liability, you have to have willful misconduct. This is an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

As if that isn't clear, and narrow, enough, on the same page, underneath this language, is a rule of construction. This rule says that this language establishes a standard for liability more stringent than a standard of negligence in any form or recklessness. So companies are not deterred from acting recklessly, or with gross negligence.

Now that is pretty narrow, but apparently it isn't narrow enough. Right here on page 12, it says that the Secretary of Health and Human Services, in consultation with the Attorney General, must issue regulations that further restrict the scope of actions or omissions that may qualify as willful misconduct.

So ''willful misconduct,'' which should just mean intentional, isn't good enough.

Well, at least we have solved that, right, to make it as narrow as possible? Wrong. Go down to the standard of evidence. The bill changes the standard of evidence in the various trials, to ''clear and convincing evidence.'' That is at the bottom of page 13.

The bill defines a very narrow standard of willful misconduct, and it sets a very high standard of evidence. Shouldn't that be enough? Wrong. You don't have a case against a company under these provisions unless the FDA begins an enforcement case against that company. So if FDA goes ahead and begins the case, you have a chance, right? Wrong again. FDA has to bring it and conclude it successfully before you have any right to proceed with your case.

A person might think, I am not very satisfied with how this liability provision has worked, maybe I will appeal to the courts of this country, right? Wrong. There is absolutely no, no, no, no judicial review when the Secretary of Health and Human Services grants a company immunity by issuing a declaration. No judicial review of that. And there is no judicial review of FDA's decision not to bring an enforcement action. So it is whatever the administration says, whatever the Secretary

says, whatever the head of the FDA says, with changed and gimmick rules. This is a sham. There is no possibility of liability here.

Now, we would say, OK, this is bad, but this liability protection is limited to just a few products, right, products that few of us will ever have to use? It actually applies to products—vaccines, drugs, diagnostic tests—for epidemics. We rarely have to worry about epidemics, right? Well, who defines ''epidemics''? It is rather interesting who defines epidemics. Senator Domenici says diabetes is an epidemic. Senator Frist himself says meth abuse is an epidemic. Bill Frist himself said obesity is an epidemic. Senator Bond says arthritis is an epidemic.

This week in Newsweek Magazine, the Secretary of Health and Human Services, who is going to enforce this provision, says this: "We're seeing an epidemic of chronic diseases. Obesity is just one example."

So how many diseases are going to be considered epidemics? A lot, perhaps, but at least we say that is all right, because it is just going to apply to drugs for that particular epidemic disease, right? Wrong again. This provides the same kind of liability protections for any of the drugs or anything else that deals with the side effects of the products for that epidemic disease.

My goodness. Generally around here we measure who the winners are and who the losers are. And we have seen over the last year and a half how the drug companies come out on top, time and time and time and time again. But never, never, never, ever, ever like they have with this sweetheart deal that was stuck into this conference report after the assurances had been given to the conferees that there were no provisions in it with regard to liability.

The Medicare drug law made it illegal for the Government to negotiate prescription drug discounts for seniors. They do it in the VA system, and drug prices for the VA are lower. But we weren't able to permit the government to negotiate drug prices for seniors. The Republican Congress blocked legislation to allow importation of safe and less expensive drugs.

And now we find in this biodefense and pandemic flu provision liability shields for companies that make dangerous drugs, with no compensation for injured patients.

That is a scandal. It has no business being in this bill. The Judiciary Committee requested an opportunity to examine it. It was rejected. We have had no hearings on this particular provision. It is the wrong thing to include in this legislation.

Let me share what one of our colleagues has said about childhood obesity:

The responsibility for this growing epidemic rests with us—the American consumer. We need to get serious about fighting fat.

Let me cite you the language of the provision, the broad definition on page 31 of what gets liability protections under this bill. It says: ''Qualified pandemic or epidemic product'' means any drug, biological product, any device to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit harm from the pandemic or epidemic. And the term includes not only those products, but any other product, any other product that is produced to deal with the side effects of those products.

This is a scandal. It is a giveaway. It is outrageous. It is rare, if ever, that we give this kind of privileged status to any industry in the country, and give this kind of authority and power solely to one branch of the Government. There is no second guessing. There is no judicial review. There is no further involvement of the Congress. That is basically and fundamentally wrong and we are asking and committing $3.7 billion to go down this road. It is outrageous and it is wrong.

I am sure that as soon as the Secretary of Health and Human Services issues what is called a declaration for a pandemic or epidemic to give immunity from liability to vaccines or other products, there is going to be a charge to the courts. The constitutionality of this provision is going to go into the Federal district courts and the circuit courts of appeal.

Included in the [Congressional] Record is legal authority that I believe shows that this provision, the way it is drafted, is absolutely unconstitutional because of the indefiniteness of the criteria under which the executive branch makes decisions and because there is the real possibility and likelihood of serious injury to individuals without any right to go to court or for judicial review of declarations.

This provision is going to be challenged along the way. We want to tell those in the bio industry—and they are healthy in my State and I have worked with them—if you want to work with us to get an effective compensation program, as we did in the past with smallpox or childhood vaccines, if you want to get an effective provision to deal with liability, one that is responsible and that responsible drug manufacturers will welcome, then we are more than willing to welcome you and to work with you.

But I think we can be certain that this provision will not be effective, and it is misleading the American people to say we are making a downpayment in the development of vaccines for the reasons I have mentioned this evening.

Slipping a provision into a major spending bill late at night at the end of Congressional session is a trick to shield from public debate a provision that is so wrongheaded that it would never stand public scrutiny.

The Republican congressional leadership has snuck yet another special favor to drug companies into the defense appropriations bill.

It is an outrageous provision that has nothing to do with protecting our troops, and it should be dropped from the bill.

This provision allows drug companies to flagrantly disregard basic safety measures in making a broad range of drugs or vaccines, while giving patients who are injured by shoddy products only an empty promise of compensation.

It is cynical to claim that this is what is needed to deal with avian flu.

Drug industry advocates will say that this debate is about trial lawyers, and we have heard phrases like ''jack- pot justice'' and ''runaway juries,'' and tales of endless lawsuits against the firms that make the vaccines. But that couldn't be further from the truth: Senator Dodd and I offered a plan

that included important legal protections for drug companies that make experimental flu vaccines and other drugs needed to respond to a pandemic or a bioterrorism attack as well as a compensation program modeled after the Vaccine Injury Compensation Program that already works well for childhood vaccines.

Our proposal follows the successful examples of the past. For swine flu, for the smallpox vaccine and for childhood vaccines, the Government has set up a way to compensate the injured. Whenever Congress has provided an alternative to liability in the past, there has always been an assured means for patients to receive compensation.

The current proposal violates that past practice.

It twists and turns the law to stack the deck against patients, and abrogates basic principles of judicial review. It is no wonder the provision's authors hid it from public debate and didn't let the Senate Judiciary Committee even look at the proposal before it was jammed into the massive conference report.

If they had allowed our Judiciary Committee to examine this proposal, we would have quickly seen its constitutional flaws. I received a detailed analysis of this provision from Professor Erwin Chemerinsky, who is the Alston and Bird Professor of Law and Political Science at the Duke University School of Law.

According to his analysis, the provision gives the Secretary of HHS ''unfettered discretion . . . to grant complete immunity from liability'' while also ''depriving all courts of jurisdiction to review those decisions…''

Senator Joseph Biden:

Mr. BIDEN. …I rise to express my surprise and deep-seated opposition to the so-called Public Readiness and Emergency Preparedness Act, which is included in the Defense Department Appropriations bill.

This provision would give the Secretary of Health and Human Services authority to provide almost total immunity from liability to the makers of almost any drug, and to those who administer it.

While the measure's proponents portray it as a simple tool to make sure we have sufficient vaccine available in the case of an avian flu pandemic, the actual language of the provision is far broader than that, and it therefore poses a danger to all Americans.

The actual provision permits immunity for the makers of virtually any drug or medical treatment. All the secretary need do is declare that it is a ''countermeasure'' used to fight an epidemic. One solitary person gets to decide what is a countermeasure and what is an epidemic. There is nothing to prevent the declaration of immunity for, say, Tylenol. There is nothing to prevent a declaration that, say, arthritis is an epidemic.

What's more, this is no typical grant of immunity. No, the breadth of this provision is staggering. A drug maker can be grossly negligent in making or distributing a drug, and still escape liability. It can even make that drug with wanton recklessness and escape scot-free after harming thousands of people.

In fact, under this provision, the only way a victim could still recover compensation from a drug maker for a dangerous drug or vaccine would be to prove ''willful misconduct,'' and then only by ''clear and convincing evidence.'' What this means is that, for a victim to be able to be compensated by the company that harmed him, he must prove that they committed a crime...

Is this the sort of justice system that Americans desire?

The answer to this question seems clear from the way this provision was inserted in the larger bill. No hearings were held on this language; no Committee vote was taken; no bill passed the House or the Senate. Not even the House and Senate conferees had a chance to give input on this provision. Indeed, I'm told it was inserted in the dead of night, after conferees had al- ready signed the conference report!

Perhaps the folks who secretly inserted this provision in the dead of night knew that it was overly broad, as I've discussed; perhaps they knew that it was constitutionally suspect, as has been noted by at least one prominent law professor; or perhaps they just knew that, if this provision ever saw the light of day, the American people would not stand for such secrecy and injustice.

This should not be how we conduct the business of the American people, and we will all suffer if this provision is permitted to go forward.

<u>Senator Hillary Clinton:</u>

I would like to take this opportunity to object to insertion of a provision in the Department of Defense appropriations bill that would provide sweeping immunity protections to pharmaceutical manufacturers. I know that this provision is being billed as a simple liability protection to help those who would manufacture avian flu vaccine, but it is nothing of the sort. I support limited liability protections for manufacturers to help cover their risks in developing products that our Nation will need in case of emergency. However, this provision would grant immunity to all claims of loss, including death and disability, for a broad range of products, including any drug that the Secretary designated as one that would limit the harm caused by a pandemic—a definition so broad as to encompass nearly any drug.

This immunity is not subject to judicial review. It preempts any State laws that provide different liability protections or that may provide stronger consumer safety protections for pharmaceutical products. In fact, the only exception to this immunity is for actions of ''willful misconduct,'' which is so narrowly defined that it would only apply to cases where a company intentionally set out ''to achieve a wrongful purpose . . . in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.''

The provision requires the Secretary and the Attorney General to narrow the scope of willful misconduct even further and states that for any FDA-approved product, willful misconduct will not apply unless the Government is already taking action against the manufacturer for such misconduct.

If the Government is providing complete immunity to manufacturers, how are those who may be injured to seek compensation in case of injury? This provision sets up a ''Covered Countermeasure Process Fund,'' but fails to provide any money for this fund. We all recognize that in a public health emergency, we may need to seek whatever protections we can find to prevent widespread death and disease—but those who are asked to take these products are told that if they are injured, their only recourse is to seek compensation from a fund which currently has no money to award.

I am also gravely concerned by the fact that this provision was included in the appropriations bill without following the process for passing legislation used by this Chamber. This authorizing — authorizing, not appropriating — language was never considered, let alone agreed to by the Senate. It was never agreed to by the HELP or Judiciary Committees, which have jurisdiction over this matter. It is a mockery of the legislative process. I believe that the American people are ill-served by Congress when controversial and potentially harmful provisions can simply be inserted without undergoing the open deliberations and debate that are fundamental to the democratic process and are designed to protect our citizens from special interests and back-room dealings. This provision should be stripped from the bill.

<u>Senator Robert Byrd:</u>

…I continue to have serious concerns about the avian flu-related liability provisions that were slipped into the conference report without debate. These liability provisions did not appear in either the House- or the Senate-passed bill. These provisions were not in the materials presented to the conference committee during its deliberations. It was not until the dead of night on this past Sunday, after signatures had already been collected on the conference re- port, that the Republican majority slipped these provisions into the bill before the Senate today. What an insult to the legislative process.

It makes sense for Congress to take steps to encourage companies to develop and manufacture lifesaving flu vaccines. Manufacturers and health professionals acting in good faith to protect the public health, by developing and distributing critical vaccines, should not be unfairly penalized for their efforts to protect the American people from the horrors of a pandemic disease.

However, our country has a moral obligation to look out for those who may become seriously ill as a result of these vaccines. We are talking about the lives of real American people. There ought to be compensation available to those persons who may suffer adverse effects from these kinds of vaccines.

But the liability amendment slipped into the bill does not contain any meaningful provisions establishing a fair compensation system to protect vaccine recipients. Americans who pull up their sleeves to receive an emergency flu vaccine must be provided with some assurance that they would not face economic catastrophe should they be harmed.

March 19, 2025 - On the absence of legal and scientific standards of evidence for public health emergency and emergency countermeasure determinations and declarations by HHS Secretary.

Jessica Hockett responding to *Erwin Chemerinsky letter to Senate, Dec. 20, 2005, on unconstitutional PREP Act*

> I find the timing of this and connection to hurricane (Katrina) recovery incredibly interesting and not-insignificant. There are numerous connections between Katrina (2005) and the initial COVID event (2020).
>
> Needless to say, Hurricanes "hit."
>
> Viruses do not.

KW: To some extent hurricanes "hit." But also, apparently natural disasters are also manipulated to make them more disastrous. For example, by demolishing levees. Orchestrated, unilaterally-declared "Public health emergencies" of all sorts — hurricanes, pandemics, others — are facilitated by the same sets of laws. And each event is used to drive the Congressional passage of the next legal instruments to concentrate power and wealth even more.

JH: Yes, I agree 100%. TPTB 'need' these disasters and emergencies for many evil reasons and they are, indeed, orchestrated and coordinated - including between countries.

Tangent - I know you are very busy, but I am curious about how you would characterize the "15 Days to Slow the Spread" decree from a legal standpoint. I hold certain views about it as an instrument of propaganda but, as I said here,[251] "The legality of such a decree—how it falls within the bounds of executive power—and the federal government's ability to declare a threat without demonstrating its existence before taking emergency action have never been fully explained."

KW: Very briefly, my understanding is that the legality is based in the absence of any legal requirement to demonstrate, with material evidence, the existence of anything.

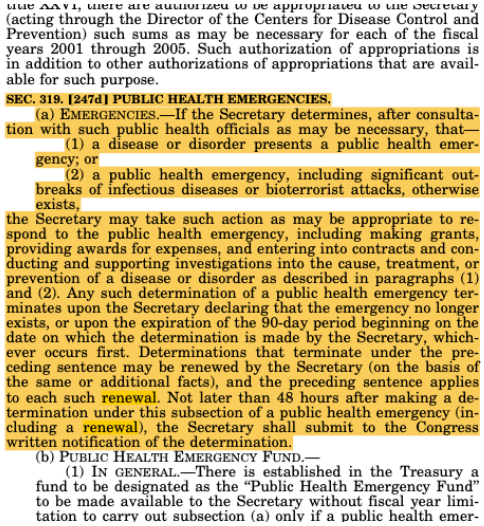
The wording of the PHE laws is such that simple statements, by the HHS Secretary, that a threat "exists," or might exist in future, made without any testable factual claims, are legally sufficient. There is no evidence required. It's just emergency-by-unilateral-declarations and determinations. And that's also why the laws are specifically written to preclude evidentiary testing by courts or Congress, and to make it so that the only way that a threat can stop existing, is if the HHS secretary says it doesn't exist anymore.

There's no legal requirement to produce any evidence to support the declaration that something exists, so there's no evidentiary standard that an HHS secretary can be challenged for not having met. HHS secretary could say that unicorns exist, and pose a threat, and that would be enough.

[251] https://www.woodhouse76.com/p/16-march-2020-15-days-to-slow-the

It's very difficult to convey that the non-presence of provisions in the laws and the presence of provisions blocking judicial review and Congressional oversight, are more important than the provisions that are in the laws.

It's a shell game con or illusion in which there's nothing under the cups at all, and no requirement that there be anything under the cups, and no opportunity for anyone to lift up the cups and see that there's nothing under them.



title XXVI, there are authorized to be appropriated to the Secretary (acting through the Director of the Centers for Disease Control and Prevention) such sums as may be necessary for each of the fiscal years 2001 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for such purpose.

SEC. 319. [247d] PUBLIC HEALTH EMERGENCIES.

(a) EMERGENCIES.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

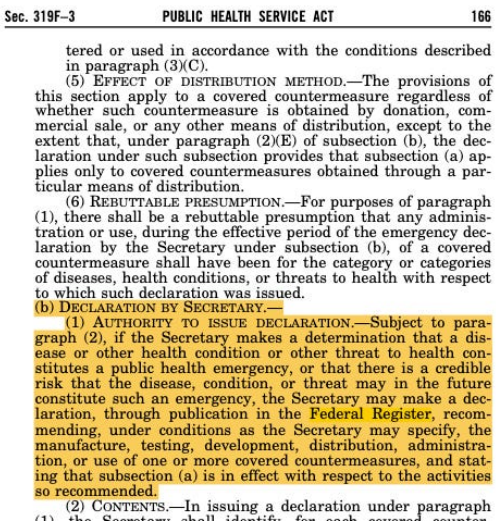
(1) a disease or disorder presents a public health emergency; or

(2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,

the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.

(b) PUBLIC HEALTH EMERGENCY FUND.—

(1) IN GENERAL.—There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emer-



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tered or used in accordance with the conditions described in paragraph (3)(C).

(5) EFFECT OF DISTRIBUTION METHOD.—The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) REBUTTABLE PRESUMPTION.—For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) DECLARATION BY SECRETARY.—

(1) AUTHORITY TO ISSUE DECLARATION.—Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) CONTENTS.—In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered counter-

Related

- Sept. 27, 2022 - On why Biden's comment that 'the pandemic is over' doesn't lift the bioterrorist police state jackboot off our necks.
- March 22, 2023 - On the utility, for inducing peaceful compliance with violent globalist control-and-kill programs, of presenting fake threats as real. Plus war criminal Xavier Becerra extends the public health emergency, effective March 15, 2023, using slightly-different wording.
- April 11, 2023 - Biden rescinding Trump-Biden Proclamation 9994 under 1976 National Emergencies Act does not terminate Azar-Becerra's Public Health Emergency authorities under 1983 PHE amendment to the 1944 PHSA. Becerra and his successors will extend the PHE until they no longer need it to kill people with pseudo-legal impunity. Or until Congress, federal judges or states repeal or nullify the enabling acts.
- Aug. 28, 2023 - March 15, 2023 and May 11, 2023 HHS Dictator-Secretary determinations and declarations.
- Dec. 6, 2023 - More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.

April 4, 2025 - Repealing PREP Act and terminating HHS Secretary determinations and declarations issued under PREP Act are two different things.

Kennedy can terminate the HHS Secretary determinations and declarations, and advise Congress to repeal PREP Act. Congress can repeal PREP Act.

Responding to some questions posted under Sasha Latypova's post *Meltdown at the FDA while 23 States, 2 Governors +DC Sue HHS/Sec Kennedy. In the meantime, the PREP Act declaration for covid pandemic remains in place*[252] about the difference between repealing the PREP Act and terminating PREP Act determinations and declarations issued by HHS Secretaries through the Federal Register.

HHS Secretary Robert F. Kennedy Jr. cannot repeal the PREP Act.

Congress can repeal it. Kennedy can advise Congress to repeal it.

Without any Congressional action at all, Kennedy has the authority to withdraw, through Federal Register notices, the determinations and declarations that previous HHS secretaries issued through Federal Register notices, using the authority Congress transferred to the HHS Secretary through the PREP Act.

There have now been 12 amendments to the original Covid PREP Act determinations and declarations, most recent issued in Dec. 2024 by previous HHS Secretary Xavier Becerra, extending the declaration through Dec. 31, 2029.[253] Every day that passes without Kennedy issuing a Federal Register notice terminating the determinations and declarations, Kennedy co-signs and ratifies license-to-deceive and license-to-kill schemes initiated by Alex Azar and extended by Becerra.

Even if Kennedy did issue a notice terminating the Covid emergency determination and the Covid countermeasures declaration, I don't think it would make anyone civilly or criminally liable for the acts and omissions committed between Feb. 4, 2020 and the effective date of the termination, when the PREP Act determinations and declarations were in effect.

Terminating the PREP Act determinations and declarations could expose perpetrators who make and use the poison products after the date of termination, to potential civil liability and criminal prosecution, although they would still have many other grounds for dismissal and defenses under 1950 Defense Production Act, 1986 NCVIA and the foundational FDA biological product non-regulation system that dates back to 1902.

Rather than expose themselves to those risks, the makers and users of the poison products might stop making and using them, and many more people might better understand the license-to-deceive and license-to-kill schemes, and might stop taking vaccines and stop vaccinating babies and children.

[252] https://sashalatypova.substack.com/p/meltdown-at-the-fda-and-25-states
[253] https://www.govinfo.gov/content/pkg/FR-2024-12-11/pdf/2024-29108.pdf

April 7, 2025 - No one can be found in legal violation of a rule they were never required to comply with, nor can anyone be found to have failed to meet an evidentiary standard they were never required to meet.

Two questions from Jessica Hockett:

> Theoretically, what would happen if COVID-19 or this description thereof [from the original "Notice of declaration under the PREP Act for medical countermeasures against COVID-19" issued by HHS Secretary Alex Azar, by Federal Register notice published March 17, 2020, retroactive to Feb. 4, 2020, 85 FR 15198] were shown to be false, fraudulent, or misleading?
>
> > "COVID-19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es)."
>
> Also, am I right that Azar was able to activate on Jan. 31, 2020 because person to person transmission was determined to have occurred in the US, vis a vis, the Chicago couple?

My reply:

Nothing would happen, for three main reasons.

First, there is no legal requirement that HHS Secretary produce any physical evidence at all in support of declarations. No one can be found in violation of or out of compliance with a requirement that they were never required to comply with at all, because it was never a requirement.

Second, there is no legal requirement that any physical evidence (which need not be presented or adduced at all, see No. 1 above) meet any legal standard of evidence or standard of proof (such as "beyond a reasonable doubt" or "clear and convincing.") No one can be found to have failed to meet an evidentiary standard which they were never required to meet.

Third, there is no venue (geographic region) or forum (court or tribunal) or legislature (Congress or state legislature) or federal or state prosecutor (US-Attorney General or state attorney general or district attorney) with legal authority to review the evidence (which need not be adduced at all, see No. 1 above) or to assess whether it meets or fails to meet any evidentiary standard (which is not required, see No. 2 above).

That's why the laws are written the way they are: to make sure that no evidence need be produced to back up foundationless and unfoundable claims that a threat to public health exists or may exist in future; and to make sure that no evidentiary review can be conducted, so that the deception programs are legally unstoppable.

In response to the second question, No.

Azar was able to activate because the PREP Act gave him unilateral, unreviewable authority to determine and declare the existence of foundationless public health threats without any legal requirement that he produce physical evidence, and without any legal requirements that any alleged physical evidence he produced (to render the projected illusion more persuasive), be subjected 1) in any fact-finding forum or venue, to 2) any adversarial, fact-finding process, or to 3) any obligation to meet any standard of proof.

The PREP Act was written to block or preempt the authority of fact-finders (courts and legislatures); to block fact-finding processes (criminal prosecution, civil litigation, investigative/oversight hearings); and to preclude legal obligations to present valid evidence and meet standards of proof.

Going a little more deeply into the wording of the PREP Act and the wording of the PREP Act declarations issued by HHS Secretaries under the authority Congress unconstitutionally transferred to the executive branch through the PREP Act, readers will find that the only "factors to be considered" by an HHS Secretary are listed at 42 USC 247d-6d(b)(6).

> 42 USC 247d-6d(b)(6) Factors to be considered
>
> In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

"Desirability" is a non-physical characteristic, and not subject to any standard of evidence or fact-finding process.

"Desirability of encouraging" also begs the questions: desirability *for whom*, of encouraging the manufacture and use of countermeasures *intended to induce which effects*?

Congress did not define or identify, in the PREP Act, the people for whom countermeasures should be deemed (by the HHS Secretary by unilateral decree) desirable, nor did Congress define the physical effects, the induction of which (by means of countermeasures) should be deemed desirable for those unidentified people.

In the PREP Act declarations and amendments issued since 2020, HHS Secretaries have simply stated at Section I:

> "I have determined that the spread of SARS-CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency" or a "credible risk of a future public health emergency" and at Section II: "I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures."

With the hindsight gained over the last five years, it's now possible to clearly see that the only factors to be considered by the HHS Secretary in issuing determinations and declarations, are the desirability for the HHS Secretary himself, for Congress, for central bankers and for depopulationists, of encouraging development, manufacture, labeling, distribution, promotion, dispensing, administration and use of countermeasures intended to induce heart failure, cancer, miscarriage and other disorders that cause sickness, infertility and premature death of recipients.

April 21, 2025 - PREP Act Brief: "License to Kill" must be repealed.

A collection of articles for ease of educating your friends, family, doctors and legislators. Please sign the petition to repeal the PREP Act linked in the post.

By Sasha Latypova

This is a video I recorded with James Roguski, explaining the monstrosity that is the PREP Act and the reasons why we are focusing on the campaign to educate the public about it and ultimately repeal it: Link to video on Rumble[254]

Brief: The Public Readiness and Emergency Preparedness (PREP) Act.

1. Purpose - liability shield for those who cause death and injury during arbitrarily declared "public health emergencies"

- The PREP Act (2005) is federal legislation designed to provide immunity from liability for certain individuals and entities involved in the development, manufacture, distribution, and administration of "covered countermeasures" during a declared public health emergency. [Wiki[255]]

- The Act is activated upon the declaration of a Public Health Emergency (PHE) by the Secretary of Health and Human Services (HHS). Such declaration is entirely arbitrary, based solely on the HHS Scy opinion that requires no justification and is non-reviewable by the judiciary branch, nor by Congress.

    - April 15, 2024 - Nothing to declare[256]
    - May 3, 2024 - Pandemics are arbitrary declarations[257] by HHS Secretary, requiring no evidence
    - Oct. 10, 2023 - Declaration of a pandemic sets up a legal cage[258]
    - Nov. 24, 2023 - "Weaponized pathogens" cannot cause pandemics[259], and April 4, 2025 - Ralph Baric explains[260]
    - Jan. 14, 2024 - Fraudulent "science" of weaponized viruses[261]
    - Feb. 10, 2023 - Pfizer failed to make animals sick from SARS-Cov-2[262]
    - Jan. 17, 2024 - Pandemics are faked: the DOD script[263] and Feb. 1, 2024 - Dutch/Erasmus script[264]

[254] https://rumble.com/v6s6i5j-an-interview-about-the-prep-act-with-sasha-latypova.html
[255] https://en.wikipedia.org/wiki/Public_Readiness_and_Emergency_Preparedness_Act
[256] https://sashalatypova.substack.com/p/pandemics-are-declared
[257] https://sashalatypova.substack.com/p/pandemics-are-declared-what-does
[258] https://sashalatypova.substack.com/p/understanding-the-pandemic-legal
[259] https://sashalatypova.substack.com/p/weaponization-of-disease-agents
[260] https://sashalatypova.substack.com/p/how-to-fake-pandemics-the-maestro
[261] https://sashalatypova.substack.com/p/the-little-known-weird-trick-you
[262] https://sashalatypova.substack.com/p/when-mutated-lab-made-viruses-are
[263] https://sashalatypova.substack.com/p/how-to-fake-pandemics-in-4-easy-steps
[264] https://sashalatypova.substack.com/p/how-to-fake-pandemics-part-2-i-do

- Feb. 15, 2023 - Pandemics are a government-pharma racket - Col Matt Hepburn (DARPA)[265]
- March 11, 2023 - Biodefense is a global pandemic racketeering enterprise[266]
- Sept. 3, 2024 - Natural epidemics are explained by lack of sanitation and anaphylaxis by animal/insect bites[267]
- May 26, 2023 - Why are they doing it - eugenics documentary[268]

- The PREP Act is currently invoked for countermeasures related to COVID-19, Marburg virus, Ebola, Zika, avian flu, RSV, monkeypox, anthrax, and smallpox. There are no pandemics or epidemics of these diseases in the United States, therefore, these declaration have no basis in reality, nor do they serve any public health interests:

  - Dec. 10, 2024 - Covid emergency extended to Dec 2029[269]

  - Jan. 11, 2024 - Marburg and Ebola[270]

Table 1: Public Health Threats Triggering Eligibility for Compensation through the Countermeasures Injury Compensation Program (CICP), by Public Readiness and Emergency Preparedness Act (PREP Act) Declaration Date, as of December 2024

Eligible public health threats	Effective date of PREP Act declaration	Expiration date of PREP Act declaration
Anthrax	October 1, 2008	December 31, 2027
Acute radiation syndrome	October 10, 2008	December 31, 2027
Botulinum toxin	October 10, 2008	December 31, 2027
Pandemic influenza	October 10, 2008	December 31, 2027
Smallpox and other orthopoxviruses (e.g., mpox)	October 10, 2008	December 31, 2032
Ebola	December 3, 2014	December 31, 2028
Zika	August 1, 2016	December 31, 2027
Nerve agents and certain insecticides	April 11, 2017	December 31, 2027
COVID-19	February 4, 2020	December 31, 2029
Marburg	November 25, 2020	December 31, 2028

Source: GAO analysis of declarations made by the Secretary of Health and Human Services. I GAO-25-107368

  - These are fake “emergencies” currently declared by HHS. There are no pandemics or epidemics of any of these diseases in the US. These declarations are in place solely to spend taxpayers’ money on purchasing unregulated and falsely labeled poisons, force them on duped civilians and military servicemembers, and then avoid any liability for death and injuries caused.

[265] https://sashalatypova.substack.com/p/pandemic-preparedness-a-government
[266] https://sashalatypova.substack.com/p/the-waiting-for-pandemic-cult-of
[267] https://sashalatypova.substack.com/p/the-second-shot-or-what-do-vaccinators
[268] https://sashalatypova.substack.com/p/why-are-they-doing-it-eugenics-to
[269] https://sashalatypova.substack.com/p/breaking-outgoing-hhs-scy-extends
[270] https://sashalatypova.substack.com/p/do-you-know-that-we-have-a-pandemic

2. Emergency Use Authorization (EUA) for deploying "Covered Countermeasures"

- The PREP Act enables the "non-investigational" (outside of the law, regulations and liability-free) Emergency Use Authorization (EUA) pathway for drugs, vaccines and other medical products:
    - Section 564 of FD&CA[271]
- EUA pathway allows for the bypassing of ALL regulatory requirements for clinical trials, manufacturing quality, safety, and labeling due to non-enforcement of those laws for countermeasures under arbitrarily-declared pandemic emergency:
    - FDA Guidance on EUA Countermeasures[272]
    - Nov. 4, 2023 - Pharmaceutical law/regs do not apply to EUA Countermeasures[273]
    - Dec. 22, 2022 - Nobody knows what is in the vials[274]
- Under 21 USC 360bbb-3(k), the "use" of EUA products "shall not constitute clinical investigation," making informed consent inapplicable/meaningless:
    - Dec. 2, 2023 - EUA Countermeasures are non-investigational[275]
    - May 20, 2024 - FDA and DOD removed informed consent for covid shots[276]
    - June 20, 2023 - Peter Marks testifies that FDA removed informed consent for covid shots[277]
    - Feb. 12, 2024 - Q&A re EUA Countermeasures[278]
- The definition of "covered countermeasures" is vague and includes vaccines, therapeutics, diagnostics, treatments, and other items. This definition can even extend to targeting technologies (mandates for false-positive PCR or lateral flow tests), as well as sophisticated informational weaponry, such as coordinated media lies, propaganda and censorship.
    - Jan. 26, 2024 - Memo re EUA Countermeasures, applicable law[279]
    - Sept. 15, 2023 - PREP Act shields hospital murder protocols as long as HHS orders are followed[280]

[271] https://www.lexology.com/library/detail.aspx?g=262e5853-126c-4fa3-870e-98c839a4bca2
[272] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#medproducts
[273] https://sashalatypova.substack.com/p/do-fentanyl-dealers-violate-cgxp
[274] https://sashalatypova.substack.com/p/nobody-knows-what-is-in-the-vials
[275] https://sashalatypova.substack.com/p/eua-countermeasures-are-neither-investigational
[276] https://sashalatypova.substack.com/p/criminals-do-not-follow-laws-they
[277] https://sashalatypova.substack.com/p/declaration-of-peter-pretzel-marks
[278] https://sashalatypova.substack.com/p/questions-from-readers-about-eua
[279] https://sashalatypova.substack.com/p/memo-re-eua-countermeasures-to-send?r=uaapz
[280] https://sashalatypova.substack.com/p/talking-to-dr-jane-ruby-about-hospital?r=uaapz

3. Liability Protection:

- “Covered Persons”: the PREP Act provides a significant liability shield to a wide range of individuals and entities, including manufacturers, distributors, program planners, qualified persons (like pharmacists and pharmacy technicians), and healthcare providers.

- As long as these "covered persons" follow the orders of HHS/DOD and comply with protocols, they are generally exempt from civil liability for injuries or deaths resulting from the administration or use of covered countermeasures.

- This liability shield applies regardless of the place of employment, and covered persons may be "deemed US Government employees for purposes of this work".

- This protection is even described as potentially covering "bribery, coercion, assault and murder" if they occur within the context of a PREP Act declared emergency and related activities.

- While criminal liability is technically not shielded by the PREP Act, the criminal pathway is available only if the state brings criminal charges first and wins:

    - April 7, 2025 - Analysis of possible state-level criminal action under PREP[281]

    - April 7, 2025 - Criminal statutes relevant to covid crimes by state[282]

- Products authorized under EUA during a PHE and any products used to treat the injury resulting from use of EUA countermeasures can be considered "countermeasures" under the PREP Act, removing liability and enabling further injuries to the public:

    - Oct. 25, 2024 - All vaccines can be deemed liability-free “countermeasures” while any declaration of emergency is extended[283]

[281] https://sashalatypova.substack.com/cp/160881332
[282] https://sashalatypova.substack.com/p/summary-of-state-criminal-laws-for
[283] https://sashalatypova.substack.com/p/all-childhood-vaccines-can-be-claimed

4. Department of Defense (DOD) Involvement

- Operation Warp Speed was a public-private partnership under military command (DOD was the Chief Operating Officer) reporting to the National Security Council. The decisions about covid response policy were made in secret and remain classified to date.
    - March 25, 2025 - Covid Dossier[284] (Sasha Latypova and Debbie Lerman)
    - Dec. 13, 2022 - Intent to Harm[285]
    - March 26, 2025 - The hidden hand - NSC and the Military[286] (Sasha Latypova and Debbie Lerman)
    - June 23, 2024 - DOD/CIA linked Resilience manufactures mRNA vaccines[287]
    - Jan. 19, 2024 - Why DOD partnered with HHS[288]
    - Dec. 28, 2022 - The role of DOD and their co-investors in covid countermeasures[289]
    - June 20, 2024 - Catherine Austin Fitts on DOD[290]
- Information from a leaked audio recording from AstraZeneca[291] shows that the DOD declared COVID-19 a "national security threat" as early as February 4, 2020, without any factual justification. This timing aligns with the retroactive declaration of the emergency under PREP Act for COVID-19.
    - April 18, 2024 - DOD pushed pandemic actions/money ahead of POTUS (Trump 1.0)[292]
- Contracts for these countermeasures are managed by the DOD and may describe the products as having "civil and military application".
    - Jan. 11, 2023 - DOD contracts for covid countermeasures[293]; Feb. 18, 2023;[294] Feb. 27, 2023;[295] March 7, 2023[296]
    - April 23, 2023 - Moderna DOD contracts;[297] April 19, 2023[298]
    - June 28, 2023 - State pharmacy distribution laws do not apply to EUA Countermeasures[299]

[284] https://sashalatypova.substack.com/p/the-covid-dossier-updated-a-record
[285] https://sashalatypova.substack.com/p/intent-to-harm
[286] https://sashalatypova.substack.com/p/the-hidden-hand-behind-the-covid
[287] https://sashalatypova.substack.com/p/all-roads-lead-to-resilience
[288] https://sashalatypova.substack.com/p/why-did-hhs-partner-with-dod
[289] https://sashalatypova.substack.com/p/the-role-of-the-us-dod-and-their
[290] https://sashalatypova.substack.com/p/musings-on-the-department-of-defense
[291] https://sashalatypova.substack.com/p/audio-leaked-from-astrazeneca-covid
[292] https://sashalatypova.substack.com/p/who-was-really-in-charge-of-the-covid
[293] https://sashalatypova.substack.com/p/reviewing-the-dod-contracts-for-covid
[294] https://sashalatypova.substack.com/p/responding-to-criticism-regarding
[295] https://sashalatypova.substack.com/p/you-cannot-contract-for-a-crime-but
[296] https://sashalatypova.substack.com/p/part-2-of-contracts-for-crimes-pfizers
[297] https://sashalatypova.substack.com/p/part-2-moderna-contracts
[298] https://sashalatypova.substack.com/p/moderna-contracts-part-1
[299] https://sashalatypova.substack.com/p/barda-subverts-licensed-regulated

5. No Legal Recourse for the Injured:

- The PREP Act severely limits the ability of individuals injured or the families of those who died after using a covered countermeasure to seek legal remedies.
- Lawsuits can only be filed in a three-judge court in the District of Columbia.
- Plaintiffs must prove direct causality between the countermeasure and the injury or death AND demonstrate "willful misconduct" on the part of the defendant.
- Even if causality and willful misconduct are proven, the defendant is not liable if they followed HHS/DOD orders and reported the injury or death to these agencies within seven days.
- To date, covid shot manufacturers, hospitals and doctors participating in murder protocols, the DOD and other defendants successfully invoked "sovereign immunity" as a defense against lawsuits related to PREP Act countermeasures. Only one court, NC Supreme Court found that some state constitutional rights are not preempted by PREP Act.

6. No Oversight:

- The PREP Act strips Congress of its authority to oversee or terminate emergency declarations made unilaterally by the HHS Secretary.
- It also removes the authority of federal courts to review or nullify these declarations and pre-empts the jurisdiction of the states.

7. Relevant Litigation Discussed on this Substack:

- March 24, 2025 - North Carolina Supreme Court finds PREP Act *does not* preempt constitutional claims[300]
- March 10, 2025 - Maine Supreme Court finds PREP Act shields those who inject children against parental consent[301]
- Sept. 18, 2023 - DOD/pharmas use claims of “sovereign immunity” to dismiss wrongful death lawsuits (Estate of George Watts v DOD)[302]
- Aug. 12, 2024 - Brook Jackson v Pfizer, whistleblower lawsuit under False Claims Act[303] and April 1, 2023[304]
- March 17, 2024 - DOJ confirms that fraud and resulting deaths and injuries from covid shots are part of the US public health policy (Brook Jackson case)[305]
- Dec. 31, 2024 - Texas v Pfizer - dismissed affirming state law preemption by PREP Act[306]

[300] https://sashalatypova.substack.com/p/good-news-first-major-blow-to-the
[301] https://sashalatypova.substack.com/p/maines-supreme-court-affirms-the
[302] https://sashalatypova.substack.com/p/update-on-chd-lawsuit-challenging
[303] https://sashalatypova.substack.com/p/brook-jacksons-2nd-amended-complaint?
[304] https://sashalatypova.substack.com/p/brook-jacksons-case-dismissed-by
[305] https://sashalatypova.substack.com/p/department-of-justice-admits-pharmaceutical
[306] https://sashalatypova.substack.com/p/breaking-the-lawsuit-v-pfizer-by

- June 25, 2024 - Kansas v Pfizer[307]
- Nov. 11, 2024 - Dressen v AstraZeneca - contractual claims not preempted by PREP[308], and May 22, 2024[309]
- April 14, 2025 - Analysis of constitutional issues of PREP Act by attorney Ray Flores[310]

8. What can you do to dismantle PREP Act and help the victims

- Pray.
- Share this information widely, attribution is nice but not necessary.
- Nov. 30, 2023 - States can nullify PREP Act[311] as it violates the rights of states and their citizens - please talk to your legislators.
- US Congress can repeal the PREP Act as unconstitutional [Dec. 2005 Chemerinsky opinion[312]], [Dec. 2005 Biden Clinton quotes[313]], [other ref[314]]

Sign Petition to Repeal Prep Act

James Roguski is organizing the work on this petition.[315] Please make sure to include your congressional district (for US residents). You can sign the petition even if you are not a US resident. We appreciate your support!

Please join me calling on HHS Secretary RFK Jr to terminate the contrived emergency declarations, closing the window for lethal/damaging products and acts of deception on the public:

- Feb. 26, 2025 - Open Letter to the HHS Secretary, RFK Jr.[316] (Sasha Latypova)

[307] https://sashalatypova.substack.com/p/breaking-news-pfizer-lied-bad-pfizer
[308] https://sashalatypova.substack.com/p/some-illusory-promises-are-more-illusory
[309] https://sashalatypova.substack.com/p/legal-complaint-filed-against-astrazeneca
[310] https://rayfloreslaw.substack.com/p/is-the-prep-acts-severability-clause
[311] https://sashalatypova.substack.com/cp/139319203
[312] https://bailiwicknews.substack.com/p/edwin-chemerinsky-letter-to-senate
[313] https://bailiwicknews.substack.com/p/senators-kennedy-biden-clinton-byrd
[314] https://jamesroguski.substack.com/p/e7acc9cb-05b2-4b92-8c8a-f1d5bd11a966
[315] https://docs.google.com/forms/d/e/1FAIpQLSezW8CBXRYl5B-WTM1Jy4w3NI8rtm4Q8rE4CYfTyYf9nRqpJA/viewform
[316] https://sashalatypova.substack.com/p/open-letter-to-the-hhs-secretary

Do not comply

Become vaccine-hostile, do not take any countermeasures nor any PCR tests. Avoid establishment healthcare as much as possible (they track your vaccination status), shield your children from pediatricians that push poison:

- April 14, 2025 - Katherine Watt on habeas corpus and communicable disease control[317]
- March 1, 2024 - Katherine Watt - comprehensive set of tools to dismantle evil law including PREP Act[318]

In conclusion

Katherine Watt refers to the framework created by the PREP Act and related legislation as the "American Domestic Bioterrorism Program"(April 28, 2022[319]), arguing that it legalized actions that were previously illegal under the guise of public health. This constitutes an overthrow of the U.S. Constitution.

- Sept. 7, 2023 - Memo prepared for Senator Ron Johnson (R-WI) in December 2022[320] (Sasha Latypova)

PREP Act creates a "license to kill" with covered weaponry/"countermeasures" by covered persons, as long as the perpetrators claim they are acting in an emergency in the interests of public health and HHS' orders are followed.

PREP Act must be repealed. Yet, not a single Congress person speaks about it. I don't know when/if material progress toward this goal will be made. In the meantime, we must educate everyone around us about this atrocity. The problem is that most people, even those who are now awake to the vaccine and hospital murders still think that "if fraud can be proven" than the perps can be prosecuted. The fraud has not only been definitively proven, it hasn't been really hidden to begin with and it is a key feature of weaponized "public health".

March 17, 2024 - Fraud and resulting deaths have been acknowledged by the Department of Justice who stated in court that they are part of the US public health policy.[321]

[317] https://bailiwicknews.substack.com/p/communicable-disease-control-quarantine
[318] https://bailiwicknews.substack.com/p/tools-for-illuminating-defying-and-874
[319] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program
[320] https://sashalatypova.substack.com/p/memo-sent-to-sen-johnson-and-his
[321] https://sashalatypova.substack.com/p/department-of-justice-admits-pharmaceutical

April 24, 2025 - PREP Act, An act of treason video discussion, Stephanie Weidle, Sasha Latypova, Katherine Watt. (Transcript)

Link to video on Rumble[322]

Excerpts [Full transcript available in Jan. to September 2025 Bailiwick collection at p. 190]

SL: ...everyone is incentivized to ignore PREP Act on both sides. I just published an article this morning about 25 states or 23 states, two governors suing HHS and Kennedy for clawbacks of the COVID pandemic funds. And that lawsuit with 25 states, legal eagles, mentions PREP Act not once, not once.

So they're incentivized to ignore it, even though it would have strengthened their case to say, because they're claiming that these pandemic dollars...are not pandemic and not emergency dollars anymore. They were meant to be after pandemic because pandemic is over. So they were meant as permanent public health funding from federal government now, right? So we can't claw them back. And while the PREP Act remains extended, like the declaration remains in place, meaning it's not over. So it would have strengths in their case to say, "hey, we're still in their emergency. You should pay us." But they're not. They're ignoring it. And so will HHS. So that's my prediction. HHS will also ignore it because it's inconvenient to point to it because that will unravel the whole scam.

SW: OK, so let's go back just a little bit and we're going to continue talking about the PREP Act. So the PREP Act is the Public Readiness and Emergency Preparedness Act. It was enacted in 2005 under George W. Bush that gave liability protections to pharmaceutical industries and health care providers during public health emergencies.

It kind of seems like a good idea, kind of, but maybe not. What is particularly of interest in our discussion today is...the ability this act gives to rapidly produce and distribute medical countermeasures with no liability and with no need to provide informed consent. And this was the justification that was given, that the military gave to their EUA, emergency use authorized vaccine campaign. This is what was pointed to when federal employees pushed back against the COVID measures. So how does this usurp the U.S. Constitution and state constitutions?

KW: There are three sections of it that are where the core of the treason sits. The overall section is 42 USC 247d-6d. And the three sections are (b)(7), (b)(8) and (b)(9).

(b)(7) is the one that precludes all judicial review of an HHS secretary declaration or determination. They have a couple different names for a couple different types of things that they do. One is the determination that an emergency exists, which they can do without any evidence. There's no requirement for any evidence. There's no standard of evidence. They just say that that exists. And that is taken as a presumption that if they say it exists, then it does. Then there's declarations which are built on that determination, and the declarations pertain to the products. And that's them saying that "given I, the HHS Secretary, have said this threat exists, I am also declaring," also unilaterally, also without any evidence, "that I recommend the manufacture, testing, development, distribution,

[322] https://rumble.com/v6secjx-83.-the-prep-act-an-act-of-treason-sasha-latypova-and-katherine-watt-the-fe.html?e9s=src_v1_ucp

administration, and use of covered countermeasures." So it covers the products and it covers the event that is the pretext for the products. There can be no judicial review of either of those things under this (b)(7) section.

Then there's the (b)(8) section, which is the preemption of state law. And that says to all of the states, "Nothing you have in your laws or your constitutions or any other legal instrument in your state can be different or can impose different standards or can do different review type things for the things that the HHS secretary has said about the threat existing and about the products."

And then the third piece is (b)(9) which is a report to Congress. And it basically says the HHS secretary should report to Congress within 30 days why he has done this. But it doesn't say anything about, again, evidence. He doesn't have to produce any evidence. And Congress has no authority explicitly, they don't explain or provide or have any provision for them to overrule or override or review what the HHS secretary has said exists, which may not exist at all. And in this case, it did not. And they have no ability to override what he says about the recommendation for these countermeasures to be produced and used.

SW: What was going on in 2005 that made the states not rise up against this act?

KW: They were traumatized into compliance by 9-11 and the so-called anthrax attacks of 2001. And those also were orchestrated, but they were used as the pretext to put into place these laws and many other laws that had been written long before the events actually happened. Yeah. Because they had been building up. That's how they do it.

They do piece by piece by piece, adding on more and more layers. So I think that's what the states were told, starting in 2001: "now there is this huge bioterrorism threat. You must prepare your states for it, and you must submit your states to federal jurisdiction and authority in the event that these things happen."

SL: And they were plainly just paid off. As I said, this money, the spigot of money that comes from the federal government, the federal government said, you know, we're going to put this law and then you're going to get all this funding for all these preparedness measures and so forth. And actually, you know,

Katherine found that Senators Joe Biden, Hillary Clinton, Edward Kennedy and Byrd, were objecting, objecting very correctly on very good grounds to the passage of this 2005 act. And so those quotes, she published those quotes and I have used them in presentations. They're terrific. And then, yes. To these people. What happened to them? And then they voted yes. After saying it's unconstitutional, it violates like five amendments of the Constitution. Those same people turned around and voted yes. So that's treason. And that's how you know the deep state is alive and well. Sorry, go ahead, Katherine.

KW: Part of that is that the Republicans slipped it into an appropriations bill on December 18th of 2005, which I think was a Sunday, Sunday night. So the other senators found out about it that night or later the next day. They were pretty quick about getting a legal opinion from [Erwin] Chemerinsky, who's a legal scholar that's, I think he's now at Berkeley. And they entered that information, their objections, based on his very good constitutional analysis. He wrote his letter to

them December 20th. December 21st, they had the only, as far as I know, debate or discussion of this provision at all because it had only been added three days before. So that's when Kennedy and Clinton and...other Democrats did their speeches on December 21st. Then they had a [cloture] vote. And then they had the vote on the overall appropriations bill to which this had been attached, and they all voted for it.

SW: Wow. So what was this act used for between 2005 and COVID?

KW: Mostly, I would say the 2009 H1N1 program. But they did not use all of the features of it. And the main thing they didn't use was the sort of shock-and-awe national campaign to get everyone to take it with employer mandates and the other kinds of pressure tactics. They made the same bad products from the same bad companies but they were more gentle about saying, "we think it's a good idea." And a lot of people did take it, and a lot of people didn't, and they didn't really push that a whole lot harder.

SL: Yeah, so, up until 2020, it's correct. So it's never been used as a national strategy or national application of this thing nationally. So it's important. So they were using it essentially as mostly as a kind of like a money laundering mechanism. So they would order these poisonous concoctions and things from their crony companies. The government is the sole buyer. It goes into the stockpile. They used it on service members. They used it on military, the anthrax, all that. They used it, but they never applied it nationally. I think those were kind of like practice runs and get everyone accustomed for 20 years that, well, "we're just buying things for national stockpile. Maybe sometime we'll need it." And then, yeah, it was the whole shock in combination with the Stafford Act declaration done in all 50 states, which has never been done before. And all this enormous campaign and then forcing everyone, all the civilian population, and then also lying.

The feature in this law is that you can lie about countermeasures. Countermeasures, they're not regulated, no consumer protections apply to them, and you can lie about them. Misbranding is legal under this law. Lying about the fact that these are fully approved medications, that they're safe and effective, all of this is legal.

That has never been used for good reason, because it would have been caught and terminated, right? They wanted to use it, but only when it mattered, which is now.

SW: And how do they say the line, "we can lie about it?" How is that phrased in the PREP Act?

SL: It says specifically that regardless of anything that happens, these products, EUA countermeasures, "shall not be considered adulterated," meaning anything goes, they're not regulated, can contain any ingredients. Or misbranded, which means lying is okay. They're not regulated for honesty in marketing or honesty in claims and safety claims, efficacy claims. None of it is applicable. It's okay to lie about them.

KW: And the other piece of that is that they don't, it's things that are missing from the law. There is no provision that requires anything to be pure or demonstrated pure or unadulterated or demonstrated unadulterated or accurately labeled and demonstrably accurately labeled. So they don't have those provisions, which means you can't be found in violation of a provision that doesn't exist. And also what Sasha said.

SW: And do you have records of the money given to the states under the PREP Act?

SL: Yes, I have some examples of, they were intergovernmental contracts...

SW: There was a North Carolina Supreme Court ruling just in late March 2025, ruling that the PREP Act does not preempt state constitutional claims for violations of fundamental rights. The case involved a boy who was administered an mRNA shot without the parent's approval. And the court held that the claims related to the parents' right to control the upbringing of their children and the individual's right to bodily integrity under the North Carolina constitution are not usurped by the PREP Act. I mean, this is kind of a big deal. What were your all's initial thoughts? And I'll start with you, Katherine. What was your initial thoughts on the significance of this court decision and trying to get rid of the PREP Act?

KW: I read Sasha's analysis of it, and I read a couple other peoples', but I had not read the case until this morning when I got your outline for the interview. So I did go through it really quickly, and I tend to think that the dissenting opinion, which said the opposite of what you just said, it said...the dissenter judges think that under the circumstances, the PREP Act preemption does apply even to the state of North Carolina's constitution. I think he or they, I think it's two judges, are probably legally correct because they mentioned this section [42 USC 247d-6d](b)(8). that I mentioned earlier about preemption of all state law, whether it's your court laws or your constitution or any other legal instrument at the state level.

And the dissenting judges seem to believe that makes sense because they're attributing to Congress the intent to make the PREP Act so broad, because they're attributing to Congress the benevolent goal of getting medical countermeasures developed and distributed and in use as soon as possible.

The majority opinion has to sort of jump through a lot of hoops to try to pretend that that's not the case. And I can understand, my sense on reading it, again, I read it today, was they're kind of in shock because the implications of the PREP Act, as it's written, may have dawned on them through this case. And what they're trying to do is express how horrified they are that Congress is doing this and leave an out by saying that can't possibly be what Congress meant, when in fact it is exactly what Congress meant. So I think it's a good case because, like you pointed out in the outline and other people pointed out, it sets up a conflict between the Maine state decision and the North Carolina state decision, which sets up an opportunity for it to go to the Supreme Court because they will need to resolve the discrepancies.

I tend to think the Supreme Court is going to come down on the side of "yes, Congress intended with the PREP Act to void the Constitution, to shut down all of the state legal instruments that might have gotten in the way or might in the future get in the way of getting these poisons into as many people as quickly as possible." And that will be like another ratification layer. But I do think it's a good case and I do think it sets up a good opportunity to clarify the disaster that the PREP Act is, for a lot more people.

SL: Yeah, one of the majority decision judges wrote a note, a concurring note, which was very good because it's a very layman terms explanation of what exactly transpires with PREP Act. So she said that, if you're standing in a coffee line at Starbucks and somebody comes in, injects everyone with poison, and people die and get injured. And then they say, "well, we were here from the government preventing the next pandemic. You can't do anything about us." So it's a license to kill. PREP Act is a license to kill.

KW: It's a license to deceive and a license to kill.

SL: So majority of this, obviously, if you want to run a deception like this, you know that by force, you're not going to get very far. You're going to get stopped. So you need to deceive people into voluntarily submitting to those injections. And then, with all this fake theater and COVID pandemic fear mongering and all these, Johns Hopkins tracker of COVID bulls all over the place, so that's what they were doing so that people voluntarily run in and get those injections.

SW: So if destruction of the PREP Act will not happen through the courts, how can it happen?

SL: This is what we're focusing on right now with a number of colleagues, including Katherine and some other collaborators. There are a couple of things that need to happen. So PREP Act must be repealed. Now, this is a difficult uphill battle, which the current administration so far has expressed no interest in even acknowledging that that's the problem. But that's the ultimate objective, is to get rid of this bad, evil law. It's illegal law. It's unconstitutional law.

Now, in the meantime, what can be done is, the public and professionals, especially health care professionals and legal professionals and any person who has interest in it, in the future of their children, doesn't matter which side they're on, even on the evil side. As I said, I'm happy to talk to anyone. Their children and their grandchildren are going to be subject to this ultimately, and so they need to be educated about the monstrous illegality of all these EUA countermeasures being pushed as safe and effective, approved FDA vaccines

So another thing that happened, Peter Marks, who is head of CBER [FDA Center for Biologics Evaluation and Research] just resigned. He is the key guy who needs to be in jail, who needs to be on trial for his life for committing mass murder, because he was the one who fronted that bait-and-switch scheme.

He was the one who went on record, even in court declarations, and I've published that. In court declarations, in other venues, he fronted this bait-and-switch. He went and said, even though, so EUA countermeasures are all these products, and the PREP Act, and the current PREP Act declaration, they can push out medicines or activities or whatever, rules, masking, vaccines, and they're not regulated, as we discussed. You can lie about them and they're not regulated.

So then Peter Marks in his position of authority as head of CBER FDA, when a couple of his colleagues resigned because they wouldn't sign off on approval of these vaccines, he took it on, this whole thing, instead, took their jobs.

And then he went and played this FDA approval. Well, there was no approval. There's no legal approval applicable to this. And then he validated the fraud. He signed off on the fraud, issuing these approval letters in August 2021 so that all of these things could be mandated. Under PREP Act, EUA countermeasures cannot be mandated. That's very clear. He did the bait-and-switch. He went on record, said, "you know, these are fully FDA approved." And then all the mandates.

KW: I would add a couple of things to that. Marion Gruber is another person who should be in that same batch of criminal prosecutions, if that ever happens, because she's the person who signed off on the EUA in December of 2020.

The other thing I would say, probably building on what Sasha said, is it would be useful if people had a look back at the civil rights movement and Martin Luther King Jr., because his analysis was largely based on the idea that the laws were illegal themselves. And therefore, the only appropriate way to respond to them is to refuse to obey them because they are immoral.

And so civil disobedience in this case takes the form of not ever taking another vaccine in your life, not ever advocating that anyone else take a vaccine, not vaccinating your children ever, not advocating that anyone else ever vaccinate their children and talking about why you are so firm and so committed to not doing those things, because you can see that the laws around vaccine development, vaccine manufacturing, and vaccine use are completely illegal, immoral anti-laws that cannot be followed if you are a person of any conscience whatsoever.

And I think that has enormous potential because what we were talking about earlier, to the extent they can deceive people into thinking that there are threats and thinking that vaccines are remedies for those, they get people to voluntarily comply. And if people don't voluntarily comply, which means you just don't go to the pharmacy, you just don't go to the pediatrician or your doctor. And if anybody there asks you, you say, "No, thanks. Walking away. That stuff is poison." Their system doesn't work very well because they really don't want to have to do that scenario that Sasha was talking about where they just walk into a coffee shop and start jabbing people.

SL: Yeah. And another thing, so there are three. So the repeal of the PREP Act, education about EUA countermeasures and lying about full approved status by Peter Marks and FDA and everybody else.

The third one is we all need to call an RFK Jr., our current HHS Secretary, to terminate current PREP Act declaration for COVID emergency, which was extended by Xavier Becerra, outgoing HHS Secretary, to last until December 31st of 2029. Nobody knows about this, and this is by design. They want you to think that COVID emergency is over. It's not. It's fully extended. It's fully operational. And the law, the PREP Act, says that HHS Secretary, it's only his opinion. Nothing else matters. He doesn't have to take into account any data, any science, nothing. So it's only his opinion that there is a current emergency of COVID.

So right now, we are supposed to interpret this as, it's personal RFK Jr.'s opinion that we have a COVID emergency and we need to have those EUA countermeasure biologics shots on babies' vaccination schedule. So that's his opinion now. Until he terminates that PREP Act declaration, which all it takes is a memo into Federal Register. Just a memo. Just him saying, "I don't think so anymore."

SW: So if the COVID emergency is not being rescinded, and we recently had an Idaho Medical Freedom Bill, which was saying anyone, so prohibiting the force of medical interventions and preventing discrimination or negative actions towards individuals who refuse the interventions. If we have a medical freedom bill like that, that was passed through the state legislator and then vetoed by the governor, what is the state in which our country is in right now?

SL: Exactly. And that's the only state that even got that far. And I was involved, I'm still involved very closely with these efforts. There are several bills there, including this one we've been working on. We've been testifying in counties, in states and everywhere.

And I'm in touch with Leslie Manookian, who's also involved in this bill. She recently said that it's moving, hopefully it's getting results. So what they vetoed, the governor vetoed it in the last minute, and then they wanted to carve out, guess what, the preschool. So, okay, you have medical freedom except for up to the age of six or seven, right? You don't. You belong to the government, we need to jab, because majority of the poisons go into the human beings before the age of six. That's why they wanted to carve it out. She said they may be able to overcome this, but we'll see what happens. But this is hanging by a thread.

KW: I think it would be interesting if the people in Idaho went back and tried to instead amend their criminal codes to add vaccines to things like gun and knife in assault-with-a-deadly-weapon criminal statutes because it gets more at the fact that they do not have a medicinal purpose they only have a poisoning purpose. And the state has an interest in letting the people know what counts as a deadly weapon and adding vaccines to that list.

SW: That is really interesting. Just even putting that in the ear, like putting that on paper and then testifying, talking about that, which would send shockwaves.

KW: Because it's not a medical, in my view, it's not a medical freedom issue. It's a self-defense issue because these are not medical products. These are weapons.

SL: It is a self-defense. And the North Carolina case prevailed specifically because they framed some of it as unwanted touching and battery. Which is, and that's how they got the judges to agree with the constitutionality of these claims. That's an avenue. I'm going to publish it. I have a summary. Actually, I'll send it to you, Katherine. I have a summary of criminal statutes currently on the books in every state...from Mimi Miller, an attorney. So she compiled a whole table of every state, which criminal statutes can be applied to this. There are already plenty in every state.

KW: It's interesting because when I first started trying to learn about the "unavoidably unsafe" phrase, you can pretty quickly get to regular law firm orientation pages that tell you "unavoidably unsafe" products are guns, knives, including kitchen knives, cleaning products, and drugs, including vaccines. And they're unavoidably unsafe because they cause harm. They are known to cause harm. Like in a regular drug situation, it's either, it's like a lethal injection drug that you're using explicitly to execute someone, or it's a drug that may have some benefits to somebody who is sick in a particular way, but you know that it also has other effects that are harmful because it's interfering with the basic body's system.

So it's not even like a radical or difficult to understand concept that "unavoidably unsafe" means can be used as a weapon or is often used as a weapon. And that's why you can, I think, now that people understand better what vaccines are and what's in them and what doesn't have to be disclosed about what's in them, that vaccines should be in that category of deadly weapons with guns and knives

SW: So if a state would pass something like that, put that into their law that this is and the vaccine is unavoidably unsafe and it can be used in criminal ways, what does that mean for the PREP Act?

SL: It becomes an even bigger license to kill. Yeah. Even more explicit license to kill. Right.

KW: Yes. This draws it out to make it more clear to people: Congress is intentionally killing as many people as possible, as quickly as possible, using drug companies as the intermediary to put the poison in the bottles and put the labels that say "vaccine" and get them distributed. And when people can see that more clearly, they stop taking vaccines.

SW: Yeah. We touched a little bit on this before, but Katherine, you highlighted the argument that framing the issue of public health rather than treason and war bolsters support of the PREP Act. So just turning the way that we're talking about this away from health to more like "this is, we're in a war here." So would you just really clearly outline to my audience, how the people who pushed these COVID measures committed the treason and how many did it knowingly.

KW: I don't know how many did it knowingly, but I tend to think it's a lot more than I used to think since I read that December 21, 2005 Senate record, because within two days of it being slipped into that defense appropriations bill, they already had a very good legal analysis that said this is clearly unconstitutional. This is clearly a violation of the separation of powers between the different branches of the federal government and clearly a violation of the federalist separation of powers between the federal government and the states. And they voted for it anyway.

So everyone who gave a speech certainly knew that they were committing treason. Everyone who heard the speech or read the letter that [Erwin] Chemerinsky wrote also knew that what they were doing was committing treason. And as for people who have been voting on some of the measures since then, I don't know. It depends how much they understood and how much they just were like, "I'm here in Congress. I do whatever they tell me to do. I vote when they tell me to vote, and I vote in the way that they tell me to vote."

But treason is "levying war against the United States or adhering to their enemies." I'm looking at it. "Giving them aid and comfort within the United States while owing allegiance to the United States." And to whatever extent, people can start to examine the actions of the members of Congress and the president and the cabinet secretaries and the judges, as far as "who do you owe allegiance to if this is what you think is what you should be doing?" And watching what they do. Clearly, they are not thinking of themselves as owing allegiance to the United States. They think they owe allegiance to somebody else. And that's why they're making war against the people of the United States.

SL: Yeah, interestingly, a law firm that we've talked to before, they FOIA'd the records of oaths of office for a bunch of high-level officials in the first Trump administration and the Biden administration. So they FOIA'd their records of their properly executed oath of office. Most of them did not have it. Like Rochelle Walensky didn't have it. Xavier Becerra didn't have it. There's a bunch of these health and related high level officials did not have those oaths of office executed while they were doing this. And that may be because they knew that they were committing treasonous acts.

KW: There are several laws related to that main treason one. Like, it is also a crime, if you know of treason, not to disclose it. It's also a crime to incite rebellion, which you can construe what the HHS secretaries have been doing as a form of rebellion or seditious conspiracy.

And then there's another one that prohibits advocating the overthrow of the U.S. government constitution and laws. And that's, Congress basically did overthrow the U.S. government, constitution and laws by passing the PREP Act and by not repealing it. Every day that goes by that they are sitting in there and they know about this, which they do, and they don't put forward bills to repeal it, they're adding their own ratification of the treason. And that's the ones who are there now, even if the ones who were there in 2005 are out of office now.

SW: So what we saw during COVID was that everything was put, all of these records, all of this data was put behind this national security line. We were told, "we can't get this to you because it's national security." Given the military countermeasures designation and liability shield provided by the PREP Act, do you suspect the justification of national security might be used to mask nefarious intentions of the United States government and the military leadership?

KW: I don't think they're even masking it. I think they're doing it right down in the open.

SL: Yes.

KW: I think they have merged public health with the military. That's one of the nuances that I'm slightly different perspective on what Sasha and Debbie Lerman put together with the COVID dossier, because I think that, they say the COVID was not a public health event, but I think it was a public health event to the extent that public health and military are the same thing. They have been the same thing for many, many decades. The public health part of it is the chemical and biological warfare part of the U.S. military. And so, yes, they're going to keep using it. They're going to keep pretending that there are threats that don't exist, but they're going to say that they do. They're going to keep pretending that what they've developed is a remedy in some way or a preventative for the threat that does not exist. And the remedy itself is a poison. And they're going to keep using the whole, the whole package is made to be used and they're going to use it.

SL: Yeah, I agree with it. So when we're saying it's not a public health event, in the sense that people expect it, right? Like normally expect it. But I did, I recently, and I'll be publishing about it more, I recently read a very detailed account of official U.S. government biological warfare program when it was going on before Nixon terminated it. It went on for 27 years, and the scripts developed back then. So I'm not going to discuss it in detail now, but yeah, all these approaches of fear-mongering about non-existent threats and then coming up with remedies and solutions which only evolve into more power and more money to the people who are implementing these things.

That's been back there. And Nixon terminated official, and then they signed up to bio-weapons convention, sort of. It's not enforceable. And by doing that, they simply moved everything into private sector and academia as "infectious disease research." But it just...

KW: And into federal government as public health programs. They didn't terminate it at all. They just renamed it...

June 2, 2025 - There cannot be product liability exposure for manufacturers of products for which no physical, objective standards exist.

(Excerpt)

...Liability for manufacturers and others in the distribution chain for vaccines and other biological products

Sasha Latypova posted a report about FDA "approval" of Moderna's mNexspike vaccine: June 1, 2025 - #MAHA-FDA has approved Moderna's "next generation" mRNA shot for covid.[323]

A reader tagged me with links to two other reports about the same FDA announcement, and asked:

> "It's not clear if this is a medical countermeasure under PREP Act emergency declaration or if it would be subject to liability. I'm guessing it's still EUA. Any idea Katherine Watt?"

My reply

To the extent this report is about a vaccine being "approved" by FDA, my understanding is that no vaccine manufacturers have ever been or are ever subject to liability for the products they produce, because there are no physical, objective standards for safety, efficacy, purity, manufacturing quality control or any other parameter against which a product can be tested for compliance; there are no valid tests that would demonstrate compliance or non-compliance with such standards (which don't exist to be applied, because FDA has never established or promulgated any such standards); FDA has no legal obligation to conduct any tests for compliance or impose any enforcement measures; and there is no access to courts or other fact-finding, law-enforcement entities, and no requirement that manufacturers submit to any fact-finding, law-enforcement procedures.

It doesn't make any legal difference whether a product is an EUA (emergency use authorization) product or a BLA (biologics license application) product, or any other classification, going back to 1902.

There are no physical standards for biologics, no methods to assess their compliance with such standards (which don't exist) and no procedures or venues for fact-finding or enforcement.

In my view, the BLA/CMC (chemistry, manufacturing and controls) charade and its precursors back to 1902 — false reports, applications, licenses, approvals and other theatrical props suggesting research studies and manufacturing standards, which are exchanged between company officers and FDA officers — is for the purpose of projecting the illusion, among the targeted population, that biomedical researchers and manufacturers have the physical ability to control and stabilize mixtures of microorganisms, human, animal and plant tissues and cells, organic components of cells of living creatures, nutrient solutions, and synthetic inorganic chemicals and metals, and have the physical ability to design such mixtures to have therapeutic value.

[323] https://sashalatypova.substack.com/p/maha-fda-has-approved-modernas-self

The purpose of the pretextual documents is to instill irrational trust and override or block calm, rational assessment of the absurd scientific, technical and medical claims made by biological product purveyors.

In my view, the EUA charade — including the same false documents simulating research studies and manufacturing quality standards — is for the purpose of projecting the same illusion of biomedical diagnostic and manufacturing competency combined with the illusion that something new and dangerous has "emerged" suddenly into airborne, casual-contact transmission, creating an "emergency," thereby instilling rapid-onset fear and confusion, and more intensely overriding calm, rational assessment of the situation overall, and the measures recommended by health authorities in response.

EUAs are about 'faking fakery *faster*'[324] to borrow Sasha Latypova's phrase.

Upon calm, rational assessment and evidentiary review, all the stories told about vaccines (virus lie + contagion lie = vaccine lie[325]), whether under routine conditions such as childhood immunization schedules, or under emergency conditions such as a unilateral HHS Secretary declaration that a public health emergency "exists" completely fall apart.

As the stories fall apart, vaccine hostility rises, and vaccine uptake rates drop.

Related

- April 7, 2025 - No one can be found in legal violation of a rule they were never required to comply with, nor can anyone be found to have failed to meet an evidentiary standard they were never required to meet.

[324] https://sashalatypova.substack.com/p/uwash-n-fold-a-science-fraud-laundering
[325] https://drmikeyeadon.substack.com/p/virus-lie-contagion-lie-vaccine-lie

June 6, 2025 - On whether 'public health emergency of international concern' declarations by WHO Director-General are required to be supported by physical evidence, or subject to fact-finding and evidentiary review

Question[326] from Jessica Hockett[327]:

> Remind me - if the WHO's 30 January 2020 [declaration of a public health emergency of international concern by WHO Director-General] were shown to be false, i.e., the conditions for activation were not met and the persons responsible for green-lighting the decree proven to have acted maliciously or against contradictory or insufficient evidence, what would "happen" (if anything)?

My reply:

Another person to ask about this is James Roguski. I have spent far less time studying the WHO International Health Regulations than Roguski has.

I think the WHO-IHR is probably the legal instrument whose contents would address this question. I've focused on studying American federal and state law, because the WHO-IHR, in itself, has limited enforcement mechanisms. My understanding is that the enforcement mechanisms the WHO-IHR does have come mostly by reference to other treaties and trade agreements, that can be used to financially penalize non-compliant countries. (Other enforcement mechanisms include the terms of vaccine supply contracts that prohibit third-party testing of delivered products and designate state assets as collateral to be forfeited in the event the purchasing government violates contract terms.)

WHO-IHR directs or requires participating member-states to adopt and implement their own domestic laws for pandemic surveillance, reporting and response measures, and subjects them to financial penalties if they don't adopt those implementing laws. For example, Article 56, Section 4: "Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement."

I looked briefly last night and this morning at the WHO-IHR, as of the 2005 amendments,[328] with your questions in mind.

In the definitions section, the WHO-IHR defines a PHEIC as "an extraordinary event which is determined as provided in these Regulations i. to constitute a public health risk to other States through the international spread of disease and ii. to potentially require a coordinated international response."

There's a schematic diagram at Annex 2, called a "decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern." One of the three potential pathways mentions an "algorithm" but I haven't located any other references

[326] https://substack.com/@jessicahockett/note/c-123157530
[327] https://www.woodhouse76.com/
[328] https://www.who.int/publications/i/item/9789241580496

to an algorithm in a keyword search of my files. (That doesn't mean there isn't an algorithm. I just don't have more information about it currently.)

In a Federal Register notice Feb. 6, 2020 (85 FR 7874) about quarantine and airline reporting requirements, HHS-CDC used the WHO-IHR definition in a footnote: "Under the International Health Regulations, a public health emergency of international concern is 'an extraordinary event' that constitutes a 'public health risk to other States through international spread of disease and to potentially require a coordinated international response."

Screenshots of the decision diagram from Annex 2 of WHO-IHR 2005 below; link to the 82-page WHO-IHR, Third Edition[329] in which the Annex is located.

The 2005 WHO-IHR language is general, circular, or self-referential: "unusual" or "unexpected," cases of disease, events "of potential concern" or events of "unknown causes or sources," with cases identified "as per WHO case definitions."

I also located a July 22, 2022 WHO document about case definitions,[330] which uses general clinical symptoms (cough, fever) or epidemiological criteria (contact with probable or confirmed cases), or positive-result from non-validated diagnostic tests.

There may be other provisions in the 2022, 2023 or 2024 amendments that Roguski would be able to describe and explain their applicability to your question.

My provisional understanding is that the WHO-IHR framework is the same unilateral, no-physical-evidence-required, no-validated-case-or-causality-validation-methods-required framework as the US federal framework that centers on the unfounded, unilateral assertions of the HHS Secretary.

To the extent there are no firm, physical criteria or requirements for validated physical/analytical methods capable of validating the stable identity of an allegedly disease-causing pathogen and its capacity to cause disease, and no procedures in the WHO-IHR for challenging claims that a PHEIC is occurring, I don't think there are any legal bases or venues on or in which the falsity or invalidity of such claims could be brought for review and reversal.

In other words, my interpretation of the PHEIC legal instruments is that, like the US federal and state laws, the WHO-IHR is also written so that no one can be found in legal violation of a rule they were never required to comply with, nor can anyone be found to have failed to meet an evidentiary standard they were never required to meet.

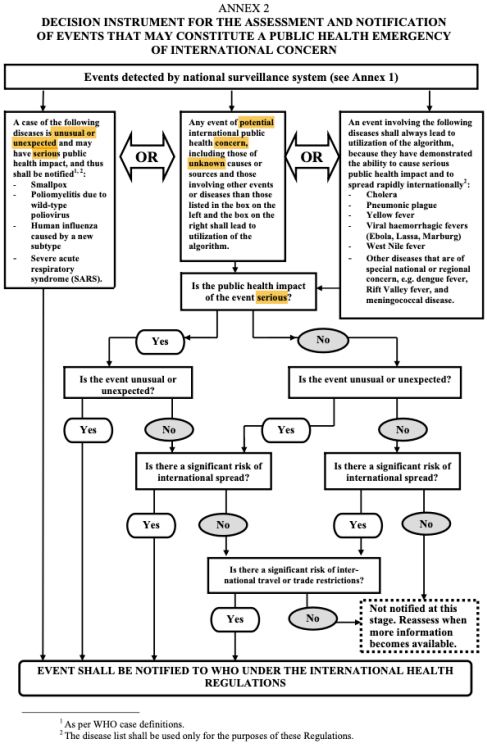
Deception, fraud, misrepresentations, mischaracterizations, etc. are legal, because there are no legal obligations to provide evidence, and no standards of evidence against which claims can be tested, and no procedures or venues through which claims can be challenged and tested.

Sometimes I think of it in terms of criminal prosecutions in a context in which framing a human suspect has been legalized. It's as if criminal prosecutors were not required to present any evidence

[329] https://iris.who.int/bitstream/handle/10665/246107/9789241580496-eng.pdf?sequence=1
[330] https://www.who.int/publications/i/item/WHO-2019-nCoV-Surveillance_Case_Definition-2022.1

that a crime occurred, nor any evidence that the human suspect had means, motive or opportunity to commit the crime, nor that he or she actually committed the crime. And it's as if the prosecutor were not required to go before any fact-finding tribunal (judge or jury), because evidence and evidentiary-review are both irrelevant to the prosecution and conviction process. The conviction occurs simultaneous to the allegation.

In the public health emergency context, allegedly stable, allegedly-disease-causing pathogens are framed, and they are not entitled to any due process. They're convicted as of the allegation, and all the pandemic management policies and programs unfold from that point in time onward.



Related

- Sept. 14, 2022 - Biotech idolatry: DOD-Pfizer contracts have replaced federal constitutions and laws. And the DOD-DOJ-HHS complex has replaced federal legislatures and courts.
- Jan. 10, 2024 - On international and US legal instruments governing "adjustment of domestic legislative and administrative arrangements" and exercise of political authority during declared public health emergencies.
- Feb. 15, 2024 - On waivers of sovereign immunity as contract provisions for nation-states buying US military countermeasures.
- April 7, 2025 - No one can be found in legal violation of a rule they were never required to comply with, nor can anyone be found to have failed to meet an evidentiary standard they were never required to meet.
- June 2, 2025 - There cannot be product liability exposure for manufacturers of products for which no physical, objective standards exist.

June 9, 2025 - On whether US-HHS Secretary Alex Azar needed UN-WHO declaration of "public health emergency of international concern" to issue determination that "public health emergency exists" in January 2020.

Response to comment[331] from Jessica Hockett:

> As far as I can tell, Azar needed the WHO PHEIC on Jan. 30, 2020 in order to issue his Jan 31, 2020 decree. Let me know if you see it differently.

My reply

I don't think Azar needed the WHO PHEIC, for several reasons.

To the extent that the worldwide, coordinated pandemic preparedness system is a deception project jointly executed by the US HHS-DoD-DHS-whole-of-government and the UN-World Health Organization, I think they have coordinated the drafting and adoption of the legal instruments each institution relies on as authorization for their respective actions.

As a coordinated team interested in maximizing public acceptance of the necessity for any pandemic preparedness and response at all (or routine communicable disease control and vaccination programs), and government and WHO authority to actually carry out pandemic preparedness and response programs, US-HHS-DoD and WHO have a mutual interest in projecting the credibility of both institutions/conglomerates, by referring to each others' acts as providing further support for the course of action taken by each institution.

So while I don't think HHS/Azar legally needed the WHO-PHEIC to conduct his own acts and direct the acts of other officials in the United States, Azar benefited from the WHO-PHEIC/Director-General's performance because the WHO performance added weight and apparent credibility to HHS/Azar's own acts, and the WHO-PHEIC/Director-General's performance benefited from Azar's US-HHS acts, because Azar's performance added weight and apparent credibility to the World Health Organization's acts.

Neither legal framework requires either performer to provide physical evidence that "something is spreading," or poses a threat to health, nor to submit any such evidence to any fact-finding, evidentiary-review tribunal.

Here are the reasons why I don't think Azar needed the WHO-PHEIC.

One reason is that one of the statutes under whose authority Azar acted also authorizes Defense Secretary and Secretary of Homeland Security (in addition to HHS Secretary) to make determinations that emergencies exist.

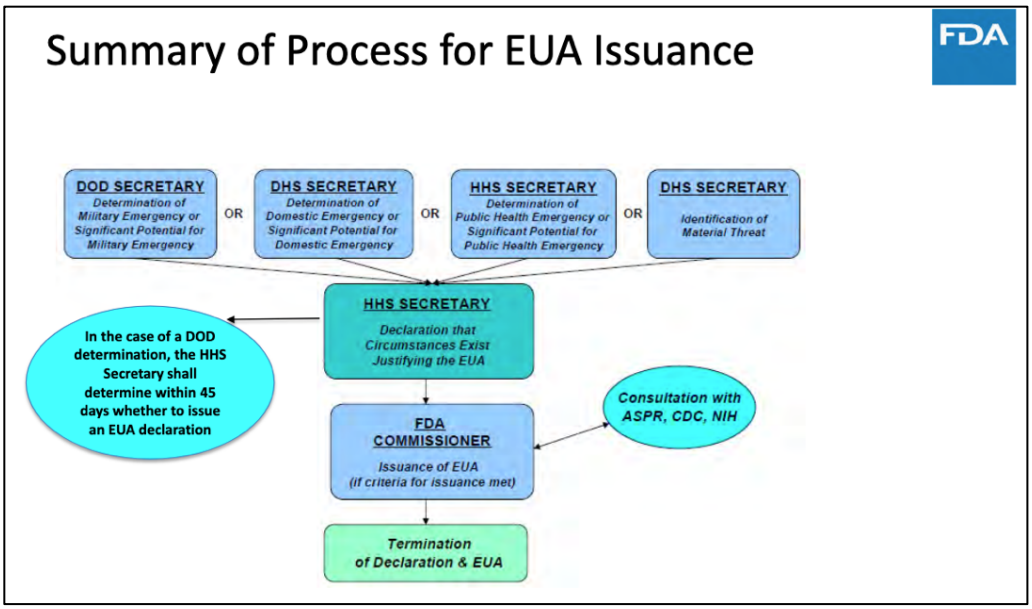
The section of the FDCA actually used by Azar (HHS Secretary) was 21 USC 360bbb-3(b)(1)(C).

[331] https://substack.com/@jessicahockett/note/c-124022990

21 USC 360bbb-3(b) Declaration of emergency or threat justifying emergency authorized use

(1) In general. The [HHS] Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

> (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;
>
> (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with—
>
> > (i) a biological, chemical, radiological, or nuclear agent or agents; or
> >
> > (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;
>
> (C) a determination by the [HHS] Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or
>
> (D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient to affect national security or the health and security of United States citizens living abroad."



Schematic from August 2020 FDA slide deck.[332]
Presenter: Elizabeth Sadove, FDA Office of Counterterrorism and Emerging Threats.

Those determinations and declarations under Title 21 (Food Drug and Cosmetic Act) are related to PHE and "material threat" determinations issued under Title 42 (Public Health Service Act) at 42 USC 247d(a), 42 USC 247d(b)(1), 42 USC 247d-6b(c)(2) and 42 USC 247d-6d(b)(1) [PREP Act declarations pertaining to the production and use of countermeasures].

> 42 USC 247d(a)
>
> Emergencies. If the Secretary determines, after consultation with such public health officials as may be necessary, that-
>
> (1) a disease or disorder presents a public health emergency; or
>
> (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,
>
> the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2)...

[332] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/02/2020.08.25-fda-cdc-regulatory-updates-use-of-mcms-table-p.-18.pdf

42 USC 247d(b)(1)

Public Health Emergency Fund

(1) In general. There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities.

42 USC 247d-6b(c)(2)

Material threat. The Homeland Security Secretary, in consultation with the [HHS] Secretary and the heads of other agencies as appropriate, shall on an ongoing basis-

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

42 USC 247d-6d(b)(1)

(b) Declaration by Secretary (1) Authority to issue [PREP Act] declaration

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) [liability protections] is in effect with respect to the activities so recommended.

*

Another reason why I don't think Azar legally needed the WHO-PHEIC is that the quarantine regulations (42 CFR 70 and 71) define “public health emergency” as having five legal sources, any one of which is legally sufficient, and two of which are unrelated to WHO acts:

"*Public health emergency* as used in this part means:

1. Any communicable disease event as determined by the [CDC] Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or
2. Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)); or
3. Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or
4. Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or
5. Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease."

Several state AGs petitioned HHS to remove reasons 3, 4 and 5 from the US quarantine regulations definitions in July 2022; their petition was denied by HHS in October 2022. Two of the states then filed a federal complaint in January 2023; their complaint was dismissed in August 2023.

I think the most detailed attempt I've made at untangling the overlapping, mutually-reinforcing relationships between FDCA-authorized determinations and declarations and PHSA-authorized determinations and declarations is this post:

- Dec. 6, 2023 - More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.

Posts about the state AG's challenge to HHS inclusion of WHO acts as among definitions of 'public health emergency:'

- Oct. 17, 2023 - Texas and Oklahoma v. US Department of Health and Human Services and Xavier Becerra: case documents
- Oct. 18, 2023 - There is never going to be another "deadly global pandemic." There have not been any in the past.

June 17, 2025 - No HHS or FDA authority or competency to standardize or regulate vaccine-bottling processes or products; notes on "recall" authority.

Comments (with some additions) on:

- June 13, 2025 - About that myocarditis warning that the good-FDA slapped on Pfizer jab[333] (Sasha Latypova)

In my view, there is no commercial market from which FDA could remove the Covid shots, or any vaccines.

EUA [emergency use authorization], BLA [biologics license application], doesn't matter.

Covid vaccines, like all vaccines, are used in war, not in commerce, not in commercial markets.

"Approval" is a legal fiction. *All* acts of FDA "approval," "authorization," and "licenses" are legal fictions.

All interactions between FDA (and precursor "regulators") and vaccine-bottlers have all been fiction, all the way back to 1902.

Vaccines are legalized weapons, trafficked for maiming and killing purposes, not medical products labeled or regulated for purity, safety or efficacy.

The labels are part of the legalized weapon delivery system; the purpose of the labels is to deceive the targets into seeing a bottle of poison as a bottle of standardized, regulated medicine.

Further, FDA has no authority to regulate manufacture of *any* biological products, not just vaccines, and not just Covid vaccines.

There are no physical standards for product identity, purity, stability, non-adulteration, non-contamination, toxicity, or potency in statute or regulation governing manufacture of any biological products, and there are no analytical test procedures that poison-bottlers or FDA could apply to determine whether contents of any container meet, fail to meet, or exceed such standards (which standards don't exist.)

The simulation for such standards in earlier decades was printed in the "Additional Standards" sections of fictional biological products regulations.

Those have been removed and replaced, since about 1996, with the current form of simulation: the "Chemistry Manufacturing and Control" or CMC package, through which poison-bottlers notify the FDA about what they (the bottlers) will pretend to have the technical capacity to do, and will pretend to do, and will pretend to self-monitor and self-report having done.

[333] https://sashalatypova.substack.com/p/about-that-myocarditis-warning-that

FDA then issues “approval” letters pretending that the poison-bottlers actually carried out the pretend processes using the pretend techniques, actually did self-monitor, and actually found themselves in compliance with the simulation of standardization.

Sometimes FDA also issues fake “lot release” documents, pretending that FDA has the technical capacity to corroborate the poison-bottlers lies, and has applied its technical capacity to confirm that the poison-bottlers properly used the fake-techniques the bottlers claim to have used.

FDA and poison-bottlers jointly use CMC packages, and labels, and “fact sheets” and fake “lot release” documents, to deceive the public into seeing bottles of poison as bottles of standardized, regulated medicine.

True physical standards don’t exist for biological products because they can’t exist. Analytical tests for assessing biological products for conformity with standards don’t exist because they can’t exist.

Such standards and analytical tests can’t exist because of the nature of biological matter.

All vaccines are intrinsically heterogeneous, unstable mixtures of biological cells, tissues, sub-components thereof, synthetic chemicals, nutrient solutions, carrier substances and other biologically-active junk.

Vaccine contents are not designed to specifications to cause predictable, controllable, beneficial effects.

Their contents are incubated, cultured, fermented, putrefied and decanted into bottles of ill-characterizable mixtures, then refrigerated, frozen and/or freeze-dried, then defrosted, dissolved and injected into bloodstream of targets to cause unpredictable, harmful effects with plausible deniability for those who recommend, bottle, transport and use the weapons.

Reader reply:

> That is my understanding too. That is, that manufacture of 'biologics' class of drugs is so high-tech that GMP have yet to be developed. Thusly, one could test for a 100 adulterants and not find another 100 that were actually in the product...

My reply:

It's not that biologics manufacturing is so "high-tech." It's not manufacturing in a technical way at all.

It's more like making yogurt, bread, beer or sauerkraut — which are made with limited, discernible, digestible bacteria and which are consumed through the digestive tract, which has the capacity to break down and use the food. And with fermented foods, or foods in which fermentation is one step in the process, humans and animals have senses (smell, taste, sight) that enable us to recognize when the food is not fit for consumption (contaminated, moldy etc.) and avoid eating or drinking it.

Vaccine propagation methods do not use only limited, discernible, digestible bacteria, and they're not subject to effective procedures that destroy most competing microorganisms to allow only the required fermenting microorganisms to outgrow all the others.

And vaccines are injected into the blood.

Vaccine propagation, as I understand it, involves throwing a bunch of living organisms (i.e. bacteria), plus cells and tissues taken out of living organisms (fungi, plant, bird, insect, animal, human) and other junk in an incubation vat with nutrient solutions; fermenting it while some of the material dies and decays; bottling it; refrigerating/freezing/freeze-drying it; and then reconstituting it at room temperature and injecting into living bodies where some of the processes resume at body temperature and many of the fragments of the dead organisms, cells and tissues (i.e. proteins) are biologically active in the form of evoking anaphylactic/allergic reactions and inducing chronic diseases known as cancer, asthma, leaky gut, and so on.

I agree that one could test for 100 adulterants or contaminants (also referred to as extraneous proteins, adventitious agents, bioburden, and other terms in pretense-regulations and Guidance for Industry documents) and not find another 100 that were in the product, and therefore there can't be GMP [good manufacturing practices] standards, but not because manufacturing is "high-tech."

It's because living organisms exist in so many forms, and are involved in so many transformations and interactions with each other over time, no one can reliably predict what might be in any sample to test for, nor can anyone predict what the effect of each thing that might be found, might be in the life and organ functioning of any person or animal into whose blood that sample might be injected, nor can anyone reliably predict whether the form that the sample contents were in at the time of testing, will be the same form that the sample contents were in at the time of injection, and there's a high probability that the two compositions will not be the same, because the contents of the bottle are not stable, and are not homogeneous...

Aug. 19, 2025 - Common law, statutory law and administrative law preclusion of judicial review of government acts allegedly undertaken for disease surveillance and control.[334]

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

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

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

In 1974, the Supreme Court issued a ruling in *Marshall v. US* (414 U. S. 417), a case about whether a thrice-convicted felon should be eligible for an experimental narcotics treatment program. The *Marshall* court cited a 1968 case (*Powell v. Texas*, 392 US 514), to point out

> "...the inescapable fact is that there is no agreement among members of the medical profession about what it means to say that "alcoholism" is a "disease." One of the principal works in this field [E. Jellinek, *The Disease Concept of Alcoholism* (1960)] states that 'alcoholism has too many definitions and disease has practically none.'…"

[334] October 2025 Note - A version of the information published Aug. 19, 2025 also incorporated into St. Benedict Memo published in September 2025.

The Marshall court continued:

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

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

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

Justice Roberts cited *Marshall* in holding that

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

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

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

<u>Statutory law and administrative law: designation of "communicable diseases" by Presidential executive order</u>

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the 1966 law, Congress codified this provision at 5 USC 701:

> "(a) This chapter applies, according to the provisions thereof, except to the extent that (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 USC 701(a)

Administrative agency definitions for "communicable disease" and related terms

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Discussion

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

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

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

At the extreme end of the spectrum, scientific and medical bases for government policies, programs and products are completely fraudulent for communicable disease classification and case diagnosis, for infectious agent classification, and for vaccination as a method to prevent alleged infection and alleged transmission.

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

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

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

Scope for judicial review of government biomedical policies, programs and products approaches zero.

Sept. 10, 2025 - 42 USC 247d et seq, Public health emergencies, enacted by US Congress through Public Health Improvement Act (2000)

Summary as published in St. Benedict Memo (September 2025)

In 2000 (PL 106-505), Congress struck the "public health emergencies" section of the Public Health Service Act [PHSA 319], that Congress had first added in 1983 (PL 98-49, see above) and codified at 42 USC 247d.

Congress replaced the 1983 version of PHSA 319 with an expanded version, codified at 42 USC 247d through 42 USC 247d-7.

Congress incorporated core provisions of the 1983 law into the 2000 law and added new programs as PHSA 319A to 319G of the Public Health Service Act, codified at 42 USC 247d-1 through 42 USC 247d-7.

42 USC 247d [PHSA 319] - Public health emergencies

As it had in 1983, Congress authorized the Secretary of Health and Human Services to "determine, after consultation with such public health officials as may be necessary" that "a disease or disorder presents a public health emergency or a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks otherwise exists," and, if he so determined, Congress authorized the HHS Secretary to "take such action as may be appropriate to respond," including making grants, entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder. 42 USC 247d(a)

As it had in 1983, Congress established a "Public Health Emergency Fund in the Treasury to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection, and authorized appropriations of such sums as may be necessary."

Congress directed the HHS Secretary to submit annual reports to House and Senate committees within 90 days after the end of each fiscal year, describing expenditures and "each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency." 42 USC 247d(b)

42 USC 247d-1 [PHSA 319A] - National Needs to Combat Threats to Public Health

In 2000 (PL 106-505), Congress directed the HHS Secretary to "establish reasonable capacities that are appropriate for national, State, and local public health systems and the personnel or work forces of such systems" to "improve, enhance or expand the capacity of... public health agencies to detect and respond effectively to significant public health threats, including major outbreaks of infectious disease, pathogens resistant to anti- microbial agents and acts of bioterrorism."

Congress specified the capacities to include capacities to:

> (A) recognize the clinical signs and epidemiological characteristic of significant outbreaks of infectious disease;
>
> (B) identify disease-causing pathogens rapidly and accurately;
>
> (C) develop and implement plans to provide medical care for persons infected with disease-causing agents and to provide preventive care as needed for individuals likely to be exposed to disease-causing agents;
>
> (D) communicate information relevant to significant public health threats rapidly to local, State and national health agencies, and health care providers; or
>
> (E) develop or implement policies to prevent the spread of infectious disease or antimicrobial resistance.

Congress authorized $4 million for fiscal year 2001, and "such sums as may be necessary for each subsequent fiscal year through 2006."

42 USC 247d-2 [PHSA 319B] - Assessment of Public Health Needs

Congress directed the HHS Secretary to award grants to States and political subdivisions to evaluate "the extent to which the States or local public health agencies can achieve the capacities" listed in the previous section, and to provide technical assistance.

Congress authorized the States to contract with outside entities to conduct evaluations, directed the States to use methods that would enable state to state comparisons, and directed the States to submit reports about the evaluations to the HHS Secretary.

Congress authorized $45 million for fiscal year 2001, and "such sums as may be necessary" for subsequent years through 2003.

42 USC 247d-3 [PHSA 319C] - Grants to Improve State and Local Public Health Agencies

Congress authorized the HHS Secretary to award competitive grants to address core public health capacity needs, "with a particular focus on building capacity to identify, detect, monitor, and respond to threats to public health."

To be eligible for grants, States and political subdivisions had to have completed the evaluations under 42 USC 247d-2.

Congress authorized grant recipients to use funds for four program areas, to (1) train public health personnel; (2) improve "participation in an electronic network by which disease detection and public health related information can be rapidly shared among national, regional, State, and local public health agencies and health care providers;" (3) develop a plan for responding to public health emergencies, including significant outbreaks of infectious diseases or bioterrorism attacks, which is coordinated with the capacities of applicable national, State, and local health agencies and health care providers;" and (4) enhance laboratory capacity and facilities.

Congress authorized $50 million for fiscal year 2001, and "such sums as may be necessary" for subsequent years through 2006.

42 USC 247d-4 [PHSA 319D] - Revitalizing the CDC

Congress stated, as "findings," that the Centers for Disease Control and Prevention "have an essential role in defending and combatting public health threats of the 21st century and requires secure and modern facilities."

Congress authorized $180 million for fiscal year 2001 to support construction and renovation of facilities, including "laboratories, laboratory support buildings, health communication facilities," and "such sums as may be necessary" for subsequent years through 2010.

42 USC 247d-5 [PHSA 319E] - Combating Antimicrobial Resistance

Congress directed the HHS Secretary to establish an "Antimicrobial Resistance Task Force" to provide advice and recommendations, to include representatives of federal agencies, and to seek input from public health, manufacturing, veterinary and medical professionals.

Congress directed the task force to consider "public health factors contributing to increasing antimicrobial resistance; public health needs to detect and monitor antimicrobial resistance; detection, prevention and control strategies for resistant pathogens; the need for improved information and data collection; the assessment of the risk imposed by pathogens presenting a threat to the public health" and any other issues determined by the HHS Secretary to be relevant.

Congress directed the HHS Secretary to work with the task force and State and local public health officials to improve "participation in a surveillance plan to detect and monitor emerging antimicrobial resistance" and improve "participation in an integrated information system...to exchange...data between public health departments."

Congress directed the HHS Secretary and the director of USDA Agricultural Research Services, to support research related to: development of new therapeutics, including vaccines and antimicrobials, against resistant pathogens; development of medical diagnostics to detect pathogens resistant to antimicrobials; epidemiology, mechanisms, and pathogenesis of antimicrobial resistance; sequencing of genomes of "priority pathogens" as determined by the NIH Director in consultation with the task force established under subsection, and other relevant research areas.

Congress directed the HHS Secretary and other federal public health officers to develop educational programs to increase general public awareness of the public health threat of antimicrobial resistance and the appropriate use of antibiotics; instruct health care professionals in prudent use of antibiotics; and train laboratory personnel in the recognition or identification of resistance in pathogens.

Congress authorized the HHS Secretary to award competitive grants to States or local public health agencies, Indian tribes or other public or private nonprofit entities. Congress authorized funds to be used to train people to identify patterns of resistance, improve participation in information systems, and develop policies to control the spread of antimicrobial resistance. Congress authorized grants for demonstration programs to promote "judicious" use of antimicrobial drugs, eligible entities to include hospitals, clinics, long-term care facilities and professional medical societies. Congress directed the HHS Secretary to provide technical assistance, and authorized $40 million for fiscal year 2001, and "such sums as may be necessary" for subsequent years through 2006.

42 USC 247d-6 [PHSA 319F] - Public health countermeasures to a bioterrorist attack

Congress directed the HHS Secretary and Secretary of Defense to establish an "interdepartmental working group on preparedness...for the medical and public health effects of a bioterrorist attack on the civilian population." Congress directed the Working Group on Preparedness for Acts of Bioterrorism to coordinate research on pathogens likely to be used, therapies to treat such pathogens, equipment to detect pathogens and protect against infection, and to develop procedures for the release of strategic reserves of vaccines, drugs, and medical supplies "which may be needed rapidly after a bioterrorist attack." 42 USC 247d-6(a)

Congress directed the HHS Secretary, FEMA Director, Attorney General and Secretary of Agriculture to set up another working group to address the Public Health and Medical Consequences of Bioterrorism. Congress directed the Working Group on Public Health and Medical Consequences of Bioterrorism to improve the preparedness of public health institutions, providers of medical care and emergency service personnel to "detect, diagnose and respond" to a bioterrorist attack, and to assure the quality of joint planning and training programs for firefighters, ambulance personnel, police and other emergency responders, hospitals, primary care facilities and public health agencies. 42 USC 247d-6(b)

Congress authorized the HHS Secretary to award competitive grants and enter cooperative agreements to increase capacity to detect, diagnose and respond to acts of terrorism. Congress authorized grant recipients to use funds to train health care professionals "to recognize the symptoms and epidemiological characteristics of exposure to a potential bioweapon," identify potential bioweapons, coordinate medical care for exposed individuals, and coordinate "rapid communication of data generated from a bioterrorist attack between national, State, and local health agencies, and health care providers." Congress directed the HHS Secretary to notify the Director of the DOJ Office of Justice Programs and Director of the National Domestic Preparedness Office each year about grants awarded, and coordinate with grants awarded with the Office of Emergency Preparedness and the CDC. 42 USC 247d-6(c)

Congress directed the HHS Secretary to provide HHS assistance to State and local health agencies. 42 USC 247d-6(d)

Congress directed the HHS Secretary and the Working Group on Public Health and Medical Consequences of Bioterrorism to develop educational programs to instruct public health officials, medical professionals and other health care workers "in the recognition and care of victims of a bioterrorist attack" and to train laboratory workers "in the recognition and identification of a potential bioweapon." 42 USC 247d-6(e)

Congress directed the HHS Secretary and the Working Group on Preparedness for Acts of Bioterrorism to conduct research related to "the epidemiology and pathogenesis of potential bioweapons, the development of new vaccines or other therapeutics against pathogens likely to be used in a bioterrorist attack, the development of medical diagnostics to detect potential bioweapons," and other relevant research, under a section titled "future resource development." 42 USC 247d-6(f).

Congress directed the Comptroller General to prepare a General Accounting Office (GAO) report for House and Senate committees describing federal research on, preparedness for and management of the public health and medical consequences of a bioterrorist attack against the civilian population, coordination and funding of those federal activities, and the effectiveness of such programs. 42 USC 247d-6(g)

Congress directed that funds appropriated under the new section shall "supplement and not supplant" other funds, and authorized $215 million for fiscal year 2001, and "such sums as may be necessary" through 2006. 42 USC 247d-6(h) and (i).

42 USC 247d-7 [PHSA 319G] - Demonstration program to enhance bioterrorism training, coordination, and readiness

Congress authorized the HHS Secretary to make grants to up to three entities for demonstration programs to improve "detection of pathogens," development of response plans, and training programs. Congress designated, as eligible grant recipients, States, political subdivisions of States, and public or private non-profit organizations. 42 USC 247d-7(a) and (b)

Congress established, as criteria for grant awards, the applicant's proximity to a major research university "with expertise in scientific training, identification of biological agents, medicine, and life sciences," proximity to a laboratory with expertise in identification of biological agents, demonstrated support from State and local governments and research institutions, proximity to an academic medical center, and any other factors deemed appropriate by the HHS Secretary. 42 USC 247d-7(c)

Congress directed the Comptroller General to prepare a GAO report for House and Senate committees describing "the ability of grantees...to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel." 42 USC 247d-7(f). Congress authorized $6 million for fiscal year 2001, and such "sums as may be necessary" through 2006. 42 USC 247d-7(g)

Sept. 10, 2025 - 21 USC 360bbb-3 [FDCA 564], Authorization for medical products for use in emergencies, enacted by US Congress through NDAA (2003) and Project Bioshield Act (2004)

Summaries as published in St. Benedict Memo (September 2025)

2003 - 21 USC 360bbb-3 [FDCA 564] - Authorization for medical products for use in emergencies

In 1997 (PL 105-115, summarized above), Congress authorized the "expanded access to unapproved therapies" program, codified at 21 USC 360bbb to 360bbb-2.

In 2003 (PL 108-136, NDAA) Congress added a new provision: "authorization for medical products for use in emergencies," codified at 21 USC 360bbb-3.

Congress authorized the HHS Secretary to "authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an 'emergency use')...notwithstanding" other legal provisions governing interstate commerce in drugs, devices and biological products including FDCA 505, [21 USC 355, *New Drugs*], FDCA 510(k) [21 USC 360(k), *Report preceding introduction of devices into interstate commerce*], FDCA 515 [21 USC 360e, *Premarket approval of devices*] and PHSA 351 [42 USC 262, *Regulation of biological products*]. 21 USC 360bbb-3(a)(1)

Congress provided that, through an "emergency use" authorization, the HHS Secretary could authorize use of two categories of products:

> (2) Approval status of product.—An authorization under paragraph (1) may authorize an emergency use of a product that—
>
> (A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an 'unapproved product'); or
>
> (B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an 'unapproved use of an approved product'). 21 USC 360bbb-3(a)(2)

Congress provided that an "emergency use" would be in addition to any other, authorized use. 21 USC 360bbb-3(a)(3)

Congress defined the term 'biological product' by reference the definition at 42 USC 262(i) [PHSA 351(i)] as of 1997 (PL 105-115):

The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Congress defined the term 'product' to mean "a drug, device, or biological product," and defined the terms ‘emergency use,’ ‘unapproved product’ and ‘unapproved use of an approved product’ by reference to the first paragraph. 21 USC 360bbb-3(a)(4)

Congress authorized the HHS Secretary to "declare an emergency justifying the [emergency use] authorization...for a product on the basis of a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents." 21 USC 360bbb-3(b)(1)

Congress provided for termination of an emergency use authorization declaration to occur upon the earlier of two events: "a determination" by the HHS Secretary in consultation with the Secretary of Defense "that the circumstances [military emergency] have ceased to exist; or "the expiration of the one-year period beginning on the date on which the [HHS Secretary's emergency justifying use authorization] declaration is made." 21 USC 360bbb-3(b)(2)(A)

Congress authorized the HHS Secretary to renew a declaration at his discretion. 21 USC 360bbb-3(b)(2)(B)

Congress provided for the HHS Secretary to consult with product manufacturers for disposing of products whose distribution and use in interstate commerce would become unauthorized if the authorization terminated. 21 USC 360bbb-3(b)(2)(C)

Congress directed the HHS Secretary to give advance notice that a declaration was to be terminated, so that users and manufacturers could make arrangements for product returns, disposition of labeling and other informational records, and other disposition. 21 USC 360bbb-3(b)(3)

Congress directed the HHS Secretary to publish "each declaration, determination, advance notice of termination, and renewal" in the Federal Register. 21 USC 360bbb-3(b)(4)

Congress provided "criteria" for issuance of emergency use authorization declarations:

> (c) Criteria for issuance of authorization.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes—
>
> > (1) that an agent specified in a declaration under sub- section (b) can cause a serious or life-threatening disease or condition;
> >
> > (2) that, based on the totality of scientific evidence avail- able to the Secretary, including data from adequate and well- controlled clinical trials, if available, it is reasonable to believe that—
> >
> > > (A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this Act [FDCA], or licensed under section 351 of the Public Health Service Act [42 USC 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and

(4) that such other criteria as the Secretary may by regulation prescribe are satisfied. 21 USC 360bbb-3(c)

Congress, under "scope of authorization" provisions, directed the HHS Secretary to state in his "emergency use" authorization declarations, "each disease or condition that the product may be used to diagnose, prevent, or treat;...the Secretary's conclusions...that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and the Secretary's conclusions... concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence." 21 USC 360bbb-3(d)

Congress, under "conditions of authorization" provisions, directed the HHS Secretary to "establish such conditions....as the Secretary finds necessary or appropriate to protect the public health," for emergency use of unapproved products, "to the extent practicable given the circumstances of the emergency," for "a person who carries out any activity for which the authorization is issued." 21 USC 360bbb-3(e)(1)(A)

Congress directed the HHS Secretary to establish "appropriate conditions" for health care professionals administering unapproved products, ensuring that they are informed that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and of the alternatives to the product that are available, and of their benefits and risks. 21 USC 360bbb-3(e)(1)(A)(i)

Congress directed the HHS Secretary to establish "appropriate conditions" for "individuals to whom [unapproved products are] administered," ensuring that they are informed that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and "of the option to accept or refuse administration of the product, of the

consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 USC 360bbb-3(e)(1)(A)(ii)

Congress directed the HHS Secretary to establish "appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product." 21 USC 360bbbb-3(e)(1)(A)(iii)

Congress directed the HHS Secretary to establish "appropriate conditions" for manufacturers of unapproved product, concerning recordkeeping and reporting, including records access by the Secretary. 21 USC 360bbb-3(e)(1)(A)(iv)

Congress authorized the HHS Secretary to establish "such conditions...as [he] finds necessary or appropriate to protect the public health," for persons who carry out other activities, such as which entities may distribute the [EUA] product...including limitation to distribution by government entities and...how distribution is to be performed...who may administer the product...and...the categories of individuals to whom, and the circumstances under which, the product may be administered...; conditions with respect to the collection and analysis of information...concerning the safety and effectiveness of the [EUA] product; and (for persons other than manufacturers), conditions concerning record-keeping and reporting, including records access by the Secretary. 21 USC 360bbb-3(e)(1)(B)

Congress directed and authorized much the same conditions for "unapproved use of an approved product" emergency use authorizations, "to the extent practicable given the circumstances of the emergency." 21 USC 360bbb-3(e)(2)(A)

Congress withheld authority for distributors or anyone else to "alter or obscure the labeling provided by the manufacturer" in the event the "emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change." 21 USC 360bbb-3(e)(2)(B)(i)

Congress authorized persons who are not manufacturers, in such circumstances (manufacturer refusal to change labeling) and who "choose to act under this clause" to "provide appropriate information with respect to such product in addition to the manufacturer's labeling, as long as he does not "alter or obscure" the manufacturer's labeling.

Congress noted that "such additional information shall not be considered labeling for purposes of [FDCA] section 50217." 21 USC 360bbb-3(e)(2)(B)(ii)

Congress prohibited the HHS Secretary from establishing, with respect to the distribution and administration of an EUA product for unapproved uses, conditions more restrictive than those for distribution and administration of the product for its approved uses. 21 USC 360bbb-3(e)(2)(C).

Congress authorized the HHS Secretary to waive or limit, "to the extent appropriate given the circumstances of the emergency," requirements regarding current good manufacturing practice

17 21 USC 352 [FCDA 502] prohibits "misbranding" of drugs and devices and deems a drug or device to be misbranded "if its labeling is false or misleading in any particular."

[cGMP] otherwise applicable to the manufacture, processing, packing, or holding of products, including requirements under FDCA Section 501 [21 USC 351[335]]. 21 USC 360bbb-3(e)(3)

Congress authorized the HHS Secretary to "establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of an EUA product including, with respect to drugs and biological products, requirements applicable to required contents of advertising for prescription drugs pursuant to FDCA 502(n) [21 USC 352(n)[336], or, with respect to devices, requirements under FDCA 502(r) [21 USC 352(r)[337]].

Congress provided for the "duration" of an emergency use authorization to be effective "until the earlier of the termination of the [HHS Secretary's emergency] declaration...or a revocation" and provided that, "notwithstanding" the termination of a declaration under subsection (b) or a revocation under subsection (g), an authorization "shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom it was administered during the [emergency declaration's period in effect], to the extent found necessary by such patient's attending physician." 21 USC 360bbb-3(f)

Congress directed the HHS Secretary periodically review the circumstances and the appropriateness of an authorization, and authorized the HHS Secretary to revoke an authorization "if the criteria...are no longer met or other circumstances make such revocation appropriate to protect the public health or safety." 21 USC 360bbb-3(g)

Congress directed the HHS Secretary to publish, in the Federal Register, notice of each authorization, and each termination or revocation of an authorization, and "an explanation of the reasons therefor (which may include a summary of data or information that has been submitted in an application [for approval] even if such summary may indirectly reveal the existence of such application." 21 USC 360bbb-3(h)(1)

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[335] 21 USC 351 [FDCA Section 501] prohibits interstate commerce in "adulterated drugs and devices," and deems a drug or device to be adulterated (among other findings) "if it consists in whole or in part of any filthy, putrid, or decomposed substance; if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 USC 351(a)

[336] 21 USC 352(n) [FDCA Section 502(n)] provides that a prescription drug shall be deemed to be misbranded... "unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e)57, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e)57, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness..."

[337] 21 USC 352(r) [FDCA Section 502(r)] provides that a device shall be deemed to be misbranded "...unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device..."

Congress affirmed the applicability of 18 USC 1905, prohibiting public disclosure by US government officers and employees of confidential information, and affirmed the applicability of an exemption provision of the Freedom of Information Act allowing federal officers to withhold "trade secrets and commercial or financial information obtained from a person and privileged or confidential" from public disclosure under 5 USC 552(b)(4). 21 USC 360bbb-3(h)(2)

Congress provided that "actions under the authority of this section by the [HHS] Secretary or by the Secretary of Defense are committed to agency discretion" and therefore beyond the reach of judicial review under the Administrative Procedure Act at 5 USC 701. 21 USC 360bbb-3(i)

Congress provided, as "rules of construction," that nothing in the "emergency use" authorization law "impairs the authority of the President as Commander in Chief of the Armed Forces" under the US Constitution;...impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law, or ...impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in [the Strategic National Stockpile])." 21 USC 360bbb-3(j)

Congress provided a categorical exclusion, for "emergency use" of products, from laws governing conduct of clinical investigations, by providing: "If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of" FDCA 505(i), FDCA 520(g), any other FDCA provision or PHSA 351. 21 USC 360bbb-3(k)

Congress provided for persons asked to carry out activities under the "emergency use" authorization law to have the "option to carry out authorized activities," but withheld from the HHS Secretary "any authority to require any person to carry out any activity that becomes lawful pursuant to an [emergency use] authorization." Congress provided that "no person is required to inform the Secretary that the person will not be carrying out such activity," with one exception. Congress required "a manufacturer of a sole-source unapproved product authorized for emergency use" to report to the HHS Secretary "if such manufacturer does not intend to carry out any activity under the authorization." 21 USC 360bbb-3(l)

Congress provided that the "option to carry out authorized activities" would only have legal effect on a person who carries out an activity for which an authorization under this section is issued, and provided that "nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an [emergency use] authorization." 21 USC 360bbb-3(l)

2004 - 21 USC 360bbb-3 [FDCA 564] - Authorization for medical products for use in emergencies

In 2004 (PL 108-276, Project Bioshield Act), Congress amended provisions for "authorization for medical products for use in emergencies" which Congress had enacted in 2003 (PL 108-136) and which had been codified at 21 USC 360bbb-3.

When first enacted in 2003 (PL 108-236), the law authorized the HHS Secretary to declare an emergency justifying the authorization of emergency use of products "on the basis of a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents." This predicate was codified at 21 USC 360bbb-3(b)(1) in 2003 and renumbered to 21 USC 360bbb-3(b)(1)(B) as of 2004.

In 2004 (PL 108-276), Congress provided two additional predicates authorizing the [HHS] Secretary to "declare an emergency justifying the authorization" for emergency use of products.

In 2004, Congress authorized the HHS Secretary to declare an emergency on the basis of "a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents" 21 USC 360bbb-3(b)(1)(A) as of 2004.

In 2004, Congress authorized the HHS Secretary to declare an emergency on the basis of his own determination: "a determination by the [HHS] Secretary of a public health emergency under [PHSA] section 319 [42 USC 247d] that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents." 21 USC 360bbb-3(b)(1)(C) as of 2004.

In 2004, Congress amended the "termination of declaration" provision, such that the HHS Secretary's declaration (of an emergency justifying authorization for emergency use of products) terminates upon the earlier of a determination by the HHS Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances (military emergency, domestic emergency, public health emergency, or significant potential for such emergencies) have "ceased to exist" or the expiration of the one-year period from the date on which the HHS declaration was made. 21 USC 360bbb-3(b)(2)(A) as of 2004

Congress maintained the HHS Secretary's authority to renew any such declaration in his sole discretion. 21 USC 360bbb-3(b)(2)(B)

In 2004, Congress amended the "actions committed to agency discretion" provision precluding judicial review, to cover the actions of the HHS Secretary, Secretary of Defense (covered by the 2003 version) and cover the actions of the Secretary of Homeland Security. 21 USC 360bbb-3(i) as of 2004

Since 2004 - Amendments to 21 USC 360bbb et seq

Congress has amended and expanded the provisions of 21 USC 360bbb many times since 2004. Two such amendments are summarized below.

In 2013 (PL 113-5) Congress added to 360bbb-3, another predicate authorizing the HHS Secretary to issue emergency use authorization declarations upon "the identification of a material threat pursuant to [PHSA] section 319F–2 [42 U.S.C. 247d–6b]...sufficient to affect national security or the health and security of United States citizens living abroad." 21 USC 360bbb- 3(b)(1)(D) as of 2013.

In 2017 (PL 115-92), Congress added provisions for "expedited development and review of medical products for emergency uses" codified at 21 USC 360bbb-3c.

Congress authorized the Secretary of Defense to request that the HHS Secretary, acting through the FDA Commissioner, take actions to expedite the development of a medical product, review of investigational new drug applications, review of investigational device exemptions, and review of applications for approval and clearance of medical products, including applications for licensing of vaccines or blood as biological products, or applications for review of regenerative medicine advanced therapy products, "if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk." 21 USC 360bbb-3c(1).

Congress directed the HHS Secretary and FDA Commissioner to respond to a request by the Defense Secretary for expedited development and review, by holding meetings with the sponsor and the review team throughout the development of the medical product; providing timely advice to, and interactive communication with, the sponsor regarding the development of the medical product to ensure that the development program to gather the nonclinical and clinical data necessary for approval or clearance is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; applying any applicable FDA program intended to expedite the development and review of a medical product; and in appropriate circumstances, permitting expanded access to the medical product during the investigational phase, in accordance with applicable requirements of the Food and Drug Administration. 21 USC 360bbb- 3c(2)

To facilitate enhanced collaboration and communication with respect to the most current priorities of the Department of Defense, Congress directed the FDA to meet with the DoD and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority [BARDA] on a semi-annual basis for the purposes of conducting a full

review of the relevant products in the DoD portfolio; and directed the Director of the Center for Biologics Evaluation and Research [FDA-CBER] to meet quarterly with the DoD to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the DoD (which may include freeze dried plasma products and platelet alternatives), unless the Secretary of Defense determines that any such meetings are not necessary. 21 USC 360bbb-3c(3)

Sept. 10, 2025 - 42 USC 247d-6d [PHSA 319F-3] and 42 USC 247d-6e [PHSA 319F-4], Targeted liability protections for pandemic and epidemic products and security countermeasures; Covered countermeasure process

Summary as published in St. Benedict Memo (September 2025)

In 2005 (PL 109-148), Congress enacted the PREP (Public Readiness and Emergency Preparedness) Act, providing "targeted liability protections for pandemic and epidemic products and security countermeasures," and a "covered countermeasure process" under 42 USC 247d-6 [PHSA 319F], *Public health countermeasures to a bioterrorist attack,* which Congress had added in 2000 (PL 106-505).

Congress added the "targeted liability protections" provisions at 42 USC 246d-6d [PHSA 319F-3] and the covered countermeasure process provisions at 42 USC 247d-6e [PHSA 319F-4].

42 USC 246d-6d [PHSA 319F-3] - Targeted liability protections for pandemic and epidemic products

42 USC 247d-6d(a) - Liability Protections

In 2005 (PL 109-148), Congress provided immunity from suit and liability under Federal and State law, for any "covered person...with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 USC 247d-6d(a)(1)

Congress authorized the HHS Secretary to put the liability immunity provisions into effect for covered countermeasures as manufactured, distributed or used by "covered persons," by making two unilateral decisions: a "determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency" and a "declaration...recommending... the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." 42 USC 247d-6d(b)(1)

Congress defined the term 'loss' to mean "any type of loss, including death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss...without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause." 42 USC 247d- 6d(a)(2)(A)

Congress provided for liability immunity to apply to "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." 42 USC 247d-6d(a)(2)(B)

Congress provided for liability immunity for a covered person with respect to a covered countermeasure to apply, "only if the countermeasure was administered or used during the effective period of the declaration [issued by the HHS Secretary]... the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration [issued by the HHS Secretary]; and...in the case of a covered person who is a program planner or qualified person...the countermeasure was administered to or used by an individual who was in a population specified by the declaration; and was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration." 42 USC 247d-6d(a)(3)

Congress provided for liability immunity to apply to a manufacturer or distributor of the covered countermeasure, "without regard to whether such countermeasure was administered to or used by an individual in accordance with the [population and geographic area]. 42 USC 247d-6d(a)(4)(A)

Congress provided for liability immunity to apply to program planner or qualified person use of a covered countermeasure including in "circumstances in which the...covered person reasonably could have believed that the countermeasure was administered or used in accordance with the [population and geographic] conditions [specified in the HHS Secretary declaration]. 42 USC 247d-6d(a)(4)(B)

Congress provided for liability immunity to apply "regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that...the declaration [by the HHS Secretary] provides that liability immunity applies only to covered countermeasures obtained through a particular means of distribution. 42 USC 247d-6d(a)(5)

Congress established, as a rebuttable presumption, that "any administration or use, during the effective period of the emergency declaration by the Secretary...of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued." 42 USC 247d-6d(a)(7)

42 USC 247d-6d(b) - Declaration by the Secretary

Congress authorized the HHS Secretary to make two unilateral decisions.

Congress authorized the HHS Secretary to make "a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." 42 USC 247d-6d(b)(1)

Congress authorized the HHS Secretary, on the basis of his own "determination that a disease...constitutes a public health emergency," to then make "a declaration...recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) [liability immunity] is in effect with respect to the activities so recommended." 42 USC 247d-6d(b)(1)

Congress directed the HHS Secretary to make such a declaration recommending manufacture, testing, development, distribution, administration or use" of countermeasures, by publishing the declaration in the Federal Register. 42 USC 247d-6d(b)(1)

Congress directed the HHS Secretary, in such declarations, to "identify, for each covered countermeasure specified...the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure; the period... during which [the liability immunity declaration] is in effect...designated by dates, or by milestones or other description of events...the...populations of individuals for which [the liability immunity declaration] is in effect...which may be a specification that such [liability immunity] applies without geographic limitation to all individuals;...the geographic...areas for which [the liability immunity declaration] is in effect including...a specification, as determined...by the Secretary, of whether the [liability immunity] declaration applies only to individuals physically present in such areas or [also] to individuals who have a connection to such areas...described in the declaration; and whether [the liability immunity declaration] is effective only to a particular means of distribution...and if so, the particular means." 42 USC 247d-6d(b)(2)

Congress authorized the HHS Secretary, in his discretion, to specify different periods [of duration of effect for liability immunity] for different covered persons to address different logistical, practical or other differences in responsibilities. 42 USC 247d-6d(b)(3)(A)

Congress directed the HHS Secretary to consult with the manufacturer of each covered countermeasure as needed, to "specify a date that is after the ending date [for the effective period of the liability immunity declaration]...that allows what the Secretary determines is a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure." 42 USC 247d-6d(b)(3)(B)

Congress directed that the effective period of a liability immunity declaration for covered countermeasures obtained for the Strategic National Stockpile during an active liability immunity declaration include the period of time when the product was administered or used after distribution or release from the stockpile. 42 USC 247d-6d(b)(3)(C)

Congress authorized the HHS Secretary to amend any portion of a liability immunity declaration, by publishing the amendment in the Federal Register, and prohibited amendments to retroactively limit the applicability of liability immunity. 42 USC 247d-6d(b)(4)

Congress authorized the HHS Secretary to withhold, from Federal Register publication, information exempted from disclosure under the Freedom of Information Act (FOIA), 5 USC 552(b).[338] 42 USC 247d-6d(b)(5)

[338] 5 USC 552(b) exempts from disclosure classified national defense or foreign policy information; records related solely to internal personnel rules and practices of an agency; exempted from disclosure by other statutes; trade secrets and commercial or financial information and privileged or confidential; interagency or intraagency memos; personnel and medical files (invasion of personal privacy; records compiled for law enforcement purposes; records pertaining to regulation of financial institutions; or geological and geophysical information and data concerning wells.

Congress directed the HHS Secretary, in deciding to issue a liability immunity declaration, to "consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure." 42 USC 247d-6d(b)(6)

Congress barred all courts of the United States (federal courts) and all States, from "subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary" pertaining to liability immunity determinations and declarations. 42 USC 247d-6d(b)(7)

Congress denied to every State and every political subdivision of a State, authority to "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any [liability immunity declaration] requirement [that] relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under" the Public Health Service Act or the Federal Food, Drug, and Cosmetic Act. 42 USC 247d-6d(b)(8)

Congress directed the HHS Secretary to notify Congressional committees within 30 days after making a liability immunity declaration, or an amendment to a declaration, by submitting a report explaining the reasons for issuing the declaration and the reasons underlying his determinations about the "categories of diseases," period of effect, populations, geographic areas and distribution means. 42 USC 247d-6d(b)(9)

42 USC 247d-6d(c) Definition of willful misconduct

For the purposes of setting a standard of liability for civil claims brought under 42 USC 247d-6d(d), Congress defined the term 'willful misconduct' to "denote an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." 42 USC 247d-6d(c)(1)(A)

Congress established, as a rule of construction, that the definition for 'willful misconduct,' establishes "a standard for liability that is more stringent than a standard of negligence in any form or recklessness." 42 USC 247d-6d(c)(1)(B)

Congress authorized and directed the HHS Secretary, in consultation with the Attorney General, to promulgate regulations, through interim final rules, "that further restrict the scope of actions or omissions by a covered person that may qualify as ‘willful misconduct.’" 42 USC 247d-6d(c)(2)(A)

Congress directed the HHS Secretary and Attorney General to "consider the need to define the scope of permissible civil actions...in a way that will not adversely affect the public health." 42 USC 247d-6d(c)(2)(B)

Congress authorized the HHS Secretary and AG to prescribe regulations that "specify the temporal effect that they shall be given." 42 USC 247d-6d(c)(2)(C)

Congress directed the HHS Secretary and AG to begin and complete an initial rulemaking process further restricting the scope of 'willful misconduct' standard of liability within 180 days after enactment[339] of the PREP Act (Dec. 30, 2005). 42 USC 247d-6d(c)(2)(D)

Congress placed the burden of proof on the plaintiff bringing any action under 42 USC 247d-6d(d), and established the standard of evidence as "clear and convincing evidence" of "willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury." 42 USC 247d-6d(c)(3)

Congress established, as an affirmative defense "notwithstanding any other provision of law," that "a program planner or qualified person shall not have engaged in 'willful misconduct' as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the [liability immunity] declaration." Congress provided, as a condition, that "either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person." 42 USC 247d-6d(c)(4)

Congress established an "exclusion for regulated activity of manufacturer or distributor." Congress provided that "if an act or omission by a manufacturer or distributor with respect to a covered countermeasure," alleged under the procedure for a plaintiff to bring a claim based on "willful misconduct," is subject to regulation under the PHSA or the FDCA, then "such act or omission shall not constitute 'willful misconduct' if neither the HHS Secretary nor the AG had "initiated an enforcement action with respect to such act or omission; or such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy." 42 USC 247d-6d(c)(5)(A)

Congress established that any action brought by a plaintiff against a manufacturer or distributor, if an HHS or AG enforcement action were in process, would be "stayed during the pendency of such an enforcement action." 42 USC 247d-6d(c)(5)(A)

Congress defined the term 'enforcement action' to mean "a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under [FDCA 505(i), for drugs or FDCA 520(g), for devices], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under [FDCA 564/21 USC 360bbb-3, emergency use], or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under [FDCA

[339] To the author's knowledge, this rulemaking has not occurred and the "willful misconduct" definition as defined by Congress is the standard applicable to claims brought under 42 USC 247d-6d(d)

501 et seq/21 USC 351 et seq, for drugs and devices] or of a licensure under [PHSA 351/42 USC 262, for biological products]. 42 USC 247d-6d(c)(5)(B)(i)

Congress defined the term ‘covered remedy’ to mean "an outcome that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under [FDCA 505(i) or FDCA 520(g)], a debarment, an investigator disqualification, a revocation of an authorization under [FDCA 564/21 USC 360bbb-3, emergency use], or a suspension or withdrawal of an approval or clearance under [FDCA 501 et seq/21 USC 351 et seq, for drugs and devices] or of a licensure under [PHSA 351/42 USC 262, for biological products] and that results from a final determination by a court or from a final agency action." 42 USC 247d-6d(c)(5)(B)(ii)

Congress defined the terms ‘final’ and ‘finally’ to mean: "with respect to a court determination, or to a final resolution of an enforcement action that is a court determination...a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and with respect to an agency action, or to a final resolution of an enforcement action that is an agency action...an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal." 42 USC 247d-6d(c)(5)(B)(iii)

Congress established, as rules of construction, that nothing in the section on "willful misconduct" should be construed "to affect the interpretation of any provision of the [FDCA], of [the PHSA], or of any other applicable statute or regulation; or to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the [HHS] Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this Act, under the [FDCA], under title 18 of the United States Code, [Crimes and Criminal Procedure] or under any other applicable statute or regulation." 42 USC 247d- 6d(c)(5)(C)(i)

Congress provided that a "mandatory recall called for in the [liability immunity] declaration [published in the Federal Register by the HHS Secretary] is not a Food and Drug Administration enforcement action." 42 USC 247d-6d(c)(5)(C)(ii)

42 USC 247d-6d(d) - Exception to immunity for covered persons

Congress provided that the "sole exception to the immunity from suit and liability of covered persons...shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct...[as defined in the preceding section] by such covered person," and referred to paragraph (f), affirming the sovereign immunity and defenses available to the United States and its employees as government officers. 42 USC 247d-6d(d)(1)

Congress provided that, for purposes of 28 USC 2679(b)(2)(B) [Federal Tort Claims Act] a cause of action for death or serious physical injury alleged to be "proximately caused by willful misconduct by a covered person, is not "an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized." 42 USC 247d- 6d(d)(1)

Congress provided standing to sue for "wrongful death or serious physical injury" for "any person who suffers such injury or by any representative of such a person." 42 USC 247d- 6d(d)(2)

42 USC 247d-6(e) Procedures for Suit

Congress required any action brought based on claims of willful misconduct by a covered person proximate to serious injury or death involving a covered countermeasure to be "filed and maintained only in the United States District Court for the District of Columbia," providing exclusive federal jurisdiction and limiting jurisdiction to only one Federal District Court. 42 USC 247d-6d(e)(1)

Congress provided that "the substantive law for decision" in willful misconduct action "shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section." 42 USC 247d-6d(e)(2)

As noted above, through the PREP Act, Congress denied to every State and every political subdivision of a State, authority to "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any [liability immunity declaration] requirement [that] relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure."

Congress required the plaintiff's complaint to "plead with particularity each element of the plaintiff's claim, including each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used...; facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury." 42 USC 247d-6d(e)(3)

Congress required the plaintiff to verify the complaint (state under oath by affidavit that the pleading is true to the knowledge of the deponent [person who gives testimony], except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true), and file it with supporting medical records. 42 USC 247d-6d(e)(4)

Congress established that any "matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff." 42 USC 247d-6d(e)(4)

If a complaint failed to comply with the verification requirement and the medical records requirement, Congress directed the court to refuse to accept it for filing, and to leave the running of the statute of limitations in effect. 42 USC 247d-6d(e)(4)(A)

Congress required the plaintiff to file "an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and certified medical records documenting such injury or death and such proximate causal connection." 42 USC 247d-6d(e)(4)(C)

Congress directed that an action be assigned initially to a panel of three judges of the US District Court for the District of Columbia, to have jurisdiction for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. 42 USC 247d-6d(e)(5)

Congress directed that after the three-judge panel had denied such motions, or if the time for filing such motions has expired, the panel would refer the action to the chief judge for assignment for further proceedings, including any trial. 42 USC 247d-6d(e)(5)

Congress provided that 28 USC 1253 [authorizing direct appeals to the Supreme Court from an order granting or denying...an interlocutory or permanent injunction in any civil action...which Congress has required to be heard and determined by a district court of three judges] and 28 USC 2284(b)(3) [directing convening of a three-judge district court panel "when otherwise required by Act of Congress, or when an action is filed challenging...constitutionality of...apportionment of congressional districts or...apportionment of any statewide legislative body"] "shall not apply." 42 USC 247d-6d(e)(5)

Congress provided, "no discovery shall be allowed before each covered person sued has had a reasonable opportunity to file a motion to dismiss; in the event such a motion is filed, before the court has ruled on such motion; and in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal." 42 USC 247d-6d(e)(6)(A)

For discovery after the close of the period for motions to dismiss and appeals from denials of motions to dismiss, Congress provided that the court should restrict discovery to be conducted "only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response." 42 USC 247d-6d(e)(6)(B)

Congress provided that, if a plaintiff obtained an award of damages, it should be reduced by the amount of "collateral source benefits" and that providers of collateral source benefits should not be entitled to recover any amount from the plaintiff or receive any lien or credit against the plaintiff's award of damages, or be equitably or legally subrogated to the right of the plaintiff (in other words, to be reimbursed for payments they made to plaintiff, from the damages paid to the plaintiff as a result of a willful misconduct case). 42 USC 247d-6d(e)(7)

Congress defined the term ‘collateral source benefit’ to mean "any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to any State or Federal health, sickness, income-disability, accident, or workers’ compensation law; any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage; any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or any other publicly or privately funded pro- gram." 42 USC 247d-6d(e)(7)(C)

Congress provided for proportional awards: "in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff" for "noneconomic damages." Congress defined "noneconomic damages" as "damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses." 42 USC 247d-6d(e)(8)

Congress provided for penalties (payments to other parties), for violations of Rule 11, Federal Rules of Civil Procedure, which requires all pleadings and motions to be signed by an attorney or the plaintiff himself if unrepresented, and to certify under oath that the papers are not being filed for improper purposes (such as harassment, delay); that the claims are supported by existing law or "nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law;" that the factual contentions have evidentiary support or will have evidentiary support after discovery; and that denials of factual contentions are warranted on the evidence. 42 USC 247d-6d(e)(9)

Congress assigned jurisdiction for interlocutory appeals by a "covered person" to the US Court of Appeals for the District of Columbia Circuit, with such appeals to be filed within 30 days, appealing district court orders denying a defendant's motion to dismiss or motion for summary judgment (based on the covered person's immunity) or, for a manufacturer or distributor, based on the preclusion [under 42 USC 247d-6d(c)(5)] of a manufacturer or distributor's acts being deemed "willful misconduct" provided neither the HHS Secretary or Attorney General had initiated an enforcement action, or, if an enforcement action had been initiated, if the action terminated without a covered remedy. 42 USC 247d-6d(e)(10)

42 USC 247d-6d(f) - Actions by and against the United States

Congress provided that "nothing in this section" [authorizing the HHS Secretary to provide liability immunity for covered persons manufacturing, distributing or using covered countermeasures by declaration] "shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of [the Federal Tort Claims Act, procedures for civil claims brought against government officers]. 42 USC 247d-6d(f)

42 USC 247d-6d(g) - Severability

Congress included a severability clause, that "if any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby."

42 USC 247d-6d(h) - Rule of construction concerning National Vaccine Injury Compensation Program (VICP)

Congress provided that nothing in the PREP Act should be construed to affect the National Vaccine Injury Compensation Program (VICP).

42 USC 247d-6d(i) - Definitions

Congress defined 'covered countermeasure' to mean a qualified pandemic or epidemic product[340]; or a security countermeasure[341]; or a drug[342], biological product[343], or device[344] that is authorized for emergency use.[345] 42 USC 247d- 6d(i)(1)

Congress defined the term 'covered person,' "when used with respect to the administration or use of a covered countermeasure" to mean

> the United States; or a person or entity that is a manufacturer of such countermeasure; a distributor of such countermeasure; a program planner of such countermeasure; a qualified person who prescribed, administered, or dispensed such countermeasure; or an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv) [manufacturer, distributor, program planner or qualified person]. 42 USC 247d-6d(i)(2)

Congress defined 'distributor' to mean

> a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; ware- houses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies. 42 USC 247d-6d(i)(3)

[340] Qualified pandemic or epidemic product as defined in PHSA 319F-3(i)(7) [42 USC 247d-6d(i)(7)]
[341] Security countermeasure as defined in PHSA 319F–2(c)(1)(B) [42 USC 247d-6b(c)(1)(B)]
[342] Drug as defined in FDCA 201(g)(1) [21 USC 321(g)(1)]
[343] Biological product as defined in PHSA 351(i) [42 USC 262(i)]
[344] Device as defined in FDCA 201(h) [21 USC 321(h)]
[345] Authorized for emergency use in accordance with FDCA 564 [21 USC 360bbb-3] *Authorization for medical products for use in emergencies*]

Congress defined manufacturer to include

> a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer. 42 USC 247d-6d(i)(4)

Congress defined the term ‘person’ to include "an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department." 42 USC 247d-6d(i)(5)

Congress defined the term ‘program planner’ to mean

> a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [liability immunity] declaration. 42 USC 247d-6d(i)(6)

Congress defined the term ‘qualified pandemic or epidemic product’ to mean a drug...biological product...or device...

> that is a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause;
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> or a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in [the preceding clause]; and
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> approved or cleared under [FDCA 505/21 USC 355, *New drugs*] or licensed under [PHSA 351/42 USC 262, *Regulation of biological products*];
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> the object of research for possible use [to address a pandemic or epidemic or to limit the harm caused by a product used to address a pandemic or epidemic] and is the subject of an exemption under [FDCA 505(i)/21 USC 355(i), *New drugs, Exemptions of drugs for research* or FDCA 520(g)/21 USC 360(g), *Registration of producers of drugs or devices, Exclusions*; or
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> authorized for emergency use in accordance with [FDCA 564/21 USC 360bbb-3, *Authorization for medical products for use in emergencies*] 42 USC 247d-6d (i)(7)

Congress defined the term 'qualified person’ "when used with respect to the administration or use of a covered countermeasure" to mean

> a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons so identified [as 'qualified persons'] in a [liability immunity] declaration by the Secretary under subsection (b). 42 USC 247d-6d (i)(8)

Congress defined the term 'security countermeasure' [42 USC 247d-6d (i)(9)] by citing 42 USC 247d-6b(c)(1)(B) [PHSA 319F–2(c)(1)(B), enacted in 2004 (PL 108-276)]:

> a drug,[346]...biological product[347]...or device[348] that the [HHS] Secretary determines to be a priority [consistent with HSA 302(2)[349] and HSA 304(a)[350]] to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat[351]...or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; [which product] the Secretary determines...to be a necessary countermeasure[352]; and is approved or cleared under [FDCA 505/21 USC 255 et seq, *New drugs*] or licensed under [PHSA 351/42 USC 262, *Regulation of biological products*]; or is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination[353]...; or is authorized for emergency use under [FDCA 564/21 USC 360bbb-3, *Authorization for medical products for use in emergencies*]. 42 USC 247d-6b(c)(1)(B)

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[346] *Drug*, as defined by FDCA 201(g)(1) [21 U.S.C. 321(g)(1)] "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)..."

[347] *Biological product*, as defined by PHSA 351(i) [42 U.S.C. 262(i)] - " a virus, therapeutic serum, toxin, anti- toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic com- pound), applicable to the prevention, treatment, or cure of a disease or condition of human beings"

[348] *Device*, as defined by FDCA 201(h) [21 U.S.C. 321(h)] - "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." [Exceptions distinguish this use from use of the word 'device' to denote labeling components similar to 'statements," 'designs' and 'words,']

[349] Homeland Security Act of 2002, Sec. 302 [6 USC 181] - Congress established Directorate of Science and Technology within DHS, authorized to develop national policy and strategic plans for identifying and developing countermeasures to chemical, biological, radiological, nuclear, and other emerging terrorist threats.

[350] Homeland Security Act of 2004, Sec. 304 [6 USC 184] - Congress authorized and directed the HHS Secretary to collaborate with the DHS Secretary to "set priorities...and policies and develop a coordinated strategy "with respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats."

[351] *Material threat*, as defined under PHSA 319F-2(2)(A)(ii)/42 USC 247d-6b(2)(A)(ii)

[352] *Necessary countermeasure*, as defined under PHSA 319F-2(2)(B)(ii)/42 USC 247d-6b(2)(B)(ii)

[353] *Determination of Countermeasures Appropriate for Funding from Special Reserve Fund,* as defined under PHSA 319F-2(5)/42 USC 247d-6b(5)

Congress defined 'serious physical injury' to mean

> an injury that is life threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. 42 USC 247d-6d(i)(10)

42 USC 247d-6e [PHSA 319F-4] - Covered countermeasure process

In 2005 (PL 109-148), Congress provided that when the HHS Secretary issued a liability immunity declaration, an emergency 'Covered Countermeasure Process Fund, would be established in the Treasury, "for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." Congress provided for the fund to include emergency appropriations under H. Con. Res 95 of 109th Congress, Sec. 402, to remain in effect through Oct. 1, 2006. 42 USC 247d-6e(a)

Congress authorized and directed the HHS Secretary to "provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to" a liability immunity declaration. 42 USC 247d-6e(b)(1)

Congress provided for the same elements, and in the same amounts, as amounts prescribed in 2003 (PL 108-20) for individuals injured as a result of smallpox countermeasures under PHSA 264, *Medical benefits*, PHSA 265, *Compensation for lost employment income*, and PHSA 266, *Payment for Death* [42 USC 239 et seq] except that PHSA 266(a)(2)(B), *Reduction of death benefit by the amount paid for lost employment income*, "shall not apply." 42 USC 247d-6e(b)(2)

Congress provided, as a rule of construction, that "neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by [PHSA] 266." 42 USC 247d-6e(b)(3)

Congress provided for "determination of eligibility for compensation" (whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under the CICP program, and the amount of such compensation) to be conducted by procedures established in PHSA 262 [42 USC 239a] and related regulations, and other regulations prescribed by the HHS Secretary.

Congress authorized the HHS Secretary to make determinations, (other than those about injuries "presumed to be directly caused" by a covered countermeasure under the Covered Countermeasure Injury Table) as to the direct causation of a covered injury, only based on "compelling, reliable, valid, medical and scientific evidence." 42 USC 247d-6e(b)(4)

Congress directed the HHS Secretary to, by regulation, "establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply."

Congress authorized the HHS Secretary to identify such covered injuries only "where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury." 42 USC 247d-6e(b)(5)(A)

Congress authorized the HHS Secretary to make amendments to the Covered Injury Compensation Table. 42 USC 247d-6e(b)(5)(B)

Congress prohibited judicial review of any action by the HHS Secretary to identify covered injuries for the covered countermeasure injury table:

> "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph." 42 USC 247d-6e(b)(5)(C)

Congress held that, in applying the provisions of the Smallpox Emergency Personnel Protection Act, for purposes of countermeasures generally the terms ‘vaccine’ and ‘smallpox vaccine’ "shall be deemed to mean a covered countermeasure." 42 USC 247d-6e(b)(6)

Congress directed the HHS Secretary to ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any liability immunity declaration "and any applicable guidelines of the Centers for Disease Control and Prevention," and that recipients of countermeasures "are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part." 42 USC 247d-6e(c)

Congress precluded any "covered individual" from bringing a civil action alleging willful misconduct under 42 USC 247d-6d(d), against a "covered person" unless he or she had exhausted CICP administrative remedies, with two exceptions: if funds have not been appropriated for the CICP fund, or if the HHS Secretary failed to make a final determination on compensation claim within 240 days after such request was filed. 42 USC 247d-6e(d)(1)

Congress provided that the time limit (statute of limitations) for filing a civil action alleging willful misconduct under 42 USC 247d-6d(d) for an injury or death to be tolled (paused) while a submitted CICP administrative claim is under review. 42 USC 247d-6e(d)(2)

Congress provided, as a rule of construction, that the countermeasures injury compensation program would not supersede or otherwise affect the application of a requirement, under 28 USC 171 [Tort Claims Procedure], to exhaust administrative remedies. 42 USC 247d-6e(d)(3)

Congress provided for the countermeasures injury compensation process to be the exclusive remedy (precluding any other civil action or proceeding), except for a willful misconduct proceeding under 42 USC 247d-6d. 42 USC 247d-6e(d)(4)

Congress authorized individuals for whom the HHS Secretary determined that they are a covered individual who qualifies for compensation under the CICP, to elect to accept the compensation, or to bring an action under 42 USC 247d-6d(d), and barred anyone who elected to accept the CICP compensation, from bringing an action under 42 USC 247d-6d(d).

Congress defined the term ‘covered countermeasure’ by reference to 42 USC 247d-6d: "a qualified pandemic or epidemic product; or a security countermeasure; or a drug, biological product, or device that is authorized for emergency use. 42 USC 247d-6e(e)(1)

Congress defined the term ‘covered individual’ to mean an individual—

> (A) who is in a population specified in [a liability immunity] declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or
>
> (B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A). 42 USC 247d-6e(e)(2)

Congress defined the term ‘covered injury’ to mean "serious physical injury or death." 42 USC 247d-6e(e)(3)

Congress defined the term ‘declaration’ to mean a liability immunity declaration issued by the HHS Secretary under 42 USC 247d-6d(b). 42 USC 247d-6e(e)(4)

Congress defined the term ‘eligible individual’ to mean "an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury." 42 USC 247d-6e(e)(5)