



John the Baptist preaching. Pieter Bruegel the Elder

PREP Act, public health emergency, and EUA countermeasure law 42 USC 247d and 21 USC 360bbb

Whole-of-government public deception campaigns.

Psychological, biological and chemical warfare, communicable disease control and vaccination reporting
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Book 2

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Learning Curve

Published Oct. 11, 2024

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.

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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 playbook¹ 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.

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

¹ <https://bailiwicknews.substack.com/p/playbook-for-poisoning-populations>

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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.

* * *

Provisions at 42 USC 247d-6d(b)(7), (b)(8) and (b)(9) lie at the core of the treason crimes committed by Congress and US Presidents, further documented in the American Domestic Bioterrorism Program timeline.

Why Pfizer and Moderna and FDA are working toward government authorization to inject babies and small children.

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KW Note, March 27, 2025

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 fevers² 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!³

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.⁴:

"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."

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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.

² <https://alexberenson.substack.com/p/moderna-wants-to-sell-mrna-shots?>

³ <https://tobyrogers.substack.com/p/urgent-call-to-action-we-have-30?>

⁴ <https://wsau.com/2021/12/31/robert-f-kennedy-jr-explains-why-fauci-is-going-after-children/>

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*⁵, 1:18-cv-03215-JMF, which ended with a July 9, 2018 stipulation⁶ 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.

Later two reports were located, filed on 5/4/88⁷ and 7/21/89.⁸ 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.

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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 Orders⁹ 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.

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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 Register¹⁰ (Vol. 87, No. 5, p. 982).

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.

⁵ <https://www.icandecide.org/ican-vs-hhs-the-great-vaccine-debate/>

⁶ <https://www.icandecide.org/wp-content/uploads/2019/09/Stipulated-Order-copy.pdf>

⁷ <https://www.documentcloud.org/documents/5835885-Report-1.html>

⁸ <https://www.documentcloud.org/documents/5835886-Report-2.html>

⁹ <https://bailiwicknews.substack.com/p/legal-walls-short-version?s=w>

¹⁰ <https://www.federalregister.gov/documents/2022/01/07/2022-00151/tenth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical>

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 (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-

¹¹ <https://www.phe.gov/emergency/events/COVID19/COVIDvaccinators/Pages/PREP-Act-Immunity-from-Liability-for-COVID-19-Vaccinators.aspx>
Selections from reporting published at Bailiwick News, January 2022 through February 2025, compiled April 2025
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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.

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

Published March 24, 2022

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 Act¹² (30 pages) was passed by Congress and signed by President George W. Bush on July 21, 2004.

The PREP Act¹³ 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 Bioshield¹⁴ 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 laws¹⁵, 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, 2020¹⁶, 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.

The only exception is for “willful misconduct,” which might apply to Pfizer and Moderna if the clinical trial fraud alleged by whistleblower Brook Jackson¹⁷ 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.

¹² <https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf>

¹³ <https://www.congress.gov/109/plaws/publ148/PLAW-109publ148.pdf#page=140>

¹⁴ <https://www.phe.gov/about/barda/Pages/Project-Bioshield.aspx>

¹⁵ <https://www.phe.gov/Preparedness/legal/Pages/default.aspx>

¹⁶ <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>

¹⁷ <https://s3.documentcloud.org/documents/21206071/brook-jackson-lawsuit.pdf>

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 amendment¹⁸).

The Project Bioshield Act of 2004 includes provisions specifically addressing how EUAs are to be declared, maintained and terminated, at 42 USC 360bbb-3¹⁹, 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.

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Today at Coffee and Covid²⁰, Jeff Childers addressed the Moderna application for EUA approval²¹ 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.

¹⁸ <https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx>

¹⁹ <https://www.govinfo.gov/content/pkg/USCODE-2019-title21/pdf/USCODE-2019-title21-chap9-subchapV-partE-sec360bbb-3.pdf>

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 Response²² 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 declarations²³: 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.

²² <https://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx>

²³ <https://crsreports.congress.gov/product/pdf/R/R46809>

Selections from reporting published at *Bailiwick News*, January 2022 through February 2025, compiled April 2025

Author: Katherine Watt, kgwatt@protonmail.com

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.

Published April 7, 2022

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

Re: “judicially-unreviewable.”

Published April 7, 2022

Commenter to previous post²⁴ 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).”

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.”

²⁴ <https://bailiwicknews.substack.com/p/responding-to-steve-kirsch-james?s=w>

Selections from reporting published at Bailiwick News, January 2022 through February 2025, compiled April 2025

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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.

Note to Attorney Aaron Siri re: US statutes nullifying US Constitution.

Published April 8, 2022

(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.”

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.

Published April 28, 2022

...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...

The investigational drugs that weren't.

Published April 25, 2022

...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 treatments for complications from previously developed and deployed covered countermeasures...

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 Program²⁵ 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 Mayorkas, Pfizer CEO Albert Bourla, Moderna CEO Stephane Bancel, and World Health Organization Director-General Tedros Adhanom Ghebreyesus.

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.

²⁵ <https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program?s=w>

Selections from reporting published at Bailiwick News, January 2022 through February 2025, compiled April 2025

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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.

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

Published Sept. 27, 2022

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.

Notes for state Attorneys General considering filing challenges to protect the people in their states.

Published Oct. 4, 2022

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.

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

Published Dec. 13, 2022

SL: 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?

KW: I think the earliest one was the 1983 establishment²⁶ of the Public Health Emergencies Program under the rubric of the Public Health Services Act, which was a 1944 law.²⁷ 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.²⁸ 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 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.

²⁶ <https://bailiwicknews.substack.com/p/22-worst-congressional-bioterrorism>

²⁷ <https://uscode.house.gov/statviewer.htm?volume=58&page=682>

²⁸ <https://www.covidlawcast.com/p/brook-jackson-pfizer-whistleblower>

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.²⁹ 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 Authority³⁰—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 Treatments³¹ [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;³² local PDF³³].

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.

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

²⁹ <https://bailiwicknews.substack.com/p/pfizers-motion-to-dismiss-the-brook>

³⁰ <https://bailiwicknews.substack.com/p/other-transactional-authority-ota>

³¹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>

³² <https://www.keionline.org/bn-2020-3>

³³ <https://ratical.org/PandemicParallaxView/KEI-Briefing-OTA-29june2020.pdf>

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,³⁴ 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.³⁵

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*.

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.

³⁴ <https://totalityofevidence.com/brook-jackson-pfizer-whistleblower/>

³⁵ <https://bailiwicknews.substack.com/p/congress-appropriated-billions-more>

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 [KW: 42 USC 247d-6d(b)(7), 42 USC 247d-6d(b)(8) and 42 USC 247d-6d(b)(9)³⁶]³⁶—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 [unintelligible] 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...

³⁶ <https://www.law.cornell.edu/uscode/text/42/247d-6d>

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

Published Feb. 9, 2023

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-3³⁷ 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, certified Good Distribution Practice and labeling and dispensing laws that Sasha Latypova has investigated so thoroughly³⁸ (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 certified 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 complaint³⁹ 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;
- 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;

³⁷ <https://www.law.cornell.edu/uscode/text/21/360bbb-3>

³⁸ <https://sashalatyova.substack.com/p/my-talk-from-lakaruppropet-conference>

³⁹ <https://bailiwicknewsarchives.files.wordpress.com/2022/10/2022.02.22-jackson-amended-complaint.pdf>

- 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 2020.⁴⁰

Another version was provided to Japanese regulators⁴¹ 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.

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.⁴²

...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...”

⁴⁰ <https://bailiwicknewsarchives.files.wordpress.com/2022/09/2020.11.09-pfizer-wistar-study-77-p..pdf>

⁴¹ <https://bailiwicknewsarchives.files.wordpress.com/2021/12/2021-japan-study-translation-lnp-in-ovaries.pdf>

⁴² <https://bailiwicknews.substack.com/p/in-nov-2020-pfizer-told-fda-reviewers>

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.”⁴³

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.”⁴⁴

Reinforcing evidence is the establishment of “real world evidence”⁴⁵ — “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 Act⁴⁶ 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.

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.⁴⁷

*

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 workshop⁴⁸ (*Medical Countermeasures Dispensing Emergency Use Authorization and the Postal Model*, at p. 26) and an August 2020 presentation by Elizabeth Sadove,⁴⁹ 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

⁴³ <https://bailiwicknewsarchives.files.wordpress.com/2021/12/2020.11-pfizer-biontech-c4591001-clinical-protocol.pdf>

⁴⁴ https://en.wikipedia.org/wiki/The_Adventure_of_Silver_Blaze

⁴⁵ <https://bailiwicknews.substack.com/p/faked-clinical-trials-and-real-world>

⁴⁶ <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>

⁴⁷ <https://www.law.cornell.edu/uscode/text/50/chapter-32>

⁴⁸ https://www.ncbi.nlm.nih.gov/books/NBK53126/pdf/Bookshelf_NBK53126.pdf

⁴⁹ <https://bailiwicknewsarchives.files.wordpress.com/2023/02/2020.08.25-fda-cdc-regulatory-updates-use-of-mcmts-table-p-18.pdf>

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.

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 laws⁵⁰ 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.

⁵⁰ <https://bailiwicknews.substack.com/p/repost-pharmaco-military-genocide>

Selections from reporting published at Bailiwick News, January 2022 through February 2025, compiled April 2025

Author: Katherine Watt, kgwatt@protonmail.com

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

Published March 22, 2023

...Yesterday, someone sent me a March 20, 2023 Federal Register notice⁵¹ 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, 2020,⁵² 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, 2023,⁵³ 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.

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...

⁵¹ <https://www.govinfo.gov/content/pkg/FR-2023-03-20/pdf/2023-05609.pdf>

⁵² <https://www.govinfo.gov/content/pkg/FR-2020-02-07/pdf/2020-02496.pdf>

⁵³ <https://www.govinfo.gov/content/pkg/FR-2023-03-20/pdf/2023-05609.pdf>

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...

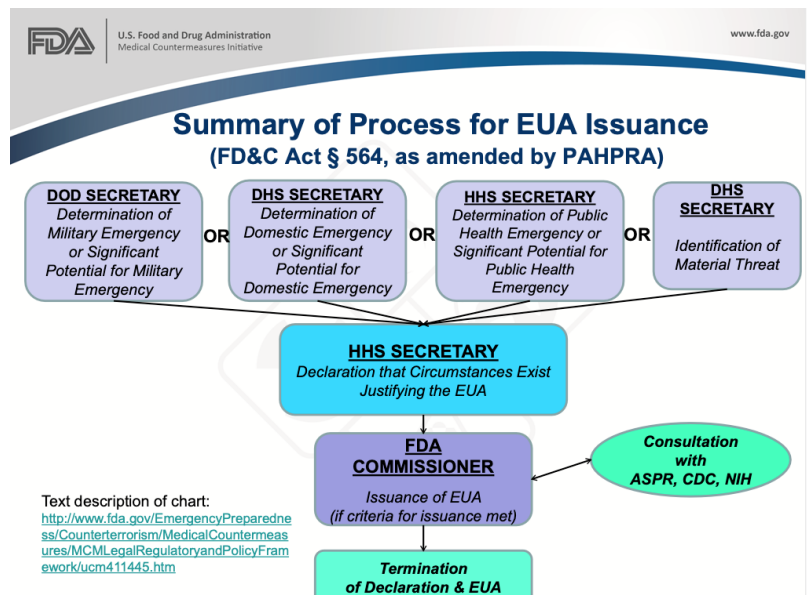
One other purpose of the new, March 15, 2023 determination, is to *de facto* void the Jan. 30, 2023 announcement⁵⁴ that the public health emergency would end effective May 11, 2023.

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

1. undercut then-pending Congressional action (H.R. 382,⁵⁵ approved by House Jan. 31, 2023, 220 to 210, and H.J. Res. 7,⁵⁶ 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.

FDA offers a slide from an April 2015 FDA slide deck⁵⁷ 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.



⁵⁴ <https://apnews.com/article/biden-united-states-government-district-of-columbia-covid-public-health-2a80b547f6d55706a6986debc343b9fe>

⁵⁵ <https://www.congress.gov/bill/118th-congress/house-bill/382>

⁵⁶ <https://www.congress.gov/bill/118th-congress/house-joint-resolution/7>

⁵⁷ <http://wayback.archive-it.org/7993/20170722114215/https://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/UCM443964.pdf>

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 enforcement⁵⁸ 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 fuel⁵⁹ and the funding.

⁵⁸ <https://bailiwicknews.substack.com/p/january-17-2017-federal-register>

⁵⁹ <https://bailiwicknews.substack.com/p/smashing-the-overton-window>

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.

Published April 11, 2023

A reader emailed today, linking to a Feb. 9, 2023 Health and Human Services Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap⁶⁰ and asking questions about the legal effects of Biden's recent signature on House Joint Resolution 7.

HJR 7⁶¹ - 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 Emergency⁶² (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.

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.

⁶⁰ <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>

⁶¹ <https://www.congress.gov/bills/118/congress/house-joint-resolution/7/text>

⁶² [https://www.theepochtimes.com/biden-signs-measure-ending-covid-19-national-emergency_5185150.html?](https://www.theepochtimes.com/biden-signs-measure-ending-covid-19-national-emergency_5185150.html?hpid=hp_hp-top-table-main-biden-signs-measure-ending-covid-19-national-emergency_5185150.html)

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 PEADs⁶³ (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, 2023.⁶⁴

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*⁶⁵) 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 countermeasures⁶⁶ 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.
- 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 9994⁶⁷ 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.

⁶³ <https://bailiwicknews.substack.com/p/peads-presidential-emergency-action>

⁶⁴ <https://www.govinfo.gov/content/pkg/FR-2023-03-20/pdf/2023-05609.pdf>

⁶⁵ <https://onlinelaw.wustl.edu/blog/legal-english-de-factode-jure/>

⁶⁶ <https://www.law.cornell.edu/uscode/text/42/247d-6d>

⁶⁷ <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

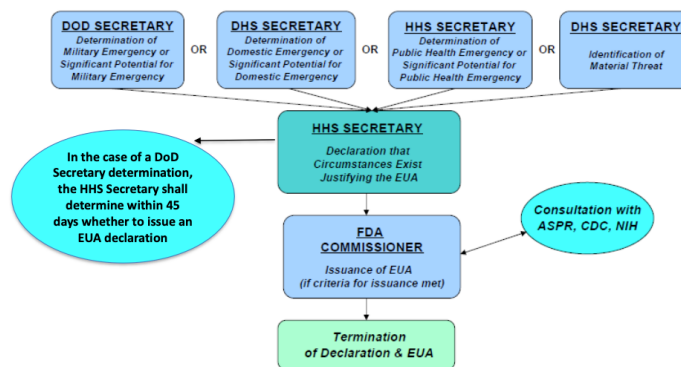
Another sign that tide of covert war is turning will be pharmacies that refuse to take delivery of DoD biochemical weapons and pharmacists who refuse to use them on targets.

Published July 1, 2023

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).

Summary of Process for EUA Issuance



www.fda.gov

Source: Feb. 13, 2018 FDA Slide Deck.

The most recent, eleventh amendment to the original PREP Act declaration was issued effective May 11, 2023.⁶⁸ 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].

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.

⁶⁸ <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>

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 pharmacies⁶⁹ 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.⁷⁰

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 Pharmacist⁷¹ 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 revisions⁷² 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.

A January 2023 HHS Office of Inspector General report, *Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19*,⁷³ 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

⁶⁹ <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/participating-pharmacies.html>

⁷⁰ <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/>

⁷¹ <https://www.aacp.org/sites/default/files/2021-12/oath-of-a-pharmacist-pdf-2021.pdf>

⁷² https://en.wikipedia.org/wiki/Hippocratic_Oath#Modern_versions_and_relevance

⁷³ <https://oig.hhs.gov/oei/reports/OEI-05-22-00010.pdf>

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 benchmarks⁷⁴ 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,⁷⁵ out of a total of 676.7 million doses CDC claims had been administered by May 10, 2023.⁷⁶

The big picture reasons for the dysfunctional reporting systems covered by the January 2023 HHS-OIG report⁷⁷ 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.

*

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.⁷⁸

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.

⁷⁴ <https://providernews.anthem.com/kentucky/articles/covid-19-vaccine-provider-incentive-program>

⁷⁵ <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/>

⁷⁶ <https://covid.cdc.gov/covid-data-tracker/#vaccination-states-jurisdictions>

⁷⁷ <https://oig.hhs.gov/oei/reports/OEI-05-22-00010.pdf>

⁷⁸ 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.

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.”

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.

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

Published Aug. 28, 2023

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 16645⁷⁹
- 2023.05.11 HHS PREP Act Amendment 11, distribution limitations, time, qualified persons, category of threat burden of seasonal influenza 88 FR 30769⁸⁰

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).]

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.

⁷⁹ <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>

⁸⁰ <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>

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...

...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...”

On civil suits against Pfizer for “contamination” of Covid-19 biochemical weapons.

Published Oct 23, 2023

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 identification⁸¹ 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. 4/12⁸², 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. Gilead⁸³.

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.

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

⁸¹ <https://anandamide.substack.com/p/dna-fragments-detected-in-monovalent>

⁸² <https://bailiwicknewsarchives.files.wordpress.com/2023/02/2022.12.18-latypova-memo-re-cgmp-intentional-noncompliance-12-p.pdf>

⁸³ <https://childrenshealthdefense.org/wp-content/uploads/Nowacki-v-Gilead-Complaint.pdf>

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.⁸⁴]

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. Glenhaven⁸⁵ 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)....

⁸⁴ <https://sashalatyova.substack.com/p/highland-hospital-rochester-ny-attempted>

⁸⁵ <https://law.justia.com/cases/federal/appellate-courts/ca9/20-56194/20-56194-2022-02-22.html>

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.

Published Oct. 26, 2023

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

21 USC 360bbb-3(e). Conditions of authorization.

21 USC 360bbb-3(e)(3). 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 - Emergency use of medical products.

21 USC 360bbb-3a(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).

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.⁸⁶ (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 notices⁸⁷ 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.

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.

⁸⁶ <https://bailiwicknewsarchives.files.wordpress.com/2023/10/2020.03.24-fda-ventilator-eua-letter-of-authorization-cgmp-waive-p.-7.pdf>

⁸⁷ <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>

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.

Separation of powers, reservation of powers (federalism), and the PREP Act.

Published Nov. 14, 2023

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*,⁸⁸ 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*,⁸⁹ 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....

*

⁸⁸ https://www.supremecourt.gov/opinions/19pdf/19a1044_pok0.pdf

⁸⁹ <https://tile.loc.gov/storage-services/service/l1/usrep/usrep469/usrep469528/usrep469528.pdf>

Selections from reporting published at *Bailiwick News*, January 2022 through February 2025, compiled April 2025

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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,⁹⁰ 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 Threats and Emergencies Act]

*

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—

⁹⁰ <https://uscode.house.gov/statutes/pl/98/49.pdf>

(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;

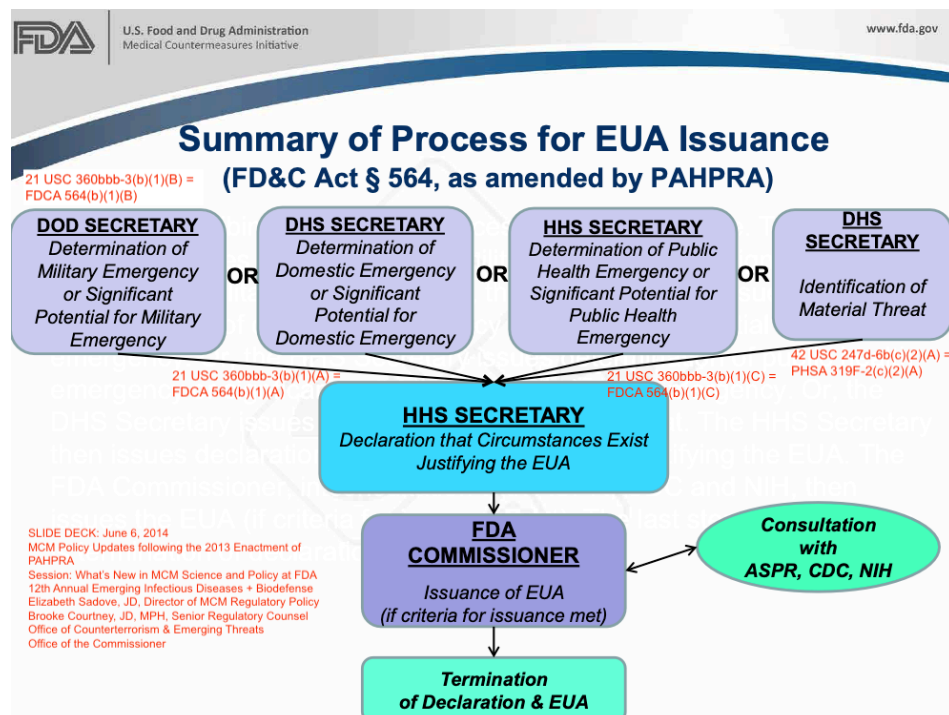
(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, United States Code, of attack 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 7316⁹¹.

Also effective Feb. 4, 2020, (signed March 10, 2020, published March 17, 2020, 85 FR 15198⁹²), as amended (signed June 4, 2020, published June 8, 2020, 85 FR 35100⁹³) 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.

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)

⁹¹ <https://www.govinfo.gov/content/pkg/FR-2020-02-07/pdf/2020-02496.pdf>

⁹² <https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf>

⁹³ <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>

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.

More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.

Published Dec. 6, 2023

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,⁹⁴ most recently Feb. 9, 2023⁹⁵ (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)].

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.

⁹⁴ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

⁹⁵ <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>

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Litigation proposals for state Attorneys General.

Published Dec. 6, 2023

...State Attorneys General should build on what has been learned through *Jackson v. Ventavia, Pfizer et al*⁹⁶; *Bridges v. Houston Methodist Hospital*,⁹⁷ and *Texas, Oklahoma et al v. US Department of Health and Human Services, Xavier Becerra et al*,⁹⁸ (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 acts⁹⁹ — have wrought, the entire PHS (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.

⁹⁶ <https://bailiwicknews.substack.com/p/other-transactional-authority-ota>

⁹⁷ <https://bailiwicknews.substack.com/p/bridges-v-houston-methodist-hospital>

⁹⁸ <https://bailiwicknews.substack.com/p/texas-and-oklahoma-v-us-department>

⁹⁹ <https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program>

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 database¹⁰⁰ and one without links.

- Ending National Suicide Act (with links, formatted)¹⁰¹
- Ending National Suicide Act (without links, formatted)¹⁰²

Related PDF reports and summaries:

- 2 pages - Weaponization of Language and Law: US Government Bioterrorism Program from 1969 to Covid.¹⁰³ (January 2023, abstract)
- 14 pages - Legal History: American Domestic Bioterrorism Program.¹⁰⁴ 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.

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¹⁰⁰ <https://www.law.cornell.edu/uscode/text>

¹⁰¹ <https://bailiwicknewsarchives.files.wordpress.com/2023/12/ending-national-suicide-act-with-links-formatted.pdf>

¹⁰² <https://bailiwicknewsarchives.files.wordpress.com/2023/12/ending-national-suicide-act-without-links-formatted.pdf>

¹⁰³ <https://bailiwicknewsarchives.files.wordpress.com/2023/06/2023.01.13-watt-k.-abstract-us-government-state-sponsored-bioterrorism.pdf>

¹⁰⁴ <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]; 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.

On international and US legal instruments governing "adjustment of domestic legislative and administrative arrangements" and exercise of political authority during declared public health emergencies.

Published Jan. 10, 2024

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; and
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. 6645¹⁰⁵ and S. 3428¹⁰⁶ (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.

¹⁰⁵ <https://www.congress.gov/bill/118th-congress/house-bill/6645>

¹⁰⁶ <https://www.congress.gov/bill/118th-congress/senate-bill/3428/text?s=1&r=1&q=%7B%22search%22%3A%22S+3428%22%7D>
Selections from reporting published at *Bailiwick News*, January 2022 through February 2025, compiled April 2025

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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..."

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.

Published Feb. 23, 2024

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, 2018.¹⁰⁷

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, 2022.¹⁰⁸

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..."

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

¹⁰⁷

<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>

¹⁰⁸ <https://www.congress.gov/bill/117th-congress/house-bill/7776/text>

Selections from reporting published at [Bailiwick News](https://www.bailiwicknews.com), January 2022 through February 2025, compiled April 2025

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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,¹⁰⁹ 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...

¹⁰⁹ <https://www.law.cornell.edu/uscode/text/22/2151b>

Globalist misleaders focus public attention on WHO International Health Regulations to distract people from understanding and repealing federal and state public health emergency law.

Published April 17, 2024

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 133,¹¹⁰ “to disallow the exercise of jurisdiction by certain international organizations” including the World Health Organization, and similar proposed bills.¹¹¹

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)¹¹² and related laws and communicable disease control program guidelines.¹¹³

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.

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)

¹¹⁰ <https://legiscan.com/LA/text/SB133/2024>

¹¹¹ <https://standforhealthfreedom.com/state-sovereignty-v-the-who/>

¹¹² <https://www.legis.la.gov/legis/Law.aspx?p=y&d=207680>

¹¹³ <https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/sanitarycode.pdf>

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 Act¹¹⁴; Repeal state public health emergency, emergency management, communicable disease control laws¹¹⁵

¹¹⁴ <https://bailiwicknewsarchives.files.wordpress.com/2023/12/ending-national-suicide-act-without-links-formatted.pdf>

¹¹⁵ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/04/2024.03-repeal-state-public-health-emergency-emergency-management-communicable-disease-control-laws.pdf>

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.

Published April 19, 2024

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, 2020,¹¹⁶ 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.

Cut-and-paste from Pfizer-Albania contract, at section 9.5,¹¹⁷ 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.

¹¹⁶ <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>

¹¹⁷ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/04/2021-albania-contract-pfizer.pdf>

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.

Pandemics are fake. Federal and state public health emergency kill box laws can be repealed and nullified.

Published May 7, 2024

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 2022,¹¹⁸ 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.

¹¹⁸ <https://bailiwicknews.substack.com/p/government-by-silent-immobility-an>

Selections from reporting published at Bailiwick News, January 2022 through February 2025, compiled April 2025

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Global pandemic preparedness and response provisions already in US domestic law.

Published May 15, 2024

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 Organization¹¹⁹) US state Attorneys General (May 8, 2024 - Montana Attorney General Austin Knudsen and 21 other AGs letter to President Biden re World Health Organization¹²⁰) 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, 2022¹²¹...On May 27, 2022,¹²² 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 pain¹²³)

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.

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 6645¹²⁴ and S 3428,¹²⁵ which should be amended¹²⁶ to include July 28, 1945, Executive F, Ratification of the United Nations Charter¹²⁷) and bills to withdraw the US from the World Health Organization

¹¹⁹ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2024.05-senator-letter-who.pdf>

¹²⁰ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2024.05.08-state-ag-letter-montana-knudsen-to-biden-re-who-ihp-pandemic-treaty.pdf>

¹²¹ <https://bailiwicknewsarchives.files.wordpress.com/2023/04/2022.01.18-us-loyce-pace-submit-us-proposed-ihp-amendments-to-who.pdf>

¹²² <https://bailiwicknewsarchives.files.wordpress.com/2023/04/2022.05.27-wha-adopts-us-proposed-ihp-amendments.pdf>

¹²³ <https://bailiwicknews.substack.com/p/government-by-silent-immobility-an>

¹²⁴ <https://www.congress.gov/bills/118/congress/house-bills/6645/text>

¹²⁵ <https://www.congress.gov/bills/118/congress/senate-bills/3428/text>

¹²⁶ <https://bailiwicknews.substack.com/p/on-the-omission-of-the-july-28-1945>

¹²⁷ <https://bailiwicknewsarchives.files.wordpress.com/2024/01/1945.07.28-senate-vote-ratify-un-charter-and-bretton-woods-executive-f.pdf>

(HR 79,¹²⁸ 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.¹²⁹ Draft.¹³⁰)

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.¹³¹ Model act.¹³²; Feb. 16, 2024 - State nullification procedure acts.¹³³)

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...

¹²⁸ <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>

¹²⁹ <https://bailiwicknews.substack.com/p/ending-national-suicide-act>

¹³⁰ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/12/ending-national-suicide-act-without-links-formatted.pdf>

¹³¹ <https://bailiwicknews.substack.com/p/repeal-state-public-health-emergency>

¹³² <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/04/2024.03-repeal-state-public-health-emergency-emergency-management-communicable-disease-control-laws.pdf>

¹³³ <https://bailiwicknews.substack.com/p/tools-for-illuminating-defying-and-d95>

Global Catastrophic Risk Management Act, enacted by Congress and Biden Dec. 2022, codified at 6 USC 821-825.

Published May 17, 2024

Following up on May 15 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 1355.¹³⁴ Subtitle C, Sec. 641 established National Preparedness System, codified at 6 USC 741¹³⁵ et seq.

Problem-reaction-solution.

Orchestrated, faked or exacerbated, falsely-characterized problem.

Manipulated, society-disordering reaction.

Pre-loaded, geopolitical power-centralizing solution.

*

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

¹³⁴ <https://www.congress.gov/109/plaws/publ295/PLAW-109publ295.pdf>

¹³⁵ <https://www.law.cornell.edu/uscode/text/6/chapter-2/subchapter-II/part-A>

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 Management¹³⁶ — 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 FY2023.¹³⁷ 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.¹³⁸ Section 7301, Global Catastrophic Risk Management Act of 2022, established global emergency management system, and was codified at 6 USC 821¹³⁹ 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,¹⁴⁰ and has been for a very long time.

Full text of the Global Catastrophic Risk Management Act from PL 117-263 is below.

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;

¹³⁶ <https://www.law.cornell.edu/uscode/text/6/chapter-2/subchapter-II/part-F>

¹³⁷ <https://www.congress.gov/117/plaws/publ263/PLAW-117publ263.pdf>

¹³⁸ <https://www.law.cornell.edu/uscode/text/22/2151b>

¹³⁹ <https://www.law.cornell.edu/uscode/text/6/821#6>

¹⁴⁰ <https://naomiwolf.substack.com/p/facing-the-beast/comment/7802768>

(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...

Top 10 US federal laws Congress should repeal to end worldwide vaccination, mutilation and killing programs.

Published May 23, 2024

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

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.

Published June 24, 2024

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*¹⁴¹ (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,¹⁴² 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*.

¹⁴¹ <https://law.justia.com/cases/federal/appellate-courts/ca9/20-56194/20-56194-2022-02-22.html>

¹⁴² <https://bailiwicknews.substack.com/p/on-civil-suits-against-pfizer-for>

Selections from reporting published at Bailiwick News, January 2022 through February 2025, compiled April 2025

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Intentional infliction of harm is not a legitimate government purpose; enabling it is not a permissible legislative object.

Published June 27, 2024

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, but that I haven't managed to write about in detail yet.

I have a lot of notes about a lot of cases, and will write more about them when I can. I've been writing shorter posts lately, on some of the dozens of subtopics of the worldwide, intentional, US-government-led mass murder campaigns.

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. See Bailiwick, Nov. 14, 2022 - Thought-stopping stage sets in legal pleadings.¹⁴³

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.

¹⁴³ <https://bailiwicknews.substack.com/p/thought-stopping-stage-sets-in-legal>

On reading PREP Act declarations as declarations of war issued by treasonous, seditious agents acting in unofficial, personal capacities.

Published July 2, 2024

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 - Devastating¹⁴⁴. 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*¹⁴⁵

"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, 2023,¹⁴⁶ Covid PREP declarations are currently scheduled to expire Dec. 31, 2024 and will probably be extended again.

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 Government¹⁴⁷ *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).

¹⁴⁴ <https://www.coffeeandcovid.com/p/devastating-tuesday-july-2-2024-c>

¹⁴⁵ https://www.supremecourt.gov/opinions/23pdf/23-939_e2pg.pdf

¹⁴⁶ <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>

¹⁴⁷ <https://conspiracysarah.substack.com/p/h5n1-bird-flu-jab-accelerated-approval>

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 5200.¹⁴⁸

An April 2024 slide deck¹⁴⁹ 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.

¹⁴⁸ <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>

¹⁴⁹ https://www.biomap-consortium.org/wp-content/uploads/2024/04/BioMaP-C-April-2024-Industry-Day-Slide-Final_040424.pdf

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.

Published July 12, 2024

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.*,¹⁵⁰ 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 more¹⁵¹) 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.

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 officials¹⁵²) are working for central bankers, United Nations-World Health Organization and related supranational organizations, to conduct fraud-based informational, psychological, biological and chemical war.

¹⁵⁰ https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

¹⁵¹ <https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program>

¹⁵² <https://www.opm.gov/policy-data-oversight/senior-executive-service/>

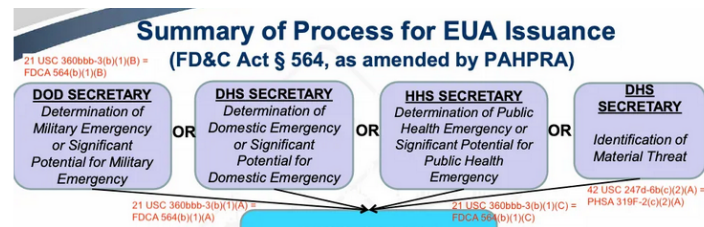
Congress members, US Presidents and federal judges have emasculated themselves.

Helping more people understand how and why¹⁵³ they've done what they've done, is an important part of challenging Congress and US presidents to reverse the procedure (repeal the enabling acts¹⁵⁴) 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.

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

¹⁵³ <https://sashalatypova.substack.com/p/since-1997-20-trillion-has-been-stolen>

¹⁵⁴ <https://bailiwicknews.substack.com/p/top-10-us-federal-laws-congress-should>

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*.¹⁵⁵

¹⁵⁵ https://www.supremecourt.gov/opinions/19pdf/19a1044_pok0.pdf

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.

Published Sept. 20, 2024

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.

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)

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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.¹⁵⁶

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...

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, 2029¹⁵⁷), 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

¹⁵⁶ <https://rayfloreslaw.substack.com/p/legal-opinion-prep-allows-for-two>

¹⁵⁷ <https://www.govinfo.gov/content/pkg/FR-2024-12-11/pdf/2024-29108.pdf>

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.

Edwin Chemerinsky letter to Senate, Dec. 20, 2005, on unconstitutional PREP Act.

Published Mar 17, 2025

Edwin Chemerinsky¹⁵⁸ 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 14240¹⁵⁹
- 2005.12.21 Congressional Record PREP Act discussion S14241 to 14254¹⁶⁰ Chemerinsky
- 2005.12.21 PREP Act Senate Roll Call¹⁶¹
- 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.

Leahy introduced Chemerinsky's letter.

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.

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

¹⁵⁸ https://en.wikipedia.org/wiki/Erwin_Chemerinsky

¹⁵⁹ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/03/2005.12.21-congressional-record-prep-act-discussion-s14233-to-14240.pdf>

¹⁶⁰ <https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/03/2005.12.21-congressional-record-prep-act-discussion-s14241-to-14254-chemerinsky.pdf>

¹⁶¹ <https://bailiwicknewsarchives.wordpress.com/treason-evidence/>

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 Council*, 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.

Senators Kennedy, Biden, Clinton, Byrd, denouncing PREP Act on Dec. 21, 2005, and then committing treason by voting for it the same day.

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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 scott-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 already 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.

Senator Hillary Clinton:

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.

Senator Robert Byrd:

...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.