<u>An American Judicial Coup d'état</u>
An Emergency Warning To The Nation
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In this paper, you'll uncover three chilling revelations about the erosion of your medical autonomy and constitutional safeguards:

(1) Thirty-one federal judges intentionally suppressed evidence of federal laws, regulations, and Executive Branch contracts—evidence that figures like Governor Newsom unlawfully forced healthcare workers to inject FDA-classified investigational drugs as a condition of employment. These same judges then upheld mandates that empower states, local governments, and hospital executives to compel you—under threat of punishment—to submit to drugs undergoing clinical trials as a condition of earning a living while denying you any right to sue if injured by the drugs. Why the subterfuge? They needed to nullify the Food, Drug, and Cosmetic Act to establish a backdoor loophole, solely for the purpose of empowering the World Health Organization as America's de facto authority over its health policies.

(2) The FDA quietly enacted 21 C.F.R. § 50.22(c)—a regulation it never formally proposed and publicly committed not to implement. This rule greenlights horrors like schools partnering with pharmaceutical companies to conduct clinical experiments on your children or hospitals secretly exposing you to trial-stage drugs. Worse, it gives the FDA and 30,000 contractors the power to create secret medical dossiers on you, which can be shared with unknown third parties for unknown purposes and for an indefinite period.

(3) The Fifth and Fourteenth Amendments' Due Process Clauses protect against arbitrary deprivations of life, liberty, or property, implicitly prohibiting Congress from enacting laws that grant absolute immunity to individuals who cause injury through non-consensual acts. However, over a dozen federal and state courts have used federal statutes as a procedural device to grant such immunity to persons injecting investigational drugs into individuals who refused to accept them, resulting in injuries, including death. Courts cannot deprive you of your right to sue someone who injures you, especially when you have told the person causing harm no. Now, imagine if you are covertly involved in an activity operating under the above-referenced FDA regulation involving a PREP Act countermeasure that causes injury; the courts are paving the way to ensure you cannot sue under that condition.

The judicial insurgency outlined in this paper is far deadlier than it seems—a stealthy overthrow of the Republic is underway, and it aims to destroy your life.

<u>An American Judicial Coup d'état</u>

What might once have seemed like the dystopian fiction of H.G. Wells' The Island of Dr. Moreau is now an unsettling biopic of 2025 America. The reader will soon discover that the Judicial Branch, engaging in a coup d'état, has already stripped them of their federally protected right to refuse investigational drugs without incurring a penalty or loss of benefits, to seek judicial relief for injuries caused by the drug's use, and to refuse participation in secret biomedical experiments where consent is not obtained and participants are not informed of their involvement. Worse, state courts are now granting absolute immunity to those involuntarily injecting such drugs into individuals who refused consent, making the Constitution's Due Process Clause meaningless. More shocking is that federal judges are engaging in a judicial usurpation of powers to pave the way for the World Health Organization (WHO) to have fiat control over America's health policies.

In 2021, the Executive Branch was under a binding federal statute—rooted in Senator Edward Kennedy's 1973 National Research Act—that obligated it to protect Americans from being pressured into receiving investigational COVID-19 drugs[1] or facing penalties for such refusal. Yet that same year, President Biden, 16 Democratic governors, scores of mayors, and hundreds of private institutions breached this duty by imposing mandates under threat of punishment, while stripping citizens of any legal recourse for resulting injuries. By 2023, federal lawsuits exposed these mandates as unlawful violations of a long-dormant contractual assurance: recipients of federal funding had pledged, decades earlier, never to pressure the public into experimental[2] medical treatments.

Largely unknown by lawyers and legislators alike, this obscure agreement suddenly placed defendants in legal jeopardy. To protect government leaders who robbed Americans of their economic livelihoods, the federal judiciary intervened with a series of extraordinary rulings—shielding violators from accountability through corrupt opinions and procedural dismissal. Then, in a pivotal geopolitical shift, President Trump withdrew U.S. support from the World Health Organization's (WHO) proposed amendments to the International Health Regulations (IHR), blocking foreign control over America's health policies. Undeterred, the powers that be handpicked circuit appellate panels to repurpose the COVID-19 litigation into a covert workaround: a three-phase judicial strategy to achieve, through domestic courts, what international law could no longer impose through the Executive Branch—to subject the reader to investigational drugs while simultaneously depriving them due process to sue when injured by the drugs.

The reader should prepare to confront a chilling narrative of stolen liberties, judicial corruption, and a global scheme to use America's population as guinea pigs in biomedical experimentation. This document serves two critical purposes: (1) to deliver a clear, accessible narrative that every American can understand, and (2) to provide robust legal evidence substantiating the claim that the federal judiciary has orchestrated a coup d'état against the Republic. To maintain clarity for all readers, the legal arguments are meticulously detailed in the footnotes, ensuring the main text remains engaging and straightforward.

Part One: An Unexpected Journey

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[1] Investigational means a drug, biologic, or device being used for a purpose not licensed by the FDA according to the product's labeling.

[2] "In FDA parlance, experimental drugs that have not yet been approved for public use [according to their labeling] are deemed investigational drug[s]. See 21 C.F.R. § 312.3(b)." (emphasis added) *Abigail Alliance v. Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007)

In October 2021, I was invited to a casual luncheon with more than a dozen United States Air Force officers to discuss the latest national news, which eventually shifted to the topic of COVID-19 mandates. Little did I know that, like Bilbo Baggins, I was about to embark on an unexpected journey where, four years later, I would have typed 3 million words, donated 4,000 pro bono hours, and consulted on nearly 30 federal lawsuits—all in an effort to help hundreds of surgeons, doctors, nurses, firefighters, police officers, EMTs, and school teachers regain their careers and to restore the honor of the military profession stolen by senior Pentagon leadership. Nor could I have imagined at the time that I would be given a front-row seat to witness a judicial coup, executing one of the darkest strategies in America's history to subject Americans to unapproved medical treatments manufactured under suspect processes while denying them any right to sue when injured.

The journey started innocently enough when the officers asked me to investigate whether the Department of Defense (DoD) COVID-19 mandates were lawful. Although I'm not a lawyer, my professional background involves solving complex problems with hundreds, if not thousands, of moving parts. God blessed me with the ability to retain virtually anything I read and to automatically connect that new knowledge to everything I have previously read about the subject, which accelerates my ability to become proficient in new industry knowledge.

It only took one week of research to discover that 10 U.S.C. § 1107(a) and Department of Defense Instructions (DoDI) 6200.02 impose a ministerial duty on the Secretary of Defense, Under Secretary of Defense (Personnel and Readiness), Assistant Secretary of Defense for Health Affairs (ASD(HA)), Secretary of the Army, the Surgeon General of the Army, Chairman of the Joint Chiefs of Staff, and the General Counsel of the Department of Defense to ensure that no DoD member, civilian or service member, is pressured into using an unlicensed drug or punished for refusing. Congress only authorizes the commander-in-chief (i.e., the president) to grant or withhold a waiver of <u>legally effective informed consent</u> when, and only when, it is determined that the investigational drug is necessary to accomplish a specific military mission within a well-defined geographic area and only upon the Secretary of Defense making such a request, which must be published in the Federal Register.

Although President Biden never issued a waiver of informed consent, SECDEF Austin permitted subordinate commanders to arrogate the President's exclusive authority. They ordered 3.5 million DoD personnel to accept emergency-use COVID-19 products—FDA-classified as investigational—or face career-ending discipline. In doing so, Austin and his chain of command violated their oaths to "faithfully discharge the duties of the office" and to "support and defend the Constitution." Incensed by this abuse of power and driven by my sincere gratitude for those who swore an oath to fight and die so my family could live freely in America, I wrote a 60-page report exposing the lawlessness. I then flew to D.C., where I worked with active-duty and retired service members to educate Congress on laws governing investigational drugs and the rights of DoD personnel to refuse such drugs without consequence. However, it would take Trump becoming president to appoint a person with the courage to face the darkness and do something about it—SECDEF Pete Hegseth.

Part Two: Legal and Factual Background

In the Summer of 2022, the spouses of military members working as civilians in the healthcare industry — including surgeons, doctors, and nurses — requested that I investigate the hospital mandates. This request required a monumental effort, as I had to start in 1906, when Congress enacted the Pure Food and Drug Act, and work my way forward through the congressional record. I discovered that in 1973, after the Nation became aware of the Tuskegee Experiment,[3] Senator Edward Kennedy conducted Senate hearings exposing the Executive Branch's human rights abuses committed against Americans involving federally funded investigational drugs under research conditions.[4] One such example is that of a New York doctor using infected feces of Syphilis patients and feeding those extracts to mentally disabled children, ensuring new research subjects would be available for his work, which fact would make Nuremberg defendants blush.

Those hearings led Congress to enact the 1974 National Research Act,[5] requiring a Commission to determine the legal nature of informed consent, establishing 42 U.S.C. § 289, and requiring the Health and Human Services Secretary ("Secretary") to take the Commission's findings and promulgate regulations on its behalf to protect the American people from future human rights atrocities. In 1978, the Commission published its findings of what constitutes informed consent in the 'Belmont Report.'[6] The Commission found that a person gives their legally effective informed consent only when they are offered the opportunity to participate under conditions that are free from "coercion," "undue influence," and/or "unjustifiable pressures." External pressure, whether negative (e.g., loss of employment) or positive (e.g., a $500 bonus or free vacation time), nullifies the consent standard, as the decision to consent is not purely autonomous. This form of consent is known as "legally effective informed consent." The duty to obtain consent arises when the offer to participate is made, not when participation commences, such as when an investigational drug is injected.

The Secretary, acting on command from Congress and being informed by the Belmont Report, issued regulations under 45 CFR Part 46 ("Common Rule") to ensure the rights of the public are protected when involved with federally funded[7] unapproved medical treatments and related activities,[8] establishing the consent standard as the fundamental right protecting against future human rights atrocities. Addtionally, Congress mandated the establishment of Institutional Review Boards ("IRB") under 42 U.S.C. § 289, as a third-

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[3] Over 100 African-American men were needlessly allowed to suffer until death from Syphilis so that medical researchers could study how the disease progressed through human anatomy. https://biotech.law.lsu.edu/cphl/history/reports/tuskegee/complete%20report.pdf

[4] U.S. Government Printing Office. "Quality of Health Care — Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public.

[5] National Research Act of 1974, Pub. L. No. 93-348

[6] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* U.S. Department of Health and Human Services, April 18, 1979

[7] 45 CFR § 46.122 "Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied."

[8] 45 CFR § 46.116 defines the consent standard in detail. § 46.101(c) binds the regulation to adherence to the Belmont Report. See Belmont Report "Voluntariness."

party guarantee that the consent standard is adhered to.[9] Curiously, four years leading up to the COVID-19 pandemic, numerous hospitals all switched to using the same IRB. Notably, all federal agencies, departments, and the military must comply with the consent standard.[10] If an activity is considered exempt from the Common Rule, that activity must still comply with the Belmont Report.[11] Twenty-four federal agencies incorporated the Common Rule into their respective regulatory frameworks.[12]

To grasp the judicial coup at its core, one must first understand the Common Rule's consent threshold—the federal gatekeeper for human experimentation. An activity triggers the consent standard when five clear conditions align:

1. Federal funding or authorization is involved (45 CFR § 46.122).
2. Humans are involved (§ 46.102(e)(1)).
3. The identifiable private information (IPI) of the participant is collected (§ 46.102(e)(5)).
4. Participants are monitored or studied for their responses to the intervention (§ 46.102(e)(1)(i)).
5. The data generated will contribute to generalizable knowledge about the product or activity (§ 45 CFR 46.102(l)).

Meet these conditions, and the activity requires Institutional Review Board (IRB) approval and legally effective informed consent pursuant to 42 U.S.C. § 289. No exceptions.[13] A single real-world example crystallizes the rule: a physician administers an investigational

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[9] 45 CFR Part 46 and 21 CFR Part 56 are the primary sources of IRB authority.
[10] 45 CFR 46.101(a)
[11] 45 CFR 46.101(i)
[12] 22 C.F.R. Part 225 (Agency for International Development); 7 C.F.R. Part 1c (Dept. of Agriculture); 28 C.F.R. Part 46 (Dept. of Prisons); EO 12333, EO 13284, EO 13555, EO 13470 (Central Intelligence Agency); 15 C.F.R. Part 27 (Dept. of Commerce); 16 C.F.R. Part 1028 (Dept. of Product Safety Commission); 32 C.F.R. Part 219 (Dept. of Defense); 34 C.F.R. Part 97 (Dept. of Education); 10 C.F.R. Part 745 (Dept. of Energy); 40 C.F.R. Part 26 (Environmental Protection Agency); 28 C.F.R. Part 46 (Federal Bureau of Investigation); 45 C.F.R. Part 46 (Health and Human Services); 6 C.F.R. Part 46 (Dept. of Homeland Security); 24 C.F.R. Part 60 (Dept. of Housing and Urban Development); 28 C.F.R. Part 46 (Office of Justice Programs); 29 C.F.R. Part 21 (Dept. of Labor); 14 C.F.R. Part 1230 (National Aeronautics and Space Administration); 45 C.F.R. Part 690 (National Science Foundation); EO 12333, EO 13284, EO 13555, EO 13470 (Office of Director of National Intelligence); 20 C.F.R. Part 431 (Social Security Information); 49 C.F.R. Part 11 (Dept. of Transportation); 38 C.F.R. Part 16 (Dept. of Veteran Affairs); 42 C.F.R. Part 50 (Public Services Act-sterilization of persons in federally assisted family planning projects); 48 C.F.R. Parts 297, 235, 252 (Defense Federal Acquisition Regulation Supplement—DFARS Case 2007-D008); DoDI 3216.02 (DoD: Research Integrity and Misconduct); DoDI 6200.02 (DoD: IND regulation for military and civilian use); DoDD 5400.11-R (DoD Privacy Program); AR 70-25 (U.S. Army: Research Protocols); ALARACT 031/2008, DTG 141557Z Feb 08 (Army Human Subjects Protection Requirements); HQ MRDC IRB Policies and Procedures (U.S. Army Medical Research and Development Command, which is responsible for investigational and EUA drug administration DoD-wide).
[13] "Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes." 45 CFR 46.102(l)

cancer drug as emergency treatment to a single patient. The patient's identity is known, the drug is FDA-authorized for emergency use, the doctor monitors the response, and the data feeds the product's broader evidence base—one injection, one research event—fully subject to the consent standard. Investigational drugs subject to the consent standard cannot be listed under a vaccination requirement because a "requirement" exerts pressure that nullifies effective consent.

The Executive Branch, under a ministerial duty[14] to comply with the consent standard under 42 U.S.C. § 289, established the Federalwide Assurance ("FWA") program[15] in 2000.[16] The FWA program requires entities and persons offering participation in Common Rule activities to contractually promise HHS that they will comply with the consent standard without exception, as a condition of administering investigational drugs and or participating in federal funding. As an example, Governor Newsom operates under California's Federalwide Assurance contract No. FWA00000681. The FWA contract exists for one singular purpose: to ensure, via a legally binding agreement, that the rights of the American people to refuse such treatments without incurring a penalty or loss of benefits are protected. To date, there are an estimated 30,000 active FWA contractors bound by the consent standard, including all U.S. states and territories, as well as most major hospitals and universities.

Through the National Research Act, the Belmont Report, 42 U.S.C. § 289, the Common Rule, and the FWA program, Congress and the Executive Branch established a fundamental principle: legally effective informed consent is the sole key that unlocks the <u>use</u> of an investigational drug on American soil. We will soon see how the federal judiciary quietly dismantled this principle to overthrow the reader's federally secured right to effectively exercise such consent.

When Congress enacted Project Bioshield,[17] establishing 21 U.S.C. § 360bbb-3 ("EUA Statute"), which permits only the Secretary to introduce unapproved medical treatments into commerce during a declared emergency, it ensured compliance with America's fundamental rights to bodily integrity[18] by requiring the Secretary to inform potential recipients of their lawful authority to refuse administration of the unapproved medical

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[14] A ministerial duty is a legal obligation imposed on a public official or entity that requires them to perform a specific act or function in a prescribed manner, without discretion or judgment. These duties are mandatory, leaving little to no room for the official to decide whether or how to act.

[15] "Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46. The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP." — https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/assurance-process/index.html

[16] The Office for Human Research Protection (OHRP), under the authority of the Assistant Secretary for Health of HHS, is responsible for program implementation and lawful compliance.

[17] Public Law 108-276 (S. 15, 108th Congress)

[18] Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990) (affirming that "competent persons generally are permitted to refuse medical treatment"); Union Pacific Railway Co. v. Botsford, 141 U.S. 250 (1891) (affirming the "right of every individual to the possession and control of his own person); Washington v. Glucksberg, 521 U.S. 702 (1997) (recognizing the "long legal tradition [of the courts] protecting the decision to refuse unwanted medical treatment"); Albright v. Oliver, 510 U.S. 266, 272 (1994) (recognizing the "right to bodily integrity" is a fundamental right).

treatments. However, Congress made clear that no person could mandate the use of EUA products by explicitly preventing the Secretary from having any authority "to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section."[19] Therefore, the Secretary can issue expanded access protocols for the unlicensed use of drugs as a temporary exemption from the FDCA's prohibition of such conduct under 21 U.S.C. § 355(a). Still, he cannot compel anyone to manufacture, distribute, administer, or use the product. The Supremacy Clause[20] prevents states from establishing legal requirements that conflict with the Secretary's mandate of ensuring complete voluntary participation in EUA-authorized activities because such a legal requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Congress understood that the EUA Statute would only activate during Chemical, Biological, Radiological, Nuclear, or Pandemic events, but still required legally effective informed consent. Notably, the EUA Statute's "option to refuse"[21] aligns with the legally effective informed consent requirements outlined in the Common Rule (45 CFR 46.116(a)(1)). The duty of the Secretary to ensure that potential recipients receive full disclosure of the EUA product's risks, benefits, and alternatives directly aligns with the Common Rule requirements under 45 C.F.R. §§ 46.116(b)(2-4). Therefore, the congressional mandate for the Secretary to ensure potential recipients are informed about their FDCA option to accept or refuse an EUA product, while expressly prohibiting the Secretary from mandating involuntary use, guarantees that the conditions for legally effective informed consent are satisfied, as any offer to use the drug is not subject to external pressure.

Now, let's apply this framework to the COVID-19 response—the CDC, operating under Federalwide Assurance contract No. FWA00001413, launched the CDC COVID-19 Vaccination Program ("CDC Program") as a "cooperative agreement" pursuant to 42 U.S.C. § 289. Its purpose: mass administration of investigational COVID-19 products to the American public.

The program squarely triggered the consent standard. It was federally funded, involved humans, mandated the collection of identifiable private information (e.g., vaccine cards), required manufacturers, states, and providers to monitor participants for six priority adverse events, and directed reporting of all events to the Vaccine Adverse Reporting System ("VAERS") or to the Centers for Biologics Research and Evaluation (CBER). These data fueled ongoing CDC studies of safety and effectiveness—contributing directly to generalizable knowledge about the products. No exemption to the consent standard applied. The drugs carried known, life-altering risks and remained investigational[22] throughout the program's rollout. Even full licensure of a product would not have altered the outcome: the

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[19] 21 U.S.C. § 360bbb-3(l)

[20] The Supremacy Clause is a provision in Article VI, Clause 2 of the United States Constitution. It establishes that the Constitution, federal laws made pursuant to it, and treaties made under the authority of the United States shall be the "supreme Law of the Land."

[21] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)

[22] The Secretary informed the nation that the drugs are "an investigational vaccine not licensed for any indication" and only introduced into commerce under an EUA and are listed as covered countermeasures under a declaration made pursuant to the PREP Act. See 86 Fed. Reg. 5200 (Jan. 19, 2021), 86 Fed. Reg. 28608 (May 27, 2021), and 85 Fed. Reg. 15198 (March 17, 2020).

activity itself was research, and research demands informed consent. Thus, the CDC owed every American legally effective informed consent when presenting them with an opportunity to participate in its federally funded program and products. That duty was absolute, giving the CDC no discretion to deviate from the consent standard. Furthermore, the issuance of an EUA did not alter the consent standard to which the CDC Program was obligated, as an EUA is a legally distinct requirement.

Furthermore, the CDC Program only provided products with protected liability under the PREP Act, meaning the reader could not sue the manufacturer or individuals causally connected to its administration if injured,[23] thereby conditioning participation on a prospective, voluntary waiver of the Fifth or Fourteenth Amendment right to seek redress for injuries caused by any program-affiliated actor or the products offered. No federal agency—or state agent it recruits—may compel forfeiture of a core constitutional guarantee as the price of accessing a public benefit. That issue will be fully dissected later. Separately, Congress expressly preempts states from enacting or continuing in effect with any legal requirement that conflicts with the FDCA's option to refuse an EUA product.[24] On this basis alone, no state had authority to condition public benefits on the use of the COVID-19 drugs.

To insulate itself from direct liability, the CDC enlisted only states and territories that maintained active Federalwide Assurances (FWAs)—binding contractual pledges to adhere to the same consent standard obligations imposed on the CDC itself. Participating states lacked discretionary authority to rewrite program terms or breach their FWAs when involving their citizens with the investigational products.[25] The CDC then permitted these states to subcontract administration to public and private entities, provided each signatory executed the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement")[26] and that the state committed to ensuring lawful compliance among the recruited agents.[27] That agreement mandated the organization's chief executive and medical officers to comply with "any EUA" and all applicable federal law, including the Common Rule's informed-consent mandate. Because the Executive Branch purchased the products[28] and bore a Fifth Amendment obligation to secure informed consent nationwide,

[23] 42 U.S.C. § 247d-6d

[24] 42 U.S.C. § 247d-6d(b)(8)(B)

[25] *Bennett v. Kentucky DOE,* 470 U.S. 656, 657 (1985), affirming that states choosing to participate in federal programs to receive funding must abide by the program's conditions.

[26] https://covidpenalty.com/wp-content/uploads/2024/02/COVID19-Vaccination_Program_Provider_Agreement_and_Profile_Form.pdf

[27] "COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations," outlined the state's duties. https://www.cdc.gov/vaccines/imz-managers/downloads/Covid-19-Vaccination-Program-Interim_Playbook.pdf

[28] "At this time, all COVID-19 vaccine in the United States has been purchased by the U.S. government (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641,

it delegated that governmental function to the states. The states, in turn, sub-delegated it—under color of the Fourteenth Amendment—to their recruited providers via the Provider Agreement. Neither tier of delegation could lawfully be violated.[29] Therefore, from the CDC to the State to the provider, no person held any authority to mandate any person to inject the unapproved drugs into their bodies or to become research subjects under the CDC Program outside of their legally effective informed consent as a condition of employment, accessing unemployment benefits, education, or use of a state-issued license. A fact that 31 federal judges have worked tirelessly to conceal from the American public.

Let us summarize the governing legal framework into ten irrefutable principles:

1. Interstate Commerce: No drug may enter interstate commerce absent FDA approval or explicit Executive Branch authorization (21 U.S.C. § 355; 42 U.S.C. § 262).[30]
2. Third-Party Oversight: Federally funded investigational drugs require independent IRB review to verify that informed consent is legally effective (42 U.S.C. § 289; 45 C.F.R. § 46).
3. Expanded Access: Only the Secretary can authorize unlicensed use of investigational drugs through expanded-access protocols (21 U.S.C. § 355(i); 21 U.S.C. § 360bbb, Id., § 360bbb-3), provided that legally effective informed consent is obtained from the individual in advance.
4. Right to Refuse: The Secretary must affirmatively notify Americans of their statutory right to refuse an EUA product; the Supremacy Clause shields that refusal from

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and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law." — CDC

[29] *West v. Atkins*, 487 U.S. 42, 54– 57 (1988), holding that if a State bears an obligation to perform a function and delegates that function to a private party voluntarily agreeing under contract to perform it, then the private party's deprivation of the obligation constitutes state action for purposes of 42 U.S.C. § 1983 enforcement. Further, the *Atkins* court took note of the circuit court's dissenting opinion, stating that a State cannot contract out its constitutional obligations to "leave its citizens with no means for vindication of those rights, whose protection has been delegated to 'private' actors, when they have been denied." *Id.* at n. 14

[30] The federal judiciary has consistently affirmed that individuals do not possess a fundamental right to access or utilize unapproved medical treatments, nor can they use such treatments outside of agency authorization conditions, to include persons mandating their use. See *L.W. v. Skrmetti,* 83 F.4th 460, 478 (6th Cir. 2023) ("Neither doctors, adults, nor their children have a constitutional right to use a drug that the FDA deems unsafe or ineffective."); *United States v. Rutherford*, 442 U.S. 544 (1979) (denying terminally ill cancer patients access to drugs not approved for any legal indication); *Abigail Alliance v. von Eschenbach,* 495 F.3d 695, 713 (D.C. Cir. 2007), cert. denied, 128 S. Ct. 1069 (2008) (rejecting an argument that terminally ill patients hold a fundamental right to access investigational drugs and affirming that authorization conditions are subject to federal government regulations). In *The Upjohn Co. v. Finch*, 422 F.2d 944, 954 (6th Cir. 1970), (the Sixth Circuit upheld the supreme authority of the Executive Branch to determine when a drug is approved for a legal indication, "[w]e hold that the record of commercial success of the drugs in question, and their widespread acceptance by the medical profession, do not, standing alone, meet the standards of substantial evidence prescribed by 21 U.S.C. § 355(d))."

penalty, ensuring the reader can effectively exercise the option. (21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III))

5. PREP Act Preemption: States are expressly preempted from enacting requirements that conflict with the FDCA's option to refuse EUA countermeasures (42 U.S.C. § 247d-6d(b)(8)(B)).
6. FWA Compliance: Every entity holding a Federalwide Assurance agreement is contractually bound to the consent standard and is contractually prohibited from listing investigational drugs and/or research activities under a vaccination requirement.
7. CDC Program Scope: The CDC COVID-19 Vaccination Program, as an FWA-covered cooperative agreement, was subject to the consent standard. Moreover, the program ensured that potential recipients were informed of the drugs' risks, benefits, and alternatives. The individual could not be pressured to use the drugs, nor would they incur a fee or penalty should they accept or refuse their administration, which is a federally funded benefit subject to the Due Process Clause.
8. Coercion Prohibited: Americans hold a due process right to refuse the administration of an investigational drug without incurring a penalty or losing a benefit to which they are otherwise entitled.[31]
9. The CDC, Secretary Becerra, and Rachel Levine were lawfully obligated to ensure that this nation did not face the threat of penalties for refusing investigational COVID-19 drugs.

Thus, the 16 Democrat governors who issued mandatory participation requirements conditioned on public benefits such as public employment, education, unemployment, and the use of state-issued professional licenses did so under *ultra vires* authority.[32]

Part Three: A Judicial Coup D'état

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[31] Neither Congress nor the Executive Branch can require an entity to obtain informed consent unless it first confers upon the potential participant a property right to grant or withhold such consent. Pursuant to *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972), this duty correlates into a property right, the violation of which is enforceable under 42 U.S.C. § 1983 via *Dennis v. Higgins*, 498 U.S. 439, 445 (1991). *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990) ("the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment").

[32] The Latin term *ultra vires* means "beyond the powers." When a public official issues an order that exceeds the scope of their delegated authority, the act is considered personal rather than official, thereby stripping them of any shield of qualified immunity. A clear example is Governor Gavin Newsom's 2021 mandate requiring all California healthcare facilities to employ only workers who would agree to inject one of the COVID-19 investigational/EUA/PREP Act countermeasures into their bodies. This order was *ultra vires* because the State of California cannot violate the terms of its FWA or CDC Program agreements, nor conflict with the Secretary's authorization conditions under any EUA, nor disregard the PREP Act's express preemption clause. Because the state cannot violate federal law, the order was issued in Newsom's personal capacity—not as a valid act of the state—and was therefore invalid from the outset.

(a) <u>Strategy step one: transfer Congress's exclusive authority to decide when, where, and how drugs enter commerce to governors, mayors, and CEOs.</u>

Since 1938, three immutable legal axioms have governed:

1. Only the FDA may deem a drug approved for general marketing pursuant to 21 U.S.C. § 355(a)—and commerce regulation is tied irrevocably to the product's precise labeling pursuant to 21 U.S.C. § 352 and 42 U.S.C. § 262(a)).
2. Only the Secretary is authorized by Congress to establish expanded access protocols for the unlicensed use of medical products for research, education, or emergency use pursuant to 21 U.S.C. § 355(i), 21 U.S.C. § 360bbb, 21 U.S.C. § 360bbb-3.
3. Congress expressly prohibits states, political subdivisions, mayors, and hospital CEOs from assuming the authority to override either determination.

In 2024, public servants—police officers, teachers, EMTs, firefighters—began reaching out for help, proving their employers could not lawfully terminate them for exercising a federally protected right. I agreed without hesitation. To date, I have consulted on nearly 30 federal and state lawsuits across ten jurisdictions. Attorneys nationwide now routinely forward me rulings, opinions, and orders on the issue, providing me with an intimate understanding of the unfolding constitutional crisis.

Federal litigation hinges on two pillars: (1) pure questions of law, and (2) the application of those laws to the plaintiff's facts to establish a viable claim. Here, every dismissal came under federal court Rule 12(b)(6) for "failure to state a claim"—a pure legal ruling. Accordingly, the underlying facts need not be rehearsed; judicial corruption is exposed by the judge's legal reasoning alone. The core claim in every case I consulted on was identical: plaintiffs possessed constitutional, statutory, and programmatic[33] rights—protected by the Due Process Clause—to refuse federally funded investigational drugs. Defendants were contractually bound (FWA & CDC Program), statutorily barred (FDCA & the PREP Act), and expressly preempted (Supremacy Clause) from mandating investigational drug injections or punishing refusal.

Note this carefully: not one defendant—not even Governor Newsom—asserted lawful authority to mandate investigational, EUA, or PREP Act products. Their defenses rested on two pillars alone: (1) Pfizer's legally distinct COVID-19 drugs were fully FDA-approved, or (2) plaintiffs lacked standing to sue for economic harm caused by *ultra vires* acts. The district courts never upheld a governmental power to compel administration. Instead, they

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[33] The Supreme Court holds that federally funded benefits are subject to the Due Process Clause. "Property interests, of course, are not created by the Constitution. Rather, they are created, and their dimensions are defined, by existing rules or understandings that stem from an independent source such as state law — rules or understandings that secure certain benefits and that support claims of entitlement to those benefits. Thus, the welfare recipients in *Goldberg v. Kelly,* 397 U.S. 254 (1970), had a claim of entitlement to welfare payments that was grounded in the statute defining eligibility for them." The CDC Program provided Americans with the property right to receive full disclosure of the products' risks, benefits, and alternatives without coming under pressure to participate or incurring a product fee for accepting or an administrative fee when refusing.

adopted defendants' factual premise—that Pfizer's Comirnaty and BioNTech formulations were fully approved—in direct contradiction to Executive Branch classifications.[34] Of the 14 dismissals, 12 turned on this fiction. Only two courts cited alternative grounds based on the judges' reengineering of the cases through the reframing of the Plaintiffs' allegations. A single case has advanced to discovery; its survival past summary judgment is improbable, given that the judge refuses to answer questions of federal preemption in violation of Supreme Court precedent.[35]

To understand the judicial takeover of Congress, let us now focus on the federal appellate circuits and state supreme courts, which establish binding precedents that govern nationwide enforcement of federal law. We begin with the Third, Fifth, Sixth, Ninth, and Tenth Circuits. Then, we examine parallel moves by Democratic-led states, revealing the strategic reasoning behind these appellate rulings to subject the nation to ongoing investigational drugs while elevating the WHO as the supreme authority over America's health policies.

Third Circuit — *Children's Health Defense v. Rutgers University*, 93 F.4th 66 (3d Cir. 2025).

The Children's Health Defense organization sued Rutgers University over its policy that a citizen could not obtain public education benefits unless they first injected an EUA-unapproved medical treatment into their body. I did not participate in the consultation on this case, but a discussion of the ruling is necessary for this paper. The case primarily revolved around whether the school could mandate the use of an unapproved drug introduced into commerce under the EUA Statute. The circuit panel ruled that Rutgers could mandate the use of such drugs, a ruling that violated well-established FDCA court doctrine.

First, let us remind ourselves that only the Secretary can issue authorization conditions for an unlicensed drug during a nationally declared emergency, provided that the Secretary ensures Rutgers' students are informed of their lawful authority to refuse the administration of the emergency-authorized product. Second, Congress denies the Secretary any authority to mandate that the students use the drugs. Third, the statute only authorizes the Secretary to accomplish a legal result, not Rutgers. Finally, the Supremacy Clause preempts Rutgers from interfering with the federal goal of ensuring voluntary participation in EUA activities, thereby ensuring that students can effectively exercise their EUA option without interference. [36]

The circuit panel first addressed federal preemption by smoking what Cheech and Chong were growing, using sleight of mouth, the panel asserted that "Rutgers has not

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[34] Secretary Becerra placed each defendant under a contractual and ministerial duty to "conspicuously" state that the drugs were "not licensed or approved by the FDA." See any EUA.

[35] *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S.Ct. 1668 (2019) ("a judge, not the jury, must decide the pre-emption question.")

[36] "[Congress's] intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive … that Congress left no room for the States to supplement it' or where there is a 'federal interest … so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012), quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

mandated any medical products in violation of 21 U.S.C. § 360bbb-3, but rather has simply made adherence to the mandate a condition to enrollment at the university." This is pure doublespeak—an unethical attempt to obscure the obvious and gaslight the students. Under the challenged policy, enrollment at Rutgers is impossible without submitting to the injection of an EUA product. The university does not merely "condition" access; it enforces the very mandate that federal law prohibits states from imposing without preserving the statutory entitlement right to refuse. By requiring compliance with an injection mandate as a condition for obtaining a public benefit, Rutgers directly violates the EUA statute's explicit protection of individual choice and prevents the Secretary from fulfilling his congressional mandate to ensure voluntary participation among New Jersey residents. This is not a neutral condition—it is coercion by another name, and it is squarely preempted under the Supremacy Clause.

The reader should take note that the court held "Rutgers has not mandated any medical products <u>in violation of 21 U.S.C. § 360bbb-3.</u>" In other words, had the court found that Rutgers mandated the products, then students would have had a viable claim; hence, the doublespeak to evade the issue.

The panel affirmed that "§ 360bbb-3(e)(1)(A) obligates only the Secretary of Health and Human Services to act, by establishing 'conditions designed to ensure' informed consent," but then ruled that "there is no unqualified right to decide whether to 'accept or refuse' an EUA product without consequence." The court continued, "To the contrary, being advised of the consequences is precisely what § 360bbb-3(e)(1)(A)(ii)(III) requires, providing explicitly that the recipient of an EUA product shall be informed 'of the consequences, if any, of refusing administration of the product.'" In the context of the lawsuit, the circuit panel used the word "consequence" to mean a civil penalty.

First, the EUA Statute not only obligates the Secretary to act, but it only empowers the Secretary to act. One will not find Rutgers' name listed or implied in the Statute. Second, if a "consequence" is to be applied, such a consequence could only be determined by the Secretary under the Statute, not Rutgers. However, because Congress prohibits the Secretary from mandating involuntary participation, a civil "consequence" cannot be imposed for exercising the option to refuse such participation. The word consequence only pertains to "possible health effects" of "stopping the use of [PRODUCT] against the recommendation of the health care provider."[37] The circuit panel concocted a legal theory having no basis in law or legal precedent. Congress expressly denies states any authority to enforce the FDCA regarding the emergency use of unlicensed drugs (21 U.S.C. § 337). Before any punishment could be imposed for refusing, Congress would need to list refusal as a prohibited act under § 331 and establish a penalty under § 333 to enforce it. However, not even then could Rutgers, an arm of the state, act under the federal statute's power to impose a state-based civil penalty to punish an option expressly secured for the students by a valid act of Congress.

[37] "Guidance Emergency Use Authorization of Medical Products" — U.S. Department of Health and Human Services Food and Drug Administration Office of the Commissioner Office of Counterterrorism Policy and Planning. July 2007.

The Supreme Court denied review, leaving intact the Third Circuit's precedential ruling—an act that marks the quiet onset of a judicial coup. Never before has the Supreme Court tolerated a state or its agencies to impose requirements that conflict with any provision of the FDCA. NEVER. Yet here, without a word of explanation, it has done precisely that. The circuit court openly acknowledged that Rutgers acted under color of the EUA statute when it attached "consequences" to refusal. The Supreme Court then permitted the Third Circuit to redefine the meaning of 'consequence' to convert a federal statute mandating voluntary participation into a law requiring mandatory participation by persons not authorized to establish such conditions under the statute. You cannot make up such madness.

The Third Circuit, with the Supreme Court's tacit approval, has rendered the option to refuse nonfunctional, permitting state actors to impose civil penalties that effectively eliminate the federally guaranteed choice. This is not mere interpretation; it is subversion. By allowing states, state universities, and political subdivisions to define their own "consequences" for refusal, the judiciary has stripped Congress of control over national EUA policy. The Equal Protection Clause nullified: the right to refuse becomes a geographic lottery, enforced or extinguished by unelected administrators wielding disparate sanctions in violation of the Fourteenth Amendment's Equal Protection under the Law doctrine.[38] For decades, the Supreme Court has held that only the federal government may set policy for the administration of unapproved medical products, as previously discussed. Now, in a single non-decision, it has abandoned that principle—sanctioning the use of a statute that forbids coercion to enforce coercion.

Finally, the Third Circuit quoted *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), stating "the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases" as justification for allowing Rutgers to mandate EUA products. However, the panel absolutely refused to find that the U.S. Congress had indeed passed laws to ensure public health and safety. Under the EUA Statute, it recognized that only unapproved medical treatments would be offered and placed the health and safety of the public into the hands of the individual considering such uses, not into the hands of Rutgers University to use public benefits as a coercive "procedural device" to "produce a result which the State could not command directly." *Speiser v. Randall*, 357 U.S. 513, 526 (1958). Importantly, the Third Circuit relied on *Jacobson,* a case decided 33 years before Congress enacted the FDCA, to elevate Rutgers as the supreme authority over Congress, despite Congress being the constitutional body with the power to govern the statute. This ruling was by design, not by error.

The Supreme Court once held that "For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person

[38] "[W]e have explained that '[t]he purpose of the equal protection clause of the Fourteenth Amendment is to secure every person within the State's jurisdiction against intentional and arbitrary discrimination, whether occasioned by express terms of a statute or by its improper execution through duly constituted agents.' *Sioux City Bridge Co.*, [260 U.S. 441], 445 (quoting *Sunday Lake Iron Co.* v. *Township of Wakefield,* 247 U.S. 350, 352 (1918))." *Village of Willowbrook v. Olech*, 528 U.S. 562 (2000)

on a basis that infringes his constitutionally protected interests." *Perry v. Sindermann*, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972). Americans hold a constitutionally protected interest in obtaining public benefits (e.g., education) while exercising their EUA option to refuse an investigational drug and a bodily integrity liberty interest to refuse unapproved medical treatments that are not licensed for safety, efficacy, or any legal indication, nor are they manufactured to the strict safety standards required of licensed medical products.

Sixth Circuit — *Norris v. Stanley,* 73 F.4th 431 (6th Cir. 2023)

The same legal circumstances applied, and the same result occurred as in *Rutgers*. The Supreme Court also denied review, further weakening federal policy and its authority, arrogating FDCA powers to the states, and allowing any third party to claim such a right to challenge Congress's exclusive authority over when, where, and how drugs enter commerce. Keep this fact in mind as we expose the judicial corruption aimed at fundamentally altering your way of life.

Fifth Circuit — *Pearson v. Shriners Hospitals*, No. 24-40436 (5th Cir. 2025)

The Fifth Circuit became the first appellate court in the nation to confront the full architecture of federal protections: the FWA program, the consent standard, the PREP Act's express preemption clause, the CDC Program, and the binding obligations these sources of authority impose on recipients of federal funds. Collectively, these mandates created an unequivocal Fourteenth Amendment-protected right for the nurses to refuse the investigational products offered by the State of Texas through its recruited agent, Shriners Hospitals for Children. The court, aware that Shriners never claimed any authority to mandate the use of such drugs, intervened by asserting that "Shriners' alleged misconduct…was not unlawful," a simple statement that fundamentally amended federal policy governing the $600 billion pharmaceutical industry by nullifying the consent standard. After all, the "alleged conduct" was that Shriners placed the nurses under threat of penalty to use the investigational drugs and later punished their refusal.

Let us pause to reflect: Federal judge Carl E. Stewart, writing the majority opinion was confronted with irrefutable, pled allegations, which he is mandated, under law, to accept as true at that stage of the pleading pursuant to Rule 12(b)(6)—that Shriners labored under a congressional and executive mandated federal contract explicitly prohibiting it from pressuring medical staff to inject unlicensed drugs into their bodies or punish such refusal. Judge Stewart proceeded to systematically excise and bury every trace of that evidence from his analysis, sealing it in a tomb. The opinion's glaring silence on the FWA, Common Rule, PREP Act preemption, and CDC Program obligations—despite their centrality to the plaintiffs' claims—betrays not mere oversight, but a deliberate obfuscation, transmuting blatant illegality into judicially sanctioned impunity. This was no impartial adjudication; it was legislative conduct, cloaked in appellate robes, rewriting federal law to shield persons subject to the consent standard from accountability and to lawfully subject Americans to investigational drug use outside of their federally secured right to refuse such products without consequence.

We must remind ourselves that in every lawsuit, there are matters of law and how those laws establish a cause of action. The court did not address the facts leading to a cause of action because it changed the law, establishing unlawful conduct as lawful. Carl Stewart's conduct is a judicial usurpation of powers and represents nothing less than a direct assault on the Republic. Neither Judge Stewart nor the other panel judges could defend their ruling before an honest court. Let me, Brian Ward, make this very clear: Judge Stewart <u>lied</u> to the public when he ruled that Shriners' "alleged conduct" of subjecting the nurses to investigational drug use was not unlawful. That conduct violated Shriners' federal obligations, and it is why Shriners never argued they could engage in such conduct. Therefore, the court made a ruling on a matter of law that no one disputed, except Judge Stewart.

Shriners, acting under FWA00025698, is prohibited from listing the drugs under a mandate and from using the threat of employment termination to coerce nurses into usage. The "alleged conduct" involves a federal scheme applied to 30,000 Federalwide assurance contractors. If Shriners' conduct is not unlawful, as a matter of law, then all FWA contractors under the circuit court's jurisdictional authority can engage in similar conduct. Now, under the Circuit's ruling, investigational drugs subject to FWA obligations are regulated by two competing authorities. First, the Executive Branch states that the conduct is a violation of federal policy. Still, the judicial branch of government exempts such drugs from that policy, which the Executive Branch is bound to comply with by a valid act of Congress under 42 U.S.C. § 289. After all, the federal government owned the drugs until human administration, and they were not the property of Texas or Shriners to list under any vaccination requirement.

Judge Stewart went further, adding facts derived from thin air, stating, "It is commonplace for companies—particularly hospitals—to place such mandates on their employees." He acknowledged that the drugs were not licensed products and that, as a result, "such mandates" meant vaccination requirements relying on unlicensed drugs. Judge Stewart unlawfully inserted these facts into the court record in an attempt to normalize the unlawful behavior and <u>to establish a precedent that "companies" can now introduce unlicensed drugs into commerce via mandates in violation of the FDCA</u>.

Finally, ignoring Shriners' federal obligations not even to list an investigational drug under threat of penalty, the judge stated, "Shriners had no obligation as an employer, as opposed to as a vaccine provider, to give them the option to refuse the vaccine." This is false because Shriners, the organization, surrendered any right to compel the use of such drugs by anyone, regardless of their relationship to the organization, when accepting federal funding—end of story.

Under the Fifth Circuit's edict, American citizens are stripped of their fundamental right to refuse federally funded or authorized investigational drugs—still in clinical trials—without facing reprisal, such as job loss, benefit denial, or worse. This, in brazen defiance of the democratic mandate etched into law under the National Research, which commands legally effective informed consent as the unbreakable bulwark against coerced experimentation. Judge Carl E. Stewart—elevating his robe above the ballot box—did not merely rewrite federal policy in a footnote. He launched a frontal assault on the very sanctity of an individual's vote, vaporizing the hard-won laws born of electoral will and consigning congressional sovereignty to judicial oblivion. In one fell swoop, he proclaimed unelected fiat supreme, rendering elections a hollow ritual and the American people as mere guinea pigs in hospitals' investigational drug mandates.

The Supreme Court received a petition exposing the Fifth Circuit's precedent for what it was: a direct assault on the FDCA, a usurpation of the Secretary's exclusive power to set conditions for unlicensed drugs in emergencies, the FDCA's prohibition on persons introducing drugs into commerce before FDA approval, and a death blow to the FWA program's enforceability. The Justices declined review without a syllable of explanation. In doing so, they ratified a regime under which hospitals may conscript employees into federally funded human research, coerce injection of investigational drugs, and compel surrender of all legal recourse for resulting harm. The entire risk—life, limb, liberty, livelihood—now rests solely on the individual; institutions, like Shriners, bear none. Following the 3rd and 6th circuits' rulings, the Supreme Court continues to allow its lower courts to obliterate entire federal regulatory schemes by judicial fiat.

Secretary Kennedy must now confront a stark question: If Judge Stewart empowers hospitals to introduce unlicensed drugs into commerce through mandates, then what purpose does the FDCA serve, since the entire Act is predicated on the FDA holding exclusive authority to determine when and how a drug is used in commerce? Moreover, what purpose does the EUA statute serve, given that hospitals routinely issue "such mandates" relying on drugs not cleared for commercial distribution outside of any Emergency Use Authorization?

Tenth Circuit — Sweeney v. University of Colorado Health Authority

This case is unique in that it was against UCHA, a political subdivision, and Jill Hunsaker Ryan, the Executive Director of the Colorado Department of Public Health & Environment (CDPHE), as well as all the board members of CDPHE. CDPHE issued a rule mandating that all healthcare workers inject investigational drugs as a legal requirement to work within the state's healthcare industry.

This case turned purely on questions of federal preemption. Could either the state or one of its political subdivisions mandate the use of an investigational drug subject to its FWA agreement? Could it, as a CDC Program provider, deny public employees their federally funded benefit to refuse under the CDC Program? Could it violate the PREP Act's express preemption clause to mandate EUA countermeasures? Could it require public employees to surrender their Fourteenth Amendment due process rights to sue if and when injured by the drugs, conditioned on public employment?

The Court stated that "the PREP Act's preemption clause does not create any right that may be vindicated under § 1983." Let's break this down, because the right to earn a living without having to use a covered countermeasure or forfeit one's Fourteenth Amendment right to sue when injured by such a product is as essential a societal question as can be asked of the Judicial Branch, which the Circuit Court evaded answering.

First, let us look at what Congress actually wrote into the PREP Act:

42 U.S.C. §247d-6d(b)(8):

> 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 chapter, or **under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].**

The PREP Act clearly states that it preempts laws enacted by states that conflict with "any matter included…under the [FDCA]." One such matter is the FCDA's option to refuse an EUA product listed as a covered countermeasure. Colorado could not mandate the use of the covered countermeasure that was issued an EUA because such mandates directly conflict with the citizenry's ability to exercise their option to refuse effectively. This is a purely legal matter that any child can understand, but which the Tenth Circuit absolutely refused to address because if it did, then it could not dismiss the case under Rule 12(b)(6).

The FDCA requires the Secretary to establish conditions ensuring Colorado's healthcare heroes are informed of their option to refuse the administration of the unlicensed products. This requires the Secretary to issue an EUA in the form of a letter[39] to the product's manufacturer, which must comply with the Secretary's "Conditions of Authorization." Under the CDC Program, only persons authorized to act under any COVID-19 EUA were the recruited states and the states' recruited agents who signed the Provider Agreement. The agents contractually promised to execute the Secretary's conditions of authorization under "any EUA." That letter established the mechanism to ensure that the plaintiffs were informed of their lawful authority to choose the option to refuse, as mandated by Congress.

The PREP Act's preemption clause incorporates not only requirements under the EUA Statute, but also any EUA letter as required under the statute. Therefore, the PREP Act expressly preempted defendants from establishing legal requirements conflicting with the Secretary's authorization conditions because those conditions are "requirements applicable to the covered countermeasure," which are under the FDCA.

Therefore, the PREP Act does not directly establish a § 1983 civil rights cause of action, but it most certainly leads to one through its preemption clause. If the state is preempted from mandating the use of a covered countermeasure authorized only under an

[39] https://covidpenalty.com/wp-content/uploads/2024/02/FDA-EUA-August-2021.pdf"

EUA, then a policy mandating such use can only be issued under ultra *vires power*. In the instant action, the ultra vires policy led to the plaintiffs' economic, emotional, and other related injuries. Such conduct is actionable under § 1983. This is factual because the CDC Program provided plaintiffs with federally funded benefits, including, but not limited to, giving their legally effective informed consent, which benefits are subject to the 14th Amendment's due process clause, enforceable as a civil rights violation.

Let's look at what Colorado and UCHA actually mandated. Defendants issued their respective mandates, compelling the plaintiffs—as a condition of public employment—to obtain an investigational drug injection from a federally authorized provider and then falsify their legally effective informed consent to secure a federally funded benefit, solely for the purpose of satisfying the employment requirements of the state and its political subdivisions. This type of conduct is precisely why the federal government established the FWA program—to prevent nonconsensual use of its unlicensed products.

The Circuit Court, joining the Fifth Circuit, absolutely refused to answer the simple question: Is legally effective informed consent a property right subject to the Fourteenth Amendment's Due Process Clause? [40]

The Tenth Circuit cherry-picked stray conversations while sidestepping the dispositive question: Could the defendants lawfully mandate these products under the very conditions they invoked? The panel didn't simply rubber-stamp the lower courts' violation of powers when claiming that rational basis immunizes defendants from liability; it usurped the constitutional authority of Congress and the Executive Branch, denying the defendants any power to mandate the use of federally funded investigational drugs, which they had prospectively contracted not to mandate. This is nothing less than an overthrow of congressional powers by three judges of the Tenth Circuit hand-picked for the dirty deed.

Ninth Circuit — *Curtis v. Inslee*, 24-1869

Let us conclude by examining a recent Ninth Circuit ruling, where the strategy of using Americans as guinea pigs and giving the WHO ultimate authority over American lives becomes clear.

Nearly ninety healthcare workers sued Governor Jay Inslee and PeaceHealth, challenging Governor Inslee's mandate that barred licensed medical facilities from granting access to any licensed worker who refused the investigational drugs distributed through the CDC Program, effectively ending their careers abruptly. The edict was void from inception: expressly preempted by the PREP Act, contractually forbidden by Washington's Federalwide Assurance, constitutionally repugnant for conditioning employment on surrender of due-process remedies, and flatly incompatible with the CDC Provider Agreement and FWA obligations that Inslee knowingly breached. The district court

[40] A petition sits before the Supreme Court discussing this question in detail: https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/25-481.html

dismissed on a fiction—that Pfizer's products were fully FDA-approved—ignoring HHS Secretary Becerra's direct order to Inslee that the available drugs were neither licensed nor approved and must comply with investigational labeling.

The Ninth Circuit then re-engineered the living daylights out of the pleadings beyond recognition: inventing concessions the plaintiffs never made, attributing statements they never uttered, vanishing inconvenient statutes and contracts, and sprinkling uncited "quotations" like a high-school debater wielding air quotes.

The panel held that it was "undisputed that the investigational drug is a COVID-19 vaccine and that the Governor and PeaceHealth believed compulsory vaccination for healthcare workers would protect public health." There are four fatal flaws to this statement:

1. An "investigational vaccine" can have its formulation changed daily and be produced using questionable processes. In contrast, a licensed vaccine is legally approved based on a consistent formulation, manufactured under strict safety protocols to ensure a specific outcome.
2. Congress never authorized governors to mandate federally funded emergency products based on personal belief in efficacy.[41]
3. Such belief does not license misbranding—an FDCA felony under 21 U.S.C. § 352.[42]
4. Federal duties under the FDCA and federal contracts cannot be jettisoned because a state official deems breach good policy.

Undeterred, the court continued: "The absence of a legal indication does not negate the obvious inference that the available COVID-19 vaccine would be rationally related to the protection of public health." This is pure sophistry. The CDC Program, the EUA statute, and the PREP Act were all crafted for catastrophic emergencies—and each rests on one non-negotiable pillar: informed, voluntary consent. The Ninth Circuit cannot allow Governor Inslee to repurpose federal statutes, programs, and funding—expressly designed for emergencies and conditioned on voluntary participation—as a "rational basis" shield for state mandates denying potential recipients their federal benefits. To do so would usurp federal supremacy, breach the terms of federally funded agreements, and unconstitutionally

[41] *The Upjohn Co. v. Finch*, 422 F.2d 944, 954 (6th Cir. 1970), ("[w]e hold that the record of commercial success of the drugs in question, and their widespread acceptance by the medical profession, do not, standing alone, meet the standards of substantial evidence prescribed by 21 U.S.C. § 355(d))."

[42] "Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – i.e., any use not specified in an application and approved by FDA." U.S. Department of Justice, Office of Public Affairs. Justice Department announces largest health care fraud settlement in its history." (September 2, 2009). Pfizer had to pay more than $2 billion in fines for promoting Bextra outside of its legal indication. "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." (21 CFR 312.7(a)). 21 U.S.C. § 352 EXPRESSLY prohibits governors from applying a purpose to an investigational drug.

delegate federal emergency powers to governors. Unless, of course, that is the Circuit's endgame—corrupting the judicial process to achieve it.

The Ninth Circuit declared that the "constitutionality of a vaccine mandate . . . turns on what reasonable legislative and executive decisionmakers could have rationally concluded about whether a vaccine protects the public's health and safety." This is a legal fallacy dressed as doctrine. The true constitutional question is one of authority, not epidemiology. Governor Inslee issued a mandate predicated solely on investigational drugs—federally owned, liability-shielded, and distributed under research protocols in which Washington expressly pledged to the United States that administration would remain voluntary. PeaceHealth and the Governor shattered that covenant.

The mandate's legality hinges not on rational-basis deference to public-health judgments, but on whether a state official may lawfully commandeer federal property, breach federal contracts, and coerce participation in human subjects research. The panel never engaged the question; it rewrote it. Moreover, what was once prosecuted as fraud—breaching federal agreements while pocketing the very funds conditioned on compliance—has been rebranded by the Ninth Circuit as rational governance.

This is the purpose of the Ninth Circuit's ruling; Governor Inslee ordered every medical facility in his state to violate their federal agreements, which should put him in prison for the societal chaos and trauma he put his victims through. Instead, the panel issued a fictitious ruling stating that, under the emergency, Governor Inslee is exempt from his constitutional and federal obligations and can do whatever he believes is right despite the harm his conduct brings to the state's population.

The three-judge panel joined twenty-nine federal judges in a studied silence: none would confront the PREP Act's express preemption clause or answer whether it bars states from imposing legal requirements that obliterate the FDCA's statutory option to refuse an EUA product. The reason is simple—there is only one answer: Congress categorically prohibits states from issuing mandates exclusively relying on EUA countermeasures. Undaunted, the panel declared that plaintiffs "failed to plausibly allege that the state action…was an exercise of arbitrary power rather than…broad discretion required for the protection of public health." When a court deletes line after line of The U.S. Code,[43] which proves the conduct was arbitrary, discretion is easily conjured. The Ninth Circuit's ruling demonstrates that due process is dead because the Circuit Court has appointed itself legislator, executive, and final arbiter—lawmaker and judge in one.

Finally, the Ninth Circuit used *Jacobson v. Massachusetts* (1905) as a procedural device to manipulate Congress out of existence, declaring: "applying Jacobson…we upheld the vaccine policy because it was more than reasonable for the [state actors] to conclude that COVID-19 vaccines would protect the health and safety of [the relevant populations]." This is not deference—it is obliteration. The panel wields a 119-year-old smallpox case to nullify a century of congressional statutes, executive regulations, and federal programs that expressly forbid mandatory use of unlicensed, investigational drugs. The plaintiffs never contested the abstract power to issue vaccination policies; they challenged what may be compelled and under what legal conditions. The courts have answered by ignoring the

[43] The U.S. Code compiles the nation's federal laws.

unmandatable—overriding FDCA safeguards, PREP Act preemption, FWA contracts, and informed-consent mandates—to impose judicial preference at the expense of the Republic, and the reader's rights, safety, and health.

Let us conclude by discussing the rational basis review in light of the CDC Program, which highlights the hypocrisy of the Ninth Circuit. Rational basis review does not apply to ministerial duties. Ministerial duties, by contrast, are non-discretionary obligations that public officials must perform without any authority to deviate from. The Ninth Circuit correctly stated, "[M]inisterial acts are unshielded by qualified immunity, which protects 'only actions taken pursuant to discretionary functions.'" *Groten v. California*, 251 F.3d 844 (9th Cir. 2001).

The ministerial duty—non-discretionary, absolute, and owed to every American by states, their subdivisions, FWA assignees, and CDC Program contractors—was singular: honor your chosen option. Full stop. No coercion to seek religious or medical exemptions as a condition of choosing the option to refuse, and no reprisal for exercising your federally enshrined right to refuse.

The *Groten* case establishes that plaintiffs have a Fourteenth Amendment due process cause of action under the CDC Program, the defendants FWAs, and the legally effective informed consent doctrine.

The *Groten* case involved the Office of Real Estate Appraisers' refusal to permit Groten "to apply for either a temporary license or a reciprocal license" despite meeting the required conditions. The Circuit held that "12 U.S.C. § 3351(a) was intended to benefit plaintiffs such as Groten," despite the statute not directly conferring any benefit on Groten; he was, however, the third-party beneficiary of the statute. Second, the court ruled that "In determining whether a particular provision of a statute creates a federal right enforceable under § 1983, however, we do not confine our consideration to the stated purpose of the Act. Rather, we are required to analyze the particular statutory provisions at issue, to determine whether the three requirements for an enforceable right under § 1983 are satisfied." The court reached the conclusion that the statue was enforceable because "individuals such as Groten are beneficiaries of the federal statute" and that the statute "unambiguously impose [s] binding obligations on the States." The Circuit held that if an applicant demonstrates that he or she meets the three prerequisites listed in § 3351, "the state must issue a temporary license. There is no discretion afforded to the appraiser licensing agency in this section; the federal statute is not merely intended to be hortatory, but places a binding obligation on the Office of Real Estate Appraisers." Finally, the court held that there is a "Fourteenth Amendment right to due process in the application procedure."

The CDC Program vested every American with an unassailable Fourteenth Amendment liberty interest: the sovereign right to select refusal without coercion, reprisal, or bureaucratic hurdles. Governor Jay Inslee held no power to pressure a choice, impose penalties for it, or—most egregiously—demand religious or medical exemptions as a condition of choosing the option to refuse. His obligation was stark and ministerial: accept the individual's decision—the end of the case.

Yet Inslee and PeaceHealth trampled this due process bulwark, inflicting ultra vires harm through mandates on investigational products. Liability should follow as night follows day. Instead, the Ninth Circuit—in a stroke of judicial usurpation of powers—has permanently excised informed consent from the constitutional canon, empowering Inslee to nullify congressional statutes, shatter federal contracts, and eviscerate the bedrock right to bodily autonomy in experimental medicine. What legislative gatekeepers barred at the Capitol's door, banana republic judges now fling wide: coercion by fiat, the Republic's safeguards reduced to judicial chaff.

Groten and Plaintiffs' cases are identical down to the slightest nuance, except that the Groten court permitted discovery of facts and was not bent on overthrowing the Legislative Branch of government.

Summary

Let us review so that we may follow Alice down the rabbit hole and see why the Circuit courts are ruling so abusively.

Over the past fifty years, Congress and the Executive Branch meticulously constructed a regulatory fortress to ensure no American is ever subjected to investigational drugs—or penalized for refusing them. Every state, hospital, and political subdivision signed an FWA contract, binding them to the gold standard of informed, voluntary consent. Congress then enacted the EUA Statute and PREP Act—emergency tools explicitly conditioned on strict voluntary participation, even amid catastrophic threats to life, liberty, or property. The Executive Branch, through the CDC Vaccination Program, mandated that providers allow the public to freely exercise the right to refuse without coercion or pressure. All defendants contractually agreed to these terms in exchange for federal funding, which they eagerly accepted. Yet they breached those ministerial obligations.

When our nation's strongest warriors—healthcare workers, police, firefighters, and teachers—exercised their federally protected right to refuse, defendants punished them by stripping away livelihoods and imposing life-altering penalties. Presenting their cases before 31 federal judges, these judges protected the violators. Instead of respecting federal discovery rules, they dismissed cases on "matters of law," laws that cannot be found in the U.S. Code, but are established by corrupt judges in defiance of the Republic's democratic process.

Let us be crystal clear. 31 federal judges were presented with ironclad evidence:

- Defendants signed federal agreements prohibiting mandates under any policy imposing a penalty. → Not one judge addressed the contract—or permitted its discovery.
- The CDC Vaccination Program guaranteed plaintiffs the funded right to refuse without pressure, fee, or penalty.[44] → Not one judge allowed discovery of this fact.

[44] "[t]he state, having power to deny a privilege altogether, may grant it upon such conditions as it sees fit to impose. But the power of the state in that respect is not unlimited, and one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights. If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United

- Congress and the Executive Branch mandated strict, legally effective informed consent. → Yet four panels under the Fifth, Ninth, and Tenth Circuits set unconstitutional legal precedent that completely nullifies the FWA program and its legally effective informed consent requirement.
- Congress only allows the Secretary to set the expanded access protocol for unlicensed drugs, biologics, and devices. → However, the Third, Fifth, Sixth, Ninth, and Tenth Circuits have elevated states, political subdivisions, and hospital CEOs above federal authority, removing the Secretary's exclusive power, rendering Congress nonfunctional under 42 U.S.C. § 289.

Why these dismissals? The answer is a federal judicial coup d'état against the Republic itself: a calculated subversion that weaponizes economic devastation and the denial of public benefits to coerce mass participation in unlicensed investigational drug trials, while extinguishing any right to sue for ensuing harms—even in cases of forcible, nonconsensual administration (detailed below). Yet the deeper stratagem lies in forging precedent to carve a covert conduit for the World Health Organization to seize de facto dominion over America's sovereign health policies.

The Rabbit Hole:

Washington State Law: RCW 43.70.183

Washington recently enacted Revised Code § 70.41.030(5), which arrogates to the state sweeping authority to "issue a...standing order for any biological product, device, or drug" aimed at "controlling, preventing, mitigating, or treating any infectious or noninfectious disease or threat to public health." In wielding this power, the statute brazenly disclaims any "duty to any person to issue a prescription or standing order pursuant to this section." This means that the state is informing the federal government that it will no longer comply with the Supremacy of the FDCA relating to when, where, and how drugs will be introduced into commerce, irrespective of accepting federal funding to comply with the legally effective informed consent standard.

This enactment marks the vanguard of a pernicious strategy to cede U.S. health sovereignty to the WHO: first, judicially dismantle the federal government's monopoly on determining when, where, and how drugs enter commerce—a feat already accomplished, as chronicled in the prior circuit analyses. Washington's statute flouts 21 U.S.C. § 355(a)'s prohibition on unapproved interstate distribution, yet the Ninth Circuit's rulings in *Curtis* and *Carvalho* sanctify such usurpations. By shielding state violations, these decisions ignite interbranch conflagration, subordinating congressional supremacy to third-party fiat and paving the Republic's path to foreign control.

Under the 3rd, 5th, 6th, 9th, and 10th Circuit Courts, Congress no longer controls when, where, and how drugs enter interstate commerce, nor can it tie its funding to the legally

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States may thus be manipulated out of existence." *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593- 94 (1926).

effective informed consent standard as required by 42 U.S.C. § 289, as enforced by the Executive Branch under the FWA program and 45 C.F.R. § 46.122. The Judicial Branch of government is actively overturning valid acts of Congress and the Executive Branch in violation of its constitutional limitations.

Illinois State Law: HB3637 - 104th General Assembly (2025-2026)

Behold the rabbit hole, laid bare: Illinois has enshrined in law a direct assault on federal drug supremacy. Under Section 25 of the Illinois Pharmacy Practice Act (as amended by HB 3637), "A drug's status as not approved by the U.S. Food and Drug Administration shall not cause it to be deemed a misbranded drug in violation of this Act if it is recommended for use by the World Health Organization."

This is no anomaly—it is the backdoor strategy of the circuit courts' orchestrated gambit. Their rulings dismantle the federal government's exclusive dominion over drug regulation, devolving that power to 50 states, 3,000 counties, and a web of public-private actors ripe for unethical persuasion by bad actors and the WHO. Empowered by judicial fiat, these entities can now issue edicts hinging on WHO recommendations, bypassing FDA gatekeepers and injecting foreign directives into American veins—quite literally—at the peril of the reader's health and that of their family. Fifteen Democratic governors have already mobilized to operationalize this shift, launching the Governors' Public Health Alliance on October 15, 2025, to coordinate multistate responses to health threats amid federal retrenchment, all based on WHO recommendations.

Framed as a response to Secretary Kennedy's actions, it portends a parallel health governance network, primed to amplify WHO guidance over domestic sovereignty. Protected by circuit precedents that greenlight gubernatorial mandates on a mere "rational basis"—a threshold now met by fealty to WHO pronouncements—these actors are judicially protected to engage in medical war against this nation. Beliefs, once tethered to evidence, become a license for coercion.

WARNING: Democratic-led states, municipalities, and licensing boards are primed to tether every professional credential—from medicine and nursing to real estate, construction, and customer service—to compliance with future investigational injections. The Biden era nearly exacted this toll on realtors; unchecked precedent will make it ubiquitous. Mark this into your calendar: unless we win now, compulsory experimental regimens, mandated digital vaccination passports, and blanket immunity from liability for harms inflicted will be the price to pay to earn a livelihood in America, which will soon demand surrender of bodily autonomy—a technocratic yoke forged in judicial shadows, where the WHO's whisper eclipses the cry for American freedom.

(b) Strategy step two: expose Americans refusing consent to experimental drugs under covert conditions.

In 2018, acting under the Cures Act, the FDA published a proposed rule to harmonize its human-subject protections with the revised Common Rule, including a new pathway for IRBs to waive informed consent under narrowly defined conditions (83 FR 5760, Feb. 8, 2018). The FDA explicitly stated that it was not considering a waiver of informed consent

"If the clinical investigation involves using identifiable private information or identifiable biospecimens, the investigation could not practicably be carried out without using such information or biospecimens in an identifiable format." — 83 FR at 5769.

Fast-forward to January 22, 2024. The Biden Administration's FDA published its final rule at 21 C.F.R. § 50.22, titled "IRB waiver or alteration of informed consent for minimal risk clinical investigations." Buried in § 50.22(c)(2) is the exact language the FDA swore it would not adopt. This is not a minor edit. This is a complete reversal of policy—implemented without any prior notice, comment, or explanation in violation of its rulemaking authority.

IPI has always been the bright-line ethical and legal boundary in human subjects research.

- When IPI is present—or could be present (e.g., coded biospecimens, linked datasets, genomic data)—legally effective informed consent is required.
- This principle protected Americans from being enrolled in experimental drug trials without their knowledge or consent.

Now, under § 50.22, sponsors and IRBs can:

- Waive consent entirely;
- Use identifiable data or biospecimens without ever informing the individual;
- Enroll people in research before, during, or after the fact—without disclosure of their participation.

This is not theoretical. This applies to investigational drugs, real-world evidence studies, and secondary use of clinical data. The regulation now permits sponsors of <u>clinical investigations</u> to waive their duty to obtain the reader's effective consent or inform them of their involvement before, during, or after the study.

(1) Clinical investigation "means any experiment that involves a test article and one or more human subjects…" (21 CFR 50.3(c)).

(2) Test article "means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n)." (21 CFR 50.3(j)).

(3) "Drugs" as defined under 21 U.S.C. § 321(g)(1), mean, in part, articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" (*Id.*) and/or "intended to affect the structure or any function of the body of man…" (*Id.*).

(4) Human subject "means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient." (21 CFR 50.3(g))

Due to the extensive explanation required to fully unpack this regulation, the author will limit disclosure here to what the rule now permits, while urging interested parties to review the comprehensive FDA Complaint at CovidPenalty.com for a detailed legal analysis of its implications. The regulation now authorizes, in part, the following, even when IPI or identifiable biospecimens are used:

1. Creation of secret medical research files on Americans, containing clinical, genetic, or behavioral data, created and shared with unknown parties for undisclosed purposes and indefinite durations—potentially triggering civil liability or criminal exposure.
2. Routine collection and genomic sequencing of newborn DNA by hospitals, without parental consent or knowledge of downstream research use.
3. Mass digital identification of schoolchildren, including biometric, behavioral, or health data, for integration into research databases.
4. Exposure of individuals to investigational drugs, biologics, or devices in real-world settings—outside their awareness or consent.
5. Large-scale clinical investigations on "target populations" (i.e., entire communities or demographic groups) without individual notification or opt-out.
6. Non-consensual use of religiously objectionable materials, such as porcine-derived biologics or human fetal tissue, in research involving people of faith.
7. Compelled participation in research labor—data extraction, sample use, or study involvement—without compensation or consent, in violation of 13th Amendment protections against involuntary servitude.
8. Complete concealment of the research, even if participants suffer injury, adverse events, or long-term consequences—denying them the ability to seek recourse.

These are not speculative fears—the FDA's waiver authority explicitly authorizes them in 21 C.F.R. § 50.22(c)(2), the very provision the agency swore in 2018 it would never adopt. When your child walks into school, you have no way of knowing whether the district has quietly partnered with a pharmaceutical sponsor or research institution to conduct clinical investigations on their body, behavior, or biology—collecting biometric data, health records, or even biological samples under a blanket IRB waiver of consent. You are equally in the dark about your own life. Your primary care physician, public employer, local hospital, or even city government could be collaborating on federally regulated research involving your identifiable data or biospecimens—building secret longitudinal files on your health, genetics, or daily activities—without ever informing you, obtaining your consent, or disclosing the purpose, duration, or recipients of that data. This is not oversight. This is systemic, state-sanctioned concealment—enabled by a rule the FDA deliberately hid from public scrutiny.

The FDA specifically stated that if the sponsor of the research believes that the potential participant might not like them, the organization they work for, or the activity, or might not have the understanding of the research activity to make an intelligent decision, then the sponsor can waive the informed consent rights based purely on those unfounded fears.

On July 3, 2025, I filed a federal lawsuit against the FDA and HHS—on behalf of myself and the American public—seeking to vacate 21 C.F.R. § 50.22 as unlawful under the Administrative Procedure Act. For 90 days, U.S. District Judge Thomas Wetherell II (N.D. Fla.) blocked service of process on Secretary Robert F. Kennedy Jr. and the FDA—preventing the defendants from even being notified of the suit. In a ruling that defied both precedent and procedure, Judge Wetherell dismissed the case for lack of standing. His reasoning: because I could not prove I was currently enrolled—or imminently would be—in a secret clinical investigation that no one is required to inform me of my involvement, I had no current case or controversy. This, despite the Supreme Court's clear holding that APA plaintiffs need only show they fall within the "zone of interests" the regulation governs—here, every American subject to non-consensual covert research. The ruling establishes a horrific judicial precedent that a federal agency can deprive Americans of their constitutional rights so long as the agency establishes covert activities, denying the nation any knowledge of their involvement. Thus, the regulation can never come under APA review by the court. Nuts, right?

However, the judge ignored the core claim: Before the FDA can authorize a sponsor to include the reader in a secret clinical investigation, it must assert dominion over their body and data as if they were its private property. The regulation effectively licenses 30,000+ FWA institutions—hospitals, universities, schools, and corporations—to treat Americans as research chattel, subject to experimentation without consent, notice, or recourse. The FDA has claimed your person as a resource that it may allocate to private or public research, without your knowledge, in direct violation of the 13th Amendment. Yet the court refused to confront this constitutional anomaly. Instead, it shielded the defendants from service, then allowed a magistrate judge to conduct merits-based fact-finding and legal argument in a one-sided proceeding—without the defendants ever appearing.

In effect, if you don't take a vaccine, the powers that be will covertly expose you to the same drug because "it is contrary to the best interests" (21 U.S.C. § 355(i)(4)) of the reader to refuse such administration. 31 federal judges in lawsuits that I consulted on now call investigational medical treatments "vaccines" as if there is no distinction between licensed and unlicensed products. However, what we discuss next will take the air out of your lungs when considering it in light of what we just learned.

<u>(c) Strategy step three: deny anyone a right to sue for investigational drug-related injuries to conceal their dangerous societal effects.</u>

What if courts could deny you the right to sue when injured from covert exposure to "investigational vaccines" you never consented to? This is where the judiciary is pushing the nation.

***Justin Sowders v. Summa Health Systems* — OH State Court Summit County**

Justin and Sarah Sowders eagerly chose Summa Hospital in Akron, Ohio, for the birth of their newborn, Willow. Before delivery, Sarah explicitly refused consent for any medications to be administered to the newborn—specifically vitamin K, erythromycin eye ointment, and the hepatitis B vaccine. This refusal was documented in the medical record by Dr. Tamrisia. Despite this clear directive, hospital staff forced erythromycin ointment into Willow's eyes and injected the hepatitis B vaccine within two hours of birth. Less than nine hours later, Willow suffered seizure activity, requiring emergency mechanical ventilation. Eight days after birth, she died.

The Sowders sued Akron Children's Hospital for assault and battery. The hospital moved to dismiss, claiming the Vaccine Injury Compensation Program (VICP)—a federal no-fault system—preempts all state-law claims for vaccine-related injuries. Ohio state court Judge Alison McCarty agreed, ruling: "The VICP is unequivocally clear in stating that no person may bring a civil action for damages arising from a vaccine-related injury or death. There is no question that this case involves a vaccine-related death. According to the plain language of the statute, it matters not what claim is brought by Plaintiffs."

Let's examine the absurdity of the ruling. First, the injury was not "vaccine-related" in the constitutional sense—it was assault and battery. The drug was the weapon, not the cause of immunity. A crime does not become a "vaccine injury" simply because a syringe was used. Second, the Fifth Amendment's Due Process Clause declares: "No person shall be… deprived of life, liberty, or property, without due process of law." (U.S. Const. amend. V). Congress cannot grant absolute immunity to one private party to injure or kill another without consent or accountability. No statute—not even the VICP—can nullify this fundamental protection. This means that Congress cannot enact a law granting absolute immunity to a person assaulting another member of society. Thus, courts cannot use the VICP statute as a procedural device to achieve such an absurd result. The VICP provides compensation, not impunity. It was never intended to shield criminal acts like non-consensual injection. Judge McCarty's ruling legalizes battery—and potentially murder—when a "vaccine" is involved, eviscerating due process and the right to bodily integrity. By dismissing the case, the court did not uphold federal law. It sanctioned state-sponsored violence—and buried Willow's constitutional rights with her.[45]

Jeremiah Hogan, et al., Petitioners v. Lincoln Medical Partners*, et al. *No. 24-1242

The U.S. Supreme Court now holds a petition for *certiorari* challenging a Maine Supreme Judicial Court ruling that shields healthcare providers from state-law assault and

[45] In *Shelley v. Kraemer*, 334 U.S. 1, 13 (1948), the Supreme Court held that when a state court enforces a private agreement that denies individuals equal protection of the laws, such judicial enforcement constitutes state action—transforming otherwise private conduct into government action subject to constitutional scrutiny. This principle extends beyond racial covenants as discussed in *Shelley*: any state court order that enforces private conduct violating fundamental rights—including due process or bodily integrity—triggers state action under the Fourteenth Amendment. Such rulings are therefore challengeable via 42 U.S.C. § 1983 as deprivations under color of law. In the Sowders case, Judge McCarty's dismissal did not merely interpret the VICP—it enforced the hospital's non-consensual injection by shielding the assailants from liability. This transformed a private battery into state-sanctioned deprivation of life—state action in its purest form.

battery claims after forcibly injecting a child with a PREP Act countermeasure—against explicit parental refusal. In a masterclass of judicial misdirection, the Maine court reasoned:

> "The provider's failure to obtain parental consent in this individual instance does not make the administered vaccine—approved for emergency use under § 360bbb-3—any less of a covered countermeasure under § 247d-6d(i)(1)(C)."

This is deceptive implicature—a sleight-of-hand that dodges the real issue. No one disputed the product's status as a countermeasure. The question was: Does the PREP Act immunize the act of nonconsensual injection? Congress answered: No. As previously discussed, the Act's express preemption clause protects an individual's right to refuse EUA products (§ 247d-6d(a)(8)). Under the PREP Act, the U.S. Congress expressly denies Maine any authority to establish a legal requirement mandating the use of EUA countermeasures, and the state cannot enforce involuntary injections as a means to circumvent that preemption. End of story.

Let me put it in as plain language as possible. No lawmaker in Congress, and no state government, has the power to enact laws denying you your fundamental right to sue someone who injures you through force or covert activities. That's straight from the Fifth and Fourteenth Amendments, which promise "due process"—fair treatment under the law, regardless of the type of injury and who injures you. That is DUE PROCESS.

Willow's parents specifically refused certain business services from the hospital, believing those services and products could injure the child, which they did. The Fourteenth Amendment prohibits the state court from denying the Sowders' use of its tort laws to seek justice for the unwanted assault and battery, and the court cannot allow the hospital to hide behind the VICP to avoid liability because Congress cannot grant such immunity under the statute. EVER! The same holds for the *Hogan* case as it relates to the PREP Act.

The following courts have held that the PREP Act shields persons committing assault and battery from liability, effectively ruling that Congress can nullify the Constitution's Due Process Clause: (1) *Dario Politella and Shujen Politella v. Windham Southeast School District et al.* Vermont Supreme Court, ("We conclude that when the federal PREP Act immunizes a defendant, the PREP Act bars all state-law claims against that defendant as a matter of law." The court added activities Congress did not preempt as an immunized activity, (2) *Happel v. Guilford Cnty. Bd. of Educ.*, 899 S.E.2d 387, 392 (N.C. Ct. App. 2024), (3) *Parker v. St. Lawrence Cnty. Pub. Health Dep't.*, 954 N.Y.S.2d 259, 262 (App. Div. 2012), (4) *M.T. ex rel. M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1074 (Kan. Ct. App. 2023)(" the PREP Act's immunity provision to apply to all claims based on the administration of a covered countermeasure, including those without parental consent.), (5) Cowen v. Walgreen Co., (N.D. Okla. Sept. 13, 2022), (6) Parker, 954 N.Y.S.2d at 260, New York Supreme Court, Appellate Division, (7) Solomon, 62 F.4th at 60; Maglioli v. All. HC Holdings LLC, 16 F.4th 393, 406-13 (3d Cir. 2021), (8) *Mitchell v. Advanced HCS, LLC*, 28 F.4th 580, 584-88 (5th Cir. 2022), (9) *Cagle v. NHC Healthcare-Maryland Heights, LLC,* 78 F.4th 1061, 1065-67 (8th Cir. 2023).

The Supreme Court holds that "what the state may not do directly it may not do indirectly." (*Bailey v. Alabama, 219 U.S. 219 (1911)).* The Maine Supreme Court may not use federal laws as a means to achieve indirectly what it could never command directly.

Now, let us circle back to a chilling facet of this erosion: the FDA's delegation of authority to over 30,000 FWA agents—hospitals, universities, research firms—empowering them to unilaterally waive legally effective informed consent when enrolling unwitting Americans in their profit-driven activities. Envision the reader, or a loved one, secretly exposed to a so-called "vaccine" or PREP Act countermeasure amid a clinical investigation: no disclosure, no choice, no recourse. The appellate courts, through their mounting precedents, are forging a shield of immunity for such acts, insulating perpetrators from any civil liability.

This is indistinguishable from the documented horrors in Willow, where a hospital covertly injected an infant with an experimental biologic while her parents were absent, or the Lincoln Hospital case, where a public school student was subjected to a countermeasure without parental knowledge or consent. These cases are harbingers of things to come. I issue this solemn warning to the nation: Absent an immediate, resolute reclamation of our sovereignty from this judicial theft, due process—the lifeblood of American liberty—will fade into the history books. Today, it only requires making our voices heard on Capitol Hill; tomorrow, it would take a monumental effort to reclaim.

<u>H.G. Wells has nothing on whoever is writing this script.</u>

Conclusion:

The good news is that we possess all the tools required to end this crisis swiftly and permanently.

1. The FDA's "research rule" (21 C.F.R. § 50.22) was issued unlawfully. President Trump can strike it down with a single Executive Order.
2. A pivotal petition awaits Supreme Court review (*Jennifer Bridges, et al. v. The Methodist Hospital*, Dkt. No. 25-481). This case is identical in nature to the Shriners' case that the Fifth Circuit dismissed. However, the Fifth Circuit in the *Houston* case literally rewrote the Plaintiffs' counts to conceal their allegations from the Supreme Court fully. Through the U.S. Solicitor General, President Trump can correct the lower courts' errors and restore federal supremacy, thereby restoring the right of the American people to refuse unwanted investigational drugs across the board.
3. We can prevent future parents from suffering the heartbreak of having their child injected with drugs without their consent, which can and will lead to death, by Trump directing the Justice Department to intervene in the *Sowders* case and having the Solicitor General step in the *Hogan* case to correct the Maine Supreme Court's significant constitutional error.
4. The President can direct the Department of Justice to intervene in every pending case against Governors Newsom, Inslee, Brown, Mayor Bass, and others—given the grave threats to federal authority and the public's loss of trust in the federal judiciary. This author can provide a list.

5. Robert F. Kennedy Jr. can launch debarment proceedings against the violators:
    - 2 C.F.R. § 180.800(b)(1): "Violation of the terms of a public agreement or transaction so serious as to affect the integrity of a Federal agency program, such as willful failure to perform in accordance with the terms of one or more public agreements or transactions."
    - 2 C.F.R. § 180.800(d): "Any other cause that is so serious or compelling in nature that it affects your present responsibility" to protect the Federal Government's interest.

This is not a wish list. It is a roadmap to reclaim federal law, protect consent, and hold those accountable who are guilty. Importantly, it restores public trust, federal authority, and America's right to refuse investigational treatments without consequence or loss of benefits.

To that end, a member of Congress should propose:

(1) adding a new subsection (i) to 42 U.S.C. § 289 (ex. § 289(i)), declaring:

(a) Any person who subjects another, under pressure or threat of penalty, to a drug, biologic, or device, not licensed within the meaning of 21 U.S.C. § 355, violates that individual's federally protected right to legally effective informed consent. This subsection confers a private federal civil right of action upon the affected individual for all resulting injuries, with a three-year statute of limitations.

(b) No federal agency, department, or employee may covertly subject any person to an investigational drug, biologic, or device without obtaining their legally effective informed consent. This subsection confers a private federal civil right of action upon the affected individual, for all resulting injuries, against any federal employee who violates that right, with a three-year statute of limitations.

(c) Any State that accepts federal funding for activities involving the administration or use of drugs, biologics, or devices that are not licensed by the Food and Drug Administration (FDA) in accordance with the product's approved labeling shall be deemed to have waived its sovereign immunity under the Eleventh Amendment to the United States Constitution with respect to any civil action brought by a resident of that State arising from a violation of such individual's right to legally effective informed consent.

(2) adding a new subsection (b) to 10 U.S.C. § 1107 (ex. § 1107(b)), declaring:

The Secretary of Defense shall establish and maintain a public list of all drugs, biologics, or devices subject to any mandatory requirement of the Department of Defense. For each entry, the list must include written, authenticated signatures from: The Secretary of Defense, Surgeon General of the Army, and the Judge Advocate Generals for the Navy, Army, Air Force, Marines, and Coast Guard—certifying that the mandated product:

- Is licensed by the FDA for general commercial marketing, in accordance with its FDA-approved labeling, and is not subject to an Emergency Use Authorization, DoDI

6200.02, 10 U.S.C. § 1107 or § 1107a, or designation as a covered countermeasure under the PREP Act.

- The list must be renewed on January 30th of each calendar year.

Finally:

I must admit that I lack the heart to understand evil. I see it, I cannot understand those who partner with it. It destroys everything, brings no joy, finds no rest, enjoys no true pleasure, and is never satisfied. For over three years, I have fought against such evil alongside some of the most patriotic and loving lawyers in the nation, on behalf of hundreds of surgeons, doctors, nurses, firefighters, police officers, teachers, EMTs, and every frontline hero who stands between us and chaos. I have forgone lucrative contracts that have left me financially in pain and watched my children grow up for the past few years with a part-time father.

I now understand the depth of judicial corruption: without President Trump's direct intervention—raising his voice and dismantling the hidden forces eroding our nation—these dedicated public servants have no realistic path to justice. If President Trump and Secretary Kennedy fail to act, Americans will become mere guinea pigs, bereft of any protection or due process right to seek remedy from injury. The American public will face an impossible choice: economic survival or life-altering medical risk. Parents will send their children to school each day, wondering if they are unwitting subjects in a clinical trial. The elderly, the poor, and the underinformed—precisely those Senator Edward Kennedy fought to protect—will once again become pawns in a biomedical system that prioritizes experimentation over consent.

This is not the America we were promised. These conditions are not merely flawed; they are tyrannical, incompatible with a free society. At its core, this crisis enables foreign influence over our health sovereignty. Recent circuit court rulings have opened a dangerous judicial loophole, paving the way for that control to take hold. We are 90 days from victory or defeat. The outcome now rests with the Supreme Court and decisive Executive Branch action.

However, We the People should demand that the Supreme Court answer: Is due process dead? Does the judicial branch have the authority to nullify federal programs, amend federal law, and deprive America of her due process rights? Is legally effective informed consent a suggestion or a command? Can Congress grant absolute immunity to one member of society injuring another under involuntary conditions? Can a federal agency claim us as its private property and use us as a lab experiment for the benefit of corporations?

I know for certain that not a single Democrat, Republican, liberal, conservative, Jew, Gentile, Muslim, atheist, mother, father, daughter, or son agrees with what the federal judiciary is doing when presented with the facts in this document. My experience has taught me that when Americans discover these facts, their only response is one of outrage.

Brian Ward — CovidPenalty.Com — November 2025