Thursday, June 6, 2024

Brian Ward — PREP Act Argument

Subject: Mandatory Participation in the PREP Act and EUA Statute[1] Violates the Federal Court's Unconstitutional Conditions Doctrine (UCD)[2]

"The doctrine of unconstitutional conditions posits that if the government is prohibited from directly limiting the exercise of constitutional rights in a given situation, the government may not achieve the same result indirectly by offering benefits subject to the condition that the recipients waive their constitutional rights."[3] — Edward J. Fuhr

The PREP Act (42 U.S.C. § 247d-6d) program is primarily an immunity statute shielding "covered persons" from liability for injuries they cause to others under the program. However, the byproduct of that immunity is a loss of Due Process rights[4] of the injured person when participation in the program is mandatory.

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[1] 21 U.S.C. §360bbb-3

[2] The first SCOTUS case to use the phrase "unconstitutional condition" comes from Doyle v. Continental Insurance Company, 94 U.S. 535 (1876), stating, "Though a state may have the power, if it sees fit to subject its citizens to the inconvenience, of prohibiting all foreign corporations from transacting business within its jurisdiction, it has no power to impose **unconstitutional conditions** upon their doing so."

[3] 'The Doctrine of Unconstitutional Conditions and the First Amendment' Case Western Law Review (1989)

[4] I.e., forfeiture of one's liberty interest to sue for damages resulting from an injury involving a "covered" "countermeasure," "person," or activity and the loss of the individual's statutory entitlement to free consent under the FDCA if involving an EUA product.

An individual has a substantial liberty interest in their statutory entitlements[5] to sue another person who deprives them of life, liberty, or property. The right to constitutional protections, statutory entitlements, and other property interests is a fundamental liberty interest under the Fifth and Fourteenth Amendments Due Process Clause. Moreover, the Due Process Clause is the quintessential underpinning of our federal and state constitutions, and the forfeiture of an individual's right to their property cannot result from a legislative or executive act. It can only result from an individual's free consent[6] surrendering the constitutional protection.

A government could not enact legislation granting immunity for certain products/ activities/persons while concurrently requiring individuals to participate under that legal environment without violating the individual's constitutional protections.

Therefore, a government may not use the PREP Act as a "procedural device" to "produce a result which the State could not command directly"[7] by mandating participation in the PREP Act as the means to deprive the individual of their federal constitutional protections. For example, Pfizer explicitly informed the federal government that it would not distribute its COVID-19 drug technology into commerce outside of the PREP Act.[8] The federal government agreed to keep Pfizer's products under the PREP Act, granting it absolute immunity from injuries

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[5] "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it," and "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." *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972)

[6] Free consent means the right to choose free from outside pressure.

[7] Perry v. Sindermann, 408 U.S. 593 (1972) quoting Speiser v. Randall, 357 U.S. 513 (1958)

[8] https://covidpenalty.com/wp-content/uploads/2024/02/DoD-funding-of-Pfizer-drugs.pdf (See, 11.1)

its products caused. Therefore, a government cannot compel an individual to inject Pfizer's technology into their body as a condition of enjoying a benefit of the state while concurrently depriving the individual of their liberty interest to sue Pfizer or a person administering Pfizer's technology without violating the individual's Due Process rights.

The same applies to any "covered person" under the PREP Act involving any "covered" product or activity.

To ensure an individual's liberty interests are protected, Congress established a legal requirement of the HHS Secretary that it "shall ensure" that "potential participants are educated with respect to the…voluntary nature of the program…"(42 U.S.C. § 247d-6e(c)). It is "voluntary" because the PREP Act is essentially a contractual agreement an individual must agree to enter into, requiring them to voluntarily surrender their right to sue the "covered person" immunized by the Act.

Congress further protected individuals involved in the federal program by expressly preempting authorities from interfering in its goals for the emergency program, stating:

> During the effective period of a declaration under subsection (b)…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…administration…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**." (42 USC 247d-6d(b)(8)) ("FDCA")[9] (emphasis added).

Therefore, a government that "establishes" or "continue[s] in effect with" a "law or legal requirement" that is "different from, or is in conflict with" the "voluntary nature" of the program

[9] 21 U.S.C. § 301 *et. seq*.

is violating the statute's express preemption doctrine and are acting outside the scope of their authority when issuing mandatory participation. Moreover, the PREP Act expressly preempts authorities from establishing or continuing in effect with any legal requirement that voids the options to accept or refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) because that section of the law is a "requirement applicable" **under the FDCA**.

The statute requires "voluntary" conditions at all times. What courts have not discussed is why the PREP Act requires voluntary conditions. It is because an individual is stripped of their liberty interest to sue a person that causes them injury as a condition of participation, and such requirement, when mandated, violates the court's "unconstitutional conditions doctrine" (UCD).

As an example, when President Biden issued a mandate for CMS workers to inject a PREP Act product into their bodies, he established an UCD by requiring the workers to involuntarily surrender their liberty interest to sue "covered persons" for damages (i.e., due process) and their option to refuse under the FDCA as a condition of enjoying a government benefit (i.e., employment in a CMS accredited facility). That fact was not argued in any court leading to the Supreme Court's decision in Biden v. Missouri, 595 U.S. ___ (2022). Moreover, President Biden is currently using the PREP Act as a "procedural device" to accomplish what he cannot "command directly" by requiring green card applicants to participate in a PREP Act product/activity involuntarily. The same UCD is true for states/municipalities/public entities issuing mandatory injections of "covered countermeasures" for school children, public sports programs, National Guard promotions, and nursing programs.

Private Entities

A private employer cannot cite a constitution, statute, regulation, or other lawful authority providing them the right to use a state's at-will employment doctrine to terminate an individual's employment, refusing to surrender their right to sue "covered persons" under the PREP Act by not injecting a PREP Act immunized drug (i.e., Pfizer-BioNTech COVID-19 Vaccine, seasonal flu shot) into their body. The state's at-will employment law is **completely preempted** when used solely to interfere in the "voluntary nature" of the program. Therefore, a private employer terminating an employee from employment for refusing to "volunteer" to participate in a PREP Act countermeasure unlawfully terminated the employee irrespective of the state's at-will employment doctrine. Moreover, it is of the highest public policy exception to the at-will employment doctrine that a person cannot be compelled to do what Congress expressly gives them the right to do—refuse to volunteer and surrender their due process rights. However, even in states without a public policy exception, the express preemption language under the PREP Act completely preempted the state's at-will employment doctrine when used to interfere with the free consent of the individual.

EUA Statute under the PREP Act

The PREP Act expressly preempts authorities from establishing or continuing in effect with any law interfering with any requirement under the FDCA, including the option to accept or refuse an EUA drug when that drug is listed as a countermeasure under the PREP Act.

Congress was explicit that although it empowered the HHS Secretary with the authority to introduce drugs, biologics, and devices not licensed for their intended use[10] into commerce

[10] 21 U.S.C. § 355(a) restricts a drug from being introduced into commerce before it is licensed for its intended use. Therefore, 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) is a statutory entitlement (property interest) held by an individual considering participation in the product's administration. The right to be informed of the risks/benefits/alternatives and of the right to accept or refuse is also a "statutory entitlement" (i.e., property interest) under the EUA Statute.

through the EUA Statute, not even the Secretary has "any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section,"[11] and the Secretary's authority is nondelegable. Therefore, how can a government require that which Congress expressly prohibits—nonconsensual participation?

Moreover, the emergency use authorization protocols under 21 U.S.C. §360bbb *et seq.* are a field completely dominated by the federal government pursuant to congressional acts preempting authorities from interfering in the federal laws regulating the statute.[12] The option to accept or refuse the medical countermeasure authorized under the EUA Statute belongs exclusively to the individual considering participation and not to a third party disagreeing with the individual's free consent.

Governments agreeing to use "covered countermeasures" under the PREP Act or "medical countermeasures" under the EUA Statute have a ministerial duty to accept an individual's chosen option whether to volunteer for the product/activity. The authorities are expressly preempted from acting under *ultra vires* discretionary authority to amend the conditions established by valid acts of Congress of the lawful use of the products/programs by voiding the option to refuse and or applying a penalty to either option.

Fundamental Liberty Interest to Refuse an Investigational New Drug

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[11] 21 U.S.C. §360bbb-3(l)

[12] *Arizona v. United States*, 567 U.S. 387, 399 (2012) ("[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.'") (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947))

Drugs, biologics, and devices authorized for use under the EUA Statute cannot be licensed with a legal indication for the intended emergency use (21 U.S.C. §§360bbb-3(2)(a),(c)(3)). All COVID-19 EUA drugs are FDA-classified as investigational new drugs (IND),[13] meaning they do not have a legal indication to prevent the transmission or effects of the Coronavirus listed under a vaccination requirement, demonstrating that the vaccination requirement is arbitrary in nature.

The Supreme Court established a two-pronged approach[14] to analyzing a substantive due process claim. First, the Due Process Clause protects fundamental rights and liberties "deeply rooted" in this nation's history and tradition (*Moore* v. *East Cleveland,* 431 U. S. 494, (1977)). Second, the Court requires a "careful description" of the asserted fundamental liberty interest (*Reno* v. *Flores,* 507 U. S. 292 (1993)).

Individuals have a fundamental liberty interest to refuse an IND without consequence because the drug does not have a legal indication for safety, efficacy, or treatment of any known disease.

Regarding being deeply rooted, starting in 1938 (the FDC Act), the federal government prohibited drugs from being introduced into commerce before the FDA approved them for general marketing according to their labeling (21 U.S.C. § 355(a)). In 1974, Congress passed the

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[13] The Secretary issued expanded access protocols for COVID-19 drugs by issuing an emergency use authorization ("EUA") for the (1) Pfizer-BioNTech COVID-19 Vaccine on December 11, 2020, stating that "Pfizer-BioNTech COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication," (2) "Moderna COVID-19 Vaccine" on December 18, 2020 stating that "Moderna COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication," and (3) "Janssen COVID-19 Vaccine" on February 27, 2021, Inc., stating that "Janssen COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication."

[14] *Washington v. Glucksberg*, 521 U.S. 702 (1997)

National Research Act[15] requiring an institutional review board to monitor research activities involving humans with unapproved therapeutics (i.e., INDs) and devices. In 1978, the Belmont Report was published and formed the basis of the Common Rule (45 C.F.R. Part 46). In 1992, the U.S. Senate ratified Article VII of the ICCPR Treaty, requiring the free consent of any individual involved in an investigational product/process/procedure. In 2001, the federal government required all persons conducting business with its agencies, departments, or the military to have an FWA on file before they use federal funding when involving humans with investigational medical products. The HHS monitors more than 30,000 active FWAs nationwide.

Congress places strict requirements upon persons relating to investigational drugs under 21 U.S.C. § 321, 331, 351, 352, 355 360bbb, and 371; 42 U.S.C. 262; 10 U.S.C. § 1107; 45 C.F.R. Part 46; 21 C.F.R. §§ 50,56; 10 U.S.C. § 980; 21 C.F.R. § 312; and the Belmont Report. The primary requirement of these statutes, agreements, and treaties is that a person offering an investigational product must ensure that the potential recipient is never under outside pressure to participate, such as "sanctions," "coercion," "undue influence," and "unjustifiable pressures." The right to refuse an investigational drug is a fundamental liberty interest that is pervasive, historical, and deeply rooted in the $600b pharmaceutical research industry and this nation.

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[15] Congress enacted The National Research Act ("NRA") in 1974 to prevent medical research abuses by the executive branch, military, and persons acting on behalf of the federal government. The NRA required the Secretary to promulgate 45 C.F.R. Part 46 to protect persons involved in investigational new drugs under research conditions. "Research" under the legal framework is not a clinical trial but an activity "designed to develop or contribute to generalizable knowledge" about the product, theory, process, etc. As an example, college students studying medical charts is "research" or the EUA statute requiring the "manufacturer," "emergency response stakeholder," and "vaccination provider" to "monitor" and "report" adverse events of the drugs' involvement with a human is research because the requirement is "designed to develop or contribute to generalizable knowledge." The Belmont Report, required by the NRA, established the principles of informed consent and is required adherence under 45 C.F.R. Part 46 (§§ 101(c),(i)) of the federal government, its agencies, departments, and the military.

All U.S. States, Territories, and Counties have a FWA agreement on file with the federal government, assuring the government that it will never place an individual under outside pressure (e.g., sanctions, coercion, mandates, unjustifiable pressures, etc.) to participate in the administration of an investigational drug, biologic, or device funded by or under the federal government's authority. Moreover, all federal agencies, departments, and the military must comply with 45 C.F.R. Part 46 and the Belmont Report anytime they involve an individual with an investigational medical product/procedure.

When President Biden required military members to participate in the Pfizer-BioNTech COVID-19 Vaccine[16] or other EUA drug, he violated his ministerial duty to obtain those members' "legally effective informed consent" as required under 45 C.F.R. § 46.116, the Belmont Report,[17] 10 U.S.C. § 1107(a), 10 U.S.C. § 980, and DoDI 6200.02. Factually, President Biden, SECDEF Lloyd Austin, and six other civilian-appointed members committed an arrestable offense when penalizing service members exercising their lawful authority to refuse a drug, biologic, or device authorized only under an EUA. Worse, SECDEF Austin allowed his subordinates to usurp from the Commander in Chief his authority to issue a waiver of informed consent as required by law regarding the EUA drugs. This means those commanders willfully violated legal requirements established by valid acts of the U.S. Congress when waiving the

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[16] The FDA improperly allowed Pfizer to include the word "Vaccine" within its investigational formal name to give the appearance that the drug was classified as a vaccine. The capital "V" denotes the formal name for Pfizer's unlicensed investigational drug "Pfizer-BioNTech COVID-19 Vaccine." "Pfizer-BioNTech COVID-19 vaccine" (lowercase v) denotes Pfizer's COVID-19 vaccine technology and is not attributed to any specific drug label. COMIRNATY® is the only Pfizer COVID-19 drug licensed by the FDA for general commercial marketing. Pfizer-BioNTech COVID-19 Vaccine is under investigational new drug application 19736.

[17] All COVID-19 EUA drugs are currently funded and owned by the federal government requiring it and persons acting on its behalf to comply with 45 C.F.R. § 46.116 and the Belmont Report. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.– Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979. See Part C "voluntariness"

informed consent rights of service members outside Presidential authority when the commanders penalized members refusing the administration of an EUA drug.

Legally effective informed consent requires the individual to be in a legally effective environment when offered participation in a federally funded investigational product/process/ procedure. That environment must ensure the individual is not under "coercion," "undue influence," "unjustifiable pressures," or a sanction.

Suppose an individual is offered the product under mandatory conditions. Under that scenario, the government did not obtain the individual's legally effective informed consent, even if the individual consented to use the product, because the individual was under threat of penalty when the offer to participate was presented.

Suppose an individual is offered the product under mandatory conditions and refuses participation. Under that scenario, the government did not obtain the individual's legally effective informed consent when the penalty was issued or enforced, even though the individual exercised their option to refuse. This is because their refusal was penalized.

Legally effective informed consent restricts mandatory participation at all times and without exception. A mandatory policy violates the informed consent doctrine because it threatens the individual with a penalty for refusing. HHS has routinely stated that informed consent must be prospective and legally effective.

A state, pharmacy, school, or hospital agreeing to administer the EUA COVID-19 drugs is acting on behalf of the federal government because the federal government owns, funds, and or authorizes their use. Therefore, the person acting on the government's behalf must adhere to the same congressional restraints as the Executive branch because the Executive branch cannot

delegate the function of administering its program without delegating its statutory and constitutional obligations.

However, suppose the federal government did not fund the drugs. In that case, all governments are still under a ministerial duty to accept an individual's chosen option under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) when involving the individual with the EUA products via a mandatory policy. Therefore, a Policy issuing a penalty to those refusing the EUA product's administration automatically and unlawfully amends the FDCA by voiding the duty to accept an individual's choice.

PREP Act and EUA Statute's Legal Impact on the End User

An individual under threat of penalty to participate in a medical countermeasure under the EUA Statute and concurrently immunized under the PREP Act means the individual must (1) forfeit civil litigation rights (due process) resulting from injuries,[18] (2) allow their private identifiable information to be collected and used for a variety of purposes by unknown persons;[19] (3) allow their use of the EUA drug to be cataloged by various persons for unknown purposes, (4) allow any of their adverse event data to be utilized by researchers for unknown purposes and eternity,[20] (5) agree to be monitored for eternity for adverse events, and (5) assume greater risks

[18] PREP Act forfeits all civil actions for damages in most situations.

[19] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to obtain private identifiable information.

[20] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to monitor, report and study a variety of adverse reactions to EUA products.

to their safety, health, and legal rights[21] as a condition to enjoy a benefit of the state, which fact violates the UCD.

Therefore, a mandate to participate in both statutes requires an individual to surrender the fundamental liberty interest (1) to sue a covered person, (2) to maintain their privacy, and (3) of their statutory entitlements (i.e., the option to volunteer for a PREP Act product/activity, and the option to accept or refuse under the EUA Statute) without being afforded a procedural due process in violation of the individual's due process rights.

Equal Protection

Under the statutes, a mandate to participate in an authorized product/activity violates the "class of one" equal protection doctrine.[22] The "class of one" (e.g., green card applicants, healthcare workers, students, etc.) is individuals considering participating in the authorized product/activity. Therefore, the government is using the statute as a "procedural device" to mandate by ultra vires authority that which it could not "command directly" by legislative or judicial acts when discriminating against one of the two legally protected options. Simply because the person in power disagrees with the class of one's chosen option does not confer legal authority to the government to discriminate against the chosen option. Under that scenario, a person could be penalized for accepting or refusing, leading to a damned-if-you-do and damned-

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[21] 21 U.S.C. §360bbb-3 requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk as defined in 21 CFR 50.3(k).

[22] "[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., supra,* at 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)

if-you-do-not society. Most certainly, it has already led to a second-class citizenry of those who did not.

Arbitrary and Capricious

No mRNA manufacturer claims that their product will innoculate a person from acquiring any COVID-19 variant or the seasonal flu or preventing their effects. For example, Pfizer's drug fact insert sheet states that "COMIRNATY may not protect all people who receive the vaccine," which means it could protect no one ("all people" is very descriptive). Additionally, no drug manufacturer has demonstrated any long-term (more than six months - at last review) risks/ benefits of their products via a clinical trial.

At the last review, VAERS tracked 94 drugs, of which three mRNA drugs accounted for more than 45% of all adverse events and deaths. Therefore, the risks/benefit analysis does not warrant the use of the product.

Under the EUA Statute, the Secretary is restricted from requiring mandatory participation. Therefore, other governments are also prohibited from mandating nonconsensual participation, demonstrating a mandate's arbitrary and *ultra vire*s nature.

Due Process

A government may not deprive individuals of their life, liberty, or property without due process of law. A drug technology reporting tens of thousands of deaths and hundreds of thousands of injuries is guaranteed to deprive an individual of their life, liberty, and property. When a government mandates participation in a product with a known history of depriving an individual of their life, liberty, and property, the government must provide the individual with

procedural due process before requiring them to play Russian roulette with their lives. NO COURT has been presented with such a simple fact and horrifying truth, nor has it been required to answer whether a government can require an individual to use a syringe to play Russian roulette with their property interest and not violate the Due Process Clause. In effect, a government's mandate is either using the intended but unlicensed indication of an EUA drug or the licensed indication of COMIRNATY and SPIKEVAX as justification to deprive an individual of their life/liberty/property by not taking into account the known and dangerous history of the drugs when issuing mandatory participation.

One mRNA drug has more than one-trillion potential contraindications involving more than 19,000 FDA-licensed drugs, hundreds of diseases, and their combinations that have not been researched by the manufacturer, state, federal agency, or the person issuing the mandate.

Neither the person issuing the mandate nor the manufacturers of the products under the mandate could promise that the product would not lead to a life-altering injury. Therefore, if no one can promise that a person's liberty interest will not be deprived and proof exists that such a risk is likely, then a mandate using such a product must come under the protection of the Due Process Clause.

Unconstitutional Conditions Doctrine

"A man may not barter away his life or his freedom, or his substantial rights"[23] because the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interest."[24] "[T]he state, having power to deny a privilege altogether, may grant it upon

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[23] *Home Ins. Co. of New York v. Morse*, 87 U.S. 455, 451 (1874)

[24] Perry v. Sindermann, 408 U.S. 593 (1972)

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 States may thus be manipulated out of existence."[25]

Therefore, a policy requiring participation in a drug, biologic, or device immunized under the PREP Act or authorized under emergency use authorization (EUA) or emergency use instructions (EUI) is unconstitutional, unlawful, arbitrary, ultra vires, and violates the UCD when such requirement is a condition of enjoying a benefit of the federal, state, or a local government.

Current Drug Status

Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, Novavax, and Janssen COVID-19 Vaccine are under EUA for various ages and indications.

Comirnaty and Spikevax are licensed for general commercial marketing with a legal indication for specific ages and as boosters, but they are not always available.

Comirnaty, Moderna, and Novavax have EUIs for specific indications - https://www.cdc.gov/vaccines/covid-19/eui/index.html

There are **only** EUA COVID-19 drugs available to persons medically immunocompromised.

There are **only** EUA COVID-19 drugs available to persons 11 years of age and younger.

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[25] *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926)

Because the CDC obscures the legal status of each drug, it is challenging to ascertain which indication is under what legal environment. It is believed that all first-time uses of any COVID-19 drug are under EUI, and the licensed versions of Comirnaty and Spikevax are for boosters only. A lawsuit against the CDC might be the only means to obtain an unambiguous document of what drug is classified for what indication and under what authorization. However, all drugs are under the PREP Act without exception.

Novavax and Sanofi entered a licensing agreement to produce a combined COVID-19/flu shot for the fall of 2024. Governments will use this drug to bypass a person's religious exemption claim.

Novavax received FDA approval to use its shot this autumn as a booster for those who cannot take an mRNA shot. Governments will use this drug to bypass medical exemptions.

The need to establish a judicial precedent for the American people's right to refuse a drug only introduced into commerce under the PREP Act is paramount to their safety, health, and legal rights. These drugs would not enter the arm of a single person if the manufacturers were not provided absolute immunity from the injuries they cause.

Finally, the author's opinion is that a company mandating the use of a PREP Act product is never immune from liability by the PREP Act for damages its mandate causes. The PREP Act expressly preempts any person from interfering in the program's voluntary nature. Therefore, the PREP Act cannot cover the mandate when the statute expressly preempts such activity.

Two Federal Court Cases

A student in North Carolina was given a COVID-19 EUA shot against his free consent because the student succumbed to coercion, demonstrating that the student had not reached the age of assent (45 CFR 46.402(b)). The state court ruled that the school was protected by the PREP Act. The ruling cannot reconcile with federal law and the federal constitution. First, the school did not obtain the student's legally effective informed consent. The PREP Act and EUA Statute required the government to perform the ministerial duty of accepting the student's free choice. Any conduct undertaken outside that ministerial duty was ultra vires, unlawful, and expressly preempted by the PREP Act. Second, the school could not deprive the student under coercion and undue influence of their Fourteenth Amendment rights to due process. The court did not consider the student's right to free consent under the PREP Act and EUA Statute and effectively denied the student his right to sue a "covered person" under the PREP Act.

However, the school could not have been covered under the PREP Act when they did not provide the student with his legally effective informed consent. Informed consent is only legally effective if it is prospective and obtained under a legal environment, ensuring the individual is not under outside pressure to participate. Therefore, the court failed to recognize that the activity of administering the PREP Act countermeasure outside the student's free consent was expressly forbidden by the statute's preemption language. If it is preempted, it cannot logically be covered by the statute's immunity doctrine.

The North Carolina state court issued a judicial right of the government to "destroy" an individual's constitutional protections under the Fourteenth Amendment, which fact cannot reconcile with the U.S. Constitution. Either the court is right, and the law is unconstitutional, or the law is correct, and the court's ruling is unconstitutional.

The court allowed the PREP Act to be used as a "procedural device" to deprive the students of their Fourteenth Amendment right to due process and their statutory entitlements under the PREP Act and EUA Statute while ignoring the government's ministerial duties under those statutes. This fact demonstrates the court's lack of constitutional understanding.

The Third Circuit Court of Appeals ruled that a person does not have the unqualified right to refuse an EUA drug without consequence.[26] The ruling means that a third party now has the judicially created but unconstitutional right to establish a prohibited act under 21 U.S.C. § 331 and a penalty under 21 U.S.C. § 333, establishing and enforcing their version of the FDCA. Moreover, thousands of third parties can establish penalties for a person accepting or refusing to destroy the Equal Protection Clause governing 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). Additionally, because the PREP Act and EUA Statutes hold statutory entitlements and property interest for individuals considering participation, the Third Circuit believes that a third party can deprive individuals of their Fourteenth Amendment rights outside of any procedural due process. Finally, if Congress only empowered the HHS Secretary to establish conditions of access under the EUA Statute and not even the Secretary can compel participation under threat of penalty (21 U.S.C. § 360bbb-3(l)), then precisely what penalty can be attributed to a person refusing to participate in the product's administration and who has authority under the statute to enforce the penalty? The court's reasoning cannot reconcile with the federal constitution and well-established law that only Congress can amend the FDCA and the Supremacy Clause regulating both statutes.

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[26] *Children's Health Defense v. Rutgers*, __ F.4th __, No. 22-2970, 2024 WL 637353 (3d Cir. Feb 15, 2024)

Rutgers usurped from Congress its authority to prohibit nonconsensual participation in the products. The Third Circuit effectively held that such legal attacks on the U.S. Congress are permitted among its courts. Finally, in denying plaintiffs' preemption claims, the court engaged in gaslighting when reaffirming the lower court's statement that "'Rutgers has not 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.'" The court is saying that the mandate to inject the EUA drugs into your body was not the mandate; only the mandate to comply with the mandate was the mandate. How does one adhere to the mandate? One must inject the drugs into their body. The judges chose to gaslight the Plaintiffs' claim instead of fulfilling their oath of office when affirming the lower court's preposterous position that the mandate was not preempted because it only required the students to comply with the mandate and not what the mandate required. The level of stupidity demonstrated in the court's ruling cannot be overstated. No federal express preemption claim could be enforced under this judicially created court doctrine. For reasons discussed herein and additional facts, such as the State of New Jersey has two federal agreements promising never to place an individual under threat of penalty when refusing a federally funded investigational or EUA drug, Rutgers was expressly preempted from engaging in the challenged conduct and issued the mandate only under *ultra vires* authority when amending the "Conditions of Authorization" outlined under each EUA. The court's ruling that Rutger's policy was not outside the scope of their authority cannot reconcile with Black Letter Law. Finally, the requirement to inject the EUA drug immunized under the PREP Act as a condition to access public education was a clear violation of the UCD.

The purpose of discussing these two rulings is to demonstrate, using the knowledge presented in this document, how the court's lack of statutory and constitutional understanding has led to absurd results.

This document was not designed to be exhaustive because explaining such work effectively would require volumes of pages. Mandates issued by various public and private entities involving unique facts require an understanding of how to effectively apply the laws to each scenario, which cannot be explained in one document.

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