The Right To Refuse COVID-19 Experimental Drugs Shall Not Be Infringed

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Federal Lawyers Claim:

1) Use of Emergency Use Authorization (EUA) medical products can be mandated.
2) Experimental drugs can be mandated if they share a formula with an approved drug.
3) Experimental products can be legally administered as if they are full licensure drugs.

Bottom Line Up Front

Federal law requires authorities sponsoring an Investigational New Drug (IND) under an EUA to ensure individuals are not under "sanctions," "coercion," and or "undue influence" when consenting to participate. International treaty, federal law, state and territorial law, plus the regulations of twenty federal agencies prohibit public and private entities from mandating the use of such drugs under the force of law.

COVID-19 Vaccines

The only COVID-19 vaccine drugs that have been available to Americans as of July 07, 2022, are classified by the Food and Drug Administration (FDA) as INDs. The FDA determined these drugs can ONLY be administered through the issuance of an EUA. Such INDs have not been licensed or approved by the FDA for general commercial marketing and have no legal intent.

What is the legal definition of an Investigational New Drug (IND)?

An IND is "a substance that has been tested in the laboratory and **approved** by the U.S. Food and Drug Administration **for testing in people**. Also called an experimental drug, IND, investigational agent, and investigational new drug."

What Laws Govern the Administration of Investigational New Drugs?

As found in several titles of the US Code, laws entitled 'The Protection of Human Subjects' govern the administration of INDs. The primary set of regulations governing the use of experimental drugs is 45CFR46 and the Belmont Report. These laws and regulations require authorities to obtain an individual's legally effective informed consent in advance.

What Constitutes a Legally Effective Informed Consent Regarding INDs?

As required by law, legally effective informed consent is obtained when authorities: 1) disclose quality information to the individual required to make an informed decision; 2) ensures the individual understands the risks and benefits of the experimental drug; 3) provides an opportunity for the individual to consider whether or not to participate; and 4) ensures the individual is not under "**sanctions**," "**coercion**," or "**undue influence**" by persons of authority when consenting to participate.

"Informed consent must be legally effective and prospectively obtained."
-US Department of Health and Human Services

What law defines Legally Effective Informed Consent?

In 1974, Congress passed the National Research Act establishing the 'National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.' Congress required the Commission to consider the basic ethical guidelines when involving humans in medical experimentation and the nature and definition of informed consent.

The Commission released their definition of informed consent in a publication titled the 'Belmont Report' in April of 1978. The Commission declared that authorities are required by law to establish a "set of adequate conditions" in order to receive the consent of the individual. Adequate conditions require authorities to ensure the individual is not under "sanctions," "coercion," or "undue influence" when consenting to participate. If an individual is under threat of penalty by persons of authority, it is illegal to provide those individuals access to investigational new drugs.

"Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied." - Belmont Report Washington, DC: U.S. Department of Health and Human Services. 1979.

What are those adequate standards of informed consent?

"This element of informed consent requires conditions **free of coercion** and **undue influence**. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. **Undue influence**, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable. **Unjustifiable pressures** usually occur when persons in positions of authority or commanding influence -- especially where possible **sanctions** are involved -- **urge a course of action** for a subject" - Belmont Report

Official Citation: 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.

Does the Belmont Report have the force of law?

Yes. Congress entered the Belmont Report into the Federal Register on Wednesday, April 18, 1979. Federal law requires heads of all federal departments, agencies, and the military to abide by its ethical principles anytime humans are involved in non-approved medical products whether that involvement is under the agency's regulatory framework or under exempted activities. No law generally exempts

anyone in the United States of America from abiding by the ethical principles of the Belmont Report when involving humans in medical experimentation.

The Belmont Report was incorporated into the regulatory framework of twenty federal agencies with Title 45 Code Federal Regulations Part 46 (hereafter "45CFR46") known as 'The Common Rule,' being established as the primary law of the land. The Common Rule has been adopted by all US states and territories; and therefore, so has the Belmont Report. However, even if a state or territory did not adopt 45CFR46 regulations into their statutes they are still obligated to abide by the Belmont Report.

"The regulations found at 45 C.F.R. part 46 are primarily based on the Belmont Report and were written to offer basic protections to human subjects involved in both biomedical and behavioral research conducted or supported by HHS" - US Department of Health and Human Services

What Are The Basic Requirements Of Federal Law To Abide By The Belmont Report:

1) 45 CFR 46.101 (c) "department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report."

2) 45 CFR 46.101(i) "unless otherwise required by law, department or agency heads **may waive** the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, **provided** the alternative procedures to be followed are consistent with the principles of the Belmont Report."

3) 45 CFR 46.101(a) (paraphrased) This policy applies to **research** conducted by Federal civilian employees or military personnel within and outside of the United States.

4) 45 CFR 46.102(l) defines research "as a systematic investigation, including research development, testing, and evaluation, designed to develop or **contribute to generalizable knowledge**. Activities meeting 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." EUA products must be

monitored and studied for efficacy and safety and operate under an Institutional Review Board that is required to abide by the ethical principles of the Belmont Report.

5) Department of Defense EUA products must abide by the Belmont Report through 45 CFR 46.101(i), 32 CFR 219.101 (i). Additionally the United States Army Medical Research and Development Command (USAMRDC) 'Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements' states, "exempt research activities should adhere to the fundamental ethical principles outlined in the Belmont Report."

The Belmont Report must be followed by all governmental and private entities when involving humans in an experimental drug, whether that involvement includes clinical research or research outside of clinical studies. In addition, the HHS Secretary must authorize all EUA products; therefore, no matter the authority, these entities must agree to abide by the Belmont Report when administering those products.

"The general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects." - Belmont Report

21 U.S.C. 355(i)(4) requires authorities using an IND for investigatory purposes to certify to the manufacturer of that IND that they will: 1) inform individuals the drug has not been approved by the FDA and 2) they will obtain the legally effective informed consent of the individual as stipulated in the Belmont Report.

Legal Fact: There is nowhere an experimental product can go where the Belmont Report does not follow because the Belmont Report is an act of Congress codified into law governing the administration of all experimental products.

The Force of The Belmont Report

In 2001, HHS created the Office of Human Research Protections (OHRP) to require a tangible agreement with public and private entities which involve humans in medical experimentation. Further, OHRP established the Federal Wide Assurance (FWA) program requiring such entities to abide by 45CFR46 and the Belmont Report. The type of entities with FWA agreements are universities, state health departments, federal agencies, Department of Defense (DoD) Components and units, state governments, hospitals, and publicly funded healthcare providers.

What about interchangeability?

NOTE: In response to the COVID pandemic, the FDA informed the medical community in 2021 to "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." However, in the same document the FDA emphasized those two drugs had certain legal distinctions.

The fundamental legal distinction between the two drugs is their attached labels. Those labels represent laws derived by an act of Congress from which no public or private entity has the authority to exempt themselves except in two scenarios: 1) the President of the United States may issue a waiver of informed consent laws for DoD personnel involved in a specific military operation and 2) if an individual is in a life-threatening event with no legal representation present**,** and the attending healthcare provider believes an unapproved drug can save the individual's life, then informed consent requirements may be waived.

Pfizer's BioNTech COVID-19 drug label is classified as an IND under an EUA and must abide by the laws governing that classification. Pfizer's COMIRNATY is an FDA-approved drug and operates under the laws governing that classification. This legal fact means the two drugs are not legally interchangeable.

Suppose an individual is administered the experimental product "as if" it is an approved product. Which of the two sets of laws will courts utilize to adjudicate litigation between plaintiffs and defendants? Courts are legally bound to use rules attached to the drug administered to the plaintiff. Suppose courts agree that for purposes of COVID-19 vaccine mandates, Pfizer's two drugs are interchangeable. In that case, they must also rule that the two sets of laws governing those drugs are interchangeable. However, since no such laws exist, we must remind the Executive and Judicial branches of government that they have no authority to legislate!

When individuals consent to participate in an IND, they are "volunteering" for biomedical research and forfeiting nearly 100% of their rights to future litigation. Americans are wholly unaware of this fact because the FDA has not properly informed them. Activist judges who rushed to judgment have created massive confusion in the

judiciary because they claim that one set of laws can be used “as if” they are another set of laws. These rulings are a direct assault on the foundation that holds our Republic together. Laws must be followed according to the intent of the United States Congress and may not be used interchangeably to fulfill a radicalized goal of any political party in power.

The drug label reflects Congress’ intent and has the force of law. No government, CEO, school board, or agency head has the legal authority to exempt themselves from that law.

Under the Public Readiness and Emergency Preparedness (PREP) Act, manufacturers of EUA drugs enjoy immense liability protections. It is for this reason authorities are prohibited from mandating the use of experimental products because the PREP Act requires the "voluntariness” nature of everyone involved to grant immunity from liability.

> “Governmental leaders concocted a scheme to bypass congressional restrictions regarding INDs by pretending an experimental drug can be mandated ‘as if’ it is an approved drug. How did they achieve this gross betrayal of the American people? They simply wrote a memorandum and declared it was law.” - Brian Ward

Only one mechanism is afforded to the legal community to ascertain which laws govern a drug and that mechanism is the label attached to the drug vial. Strict adherence is required by law irrespective of another drug sharing the same formula. Therefore, Pfizer’s BioNTech Vaccine may not be legally administered as if it is a full licensure drug for any purpose because there is no precedent or law establishing that fact.

Section 564

21 USC 360bbb-3 is known as section 564 and was established by Congress to effectively allow healthcare providers to respond to a chemical, biological, radiological, or nuclear (CBRN) event. If there was an event involving an unknown CBRN agent that was causing significant harm and an unapproved medical product existed that “may have benefit,” then there needed to be a legal process in place to authorize the use of that product.

The main components of section 564 are:

1. That Congress only empowers the HHS Secretary to approve medical products that have not been approved by the FDA during a declared emergency.
2. That section 564 does not create a new classification of products. The law ONLY provides "expanded access" to experimental medical products for emergency use.
3. That it requires certain information to be furnished to providers and recipients of the product.
4. That it exempts the healthcare provider from having to provide certain information when events make such acts impractical. However, the Secretary has required recipients to receive a drug insert sheet during this pandemic, demonstrating the definition of practicality.
5. That authorities are never exempt from ensuring individuals are under no "sanctions," "coercion," or "undue influence" to participate in the experimental product. Regardless of what information is, or is not presented to the individual, authorities are always required to obtain the legally effective consent of the individual.

14th Amendment

21 USC 360bbb-3 affords Americans access to unapproved medical products during a declared emergency. Congress has promised individuals involved in these products that they have the option of accepting or refusing their administration.

Activist judges are ruling that a person's legislated option to refuse can be penalized, creating a constitutional crisis without an appropriate response by all fifty states' attorneys general. If a person's refusal of an EUA product results in adverse actions by persons of authority who disagree with that choice, it is no longer a right. Courts are being allowed to establish a historical precedent that legislated rights can be denied by authorities who disagree with that right.

Suppose the 14th Amendment still has the force of law in America, guaranteeing equal civil and legal rights to citizens. To be just and fair, could a business owner penalize employees who participated in a COVID-19 Investigational New Drug? Same business owners have punished those who did not. This begs the question, what other "rights" have been legislated for us that can now be penalized by rogue government actors because activist judges refuse to follow the law?

Governments and corporations which penalized only those who exercised their protected right not to participate in an experimental drug violated one of the most sacred ideals of our society – to be treated equally before the law as guaranteed to us by our Constitution.

Political Rights Treaty

In 1992 the U.S. Senate ratified the International Covenant on Civil and Political Rights Treaty. Article VII of that treaty states, "no one shall be subjected without his free consent to medical or scientific experimentation." To be subjected does not mean 'physical' restraint. Instead, it means to be subjected to the force of law by one's government.

Why Do Americans Have The Right To Refuse The Administration Of An EUA Drug?

The adverse reactions to Pfizer's BioNTech COVID-19 drug are at historical levels compared to other Pfizer drugs. For example, Pfizer was fined $2.3 Billion for drug fraud involving Bextra, an anti-inflammatory therapy. Bextra recorded 9,443 serious adverse reactions and 1,054 deaths in over 18 years. Meanwhile Pfizer's BioNTech COVID-19 vaccine has recorded 18,638 deaths and 162,000 serious adverse reactions in the Vaccine Adverse Event Reporting System over 18 months. Yes! You read that correctly.

Would you freely volunteer to participate in an experimental drug that forfeited your rights to judicial remedy, had historic levels of severe adverse reactions, and did not even claim to inoculate you from any COVID-19 variant? The obvious answer is NO.

This is precisely why Congress requires your legally effective informed consent before participating in an investigational new drug under an Emergency Use Authorization.

Conclusion

No individual under US Government authority can be forced under duress to participate in an EUA experimental product. Authorities involved in the manufacturing and/or administration of the product must establish a "set of adequate conditions" ensuring the individual is not under "sanctions," "coercion," or "undue influence" to have the legal right to accept the consent of the individual. Therefore, COVID-19 vaccine mandates to date have been illegal because they required compliance before the availability of FDA-approved drugs.

Civilians and service members who were penalized for refusing the administration of any COVID-19 EUA product had their federal and constitutional rights violated. Authorities imposing penalties: 1) abused the powers of their office; 2) violated an international treaty; 3) violated federal laws governing unapproved substances; 4) failed to abide by the Belmont Report; 5) violated Common Rule laws of all US states; 6) disregarded health department regulations of all US states; 7) violated the 14th Amendment rights of those under their authority; 8) engaged in acts of harassment, intimidation, and coercion; 9) potentially committed felonies by requiring persons under their authority to inform them if they participated in medical experimentation; 10) are liable for injuries sustained by the EUA drug because the PREP act does not cover "forced acts" nor does law protect authorities engaged in unlawful behavior; and 11) violated FWA agreements on file.

The majority of laws referenced in this document have never been argued in a court of law, and the legal community is wholly unaware of them. Since the Belmont Report became codified, the "only" time the authorities overstepped with an experimental product on Americans was in 2003, when the Department of Defense attempted to force an anthrax investigational drug on service members.

The result? "Congress has prohibited the administration of investigational drugs to service members without their consent. This court will not permit the government to circumvent this requirement." — U.S. District Judge Emmet G. Sullivan 2004

These civil and criminal violations demand significant remedial actions by our legal community.