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

DISCLAIMER: This document does not have the force of law. Please consult with a licensed attorney for personalized guidance before engaging in legal efforts utilizing the contents herein.

Due to the urgent need for this document's development consider this paper as version 1.0 with updates coming throughout July of 2022. **Version July 08, 2022**

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.

Suggestions to State Attorneys General Coming in version 2.0 @ CovidPenalty.Com

United States Armed Forces

Bottom Line Up Front

Military regulations require the legally effective informed consent of the service member before the administration of an Investigational New Drug (IND), whether the IND is under an Emergency Use Authorization (EUA) or an IND application. This requirement comes with only one exemption: written approval of the President of the United States and limited to a specific military operation. DoDI 6200.02, the Belmont Report, and FDA instructions make it clear that service members may not be penalized under the Uniform Military Code of Justice when choosing to not participate in an experimental drug according to the product's labeling.

Court and Administrative Precedent

Judge Sullivan ruled in 2004 that "**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."

The FDA informed the DoD in 2005 that "**Refusal** [to participate in an investigational drug] **may not be grounds** for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action."

In 2005, the FDA issued an EUA to the DoD for an investigational anthrax drug with the following statement, "**You may refuse** anthrax vaccination under the EUA, **and you will not be punished**. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination." This statement was required because the drug was classified by the product's labeling as investigational, having no legal intent.

COVID-19 Substances Available To Service Members Are:

1) Pfizer BioNTech COVID-19 Vaccine IND number 19736
2) Janssen Biotech COVID-19 Vaccine IND number 22657
3) ModernaTX COVID-19 Vaccine IND number 19745

DoD Regulations Requiring Legally Effective Informed Consent are Indisputable

The primary laws and regulations governing the implementation and administration of INDs under an EUA or application are: DoDI 6200.02, 21CFR50.23, 21CFR312, 1107 10 U.S.C., EO 13139, 21 U.S.C. 355(i)(4), HQ USAMRDC IRB policies, and U.S. Food and Drug Administration (FDA) Guidance, Emergency Use Authorization of Medical Products and Related Authorities (Jan 2017).

The Under Secretary of Defense (Personnel and Readiness) USD(P&R) and the Assistant Secretary of Defense for Health Affairs ASD(HA) have primary responsibilities for DoDI 6200.02 policy implementation and enforcement. They are obligated to issue instructions and legal guidance to DoD Components, ensuring those Components comply with international treaties, federal law, and military regulations when executing their authority relating to the administration of DoDI 6200.02 substances.

The Secretary of the Army is the lead component for implementing DoDI 6200.02 drugs. The Surgeon General of the Army and HQ USAMRDC act as the single Institutional Review Board monitoring the safety, efficacy, and reporting of adverse events of EUA substances to DoD personnel.

The Heads of DoD Components may request approval of the ASD(HA) to administer an EUA product if they agree to abide by DoDI 6200.02 requirements as follows:

5.2.1.3 - Coordinate their efforts with the Secretary of the Army who acts as the Lead Component.

5.2.2 - <u>Develop medical protocols</u> for the legal administration of the product in coordination with the Secretary and Surgeon General of the Army. They must swear to execute such protocols in strict compliance with their requirements.

5.2.3 - Requirement to uphold the oath of office in reference to the 14th Amendment by ensuring service members are treated equally in reference to 21 U.S. Code § 360bbb–3 options to accept or refuse before the activation of a 1107 10 U.S.C. waiver.

5.2.4 - Ensure the approved protocols require DoD leadership to inform service members: a) that the HHS Secretary has authorized the use of an EUA product; b) of the risks and benefits of the product; c) of the known side effects of the product when interacting with other drugs or treatments being administered to the service member; d) alternatives to the product; e) that that the drug is unapproved for its applied use, and f) the reason why the IND is being administered in reference to 1107 10 U.S.C.

5.2.4 - Conform to 21 U.S.C. 355(i)(4) and "certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings" unless a waiver in writing has been issued by the President in reference to 1107 10 U.S.C.

5.2.4 - Ensure the protocol administers the EUA product according to its Scope of Authorization in reference to 1107 10 U.S.C.

5.2.4 - Ensure the protocol abides by the ethical guidelines of the Belmont Report in reference to 45 CFR 46.101(i) and HQ USAMRDC EUA exemption regulations that "exempt research activities should adhere to the fundamental ethical principles outlined in the Belmont Report."

5.2.4 - Ensure service members are not under a mandate to participate in the EUA product until the President issues a waiver in reference to 1107 10 U.S.C.

5.2.4 - Ensure the protocol informs DoD leadership that commanders may not impose a penalty or withhold a benefit to which a service member is otherwise entitled when choosing not to participate in a substance under DoDI 6200.02 in reference to the Belmont Report, DHA-IPM 20.004, and FDA instructions.

5.2.5 - Provide access to EUA products, unless otherwise notified by ASD(HA), to Emergency-Essential civilian employees, and/or contractor personnel accompanying the Armed Forces.

5.2.5 - Ensure Heads of DoD Components obtain the legally effective informed consent of civilian employees even if a Presidential waiver of informed consent is issued for a specific military operation to service members.

E2.4 - Apply the protocol to products not approved for their intended use according to the product's labeling.

E2.7 - Apply the protocol to products the FDA has determined may not be used for its intended use without an Emergency Use Authorization.

E3.4 - Ensure the EUA product is not mandated to service members until after the President issues a waiver of the informed consent process pursuant to 1107 10 U.S.C.

EO13139 Section 3 (a) - "**Before** administering an investigational drug to members of the Armed Forces, the Department of Defense (DoD) **must obtain informed consent** from each individual unless the Secretary can justify to the President a need for a waiver of informed consent in accordance with 10 U.S.C. 1107(f). Waivers of informed consent will be granted only when absolutely necessary."

NOTE: Although military regulations state "informed consent," we must understand its nature and legal definition as outlined in the Belmont Report. That legal definition requires DoD Components to ensure service members are not under "sanctions," "coercion," or "undue influence" to participate. They must be informed that participation is voluntary and refusal will not incur a penalty or lose a benefit to which they are otherwise entitled. This legal fact is backed by law, court precedent, FDA regulations, and administrative history.

The USD(P&R) is obligated to ensure DoD Components involved in the implementation of EUA and IND substances shall provide ongoing training and health risk communication to leadership positions about medical protocol requirements. That information must include training on informed consent requirements in reference to 1107 10 U.S.C. and the Belmont Report in reference to 45cfr46, 32cfr219, and USAMRDC protections of human subjects 2018 regulations.

FACT: No law exists allowing the DoD to administer an investigational drug to service members without their consent before the President issues a waiver pursuant to 1107 10 U.S.C. No law exists that affords the DoD legal authority to exempt itself from the laws governing drug labels except the informed consent process pursuant to 1107 10 U.S.C. No law exists that permits the DoD to penalize service members under the Uniform Code of Military Justice when they refuse to participate in a substance under DoDI 6200.02 requirement because it is not a crime to refuse. No law authorizes civilian military leaders the right to issue a memorandum pretending "as if" that memorandum supersedes the authority of the United States Congress. These facts are indisputable and without debate.

The FDA determined the Pfizer BioNTech COVID-19 Vaccine may not be distributed for general commercial marketing and required the issuance of an EUA for its administration. DoD Components are required by law to obtain the legally effective informed consent of service members before administering this product. In addition, DoD Components are required to ensure service members are not penalized for refusing the Pfizer BioNTech COVID-19 experimental substance. The USD(P&R) must not mandate the use of DoDI 6200.02 substances until after the President activates 1107 10 U.S.C. waiver exemptions. If a waiver is approved, it must be entered into the Federal Register, and to date (as of July 06, 2022), no such entry exists.

What "law" allows USD(P&R) Cisneros To Exempt DoD from Legislative Requirements?

Unknown. However, Dr. Terry Adirim was appointed Principal Deputy Assistant Secretary of Defense and performed the duties of Assistant Secretary of Defense for Health Affairs under SECDEF Lloyd Austin in 2021. Dr. Adirim advised DoD Components in 2021 that "healthcare providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." She concluded with saying "Consistent with FDA guidance, DoD health care providers will use both the Pfizer- BioNTech COVID-19 vaccine and the Comirnaty COVID-19 vaccine interchangeably for the purpose of vaccinating Service members in accordance with Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021."

Dr. Terry Adirim's guidance was unlawful to the first degree. She engaged in criminal behavior by telling DoD healthcare providers they "will" administer an experimental drug "as if" it is an FDA-approved drug which is illegal. USD(P&R) Cisnero and Dr. Terry Adirim have the legal obligation to ensure DoD Components follow federal law and military regulations under DoDI 6200.02 policy requirements. Dr. Adirim used her authority under DoDI 6200.02 to issue guidance that violated several conditions of the policy. Pfizer- BioNTech COVID-19 vaccine must be administered according to its Scope of Authorization and DoDI 6200.02 medical protocol requirements whereas Comirnaty does not. To pretend "as if" she and DoD Components are fulfilling their legal obligations by issuing memorandums containing laws that Congress did not authorize while involving DoD active service personnel should result in prison time. Furthermore, FDA guidance to medically use an experimental drug as if it is an approved drug does not supersede military regulation requirements under DoDI

6200.02. Lastly, she has no defense because she references SECDEF Austin's memorandum that clearly states DoD Components will only use full-licensure drugs according to the product's labeling which will not come under the purview of DoDI 6200.02. There is no "as if" within the military command or the judiciary. The thing is, or it is not, but it is never "as if"it is.

Dr. Terry Adirim's "order" claimed the authority of the President by mandating the use of a DoDI 6200.02 substance requiring a 1107 10 U.S.C. waiver. Her order was a seditious directive to military commanders that effected severe maltreatment of thousands of service members. The Office of Inspector General and the Judge Advocate General's Corps refused to correct Dr. Adirim's criminal guidance, and the Department of Justice is further protecting this unconstitutional behavior. The actions of the Under Secretary of Defense for Personnel & Readiness (USD(P&R)) Gil Cisneros and former ASD(HA) Dr. Terry Adirim are nothing less than a seditious attempt to subvert the Constitutional Authority of the Commander in Chief and the Legislative branch of the United States of America.

Pages 100 - 103 of HQ USAMRDC 'Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements' detail the legal process by which the President can mandate the use of a substance under DoDI 6200.02 in reference to 1107 10 U.S.C. Furthermore, 1107 10 U.S.C. clearly outlines that the Secretary of Defense is the only person empowered by Congress to request a Presidential waiver, and only the President may issue the waiver. Dr. Terry Adirim had zero authority to mandate the administration of an experimental substance without that waiver. Her memorandum is a criminal attempt to circumvent the Legislative branch of government that issued lawful orders contrary to her memorandum.

The Under Secretary of Defense (Personnel and Readiness) April 4 Memorandum
'Consolidated Department of Defense Coronavirus Disease 2019 Force Health Protection Guidance'

USD(P&R) Gil Cisneros' April 04, 2022 memorandum rescinded guidance for religious, medical, and administrative exemptions. Furthermore, the Secretary provided a definition for fully vaccinated status that is unlawful and has placed the DoD under significant remedial pressure from 2.1 million service members.

The memo defined fully vaccinated as, “An individual is considered “fully vaccinated” when at least 2 weeks have elapsed after a second dose of a two-dose COVID-19 vaccine series (e.g., **PfizerBioNTech**/Comirnaty, or **Moderna**/Spikevax vaccines), or 2 weeks after receiving a single dose of a one-dose COVID-19 vaccine (e.g., Johnson & Johnson’s **Janssen** vaccine) that are: (1) fully licensed **or authorized** or approved by the FDA; (2) listed for emergency use on the World Health Organization Emergency Use Listing (e.g., **AstraZeneca/Oxford**); or (3) approved for use in a clinical vaccine trial for which vaccine efficacy has been independently confirmed (e.g., **Novavax**).”

Because DoD Components are using this definition to impose penalties and/or withhold benefits from service members for non-compliance, it violates an international treaty, federal law, military regulations, and the Belmont Report. Furthermore, this definition is a criminal attempt to circumvent the Legislative branch of government because it circumvents the aforementioned legal requirements involving highlighted drugs in the definition.

Esteemed Members of Congress, please note USD(P&R) Gil Cisneros wrote legislation into law with this one definition. He is exempting himself from your constitutional authority and previous regulatory bodies by mandating compliance before the availability of FDA-approved drugs or presidential waiver. His guidance to use EUA drugs as though they are not EUA drugs illegally exempts the DoD from their lawful obligations. Moreover, such directives are criminal because they subvert the rights of service members, courts, and Congress. The Belmont Report prohibits the USD(P&R) from even listing DoDI 6200.02 substances in his legal definition because it is impossible to obtain the legally effective informed consent of service members who are under threat of penalty for non-participation.

How Does The Under Secretary’s Fully Vaccinated Definition Violate Known Laws?

USD(P&R) Gil Cisneros’ defined status of fully vaccinated can have no force of law to penalize service members under the UCMJ because it relies solely on the use of DoDI 6200.02 substances that require 1107 10 U.S.C. exemptions of which none have been granted.

His definition lists: a) drugs that have not been approved for their intended use according to the product's labeling (E2.4); b) drugs requiring the issuance of an Emergency Use Authorization for their administration (E2.7); c) FDA-approved drugs that are not in distribution and are therefore unattainable to comply with his definition; d) substances requiring a presidential waiver before the waiver has been issued (E3.4).

Because USD(P&R) Cisneros wrote a definition utilized by commanders to issue letters of reprimand to service members who do not conform to that definition, the fundamental ideals of the Belmont Report and DoDI 6200.02 requirements have been violated. Cisneros' definition violates DoD Component FWA agreements and laws issued by the Legislative branch of the government.

Since only DoDI 6200.02 substances are available to service members and civilian employees, additional unlawful orders in USD(P&R) April 04, 2002 memo are as follows:

1. "If they have not already done so, supervisors of DoD civilian employees must ask DoD civilian employees whether they are fully vaccinated. Employees who indicate they are fully vaccinated must provide proof of that vaccination status to their supervisors." USD(P&R) Gil Cisneros already knows that DoDI 6200.02 5.2.5 provides an explicit exemption from required administration of DoDI 6200.02 substances even if the President issues a waiver. Furthermore, requiring employees to "provide proof of that vaccination status" can be a felony under health privacy laws protecting the right of individuals from exposing their involvement in medical experimentation.
2. "COVID-19 screening testing is required at least weekly for Service members who are not fully vaccinated." This requirement violates service members' 14th Amendment rights to be treated equally before the law. EUA products under DoDI 6200.02 provide service members options to accept or refuse the product. USD(P&R) Cisneros penalizes one of those two federally protected choices.

USD(P&R) Gil Cisneros is abusing the powers of his office by issuing directives contrary to laws enacted by the United States Congress. He attempts to thwart federal statutes by redefining what courts, regulatory bodies, and administrative history have declared illegal. USD(P&R) Cisneros can not demonstrate how DoDI 5124.02 empowers him to mandate the use of DoDI 6200.02 substances without a Presidential

waiver, which he is currently forcing onto service members by mandating their compliance without availability of FDA-approved COVID-19 vaccines. USD(P&R) Gil Cisneros knows the only COVID-19 drugs available to service members and DoD civilian employees are drugs operating under the authority of DoDI 6200.02. Therefore, those substances may not be included in a definition that will be utilized to punish DoD personnel for non-compliance. By including FDA-approved drugs that have not been in distribution and have no known distribution date, he exposes his deception to subject the entire military structure to a biomedical research project without the free will and voluntary consent of DoD personnel. Furthermore, he has not provided guidance to DoD Components that the refusal of DoDI 6200.02 substances by service members may not be grounds for disciplinary actions under the UCMJ unless the President issues a waiver.

These actions are unheard of in modern day America and should open USD(P&R) Gil Cisneros to civil suits for his willful failure to fulfill his fiduciary obligations according to his oath of office.

DoD Components and civilian leadership military cite laws and regulations only to ignore those laws and regulations in their directives. For example, the Defense Health Agency issued a Memorandum on June 16, 2022 (DHA-IPM 20.004) that is schizophrenic in nature and an affront to our Republic.

Lt. General Ronald J. Place, Director of the Defense Health Agency stated:

1. "Use of vaccine products for force health protection under EUA will be executed in accordance with DoDI 6200.02, 1107 10 U.S.C., and U.S. Food and Drug Administration (FDA) Guidance, "Emergency Use Authorization of Medical Products and Related Authorities," January 2017."
2. "They [service members] have the option to accept or refuse the EUA product **and are free from any consequences of refusing** administration of the product."
3. "Mandatory vaccination against COVID-19 **will only use** COVID-19 vaccines that receive **full licensure** from the FDA in accordance with FDA- **approved labeling** and guidance."
4. "Providers will use the PBS-buffer Pfizer-BioNTech COVID-19 vaccine [requires DoDI 6200.02] and the PBS-buffer Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine [does not require DoDI 6200.02] interchangeably for the purpose of

vaccinating Service members to meet DoD COVID-19 vaccination requirements."

According to the product's labeling, Lt. Gen Place declared that the DoD would ONLY use full licensure drugs for vaccine mandate compliance. He said such drugs must be administered according to DoDI 6200.02, 1107 10 U.S.C., and FDA instructions. He then DECLARED that service members have the right to refuse a product under an EUA, and such refusal will not have consequences.

However, what does Lt. Gen Place declare after he gives those instructions? He lists drugs that have not received full licensure by the FDA in a definition commanders will use to apply consequences to service members refusing their administration. His deceptive scheme to bypass the United States Congress is the same as USD(P&R) Cisneros. That scheme lists drugs receiving full licensure (but are not available) with drugs that have not received full licensure but are available.

Lt. Gen Place demonstrated schizophrenic leadership by declaring that service members can refuse a product under an EUA without consequence. He then turns around and lists EUA drugs required for vaccine compliance because those EUA drugs are the only COVID-19 drugs available to service members. One must admire his deceptive mingling of directives, but they should be used against him for prosecution and resulting incarceration.

Legal Fact: Lt. Gen Place, the USD(P&R), and ASD(HA), can not point to a statute issued by any authority to "legally" use a DoDI 6200.02 substance "as if" it is a full licensure drug. To declare or even imply that drugs having two legally distinct regulations can be used interchangeably to comply with federal law and military regulations is most likely a felony on numerous levels. Lt. Gen Place's memorandum makes a declaration that an experimental drug can be treated as a full licensure drug in an effort to write legislation contrary to the United States Congress. This combined effort by heads of DoD Components is a Constitutional crisis and it has led to the severe maltreatment of service members.

Let us look at what Lt. Gen Place should have included in his memorandum, but willfully left out. DoD personnel will abide by DoDI 6200.02 requirements as follows:

1) "develop, in coordination with the Secretary of the Army, medical protocols, compliant with this Instruction, for use of the [EUA] product and, if the request is

approved, execute such protocols in strict compliance with their requirements." (5.2.2).

2) The protocol must ensure that service members are informed of: 1)"The reasons why the IND is being administered;" 2)"Information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug;" and 3) "the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President." (5.2.4 in reference to 1107 10 U.S.C.)
3) "Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DoD) **must obtain informed consent** from each individual [for products defined in E2.7 and E2.4] unless the Secretary can justify to the President a need for a waiver of informed consent in accordance with 10 U.S.C. 1107(f). Waivers of informed consent will be granted only when absolutely necessary." (5.2.4 in reference to EO13139).
4) "Ensure that the Army Medical Research and Materiel Command Human Subjects Research Review Board (HSRRB), under the Surgeon General of the Army, carries out the responsibilities described in paragraph E4.4" and "adhere[s] to the fundamental ethical principles outlined in the Belmont Report." (5.3.2 in reference to USAMRDC IRB 2018 policies (7.4) & 45CFR46)
5) Such protocols **MUST** be utilized for "a medical product…the FDA has determined may not be used for its intended purpose without an Emergency Use Authorization" (E2.7) or "an FDA-approved drug or biological product administered for a use **not described in the approved labeling.**" (E2.4).

Now let me write, in plain language, how SECDEF Lloyd Austin should direct his subordinate to comply with his Memorandum dated August 24, 2021.

Lt. General Ronald J. Place, I order you to establish procedures to implement instructions, assign responsibilities, and prescribe procedures for the DHA's implementation of the DoD's COVID-19 Vaccination Program. According to the product's labeling, there are no FDA-approved drugs, and the FDA has determined that the only way COVID-19 INDs can be administered to DoD personnel is through the issuance of an EUA. Therefore, you are obligated to implement instructions under DoDI 6200.02 policy requirements for their administration.

You must instruct DoD leadership to obtain the legally effective informed consent of service members before administering a DoDI 6200.02 EUA drug. In addition, you must issue a statement to service members that participation is voluntary and that refusal to participate will not incur a penalty or loss of benefits to which they are otherwise entitled. This statement is a legal requirement that the President can only waive under 1107 10 USC. Failure to follow the policy directives of DoDI 6200.02, 1107 10 USC, the Belmont Report, and the US Food and Drug Administration (FDA.) Guidance, "Emergency Use Authorization of Medical Products and Related Authorities, (Jan 2017) will result in significant remedial actions by service members.

You may not use a drug requiring the issuance of an EUA as if it is a drug that does not. Engaging in such acts would violate the fundamental policy requirements of DoDI 6200.02 and endanger DoD personnel of violating the Uniform Code of Military Justice. Additionally, you may not issue guidance that an unapproved product may be used interchangeably as if it is an approved product because that would criminally circumvent the constitutional authority of the Executive and Legislative branches of government. Such acts would certainly be considered for prosecution, potentially leading to significant incarceration.

Legal Community

This research has provided you with the basic components for the successful conclusion of an untold number of lawsuits. I encourage you to provide your services to our men and women in uniform on a contingency basis. Service members who have given decades of their lives and are within a year of retirement eligibility are being threatened with the loss of their retirement simply because they chose their federally protected right to refuse the administration of an experimental product. Service members are being denied legitimate medical exemptions, early retirement options, honorable discharges, deployment opportunities, promotions and transfers, educational and professional training and so much more for the exact same reason.

The current civilian leadership in charge of our military has dishonored, disrespected, and devalued those who protect our freedoms. We must not turn a blind eye to our service member's time of dire need.

I encourage you to take a peek under the legal hood to see what new Bentley awaits you. Should the DoD provide FDA-approved products, that action would not negate the right of service members to seek judicial remedy for leadership's past crimes.

1. 2.1 million service members can sue the DoD for: a) violating their federally protected protected rights to refuse the administration of an unapproved drug without incurring a penalty or losing a benefit to which they were otherwise entitled; b) violating their 14th Amendment rights to equality; c) injuries sustained from the unlawful mandated use of DoDI 6200.02 substances under medical malpractice; and d) forced under duress to participate in a chemical that can not be removed from their anatomy.
2. 768,000 civilian employees can sue the DoD for violating their: a) 14th Amendment rights; b) health privacy laws; and engaging in c) harassment, discrimination, coercion, and intimidation tactics to participate in an experimental product.
3. Civilian contractors can sue the DoD for forcing them to violate their Office of Human Research Protections (OHRP) Federal Wide Assurance (FWA) agreements.

Recommendations:

1) Request to view the health/benefit analysis conducted by the DoD when approving the use of Pfizer's BioNTech/Comirnaty drugs. There is NO benefit of COVID-19 drugs that is greater than the risk to DoD personnel demographics.
2) Request DOJ and DoD cite which laws authorize department heads to treat experimental drugs 'as if' they are full licensure drugs.
3) US Armed Services Committee members MUST generate an Unfavorable Information File on errant commanders to reference when considering those commanders' future promotions.
4) The House of Representatives MUST appoint a special prosecutor to investigate and prosecute these human rights abuses by civilian authorities.

Version 2.0 will include a list of recommendations, references, and diagrams. The desire to protect our men and women in uniform prompted early release of the main document.

I, Brian Ward, attest that the contents of this document are my own, as gathered from nine months of research. I have no conflict of interest other than I hate injustice with a

passion and the abuses our service members are enduring under the unlawful actions of a radicalized political power bent on destroying the morale and readiness of our military forces.

Brian Ward is available for expert testimony, critical analysis of legislative and legal efforts, live and online lectures, corporate training, and other activities to help save our nation from destructive tyranny. CovidPenalty.Com