2024 COMMON RULE REPORT

This report details the Executive branch's use of “deceptive implicature” to deprive DoD service members, CMS healthcare providers, and green card workers of rights created for their benefit by valid acts of Congress to refuse investigational new drugs without consequence.

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DECEPTIVE IMPLICATURE & COMMON RULE

Deceptive implicature is a form of communication designed to cause an individual to imply a false belief within themselves to influence their behavior, emotions, and opinions, causing them to act in a manner detrimental to their health, safety, and legal rights. This tactic provides the author plausible deniability in future civil or criminal prosecutions from resulting injuries sustained by the individual acting on the implied false belief.

An example of deceptive implicature is the FDA allowing Pfizer, Inc. to use the word vaccine within its formal investigational new drug name, "Pfizer-BioNTech COVID-19 Vaccine."[1] Notice the capital letter V causing the public to falsely imply to themselves that the drug is a licensed vaccine instead of an investigational new drug (IND) with no legal indication to treat, cure, or prevent any known disease.

The FDA approved COMIRNATY® on August 23, 2021, but Pfizer never manufactured its original or "tris-sucrose" licensed versions to introduce them into commerce for general commercial marketing. Starting on August 24, 2021, the Executive branch, DoD, CMS, state governors, hospitals, and other authorities set into motion a series of communications designed to mislead the American people into the false belief that all of Pfizer's COVID-19 drugs were effectively FDA licensed with a legal indication to prevent the coronavirus since it "shared formulation" with a licensed drug.

The deception was powerful because persons with positions of authority utilized equivocation to compel participation under threats of penalty while ignoring the legal consequences of their actions or the rights of their victims.

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[1] Pfizer-BioNTech COVID-19 Vaccine is an investigational new drug according to its labeling under IND 19736.

The Executive branch, acting through several federal agencies, enacted mandatory vaccination policies under the guise that mandatory drugs would only include those drugs that received "full licensure" from the FDA according to the product's labeling. A separate section of the policy would inform the reader that the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® shared formulation and, therefore, the Pfizer-BioNTech COVID-19 Vaccine could be administered "as if" it was the "licensed" version for purposes of administration giving the false implied belief that both drugs could come under the mandatory requirement. Finally, in another section of the policy, it defined what it "considered" "fully vaccinated" to mean "when at least 2 weeks have elapsed after a second dose in a two-dose COVID-19 vaccine series, such as of the Pfizer-BioNTech/COMIRNATY® or Moderna COVID-19 vaccines."

One keyboard character, the forward slash—"/"—is responsible for Americans' deprivations of rights to Equal Protection, Due Process, and the Excessive Fines Clause under the federal constitution. The slash character was designed to mislead the public and ensure plausible deniability of its effects.

Why should the deception concern the United States Congress? First, the Executive branch used the deception to usurp from Congress its authority to prohibit nonconsensual participation in unlicesned investigational new drugs only offered through a federally funded program. Second, the legal impact on citizens agreeing to participate in a drug only authorized under 21 U.S.C. §360bbb-3 ("EUA Statute") and PREP Act immunity severely impacts their legal rights, financial livelihoods, and health goals. Third, the deception has now entered the federal judiciary, where judges are pretending "as if" the drugs do not have legal distinction, resulting in the complete deprivation of equal protection and due process rights of an entire nation.

The reader should be aware that the Supreme Court (Biden v. Missouri, 142 S.Ct. 647, 211 L.Ed.2d 433 (2022)) only ruled on the authority of the President to issue a vaccine mandate under certain conditions. The Court never ruled on how President Biden applied his mandates to the exclusive use of federally funded EUA investigational new drugs under PREP Act immunity. Had the President been challenged along those lines, no person within the nation could have come under the compulsory use of any COVID-19 EUA drug because federal and case law demonstrates that an individual has the absolute and qualified right to refuse an investigational new drug without exception and without incurring a penalty when exercising that right.

THE COMMON RULE

To understand the deception, one must first understand its need.

In 1972, the American people learned of the human rights atrocities committed against African-American males and their family members in Tuskegee, Alabama, involved in a federally funded syphilis research project. One hundred male participants were needlessly allowed to suffer until death, 40 wives contracted syphilis, and 19 of their children were born with congenital syphilis for no other reason than researchers desiring to study how syphilis progressed within the human anatomy without regard to the value of human life.

In 1973, Senator Edward Kennedy held live hearings regarding medical research abuses committed against persons of color, women, children, mentally disabled, poor, and indigenous Indians by the federal government, the military, and persons acting on behalf of the government. Some of the research abuses include:

A. The US Navy sprayed the entire city of San Francisco with a bacterial agent to study biological warfare (Operation Sea-Spray), injuring many unsuspecting residents;

B. Chester M. Southam of Sloan-Kettering Institute injected live cancer cells into 300 healthy female prisoners without informing them or asking permission;

C. In the early 1960s, Saul Krugman of Willowbrook State School in Staten Island, New York, deliberately infected children with viral hepatitis by feeding them extracts made from infected feces;

D. In 1966, the U.S. Army injected gas, infused with bacteria, throughout the New York City Subway system to study the impact of biological warfare;

E. In the 1950s, the Atomic Energy Commission (AEC) and Nebraska College of Medicine subjected healthy newborns to radioactive iodine to test its effects on the thyroid gland;

F. Throughout the 1960s, Inuit natives in Alaska were treated with radioactive iodine without being informed of the potential dangers, nor did the AEC conduct any long-term follow-up;

G. In the late 1960s, the Department of Defense funded non-consensual whole-body radiation experiments on African-American, poor, and terminally ill persons without informing them of the life-altering dangers;

H. Other illegal research activities numbering in the thousands included irradiating thousands of male testicles, removing skull parts of babies still in the womb, sterilizing black females, chemical baths, irradiating entire towns with nuclear material, infecting prostitutes with STDs to study the spread of disease within prison populations, and untold other horrors that shock the conscience.

In 1974, Congress enacted the National Research Act (NRA)[2] to end federally funded medical research human rights abuses in honor of Senator Edward Kennedy's heroic efforts. The NRA established Institutional Review Boards,[3],[4] the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and required the Health and Human Services Secretary to promulgate regulations on behalf of Congress to ensure the Commission's findings were given the force of law.

The NRA required the Commission to define the legal nature of informed consent. In 1979, the Commission published its findings in the Belmont Report. The Report found that informed consent must be prospectively obtained within a legally approved environment, ensuring the individual considering participation in the research activity is not under "sanction," "coercion," "undue influence," or "unjustifiable pressures," such as financial inducement,[5] to participate.

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[2] Title II of the National Research Act, https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

[3] 45 CFR 46.109(a)

[4] "IRB reviews help to ensure that research participants are protected from research-related risks and treated ethically, a necessary prerequisite for maintaining the public's trust in the research enterprise and allowing science to advance for the common good." — HHS

[5] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

The HHS Secretary codified the findings of the Belmont Report into 45 C.F.R. Part 46, 'The Protection of Human Subjects." The HHS states, "The regulations found at 45 CFR Part 46 are based in large part 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."[6] 45 C.F.R. Part 46 has become known as "The Common Rule."

Today, the federal government is bound to adhere to the Common Rule when it involves humans with investigational medical products, processes, or research activities using federal funds or its authority (§ 46.101). Additionally, the entire federal budget must filter through 45 C.F.R. § 46.122.[7]

The first of two fundamental components to learn from the Common Rule relating to the current emergency declaration is that Congress broadly defined research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[8]

Examples include public university students studying medical charts in a hospital, which requires adherence to the regulatory framework, and a medical doctor prescribing an investigational new drug (IND) to a cancer patient. An IND released under emergency conditions to large populations during a pandemic under the EUA Statute is also a research activity. However, a research activity under the Common Rule is not the same as a clinical trial conducted by the FDA for the purposes of a manufacturer obtaining a marketing license for general commercial marketing.

Congress broadly defined "Human Subject" under the Common Rule to mean an individual whose private identifiable information is known, and data regarding the individual's involvement with the research activity is analyzed and added to the generalizable knowledge. An example of a human subject can be found in the EUA Statute requirement to monitor and report adverse events relating to an individual's interaction with the Pfizer-BioNTech COVID-19 Vaccine drug.

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[6] 45 CFR 46 FAQs. HHS.gov. Published 2018. Accessed March 8, 2024. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html#:~:text=The%20regulations%20found%20at%2045,conducted%20or%20supported%20by%20HHS.

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

[8] 45 CFR 46.102(l)

The federal government purchased the drugs, it requires research activities of individuals whose private identifiable information is collected, and the collected data is added to the generalizable knowledge of the drug. Americans who received one of the federally funded EUA drugs are human subjects[9] involved in a federally funded research activity requiring the federal government to adhere to the Common Rule.

The second fundamental component to understand is that Congress defined informed consent under 45 C.F.R. § 46.116, requiring the individual to be free from outside pressures to participate in a federally funded product, process, or activity involving investigational medical products.[10] Congress changed from requiring "informed consent" to requiring "legally effective informed consent," as outlined under the Belmont Report and 45 C.F.R. § 46.116. Outside pressure to participate in a federally funded IND nullifies legally effective informed consent, even if the individual consents to participate, creating liability for the person offering participation in the product.

"Informed consent procedures which provide for other than legally effective and prospectively obtained consent, fail to constitute informed consent under the HHS regulations for the protection of human research subjects." — Gary B. Ellis, Ph.D., Director Office for Protection from Research Risks.[11]

As an example, when the Department of Occupational Safety and Health Administration (OSHA) issued a requirement for employers to mandate employee participation in the administration of the Pfizer-BioNTech COVID-19 Vaccine drug, it violated 45 C.F.R. § 46.116, 10 U.S.C. § 980 (drugs were procured through DoD funding), and the Belmont Report because the requirement exclusively relied on federally funded investigational new drugs for compliance. (see *infra*, CDC COVID-19 Vaccination Program).

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[9] Americans who received any of the COVID-19 drugs under EUA are currently monitored for adverse reactions to those drugs. They are human subjects in the CDC COVID-19 Vaccination Program and will remain human subjects for years to come, with significant legal consequences to their personal privacy.

[10] "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative." — 45 CFR 46.116(a)(1)

[11] Office. Informed Consent, Legally Effective and Prospectively Obtained (OPRR Letter, 1993). HHS.gov. Published November 30, 2010. Accessed March 8, 2024. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/legally-effective-and-prospectively-obtained/index.html

Lastly, the Common Rule requires strict adherence to the Belmont Report by all federal agencies, departments, and the military.[12] Correspondingly, the Common Rule states, "Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes."[13]

Today, twenty federal departments have adopted the Common Rule within their regulatory framework, including: Agriculture (7 CFR Part 1c), Commerce (15 CFR Part 27), Energy (10 CFR Part 745), Education (34 CFR Part 97), Defense (32 CFR Part 219), Homeland Security (6 CFR Part 46), Housing and Urban Development (24 CFR Part 60), Justice (28 CFR Part 46), Labor (29 CFR Part 21), Transportation (49 CFR Part 11), VA (38 CFR Part 16), International Development (USAID) (22 CFR Part 225), CIA (EO 12333 (1981) amended by EO 13284 (2003) EO 13355 (2004) and EO 13470 (2008)), Consumer Product Safety Commission (16 CFR Part 1028), EPA (40 CFR Part 26), National Aeronautics and Space Administration (14 CFR Part 1230), National Science Foundation (45 CFR Part 690), Office of the Director of National Intelligence (EO 12333 (1981) amended by EO 13284 (2003) EO 13355 (2004) and EO 13470 (2008)), and the Social Security Administration (20 CFR Part 431).

Additionally, Congress was emphatic that the entire military budget must filter through 10 U.S.C. § 980,[14] which requires legally effective informed consent of individuals involved in the agency's research activities.

The Common Rule and supporting statutes exist to ensure individuals will not incur a penalty or lose a benefit to which they are otherwise entitled[15] should they refuse participation in a federally funded research activity (e.g., CDC COVID-19 Vaccination Program). The assurance provides the legally effective informed consent required to prevent future human rights atrocities under the guise of medical research by the Executive branch of the federal government.

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[12] 45 CFR 46.101(c),(i)

[13] *Id.*

[14] "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless—(1) the informed consent of the subject is obtained in advance..."

[15] 45 CFR 46.116(b)(8)

THE FEDERAL WIDE ASSURANCE

In 2000, the federal government created the Office for Human Research Protection (OHRP) "to lead the Department of Health and Human Services' efforts to protect human subjects in biomedical and behavioral research and to provide leadership for all federal agencies that conduct or support human subjects research under the Federal Policy for the Protection of Human Subjects, also known as the Common Rule."[16]

In 2001, the federal government created the Federal Wide Assurance (FWA) program to ensure that it and persons acting on its behalf comply with the Common Rule and the Belmont Report. The program requires any person acting on behalf of the federal government to submit an agreement to HHS of its voluntary compliance with the Common Rule and the Belmont Report.

Today, anyone involving humans with a federally funded research activity must have a FWA agreement on file with HHS under OHRP. All US States, Territories, and Counties have FWAs. The OHRP supervises over 30,000 active FWAs, including federal agencies, military units, hospitals, universities, medical clinics, and federal contractors.

An example is the state of New Jersey Department of Health, which assured HHS that it would comply with the Common Rule and the Belmont Report whenever it involved individuals under its jurisdictional authority with federally funded investigational activities. In exchange for that assurance, HHS assigned New Jersey FWA00029683, providing the state authority to receive federal funds such as funds awarded under the CDC COVID-19 Vaccination Program. New Jersey violated its FWA when issuing its mandatory vaccination policy, exclusively relying on the federally funded COVID-19 EUA drugs for compliance.

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[16] Office. History. HHS.gov. Published June 16, 2009. Accessed March 8, 2024. https://www.hhs.gov/ohrp/about-ohrp/history/index.html#:~:text=The%20Office%20for%20Human%20Research,subjects%20research%20under%20the%20Federal

OHRP, the Common Rule, and the FWA exist for one explicit purpose: to ensure that no individual is threatened with a penalty for refusing to participate in a federally funded investigational medical product or activity such as the federally owned COVID-19 EUA drugs adminsitered to the nation starting in 2021.

OHRP had one job: to prevent involuntary participation in federally funded biomedical and behavioral research activities sponsored by the Executive branch. The question for Congress is why the OHRP leadership willfully failed to perform the duties of its office by allowing the Executive branch to commit human rights abuses against the American public through issuing compulsory mandates involving federally funded investigational new drugs.

The Executive branch would point to the fact that in all of its communications, it explicitly stated that only drugs having received full licensure could be subject to mandatory participation. However, the executive branch knew that Pfizer, Inc. had yet to introduce into commerce its licensed version of the COVID-19 drug for general commercial marketing by the date it had established for compliance with many of its mandatory vaccination policies.

EUA AND THE PREP ACT

In 1938, Congress established the Food, Drug, and Cosmetic Act (FDCA), restricting the introduction of drugs into commerce before the FDA licenses them for general commercial marketing.[17] However, for reasons of education, compassion, and emergency use, Congress created "expanded access protocols for unapproved therapeutics and diagnostics" under 21 U.S.C. §360bbb et. seq., providing access to unlicensed drugs, biologics, and devices under the strict protocols outlined by Congress and the HHS Secretary. Other than 21 U.S.C. §360bbb-3, persons offering a product under the expanded protocol must obtain the individual's written, legally effective informed consent before the product's administration.

On July 21, 2004, Congress enacted Project Bioshield to authorize expanded access protocols[18] during a declared emergency[19] for drugs, biologics, and devices not licensed by the FDA for

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[17] 21 U.S.C. § 355(a)

[18] Project Bioshield amended 21 U.S.C. §360bbb-3. 21 U.S.C. § 360bbb *et. seq.*, has the short title, "Expanded Access to Unapproved Therapies and Diagnostics."

[19] 21 U.S.C. §360bbb-3(b)

their intended emergency use[20] according to the product's labeling when such products do not exist in the marketplace to meet the intended emergency use.[21] Project Bioshield amended 21 U.S.C. §360bbb-3.

"Unlicensed use" means using a medical product for a purpose not licensed by the FDA (e.g., legal indication, usage, and contraindications) according to the product's labeling. "Legal indication" means the FDA-licensed purpose of the drug under 21 U.S.C. § 355(a) and labeled according to 21 CFR 201.57(c). A drug or biologic is regulated according to its labeling, not its formulation. This fact demonstrates that although the FDA licensed COMIRNATY® for ages 12 and older, Pfizer was required to come under EUA for ages 11 and younger because its label did not have a FDA-licensed legal indication for that age group. However, Pfizer only shipped its investigational new drug, requiring all its inventory to be introduced into commerce under emergency use protocols.[22]

An investigational drug does not have a legal indication to treat, cure, or prevent any known disease or virus. The terms "investigational new drug" and "investigational drug" are deemed synonymous under 21 CFR 312.3. Investigational new drug "means a new drug or biological drug that is used in a clinical investigation." (21 CFR 312.3 "Investigational new drug") Clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." (21 CFR 312.3 "Clinical investigation").

Also, an investigational new drug is "a substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people...Also called experimental drug, IND, investigational agent, and investigational drug."[23]

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[20] 21 U.S.C. §§360bbb-3(a)(2)(A)

[21] 21 U.S.C. §360bbb-3(c)(3)

[22] Pfizer made a corporate decision not to manufacture the licensed version of COMIRNATY® after receiving marketing approval in violation of 21 C.F.R. 312.7(c)

[23] NCI Dictionary of Cancer Terms. National Cancer Institute. Published 2023. Accessed June 25, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-new-drug

Congress only authorizes the HHS Secretary to introduce medical products into commerce that are not FDA-licensed for their intended use, and the Secretary's authority is nondelegable. Moreover, Congress requires the Secretary to establish the conditions under which individuals can participate in any activity authorized under the EUA Statute. The Secretary outlines the "Conditions of Authorization" within an emergency use authorization (EUA) letter issued to the authorized product's manufacturer. The manufacturer is legally responsible for ensuring that all volunteering parties adhere to the conditions of authorization. Therefore, the EUA letter becomes the force of law on behalf of Congress during a declared emergency.

To comply with 21 U.S.C. § 355(a)[24] and the Common Rule, Congress requires the Secretary to establish "appropriate conditions"[25] ensuring healthcare providers are informed that the unlicensed product is authorized for emergency use and that individuals are informed of their lawful authority to accept or refuse the product according to their autonomous health goals.

However, Congress was explicit that "Nothing in this section provides the Secretary any authority to require any person[26] to carry out any activity that becomes lawful pursuant to an authorization under this section…".[27] In other words, the Secretary may grant expanded access protocols for the unlicensed use of the medical product. Still, the Secretary cannot require anyone to manufacture, distribute, or participate in the product's administration.

For example, the HHS Secretary issued an EUA on August 23, 2021, for the Pfizer-BioNTech COVID-19 Vaccine drug on the same day the FDA approved COMIRNATY®. Immediately following, the Secretary established conditions of authorization for Pfizer, Inc., "emergency response stakeholders," and "vaccination providers" involved in administering Pfizer's IND.

The Emergency Response Stakeholder is defined as a state's health agency,[28] with assigned duties including:

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[24] "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." 21 U.S.C. §360bbb-3 exempts the drug from this restriction upon the Secretary's issuance of an EUA for the drug.

[25] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)

[26] 21 U.S.C. § 321(e)

[27] 21 U.S.C. §360bbb-3(l)

[28] FDA, EUA letter to Pfizer, August 23, 2021, footnote 12

(1) "Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program,"[29] and

(2) "Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website)."[30]

Therefore, we see that each State was legally responsible for the lawful administration of the COVID-19 investigational new drug ("instruct them about the means" to "administer the vaccine under the EUA"), including ensuring individuals under its jurisdictional authority were made aware of their lawful right to accept or refuse the product without consequence (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)).

The HHS Secretary also assigned duties to "vaccination providers" who are "Organizations" under the CDC COVID-19 Vaccination Program (see *infra*).[31] Those duties include:

(1) "Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program,"[32]

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[29] FDA, EUA letter to Pfizer, August 23, 2021 Letter "O"

[30] FDA, EUA letter to Pfizer, August 23, 2021 Letter "P"

[31] FDA, EUA letter to Pfizer, August 23, 2021 Footnote 13

[32] FDA, EUA letter to Pfizer, August 23, 2021 Letter "R"

(2) "Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose,"[33] and

(3) "Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine."[34]

Therefore, the Organization (e.g., hospitals, medical offices, county health clinics, etc.) was bound to provide the Fact Sheet to potential recipients (e.g., employees, patients, contractors), which served as the official drug label,[35] ensure conditions were established to inform individuals of their lawful right to accept or refuse the product without consequence and monitor and report on adverse events individuals had with the drug to add to the generalizable knowledge about the product.

To ensure all parties involved in the EUA were made aware of the legal status of the Pfizer-BioNTech COVID-19 Vaccine drug despite COMIRNATY® being approved, the FDA required Pfizer, emergency response stakeholders, and vaccination providers to "conspicuously" state on all printed matter and advertising that the Pfizer-BioNTech COVID-19 Vaccine drug "**has not been approved or licensed** by FDA, but has been authorized for emergency use by FDA"[36] (emphasis added).

Under EUAs for the federally funded COVID-19 drugs, a state's health agency was legally responsible for ensuring all persons under its jurisdictional authority were made aware of their lawful authority to accept or refuse the product without consequence. The state had a ministerial duty to ensure vaccination providers it recruited to administer the federal property accepted an individual's chosen option under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

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[33] FDA, EUA letter to Pfizer, August 23, 2021 Letter "S"

[34] FDA, EUA letter to Pfizer, August 23, 2021 Letter "T"

[35] "Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling)" FDA, EUA letter to Pfizer, August 23, 2021, pg 7.

[36] FDA, EUA letter to Pfizer, August 23, 2021 Letter "Y"

As an example, when Marc L. Boom, CEO of Houston Methodist Hospital, issued mandatory participation in the COVID-19 investigational drugs only authorized for emergency use by his employees, he willfully violated the terms of the EUA letter committing fraud (i.e., violated EUA letters, FWA, and the CDC program) against the federal government because the mandate denied the right of healthcare workers to give their legally effective informed consent. Moreover, he willfully interfered in the right of the employees to enjoy a federally funded program, which might constitute an arrestable offense.

The PREP Act was enacted on December 30, 2005, and codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e. The PREP Act is a "program" providing immunities for "covered countermeasures,"[37] "covered persons,"[38] "covered individuals,"[39] and "qualified persons"[40] volunteering to participate in activities or countermeasures authorized under the statute.

The immunities mean the recipients must voluntarily surrender their Fifth and Fourteenth Amendment rights to due process (civil litigation) should they incur injury resulting from participation in the program.

The requirement of a person to voluntarily surrender their due process rights is why Congress explicitly stated that "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."[41]

In plain language, no state or its political subdivisions can establish a legal requirement conflicting with the PREP Act or any requirement under the FDCA covering a countermeasure

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[37] 42 USC § 247d-6d(i)(1)

[38] 42 USC § 247d-6d(i)(2)

[39] 42 USC 247d-6d(a)(3)(C)(i,ii)

[40] 42 USC § 247d-6d(i)(8)

[41] 21 U.S.C. § 301 *et. seq*.

such as the option to accept or refuse an EUA drug, biologic, or device under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). As an example, when Governors in CA, ME, WA, HI, DE, MN, PA, OR, NY, IL, NM, VT, MD, DC, Guam, Puerto Rico, CT, RI, MA, CO, and NJ established the compulsory requirement of specific individuals to participate in a PREP Act covered countermeasure (e.g., Pfizer-BioNTech COVID-19 Vaccine drug, masks, testing articles) they violated the PREP Act's requirements. They deprived individuals of their fundamental due process rights, a legal requirement that the PREP Act expressly preempted those authorities from enacting. Resultantly, their actions were under *ultra vires* authority, which lacked the force of law.

When Governor Newsom (CA) enacted a policy requiring certain individuals in the state to inject one of the listed covered countermeasures into their bodies as a condition of continuing employment under the state's licensing or employment requirements, he established an unconstitutional condition because his policy required the victim to choose between surrendering their constitutional right to due process should they incur injury from the product or its administration or cease enjoying a state benefit. Governor Newsom acted under ultra vires authority because he required individuals to "barter away his life or his freedom, or his substantial rights"[42] as a condition to enjoy a benefit of the state in violation of the federal constitution.

Therefore, when the federal government funds or authorizes the use of an IND involving humans, it and anyone involved in its administration must adhere to the Common Rule, FWA, Article VII of the ICCPR Treaty,[43] and the Belmont Report, among other legal requirements. Those requirements exist specifically for the benefit and protection of the individual involved in the investigational medical product by ensuring individuals can never come under threat of penalty for refusing the administration of the investigational product.

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

[43] The U.S. Senate ratified the ICCPR Treaty in 1992. Article VII states in part "...no one shall be subjected without his free consent to medical or scientific experimentation." The FDA defines medical experimentation as "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." 21 CFR 312.3 "Clinical investigation"

Moreover, Congress completely dominates the field of emergency use protocols for unlicensed products, preempting any state law that conflicts with the federal goals of the statute.[44] Additionally, the PREP Act expressly preempts states and its political subdivisions from interfering in the "voluntary nature" of the PREP Act and/or any requirement under the FDCA for listed countermeasures, including an individual's option to accept or refuse the product. This indisputable fact means that all state and local governments issuing mandatory participation in a product authorized under an EUA or listed as a countermeasure violate federal law and the individual's Constitutional rights.

The preemption language of the two statutes also means that private employers are preempted from using their state's at-will employment law to interfere with an individual's choice when terminating an employee for refusing to participate in activities authorized under the statutes.

CDC COVID-19 VACCINATION PROGRAM

In 2020, the CDC created the CDC COVID-19 Vaccination Program (CDC Program) to distribute federally funded INDs to states in tandem with the state's existing immunization programs. The required use of a state's health department results from that agency having an FWA on file requiring it to adhere to the same laws and regulations the Executive branch was bound to when it purchased the INDs.

The CDC informed the states, emergency response stakeholders, and vaccination providers that:

> "At this time, **all COVID-19 vaccine in the United States has been purchased by the U.S. government** (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use

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[44] *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))

> USG-purchased COVID-19 vaccine. **Other** possession, distribution, delivery, **administration**, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law" (emphasis added).

Because the COVID-19 drugs were FDA-labeled as investigational, the state would become legally obligated to perform for the federal government while owing constitutional obligations (equal protection and due process) to individuals under its authority.

Therefore, the CDC, bound by constitutional, statutory, and regulatory duties to individuals involved in the federally owned INDs, created the CDC COVID-19 Vaccination Program Provider Agreement (Provider Agreement).[45] The Provider Agreement required the Chief Executive Officer, Chief Medical Officer, and other responsible parties within an organization volunteering to participate in the CDC program to agree to "comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in **any EUA** that covers COVID-19 Vaccine"[46] among many other requirements (emphasis added). This includes informing an individual of their lawful authority to accept or refuse the product without consequence to obtain the individual's legally effective informed consent.

Only the state could recruit private parties to act on its behalf to administer the federally funded INDs. For this reason, the state was required to incorporate the CDC Provider Agreement into official state policy. Every state participating in the CDC Program adopted the language into state policy. States would only allow an organization to become authorized to participate if it signed the Provider Agreement, among other state requirements.

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[45] The CDC COVID-19 Vaccination Program Provider Agreement is a contract required of any organization involved in the administration of the federal COVID-19 drug property. The Provider Agreement is an additional layer of responsibility upon the "Organization" to adhere to and does not replace its duties under the EUA Statute or its EUAs.

[46] CDC COVID-19 Vaccination Program Provider Agreement, paragraph 12(a)

In October 2020, the CDC published its "COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations"[47] (playbook) to states willfully volunteering to participate. The playbook was designed to help states "operationalize a vaccination response to COVID-19 within their jurisdictions" and help states with their "COVID-19 vaccination program planning and implementation."

The Playbook informed the state of its duties before any COVID-19 drug was distributed within the State's jurisdiction, stating:

> (1) "Vaccination provider" refers to any facility, organization, or healthcare provider licensed to possess/administer vaccine or provide vaccination services. A "COVID-19 vaccination provider" is any vaccination provider who has been enrolled in the COVID-19 Vaccination Program.[48]
>
> (2) "Jurisdiction/jurisdictional," as used in this document, refers to the federal immunization funding awardees described in the Executive Summary and their state public health emergency preparedness counterparts who are tasked with developing COVID-19 vaccination plans for submission to CDC.[49]
>
> (3) To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program.[50]
>
> > (a) the vaccination provider must agree to the Provider Agreement whereby they promise to "Comply with FDA's requirements, including EUA-related requirements **described in FDA's Letter of Authorization**, as applicable. Providers **must also administer COVID-19 vaccine in compliance with all**

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[47] COVID-19 Vaccination Program Interim Operational Guidance for Jurisdictions Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.; 2020. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

[48] CDC Playbook, Footnote 1

[49] CDC Playbook, Footnote 2

[50] CDC Playbook, p. 21

applicable state and territorial vaccine laws (emphasis added)."[51]

(4) Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement.[52]

(5) Jurisdictions must facilitate and monitor IIS reporting by enrolled vaccination providers.[53]

(6) State-level personnel must closely monitor activities at the local level **to ensure** the COVID-19 Vaccination Program is implemented throughout the jurisdiction **in adherence with federal guidance and requirements**.[54] (emphasis added)

(7) Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).[55]

(8) Jurisdictions will be provided an opportunity to opt out of having pharmacies in their area receive direct allocations.[56]

(9) Ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for a minimum of 3 years, and made available to CDC upon request.[57]

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[51] The State incorporated the Provider Agreement as its policy when requiring each public or private party to sign and agree to the terms of the CDC Program as a condition to engage in the joint conduct of administering the federally owned COVID-19 drugs on the state's behalf.

[52] CDC Playbook, p. 21

[53] CDC Playbook, p. 35

[54] CDC Playbook, p. 8

[55] CDC Playbook, p. 42

[56] CDC Playbook, p. 26

[57] CDC Playbook, p. 22

Therefore, it is clear that the federal government was bound to comply with the Common Rule and the Belmont Report when it purchased the investigational new drugs. To adhere to its legal responsibilities, it created the CDC Program using a state's FWA to administer the INDs to its inhabitants. The state willfully participated, incorporated the Provider Agreement into state policy, and, as the emergency response stakeholder, assumed the legal duties of recruiting, monitoring, and enforcing the provisions of the Provider Agreement among its recruited parties. Moreover, the recruited parties (i.e., organizations under the Provider Agreement) were obligated to ensure individuals were made aware of their lawful authority to accept or refuse the federally funded products.

The only drugs offered through the CDC Program were federally funded, FDA-labeled as investigational, authorized only for emergency use, and under PREP Act immunity.

The Secretary issued EUAs for the COVID-19 drugs including (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,"[58] (2) "Moderna COVID-19 Vaccine" on December 18, 2020 stating that "Moderna COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication,"[59] 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."[60]

At bottom, the federal government, states, and organizations under the state's CDC program were legally bound to ensure they prospectively obtained an individual's legally effective informed consent without applying punitive actions to individuals refusing the product's administration. Legally effective informed consent under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) is passive and does not require an individual's signature. It simply requires the authority offering the product to create a legally approved environment, ensuring potential participants are free from outside pressures to participate by performing the ministerial act of accepting the individuals' chosen option under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

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[58] 86 Fed.Reg. 5200, Jan. 19, 2021

[59] 86 Fed.Reg. 5200, Jan. 19, 2021

[60] 86 Fed.Reg. 28608, May 27, 2021

As an example, when Governor Inslee (WA) issued Proclamation 24-14.1 requiring healthcare workers to inject the federally funded INDs into their bodies as a condition to continue employment within the state's healthcare industry, he violated the state's FWA, and his agreement under the CDC Program. He required all medical facilities to commit fraud against the U.S. Federal Government by ordering them to engage in "other administration" outside the terms of the Provider Agreement. Moreover, Governor Inslee established an unconstitutional condition and deprived healthcare workers of their equal protection rights under the federally funded program. His Proclamation directly interfered with an individual's right to enjoy a federally funded program, which could be considered an arrestable offense because he knew that he could not enact the Proclamation as applied to the exclusive use of the federal property, but proceeded anyway despite his agreement.

When the executive branch established the CDC program, Congress explicitly required it to ensure individuals were not under "coercion," "unjustifiable pressure," or "undue influence" to participate in the federally funded COVID-19 INDs. Moreover, Congress was explicit that no person could incur a penalty or lose a benefit to which they were otherwise entitled when refusing participation in the federally funded program.

Therefore, why deception? First, it is an individual's qualified right to refuse participation in the federal program and its investigational drugs without consequence. Second, had Pfizer shipped its licensed drug, then all of the adverse events would have required investigation by Pfizer, and those events would have been attributed to Pfizer's licensed version under the FDA's FAERS reporting system, which holds liability for drug manufacturers. For example, Pfizer had to pay over $1.2b for fraud relating to Bextra and other drugs. Bextra was linked to 1,054 deaths and 10,497 serious adverse events over 20 years. The Pfizer-BioNTech COVID-19 Vaccine drug has well surpassed those numbers in less than three years. Third, the deception allowed incompetent federal employees (e.g., DoD, CMS, VA, etc.) to do the dirty work of violating individuals' legal rights while protecting the Executive branch from the resulting consequences.

DOD COVID-19 EUA

On August 24, 2021, Secretary of Defense Lloyd Austin (SECDEF) issued his "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members" memorandum.

The Secretary stated in part:

> (1) "After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people,"
>
> (2) "I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19,"
>
> (3) "Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated,"
>
> (4) "Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance,"
>
> (5) "Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy <u>are considered fully vaccinated</u>" (emphasis added).

On that account, one could say that SECDEF's mandatory vaccination requirements are met if a person receives the administration of a mandatory (FDA-licensed)/voluntary (EUA) COVID-19 drug.

The Department of Defense (DoD) issues Department of Defense Instructions (DoDI) to its commanders, which are plain-language interpretations of federal laws impacting DoD affairs.

DoDI 6200.02[61] is activated when the "FDA has determined [the drug] may not be used for its intended purpose without an Emergency Use Authorization or under rules applicable to investigational new drugs or investigational devices" (emphasis added).[62]

DoDI 6200.02 clearly states who is legally responsible for what, where, when, and how an EUA or IND product is introduced within the DoD. This report lists the persons responsible for introducing COVID-19 INDs under EUA during 2021.

Dr. Terry Adirim, Assistant Secretary of Defense for Health Affairs, was required to authorize the use of an EUA/IND product within the DoD. Once authorized, she and Under Secretary of Defense for Personnel and Readiness (USD(P&R)) Gil Cisneros had primary legal oversight responsibilities.

The Secretary of the Army, Christine Wormuth, was the lead component liable for the lawful implementation of the drug's "medical protocol" DoD-wide.

The Surgeon General of the Army, Scott Dingle, and Headquarters US Army Medical Research and Development Command (HQ USAMRDC) act as the single Institutional Review Board, monitoring the drug's safety and reporting adverse events, and ensuring lawful compliance with 45 C.F.R. Part 46, 32 C.F.R. 219, and the Belmont Report.

The above-named persons were required to develop a medical protocol for the use of the EUA/IND drug and then submit it to Joint Chiefs of Staff General Mark A. Milley and General Counsel Caroline Krass, who approved the protocol for use.

At all times material, the aforementioned DoD officials (Cisneros, Terry Adirim, Christine Wormuth, and Scott Dingle) were legally bound to monitor the lawful implementation of the EUA drugs and enforce the laws regulating the drugs within the DoD.

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[61] https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620002p.pdf

[62] DoDI 6200.02, E2.7

The DoD is bound to voluminous laws regarding the administration of drugs not licensed by the FDA for general commercial marketing, including, but not limited to, 32 C.F.R. 219, DoDI 6200.02, 21 C.F.R. 50.23, 21 C.F.R. 312, 10 U.S.C. 1107, EO 13139, HQ MRDC Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements,[63] U.S. Food and Drug Administration (FDA) Guidance, Emergency Use Authorization of Medical Products and Related Authorities (Jan 2017),[64] 21 C.F.R. 54&56, Defense Acquisition Regulations System 48 CFR Parts 207, 235, and 252, Defense Federal Acquisition Regulation Supplement; Protection of Human Subjects in Research Projects (DFARS Case 2007-D008), DoDI 3210.07, DoDI 3216.02, DoDD 5400.11-R, Army Regulation (AR) 70-25, 21 U.S.C. §360bbb-3, 10 U.S.C. § 980.

To this end, the DoD provides an assurance[65] that it will comply with the following protocols anytime it involves humans under its authority with investigational medical products:

> (1) Nuremburg Code, 1946;
>
> (2) Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 18 April 1979: Protections for human research subjects are primarily founded on the three basic principles of the Belmont Report (1979). These principles are: (1) respect for persons; (2) beneficence; and (3) justice. These fundamental principles for the protection of human research subjects are embodied in the Federal regulations at 32 CFR 219, also called the Federal Policy or the Common Rule. The HQ MRDC IRB's written operational policies and procedures are based primarily on the requirement of these Federal regulations and also other requirements.
>
> (3) World Medical Association (WMA) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza, Brazil, October 2013

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[63] https://mrdc.health.mil/assets/docs/orp/irbo/IRB_Policies_Procedures_2018_Common_Rule.pdf

[64] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

[65] HQ MRDC Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements, pg 141

(4) Council for International Organizations of Medical Sciences - International Ethical Guidelines for Health-Related Research Involving Humans (Council for Organizations of Medical Sciences ((CIOMS)) International Ethical Guidelines) Prepared by CIOMS in collaboration with the World Health Organization (WHO), 2016

(5) International Conference on Harmonization (ICH) - Harmonized Tripartite Consolidated Guideline for Good Clinical Practice: Efficacy Guideline – 6(R2) (ICH-GCP-E6(R2)), 2016

Moreover, the DoD is required to provide ongoing education to commanders of their lawful requirements under the Common Rule and the Belmont Report.[66]

On January 28, 2005, HHS issued the first EUA[67] under its new Section 564 authority. The military requested EUA protocols for Anthrax Vaccine Adsorbed (AVA) for civilian and active service members. HHS stated, "The issuance of this Authorization for the emergency use of AVA is the first time that the EUA authority is being used. FDA intends to explain clearly the reasons for each issuance, termination, or revocation of an EUA. The agency wishes to make its decision-making understandable to help ensure that members of the public, and particularly those individuals who may be eligible to receive a medical product authorized for emergency use, are informed about the basis of an EUA determination."

HHS mandated that individuals participating in the AVA investigational product must be informed of the following statements:

A. Individuals (service members and civilians) who refuse anthrax vaccination will not be punished (emphasis added)

B. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice

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66 HQ MRDC Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements, pp, 8,9,33,64,136, and 141

67 https://www.govinfo.gov/content/pkg/FR-2005-02-02/pdf/05-2028.pdf

C. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination

D. There may be no penalty or loss of entitlement for refusing anthrax vaccination

E. This information shall read in the trifold brochure provided to potential vaccine recipients as follows: 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[68]

Section 564 has yet to be amended since the first issued EUA that would authorize legal consequences of DoD personnel refusing the administration of a drug, biologic, or device authorized under its authority.

DoDI 6200.02 is explicit that no service member can come under the compulsory requirement to inject an investigational new drug into their bodies until the President issues a waiver and then only for a specific military operation (E3.4).

EO13139 Section 3 (a) states - "**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" (emphasis added).

The Secretary of Defense is the only person within the DoD authorized by Congress to request a waiver of informed consent[69] involving investigational new drugs. Such a request must be published in the Federal Register,[70] and no such notice has been posted in the Federal Register.

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[68] Federal Register/Vol. 70, No. 21/Wednesday, February 2, 2005/Notices 5455 IV Conditions of Authorization

[69] 10 U.S.C. 1107(f)((3)

[70] DoDI 6200.02, 4.7.3

Therefore, DoD personnel have the absolute and qualified right to refuse an investigational new drug or a product authorized under Section 564 without incurring a penalty or losing a benefit to which they are otherwise entitled. Moreover, DoD personnel are not required to seek a medical or religious exemption to enjoy that right.

At all times material, the only COVID-19 drugs procured by SECDEF Austin for compliance with his "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members" memorandum were the federally funded, investigational new drugs authorized only for emergency use under PREP Act immunity. The DoD was bound to comply with its lawful obligations regarding the Protection of Human Subjects and the CDC Program, including requirements under any EUA.

In plain language, the only drugs made available to service members were those listed under SECDEF Austin's "voluntary" conditions.

Considering that fact, how did SECDEF Austin and other Executive branch civilian appointees justify the punishment of service members exercising a legal right to refuse the administration of the federally funded EUA investigational new drugs?

DOD DECEPTIVE IMPLICATURE

Under the Secretary of Defense for Personnel and Readiness (USD(P&R)), Gil Cisneros had primary legal responsibilities for investigational medical products under a Force Health Protection protocol, regardless of the product's expanded access authorization.[71]

On September 07, 2021 Secretary Cisneros issued his memorandum, "Force Health Protection Guidance (Supplement 23) - Department of Defense Guidance for Coronavirus Disease 2019 Vaccination Attestation and Screening Testing for Unvaccinated Personnel," stating in part:

> (1) "This memorandum applies to all individuals issued a credential by DoD that affords the individual recurring access to DoD facilities,"
>
> (2) "Service Members are required to be vaccinated for COVID-19,"

[71] DoDI 6200.02, 5.1

(3) "Attestation of an individual's status as fully vaccinated or presentation of a recent negative COVID-19 test is a condition of physical access to DoD buildings and DoD-leased spaces in non-DoD buildings in which official DoD business takes place,"

(4) "An individual [civilian or service member] will be considered 'fully vaccinated' when at least 2 weeks have elapsed after a second dose in a two-dose COVID-19 vaccine series, such as of the Pfizer-BioNTech/Comirnaty or Moderna COVID-19 vaccines; or at least 2 weeks have elapsed after a single-dose COVID-19 vaccine, such as Johnson & Johnson's Janssen COVID-19 vaccine. The vaccine **may be** either authorized for emergency use or fully approved; or he or she has completed the recommended dose series of COVID-19 vaccines authorized for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford)" (emphasis added),

(5) "Refusal of COVID-19 testing by unvaccinated DoD civilian employees: (a) DoD Components may initiate adverse employment action, up to and including removal, against unvaccinated civilian employees who refuse COVID-19 testing,"

(6) "begin implementing the attestation requirements of this memorandum no later than September 13, 2021...".

First, Secretary Cisneros would have needed to procure 10 million doses of COMIRNATY® to ensure commanders could comply with his policy by September 13, 2021. Second, Secretary Cisneros violated the Equal Protection and Due Process Clauses by requiring persons refusing the IND to take a COVID-19 test, also under EUA, and not personnel who received the administration of a drug not licensed for any legal indication of which the manufacturer plainly stated that the level of protection was unknown. Third, the Secretary violated the ethical principles of the Belmont Report and the Common Rule by placing service members under threat of penalty for refusing participation in the federally funded investigational program.

We see the first use of the 'either' punctuation mark "/" character in the phrase, "Pfizer-BioNTech/Comirnaty." This means a person is "considered" "fully vaccinated" if they receive the administration of either the EUA or licensed drug. However, there is no context regarding how the drugs apply to SECDEF Austin's voluntary/mandatory options mandate. That being so, Secretary Cisneros omitted guidance on how to apply his Memorandum until mandatory drugs were made available within the DoD, nor did he reference the option to refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) or commanders' lawful obligations under DoDI 6200.02.

Secretary Cisneros required vaccination for the Coronavirus but then stated the vaccines "may be" either EUA, or licensed, without context to SECDEF's mandatory/voluntary conditions. The provided context of "may be" is not clear and was designed to cause commanders to falsely imply to themselves that they can order service members to take either mandatory/voluntary drugs for compliance with Secretary Cisneros' memorandum.

Secretary Cisneros issued eight additional COVID-19 guidance memoranda on October 18, 2021; October 29, 2021; December 20, 2021; December 30, 2021; April 04, 2022; June 29, 2022; August 08, 2022; and August 29, 2022. He does not mention DoDI 6200.02, informed consent, or that the Pfizer-BioNTech COVID-19 Vaccine drug was FDA-classified as investigational and offered only under voluntary conditions.

Secretary Cisneros engaged in fraud by concealment in all of his memoranda and wilfully neglected the duties of his office to ensure the rights of service members were protected when involved in drugs offered only under voluntary conditions.

On September 14, 2021, Terry Adirim, M.D., acting Assistant Secretary of Defense for Health Affairs (ASD(HA)) issued a Memorandum, "Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines" stating in part:

> "On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the Comirnaty vaccine, made by Pfizer-BioNTech, as a two-dose series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the COMIRNATY vaccine. Per FDA guidance, these two vaccines are

> 'interchangeable,' and DoD health care providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine. 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..."

Dr. Terry Adirim purposely used the phrase "as if the doses were the licensed vaccine" to cause DoD personnel to imply to themselves that the two drugs did not have legal distinction within military regulations. The FDA stated the two drugs were legally distinct but were medically interchangeable. Moreover, the FDA informed Dr. Adirim that she was to "conspicuously" state on all printed matter that the Pfizer-BioNTech COVID-19 Vaccine drug was not licensed or approved by the FDA but only offered under EUA.

Dr. Adirim stated, "DoD health care providers **should use** doses distributed under the EUA to administer the vaccination series **as if** the doses were the licensed vaccine." (Emphasis added) Further, Dr. Adirim stated, "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." (Emphasis added).

The phrase "should use" is a non-binding recommendation left up to the discretion of the DoD health care provider. The phrase "will use" is a legally binding directive from which DoD healthcare providers cannot deviate.

The deception lies in the phrases "should use" and "will use" in relation to SECDEF's memorandum. The "should use" applies to the medical interchangeability of the two drugs without Dr. Adirim providing that context. The "will use" applies to SECDEF Austin's mandatory/voluntary conditions to mean the healthcare worker "will use" both to comply with those conditions, but it's left up to the service member's autonomous health goals of which drug he or she will participate in. However, the memorandum lacked the context to effectively instruct DoD personnel when the healthcare worker "will use" the mandatory drug and "will use" the voluntary drug.

On average, commanders or health care providers not familiar with the laws requiring adherence to DoDI 6200.02, seeing this memorandum, would not know to seek a person's legally effective informed consent for the EUA product because they were just ordered to use both products "as if" they were licensed to fulfill SECDEF's mandatory requirements and the term "will use" has significant legal meaning within the DoD.

Instead of writing in unambiguous terms, Dr. Adirim intentionally obfuscated the true meaning of her statement, which would have become abundantly clear had she informed healthcare providers under her authority that they were to ensure DoD personnel were made aware of their rights to refuse Pfizer's EUA drug. Moreover, Dr. Adirim provided no guidance on using EUAs, which can only be attributed to a willful interference in service members' enjoyment of a federal program because only EUA drugs were made available to DoD healthcare personnel, a fact she was intimate with.

However, one must understand the deception in Dr. Adirim's statement that "the Pfizer-BioNTech COVID-19 vaccine" "has the same formulation as the COMIRNATY vaccine." This is a false statement. The FDA stated that on August 23, 2021, the two drugs had the same formulation, but that was only on paper. The Pfizer drugs that were distributed in commerce had differing formulations, and within months, Pfizer would change the formulation once again without manufacturing the licensed version. Therefore, the FDA's statement applies to formulations written on paper, which are not distributed within commerce. Moreover, FDA-licensed drugs are manufactured according to strict safety protocols not found in INDs under an EUA.

Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER), United States Food and Drug Administration, also served as interim director for FDA's Office of Vaccines Research and Review (OVRR) issued a declaration[72] stating:

> (1) "FDA included the interchangeability information in the authorization letter to avoid the unnecessary operational complications that may have resulted if pharmacies or other healthcare practitioners had believed that individuals who had received Pfizer-BioNTech for the first dose were not authorized to receive Comirnaty for the second dose, or vice versa,"

[72] Declaration of Peter Marks, M.D., Ph.D, Rec. Doc. 65-14 in Coker v. Austin, USDC, NDFL, Civil Action No. 3:21-cv-1211.

(2) "While FDA determined Comirnaty and the Pfizer-BioNTech COVID-19 vaccine are medically interchangeable, there are legal distinctions between BLA-approved and EUA-authorized products."

The "legal distinctions" have significant legal consequences for users of the product. Individuals who consent to use an EUA product under PREP Act immunity must consent to:

A. forfeit due process rights resulting from injuries;[73]

B. allow their private identifiable information to be collected and used for a variety of purposes by unknown persons;[74]

C. allow their involvement with the EUA product to be cataloged by various persons for unknown purposes,

D. allow the data collected about their adverse events to be utilized by researchers for unknown purposes and for eternity,[75]

E. assume greater risks to their safety, health, and legal rights.[76]

Military commanders, trained in defending our nation, are not legally sophisticated in treaties, statutes, and the abundance of military regulations protecting service members from experimental drug research abuse. They rely on the honesty of military leaders to guide him or her in effectively protecting the rights of members under their respective authorities.

Gil Cisneros, Dr. Terry Adirim, Scott Dingle, and Christine Wormuth were legally bound by the duties of their offices to ensure military personnel were made aware of their lawful authority to accept or refuse the EUA products without consequence and that commanders were made aware of service members' rights through guidance, education, and instruction and that such

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73 PREP Act forfeits all civil actions for damages in most situations.

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

75 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.

76 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).

failure to perform those duties must be deemed wilful and not through a lack of knowledge because they had to develop the medical protocols for the EUAs and have those protocols approved by DoD General Counsel in advance of the product's administration to DoD personnel.

Dr. Terry Adirim's and Gil Cisneros' memoranda did not provide guidance on service members' rights under the EUA Statute. Dr. Adirim's memorandum gave the impression that laws associated with EUA products could be used interchangeably with laws associated with licensed medical products, which is a felony (misbranding violation) under 21 U.S.C. §331(a).[77]

Subsequently, Gil Cisneros and Dr. Adirim issued memoranda that provided no guidance to the DoD regarding service member rights under the CDC Program, 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), or DoDI 6200.02. Moreover, the guidance gave the false implied belief to commanders within the DoD that the voluntary/mandatory requirements were actually mandatory/mandatory requirements because, according to the implied meanings under the memoranda, there were no legal distinctions between Pfizer's investigational new drug or its licensed drug.

The "should use" and "will use" phrases were designed to cause the healthcare worker and battle commander to violate the rights of service members while providing Dr. Terry Adirim plausible deniability from criminal prosecution because her statement "as if" does not legally mean it is. Moreover, Dr. Adirim is not sophisticated in the use of deceptive implicature; therefore, it is presumed that someone wrote the memorandum on Dr. Adirim's behalf. She, being "plainly incompetent,"[78] issued the memorandum with no regard to the legal consequences of her actions or its impact upon her victims.

Therefore, SECDEF Austin issued a mandate that only FDA-licensed drugs, according to their labeling, would be subject to his mandatory requirement. Gil Cisneros followed up on SECDEF's

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[77] "Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called 'off-label' uses – i.e., any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter." - Justice Department Announces Largest Health Care Fraud Settlement in Its History. Justice.gov. Published September 2, 2009. Accessed November 12, 2023. https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history

[78] "As a matter of public policy, qualified immunity provides ample protection to all but the plainly incompetent or those who knowingly violate the law." *Malley v. Briggs*, 475 U.S. 335, 341 (1986).

memo and issued a memorandum failing to mention the voluntary nature of EUA drugs or that the DoD would operate under DoDI 6200.02 until licensed drugs were procured. Then, Dr. Adirim issues a memorandum conflating medical interchangeability with legal interchangeability through the use of deceptive implicature. The result of the deception is the unlawful separation of more than 8,500 service members and untold tens of thousands of negative consequences applied to members still in service.

Legal Fact: Pfizer, Inc. did not introduce its licensed COMIRNATY® drug into commerce for general commercial marketing before Congress rescinded SECDEF Austin's vaccine mandate.

Pfizer informed the CDC in September of 2022 that they "received initial FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. These NDCs **will not be manufactured**. Only NDCs for the subsequently BLA-approved tris-sucrose formulation will be produced"[79] (emphasis added). However, we also know that Pfizer did not manufacture its licensed tris-sucrose version for general commercial marketing.

Therefore, it cannot be disputed that the DoD did not procure a single drop of COMIRNATY® to lawfully comply with any order given by any DoD authority having a compliance date before Congress rescinded the COVID-19 vaccine mandate.

Let us learn how the various military branches used deceptive implicature established by the aforementioned civilian leaders (Scott Dingle is appointed as the Surgeon General but is not a civilian).

NAVY

On August 30, 2021, Secretary of the Navy (SECNAV) Carlos Del Toro issued a COVID-19 vaccine mandate in reference to SECDEF's mandatory vaccination requirement:

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[79]https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html, accessed September 28, 20222

(1) “Vaccination is the most effective tool we have to prevent widespread manifestation of COVID-19 in our force. Within the last year, millions of Americans have received **approved COVID-19** vaccines in response to this emergency. One of the approved vaccines has received full licensure from the Food and Drug Administration (FDA). This licensure approval provides additional confidence and comfort in the safety of the most effective tool we have in our arsenal against this threat. Considering this threat to the health and readiness of Service Members, vaccination against COVID-19 using a vaccine that has received full licensure from the FDA is now a mandatory requirement…” (emphasis added). Notice the use of the word “approved” and not EUA,

(2) “Effective immediately, all DON active-duty Service Members, who are not already vaccinated or exempted, are required to be fully vaccinated within 90 days, and all Reserve Component Service Members are required to be fully vaccinated within 120 days of this issuance with an FDA approved vaccination against COVID-19.”

(3) “Service Members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated,”

(4) “The order to obtain full vaccination is a lawful order and failure to comply is punishable as a violation of a lawful order under Article 92, Uniform Code of Military Justice, and may result in punitive or adverse administrative action or both.”

The order to receive a “full licensure” vaccine is a lawful order. However, there are unlawful assertions and concealments within the directive, too:

(1) there was no information provided on the requirements of Navy officers to comply with 10 U.S.C.§ 1107&1107(a), 21 U.S.C. §360bbb-3, or DoDI 6200.02,

(2) the Secretary would need to procure more than 700,000 doses (Navy only) of Comrinaty within 90 days for his order to be deemed lawful,

(3) threats of penalty for not being vaccinated were assigned before the availability of a licensed COVID-19 vaccine,

(4) the assertion that a person voluntarily receiving an investigational drug would be immunized from the virus is a prohibited act (21 CFR 312.7(a)) and a misbranding violation under 21 U.S.C. §331(a),

(5) the requirement to obtain a vaccine within 90 days violated the Belmont Report (outside pressure), 45 C.F.R. Part 46, the CDC Program because only investigational new drugs were available for compliance with his order.

On August 31, 2021, Vice Admiral William Merz, Deputy Chief of Naval Operations for Operations, Plans and Strategy, issued administrative instructions for complying with SECNAV's vaccination requirements. His order states:

(1) "COVID-19 vaccination is mandatory for all DoD service members who are not medically or administratively exempt." Under EUA, requiring a person to seek an exemption from an investigational new drug is unlawful. The service member's right to refuse is absolute and exclusively held by the service member, not Secretary Carlos Del Toro,

(2) "Active-duty Navy service members will be fully vaccinated within 90 days from the date of the reference (b). Ready Reserve Navy service members will be fully vaccinated within 120 days from the date of reference (b). New accessions will be fully vaccinated as soon as practicable following service entry,"

(3) "In accordance with references (a), (b), and this NAVADMIN, Navy service members will be fully vaccinated against COVID-19 through administration of vaccines that have received Food and Drug Administration (FDA) licensure or through the voluntary administration of vaccines under FDA Emergency Use

> Authorization (EUA) or World Health Organization (WHO) Emergency Use Listing,"
>
> (4) "This NAVADMIN constitutes a lawful order. Refusal to be fully vaccinated against COVID-19, absent an approved exemption, will constitute a failure to obey a lawful order and is punishable under the Uniform Code of Military Justice and/or may result in administrative action."

The statement that "This NAVADMIN constitutes a lawful order" is false because the Navy did not procure FDA-licensed drugs to comply with its orders. The"will be fully vaccinated within 90 days" was a direct order to all naval commanders to vaccinate sailors without context to the mandatory/voluntary conditions of SECDEF Austin's memorandum. Vice Admiral William Merz's order was illegal, deceptive, lacked context, and, in this author's opinion, an act of wilful concealment of his duties under DoDI 6200.02 to the detriment of America's finest sailors.

On October 13, 2021, ADM William Lescher, Vice Chief of Naval Operations, and VADM John B. Nowell, Jr., Chief of Naval Personnel, issued procedural instructions to Naval personnel stating in part:

> (1) "Per references (a) through (c), active duty Navy service members must be fully vaccinated against COVID-19 NLT 28 November 2021"
>
> (2) "Navy service members refusing the COVID-19 vaccination, absent a pending or approved exemption, shall be processed for administrative separation per this NAVADMIN and supporting references. To ensure a fair and consistent process, separation determinations will be centralized under the CCDA,"
>
> (3) "A Navy service member refusing the vaccine is one who has: (1) received a lawful order to be fully vaccinated against COVID-19; (2) is not or will not be fully vaccinated on the date required by the order; and (3) does not have a pending or approved exemption request per references (d) through (f),"
>
> (4) "Service members are considered fully vaccinated two weeks after completing an approved COVID-19 vaccination series per reference (c)."

ADM William Lescher and VADM John B. Nowell, Jr. (1) established a final compliance date before procuring licensed vaccines, (2) changed the direction of the Navy from threatening members refusing to volunteer for EUA drugs with a criminal prosecution where laws applicable to the issue would exonerate such persons, to allowing combatant commanders not sophisticated in matters of law to "administratively" discharge sailors disobeying a "lawful order," (3) implied that if a sailor "is not or will not be fully vaccinated on the date required" then they have committed a crime under the UCMJ.

ADM William Lescher and VADM John B. Nowell, Jr. refused to reference 10 U.S.C. § 1107&1107(a), 21 U.S.C. §360bbb-3, or DoDI 6200.02. The omitted guidance to Naval officers to hold off on punishments until licensed vaccines were in distribution. Both officers implied that licensed vaccines existed by issuing significant threats of penalty in violation of the U.S. Constitution and the chain of command. They effectively issued a waiver of informed consent without requesting SECDEF Austin for such a waiver to be granted by the President (Commander-in-Chief).

On October 5, 2021 the Navy published the "Covid Vaccine Information for Leadership"[80] FAQ. One of the questions answered was, "How is Comirnaty (COVID-19 VACCINE, mRNA) related to the PFIZER- BIONTECH COVID-19 VACCINE?

> Answer: The FDA-approved Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers provides additional information about both the approved and authorized vaccine." "Per the Assistant Secretary of the Navy (Manpower and Reserve Affairs), ASN(M&RA) memorandum/8SEP21, Use of Pfizer-BioNtech Vaccine for Mandatory Vaccination, **indicates** the Pfizer-BioNtech and Comirnaty vaccines are the

80 https://www.med.navy.mil/Portals/62/Documents/NMFA/NMCPHC/root/Health%20Promotion%20and%20Wellness/Women's%20Health/Documents/Covid19_Resources/Navy_Medicine_COVID-19_Vaccine_Mandate_FAQs_for_Leadership.pdf

same formulation and are interchangeable, and **can be** utilized for the Secretary of Defense COVID-19 vaccination mandate (emphasis added)."

The statement "for purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses" was designed to mislead naval commanders. Most naval commanders would interpret the word "administration" to mean the administration of the vaccination order when, in fact, it means the physical administration of the drugs.

The answer to the FAQ implies, absent contradicting information, that Navy leadership can mandate the voluntary Pfizer-BioNTech COVID-19 EUA drug to meet SECDEF's mandatory requirement.

The word "indicates" was specifically chosen because it gives the reader the impression that Naval leadership is stating "it is" a mandatory drug because it shares formulation with COMIRNATY® even though the word 'indicates' does not factually state that Pfizer-BioNTech is a drug under mandatory conditions.

Should Congress explore the gross abuse of powers within the DoD to be investigated, Congress would find that each military branch issued a highly deceptive FAQ regarding the COVID-19 vaccination order absent an individual's name for accountability purposes.

Naval combatant commanders were naive about laws protecting sailors from medical research abuses. It follows that commanders were remiss of their duties under 10 U.S.C. §1107(a), DoDI 6200.02, and, by voting to remove service members through administrative discharge boards, commanders violated significant Constitutional, statutory, and military regulations.

At all times material, Secretary Carlos Del Toro and his subordinates refrained from guiding naval commanders regarding their lawful obligations under DoDI 6200.02 and applicable federal laws and treated an investigational new drug "as if" it were a licensed drug in violation of federal misbranding laws and sailors' rights.

Moreover, the level of linguistic deception built into the orders required a technical sophistication that the person issuing the orders needed to be educated in. Therefore, the aforementioned naval leaders most likely did not write their memorandums. However, they issued the orders in their name and are liable for the resulting consequences.

MARINES

On September 01, 2021, the United States Marines issued Marine Administrative Message (MARADMIN) 462/21 with the subject "Mandatory COVID-19 Vaccination of Marine Corps Active and Reserve Components."

The MARADMIN states in part:

> (1) "All non-exempt active component personnel will achieve full vaccination no later than 90 days from the date of ref (c),"
>
> (2) "FDA Licensed vaccine(s) are the only vaccine(s) that can be mandated for DoD personnel at this time,"
>
> (3) "However, service members who voluntarily receive a complete initial series of an FDA Emergency Use Authorization (EUA) COVID-19 vaccine, or a vaccine included in the World Health Organization (WHO) Emergency Use Listing, will meet the requirements of refs (b) and (c) [SECDEF Vaccine Requirements] and this MARADMIN,"
>
> (4) "The provisions contained within paragraph 3.a of this MARADMIN constitute a lawful general order and any violation of these provisions is punishable as a violation of Article 92 of ref (i) [UCMJ],"
>
> (5) "COVID-19 vaccines are extremely safe and effective."

On October 07, 2021, the Marines issued MARDMIN 533/21 authorized by Lieutenant General D. J. Furness Deputy Commandant, Plans, Policies, and Operations, stating in part:

> (1) "In order to meet Commandant-directed deadlines as stated in ref (a), all active component service members must receive their first dose of Pfizer-BioNTech/COMIRNATY vaccine no later than 24 October 2021 and all reserve component service members must receive their first dose no later than 24 November 2021,"

(2) "Service members who elect to receive a Food and Drug Administration Emergency Use Authorization COVID-19 vaccine (e.g., Janssen or Moderna) or a vaccine included in the World Health Organization Emergency Use Listing (e.g., AstraZeneca) in lieu of the Pfizer-BioNTech/COMIRNATY vaccine will ensure completion of final dose no later than their respective component deadline,"

(3) "Refusals will be coded in MRRS as "Admin Refusal". Commanders, Commanding Officers, and Officers in Charge may initiate adverse administrative or judicial proceedings in accordance with their authority,"

(4) "Example 1: Commanding Officer (CO) orders Marine to take the vaccine. Marine refuses and does not request a medical exemption or religious accommodation. The CO will document the refusal in MRRS as 'Admin Refusal' and the General Court-Martial Convening Authority (GCMCA) may initiate adverse administrative or judicial proceedings."

Notice how LTG Furness deceptively implied that the "Pfizer-BioNTech" EUA drug was not under EUA when stating "in lieu of the Pfizer-BioNTech/COMIRNATY vaccine." Also, notice how he does not use the full name of "Pfizer-BioNTech COVID-19 Vaccine" within "Pfizer-BioNTech/COMIRNATY." This provides him with plausible deniability by claiming that the "Pfizer-BioNTech" only meant the manufacturer of COMIRNATY® and not an indication of the EUA drug. The use of linguistic deception against our Armed Forces required significant involvement from within the Senior Pentagon leadership, and it is highly doubtful that LTG Furness wrote his memorandum.

The above orders were unlawful because they relied exclusively on investigational new drugs for compliance.

MARINE JAG DIVISION

On September 1, 2021, Col. David J. Bligh was promoted to the rank of Major General and assigned to serve as the Staff Judge Advocate to the commandant of the Marine Corps.

On September 10, 2021, Military Justice Branch of the USMC, Legal Services, issued a "Practice Advisory" under the authority of Major General Bligh stating in part:

> "Food and Drug Administration (FDA) licensed vaccinations are subject to the vaccination mandate. Currently, the only vaccine with a FDA license is the Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA)," "However, in accordance with FDA guidance available at https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, doses of the Pfizer-BioNTech COVID-19 vaccine authorized under the FDA Emergency Use Authorization (EUA) produced prior to the issuance of the FDA license may be used interchangeably with doses produced post-licensing by Pfizer (Comirnaty). The Pfizer COVID-19 vaccines produced prior to and after FDA licensure have the same formulation," (5) "Accordingly, **commanders may order an unvaccinated Marine to receive the Pfizer produced vaccine regardless of whether the particular dose of the Pfizer vaccine to be administered was produced before or after FDA licensure.** Commanders, however, cannot order a Marine to receive any other COVID-19 vaccine, even if the vaccine is approved for use under an EUA or WHO or World Health Organization, (WHO) Emergency Use Listing (i.e., the Moderna or Johnson & Johnson vaccines)," (emphasis added) "Despite not being able to order an unvaccinated Marine to receive the Moderna or Johnson & Johnson vaccines, active duty Marines who voluntarily receive the complete series of these vaccinations by 14 November 2021, or who have previously received a complete series of these vaccinations, will be in compliance with the mandate to be fully vaccinated by 28 November 2021."

The Military Justice Branch of the USMC Legal Services unlawfully advised Commanders that they could commit a felony of misbranding under 21 U.S.C. § 331(a) by treating vials of drugs labeled as an IND "as if" they were labeled as licensed by the FDA. Moreover, the memorandum advised Marine commanders that they could defy SECDEF Austins' memorandum holding that "Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), **in accordance with FDA-approved labeling"** (emphasis added).

Shockingly, the Practice Advisory contradicts itself when it states, "Commanders, however, cannot order a Marine to receive any other COVID-19 vaccine, even if the vaccine is approved for use under an EUA." How does one know if a drug is under EUA? By its labeling, not according to its formulation.

Worse, the offending memorandum advised the USMC that commanders could usurp the Commander-in-Chief's authority to issue a waiver of informed consent for the INDs without the President's knowledge or authority.

The Military Justice Branch of the USMC represents a clear and present danger to the security of the United States of America because it is actively recommending Marines violate civilian authority and the federal constitution.

There is no question that the Military Justice Branch of the USMC fabricated laws to justify political goals and that Col. David J. Bligh approved the unlawful and unconstitutional activity by not correcting the illegal acts resulting from the unlawful Practice Advisory.

Legal Fact: Pfizer, the FDA, CDC, and HHS never informed anyone that the "Pfizer-BioNTech COVID-19 Vaccine" drug was licensed for general commercial marketing. One only has to look at each EUA issued for the IND to know that the FDA was unambiguous that the drug was not licensed or approved by its agency. Moreover, after Comirnaty's approval, the agencies continued regulating the Pfizer IND as an IND. Only DoD personnel changed the legal status of the Pfizer-BioNTech COVID-19 Vaccine drug without any statutory authority to do so.

AIR FORCE

On September 03, 2021, Secretary of the Air Force Frank Kendall issued a memorandum titled "Mandatory Coronavirus Disease 2019 Vaccination of Department of the Air Force Military Members."

Secretary Kendall stated:

> (1) Airmen and Guardians must be "fully vaccinated by 2 November 2021,"
>
> (2) "Only COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA) will be utilized for mandatory vaccination unless a military member volunteers to receive a vaccine that has obtained U.S. Food and Drug Administration Emergency Use Authorization or is included in the World Health Organization's Emergency Use Listing."

To legally apply his legally binding order, Secretary Kendall would need to procure 1.2 million doses of licensed COMIRNATY® by November 2, 2021. As such, Secretary Kendall failed to procure the licensed drugs before penalizing service members for exercising their lawful right to refuse the Pfizer-BioNTech COVID-19 Vaccine drug and/or other EUA drugs.

Secretary Kendall did not reference DoDI 6200.02, 21 U.S.C. §360bbb-3, or 10 U.S.C. § 1107&1107(a) in his memorandum.

On September 03, 2021, the Department of the Air Force released "COVID-19 Vaccination Implementation Guidance" (FAQ sheet) as referenced in Secretary Kendall's memorandum.

The guidance engages in significant use of deceptive implicature as follows:

> (1) "The FDA approved COMIRNATY® and the FDA authorized Pfizer-BioNTech COVID-19 vaccine under emergency use authorization have the same formulation and can be used interchangeably,"
>
> (2) "Providers can use doses distributed under the EUA to administer the vaccination series **as if** the doses were the licensed vaccine according to the FDA. Other vaccines may be added to this list in the future" (emphasis added),
>
> (3) "All other vaccines authorized by the FDA under an EUA will remain voluntary until they receive full FDA approval."

The statement "all other vaccines…under an EUA will remain voluntary" implies that the Pfizer-BioNTech COVID-19 Vaccine drug is not included in that statement. The average Air Force officer would not read between those lines, and as witnessed in the punishments they issued, implied to themselves that the Pfizer-BioNTech EUA Vaccine drug was a mandatory drug under Secretary Kendall's mandate because it had no legal distinction from Comirnaty.

On November 29, 2021, LTG Brian T. Kelly, Deputy Chief of Staff, Manpower, Personnel, and Services, issued unlawful orders when stating, "Airmen who are not fully vaccinated against COVID-19, including those awaiting final decision on a medical exemption or religious

accommodation, are restricted from proceeding on existing PCS orders, or selection for future PCS."

LTG Kelly violated the United States Constitution when assuming the authority of the Commander-in-Chief by waiving the informed consent rights of Airmen refusing EUA and or WHO experimental drugs and applying punishment for refusing their administration.

On December 07, 2021, Secretary Kendall issued a memorandum, "Supplemental Coronavirus Disease 2019 Vaccination Policy," to increase pressure on service members to participate in EUA drugs by stating, "Commanders will take appropriate administrative and disciplinary actions consistent with federal law and Department of the Air Force (DAF) policy in addressing service members who refuse to obey a lawful order to receive the COVID-19 vaccine and do not have a pending separation or retirement, or medical, religious or administrative exemption. Refusal to comply with the vaccination mandate without exemption will result in the member being subject to administrative discharge proceedings."

Secretary Kendall violated his oath of office and a direct order from SECDEF Austin to only use the Pfizer-BioNTech COVID-19 Vaccine under voluntary conditions. He effectively waived the informed consent rights of airmen under his command outside of 10 U.S.C. § 1107 requirements. Moreover, he subjected airmen to the use of investigational new drugs outside of their free consent in violation of the CDC Program requirements, federal law, and military regulations.

ARMY

Christine Wormuth is the Secretary of the Army and executive agent for implementing any investigational medical product, irrespective of its authorized access protocols, DoD-wide.[81]

As the executive agent for implementation, Secretary Wormuth is legally responsible to:

(1) develop "medical protocols" for each product's use within the DoD (DoDI 6200.02 (5.3)),

(2) submit "regulatory" reports to the FDA (5.3),

[81] DoDI 6200.02 (1.3) "the Secretary of the Army as the Lead Component for the use of medical products under EUAs or IND applications."

(3) establish a record-keeping system to report "adverse events" (5.3.1),

(4) "ensure" the USAMRDC initiates an institutional review board under Surgeon General Scott Dingle for the protection of service members' health, safety, and rights (5.3.2, E4.4),

(5) monitor the implementation protocols while the investigational medical products are active.

Secretary Wormuth was well aware that DoDI 6200.02 E3.3 mandated:

> "DoD Components using medical products under an EUA shall comply with all requirements of section 564 of Reference (d), FDA requirements that are established as a condition of granting the EUA (except as provided in section E3.4 concerning a waiver of an option to refuse), guidance from the Secretary of the Army as Lead Component, and instructions from the ASD(HA)." (Emphasis added).

DoDI 62002.02 E3.3 is the "Implementation of EUA" guidance that directly applies to Secretary Wormuth's legal duties.

DoDI 6200.02 E3.4 informed Secretary Wormuth, "Request to the President to Waive an Option to Refuse. In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, the President may, pursuant to section 1107a of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces. Such a waiver is allowed if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security. Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse."

Secretary Wormuth would know if the President issued a waiver, and she knew that the President had yet to issue a waiver for any COVID-19 EUA medical countermeasure before she issued the below order.

On August 25, 2021 Secretary Wormuth's command issued a Fragmentary Order (FRAGO) "FRAGO 4 to HQDA EXORD 225-21 COVID-19 STEADY STATE OPERATIONS/"

A Fragmentary order amends an existing order. The Order states, "This order addresses the Department of the Army implementation of annex FF, mandatory coronavirus disease 2019 vaccination of Department of Defense service members, 24 August 2021.

The order states in pertinent part: (1) "The Army will achieve a minimum of 90% of active-duty soldiers vaccinated NLT [not later than] 01 December 2021," (2) Army National Guard and Army Reserve formations will reach a minimum of 90% vaccinated NLT 1 April 2022."

Secretary Wormuth would need to procure an estimated 1.65 million doses of COMIRNATY® for her order to have the force of law. On August 25, 2021 COMIRNATY® was not in distribution, nor was there an expected or announced date for distribution. Like all other Military Departments, Secretary Wormuth's compliance date was capricious and unlawful because it applied outside pressures on Army personnel to push investigational countermeasure products to meet the compliance deadline.

Secretary Wormuth's office stated, "HQDA has facilitated distribution of doses to meet 75% or more of the command reported service member vaccine demand with an arrival date O/A [on or about] 01 September 2021." September 01 was the ninth day after the FDA approved COMIRNATY®, and Pfizer Inc. had several tasks to complete before manufacturing and distributing the products. Therefore, Secretary Wormuth did not state that she expected enough doses of COMIRNATY® to meet 75% of the Army's vaccine demand.

Secretary Wormuth planned only to use voluntary EUA countermeasure medical products to meet SECDEF's mandatory vaccination requirements from the outset of the Army's initial vaccination mandate.

The FRAGO stated, (1) "Conduct mandatory COVID-19 vaccination operations of unvaccinated service members with the FDA-approved Pfizer/Comirnaty COVID-19 vaccine, or continue voluntary vaccination with Moderna or J&J's Janssen vaccine, (2) While the only mandatory COVID-19 vaccine is the FDA-approved Pfizer/Comirnaty COVID-19 vaccine, service members may choose to receive any EUA authorized vaccine to satisfy the Secretary of Defense COVID-19 vaccination requirement."

Secretary Wormuth joined the other Service Secretaries in deceptive implicature when issuing directives. The overwhelming supply of EUA COVID-19 drugs within the DoD was the EUA Pfizer-BioNTech COVID-19 Vaccine. Yet, Secretary Wormuth also references COMIRNATY® as Pfizer-BioNTech/Comirnaty and, calculatedly, omitted listing the Pfizer-BioNTech COVID-19 Vaccine drug as an example of drugs under voluntary conditions.

The FRAGO continues, "if the soldier continues to refuse to be immunized, counsel the soldier in writing that he or she is legally required to be immunized, that if the soldier continues to refuse to be immunized that he or she will be legally ordered to do so and that failure to obey the order may result in adverse administrative or punitive action as deemed appropriate by the commander." At no time did Secretary Wormuth instruct Army personnel as Secretary of the Army or DoD personnel as the executive agent for EUA implementation protocols on how to proceed until licensed COVID-19 drugs were available to legally enforce SECDEF Austin's mandatory COVID-19 vaccination requirements.

Secretary Wormuth refused to reference DoDI 6200.02, 10 U.S.C. § 1107&1107(a), 21 U.S.C. §360bbb-3, and neglected to discuss presidential waiver requirements in the aforementioned FRAGO.

On November 16, 2021, Secretary Wormuth issued a memorandum titled "Flagging and Bars to Continued Service of Soldiers Who Refuse the COVID-19 Vaccination Order."

The purpose of the Memorandum was to provide "policy and procedures for flagging Soldiers who refuse the COVID-19 vaccination order and are not pending an exemption request." As of November 16, 2021 Secretary Wormuth had not procured a single drop of any COVID-19 drug licensed by the FDA that was also introduced into commerce for general commercial marketing. Wherefore did she issue guidance on flagging soldiers refusing the COVID-19 vaccination?

Secretary Wormuth stated:

> (1) "I have determined all soldiers who refuse the mandatory vaccination order, and who have not received, and are not pending final decision on, a medical or administrative exemption, will remain flagged under flag code 'A.' Soldiers who were previously flagged, and whose flags have since been removed, will be reflagged in accordance with this policy,"

(2) “The effective date of the flag will be the date the Soldier makes a final declination of immunization, following a meeting with a medical professional and second order to receive the vaccine from an immediate commander, as instructed in FRAGO 5 to HQDA EXORD 225-21, paragraph 3.D.8.B.5.A.”

In effect, Secretary Wormuth is ordering members under her command to participate in an investigational medical product by requiring Army officers and medical counselors to initiate the counseling of soldiers before the arrival of a licensed product and to force a soldier into declining the available EUA drugs thus leading to the officer flagging the soldier for punishment. Such an unlawful and wicked scheme is morally reprehensible by any measure.

Finally, Secretary Wormuth states, “In conjunction with this policy, I authorize commanders to impose bars[82] to continued service, under the provisions of AR601-280, for all Soldiers who refuse the mandatory vaccination order without an approved exemption or a pending exemption request.”

How could Secretary Wormuth flag and bar a Soldier for refusing mandatory COVID-19 vaccination when there were no drugs under mandatory requirement available to Army personnel to refuse? Precisely, what was Army personnel penalized for? Refusing an investigational new drug?

Moreover, Secretary Wormuth must inform the DoD of any EUA and knew that she must inform DoD commanders that the FDA did not license or approve the Pfizer-BioNTech COVID-19 Vaccine drug but only offered it under emergency use protocols. Her illicit conduct can only be viewed as an intentional act to deceive.

There can be no argument that SECDEF Austin, Secretaries of Military Branches, and subordinates of the Secretaries issued orders that personnel must be “considered” vaccinated before the DoD procured FDA-licensed vaccines according to the product’s labeling. If they were not considered vaccinated, they would be punished, and they were punished most severely.

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[82] Bar to continued service - “A bar to continued service places a Soldier on notice that his or her continued service may not be in the Army’s best interest…a bar to continued service limits continued service to Soldiers of high moral character and personal competence.” - Army Directive 2016-19

Many NCOs requested to come under court-martial to have the right to defend their actions in a court of law. However, the Senior Pentagon Leadership (SPL) refused such requests. It used administrative separation boards to hide their misconduct, knowing that company commanders would not have the legal knowledge to effectively judge the service member's conduct in light of the law and the federal constitution.

Officers who engaged in the administrative separation of any member that exercised their lawful right under SECDEF Austin's mandate engaged in conduct that dishonored the military profession, and he or she is no longer fit to command the obedience of their subordinates to complete the military mission.[83]

Congressmembers, what should be most shocking is that NOT ONE Judge Advocate General (JAG) issued a public notice of the laws, regulations, and rights of service members pertaining to the use of Pfizer's investigational drug.

Only **ONE** officer within the DoD provided lawful guidance.

LTG Ronald J. Place, the former Director of the Defense Health Agency, which oversees 130,000 military personnel and 400 medical facilities, issued a memorandum "Defense Health Agency Implementation of Department of Defense (DoD) Coronavirus Disease 2019 (COVID-19) Vaccination Program Implementation," on June 16, 2022, informing the Senior Pentagon Leadership and military commanders that "vaccine products for force health protection under EUA will be executed in accordance with" "DoDI 6200.02" and the DoD must inform service members that "they have the option to accept or refuse the EUA product and are free from any consequences of refusing administration of the product."

Congress would find it most difficult to discover another person within the Pentagon leadership who mentioned DoDI 6200.02 or that the Pfizer-BioNTech COVID-19 Vaccine drug was only under EUA according to its labeling and, therefore, could not come under the mandatory requirement.

For his admirable honesty, Senior Pentagon Leadership retired LTG Place.

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[83] *United States v. Forney*, 67 M.J. 271, 275 (C.A.A.F. 2009))

Should any Congressional Committee subpoena any person listed within this report and ask them if they explicitly required any member of the US Armed Forces to inject an unlicensed investigational new drug into their bodies as a condition to continue service, they would not affirm such an act due to the resulting felonies associated with that unlawful conduct. It is stunning that no civilian appointee ever claimed that the Pfizer-BioNTech COVID-19 Vaccine drug was not under EUA; they only implied full-licensure through deceptive implicature.

Civilian appointees and their military subordinates issued an order that service members must be "considered fully vaccinated" before the DoD procured licensed drugs and told them to use the EUA drugs "as if" they were fully licensed for purposes of administration. Then, Senior Pentagon leaders sat back and watched their company commanders falsely imply to themselves that personnel under their authority were required by an act of law to use Pfizer's EUA drug "as if" it was fully licensed. The Senior Pentagon Leadership never educated those commanders of their lawful requirements under DoDI 6200.02 and acted as if those instructions and applicable laws never existed.

The Senior Pentagon leadership engaged in the greatest assault on the United States Armed Forces in the history of our great nation. Service members were not only deprived of their substantive due process rights to refuse an investigational new drug; they were also denied their procedural due process rights because at no time did officers recommending their separation acknowledge the service members' lawful right to refuse the federally funded investigational drugs without incurring a penalty or losing a benefit to which they were otherwise entitled.[84]

Moreover, the custom of ignoring federal law developed by the wilful dereliction of duty by the Senior Pentagon leadership still exists. Congress does not authorize the DoD to require service members to involuntarily surrender their Fifth Amendment Due Process rights by requiring their participation in PREP Act countermeasures as a condition of continued service to the nation. All seasonal influenza vaccines are under the PREP Act, and the DoD has issued a 100% mandatory participation and has issued direct threats to service members refusing the countermeasures.

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[84] Due process means service members had the right "to present [their] case and have its merits fairly judged." *Logan v. Zimmerman Brush Co.*, 455 U.S. 422 (1982). The DoD refused to acknowledge service members' right to refuse Pfizer's investigational new drug, which means the merits of their argument were not "fairly judged."

The moral turpitude of the Senior Pentagon leadership is aptly demonstrated in the fact that after service members were unlawfully separated by their commanders' unconstitutional acts, they required certain service members to repay various bonuses. The Senior Pentagon leadership is actively engaging in the theft of property owned by our greatest heroes because they cannot prove the service members' separation was caused by any illegal act or misconduct committed by the separated member.

Congress should immediately require SECDEF Austin to refute this report. If he cannot, Congress must take appropriate steps to restore faith and trust in military leadership by making all affected members, separated or still serving, whole.

There is no honor in treating those who took an oath to give their lives so that we might live ours as if they are the dirt upon which our feet walk. Should Chairman Mike Rogers of the House Armed Services Committee not act upon this report, we will know what little value the Committee holds for its greatest warriors.

CMS, VA, AND USCIS

The facts regarding the DoD's use of deceptive implicature are replicated in the whole under the Centers for Medicare & Medicaid Services (CMS), Veteran's Administration (VA), and the U.S. Citizenship and Immigration Services (USCIS).

The primary difference is that the executive leadership of CMS and the VA allowed lower-level managers to issue their guidance. Those managers, not legally sophisticated in the laws pertaining to the protection of human subjects, actually issued orders requiring a person to inject the investigational Pfizer-BioNTech COVID-19 Vaccine drug as a condition to continue employment or participate in other related benefits.

CMS ordered medical facilities to ensure personnel were vaccinated by a specific date. However, it was up to the medical facility to inform CMS that no licensed vaccines existed to meet the deadline or that they achieved 100% vaccination status of all individuals agreeing to participate in an EUA drug. After all, every medical facility under the authority of CMS had contracted with the federal government to administer the EUA federal property under the explicit condition they perform the ministerial act of accepting an individual's chosen option

under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).[85] Therefore, the federal government would not have required those facilities to sign a contract promising never to place an individual under outside pressure to participate in the EUA drugs only to turn around and issue a directive requiring them to violate that contract.

However, the order itself was unconstitutional on its face because it required individuals to surrender their due process rights under the PREP Act since all drugs, irrespective of classification, were under immunity by the PREP Act.

Currently, the Executive branch of the federal government requires individuals and their family members under a green card application to inject the EUA drugs (children and immunocompromised) and PREP Act countermeasures (any age) into their bodies as a condition to enjoy a benefit of the federal government which is an unconstitutional condition. As such, that condition has historically been despised by the Supreme Court. Due Process is a fundamental right that the Executive branch cannot require individuals to barter away as a condition of anything, and such a requirement is a direct assault on the fundamental protections under the U.S. Constitution.

The VA harassed, discriminated, terminated, and otherwise legally and financially injured many Americans employed by the agency who exercised their lawful authority to refuse the federally funded investigational drugs. Moreover, the VA required patients to participate in research activities outside of their free consent, which severely violated federal law.

Should Congress sue the Executive branch over its current policies exclusively relying on EUA/PREP Act drugs as a condition for enjoying government benefits, courts would be constitutionally compelled to enjoin the administration's continued use of those policies.

FEDERAL JUDICIARY

Several federal judges are willfully refusing to acknowledge the authority of Congress or its federal agencies, as well as the United States Supreme Court, in their rulings relating to COVID-19 vaccine mandates. Moreover, licensed attorneys nationwide inject false claims without correction from the federal judiciary, even when plaintiffs prove those claims are indisputably false. This is no small matter for Congress to consider because these federal

[85] CDC COVID-19 Vaccination Program Provider Agreement

judges are usurping from Congress its authority to prohibit nonconsensual participation in investigational new drugs or products listed as a countermeasure under the PREP Act.

Although there is much to discuss regarding the malfeasance of the cited judges and law firms, this report will only speak to how the judges and defense lawyers are working to enact fictitious legislation within the judiciary to circumvent the legislative branch of the federal government.

In the below-cited cases, all judges and defense lawyers were notified that the FDA informed the defendants that their "descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that 'This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA.'"

Jill Hunsaker Ryan is the Executive Director of the Colorado Department of Public Health and Environment (CDPHE), lawfully responsible for the state's implementation of the CDC Program, including recruiting medical facilities to administer the federal COVID-19 property. Ms. Ryan knew that she, the State, and its recruited medical providers were legally required to perform the ministerial act of accepting a person's chosen option to accept or refuse and could not engage in discretionary acts interfering with that right. Ms. Ryan and CDPHE's Board Members are under a civil suit[86] for requiring nonconsensual participation in the COVID-19 federal property of healthcare workers. Ms. Ryans' defense is that "Plaintiffs had available a fully approved, and therefore not 'investigational,' vaccine available before they faced disciplinary action" because the FDA approved COMIRNATY®. However, Ms. Ryan refused to speak to the FDA, informing her that Comirnaty might have been approved, but it was unavailable, and she could not treat the IND as if it were licensed. Ms. Ryan and her board members issued a state requirement that effectively required medical facilities to commit fraud against the U.S. Government by requiring them to engage in "other administration" of the EUA drugs outside of the Provider Agreement terms.

Similar responses have been injected into courts involving lawsuits against Governor Newsom (CA), Governor Inslee (WA), Governor Brown (OR), UCHealth (CO), Shriners Hospitals for Children in several states, PeaceHealth in WA and OR, and a dozen others. Law firms refuse to acknowledge lawful notices issued by the FDA or the laws of Congress and are working with the judiciary to change the very nature of those laws established by valid acts of Congress.

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[86] Sweeney v. UCHA, 1:23-cv-2451 (D. Co.)

Federal District Court Judge Thomas O. Rice (Eastern District of Washington) ruled in a case[87] involving healthcare workers suing Shriners Hospitals for Children and Governor Inslee mandating individuals participate in the federally funded investigational new drugs under threat of penalty.

Judge Rice, without citing the Plaintiffs' FDA exhibit stating that the EUA drug was not approved or licensed, incredulously stated that **"the Pfizer-BioNTech vaccine was effectively FDA approved and was not...under the EUA statute or PREP Act"** and therefore, "Plaintiffs' claims that Defendants' vaccination policy was unlawful because an FDA-approved vaccine was unavailable fall short."[Emphasis added.]

Moreover, the Plaintiffs informed the Judge that if he ruled that the investigational drugs were "effectively approved," he would be implying that the HHS Secretary committed a felony by lying to Congress when the Secretary issued additional EUAs since Congress restricts that action if an FDA-approved drug exists in the marketplace.

Judge Tom Rice willfully defied the authority of Congress to establish drug classifications and its agencies' empowerment to manage those classifications. Moreover, Judge Rice was educated not only on drug labeling laws but also on how those laws impact the financial, health, and legal rights of Plaintiffs. Still, Judge Rice chose to invent a drug classification to provide legal cover for Shriners Hospitals for Children, who signed a contract with the federal government and then committed fraud against the Republic by engaging in other administration[88] of the federally funded drugs outside of Plaintiffs' legally effective informed consent.

Federal District Court Judge Robert J. Bryan (Western District of Washington) ruled in a case[89] involving medical practitioners, PeaceHealth, and Governor Inslee mandating individuals

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[87] *Roberts v. Shriners*, 2:23-cv-295-TOR (E.D. Wash. Feb 8, 2024)

[88] "Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if Organization fails to comply with these requirements with respect to the administered COVID-19 Vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose" and "Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq*., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349." — CDC COVID-19 Vaccination Provider Agreement

[89] *Curtis v. Inslee*, 3:23-cv-5741-RJB (W.D. Wash. Dec 21, 2023)

participate in the federally funded investigational new drugs under threat of penalty. Moreover, PeaceHealth's CEO, Liz Dunn, required healthcare workers to publicly display their private health information on badges under threat of penalty, a most severe violation of HIPAA laws enacted by Congress.

Judge Robert J. Bryan was provided with similar facts as in the Shriners case but stated that "a difference in [drug] labeling does not change the outcome of this case" (emphasis added). Why should such a statement concern Congress? The $600 billion pharmaceutical industry operates under laws attached to their product's labeling. Could an injured person, having received the Pfizer-BioNTech COVID-19 Vaccine drug, sue Pfizer "as if" they injected COMIRNATY® into their body and use those corresponding laws in civil litigation? It is a well-established legal and judicial fact that drugs are regulated according to their labeling. Therefore, if a drug is labeled as investigational, then laws regulating that classification should matter to a court of law.

Federal Judges Bryan and Rice are effectively enacting laws declaring that once a drug is approved on paper, then all existing vials of the manufacturer's investigational version are automatically considered approved despite those drugs not being manufactured, distributed, labeled, or administered under BLA-approved laws (21 U.S.C. §355(a)). **If the drugs are retroactively approved, then the laws governing all past administrations must be retroactive, which means injured parties have new legal theories to seek judicial relief in court from those injuries.**

THIRD CIRCUIT COURT OF APPEALS

Third Circuit Appellate Judges Jordan, Krause, and Montgomery-Reeves ruled on a case involving students under threat of penalty by Rutgers University to inject the federally funded investigational new drugs into their bodies as a condition to enjoy a public benefit (education).[90]

Unfortunately, much of what has been discussed in this document was not presented in the Plaintiffs' claims. However, Congress would find it most difficult to discover another three-judge appellate panel that gaslit Plaintiffs' claims and demonstrated a complete lack of judicial and constitutional literacy.

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[90] *Children's Health Defense v. Rutgers*, 22-2970 (3rd Cir. Feb 15, 2024)

First, the three-judge panel cited a statement from the trial court, “As to the Students' preemption claim, the District Court rejected the argument that federal law preempted Rutgers' Policy, in part because ‘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.’” This statement is atrocious, especially coming from the federal judiciary. Mandating adherence to enrollment policies that mandate the use of EUA products is one and the same. The fact that these three judges did not rebuke the lower court for such a ridiculous statement demonstrates that these three judges are judicially incompetent to judge matters of law. The statement was designed to gaslight Plaintiffs’ claims by making plaintiffs second guess what a mandate is and what was mandated.

However, what the judges said next is utterly atrocious: “there is no unqualified right to decide whether to ‘accept or refuse’ an EUA product without consequence. To the contrary, being advised of the consequences is precisely what § 360bbb-3(e)(1)(A)(ii)(III) requires, providing explicitly that the recipient of an EUA product shall be informed ‘of the consequences, if any, of refusing administration of the product.’” The judges judicially implied that the word consequence can mean civil or criminal consequences.

Words cannot describe the number of laws voided by this ruling, which upends more than 50 years of Congressional effort to restrict compulsory requirements in federally funded investigational drugs. Individuals under the Third Circuit Court of Appeals have lost the right to refuse unlicensed medical products under an EUA without incurring a penalty or losing a benefit to which they are otherwise entitled.

Let us review the statute and the federal constitution in light of the ruling. The word “consequence” lacks a definition or contextual meaning within the statute. Therefore, honest judges would examine the statute to discover its true meaning. Although one could not ascertain its true meaning, it is easily found that it could not possibly mean civil or criminal consequences. Congress was explicit that “Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section…”[91] Therefore, if the Secretary is the only person authorized to establish conditions of access to unlicensed drugs during a declared emergency and not even he is authorized to compel participation, then by what authority does a third party possess to

[91] 21 U.S.C. §360bbb-3(l)

require that which Congress prohibits? More importantly, how can a third party apply civil penalties to a federal statute under the FDCA by fiat?

Congress would have had to establish a legal fact under 21 U.S.C. § 331 that refusing an EUA product violates federal law, establish the penalty for non-compliance, and then determine how due process would allow property to be taken from the individual violating the federal statute for these judges to arrive at the legal conclusion that "consequences" is attached to a prohibited act under the FDCA.

The judges' failure to understand fundamental law should disturb Congress because their ruling has led to an absurd result that only results from the judges intentionally misinterpreting the statute's plain language.

Should the Supreme Court allow the Third Circuit to create legislation granting third parties the lawful authority to impute penalties under the FDCA by fiat, then equal protection, due process, and the excessive fines clause will no longer have the force of law under the federal Constitution.

For example, the state university could impose the penalty of losing access to education. Still, a private employer could charge a $200 monthly fine for refusing the product, while another authority could take a doctor's license and career for refusing to participate in the products' administration. Under such a scenario, one can easily see how there is no equality of applied penalty under the same federal statute for the same act.

The FDA provided guidance[92] to the medical community regarding the newly enacted EUA legislation and its meaning of the word "consequence," stating that persons should inform recipients of the "possible health effects" and "stopping the use of [PRODUCT] against the recommendation of the health care provider." The Third Circuit panel did not and could not demonstrate by the federal statute how it derived civil and/or criminal consequences from that word because it does not exist within the statute. Moreover, if consequences could be applied, and they cannot, they must derive from the authority of the HHS Secretary and not from a state university.

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[92] FDA: Guidance Emergency Use Authorization of Medical Products, 2007

The right to refuse an investigational new drug or to refuse participation in medical research activities is "deeply rooted in [our] history and tradition," and it is essential to this Nation's "scheme of ordered liberty." *Timbs v. Indiana*, 586 U. S. ___, 139 S.Ct. 682, 203 L.E.2d 11 (2019).[93] That right is a heightened liberty interest that cannot be taken away without due process.

The Third Circuit panel looked at a right created for the benefit of the individual by a valid act of Congress and then declared that authorities have the ultra vires power to interfere with that right. We know it's ultra vires because Congress does not allow any person's authority to amend the FDCA, penalize individuals refusing an unlicensed medical product, or refuse participation in medical research activity. Like many others, Rutgers University misrepresented its authority and amended the EUA that Congress and the HHS Secretary established. However, the Third Circuit Court of Appeals did not have a problem with such unconstitutional activity. How can a state agency amend federal statutes? Not by the federal constitution, that is for certain, but only under the ultra vires rulings of the Third Circuit Court of Appeals.

The fanciful ideas that the aforementioned federal judges and state actors present to the judiciary demonstrate the nonsensical nature of their rulings. The House Judiciary Committee should review the cases and, upon affirmative findings, take appropriate steps to ensure that the judiciary upholds the integrity of the laws passed by Congress.

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[93] The Supreme Court "has long said that it will recognize those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 720– 21 (1997) (cleaned up). And it reaffirmed this approach earlier this year. See *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2242, 2246 (2022)." *Golden Glow Tanning Salon, Inc. v. City of Columbus, Miss.*, 52 F.4th 974 (5th Cir. 2022) Congress enacted the Federal Food, Drug, and Cosmetic Act (June 25, 1938, ch. 675. § 1, 52 Stat. 1040) prohibiting persons from introducing drugs into commerce before FDA approves the drug for general commercial marketing. Since 1938, it has extensively regulated the pharmaceutical industry and established who, what, when, and how drugs will be introduced to the public. In 1974, Congress took a strong position that no person can require another person to participate in the administration of an investigational new drug, biologic, or device under threat of incurring a penalty or losing a benefit to which they are otherwise entitled by enacting the National Research Act. That Act led to the Belmont Report, 45 C.F.R. § 46, 21 C.F.R. § 312, 21 C.F.R. §§50,56, Article VII ICCPR Treaty, FWA, 10 U.S.C. § 980, 10 U.S.C. §§ 1107,1107(a) demonstrating rights "deeply rooted in the Nation's history" and for this very specific reason Congress created the right to refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) to ensure the fundamental right to refuse an investigational new drug was secured even when a declared emergency exists. Moreover, *Abigail Alliance v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) held that the Secretary alone has authority to establish conditions under which the public can access investigational new drugs and that such authority was deeply rooted in the concepts of liberty for the explicit purpose of protecting humans involved in the investigational use of drugs. The *Abigail* Court held there is no fundamental right to access an investigational new drug, and the Supreme Court denied certiorari.

The Judicial Conduct and Disability Act of 1980[94] provides one such remedy for judges whose "conduct [is] prejudicial to the effective and expeditious administration of the business of the courts" (emphasis added).

CONCLUSION

The purpose of this report was not meant to be political, although one understands the political nature of events spoken about within. Its purpose was to compel Congress to act to secure its laws for the benefit of the American people, restoring order and liberty. Congress can act by using the authority and funding of its committees to sue the Executive branch regarding its current policies requiring Americans to surrender their Fifth Amendment due process and federal statutory rights as a condition to enjoy federal benefits. Additionally, Congress must use its authority to enact legislation restoring the rights and finances of victimized federal employees and our nation's Armed Forces members.

Moreover, Congress could request the Supreme Court to issue a ruling on the laws pertaining to the EUA Statute and PREP Act as a matter of law, not pertaining to any set of particular facts. Such a ruling would immediately restore Congress's authority to prohibit nonconsensual participation in drugs, biologics, or devices authorized only for emergency use.

WARNING

History has proven that when courts no longer provide just and fair rulings, ensuring citizens of the nation are treated equally before the law, then victims of unjust acts secure their version of due process. History has also proven that a civilized society must avoid such personal acts of justice at all costs. The federal judiciary is losing its credibility with the American people. Should Congress not work expeditiously with the Supreme Court and its Appellate Courts to restore faith in the federal judiciary, we will witness the fire such failure brings within the next few years. If there is one thing that history has proven beyond dispute, it is that it repeats itself.

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[94] 21 U.S.C. §§ 351-364

ABOUT THE AUTHOR

Brian Ward is gifted in solving complex problems and was approached in the fall of 2021 by members of the Armed Forces and in the fall of 2022 by healthcare workers to solve the COVID-19 vaccine mandate problem. This document represents 2,000 hours dedicated to fulfilling his promise to service members and healthcare workers to restore their equality before the law and to secure what was stolen from them, including the dignity of the healthcare worker and the honor of the military profession. A PDF copy of this report can be downloaded at COVIDPenalty.com