THE LEGAL RIGHT TO REFUSE

COVID-19 Report

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BRIAN WARD

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The Legal Right to Refuse COVID-19 EUA Medical Products Without Consequence or Loss of Benefits

SUMMARY

On August 23, 2021, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) letter to pharmaceutical manufacturer, Pfizer, Inc. regarding licensed and unlicensed COVID-19 drugs. In that EUA letter, the FDA informed Pfizer, "The licensed vaccine has the same formulation as the EUA vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness."

We can ascertain the true meaning of 'interchangeability' by reading Pfizer's press release, "An individual may be offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2." (https://www.businesswire.com/news/home/20210823005499/en/)

Both political and corporate actors ignored the FDA's statement concerning the legally distinct nature of the unlicensed vaccine and used the above 'interchangeability' statement of medical intent as the paradigm to deprive Americans of employment, health, and for many, life itself. Executive Branch leaders in federal and state governments engaged in the most comprehensive misinformation campaign ever devised to deny citizen rights and destroy the lives of the American people.

"Legally distinct" carries enormous weight in the context of the COVID-19 pandemic. Authorities at the FDA and other Executive Branch agencies intentionally obfuscated the distinction's significance. The result of their gross negligence (willful conduct affecting the life or property or another) has led to the slaughter of thousands of Americans and harm to the financial, physical, and mental well-being of millions of others.

Government actors and corporate employers NEVER had the right to penalize individuals who refused a 21 CFR 312.3 Investigational New Drug, such as Pfizer's BioNTech COVID-19 Vaccine. This statement is irrefutable by statute.

Current COVID-19 vaccine mandates are illegal because they rely solely on the use of clinical research drugs for compliance.

DOCUMENT NOTE

Special consideration was given to ensure the contents herein are intelligible for all readers. Laws governing bioethics and clinical research drugs are too numerous to all be listed here. Nevertheless, the author provides a comprehensive foundation attesting each U.S. citizen's *right to refuse EUA products without penalty*. Lastly, the author is not affiliated with any organization. Many have joined in the production of this document to save the rights and lives of an entire nation.

COVID-19 VACCINE FACTS

To this date, the only available COVID-19 vaccines in the United States are still classified by the FDA as Investigational New Drugs (IND). For example, on August 23, 2021, the FDA informed pharmaceutical manufacturer Pfizer that BioNTech's COVID-19 Vaccine had "not been approved or licensed by the FDA" and they "must submit to Investigational New Drug application number 19736." The FDA has reissued and amended Pfizer's EUA several times and the same language exists in them all.

An IND is defined as “a new drug or biological drug that is used in a clinical investigation (21 CFR 312.3).” A clinical investigation is “any use of a drug except for the use of a marketed drug in the course of medical practice. (21 CFR 312.3)” Legally speaking, medical experimentation is to involve a human in an IND under any element of research (e.g., study of adverse events). Furthermore, all EUA medical products are legally regarded as experimental for their intended purpose.

Adherence to the protocols resulting from the National Research Act (1974) strictly requires the free will and voluntary consent of individuals agreeing to participate in the administration of drugs or biologics classified as IND.

To date, the FDA has assigned IND classification to each COVID-19 drug under an EUA, namely:

a. Pfizer BioNTech COVID-19 Vaccine 19736
b. Janssen IND 22657
c. Moderna IND 19745
d. Novavax IND 22430

BRIEF HISTORY OF MEDICAL HUMAN RIGHTS ABUSES

In 1906, Americans were riveted by Upton Sinclair’s investigative report titled 'The Jungle,' where he described the unsanitary manufacturing process of canned meats, including the use of rotten meat and pulverized rats. Across the country, individuals experienced life-altering health conditions, even death, after consuming these tainted products. Congress responded with the Pure Food and Drug Act in 1906, providing oversight and regulation of pre-made food products.

In 1937, when Elixir Sulfanilamide, a poisonous antibiotic, was administered to 107 subjects, primarily children, 107 were killed. In 1938, Congress passed the Federal Food, Drug, and Cosmetic (FDC) Act, requiring safety and efficacy testing before a drug is introduced into commerce. In 1951, Congress passed the Durham-Humphrey Amendment mandating that certain drugs

can only be dispensed through a prescription. In 1962, Thalidomide was found to cause congenital disabilities in thousands of babies throughout Western Europe. Congress proactively passed the Kefauver-Harris Drug Amendments requiring manufacturers to prove a drug's safety and efficacy according to the FDC Act prior to marketing in the United States.

Although Congress enacted laws preventing life-altering health issues from marketable food and drug products, their efforts inadvertently led to a new, far more dangerous human rights abuse: product research. The burgeoning requirement to prove a product's safety and efficacy before marketing led to unethical medical research practices not restrained by protective law.

In 1941, virologist Thomas Frank and other researchers at the University of Michigan infected mentally disabled patients with the influenza virus through the use of nasal spray without the effective consent of the patient. From 1946 to 1948, the United States Army and the National Institutes of Health injected sexually transmitted diseases into prostitutes. The prostitutes were subsequently trafficked into prisons, insane asylums, and the Guatemalan army to spread the diseases for study. Researchers at Harvard University, in conjunction with the University of Chicago, injected pregnant women with synthetic estrogen without their knowledge in the 1940s, leading to a high rate of miscarriages and overall fewer babies born resulting in an artificially low birth rate. In 1950, the United States Navy simulated a biological warfare attack by spraying large quantities of bacteria over the city of San Francisco, ensuring that each resident would be subjected to the foreign agent. Several residents contracted pneumonia-like illnesses. In 1952, Sloan-Kettering Institute researcher Chester M. Southam injected live cancer cells into 300 healthy female prisoners without their knowledge or consent.

The horrific abuse of human rights by medical researchers in America was so pervasive that Nazis used that research as the basis of their defense during the Nuremberg Trials.

In 1972, newspapers exposed a Centers for Disease Control (CDC) research project in Tuskegee, Alabama. To study how syphilis progressed in human anatomy, researchers intentionally withheld known treatment for syphilis and allowed African-Americans to suffer until death, leaving 128 men dead, 40 wives disease-ridden, and 19 children born with congenital syphilis.

The medical community's atrocities against the American people under the excuse of advancing medicine for humanity required Congress to take swift, definitive action.

THE NATIONAL RESEARCH ACT (1974)

In response to the atrocities committed against individuals by medical researchers, Senator Edward Kennedy led a series of congressional hearings on the abuses of human-subjects research. Congress subsequently passed the National Research Act in 1974. This Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including ethical guidelines when involving humans in medical experimentation. The National Research Act included publication of the Belmont Report, the formalized process of Institutional Review Boards (IRB), and the creation of specific Codes of Federal Regulation (CFR), namely 45 CFR 46 which is also known as the Common Rule.

INSTITUTIONAL REVIEW BOARDS

An Institutional Review Board is established "to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research." (Office. (2019). *IRB-FAQs*. U.S. Food and Drug Administration.)

These IRBs "use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research." (Office. (2019). *IRB-FAQs*. U.S. Food and Drug Administration.)

21 CFR Parts 50 & 56 and 45 CFR Part 46 are the primary regulations governing IRBs.

IRBs must comply with the following conditions:

(1) Must provide a written assurance to HHS that they will comply with the protection of human subjects regulations (45 CFR 46) and, by extension, the ethical principles of the Belmont Report.

(2) "The fundamental purpose of IRB review of informed consent is to assure that the rights and welfare of subjects are protected." - FDA

(3) IRB review is not required for the first use of a test article administered under emergency conditions but subsequent uses do require IRB review. 21 CFR 56.104(c)

(4) Required for all expanded access protocols (Title 21 US Code Chapter 9 Subchapter V Part E) even if only one individual is involved.

As quoted above, the IRB review assures "appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research." - FDA (IRB Purpose, 2019)

NOTE: IRB review is required for all current EUA protocols.

THE BELMONT REPORT

Congress charged the Commission writing the report to consider the nature and definition of informed consent, among other requirements. In February 1976, the Commission met at the Smithsonian Institution's Belmont Conference Center in Maryland and drafted the Belmont Report from nearly 800 pages of submitted essays by respected medical professionals. The report was published in the Federal Register on April 18, 1979, and was later codified into federal law, the regulatory framework of 24 federal agencies, and all U.S. States and Territories.
(The National Commission for the Protection of Human Subjects of

Biomedical and Behavioral Research.- Belmont Report. Washington, DC: U.S. Department of Health and Human Services,1979.)

The Belmont Report provided contextual meaning to informed consent:

> (1) Respect for Persons requires the acknowledgment of the individual's autonomy: "An autonomous person is an individual capable of deliberation about personal goals and acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions…"
>
> (2) "To show lack of Respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments…"
>
> (3) "Respect for persons requires subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied,"
>
> (4) The Belmont Report defines what is considered "adequate standards of informed consent" as follows:
>
> a. "An agreement to participate in research (e.g., participation in COVID-19 EUA drugs) constitutes valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence."
>
> b. "Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance."
>
> c. "Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may

become undue influences if the subject is especially vulnerable (economically poor, uneducated, imprisoned, etc.)"

d. "Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject."

e. "…undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled."

Researchers could no longer rely on a simple 'Yes' or 'No' to participate in clinical research drugs. They were required to create a legally approved environment before allowing individuals to participate. That environment required "conditions" free of outside pressures to participate. The federal government would soon take this new approach and codify it into law by requiring an individual's "Legally Effective Informed Consent" in advance of any research activity (e.g., Coronavirus Disease COVID-19 Pandemic EUA program).

We must first discuss 45 CFR 46 before we can understand "Legally Effective Informed Consent."

45 CFR 46 (The Common Rule)

In the late 1970s and early 1980s, the U.S. Department of Health and Human Services (HHS) developed 45 CFR 46 (Common Rule) to protect individuals involved in clinical research products to ensure past human research atrocities were never repeated. HHS stated that "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."

On July 19, 2018, federal agencies adopted an updated Common Rule (2018 Revised Common Rule) impacting the entire federal government and those entities conducting business with those entities.

45 CFR 46 "applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel…and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy."

A subject is legally defined as:

(1) human being
(2) information about the human's involvement with research activity is obtained and studied and used to add to the generalizable knowledge of the product and
(3) personal identifiable private information of the human is obtained during any part of the research activity. (45 CFR 46.102(e)(1)(i)-(ii))

Research requiring IRB review is defined as:

(1) private identifiable information about the subject is known
(2) information about the individual's involvement with the drug is:
    (a) recorded
    (b) studied
    (c) monitored
    (d) researched to contribute to the product's knowledge

Pursuant to 45 CFR 46.102(l), "research" means "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Activities are considered research

under this policy "whether or not they are conducted or supported under a program that is considered research for other purposes."

HHS Office of Research Integrity defines research as: (1) "conducted with the intention of drawing conclusions that have some general applicability," and (2) "uses a commonly accepted scientific method." Examples of systemic investigations include: questionnaires, surveys, epidemiological studies, medical chart reviews, and post surgery sample collection studies.

These non-invasive "research" activities fall under 45 CFR 46 compliance requirements and are pointed out to demonstrate that laws protecting humans in research activities are not limited in scope only to clinical trial studies. Research is any activity designed to contribute to generalizable knowledge about the subject matter.

Title 21 US Code Chapter 9 Subchapter V Part E (expanded access protocols) requires pharmaceutical companies and vaccination providers to monitor, record, study (research), and report adverse reactions of drugs, biologics, or devices utilized for expanded access protocols or under emergency authorizations. Moreover, these protocols require either written or oral informed consent and the private identifiable information of the subject before administration of the product. Therefore, participants are considered subjects in a medical research activity even if that activity is not considered a clinical trial.

For example, the FDA issued an EUA for Pfizer's BioNTech COVID-19 Vaccine on August 23, 2021. The FDA required Pfizer:

(1) "report to Vaccine Adverse Event Reporting System:" a) "serious adverse events", b) "cases of multisystem inflammatory syndrome (MIS)," c) "cases of COVID-19 that result in hospitalization or death," and d) submission of periodic safety reports for evaluation.

(2) "Vaccination providers administering the vaccine must report," a) vaccine administration errors, b) adverse reactions, c) MIS cases, and d) hospitalizations and deaths from a vaccine.

(3) Vaccination providers must: "conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances."

21 U.S.C. §360bbb-3 and all current EUAs require the following:

(1) Human Beings
(2) Disclosure of private identifiable information of humans involved in the EUA product for purposes of billing and adverse event reporting
(3) Reporting of any adverse reaction to the vaccine by the individual
(4) Reporting of specific adverse reactions to the vaccine by the individual
(5) Periodic safety reporting of those adverse events to draw a conclusion

Therefore, utilizing just a few of the required conditions under each assigned EUA, we see that individuals involved in an EUA medical product are considered research subjects. Therefore, these subjects are required to come under the review of an IRB which is regulated by 45 CFR 46.

The Belmont Report made explicit when activities must be scrutinized: "the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."

The above citation repudiates false claims and misstatements by lawyers that 45 CFR 46 applies ONLY to clinical trial studies.

Moreover, if EUA medical products are not researched for safety and efficacy, would that not incur serious violation of human rights and trigger liability? Should a healthcare provider notice severe adverse reactions and not report and or take action to protect human life, would they not be culpable in future injuries? Title 21 US Code Chapter 9 Subchapter V Part E expanded access protocol implementation requires research activity.

A fundamental lack of knowledge about the legal definition of research and its application of COVID-19 EUA Vaccines to 45 CFR 46 and the Belmont Report has delayed victory for the American people to opt out of these INDs without penalty effectively.

LEGALLY EFFECTIVE INFORMED CONSENT

HHS codified a "set of adequate conditions" to obtain informed consent. Those conditions, when adhered to, provide the healthcare professional the ability to obtain the individual's legally effective informed consent.

21 U.S. Code, SECTION 360bbb-3 564 (A)(i) is a congressional requirement for the Secretary (HHS) to "Appropriate conditions designed to ensure that individuals to whom the product is administered are informed." This section of the law outlines the information required to be given in advance to the recipient. Once the individual is adequately informed of all relevant information, they must agree to accept or refuse based on their autonomous belief that the product may or may not benefit their personal health goals. This process is called 'informed consent.'

However, federal law does not just require the informed consent of individuals involved in INDs under an EUA. More accurately, federal law requires the legally effective informed consent of individuals involved in EUA products.

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

The term "legally effective" means to obtain consent in accordance with all applicable laws and ethical guidelines in advance of the product's administration.

To ensure the individual's informed consent is legally effective, Congress defined the practical application of "the adequate standards for informed consent" as detailed in the Belmont Report.

(1) 45 CFR 46.116(a)(1) "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."

(2) 45 CFR 46.116(a)(2) "An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence."

(3) 45 CFR 46.116(a)(3) "The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative."

(4) "The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."

(5) 45 CFR 46.116(a)(6) "No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."

(6) "A description of any reasonably foreseeable risks or discomforts to the subject."

(7) "A description of any benefits to the subject or to others that may reasonably be expected from the research."

(8) "A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject."

(9) "A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled."

Combining the principles of the Belmont Report and the legal requirements of 45 CFR 46, informed consent is only legally effective if the offer to participate contains no coercion, undue influence, sanctions, or unjustifiable pressures. Further, the offer must inform the individual of the product's benefits, risks, alternatives, in language that is understandable, and to include a statement that participation is voluntary and refusal will not involve a penalty or loss of benefits. Notice how these laws ensure an individual is under no outside pressure to participate and provide them with quality information? This legally approved environment is what courts allow as "legally effective informed consent." The reader should take note how these requirements are "required" conditions under 21 U.S.C. §360bbb-3, discussed later.

IMPORTANT NOTE: 45 CFR 46, and the ethical requirements of the Belmont Report, do not prevent individuals from participating in products under an EUA. On the contrary, these legal obligations are enforced to deter governments, corporations, and individuals from engaging in horrific human rights atrocities during a declared emergency or otherwise. Congress codified the legal meaning of informed consent in the Common Rule to ensure that no individual is coerced under threat of penalty into medical experimentation against their free will and voluntary consent. This is why Congress explicitly did not claim exemption from 45 CFR 46 when enacting Title 21 US Code

Chapter 9 Subchapter V Part E that expands access to drugs and biologics not approved by the FDA for their intended use.

Under 21 U.S.C. §360bbb-3, healthcare professionals are not required to obtain legally effective informed consent in writing for EUA drugs, biologics, or medical devices. The consent process under this section of the law is oral consent, which can be as simple as walking into a pharmacy and requesting a COVID-19 vaccine shot. However, the healthcare professional is legally obligated to ensure they do not place individuals under outside pressure to participate and provide them with the required information in advance of the product's administration.

FEDERAL WIDE ASSURANCE

The Department of Health and Human Services created the Office of Human Research Protections (OHRP) in 2001, which, in turn, established the Federal Wide Assurance (FWA) program. The FWA requires assurances from institutions receiving funding or conducting business with HHS that they will comply with regulations found at 45 CFR 46 and the ethical guidelines of the Belmont Report when engaging in medical research activities. Entities that have FWA agreements are state health agencies, universities, research institutions, hospitals, etc. Institutions with active and deactivated FWA agreements can be found in the following database: https://ohrp.cit.nih.gov/search/fwasearch.aspx

Institutions violating FWA agreements are in danger of losing federal funding and the ability to engage in grants, contracts, and or other activities with HHS. Hospitals have violently ignored their FWA obligations during the COVID-19 pandemic.

BELMONT REPORT'S FORCE OF LAW

Long before legal arguments surrounding COVID-19 mandates came about, lawyers have errantly attempted to attach the Nuremberg Code or Helsinki Declaration to their lawsuits against unethical research practices. However,

if a lawyer takes a legal position in a court of law, it must be from a position of law. International laws, like the Nuremberg Code, do not have the force of law within the United States without separate statutory provisions.

In a 2002 ruling, U.S. District Court Judge Cook tackled this very issue and ruled against plaintiffs claiming the private right of action under the Nuremberg Code, stating:

> "This Court agrees [with] other jurisdictions which have found that there is no private right of action for an alleged violation of international law for the protection of human research subjects under the Declaration of Helsinki and the Nuremberg Code. Moreover, the standard in the United States for conducting research on human subjects is contained in the Code of Federal Regulations and, thus, there is no need for the courts to resort to international law to impute a standard." *Robertson v. McGee*, Case No. 01-CV-60-C, (N.D. Okla. Jan. 28, 2002)

That "standard" for the purpose of our conversation resides in 45 CFR 46 and the Belmont Report.

45 CFR 46.101(a) "This policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel… It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy."

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

45 CFR 46.101(i) "Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report…The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report."

To recap, anytime the federal government funds or supports any research activity involving a human, that activity is required to comply with the ethical principles outlined in the Belmont Report. This legal fact is the purpose behind the FWA program.

The United States Federal government funds all COVID-19 EUA drug research activity.

ICCPR RATIFIED TREATY

In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights (ICCPR) Treaty. Article VII of the Treaty declares that "no one shall be subjected without his free consent to medical or scientific experimentation." In this context, 'subjected' means to be under the rule of law by one's authority or government. 'Free' means to have no outside pressures to participate. Medical experimentation is defined as the use of a non-licensed drug in the course of medical practice.

Extrapolated: No one shall be under the rule of law to participate in an investigational medical product, nor will they incur a penalty or lose a benefit to which they are otherwise entitled for refusing to participate.

Constitutional conditions imbued this Treaty such that American Senators declared, "the United States considers itself bound by Article VII to the extent that 'cruel, inhuman or degrading treatment or punishment' means the cruel

and unusual treatment or punishment prohibited by the Fifth, Eighth and/or Fourteenth Amendments to the Constitution of the United States."

Readers of this treaty might believe Article VII only relates to torture, but case law proves otherwise. Mental suffering caused by the unlawful deprivation of liberty, property, living wages, pursuit of happiness, or dignity by government authorities meets the legal threshold of this treaty. Furthermore, threats to remove healthcare services as a means to coerce medical experimentation are clearly in violation of this treaty.

To compel an individual to participate in an experimental drug under threat of penalty absent legal authority violates: (1) the Fifth Amendment by depriving the person of their liberty, personal financial property, and potentially their physical life without due process (ignoring a legal right denies dues process), (2) the Eighth Amendment by applying "unusual" punishment for exercising a federally protected right, and (3) the Fourteenth Amendment by depriving individuals of rights granted to them by Congress without due process and the equal protection of laws.

Governors, mayors, school boards, and other state actors that debased an individual's dignity by punishing a legally protected Section 564 option are considered inhumane, according to our Constitution, treaties, and federal law.

The importance of the ICCPR Treaty has been recognized and signed by one hundred seventy-three nations, including Canada, Australia, and New Zealand. Upon review of New Zealand's definition of medical experimentation, research, and informed consent laws, evidently the government is subjecting citizens to experimental COVID-19 drugs without the free will and voluntary consent.

Lawyers in foreign nations should first seek out their nation's definition of what constitutes medical research to effectively ascertain the rights of citizens to refuse Pfizer's experimental COVID-19 vaccine without consequence.

21 U.S.C. §360bbb-3 EMERGENCY USE AUTHORIZATION

No lawsuit has effectively fleshed out the legal requirements of this section of U.S. Code proving more than the right to refuse.

In 2004, Congress passed 'Project Bioshield,' amending 21 U.S.C. §360bbb-3 (Section 564). The legislation provides a legal mechanism whereby Americans can access experimental medical products that "may be effective" to counter a chemical, biological, radiological, or nuclear (CBRN) event causing disease where no approved medical countermeasure exists in commerce. Under Section 564 'expanded access protocols', Congress authorizes the HHS Secretary to introduce drugs, biologics, or devices into interstate commerce that are unapproved for their intended use.

IMPORTANT NOTE: Federal law mandates that only experimental products can be included under an EUA and, if a licensed product exists to counter the medical threat, then the HHS Secretary is prohibited from issuing an EUA for the declared emergency. **Therefore, all EUA products are legally considered experimental for their intended purpose under the declared emergency.**

Declarations made by Congress in §360bbb-3 are being intentionally ignored by errant authorities. For ease of reading, all references below are under Title 21 U.S.C. §360bbb:

> §360bbb-3(l) states: "Nothing in this section provides the Secretary <u>any authority to require</u> any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity."

Thus, the HHS Secretary may authorize access to Pfizer BioNTech COVID-19 Vaccine; however, no person may be subjected by law to manufacture, distribute, store, or participate in the vaccine's administration. The purpose of

this requirement directly relates to a Constitutional understanding of what a 'right' is, which will be presented later in detail.

Any person involved in any EUA product activity must *participate out of their free will and voluntary consent*. Therefore, if a vaccination mandate is to be considered lawful and not capricious ("Arbitrary and capricious behavior is willful and unreasoning action without consideration or regard for the facts and circumstances." *Boothe v. Roofing Supply*, 893 So. 2d 123, 126 (La. Ct. App. 2005)), it must have the authority to mandate persons to manufacture, distribute, administer, and/or receive the product. The current structure of COVID-19 vaccine mandates is capricious and illegal because it relies exclusively on Section 564 products for compliance. Congress prohibits the involuntary actions of any person carrying out any activity under the law including recipients.

> §360bbb-3(3)(1)(A) requires, "...shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health…"

Congress requires the Secretary to establish a subset of regulations to govern the emergency EUA process, known as the Scope of Authorization. No governor, mayor, school board, CEO, or Department of Defense official has authority to amend that Scope of Authorization. Therefore, if Congress declared that a person can not be required to participate in any activity under emergency authorization, then by what provision are mandates (i.e. not voluntary) lawful? Furthermore, who empowered authorities to amend the Scope of Authorization to require what Congress said can not be required under this section of law?

> 21 U.S.C. §360bbb-3(3)(1)(A)(i) requires, "conditions designed to ensure that <u>health care professionals</u> administering the product are informed"

a) "of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown"

b) "of the alternatives to the product that are available, and of their benefits and risks"

21 U.S.C. §360bbb-3(3)(1)(A)(ii) requires, "conditions designed to ensure that individuals to whom the product is administered are informed…"

a) "of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown"

b) "of the option to accept or refuse administration of the product"

"of the consequences, if any, of refusing administration of the product" (see section titled 'fallacy of consequences')

c) "of the alternatives to the product that are available and of their benefits and risks."

Congress requires the HHS Secretary to provide medical information about pharmaceutical EUA products to healthcare professionals. This legislated requirement ensures the medical community can provide a quality standard of healthcare specific to the medical needs of the individual. Before the healthcare professional administers the EUA product, they must provide medical counseling with the individual to inform them of the risks and potential benefits of the product. The individual must then be allowed to consider whether or not the product will help them achieve their personal health goals.

Authorities are prohibited from applying a blanket requirement for participation in investigational drugs because an EUA product can have significant life-altering consequences based on innumerable health factors. The healthcare professional is in a consultative-only position for each individual deciding the correct course of action. The historic rate of serious

adverse reactions to mRNA drugs, including death, demonstrates the validity behind this legal requirement.

21 U.S.C. §360bbb-3(3)(1)(B)(iii) requires the Secretary to appropriate "conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use."

Governors, CEOs, mayors, city councils, boards of education, and DoD officials are prohibited by Congress from appropriating conditions on who must participate in Section 564 products. Authorities are fraudulently claiming an authority they do not possess by law.

Notwithstanding a significant CBRN event, Congress declared individuals have "the option to accept or refuse administration of the product." Where did such resolve for human autonomy come from? The Belmont Report states, "An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions."

> **The option to accept or refuse EUA products is a RIGHT bestowed upon the American people which no authority has the legal power to interfere. Both options have been granted equal protection and must be protected with equal force.**

What is Congress attempting to achieve with such strict guidelines? First, to ensure that if America is afflicted by a CBRN event, a legal mechanism exists to respond to it with all available resources. Second, to guarantee that at all times, legally effective informed consent is obtained to prevent human rights abuses by unethical entities. Although Section 564 exempts healthcare professionals from having to provide information to a CBRN victim if circumstances are not practical, no authority may forgo obtaining from the individual their legally effective consent. However, the HHS, CDC, and EUA

appropriated conditions for declared COVID-19 emergency that individuals MUST be informed via pharmaceutical manufacturer's drug fact sheet in advance of the product's administration. No healthcare provider has been given authority to forego the informed consent requirement under the COVID-19 pandemic emergency access protocols.

The Belmont Report, 45 CFR 46, and the required conditions of Section 564 authorization do not prevent individuals from accessing EUA drugs, biologics, or devices introduced into commerce by the HHS Secretary under a declared emergency. Rather, the three aforementioned codified statutes prevent individuals from being abused by governments, agencies, and other legal entities during a declared emergency. Protection is achieved by ensuring individuals are never under outside pressures to participate in an experimental medical product by force of constitution, law, regulation, or rule by unethical persons. In addition, the individual has the explicit right to accept or refuse the product based on their autonomous belief that the product will or will not benefit their personal health goals.

> **Federal law prohibits any authority from issuing a waiver of protecting humans involved in clinical research drugs.**

The PREP ACT, RIGHTS, and the 14TH AMENDMENT

Section 564 contains verbiage that requires individuals to be informed: "of the option to accept or refuse administration of the product." The word "option" denotes a federally protected right (choice) backed by the 14th Amendment requiring equal treatment before the law irrespective of the choice.

The legal definition of a right is a power held by an individual as the result of a constitution, law, rule, regulation, or court precedent with which no authority may interfere except when authorized by law.

If Congress establishes an explicit right, then for an exemption, Congress must have prescribed it in the law.

Rights of American citizenry obtained through duly elected representatives may not be infringed upon by rogue actors simply because they disagree with freely exercised choice. Unfortunately, governors in New Jersey, Washington, New York, and Oregon have demoted their citizens to a 'lower class' of rights simply because they disagree with the "option" those citizens chose.

All U.S. citizens are under the same jurisdiction of the United States government and its laws. However, those who opted to refuse EUA COVID-19 drugs have legally become second-class citizens by the fiat dictates of governors refusing to comply with those laws.

The 14th Amendment and the Belmont Report require civilian authorities to apply the same standards equally to citizens who refuse or accept medical experimentation (e.g., COVID-19 testing, masking, vaccination, etc). Congruently, authorities may neither prevent citizens from participating in activities (e.g., educational access, travel, etc) if they refuse medical experimentation nor permit activities exclusively to those who participated in EUA products.

Should courts be allowed to establish a legal precedent that legislated rights are not protected when subject to the whims of authorities who disagree? If an individual can be penalized for exercising a right, volition gives way to compulsion.

Why did Congress require that all persons involved in any activity under Section 564 do so out of their free will and voluntary consent? It involves rights and remedies.

> 42 U.S. Code §247d-6e(c) "The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure (e.g., Pfizer BioNTech COVID-19 Vaccine)…are educated with respect to contraindications, the voluntary

nature of the program…" The program is called the Prep Act under 42 U.S.C. §247d–6d.

On December 30, 2005, Congress enacted legislation titled the Public Readiness and Emergency Preparedness Act (PREP ACT). Unfortunately, this legislation encouraged unlawful behavior during a declared emergency by providing significant immunities for program participants from civil suits. To understand PREP ACT's reliance on the "voluntary nature of the program," we must understand the constitutional requirement of courts to enact a remedy when a right has been violated.

The United States Supreme Court issued a capstone ruling in 1803, *Marbury v. Madison*. Chief Justice Marshall had much to say about rights and remedies regarding the newly formed American government.

> "The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws whenever he receives an injury. One of the first duties of government is to afford that protection. [The] government of the United States has been emphatically termed a government of laws, and not of men. It will certainly cease to deserve this high appellation, if the laws furnish no remedy for the violation of a vested legal right. . . ." The Supreme Court has emphatically declared time and time again that where Congress legislates a right, courts must provide a remedy when those rights are violated.

Both the PREP ACT and Section 564 require explicit voluntary participation. Federal law provides impenetrable immunity for persons participating in emergency "covered" programs during a declared emergency. How can courts permit Congress to grant immunity from civil suits if program participants injure a person? Simple. Congress empowered individuals with the explicit right to accept or refuse participation once they have been made aware of the risks of the program/product. In addition, federal law dictates the offer to participate must not include "sanctions," "coercion," or "undue influence" as those actions nullify the legally effective informed consent of the participant.

Suppose you volunteer to participate in an emergency-covered product, and you sustain injuries of which you were aware of their possibility in advance. In that case, the courts believe your rights were not injured under the PREP Act because you freely exercised your right to participate despite knowing the inherent dangers.

When fiat rulers demand participation in the COVID-19 emergency covered program, they violate the voluntary requirements of the PREP ACT and Section 564 thus opening themselves to significant liability.

Congress grants only the INDIVIDUAL authority to determine participation in an EUA product or activity under PREP ACT protection. Participation CAN NOT be mandated.

Congress wrote into law that individuals have the irrefutable RIGHT to accept or refuse emergency authorized products. In addition, they wrote into law one exception (e.g., 10 U.S.C. 1107a Presidential waiver).

> **When authorities claim they have a right to mandate Pfizer's EUA drug because it shares formulation with licensed COMIRNATY the first request of a court should be, "show me the statute." None exists.**

THE FALLACY OF INTERCHANGEABILITY

On August 23, 2021, the FDA sent an EUA letter to pharmaceutical manufacturer Pfizer, inc. stating, "The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns."

Pfizer immediately issued a press release stating, "An individual may be offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2." Formulations aside, these statements

share the same medical intent not legal exemptions of an individual's federally protected right to refuse the EUA product without penalty.

The FDA also informed authorities in the same letter that, "the products are legally distinct with certain differences that do not impact safety or effectiveness."

Peter Marks, M.D., Ph.D., is the director of the Center for Biologics Evaluation and Research at the Food and Drug Administration. Mr. Marks provided a declaration in COKER v. AUSTIN et al (3:21-cv-01211):

> "FDA provided this information [interchangeability] in the authorization letter to make clear that pharmacies and other healthcare practitioners could provide the vaccination series to recipients using Pfizer- BioNTech, Comirnaty, or both (e.g., first dose of Pfizer-BioNTech followed by second dose of Comirnaty, or vice versa), since the formulation was the same and both products are made by the same manufacturer under current good manufacturing practice requirements. 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. 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."

Those legal distinctions have evaded courts due to a lack of subject matter knowledge within the legal community. The most prominent legal distinction is each drug's classification and approved indication. Congress requires the FDA to assess the formulation of a drug or biologic and then assign it a classification, category, or class based on the product and the stage of its

approval process. Once the drug has been assigned a classification or an approved indication, the formulation is irrelevant for purposes of regulation.

Having their Biologics License Application (BLA) approved, drugs and biologics are assigned an approved indication. An approved indication means the FDA approves the use of the drug for the named medical condition under which it is being administered. The approved condition often involves more than just the name of the medical condition but also includes factors such as age, weight, sex, and contradictions (a drug's potential negative interaction with other medical conditions).

The FDA requires the indications and usage of the drug to be included in the product's fact sheet. COMIRNATY's indication states: "COMIRNATY is a vaccine indicated for active immunization to **prevent** coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older."

Consequently, if Pfizer promoted COMIRNATY to prevent shingles, that would constitute a felony because it was not approved for treating the medical condition. For example, in 2009, the Department of Justice secured a felony conviction against Pfizer for promoting Bextra outside its approved indication with the intent to mislead or defraud. They were handed a criminal fine of $1.3 billion. Additionally, Pfizer agreed to pay an additional $1 billion under the False Claims Act for illegally promoting Bextra, Geodon, Zyvox, and Lyrica, causing false claims to be submitted for uses that were not medically accepted indications.

> "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." (*Justice Department Announces Largest Health Care Fraud Settlement in Its History*, 2009)

One area of concern with officials at the FDA relates to how they approved COMIRNATY under the approved condition to "prevent coronavirus disease 2019 (COVID-19)." Pfizer BioNTech COVID-19 Vaccine states in its drug insert sheet, "The duration of protection against COVID-19 is currently unknown." Therefore, how did FDA officials approve an indication that BioNTech, sharing the same formulation, can neither state nor prove? "Unknown" can mean zero or eternity, but it can not be construed as "prevent."

More troubling is Pfizer combining the legally distinct COMIRNATY indications and usage with BioNTech's EUA COVID-19 Vaccine in the EUA fact sheet. Both are legally distinct, with significant legal consequences to the recipient. Is Pfizer attempting to mislead and defraud the American people again by using approved claims for COMIRNATY while inferring they relate to BioNTech? Could the fact that Pfizer has refused to ship a single vial of COMIRNATY be proof of the intent to defraud? Why are FDA officials allowing a pharmaceutical company with historic abuses of misleading consumers to combine information about an EUA drug with an unavailable licensed drug?

An IND (e.g., Pfizer BioNTech COVID-19 Vaccine) is governed by a distinct set of laws designed to protect individuals involved in biomedical research that are uniquely different from the laws governing licensed (e.g., COMIRNATY) drugs.

For example, should a healthcare provider administer the Pfizer BioNTech COVID-19 Vaccine to an individual, they must do so according to the Scope of Authorization as outlined in the EUA and the laws governing that classification. In contrast, FDA-licensed COMIRNATY is under no such legal requirement, despite sharing the same formulation. The ONLY reason for the distinction is the classification of the drugs.

To illustrate the danger of authorities enacting fiat legislation outside their authority, a simple question illuminates the danger. Will a court allow a Plaintiff to claim statutes in accordance with the FDA-licensed drug

COMIRNATY if they were administered Pfizer's IND, BioNTech COVID-19 Vaccine?

Entities are issuing mandates under the guise that both products are medically interchangeable and therefore legally interchangeable. This is judicial heresy according to laws enacted by Congress. Pfizer agreed to manufacture and distribute BioNTech COVID-19 Vaccine under the protective umbrella of laws associated with an IND and SECTION 564, resulting in extended immunity for the manufacturer. If errant entities declared the two (EUA and FDA-licensed) drugs as interchangeable, could a court legally apply liability to Pfizer as related to COMIRNATY if plaintiffs were administered BioNTech COVID-19 Vaccine? And, can both be administered as if they do not have legal distinctions? Hence, entities have no statutory authority to deprive citizens of their right of refusal, a right granted by Congress, simply because a licensed drug shares the same formulation with an IND.

There is significant legal armature regarding the classification of drugs, and authorities are only exempt from those laws as prescribed by Congress. Moreover, entities ignoring legal distinctions between the two drugs are, in effect, outlawing the intent of Congress under SECTION 564. The FDA has issued an EUA for Pfizer BioNTech COVID-19 Vaccine because it denotes legal distinction irrespective of COMIRNATY sharing the same formula.

Suppose a licensed product will be utilized for an unapproved use not included in the indications and usage section of the product's approved labeling. In that case, it, too, requires the issuance of an EUA for inclusion in the declared emergency. Therefore, the classification and legal intent of the product, according to its labeling, determines the product's regulation; not its formulation.

Pfizer BioNTech COVID-19 Vaccine is a legally distinct drug with no legal intent other than investigation to prevent the Coronavirus. COMIRNATY is a licensed drug, has the legal distinction to PREVENT the Coronavirus, and is no longer under investigational study. COMIRNATY may advertise that it is safe and effective, whereas BioNTech COVID-19 Vaccine may not. While they

may share formulation, they are under different regulatory requirements based on each product's classification and marketing approval.

Had COMIRNATY been released to the public under its legal intent, then state attorneys general could have sued them in court for fraud since the evidence is now overwhelming that the product does not prevent the coronavirus. However, BioNTech is undergoing clinical research and must prove nothing. Pfizer should come under investigation for avoiding the legal requirement (21 CFR 312.7) to only ship its licensed product after the FDA found "sufficient data to support a marketing application." This fact could not be sustained without the help of officials at the FDA.

When an individual participates in the BioNTech COVID-19 Vaccine, they agree to become a subject in a research activity, thus forfeiting significant litigation rights for sustained injuries. **The legal distinctions between the two drugs have significant legal consequences for consumers, and authorities may not rob individuals of their right to choose because of those legal consequences.**

21 CFR 312.3 drugs can have its formulation amended several times during its investigational phase whereas a full licensure drug can not. Because of potential formulation alterations, clinical research drugs must be administered under a quality standard of healthcare protecting the health of the individual. Pfizer has changed its formulation several times but never shipped a licensed product. Therefore, the claim that both drugs share formulation is misleading **because COMIRNATY has never been introduced for general commercial marketing in the U.S**.

In reviewing court cases from around the nation, defendant lawyers (civilian and DOJ) argue that because the two drugs share formulation, there is no difference for purposes of legal mandates. However, one will not find a discussion on the consequences associated with each drug's legal distinctions in those courtrooms.

To treat a clinical investigational drug as a licensed product is an unlawful attempt to nullify Congressional authority and subject Americans to medical experimentation outside of their free will and voluntary consent.

Furthermore, authorities that create an impression through official communications that the unlicensed product is the same as the licensed product (i.e., legal, chemical, safe, effective, etc.) opens themselves up to potential criminal prosecution of fraud and civil litigation for damages caused by their misrepresentation and misinformation.

> **"I would say the difference between the BLA compliant and Comirnaty is nothing but the label."** (ANDREW E. CARMICHAEL, Senior Trial Counsel Coker v. Austin)

Attorney Carmichael is either willfully attempting to mislead the judge or is wholly ignorant of the exactness of his own statement. He is absolutely correct in stating that the only difference is the label. The lack of extrapolating on the statutes behind that label is the mischievousness of his statement in the context of his argument. The label is attached to a set of laws and those laws govern that vial. The laws governing COMIRNATY are wholly distinct from those governing Pfizer BioNTech COVID-19 Vaccine.

Department of Justice (DOJ) lawyers are supposed to protect our nations' laws, not the actions of executive branch appointees. To protect our laws is to protect our Republic because it protects the consequences of the elections that led to the creation of those laws.

For purposes of a legal mandate, one may not substitute a vaccine licensed for general commercial marketing for a vaccine undergoing clinical research with no approved indication by the FDA. The DOJ previously called this activity a criminal attempt to defraud the American people.

42 U.S.C. §242 outlines the requirements for legal interchangeability. Pfizer's

COVID-19 drugs do not meet the required standards under this section of law.

The fallacy of interchangeability by law:

(1) 21 U.S.C. §355(a) prohibits EUA drugs from being promoted, classified, or treated "as if" they are licensed products.
(2) 21 U.S.C. §360bbb-3(a)(2)(a),(b) defines when and how a drug, biologic, or device can be authorized under an EUA. The legal nature of EUA products means listed products are not licensed for general commercial marketing.
(3) Drug vials are governed by their labels and not by their formulations. The labels are attached to laws having significant consequences to the end user.
(4) An EUA drug requires the recipient to be informed of their loss of litigation rights (under the PREP countermeasure program,) involvement in research activities, and the inherent risks associated with the product. The EUA program operates under a legal environment completely different from that of a licensed product.
(5) CBER testified that the two drugs have legal distinctions and the FDA only spoke to medical intent.
(6) It is a felony to promote an EUA drug "as if" it is a licensed drug. Pfizer was fined billions for promoting their drugs "as if" they were approved for indications outside of FDA approval.

No statute exists that allows for an EUA drug to be treated as if it is a licensed product irrespective of shared formulations. This statement is irrefutable by statute.

THE FALLACY OF CONSEQUENCES

SECTION 564 requires healthcare providers to inform the recipient, "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

Unethical lawyers have misled the judiciary of the intent of this phrase by inferring the word to mean "legal" consequences. However, a Latin phrase used in American courts declares "Nulla poena sine lege" (no penalty without law). Congress did not identify what a violation of the policy is, whether that violation is civil and/or criminal, and what the penalties are for violating the policy. Congress openly and plainly declared that the HHS Secretary has no authority to require any person to participate in any activity that becomes lawful pursuant to the policy and individuals have a federally protected right to refuse all products under an EUA.

Therefore, since Congress did not prescribe what a violation of the policy is and what the penalties should be, *there can be none*. This is why the FDA issued guidance to the legal and medical communities regarding the new law:

> "**Consequences** of not taking/using [PRODUCT], including possible health effects and quarantine, and of stopping the use of [PRODUCT] against the recommendation of the health care provider." Health consequence is the only logical conclusion given the absence of reference to any "legal" consequence contained within the section of law. (*Regulatory Information Emergency Use Authorization of Medical Products Guidance -Emergency Use Authorization of Medical Products*, 2007)

Individuals may not be prosecuted for acts not declared illegal under the law. Therefore, one must assume that lawyers arguing this heresy in court are wilfully attempting to mislead the judiciary. Accordingly, courts and state Attorneys General should seek to remove the lawyers' license to practice law due to an intentional attempt to rob Americans of their federally protected

rights. Such expropriation directly attacks and attempts to nullify our Republic, the consequence of a freely elected representative form of government.

CDC COVID-19 VACCINATION PROGRAM PROVIDER AGREEMENT

The Centers for Disease Control and Prevention (CDC) declaration:

> "At this time, all COVID-19 vaccines in the United States have been purchased by the U.S. government (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remain U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law." (*How to Enroll as a COVID-19 Vaccination Provider*. (2023) website 01/28/2023.)

Healthcare companies and practitioners desiring to participate in the COVID-19 cash cow must sign the CDC COVID-19 Provider agreement or equivalent which states in part:

1) "Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative." Citizens and Armed Forces members have all testified

across the nation that they neither received a copy and/or only received a blank sheet of paper.

2) "Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)" Take note of the clinical research requirement of this legal obligation.

3) "Organization must 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." EUAs published to date also require recipients to receive a drug fact sheet before administration of the product to serve as the informed consent process.

4) "Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws." Why? Because federal law dictates compliance with any foreign or state law providing *additional protections* for humans involved in research beyond those of federal statute. (45 CFR 46.101(e),(f),(g))

5) "The above requirements are material conditions of payment for COVID-19 Vaccine-administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. 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. 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."

Therefore, by what authority have participating organizations (e.g., hospitals, medical facilities, state government health agencies, etc.) penalized employees, contractors, and others who agreed not to participate in EUA COVID-19 products? Have they not all committed fraud against the United States Government when submitting reimbursement for each administered COVID-19 dose?

CHEVRON DEFERENCE DOCTRINE

The Chevron deference doctrine would not apply to SECTION 564 claims of the right to refuse because Congress was explicit in determining when and how products can be included under the section of law. In addition, Congress made clear that all drugs, biologics, and devices under EUA provide individuals with the irrefutable right to refuse. Those drugs are under IRB review requiring adherence to 45 CFR 46 and as such must ensure the individual understands that refusal will not incur a penalty or loss of benefits (because the right to refuse is an authority held by a person of which no other person may interfere).

HOW DO YOU SUE?

The below content is not presented as professional legal advice but for purposes of furthering this conversation. Should the reader desire to utilize the contents of this publication for litigation purposes, he or she is strongly encouraged to seek out a licensed attorney for personalized legal guidance.

The legal professional should avoid citing the defendant's vaccine mandate in the legal brief because the mandate is wholly irrelevant. Why they committed a crime is not the cause of action. The cause of action is the laws they violated. Why they violated those laws are of no concern to the legal effort.

The professional should sue the errant entity for engaging in unlawful activities designed to force a person under threat of penalty into medical experimentation outside of their free will and voluntary consent.

The right to refuse is irrefutable and violating that right opens up an entire world of litigation success. This legal strategy bypasses the EEOC process because it avoids Title VII claims.

Section 564 provides a legal mechanism for individuals to consider whether or not to participate in a drug, biologic, or device not authorized for its intended use during a declared emergency. However, this legal mechanism exists only between the healthcare professional and the individual. Persons in positions of authority are not allowed to participate in that discussion.

Therefore, when an employer established a condition of employment based on participating in a clinical research drug under threat of penalty, what laws did they violate?

Did the employer have the right to:

(1) Amend the Scope of Authorization in the EUA?
(2) Fraudulently represent authority under law to require what no other authority can require under law?

(3) Amend an employee's schedule for exercising a federally protected right?
(4) Invade the employee's privacy rights by continually asking if they participated in medical experimentation? Such involvement is a private matter unlike disclosure of licensed vaccine products.
(5) Interfere with an employee's private decision to exercise a federally protected right?
(6) Discriminate only against those who chose one of the two protected options?
(7) Commit fraud by informing state unemployment offices that the employee was fired for misconduct simply because the individual exercised a right under federal law?
(8) Fraudulently request private medical information from employee's medical records only to determine participation in a clinical research activity?
(9) Terminate employment for agreeing not to participate in a Section 564 drug?
(10) Deny or alter employment based on a medical condition? Such as those listed under the ADA?

Should the legal professional start at the position that an individual has the irrefutable right to refuse without penalty and **third-party authorities are prohibited by federal law from interfering with the individual's decision**. In that case, laws will lead the professional to a successful conclusion.

Moreover, entities that operate under the color of law, receive federal funding, or are considered covered entities under HIPAA regulations are at the greatest risk of significant remedial actions.

PEACEHEALTH CASE STUDY

For review is PeaceHealth, a not-for-profit healthcare system primarily located in Washington and Oregon.

On August 03, 2021, executive staff under CEO Liz Dunn issued a COVID-19 vaccination mandate requiring employees to participate in Pfizer's and/or other EUA clinical research drugs or face loss of living wages. Dunn's mandate appeared twenty days before the FDA licensed the COMIRNATY COVID-19 vaccine. In addition, the memorandum stated that those who received the vaccine would be required to wear a badge denoting forced public disclosure of private medical information. Furthermore, to apply as much coercion as possible, binders containing a list of unvaccinated employees were left throughout corridors for other employees or the public to view on demand. Lastly, under direct threat of penalty, Liz Dunn and executive staff required employees to sign a statement when receiving the vaccine that their participation was out of their free will and voluntary consent. CEO Dunn acted on her threats and terminated, amended schedules, and placed employees on unpaid administrative leave. How might these activities violate the principles discussed herein? PeaceHealth has a FWA agreement, IRB, and participates in the CDC COVID-19 Provider program.

BULLET POINTS

The following points require too much space to fully flesh out but are worthy of consideration for professionals and elected representatives to consider.

1) Current vaccine passports are most likely illegal because they rely on public disclosure of private involvement in experimental drugs, not licensed products.

2) Children may not be given the option to participate in EUA vaccines without parental consent because it potentially violates federal laws of "assent." (45 CFR 46.402(b)) Assent requires a child to have enough life knowledge to adequately understand the risks involved. Washington D.C. mayor's requirement of minor's involvement in clinical research drugs violated federal law. Her actions are worthy of incarceration.
3) Prisoners are prohibited from required participation.
4) Employers who incentivized clinical research participation (e.g., time off, bonus pay, vacations, etc.) are most likely liable for vaccine injuries especially if they took an advisory role in promoting the available vaccines as safe and effective.
5) Universities have FWA agreements and already know they were not allowed to persecute those who agreed not to participate in EUA products. A federally funded academic institution MUST NOT interfere with a student's Section 564 rights.
6) Research that has ANY chance of harming a fetus may not be mandated. The laws are VERY strict regarding involvement of pregnant mothers in clinical research drugs.
7) Any negative action taken against an individual by any authority on the basis of COVID-19 vaccination status was illegal because the authority relied exclusively on clinical research products for compliance.
8) The requirement for testing/masking/travel restrictions based on EUA participation is illegal and violates 14th Amendment if not required of those who chose to participate.
9) Federal government does not require illegal aliens to vaccinate because they have access to world courts to sue Pfizer for vaccine injury.
10) FDA removed monoclonal antibody treatments because Section 564 requires notification of alternatives to the mRNA vaccines. Despite the fact that antibody treatments demonstrated real world positive results without adverse reactions.

11) Professionals should explore section 1983 and Bivens lawsuits to provide relief for victims assaulted by persons acting under the color of law.

CONCLUSION

Authorities lack the statutory right to require individuals to participate in Section 564 protocols. Furthermore, such requirements are a violation of both civil and criminal law. When in court, demand defense attorneys produce a statute affording their client's right of exemption from accepting plaintiffs' right to refuse EUA products without penalty. It can not be done. Hence the reason for the misinformation campaign to inject the lie that an EUA drug can be mandated if sharing formulation with a licensed drug.

The reader is highly encouraged to read the document titled, 'DoD/Coast Guard Criminal Complaint' located at CovidPenalty.Com. The document details significant malfeasance by federal agency employees and delves further into the interchangeability issue.

Individuals have the right to refuse the administration of INDs under an EUA without incurring a penalty or losing a benefit to which they are otherwise entitled. Authorities can not demonstrate by law the right to treat EUA products as licensed products. EUA products require individuals to freely participate in a legal environment where they forfeit litigation rights, assume more significant risks, and participate in research activities. Persons in authority may not mandate participation in that legal environment.

Employers, governors, mayors, and other persons in positions of authority that penalized an individual for refusing participation in a clinical research drug violated the Section 564 rights of the individual. In addition, the errant authority engaged in discrimination and gross negligence, leading to a loss of living wages, property, and life itself.

The courts will now be called upon to provide significant remedial actions.

BRIAN WARD

Brian Ward invested 1,200 hours of research into the history and legal administration of clinical research drugs to understand the unlawful activities relating to COVID-19 vaccine mandates. Brian is not a licensed attorney but has 25 years of working in corporate America as a strategist solving problems using research and critical thinking skill sets. A love for the American people compelled him to engage in this process as if they were his personal client.

Visit CovidPenalty.Com to see his next steps for America.

Brian Ward is available for purposes of expert consulting, testimony, and legislative efforts.

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