A COVID-19 Legal Armageddon Is Storming Its Way Into America

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

In 1972, America woke up to a horrifying story about a Nazi-style research project in Tuskegee, Alabama, where healthcare providers criminally replaced effective treatments for syphilis with placebos. Those researchers allowed black Americans to suffer until death to study how syphilis progressed in human anatomy. One hundred twenty-eight men died of complications, forty of their wives contracted the disease, and nineteen babies were born with congenital syphilis. How did this happen? Medical researchers viewed black Americans as expendable research assets instead of valuable human beings worthy of being treated with respect and dignity.

From 1956 through 1971, Willowbrook State School in Staten Island, New York, agreed to enroll mentally disabled children in exchange for the parent's consent to involve them in "vaccination" procedures. However, the school did not vaccinate their children; instead, they were fed extracts from the feces of infected hepatitis patients so that researchers could use them as guinea pigs in another horrific abuse of human rights. Researchers argued the ethics of their abusive research by stating, "all the children would eventually contract hepatitis."[1] This led theologian and ethicist Paul Ramsey to state, "[t]o experiment on children in ways that are not related to them as patients is already a sanitized form of barbarism."[1]

Human rights abuses by American medical researchers reached a fever pitch when, in 1974, Congress passed the National Research Act.[2] The Act required establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In addition, Congress required The Commission "to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects" and to consider "the nature and definition of informed consent in various research settings."[2] - U.S. Congress 1974

On April 18th, 1979, The Commission released its' findings in 'The Belmont Report.'[3] This Report is unique in that federal statutes require "department or agency heads" to ensure they are "consistent with the ethical principles of the Belmont Report" when involving humans in medical experimentation.[4]

The Belmont Report took its cues from the Nuremberg Code, which stated, "The voluntary consent of the human subject is absolutely essential" when conducting medical experimentation.[5] The Commission drafted their version of this ideal by saying, "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."[5]

The Commission was unapologetic to medical researchers by describing in explicit detail what those adequate standards were. "An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance…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…But 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."[3]

The Belmont Report authors made it abundantly clear that there must be a legally approved environment established when an individual agrees to participate in medical experimentation. **That environment must ensure the individual is under no "sanctions," "coercion," or "undue influence" when giving their consent.**[3] Congress wrote into law that it is legally impossible for individuals to give their honest free will and voluntary consent when under outside pressures to participate.

HHS turned the Belmont Report into a set of regulations known as The Common Rule.[9] At the heart of this rule is the requirement that, "an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative" before involving subjects in medical experimentation.[9]

Legally effective informed consent is obtained when the researcher: 1) discloses quality information to the individual required to make an informed decision; 2) ensures the individual understands the risks and benefits of the experimental drug; 3) provides an opportunity for the individual to consider whether or not to participate; and 4) ensures the individual is under no sanctions, coercion, or undue influence by persons of authority when consenting to participate.

“Informed consent must be legally effective and prospectively obtained.”[6] -Health and Human Services (HHS)

In 1992, the U.S. Senate ratified the International Covenant on Civil and Political Rights Treaty.[7] Article VII of that treaty states, “No one shall be subjected without his free consent to medical or scientific experimentation.”[7] The word “subjected” does not mean physical force in this context. Instead, it means to be subjected under governmental authority to participate in medical experimentation by an act of law. When Hawaii applied penalties to citizens who refused to participate in Pfizer’s experimental COVID shot, the state violated this treaty and its own state laws. To enforce penalties for non-compliance is how a government “subjects” persons to medical experimentation without their free consent.[7]

The Common Rule requires researchers to provide individuals with "a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled."[9] The right to refuse medical experimentation without penalty has been enshrined into federal law to ensure public and private entities treat individuals as humans with dignity instead of as expendable lab rats.

To treat Americans as individuals with dignity requires that information presented to them is accurate, complete, and in a language they can easily understand. Courts have said without it, effective consent can not be obtained.

“With increasing frequency, courts have held that when a patient is harmed by a treatment to which he or she might not have consented had he or she been adequately informed of the risks involved in that treatment, the doctor's failure to obtain informed consent may result in a finding of liability for negligence.”[10] - FDA

In the lawsuit *Cobbs v. Grant (1972)*, the California Supreme Court ruled "It is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie. To enable the patient to chart his course knowledgeably, reasonable familiarity with the therapeutic alternatives and their hazards becomes essential."[11] (Supreme Court of California 1972)
Cobbs, supra, at 242-243. Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1 (1972)

In *Schloendorff v. Society (1914),* - the Court of Appeals of New York ruled that the physician was liable for battery because the surgeon engaged in a procedure that the patient had not consented to.[12] (Federal Register 1914) The court said the surgeon violated the "individual's fundamental right to decide what is being done with his or her body."[12] (Federal Register 1914) - Schoendorff v. Society of New York Hosp., 105 NE 92, 93 (NY 1914)

"It has become increasingly clear that a lack of informed consent will result in actionable negligence where injury results, and that the physician's duty to inform includes a duty to impart information sufficient to enable a patient to make an informed decision. The courts recognize that standard of informed consent has evolved and that the standard now requires full disclosure in all but the exceptional case."[10] (US Food and Drug Administration 1981) See Dessi v. United States, 489 F. Supp. 722 (E.D.Va. 1980); Rogers v. Okin, 478 F. Supp. 1342 (D. Mass. 1979)."

When the FDA opened public comments regarding changes to 21 CFR Part 50 regulations titled, 'Protections of Human Subjects,' they demonstrated absolute resolve in their mandate of researchers to obtain informed consent.

The "FDA is concerned that research subjects be adequately protected from abuses of the kind that have taken place in the past (44 FR 47713-17); and is convinced that one way to protect research subjects against abuse is to ensure that they have the opportunity to be adequately informed before they consent to participate."[10]

Several persons requested the FDA to exclude informed consent requirements for research involving "minimal risk."[10] The FDA balked at such an idea and replied, "The National Commission stated that even in no-risk or low-risk studies, respect for the rights and dignity of human subjects would require informed consent before participation in any clinical investigation."[10] To another request, the FDA made it crystal clear, "Both the HHS regulations and the FDA regulations reflect the belief that even

minimal risk studies require the informed consent of human subjects before they may participate in a research study. Informed consent is, therefore, a uniform requirement for all investigational studies, no matter how low risk an investigator may believe them to be."[10]

Even when the HHS Secretary exempts drugs from other FDA regulations, the FDA declared, “These sections of the act direct FDA to promulgate regulations that will ensure that informed consent will be obtained from each subject or each subject's legally authorized representative as a condition to the issuance of the exemption."[10]

Obtaining legally effective informed consent from individuals involved in medical experimentation is currently codified into federal law, the regulations of 20 federal agencies, and all 50 states. The Office of Human Research Protection - under HHS created a Federal Wide Assurance program to police government agencies ensuring the human rights of American citizens are never abused again.[6] No law exempts public and private authorities from their legal obligations to ensure civilians are not under sanctions, coercion, or undue influence when consenting to participate in medical experimentation. This simple but powerful law has not been discussed in a court of law regarding COVID-19 mandates.

What do medical experimentation laws have to do with COVID-19 vaccine mandates? The only COVID-19 drugs available to civilians and service members at the time of this article are classified by the FDA as investigational new drugs (IND). The federal government defines an IND as, "A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration for testing in people. Also called an experimental drug, IND, investigational agent, and investigational new drug."[13]

Medical products classified by the FDA as experimental require authorities to obtain the legally effective informed consent of the individual before they participate in those products. To deny the right of refusal by authorities is a violation of international treaty, federal law, and the 14th Amendment. YOU, have a right to refuse participation and because they violated that right you now have the right to seek judicial remedy in a court of law.

Congress authorized the DHHS Secretary to provide Americans with “expanded access” to experimental products during a declared emergency when responding to a

chemical, biological, radiological, or nuclear event.[14] These experimental products only have to show that they “may have benefit” in treating a released agent causing harm to Americans at home or abroad. The Secretary issues an Emergency Use Authorization (EUA) letter notifying the medical community of the legal right to access unapproved products and how they may be administered. This law does not authorize public or private entities the right to mandate the use of these products under any circumstances. The reason is because they are experimental according to FDA labeling guidelines and come with inherent dangers such as permanent disability and death. Furthermore, EUA products have significant legal consequences for individuals who participate in them.[15]

Congress requires certain information be communicated to the recipient of investigational drugs authorized for use under an EUA, including: 1) that the Secretary has authorized the use of the product; 2) the risks and benefits of the product; 3) the potential health consequences of not participating in the product or discontinuing the use of the product early; 4) the alternatives to the product and their risks and benefits; and, 5) the option to accept or refuse the product.[14]

Federal lawyers argue that this information is not required because the law says that only "to the extent practicable given the applicable circumstances."[14] That argument misdirects the true meaning of the law because it declares that it is up to the Secretary to make that determination. The Secretary has required all recipients of COVID-19 Vaccines under an EUA to receive a drug fact sheet. This requirement demonstrates extreme practicality for disseminating information regarding the current declared emergency. Congress also spoke to the consent part of the formula by granting citizens "the option to accept or refuse administration of the product."[14]

EUA-authorized products are not considered within the auspices of clinical research but are still research products nonetheless. EUA products are studied, monitored, and assessed for effectiveness and safety. Congress only required the Secretary to believe that “the product may be effective in diagnosing, treating, or preventing” disease. However, this also means the product may NOT treat the disease effectively.[14] So, how do we conclude that the product is effective? We “research” the efficacy and safety of the product in a real-world environment.

Unethical lawyers are attempting to convince the judiciary that laws protecting Americans from research abuse do not apply to EUA products. Their argument is

legislative heresy and, in my opinion, criminal contempt. Why? The FDA told Pfizer to clearly and conspicuously state on all printed matter that BioNTech COVID-19 Vaccine has not been licensed or approved by the FDA. In addition, they must submit to the investigational new drug (IND) process using IND number 19736. Furthermore, the word “investigational” is a big clue that the product is being investigated or researched. Congress only provided a legal means for Americans to “access” products that have not been approved if they believe it could benefit their individual health goals. However, Congress absolutely requires the legally effective consent when individuals access those products.

In 2005, the FDA issued an Emergency Use Authorization (EUA) for an investigational Anthrax drug for the U.S. Armed Forces. The FDA stated in the EUA, "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."[8] This statement allowed service members to make an informed decision based solely on their healthcare desires, free from outside pressures. This approach is how to achieve legally effective informed consent.

The current COVID-19 vaccine drugs do not claim to inoculate humans from any COVID-19 variant. Furthermore, current COVID-19 Vaccines under an EUA have no proof of short-term or long-term efficacy in the real-world environment based on the data that I’ve studied. For example, Pfizer’s BioNTech COVID-19 Vaccine drug was designed to undergo a 24-month clinical trial but lost 44% of its blinded group by the fourth month and 93% by the sixth month. Pfizer reported efficacy was down near 84% when the clinical trial failed, and that efficacy was dropping 6% every two months. However, real-world data from countries tracking effectiveness reported that after the sixth month, the drug effectively collapsed, offering little to no protection from the coronavirus.[16] The FDA chose to ignore this final report by Pfizer that came out 30 days before they approved COMIRNATY.

The adverse reactions to Pfizer’s BioNTech drug are at historical levels compared to other Pfizer drugs. For example, Pfizer was fined $2.3 Billion for drug fraud involving Bextra, an anti-inflammatory therapy. Bextra recorded 9,443 serious adverse reactions and 1,054 deaths over a period of 18 years.[17] Pfizer’s BioNTech COVID-19 Vaccine drug has recorded 18,638 deaths and 162,000 serious adverse reactions in the vaccine

adverse injury database over a period of 18 months.[18] Laws were written against the inhumane use of drugs and those laws grant Americans the right not to participate in them.

Let us come to grips with the fact that "the option to accept or refuse the product" has far-reaching legal implications for the modern day governments and corporations who ignored this right.

The 14th Amendment guarantees Americans "the equal protection of the laws." Therefore, if a company can fire an employee for choosing not to participate in an EUA product, then a company can fire an employee for choosing to accept the product. The reason lawyers would line up at the door to sue a company who fired their employees for participating in that drug is because those employees believed it would help them achieve their health goals. It would be their right. The same right exists for those who believe the product will be detrimental to their health goals.

To demonstrate the lawlessness of executives who violated federal law by mandating COVID-19 experimental products, let us consider the following. If there are two legally protected choices and authorities only penalize one of those choices, then the 14th Amendment rights of those penalized individuals were violated because they were not treated equally before the law. Therefore, governments may not exempt one group of individuals while not exempting all others from the same legal requirement. This right to equal protection of the laws is the heart of our constitutional republic.

"Option" denotes a legal right to participate or not to participate. A right is absolute and may not be infringed upon. You have a right to free speech, religious beliefs, private property, and to read your daily newspaper. The government does not have the right to penalize you on your way to church because you exercised that right. As incredible as it sounds, no attorney has argued this basic legal fact in a court of law regarding COVID-19 mandates. Congress declared that individuals have the right to refuse administration of an Emergency Use Authorized drug, which denotes protection from penalties when exercising that right. Lawyers, who solemnly swore to support the Constitution of the United States, are now attempting to subvert the foundational concepts of our Republic by setting court precedent that a person can be penalized by government authorities who politically disagree with that individual's protected right.

Rogue public and private leaders willfully used guidance issued by the FDA to "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine" to justify their abuse of human rights. This illegal song and dance is about to bite these leaders because the FDA also informed the public that "the products are legally distinct with certain differences."[19] Those legal distinctions should have concerned elected leaders and CEOs because they certainly warranted more investigation. Drugs are legally governed by their labels and not by their formulas. For example, If a healthcare provider administers the BioNTech vaccine, they must do so according to the Scope of Authorization laid out in the EUA. However, if a healthcare provider administers Pfizer's approved COMIRNATY vaccine, they are not under those requirements despite the two drugs sharing the same formula. Drug labels are laws, an act of Congress instituted those laws, and no public or private entity has the legal right to exempt themselves from them. The legal community would do well to inform judges what makes an experimental drug experimental is not the formula but the label attached to that formula. Although drugs may share the same formula they do not share the same drug labels and therefore they are legally not the same product.

When Ford Motor Co. required their salaried employees to participate in experimental COVID-19 drugs in 2021, they violated the legally effective informed consent requirements of federal law. Mandates enforce penalties, and penalties automatically nullify an effective consent. However, Ford Motor Co. forced its employees under duress to enter a contractual agreement against their voluntary consent. This agreement is spelled out in the Public Readiness and Emergency Act - which denies anyone participating in a COVID-19 IND from seeking judicial remedy resulting from injuries sustained by the drug's use.[20] As bad as it seems now for Ford, civil suits could turn criminal because most states make it a felony of the first degree for those "who falsely represents any factual matter contained on any prescription label or prescription drug label."[21] To represent to your employees that an experimental drug is classified by the FDA as fully approved is most certainly misrepresenting the facts on a drug label. Furthermore, there are privacy laws at the federal and state level prohibiting the forced acknowledgement of whether or not an individual participated in medical experimentation.

Civilians are not the only ones fighting to retain their medical liberties. Service members are being assaulted by the senior Pentagon leadership who are outright refusing to obey a lawful order by the Secretary of Defense (SECDEF). SECDEF Austin issued an order on August 24, 2021, for the military to begin vaccinating service

members using only non-experimental drugs according to FDA labeling guidelines. Unfortunately, senior Pentagon leadership took the advice of Dr. Terry Adirim to "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine."[19] Dr. Adirim's advice to the military command was, in effect, to pretend "as if" they were obeying SECDEF's order by using an experimentally labeled drug in place of a full licensure drug. JAG has stood by as senior Pentagon leadership penalizes service members for obeying SECDEF's lawful order while promoting and praising military commanders who disobey that order. Congress was absolute in its mandate that DoD obtains the legally effective informed consent of service members before involving them in medical experimentation. Unfortunately, The Judge Advocate General Corps (JAG) has taken a 'see no evil hear no evil' approach to this injustice and they absolutely refuse to "bear true faith and allegiance" to the Constitution.

In 2005, the FDA provided guidance to the DoD regarding another investigational drug requiring them to inform service members that, "Refusal [of the investigational drug] may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action."[22] Judge Sullivan put an end to the abuses of power by the DoD in 2005, and now, history is calling on new heroes to put an end to Secretary of Defense Lloyd Austin's abuses.[22]

Unethical lawyers and their researchers argue that laws governing clinical approaches do not protect citizens against research abuses when that research is conducted outside of those parameters. The Belmont Report spoke directly to this argument by declaring, "the general rule is that if there is an element of research in an activity, that activity should undergo review for the protection of human subjects."[3] Research is defined by the federal statute as a means of "systematic investigation…designed to develop or contribute to generalizable knowledge."[22] Section 564 authorzied products are research products. If a court says otherwise, it does so in contradiction of the laws established for the protection of human subjects. If these laws are randomly applied to EUA products, then that opens the door to medical experimentation abuses again since any pharmaceutical could suggest their product "may have benefit" just to conduct "research."

The Department of Justice, OHRP, HHS, FDA, and the DoD know that governments in authority must ensure that individuals participating in investigational drugs are under no coercion, undue influence, or sanctions when they consent to participate in those

experimental drugs. Individuals who refuse participation may not incur a penalty or lose a benefit to which they are otherwise entitled. Should a mandate exist to vaccinate against a virus, that mandate may not list an experimental drug as acceptable compliance because it is impossible to obtain the legally effective informed consent of an individual who is under threat of penalty.

Public and private entities that required compliance before the availability of FDA-approved drugs and relied solely on experimental products for compliance violated ratified treaties, federal law, state laws, health department regulations, and the 14th Amendment rights of everyone under those mandates. Moreover, the military is only authorized to waive informed consent requirements by a written act of the Commander-In-Chief. Therefore, commanders who penalized their subordinates for refusing the administration of experimental products violated a lawful order by SECDEF Austin, 14th amendment rights of their service members, military regulations, and a ratified treaty.

America, these violations will require significant judicial remedies. Unfortunately, for both civilian and service members, legal representation in current litigation has been lacking in the quality of content. The judiciary has not discussed The Belmont Report, ratified treaties, the nature and definition of legally effective informed consent, how drugs are governed by their labels and not by their formulas, and the right of individuals not to participate in medical experimentation without incurring a penalty. One might argue that plenty of suits have argued informed consent, but when an attorney does not define what it means to obtain informed consent, then that argument is void of effectiveness.

Last year, I sat down with my caramel macchiato and soothing music to study vaccine mandates. My goal was to help friends in military service abused by the unlawful orders of their commanders. However, little did I know that I was about to embark on a 200-hour research journey into experimental drug history and its legal administration.

Therefore, I launched CovidPenalty.Com to raise funds and educate Americans about their right to say no. This endeavor isn't an organization, nor will it ever become one, because there are solid, established people who have already done the heavy lifting for us all. No, I decided to work with those organizations by educating them about my research, litigating that research, and taking principles I learned along the way to request our elected leaders legislate those principles into law.

With adequate funding, I will finance litigation to restore the honor of the military profession, demonstrate to trial lawyers the right of employees to say no, and seek a court order mandating the FDA include certain information in all future EUAs to comply with legally effective informed consent laws.

I leave you with one question. Would you freely volunteer to participate in an experimental drug that forfeited your rights to a judicial remedy, had historic levels of adverse reactions such as permanent disability and death, and did not even claim to inoculate you from any COVID-19 variant?

Now you understand why Congress requires authorities to obtain the legally effective informed consent of the individual before administering an investigational new drug such as Pfizer's BioNTech COVID-19 vaccine.

Brian Ward
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Hear my heart America. I personally invested 200 hours of research into the history and legal administration of experimental drugs to understand our current COVID-19 vaccine mandate crisis. As a result, I now know that no American can "incur a penalty or lose a benefit to which they are otherwise entitled" for simply refusing to participate in an experimental drug such as Pfizer's BioNTech COVID-19 Vaccine drug.

The principles of the Belmont Report Have NEVER been argued in a court of law since its inception, nor have the regulations attached to it. Therefore, your financial support is needed to educate our legal community on the right to say no and remedy these injustices in courts of law. I have the passion; I just need the financial tools to accomplish the mission.

Did you know that the USAF denied their health advisor's request to hold off on punitive actions for members wanting to wait for a licensed product? Those who "did not concur" to that request said that changing policy would require "significant remedial actions." You BETCHA! A legal Armageddon is coming to America because the same laws protecting our soldiers from research abuses are the same laws protecting you and me.

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