CURRENT VACCINE MANDATES ARE ILLEGAL AND UNCONSTITUTIONAL BY AN ACT OF LAW

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This document does not have the force of law. A person should engage the services of a licensed attorney before using the below content for litigation efforts.

This document is continually updated based on court rulings and additional discoveries. Maintaining a referenced citation section is difficult when the document is updated regularly. However, I include links throughout so the reader can further educate themselves on the subject.

A sample letter is included at the bottom of this document that may be of use to those under vaccine mandates.

Legal Statement: Vaccine mandates requiring compliance before the availability of a fully licensed and approved drug by the FDA are illegal and unconstitutional. They are illegal because they rely solely on investigational new drugs for compliance. They are unconstitutional because they deny citizens within the mandate's jurisdiction "the equal protection of the laws."

Let us now understand why the above statement is factual and what this means for those authorities who illegally issued mandates without the backing of the law.

During the Nuremberg Trials, Nazi scientists, who were under prosecution for engaging in horrific abuses of human rights, used biomedical research conducted by the U.S. government and U.S.-based educational institutions as part of their defense. Here are just a few of those research projects conducted by the U.S. government:

1. University of Michigan researchers deliberately sprayed the Influenza virus into the nasal passages of mentally ill patients to study treatments.
2. The University of Chicago infected prisoners with malaria to study treatments.
3. The U.S. Army and the National Institute of Health used prostitutes to infect prisoners and Guatemalan soldiers with syphilis and other STDs.

4. The U.S. Navy sprayed bacterial agents over San Francisco to study the effects of biological warfare. Citizens all over the city contracted pneumonia-like illnesses.
5. The University of Pennsylvania infected 200 female prisoners with viral hepatitis.
6. Mentally disabled children at the Willowbrook State School in Staten Island, New York, were infected with viral hepatitis when fed extracts from the feces of infected patients.
7. Sloan-Kettering Institute injected live cancer cells into 300 healthy females knowing that it could cause cancer.
8. The U.S. government dropped over 300,000 mosquitos onto an unsuspecting population in Georgia to study the use of entomological weapons.
9. 22 patients at the Jewish Chronic Disease Hospital were injected with live cancer cells by Chester M. Southam. Two years later, the American Cancer Society elected Chester Southam as their Vice President.
10. The University of Iowa injected high doses of radioactive Iodine into newborns and pregnant women to study the effects of radiation on infants and pregnant women.

We could spend a week discussing these and thousands of other research projects conducted by very unethical researchers in the United States. What will shock most readers is that none of the patients knew they were part of a research project. They were not informed of the risks associated with the research nor given the option to opt out. Most of the patients involved in these research projects were healthy citizens with no need to participate.

In 1972, the United States woke up to an alarming story involving citizens who were unknowingly part of a Health and Human Services (HHS) research project in Tuskegee, Ala. Researchers promised to offer "treatment" to "negros" who contracted syphilis. Although penicillin was a known cure, researchers lied to the subjects about their disease in order to study how syphilis progressed in human anatomy. In 1972, the horrors of the research project were discovered when details leaked to the press. 128 men had died of the disease or disease-related complications, 40 of the wives contracted the disease, and 19 babies were born with congenital syphilis.

The national outcry of this event and thousands of others resulted in congress passing The National Research Act (H.R. 7724). On July 12, 1974, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was endued with power, by an act of congress, to "identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research." The Commission was to "develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles." One of the main goals of the commission was to define "the nature and **definition of informed consent** in various research settings."

On April 18, 1979, the Commission released their findings in a publication known as the Belmont Report. The report is unique in that the entire report was submitted and entered into the Federal Register. The HHS Secretary stated that "by publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees." https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

The report states that at the core of protecting human subjects is the understanding that medical investigators must have "**respect for persons**." This respect begins and ends with the belief or conviction that "individuals should be treated as autonomous agents." The report states that "an autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation."

The report states that "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**."

"An agreement to participate in research constitutes a valid consent **only if voluntarily given**." The report defines voluntary consent by stating, "this element of informed consent **requires conditions free of coercion and undue influence.**"

Conditions that nullify voluntary consent are, 1) “Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.” 2) “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.” 3) “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.”

Congress established the idea that a citizen can only give legally effective informed consent if the conditions surrounding that consent involve no undue influence or coercive policies. Undue influence can be both positive and negative. The negative undue influence could involve a mandate threatening an employee with termination should they choose not to participate in a biomedical project. The positive undue influence could involve a school giving pizzas to students who participate in a biomedical research project.

A few years after the publication of the Belmont Report the HHS revised its regulations for the protection of human subjects by codifying them into 45 CFR 46, subparts A through D. The statutory authority for the HHS regulations derives from 5 U.S.C. 301; 42 U.S.C. 300v-1(b); and 42 U.S.C. 289.

“The regulations found at 45 CFR part 46 are primarily based on the Belmont Report and were written to offer basic protections to human subjects involved in both biomedical and behavioral research conducted or supported by HHS.” - HHS

The 45CFR46 regulations have become known as “**The Common Rule**”.

45CFR46 states in part that, “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.” It further states that, “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."

HHS, honoring the requirements of the Belmont Report, conspicuously and clearly stated that no person may lose a benefit, such as a job or retirement funds, for refusing to participate in a biomedical research project.

What do biomedical research projects have to do with the current vaccine mandates?

Current vaccine mandates rely solely on the use of investigational new drugs. As of December 13, 2021, no approved or licensed vaccine for COVID-19 is available to the public.

What Is an Investigational New Drug?

The U.S. National Cancer Institute 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**." https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-drug

Investigational New Drugs are authorized by the FDA for the purpose of conducting biomedical research and have no approved intent. When a citizen takes an IND they are volunteering for biomedical research whether they realize it or not.

On August 23, 2021, the FDA announced they had approved the Pfizer vaccine COMIRNATY. That same day, the media announced to the world that the FDA approved the Pfizer-BioNTech COVID-19 drug, but that was a false statement.

We know the media made a false statement because on the same day the FDA approved COMIRNATY, they revised their Emergency Use Authorization (EUA) and informed Pfizer that the BioNTech COVID-19 Vaccine drug had "not been approved." The FDA told Pfizer they must submit the BioNTech COVID-19 drug "to Investigational New Drug application (IND) number 19736." They required Pfizer to state on all

printed materials relating to the BioNTech COVID-19 drug that, **“This product has not been approved or licensed by FDA.”**

All current vaccine mandates are illegal because they rely solely on the following experimental drugs for compliance. All investigational new drugs are governed by 45CFR46 regulations.

Pfizer BioNTech COVID-19 Vaccine IND number 19736
https://www.fda.gov/media/150386/download
Janssen Biotech COVID-19 Vaccine IND number 22657
https://www.fda.gov/media/146303/download
ModernaTX COVID-19 Vaccine IND number 19745
https://www.fda.gov/media/144636/download

The FDA clearly states in their Emergency Use Authorizations that COVID-19 INDs are “investigational vaccine[s] not licensed for any indication.”

Therefore, every American who has participated in one of the above-listed drugs volunteered for biomedical research using experimental drugs, whether they knew it or not.

How do we know that COMIRNATY isn’t available for consumption?

Section 564 is the statute granting the FDA power to authorize the use of an experimental drug during a declared emergency. One of the primary conditions that must be met before section 564 can be activated is “that there [can be] no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition.” In every EUA since COMIRNATY was approved, the FDA states the reason for issuing the EUA is because COMIRNATY is not available to the American people.

In 2000, HHS created The Office for Human Research Protections (OHRP) “to lead the Department of Health and Human efforts to protect human subjects in biomedical and behavioral research and to provide leadership for all federal agencies that conduct or support human subjects research under the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.” - HHS

HHS said, “The Health and Human Services oversees the Office for Human Research Protections (OHRP) which is responsible for ensuring that all biomedical research institutions comply with federal law, international treaty, and 45CFR46 regulations.” https://www.hhs.gov/ohrp/index.html"

OHRP created the Federal Wide assurance program (FWA) to ensure that all federal agencies respect the right of American citizens to opt out of investigational drugs. HHS stated that “Through the FWA and the Terms of the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP.” -HHS

FWA - https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html & https://www.hrsa.gov/about/organization/bureaus/opae/human-subjects

"When an Institution becomes engaged in research to which the FWA applies, the Institution and IRBs upon which it relies for review of such research at a minimum will comply with one or more of the following" - HHS

The Common Rule

One of the fundamental principles of the Common Rule is that no person may be subjected to biomedical research outside of their free will and voluntary consent. Free will and voluntary consent cannot be obtained if the subject is under duress to participate in an investigational drug.

20 U.S. agencies have adopted the Common Rule into their regulations, and they are:
Department of Agriculture (7 CFR Part 1c)
Department of Commerce, National Institute of Standards and Technology (15 CFR Part 27)
Department of Energy (10 CFR Part 745)
Department of Education (34 CFR Part 97)
Department of Defense (32 CFR Part 219)
Department of Health and Human Services (45 CFR Part 46)
Department of Homeland Security (6 CFR Part 46)

Department of Housing and Urban Development (24 CFR Part 60)
Department of Justice, National Institute of Justice (28 CFR Part 46)
Department of Labor (29 CFR Part 21)
Department of Transportation (49 CFR Part 11)
Department of Veterans Affairs, Office of Research Oversight, Office of Research and Development (38 CFR Part 16)
Agency for International Development (USAID) (22 CFR Part 225)
Central Intelligence Agency
Consumer Product Safety Commission (16 CFR Part 1028)
Environmental Protection Agency, Research and Development (40 CFR Part 26)
National Aeronautics and Space Administration (14 CFR Part 1230)
National Science Foundation (45 CFR Part 690)
Office of the Directory of National Intelligence
Social Security Administration (20 CFR 431)
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

OHRP lists other regulations and international agreements they comply with when granting companies the right to conduct biomedical research.

The U.S. Food and Drug Administration regulations at 21 CFR parts 50 and 56;
The current International Conference on Harmonization E-6 Guidelines for Good Clinical Practice; https://www.ich.org/page/efficacy-guidelines
NOTE: The Federal Government entered this document into The Federal Register and signed an agreement to abide by its requirements. The document states that it abides wholly by the Helsinki Declaration's ethical rules protecting human subjects involved in biomedical research. The Helsinki Declaration was developed on the principles outlined in the Nuremberg Code
The current Council for International Organizations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects
The current Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;
The current Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or

Other standard(s) for the protection of human subjects recognized by U.S. federal departments and agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Not long after the publication of the Belmont Report, the FDA adopted its own rules to protect human subjects involved in biomedical research. The FDA created regulations to comply with the report's findings now embodied in 21CFR50. 21CFR50.20 states that "no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent **only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.**"

In 1992 the U.S. Senate ratified the International Covenant on Civil and Political Rights Treaty. Article VII of that treaty plainly states that "…**no one shall be subjected without his free consent to medical or scientific experimentation.**"

14th Amendment

"No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; **nor deny to any person within its jurisdiction the equal protection of the laws**." There are two legal options regarding investigational new drugs. 1) Choose to engage in biomedical research or 2) Choose not to engage in biomedical research. Citizens may not be punished for choosing one of the two legally approved options. A corporation that fired an employee for choosing one of the two legally protected rights engaged in discrimination by violating one of the most sacred rules of our Republic, and that is the rule of equality before the law.

When President Biden and other executive leaders exempted certain groups of citizens from their vaccine mandates while requiring others to comply, they violated their oath of office to uphold the U.S. Constitution.

Question for the court. Do citizens have the right to participate in investigational drugs? The answer is yes. Do citizens have the right to opt-out of investigational drugs? The answer is yes. If authorities punish only one group of citizens, based on one of the two legal options, then were the 14th amendment rights of the punished group violated? The answer is yes. Therefore, these mandates have clearly violated the 14th amendment rights of all citizens.

Second-Class Citizen

A second-class citizen is a person who has been demoted to a lower class of rights as established by the force of law despite their status as a legal resident. Citizens who are being forced under duress into biomedical research while other citizens are free to choose, have been demoted to a second-class citizen because they are not enjoying the rights afforded to other citizens within the U.S. jurisdiction. These violations of human rights have led to the mistreatment and neglect of citizens who have been left scurrying, with limited legal options, due to their socioeconomic status.

The Supreme Court has ruled against all laws that establish a second-class citizenry.

Conclusion: The United States Congress established a commission to make recommendations on how to protect American citizens involved in investigational drugs. HHS created 45CFR46 regulations for the specific purpose of protecting American citizens involved in investigational drugs and those regulations have been adopted by more than 20 federal agencies, all 50 states, and every major university in America. These regulations require the effective legal consent by the recipient before the administration of an investigational drug. Effective legal consent can only be obtained if it is given out of the free will and voluntary agreement of the subject. This voluntary consent is nullified if the subject is under duress by threats of harm by other persons of authority or dominance. Therefore, vaccine mandates having compliance dates before the availability of fully licensed and approved drugs are illegal, unconstitutional, and violate international treaties. They are illegal because refusal to participate in the

investigational vaccines **involves a penalty, or loss of benefits**, to which the citizen is otherwise entitled. They are unconstitutional because they violate the 14th amendment, and they violate treaties ratified by the Senate.

The below content is designed for elected leaders and the legal community and will be more technical in nature.

Religious Exemption: This is getting the cart before the horse. No citizen is required to give a religious exemption when considering whether or not to participate in biomedical research. The option to opt-out is a legally protected right and no other reason is required to be given by an act of law.

How are citizens being legally informed prior to the administration of the Pfizer-BioNTech COVID-19 Vaccine?

The Drug Fact Sheet serves as the informed consent process under the Emergency Use Authorization.

The FDA stated in their EUA that, "Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19)"

Most notably on the fact sheet is the statement that "Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care." This statement serves the purpose of fulfilling the legal requirements ensuring the protection of human subjects involved in biomedical research.

By agreeing to ingest the Pfizer-BioNTech COVID-19 Vaccine, a person is volunteering to participate in biomedical research by their free will and voluntary consent.

The Pfizer-BioNTech COVID-19 Vaccine fact sheet gives specific information to comply with the above-noted regulations and some of those facts are:

- Benefits
- Risks
- Information on additional help if subject encounters an adverse reaction
- The option to opt-out
- Where to report an adverse reaction

How does section 564(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetic Act impact the right of American citizens to opt-out of investigational drugs?

What is section 564 of the FD&C Act? - https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uMzYwYmJiLTNh%7C%7C%7C0%7Cfalse%7Cprelim

Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) allows the FDA to authorize the use of unapproved medical products during a declared emergency resulting from a chemical, biological, radiological, or nuclear attack.

21 USC 360bbb-3 (1) Declares what constitutes an Emergency use under Section 564.

“Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the **Secretary may authorize** the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of **a drug, device, or biological product** intended for use in an actual or potential emergency."

The goal of Congress is to introduce unapproved medical products into the marketplace during a declared emergency outside of the normal approval processes contained in chapter nine of Title 21 and section 351 of the Public Health Service Act. The purpose of Congress amending section 564 with the passage of Project Bioshield in 2004 was to allow the medical community to create medical countermeasures in response to a CBRN event or the threat of one. Imagine a city attacked with a CBRN agent resulting in mass casualties, and you can see what Congress was attempting to accomplish through section 564.

Lawyers for defendants who are mandating the use of investigational drugs use the following as the basis for their argument. 564(e)(1)(A)(ii)(III) states, [person receiving the drug must be informed] “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.”

Governors argue that since their executive orders list the consequences of not taking the EUA drug then their mandates are legal; while at the same time fulfilling the notification requirements of this statement.

This argument is not only a fallacy it is **statute heresy**.

Like much of the U.S. Code, one must read the entire chapter and the mountain of referenced links, to fully understand the legal meaning of section 564.

We know that section 564 does not grant any authority the legal right to apply punitive actions against a citizen who chooses to opt-out of the investigational drugs covered under this section because it makes no claim to do so. Remember that Congress only claimed that the "Secretary may authorize the introduction into interstate commerce...a drug, device, or biological product intended for use..."

Congress required the following conditions when administering the product to an individual:
(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed-
(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
(III) 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.

Congress wanted to ensure that a citizen knew the health risks and benefits of the EUA drug before consenting to its administration. This requirement was to fulfill the laws protecting citizens involved in biomedical research. The word "consequences" can only mean health consequences since that is the only subject written about by Congress under the Required Conditions for authorizing an unapproved product.

The FDA provided us with the legislative history of the intent of Congress when they issued a report in 2007. The FDA stated that "**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." https://www.emergobyul.com/sites/default/files/file/usa-fda-emergency_use_authorization_of_medical_products.pdf

Section 564 states that "With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), 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." In effect, this means that Congress has granted the Secretary authority to establish conditions by which others may manufacture, distribute, and administer EUA authorized medical products. Those conditions are located under The Scope of Authorization in each EUA. No EUA has required persons to impose vaccination requirements as a condition of authorization. Therefore, if the Secretary has not authorized executive leaders to impose those requirements, then how are those leaders claiming that right to do so, such as Oregon's Governor, Kate Brown?

The Justice Department wrote a memo in July of 2021 regarding this subject. The author of the DOJ memo is Dawn Johnsen, Acting Attorney General at the Office of Legal Counsel. Concluding her opinion to President Biden, she states that, "we conclude that section 564 of the

FDCA does not prohibit public or private entities from imposing vaccination requirement, even when the only vaccines available are those authorized under EUAs."

A southern phrase comes to mind when reading her memo, and that is "**the devil will sell you on a whole lie by only telling you half a truth**." She is accurate in stating that section 564 does not prohibit entities from imposing mandates. However, the half-truth is that section 564 does not grant entities the authority to impose vaccine requirements either. Section 564 only grants the Secretary power to authorize the use of an unapproved drug during a declared emergency and makes no other claim.

What should be concerning to the American people, given the unethical practices of researchers, is that Dawn Johnsen never speaks to the legal requirements of the Common Rule once in her memo. How can a legal advisor speak about mandates involving experimental drugs and not reference laws prohibiting those mandates from applying punitive acts against those who opt-out? These laws are codified in all 50 states and the regulatory framework of 20 federal agencies.

However, the legal danger of Dawn Johnsen making this argument is that she is endangering section 564 being ruled illegal by a court of law. This would mean that the FDA and HHS have been acting illegally since its inception. We have a treaty ratified by the U.S. Senate stipulating that, "no one shall be subjected without his free consent to medical or scientific experimentation." We know that "free consent" is only legally given when conditions are provided ensuring the subject is free of sanctions, undue influence, and coercive policies when making their decision to participate or opt-out of the investigational drug. To state that section 564 somehow grants authorities the right to ignore the conditions of consent could lead a court to invalidate the entire section since it contradicts the requirements of a ratified international treaty and other federal laws. I doubt any judge would agree with the sentiments of Dawn's conclusion so I make this point only for the purpose of clarity.

Dawn Johnsen attempts to nullify the Belmont Report in its entirety by redefining what "informed consent" means.

She states that "564(e)(1)(A)(ii)(I)–(II). These provisions all appear to require only that certain factual information be conveyed to those who might use

the product." Notice the phrase "require only." This is simply not accurate. Informing a subject of the risks and benefits of an EUA drug is only half of the requirement. Receiving the "consent" is the other half, and that half legally requires authorities to ensure the subject is free of coercion, sanctions, and undue influence when giving said consent. The author never spoke about those requirements, and for good reason, since it would invalidate her entire opinion.

Section 564 only claims to authorize a medical product for use in a declared emergency "notwithstanding" the laws governing the normal approval process for that medical product. It does not claim to exempt itself from the "informed consent" process required by 45CFR46 regulations as Dawn Johnsen implies.

Conclusion: Section 564 only grants the secretary power to authorize medical products intended for use in a declared emergency. Congress never authorized any authority to ignore the Common Rule when amending section 564 in 2004. Congress never referenced legal "consequences" anywhere in section 564, and since no punitive acts for refusing administration of an EUA drug exists in this law, then there can be no legal consequences for that refusal. This is law 101 and defendant attorneys should be ashamed of their statute heresy. Therefore, no citizen can incur a penalty or lose a benefit they are otherwise entitled to when choosing to opt-out of investigational drugs authorized under section 564.

https://uscode.house.gov/view.xhtml?req=(title:21%20section:360bbb-3%20edition:prelim)

The FDA stated that COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine can be used interchangeably. Does this mean that the Pfizer-BioNTech COVID-19 Vaccine is exempt from the Protection of Human Subjects regulations and laws?

No!

The FDA approved COMIRNATY on August 23, 2021, and after that approval, they informed Pfizer that the Pfizer-BioNTech COVID-19 Vaccine had not been approved and would be required to operate under the investigational new drug process.

The FDA has refused to clarify the statement that, “The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide doses for primary vaccination or a booster dose without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.”

Here are some legal facts regarding The Pfizer-BioNTech COVID-19 Vaccine irrespective of the FDA statement:

- All vaccination providers must abide by the requirements outlined in 21CFR50 (except for exemptions claimed under the EUA) and 45CFR46 when administering the Pfizer-BioNTech COVID-19 Vaccine. Failure to do so is illegal and risks the medical provider of being criminally charged.
- All vaccination providers must abide by the legally effective consent requirements of the Belmont Report and Section 564 of recipients before the administration of the Pfizer-BioNTech COVID-19 Vaccine.
- No provider may tell a person that the Pfizer-BioNTech COVID-19 Vaccine has been approved by the FDA. To do so would nullify the legally informed consent process. There have been several legal cases where a person successfully sued a doctor who failed to adequately obtain a “quality” informed consent from the patient. This lack of quality informed consent was due to a lack of information or false information given at the time of treatment involving an IND.
- The FDA has required that Pfizer submit monthly reports of adverse reactions, distribution, stakeholder involvement, and other requirements found in 21CFR50 and section 564. These requirements are not required of the COMIRNATY vaccine.
- The Pfizer-BioNTech COVID-19 Vaccine is considered experimental as noted in the October 20, 2021 Emergency Use Authorization letter issued by the FDA. COMIRNATY is not considered to be an experimental drug.

The drugs may share the same formula, but they do not share the same drug label. This simple fact legally demonstrates that vaccination providers may not use the drugs interchangeably to provide the vaccination series. A vaccination provider may not legally administer The Pfizer-BioNTech COVID-19 Vaccine in the same way it administers COMIRNATY. If the

provider did so, then he or she would be subject to criminal charges and liability lawsuits. Therefore, the FDA has done great harm to the American people by not clarifying their statement. The officials who made that statement failed to fulfill their fiduciary responsibilities of ensuring judicial integrity of the regulations they have sworn an oath to uphold.

Court Role Play: The judge might repeat the FDA statement that the drugs are interchangeable and can be used to provide the vaccination series.

Response: This is a false statement, your honor, by FDA officials. Pfizer-BioNTech COVID-19 Vaccine is an unapproved medical product and can only be administered under the Scope of Authorization outlined in the Emergency Use Authorization letter and must adhere to 45CFR46 regulations. Furthermore, Pfizer-BioNTech COVID-19 Vaccine operates under the aforementioned laws, whereas COMIRNATY does not. If a citizen walks into a vaccination provider's office and is offered the Pfizer-BioNTech COVID-19 Vaccine without the doctor providing the required documentation under Title 21 section 564 and 45CFR46 regulations, then that doctor can be charged with a felony and opens himself or herself up to liability charges. If a citizen walks into a vaccination provider's office and requests the COMIRNATY vaccine the doctor is then free from those requirements. Therefore, your honor, how can the defendant or officials at the FDA convey to this court, the medical community, and to the various regulatory bodies, that both drugs can be used interchangeably when it's plain to see that they cannot be administered interchangeably?

Vaccination providers who administer the two drugs are required by law to administer them according to the laws governing the label on the drug vial and not the drug inside of the vial. Do the defendants disagree with this statement?

Have there been court cases involving INDs?

Yes, but never before in American history has a political party controlling the federal government, state governments, and corporations, worked in tandem to force Americans into biomedical research against their free will and voluntary consent. Therefore, the number of legal cases has been few to date.

Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1 (1972)

"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." Cobbs, supra, at 242-243.

“in Cobbs, the California Court found that consent of the quality required by this regulation should have been obtained from the patient and that it was the patient's prerogative to make the treatment decision based upon adequate information, not the physician's prerogative to limit the patient's choices by limiting the information provided.” FDA See generally, Pharmaceutical Manufacturers v. Food Drug Administration, 484 F. Supp. 1179, 1188 (D. Del. 1980). - FDA

Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972)

"every human being of adult years and sound mind has a right to determine what shall be done with his own body…”

“Canterbury court defines ‘true consent’ as the informed exercise of a choice that, in turn, entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. Canterbury, supra, at 780.” - FDA

“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.” - FDA

The above court rulings point to the dangers of FDA officials not adequately informing the medical community of their requirement to give quality information to, and to receive a quality informed consent from, the patient before the administration of the Pfizer-BioNTech COVID-19 Vaccine.

The FDA will argue that section 564 states when it’s practical to give or receive an informed consent. However, they would be hard pressed to

prove in our current environment that adding additional information to a drug sheet isn't practical.

What Rights do I lose when I volunteer for an IND?

IND drugs are legally considered experimental to conduct biomedical research and have the backing of international and federal laws preventing participants from suing medical investigators or pharmaceutical companies relating to adverse reactions. Pharmaceutical companies have the backing of law specifically because they rely on a voluntary and informed consent process. By participating in an experimental drug, a person is declaring they have been informed of the potential side effects of the drug and have made an informed consent to participate in the biomedical research regardless of possible adverse reactions. This voluntariness legally denies patients certain rights to pursue financial damages in a court of law.

Can I be fired from my government, private job, or denied educational access before the availability of COMIRNATY if I don't take an IND?

No!

Virtually all government agencies have adopted the Common Rule into their regulations. Therefore, officials at these agencies may not require anyone under their care to participate in an IND when their own published regulations prohibit them from doing so. These officials are opening themselves up to criminal charges and civil suits for failing to fulfill their fiduciary responsibilities.

Let's take the DoD as an example to demonstrate how their regulations deny them the right to force service members into taking the Pfizer-BioNTech COVID-19 Vaccine. 32 CFR 219.116(a)(1) adopts the Common Rule language by stating, "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." It further states that "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."

In 2003, US District Judge Emmet G. Sullivan ruled against the DoD mandatory anthrax vaccination program stating, "This court is persuaded that AVA is an **investigational drug** and a drug being used for an unapproved purpose." He then stated, "Absent an informed consent…the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." He then made it extremely clear regarding the Belmont Report that, "**Congress has prohibited the administration of investigational drugs to service members** without their consent. This court will not permit the government to circumvent this requirement." Although this ruling was related to U.S. Service Members, Sullivan applied it to civilian life as well.

SECDEF Austin clearly stated in his memo that only approved drugs per FDA labeling guidelines would be used. Therefore, how are U.S. Service Members being punished for choosing to opt out of investigational drugs that have not been approved by the FDA? Why is SECDEF Austin willfully ignoring federal law and past court rulings by forcing the administration of investigational drugs onto service members under duress without their consent?

Let's look at the State of Hawaii which demanded vaccination for all state workers before September 01, 2021. Did the state provide citizens with the required statement that "participation [in INDs] is voluntary, [and] 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?" The answer is no. Did the state inform citizens that taking an IND would invalidate some, or all, of their legal rights to future litigation efforts? The answer is no.

Hawaii's governor failed to fulfill the requirements of international treaties, federal and state laws, and 45CFR46 regulations governing investigational drugs. Furthermore, the governor engaged in criminal activity by enacting an illegal executive order coercing citizens into participating in biomedical research against their free will and voluntary consent.

Furthermore, Section 564 REQUIRES that recipients be made aware of alternatives to the product including those that can treat the virus. Section 564 does not allow the government to only focus on one product given the experimental nature of the event. Officials at the FDA have failed to fulfill the requirements of section 564 because they are only notifying recipients of one drug and not the alternatives as required by law.

What should I do if I already participated in the Pfizer-BioNTech COVID-19 Vaccine under duress?

Contact a local attorney and discuss the option of filing a lawsuit claiming coercive intimidation to engage in an activity that was against your better judgment.

Questions to answer:

1. Did your public or private institution inform you that by taking the Pfizer-BioNTech COVID-19 Vaccine that you would in effect be engaging in biomedical research?
2. Were you informed of the potential loss of rights to sue Pfizer and others if you took the Pfizer-BioNTech COVID-19 Vaccine?
3. Did your public or private institution inform you that you could wait for the approved vaccine labeled COMIRNATY?
4. Did your public or private institution provide guidance on what to do in case of an adverse reaction?
5. Were you informed that the Pfizer-BioNTech COVID-19 Vaccine has a known history of degradation, making it ineffective in less than a year?
6. Were you informed that you could take the highly effective Regeneron therapy treatments should you contract COVID?
7. Were you informed by the issuer of the mandate that the Pfizer-BioNTech COVID-19 Vaccine has not been approved by the FDA?

Legal Questions

Based on recent court rulings and how judges have worked to help defendants to win their cases, I'm providing you with some questions to answer before they are asked of you.

A judge might ask, “can you prove that COMIRNATY isn’t available in your local market?”

Response: The FDA has stated in each of its EUAs that COMIRNATY isn’t available to the American people and its why they have issued the EUA for the other investigational drugs.

A judge might ask if the Pfizer-BioNTech COVID-19 Vaccine had the COMIRNATY label attached to the vial then would that be considered a legal vaccine under current mandates?

Response: No, your Honor. This is because the FDA has plainly stated that the two drugs have certain differences and we do not know the specifics of those differences. Furthermore, it has been stated that the formulation has not changed since the name changed. This statement could mean that the formula for existing Pfizer-BioNTech COVID-19 Vaccine drug vials is different from what was used before the name changed. However, the formulation of the two drugs has no bearing on this case since the drug label is what determines how vaccination providers must administer each drug regardless of the mandates or the shared formula.

NOTE: We must always drive the conversation back to this point to keep the court focused on this one fact: Shared drug formula is irrelevant to the laws that govern the drug labels.

Statement to make to the court. Your Honor, does this court have the legal right to nullify laws governing drug labels? This is not a rhetorical question since the defendant is implying that the Pfizer-BioNTech COVID-19 Vaccine drug label is invalidated simply because another approved drug shares the same formula. The regulations governing the Pfizer-BioNTech COVID-19 Vaccine drug label were derived by an act of Congress. The fact that two drugs share the same formula is irrelevant since they do not share the same drug label. The FDA could not be any clearer, when they told Pfizer to place on all materials relating to the Pfizer-BioNTech COVID-19 Vaccine, that it was not an approved drug. We do not know the reason why the FDA did not approve the vaccine, but they have required Pfizer to operate under regulations governing the protection of human subjects involved in biomedical research for that drug. The FDA declared that there were legal distinctions and certain differences between the two

drugs and maybe this is why it has made this requirement. Does this court have the authority to allow governments to ignore laws governing drug labels derived by an act of congress? I ask because this is precisely what the defendant is asking this court to do.

Court Role Play: Your honor, defendant's counsel is asking you to completely ignore the FDA approved labels attached to the drugs in question before you today. Those drug labels were derived by an act of Congress and represents the will of the people. Congress gave the FDA the legal authority to approve drugs and then determine what labels will be attached to those drugs. The FDA made it abundantly clear AFTER they approved COMIRNATY that they would not approve the Pfizer-BioNTech COVID-19 Vaccine drug. We know this because they told Pfizer to place that notification on all printed materials relating to that drug. Then, they told Pfizer to use an investigational drug identification which mandates they must abide by the rules governing such a drug. Defendant's counsel is literally asking you to ignore the laws governing such drugs. Congress makes the laws and courts adjudicate those laws when disputes arise. Your honor we took an oath to uphold the Constitution and the laws of the land when we became practicing attorneys. Nowhere in my years of learning at my educational institution did my professor tell me that my best defense was to convince the court to ignore the laws on the books and to adopt my personal desires regarding those laws. Such acts by licensed attorneys would be considered highly unethical in most societies. This court must recognize FDA's authority to approve or not approve drugs and subsequently the labels they attach to those drugs. The Pfizer-BioNTech COVID-19 Vaccine is an investigational drug as determined by FDA's Biologics Board and defendant's counsel is asking you to ignore their decision simply because they approved another drug using a shared formula. However, remember that the Biologics Board gave that other formula a different drug label governed by different laws. If the FDA wanted to approve the Pfizer-BioNTech COVID-19 Vaccine drug they could have done so but they chose not to for reasons they have not made public. Therefore, we ask this court to take the only course of action that it can and that is to recognize the actions of the FDA and to judge our case by the laws governing those actions. COMIRNATY has one drug label and the Pfizer-BioNTech COVID-19 Vaccine has a different label. The Pfizer-BioNTech COVID-19 Vaccine label states that it has not been approved by the FDA and is legally considered to be an experimental drug. How can defendant's counsel disagree with such a black and white truth?

Be mindful not to use the word force when speaking about mandates. It detracts from the real issue at hand. No mandate forces a citizen under armed guard to take an investigational drug. Mandates require (not force) citizens to take an investigational drug under duress. This last statement is 100% accurate and 100% illegal.

Legal Conclusion: To effectively pause all current vaccine mandates in our nation we should only focus on the legal right of Americans to opt-out of investigational drugs. No attention should be made to other issues such as effectiveness, or the failed clinical trial of the Pfizer vaccine. Those issues detract from the point at hand. We know that all current vaccine mandates rely on INDs and therefore they are unenforceable. This is a very clean argument to make in a court of law and it makes it very hard for a court to deny such an argument. Therefore, start with this endeavor, and then we will have the time to build legal cases regarding the other issues which are truly just as important.

Remember: The laws governing the Pfizer-BioNTech COVID-19 Vaccine drug label are what we want the court to focus on and not the drug contained inside the drug vial. What we are arguing isn't the right of Americans to opt-out of vaccine mandates in this case. We are arguing that Americans have the right to opt-out of investigational drugs without losing benefits and according to the FDA, the Pfizer-BioNTech COVID-19 Vaccine is an investigational drug. I believe that any federal judge would be compelled to grant an injunction based on the above research. No argument is to be allowed regarding vaccine mandates. Only the argument that no investigational drug can be forced onto the public under duress.

SAMPLE LETTER

To whom it may concern:

On (date), I received a letter requiring me to ingest a COVID-19 drug by (date) for (continued employment, access to educational services, etc.) I have enjoyed working for (company) and have a personal desire to continue our relationship. However, I am concerned that (company) has set a compliance date before the availability of a fully licensed and approved drug per FDA labeling guidelines.

On August 23, 2021, the FDA approved a Pfizer COVID-19 drug called COMIRNATY. This drug is currently unavailable to U.S. consumers, as noted in the FDA's Emergency Use Authorization.

The only available COVID-19 vaccines are investigational new drugs (INDs). An investigational drug is a substance that has been tested in the laboratory and authorized by the U.S. Food and Drug Administration for **testing in people**. Investigational drugs must abide by the laws and regulations governing the Protection of Human Subjects Involved in Biomedical Research.

Pfizer BioNTech COVID-19 Vaccine has IND number 19736
Janssen Biotech COVID-19 Vaccine has IND number 22657
ModernaTX COVID-19 Vaccine has IND number 19745

The laws governing the Protection of Human Subjects Involved in Biomedical Research can be found at 45CFR46. These regulations clearly state that “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**…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 to.” 45CFR46 has been adopted by 50 states, 20 federal agencies, and every major university in America.

The compliance date of your vaccine mandate would require me to participate in biomedical research against my free will and voluntary consent because only INDs are currently available in our health market.

Should I ingest an investigational vaccine drug, I would be volunteering for biomedical research and forfeiting certain legal rights to future legal settlements according to federal law. **I currently do not have a desire to participate in COVID-19 research projects.**

Since your vaccine mandate relies solely on investigational drugs, it lacks the force of law, and it violates my 14th amendment rights to equal protection of laws. I am concerned that you are currently engaging in acts of harassment, intimidation, and coercion by setting a compliance date before the availability of a fully approved and licensed drug per FDA labeling guidelines. Should you continue threatening me with punitive actions for my choice of opting out of biomedical research, I will seek remedy in a civil court. Your letter has already caused unwarranted emotional stress in my life because you are forcing me, under duress, to participate in experimental drugs.

Therefore, I require (company name) to formally submit a written apology. I need that letter to affirm my rights to opt out of biomedical research projects without losing a benefit that I am otherwise entitled to. These rights are legally protected under the International Covenant on Civil and Political Rights Treaty, 45CFR46 regulations, and (name your state here) Florida laws.

I encourage you to contact the Office for Human Research Protections within the Federal Department of Health and Human Services. Ask them if a citizen can lose (employment, access to educational services, etc.) for choosing to opt-out of biomedical research such as the Pfizer BioNTech-COVID 19 Vaccine project. OHRP is responsible for ensuring that all federal agencies and contractors abide by 45CFR46 regulations.

I reaffirm my desire to continue (my employment or educational services, etc.) However, should (company name) continue threatening me with punitive actions, I will file a formal criminal complaint with our state's attorney general, surgeon general, department of labor, human rights commission, and the city council.

Kind Regards,

NOTE: When researching laws governing the protection of human subjects, Google the following phrase: (state, university, etc.) protection of human subjects in biomedical and behavioral research (or science.) You will quickly discover the laws and regulations governing the administration of investigational drugs in your community. NOTE: Not all states have laws specifically for this protection, though most do. However, those states that lack legislative statutes have department of health regulations that clearly state they abide by 45CFR46 regulations.

EUA issued for Pfizer-BioNTech COVID-19 Vaccine https://www.fda.gov/media/150386/download
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=50.20
https://www.fda.gov/media/144414/download
https://www.cidrap.umn.edu/news-perspective/2003/12/judge-orders-dod-stop-requiring-anthrax-shots
Federal Food Drug And Cosmetic Act (21 U.S.C. § 331) - It is a crime to adulterate or misbrand consumer products, it is also a federal offense to knowingly "traffic" mislabeled products. https://www.law.cornell.edu/uscode/text/21/331
"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." - Judge Sullivan https://www.ncbi.nlm.nih.gov/pmc/articles/PMC526141/

The below is simply to inform legal authorities of the failed clinical trial conducted by Pfizer that officials at the FDA used for approving COMIRNATY.

PFIZER'S CLINICAL FAILURE

The Pfizer-BioNTech COVID-19 Vaccine clinical trial was designed to:

- Run for 24 months of academic study [1]
- Prove a 50% vaccine efficacy (VE) at the end of the trial [2]
- Study a brand new and untested vaccine technology [3]
- Prove safe for users

The FDA was going to:

- Provide for public input [4]
- Allow the vaccine advisory board to give input [4]
- Make the clinical trial data transparent for public study [4]

The clinical trial actually:

- Lost 44% of blinded group participants by the fourth month
- Lost 93% of blinded group participants by the sixth month [5]
- Only reached 83.7% VE at the end of the sixth month [6]
- Proved VE degraded 6% every two months [6]
- Proved VE degradation was accelerating after the fourth month
- Ended prior to Delta becoming dominate in the USA; therefore no conclusion
- Did not study impact on pregnancy [7]
- Failed and ended six months into a 24-month study
- Proved the vaccine would not be able to meet the required 50% VE threshold

Israeli Ministry of Health documented:

- The Pfizer-BioNTech COVID-19 Vaccine only had a 39% VE at the beginning of the seventh month
- The Pfizer-BioNTech COVID-19 Vaccine only had a 16% VE at the end of the seventh month [8]
- Ninety-percent of all new COVID cases for ages 50 and older are from fully vaccinated persons

The U.K. reported that from Feb. 01 through June 21, 2021 more citizens died from Delta who were fully vaccinated than those were unvaccinated. [9]

Adverse Reactions:

- CDC tracks 94 vaccines for adverse reactions.
    - Pfizer and Moderna RNA vaccines account for nearly 50% of deaths and 45% of all adverse reactions out of 1,230,785 reports.
- The European Adverse Reporting system has logged 385,441 adverse reactions to Pfizer's vaccine through the end of August 2021.
- As a comparison, the drug Bextra was pulled from the shelf after Pfizer was fined $2.3 billion for drug fraud. Bextra had 12,318 adverse reactions and 1,054 deaths reported over a span of 18 years. Pfizer has 300% more reported deaths and 1,920% more reported adverse reactions in less than 12 months

The FDA:

- Refused to order Pfizer to conduct another clinical study
- Ignored Pfizer's VE of 83.7% and instead used an earlier report of 91%
- Refused to report that Pfizer noted a minimum 6% degradation in VE
- Approved a brand new and untested vaccine technology in four months which was the shortest amount of time a vaccine was approved in the agency's history
- Refused to open clinical trial data for public review
- Refused to allow public input
- Ignored the fact that the clinical trial proved Pfizer could not meet the 50% VE at the endpoint of a 24-month trial
- Ignored data from Israel that Pfizer's VE degraded down to 16% within eight months
- Cannot prove VE past six months
- Ignored historical levels of adverse reporting in the CDC database
- Approved a clinical trial that lost 93% of its blinded group participants and only completed 25% of its required academic study time
- Appears to have only used data from the clinical trial for approval
- Ignored a report by Israeli researchers who conducted the largest study in the world proving that a person previously infected with COVID-19 is 1200% more protected against Delta than a person fully vaccinated with Pfizer-BioNTech COVID-19 Vaccine [10]

TheRepublicJournal.Com

Citations Below

[1] “It is already concerning that full approval is being based on 6 months’ worth of data despite the clinical trials designed for two years.” - Kim Witczak, a drug safety advocate who serves as a consumer representative on the FDA’s Psychopharmacologic Drugs Advisory Committee. - https://www.bmj.com/content/374/bmj.n2086

[2] Page 14 letter E - https://www.fda.gov/media/139638/download

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html

[4] This is an FDA blog post. Read the bottom 2 paragraphs - https://www.healthaffairs.org/do/10.1377/hblog20200814.996612/full/

[5] Look at the staring number for the randomized group of 44,165. Then the placebo group on the right received the vaccine within the first 4 and 6 months which reads as “received dose 1” and “received dose 2”. Then the bottom boxes show those who “entered open-label follow up.” meaning they were no longer part of a blinded group study. This means that only 3,037 participants remained in the blinded group study out of 44,165 participants within the first six months for a study designed for 24 months - https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf#page=14

[6] “Efficacy peaked at 96.2% during the interval from 7 days to <2 months post-dose 2, and declined gradually to 83.7% from 4 months post-dose 2 to the data cut-off, an average decline of ~6% every 2 months.” Page 7 - https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf

[7] “This report does not address VE and safety in pregnant women” page 8 - https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf

[8] View the graphic - https://www.infectioncontroltoday.com/view/latest-data-point-to-a-need-for-covid-19-booster-shots

[9] Bottom of page 17 add columns for “dose 1” and “dose 2” compared to “unvaccinated. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001358/Variants_of_Concern_VOC_Technical_Briefing_18.pdf#page=17
Note for Adverse Reactions. These numbers were pulled from active government official databases at the end of August. The numbers are continually growing and can’t be linked to directly. FDA CDC EUROPE

[10] https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf