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Department of Defense (DoD) COVID-19 Violations

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To DoD Commanders, Elected Leaders, and State Attorneys General

SUMMARY:

Military commanders are at risk of prosecution under the Uniform Code of Military Justice, as well as federal, state, and foreign laws for penalizing service members who refuse to volunteer for COVID-19 experimental substances. Civilian-appointed authorities are engaging in significant abuse of powers by refusing to fulfill the fiduciary responsibilities of their office to ensure federal statutes and military regulations are followed by military departments regarding COVID-19 experimental substances.

The Department of Defense can not produce a single statute exempting them from DoDI 6200.02 requirements to secure a service member's informed consent involving COVID-19 substances without the written authorization of the Commander in Chief.

Let us lay out the facts to back up these claims so that authorities may take appropriate action to remedy the injustice perpetrated against our men and women in uniform.

COVID-19 VACCINE FACTS:

As of August 11, 2022 there are only COVID-19 Investigational New Drugs (IND) available to Department of Defense (DoD) personnel. An IND is legally defined as "a substance that has been tested in the laboratory and approved by the U.S. Food and Drug Administration (FDA) for testing in people. Also called an experimental drug, IND, investigational agent, and investigational new drug (*National Cancer Institute (NCI) Dictionary of Cancer Terms*, 2022)." No fully FDA-licensed vaccines are known to be available to DoD Personnel.

DoD Instruction (DoDI) 6200.02 :

DoDI 6200.02 regulates INDs and EUA medical countermeasures which are activated upon one of the two following conditions:

1) (DoDI 6200.02 E2.4) “An approved medical product is utilized for an unapproved purpose according to the product’s labeling (e.g., COMIRNATY for certain age groups).”
2) (DoDI 6200.02 E2.7) “A medical product requires the issuance of an EUA for its administration (e.g., Pfizer-BioNTech COVID-19 Vaccine).”

As of the date of this publication, only substances that fall under DoDI 6200.02 regulation have been available to DoD personnel.

DOD HIERARCHY:

DoDI 6200.02 (5. Responsibilities) defines the DoD components required to participate in the approval, guidance, and implementation process for substances authorized for access under 21 USC §360bbb-3 (Section 564). The Under Secretary of Defense (Personnel & Readiness) is the lead authority and is required by statute to ensure implementation protocols abide by international treaties, federal statutes, and military regulations. The Assistant Secretary of Defense for Health Affairs is required to approve all Emergency Use Authorization (EUA) drugs for use by DoD personnel. The Secretary of the Army is the lead component for implementation of EUA drugs. The Surgeon General of the Army and the United States Army Medical Research and Development Command (USAMRDC) are required to act as the single Institutional Review Board (IRB) and to monitor and report on all adverse reactions of EUA drugs, to include COVID-19 IND vaccines.

INFORMED CONSENT REQUIREMENTS:

According to DoDI 6200.02 (E3.3) “DoD Components using medical products under an EUA shall comply with all requirements of Section 564 of Reference (d), FDA requirements that are established as a condition of granting the EUA (**except as provided in Section E3.4** concerning a waiver of an option to refuse), guidance from the Secretary of the Army as Lead Component, and instructions from the ASD(HA).”

DoDI 6200.02 (E3.4) Request to the President to Waive an Option to Refuse. “In the event that an EUA granted by the Commissioner of Food and Drugs **includes a condition that potential recipients are provided an option to refuse administration of the product**, the President may, pursuant to **Section 1107a** of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces.” These instructions require the informed consent of service members without penalty when involving EUA vaccines. All DoD and civilian health care providers agree to abide by the informed consent process in reference to a signed agreement with the Centers for Disease Control (CDC) for vaccines under an EUA. COVID-19 vaccine EUAs require that recipients be informed of the option to accept or refuse participation in reference to the required drug fact sheet.

21 U.S. Code §360bbb-3 (l) states “Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section.” DoDI 6200.02 (5.2.3) requires adherence to Section 564 FDA requirements, and the DoD has no authority to amend or alter those requirements except the option to accept or refuse in reference to 10 USC 1107a. Therefore, if the Secretary does not have the authority to require participation by any person in any activity, then the DoD has no authority to require the involvement of service members in EUA administration activities.

The Secretary of the Army and the Surgeon General of the Army must abide by the Human Subjects Research Review Board’s (HSRRB) ‘Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements’ (DoDI 6200.02 5.3.2). Those “requirements” (2-1 and 7-4) mandate DoD leadership to abide by the ethical guidelines as described in the Belmont Report when obtaining a service member's informed consent.

The Belmont Report defines Informed Consent:

> “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**.”
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> “This element of **informed consent requires** conditions **free of coercion** and **undue influence**.”

- “**Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.”
- **“Undue influence**, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.”
- **“Unjustifiable pressures** usually occur **when persons in positions of authority** or commanding influence -- especially where possible **sanctions** are involved -- **urge a course of action** for a subject.”

The Belmont Report has been embedded into the regulatory framework of 20 federal agencies, 50 US States, and thousands of legal entities. Any time an experimental product, according to its labeling, is classified by the FDA as experimental, it is required to abide by the ethical guidelines of the Belmont Report per federal and state statutes.

Military commanders are legally bound to obtain the informed consent of service members before the administration of an IND. That informed consent obligates DoD leadership to ensure service members are not under threat of penalty for refusing to participate in experimental substances. Only the President has been endowed with power by Congress to waive the informed consent requirements (10 USC 1107 & 1107a) as established in 45 Code of Federal Regulations (CFR) 46, 32 CFR 219, the Belmont Report, DoDI 6200.02, and USAMRDC ‘2018 Common Rule’ regulations.

Military commanders penalizing service members who refuse the administration of an experimental substance are ***illegally*** waiving informed consent requirements. The waiver is explicitly reserved by Congress for the Commander in Chief. Furthermore, the Belmont Report obligates civilian authorities to establish a "set of adequate conditions" to receive service members' legally effective informed consent. Those conditions require instructions to be transmitted to military commanders that refusal to participate in DoDI 6200.02 substances by service members may not lead to punishment.

The DoD is now under significant liability by two million service members whose legally effective informed consent could not be obtained since they were under threat of penalty when offered an IND, in violation of the Belmont Report's ethical guidance and DoDI 6200.02 legal requirements.

US SENATE RATIFIED TREATY:

In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights Treaty. Article VII of that treaty declares that "no one shall be subjected without his free consent to medical or scientific experimentation." The word "subjected" does not mean physical restraint; instead, it means to be under force of law by one's government. Therefore, to mandate participation in medical experimentation by law, rule, and or regulation under threat of penalty violates this treaty, federal statutes, and military regulations. Civilian authorities will confirm they never required the administration of EUA products under threat of penalty in their published directives. Their statement would be correct, but their wilful failure to require adherence to those directives is their true crime.

OTHER APPLICABLE LAWS:

32 CFR 219 Protection of Human Subjects regulations apply to all medical research activities under DoD authority. Those research activities include clinical trials but are not limited to such narrow projects. The policy defines research activities as "a systematic investigation, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge**." All EUA substances under DoD authority are under an Institutional Review Board (IRB) and are required to abide by DoDI 6200.02, 21CFR50.23, 21CFR312, 1107 10 U.S.C., EO 13139, 21 U.S.C. 355(i)(4), HQ USAMRDC IRB policies, and U.S. Food and Drug Administration (FDA) Guidance, Emergency Use Authorization of Medical Products and Related Authorities (Jan 2017).

> 32 CFR 219.101(f) states, "This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that **provide additional protections** for human subjects."
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> 32 CFR 219.101(g) states, "This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research."
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> 32 CFR 219.101(e) states, "Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects."

> 32 CFR 219.101(c) states, "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report."

Civilian leaders and Military commanders who require participation in experimental products under threat of penalty must contend with additional laws and regulations by federal, state, and foreign governments if those laws provide for "additional protections."

Furthermore, the DoD has a signed agreement with the Health and Human Services 'Office of Human Research Protections' in reference to the Federal Wide Assurance (FWA) program. That FWA agreement requires adherence to 45CFR46 and the Belmont Report when an experimental substance involves a human.

SECRETARY OF DEFENSE (SECDEF) AUSTIN'S VACCINE MANDATE:

On August 24, 2021, SECDEF Lloyd Austin provided **two paths** for vaccine mandate compliance.

Path one is **mandatory** and is a legally binding requirement, "**mandatory vaccination** against COVID-19 **will only use** COVID-19 vaccines that receive **full licensure** from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."

Path two is a **voluntary** option but not legally binding, "**Service members voluntarily** immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated."

Military commanders will not be able to produce a single directive from the above DoD hierarchy requiring the administration of EUA substances under threat of penalty by service members. Such orders are illegal and directly contradict SECDEF Austin's "mandatory vaccination" requirements.

To date, the voluntary path has been the only option afforded to service members, and as such, no service member can be penalized for non-compliance. However, civilian authorities are allowing commanders to unlawfully punish service members who refuse to volunteer for path two.

INTERCHANGEABILITY:

The FDA provided notice to Pfizer on August 23, 2021 that both of their COVID-19 vaccines (i.e., COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine) have the same formulation and may be used interchangeably to fulfill the vaccination series. That same day, Pfizer issued a press release echoing that statement saying, "the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. An individual **may be offered either** COMIRNATY® (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine **to prevent** coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2."

Pfizer defines interchangeably as an option to use either the experimental or the approved vaccine to fulfill the same medical purpose. Therefore, this scientific statement is explicitly related to their products and may not be utilized by authorities as the legal basis to bypass statutes protecting human subjects involved in INDs under an EUA.

Neither private business (e.g., Pfizer, Inc.) nor government entities (e.g., FDA) have the authority to exempt themselves from congressional statutes governing the administration of EUA substances.

On September 14th, 2021, Dr. Terry Adirim, Acting Assistant Secretary of Defense for Health Affairs, issued guidance containing both a recommendation and a directive.

Recommendation: “Per FDA guidance, these two vaccines are interchangeable and DoD health care providers **should use** doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine.”

Directive: “DoD health care providers **will use** both the Pfizer- BioNTech COVID-19 vaccine and the Comirnaty COVID-19 vaccine interchangeably for the purpose of vaccinating Service members **in accordance with** Secretary of Defense Memorandum, ‘Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members,’ August 24, 2021.”

SECDEF Austin provided two paths for vaccine compliance, one of which is mandatory and one is voluntary. Dr. Adirim was not speaking to military commanders in her memorandum. Instead, she guided DoD health care providers to use both vaccines to

comply with both paths issued by SECDEF Austin's memorandum according to a service member's choice.

Dr. Adirim did not order health care providers or military commanders to use BioNTech COVID-19 Vaccine, an EUA drug, in place of fully-licensed COMIRNATY without the consent of service members because such a directive would be illegal.

Lt Gen Place, Director of Defense Health Agency, clarified the right of service members to refuse a COVID-19 experimental substance by declaring, "they (service members) have the option **to accept or refuse** the EUA product **and are free from** any **consequences** of refusing administration of the product." (DHA-IPM 20.004 (1)(d)(3))

COVID-19 vaccines classified by the FDA as an IND require the informed consent of the service member before their administration. That requirement is based on their classification irrespective of another drug sharing the same formula.

DoD health care providers must administer the Pfizer-BioNTech COVID-19 Vaccine according to the Scope of Authorization outlined in the FDA's EUA. However, those health care providers are not under such requirements when administering the FDA-approved COMIRNATY despite both vaccines sharing the same formulation. This distinction is important because Congress established guidelines based on classifications, not formulas.

The Judge Advocate General Corps will not be able to produce a single federal statute or military regulation providing an exemption from informed consent requirements based on a formula. All such statutes are based on the product's labeling, which is why SECDEF Austin issued a legally binding order to military commanders to only use "full licensure" vaccines "in accordance with FDA-approved labeling."

Civilian leaders and military commanders are not able to produce a single statute or FDA guidance legally authorizing them to utilize classified experimental substances "as if" they are full licensure drugs without the explicit informed consent of the service member.

Pfizer's COVID-19 vaccines may share the same formulation, but they do not share the same classification. Those classifications are the legal distinctions the FDA informed the DoD of on August 23, 2021, and those legal distinctions have significant legal consequences for service members.

Can statutes associated with COMIRNATY be used interchangeably with statutes that govern Pfizer's BioNTech COVID-19 Vaccine in a court of law simply because they share the same formulation? Absolutely not! A judge would immediately dismiss such a claim. Therefore, JAG officers guiding military commanders to use a non-approved substance as if it is a full licensure drug without the informed consent of the service member should be removed from active service for abject failure to distinguish the proper course of action as written.

LEGISLATIVE & COURT PRECEDENT:

In 2004, US District Judge Emmet G. Sullivan ruled 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."

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

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

14th AMENDMENT:

Military commanders must apply the same standards equally to service members who either refuse or comply with medical experimentation (e.g., COVID-19 testing, quarantining, etc).

Congruently, military commanders may neither prevent service members from participating in activities (e.g., educational access, deployment, etc) if they refuse medical experimentation nor permit activities exclusively to those who comply with experimental substances.

The option to accept or refuse denotes an equal option of which no authority has the legal right to interfere. However, civilian authorities have issued guidance that violates service members' fundamental 14th Amendment rights by requiring activities for those who refused administration of DoDI 6200.02 substances not required of those who accepted those experimental products.

PFIZER COMIRNATY LABELED VACCINE:

The Surgeon General of the Army has released gray-capped COMIRNATY labeled vials for use by service members under strict requirements. These vials are being promoted as BLA-Compliant vaccines, but no one in authority will call them FDA-licensed vaccines. DOJ lawyers in current court cases will not refer to them as FDA-licensed vaccines. Military commanders are being informed to only use these vials for legal purposes (e.g., vaccine mandates) and not for general administration to service members. The FDA refuses to acknowledge if they are licensed vaccines and refers inquiries to Pfizer. Pfizer, Inc. reps will only state that these vials were manufactured in Kalamazoo, MI. Lastly, no one from the FDA, CDC, DHA, DOJ, or DOD will provide the FDA lot number release letter that should be able to provide authentication.

State Attorneys General should immediately seek clarification on these suspect vials. However, should the vials prove to be FDA-licensed products, these should be referred to courts for review because the federal government is treating these COMIRNATY-labeled vials as an investigational drug research project. The DoD is limiting these vials to a select number of service members. As required by IND statutes, Pfizer has not made these available for general commercial marketing.

Please review:
https://childrenshealthdefense.org/defender/whistleblowers-coast-guard-military-pfizer-comirnaty-vaccine-fda/

MILITARY COMMANDER'S PLAN OF ACTION:

Military Commanders are not responsible for procuring full licensure COVID-19 vaccines to comply with SECDEF Austin's mandatory vaccination requirements, nor have they been endued with authority by Congress to mandate the administration of experimental substances. Commanders should take steps to counter potential future judicial remedial actions by prosecutors, civilian courts, and unfavorable views towards

future promotions by Armed Services Committee members. Affirmative actions might include:

1. Rescind and delete service member's UIFs.
2. Rescind and delete service member's LORs.
3. Cease all separation board hearings.
4. Request the Surgeon General of the Army to declare ***in writing*** if gray cap COMIRNATY labeled vaccines are FDA-licensed vaccines according to FDA labeling guidelines.
5. Request the Under Secretary of Defense (Personnel & Readiness) to provide guidance in writing on how to proceed when licensed vaccines are not readily available.
6. Request the Secretary of Army to declare ***in writing*** if a commander may order a service member to participate in COVID-19 experimental substances under threat of penalty.
7. Issue instructions to service members that refusal to participate in COVID-19 vaccines classified by the FDA as Investigational New Drugs will not incur a penalty or a loss of benefits to which the service member is otherwise entitled. (NOTE: This is required to comply with LT Gen Place's directive.)
8. Reverse any related punitive and/or administrative actions that could impact service member's future promotions.
9. Visit CovidPenalty.Com and read 'DoD Policy Paper' for further information.

CONCLUSION:

The DoD, DOJ, FDA, JAG, or civilian authorities can not produce a single statute exempting them from the informed consent requirements involving DoDI 6200.02 substances. Instead, civilian authorities created legislation bypassing Congress through the issuance of deceptive memorandums designed to confuse military departments. This confusion is evident in the fact that they never guided commanders on what to do until full licensure vaccines were made available to DoD personnel.

Civilian authorities listed in the DoD hierarchy are wilfully ignoring their office's fiduciary requirements to respect the President's authority relating to informed consent waiver. Instead, knowing the President has not issued a waiver of informed consent, they joyfully watch commanders destroy the faithful service of our men and women in

uniform who only exercised their federally protected right to refuse medical experimentation. These abuses of human rights have occurred because statutes protecting human subjects involved in medical experimentation are wholly unknown by the legal community due to them never being called upon by the judiciary.

Let us leave with one legal fact: 100% of service members have only been offered the voluntary path ('Path two') for compliance. Therefore, how is it that we have tens of thousands who are being penalized because they refused to volunteer for Pfizer's biomedical research project? This legal fact requires significant and immediate remedial actions by State Attorneys General.

Attorneys General should initiate a simple lawsuit affirming the right of service members to refuse administration of experimental substances without incurring a penalty or loss of benefits to which they are otherwise entitled. Courts will only have the option of affirming that right due to the significant weight of law backing up that claim. This action will force the DoD to immediately resume payments to National Guard members and cease all negative activities against members of a uniformed service. However, once courts affirm, the thousands of service members illegally separated will require judicial remedy.

No statute authorizes punishment against uniformed service members refusing the administration of a DoDI 6200.02 substance without a written presidential waiver.

The reader is encouraged to visit CovidPenalty.Com and read the document titled, 'Civilian COVID-19 Violations' for an educational background relating to the Belmont Report and the force of law it carries. This document is a brief introduction into the regulations governing the administration of EUA products within the DoD. State attorneys general are encouraged to contact Brian who can help make quick work of legal efforts.

Brian Ward is available for expert testimony, legislative initiatives, online workshop training, legal brief analysis, and other related activities. Send a request @ https://covidpenalty.com/

Brian has invested over 1,000 hours researching the history and legal administration of investigational new drugs and its application to current COVID-19 mandates. Consider financially supporting his efforts to secure justice for those harmed by the unlawful actions of rogue political actors.

References

DoDI 6200.02 - https://mrdc.amedd.army.mil/assets/docs/orp/irbo/11_DOD_6200.2_Use_of_INDs_for_FHP.PDF

'Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements' - https://mrdc.amedd.army.mil/assets/docs/orp/irbo/IRB_Policies_Procedures_2018_Common_Rule.pdf

The Belmont Report - https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

(The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.- Belmont Report. Washington, DC: U.S. Department of Health and Human Services,1979.)

32 CFR 219 - https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-219

45 CFR 46 - https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

SECDEF Austin Memo - https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF

U.S. Code 21 Section 564 - https://www.law.cornell.edu/uscode/text/21/360bbb-3

U.S. Code 10 Section 1107 - https://www.law.cornell.edu/uscode/text/10/1107

U.S. Code 10 Section 1107a - https://www.law.cornell.edu/uscode/text/10/1107a

International Covenant on Civil and Political Rights Treaty - https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights

HHS Office of Human Research Protections - https://www.hhs.gov/ohrp/index.html

LT Gen Place Memorandum - https://www.health.mil/Reference-Center/Policies/2022/06/16/DHA-IPM-20-004

Dr. Terry Adirim memorandum - https://childrenshealthdefense.org/wp-content/uploads/COVID-19-COMIRNATY-EUA-BLA-equivalent-memo_v3.1-clean-DIGITAL.pdf

Pfizer's press release - https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full

FDA 2005 instructions to DoD - https://www.federalregister.gov/documents/2005/02/02/05-2028/authorization-of-emergency-use-of-anthrax-vaccine-adsorbed-for-prevention-of-inhalation-anthrax-by#:~:text=The%2520Food%2520and%2520Drug%2520Administration%2520(FDA)%2520is%2520announcing%2520the%2520issuance,to%2520be%2520at%2520heightened%2520risk

DoD Policy Paper - https://covidpenalty.com/

DoD Graphic - https://covidpenalty.com/wp-content/uploads/2022/07/Minimalist-Timeline-Diagram-Concept-Map-2.pdf