COVID-19 Crimes & Remedies DoD/Coast Guard

RESTORING THE HONOR OF THE MILITARY PROFESSION

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DoD/Coast Guard Criminal Complaint

Civilian Appointees and Rogue Military Commanders Violated their Oath of Office Leading to the Gross Negligence of Service Members, Civilian Employees, and Contractors

SUMMARY

On August 24, 2021, SECDEF Lloyd Austin issued a mandatory order for service members to become vaccinated against the coronavirus SARS-CoV-2 virus only using full licensure drugs according to FDA labeling guidelines. However, the actions of SECDEF following that order prove beyond a reasonable shadow of a doubt that he never intended to comply with his mandate.

SECDEF Austin, civilian appointees, and the senior Pentagon leadership used the mandatory order to engage in a military assault on those who SWORE to uphold the Constitution and to give their very lives if required to fulfill that oath. This assault was witnessed by the unlawful punishment of service members exercising a federally protected right not to participate in clinical research drugs.

Committee members must demonstrate to the estimated 1.9 million service members and civilian employees that their oath is valued by removing those who committed crimes against our Constitution and prosecuting them to the fullest extent of the law.

History informs us that we must take immediate and swift action should we desire to maintain our liberties, health, and lives. Those who hate our military have effectively demonstrated their disdain for the Constitution and America's sovereignty, of which respect for the rule of law and a strong military deterrence doctrine can only be maintained.

What will history write about those of you in positions of power by the will of the American people? Will it write about your heroic deeds one hundred years from now, or will it even remember you existed?

History places the pen in your hands; it's up to you to write the story!

DOCUMENT NOTE

The section titled 'The Legal Right To Refuse' effectively demonstrates the illegal nature of SECDEF's leadership relating to his COVID-19 vaccine mandate. The reader will not fully understand the context of this document without the education provided in that document. Furthermore, documenting every nuance of the criminal fallout of his dereliction of duty would require the space of the King James Bible.

Therefore, this document aims to educate committee members on the responsibilities, processes, laws, and regulations of EUA medical product administration within the DoD and the criminal disregard for those legal obligations by civilian appointees. The Committees should use this document as foundational context to initiate a DoD-wide review to remove errant commanders and correct their abhorrent behavior.

SECDEF'S MANDATORY ORDER

> August 24, 2021:
>
> To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination

against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

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. 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. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.

> Mandatory vaccination requirements will be implemented consistent with DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019. The Military Departments should use existing policies and procedures to manage mandatory vaccination of Service members to the extent practicable. Mandatory vaccination of Service members will be subject to any identified contraindications and any administrative or other exemptions established in Military Department policy. The Military Departments may promulgate appropriate guidance to carry out the requirements set out above. The Under Secretary of Defense for Personnel and Readiness may provide additional guidance to implement and comply with FDA requirements or Centers for Disease Control and Prevention recommendations.
>
> The Secretaries of the Military Departments should impose ambitious timelines for implementation. Military Departments will report regularly on vaccination completion using established systems for other mandatory vaccine reporting. Our vaccination of the Force will save lives. Thank you for your focus on this critical mission.

SECDEF Austin's COVID-19 mandatory vaccination campaign lacked the one essential component required to enforce legal compliance: full-licensure drugs.

SECDEF Austin was informed by the FDA one day before his memorandum that there were no full licensure COVID-19 vaccines available, nor was there an expected ship date published by Pfizer. Therefore, by what reasonable expectation did he order Secretaries of the Military Departments to "impose ambitious timelines for implementation?" Given his complete disregard for the rights of those under his command, his initial intention may have been to unlawfully rely exclusively on clinical research (i.e., voluntary) drugs.

Let us effectively evaluate his mandatory order:

(1) "After careful consultation" - there does not exist a risk/benefit analysis to support this decision because:

(a) Pfizer released data 30 days prior to SECDEF's order stating that the drug had failed in nearly 15% of those in the clinical study and was failing others at a rate of 6% every two months.

(b) Civilian COVID-19 hospitalization rates among military demographics were extremely low, especially for the healthy.

(c) Pfizer informed SECDEF that, "Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine, more commonly in adolescent males and adult males under 40 years of age (military demographic)."

(2) "Inoculation" - No COVID-19 vaccine maker under an EUA claims to inoculate any person from any COVID-19 variant. For example, the Pfizer BioNTech COVID-19 Vaccine fact sheet states, "The duration of protection against COVID-19 is currently unknown." Therefore, the use of the word, "inoculate" was intentionally deceptive in the context of his order.

(3) "Our administration of safe, effective COVID-19 vaccines…" 21CFR312.7(a) states, "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." SECDEF promoted clinical research drugs in a manner outside of his authority having significant health consequences by those who accepted his opinion as fact.

(4) SECDEF Austin provided two paths for service member compliance: (1) "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." (2) "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." What legal authority has allowed SECDEF to penalize and separate service members not agreeing to volunteer? SECDEF's bifurcated option laid the groundwork for future fraud, (e.g., forthcoming mandate memoranda) discussed later.

(5) "Voluntary" - to list an EUA drug as acceptable to fulfill a mandate (even with the statement of it being voluntary) is a violation of the ethical principles of the Belmont Report because outside pressure is placed upon individuals to participate.

(6) "Other exemptions established in Military Department policy" - This is his defense since all Military Departments have policies preventing commanders from ordering service members to participate in clinical research drugs under threat of penalty.

The Department of Defense issues instructions (hereafter referred to as DoDI) as guidance to military personnel to maintain compliance with applicable policy and laws.

Most troubling of SECDEF Austin's order is his reference to DoDI 6205.02, "DOD Immunization Program," which primarily applies to licensed products. DoDI 6205.02 informed SECDEF that "Requests to use non-FDA-approved immunizations will be processed as outlined in DoDI 6200.02" Therefore, DoDI 6200.02 has been the only policy applicable to his mandatory order given the absence of licensed vaccines.

DoDI 6200.02

For purposes of readability, the below references apply to DoDI 6200.02.

DoDI 6200.02 is activated when the Department of Defense (DoD) issues a Force Health Protection (FHP) program involving medical products required under an EUA or Investigational New Drug (IND) application.

To make it very clear for commanders and DoD lawyers alike, Section E2.7 states that if "the FDA has determined [a drug] may not be used for its intended purpose without an Emergency Use Authorization," then military personnel must obtain the informed consent of service members until the President issues a waiver. To date, only DoDI 6200.02 drugs have been introduced within the DoD for administration, and the Federal Register has not published a Presidential waiver as required by law.

SECDEF Austin (and additional civilian appointees) is responsible for all incidents within the DoD relating to EUA medical products.

DoDI 6200.02 APPLICABILITY AND RESPONSIBILITIES

The instructions apply to:

1) SECDEF, 2) Military Departments, 3) the Chairman of the Joint Chiefs of Staff, 4) the Combatant Commands, 5) DoD Office of Inspector General, 6) Defense Agencies, 7) and all other organizational entities within the DoD. (2.1)

The responsibilities of appointees:

1) Assistant Secretary of Defense for Health Affairs referred to as ASD (HA).

    a) "Use of a medical product under a force health protection program pursuant to an EUA or IND application requires approval of the

Assistant Secretary of Defense for Health Affairs (ASD(HA))" (4.2)

b) ASD (HA) "shall have primary responsibility for policy under this Instruction and is authorized to issue Instructions or other guidance for implementation of, and grant exceptions otherwise authorized by law to, this Instruction, and shall monitor implementation of this Instruction." (5.1) (Emphasis added.)

2) "The Secretary of the Army shall serve as Lead Component for development of medical protocols and regulatory submissions to the FDA under this Instruction" (5.3)

3) "Ensure that the Army Medical Research and Materiel Command Human Subjects Research Review Board (HSRRB), under the Surgeon General of the Army, carries out the responsibilities described in paragraph E4.4." (5.3.2) (Emphasis added.)

a) "An Institutional Review Board [IRB]…shall approve every protocol for the use of an IND under a force health protection program. The Army Medical Research and Materiel Command HSRRB, under the Surgeon General of the Army, is designated as the single IRB responsible for purposes of IRB activities under this Instruction." (E4.4)

4) "Chairman of the Joint Chiefs of Staff and the General Counsel of the Department of Defense" must approve all medical protocols developed for the use of the product within the DoD. (5.2.1.3) (5.2.2)

5) The Under Secretary of Defense for Personnel and Readiness (USD ((P&R)) is lead authority for all EUA and IND protocols within the DoD. (5.1) (DoDI 5124.02)

NOTE: COVID-19 vaccination implementation memoranda signed by senior pentagon leaders reference the aforementioned authority of USD (P&R) to modify their memos as needed.

6) "May, unless otherwise provided by ASD(HA), make available [EUA products] to Emergency Essential civilian employees… and/or contractor personnel accompanying the Armed Forces…except that the authority to waive an option to refuse under section 1107a of Reference (e) or informed consent under section 1107 of Reference (e) is inapplicable to these personnel." There does not exist statutory authority to mandate civilian employee participation in FDA-classified EUA products even by the Commander in Chief. (Emphasis added.)

7) "Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse." E3.4 When did SECDEF request a waiver from the informed consent rights of service members?

   Note: If SECDEF, civilian appointees, and military commanders have not been notified of the President issuing a waiver of informed consent rights relating to EUAs, then ALL are committing a felony by assuming the authority of the Commander in Chief and issuing that waiver as a result of their dereliction of duty.

DoDI 6200.02 EUA PROTOCOL PROCESS

The ASD (HA) approves the medical product for use after USD (P&R) conveys approval. Once the EUA product is approved, the Secretary of the Army must develop a medical protocol for implementation in coordination with ASD (HA) and the HSRRB directed by the Surgeon General of the Army. After the drug use protocol has been developed, the Chairman of the Joint Chiefs of Staff and the DoD General Counsel must approve practical implementation, and legality, respectively.

DoDI 6200.02 OFFICE HOLDERS (date assumed office)

1) USD (P&R) Gil Cisneros (August 24, 2021)
2) ASD (HA) Dr. Terry Adirim (initial), others
3) Secretary of the Army Christine Wormuth (May 28, 2021)
4) Surgeon General of the Army LTG R. Scott Dingle (October 19, 2019)
5) General Counsel of the DoD Caroline Krass (August 02, 2021)

6) Chairman of the Joint Chiefs of Staff Gen Mark A. Milley (October 01, 2019)

HQ USAMRDC IRB POLICIES AND PROCEDURES REGULATIONS

DoDI 6200.02 (4.4) assigns IRB responsibilities for INDs and EUA drugs and biologics to the 'Headquarters, United States Army Medical Research and Development Command (HQ USAMRDC).' The regulations that govern this IRB are called 'HQ USAMRDC Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements.'

This policy and procedures document states:

1) "These protections (human research) adhere to the ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report."

2) "Exempt research activities should adhere to the fundamental ethical principles outlined in the Belmont Report."

3) "DoDI 6200.02 designates the USAMRDC Human Subjects Research Review Board (now the HQ USAMRDC IRB) as the single IRB for review and approval of the DoD treatment IND protocols for FHP. These protocols undergo initial and continuing IRB review and approval, and are available for implementation when/if needed."

4) "In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 USC. 355 (i)(4)) may be waived only by the President."

5) "Authority of the HQ USAMRDC IRB in the Review of Treatment IND protocols for FHP. Paragraph E4.4 of DoDI 6200.02 designates the HQ

USAMRDC IRB as the IRB responsible for review the treatment protocols for FHP."

6) FWA regulations.

The policy details the specific instructions on educating commanders of service members' right to refuse EUA products, the Presidential waiver process, reporting of adverse reactions, and safety and health oversight of Force Health Protection (FHP) programs.

The DoD must publish an ethical policy under its Federal Wide Assurance agreement detailing the principles they follow when involving humans in medical research activity. Their listed principles are as follows:

Nuremberg Code, 1946

Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 18 April 1979: Protections for human research subjects are primarily founded on the three basic principles of the Belmont Report (1979). These principles are: (1) respect for persons; (2) beneficence; and (3) justice.

These fundamental principles for the protection of human research subjects are embodied in the Federal regulations at 32 CFR 219, also called the Federal Policy or the Common Rule.

The HQ USAMRDC IRB's written operational policies and procedures are based primarily on the requirements of these Federal regulations, to include other requirements such as:

World Medical Association (WMA) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

59th WMA General Assembly, Seoul, October 2008 Council for International Organizations of Medical Sciences - International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for Organizations of Medical Sciences ((CIOMS)) International Ethical Guidelines) Prepared by CIOMS in collaboration with the World Health

Organization (WHO), 2002 International Conference on Harmonization (ICH)

Harmonized Tripartite Consolidated Guideline for Good Clinical Practice: Efficacy Guideline - 6 (ICH-GCP-E6), 2002

10 USC §980 prohibits the DoD from appropriating funds for research activities involving humans if the informed consent of the individual is not obtained in advance. The committees are advised to ascertain the funding source for COVID-19 EUA drugs purchased by the DoD.

At present, Brigadier General Anthony McQueen is the commanding general of USAMRDC, Ft. Detrick, MD. According to his bio (see link), BG McQueen was detailed to Operation Warp Speed May 2020 - May 2021. He should testify before the committees about the roles he and Army Surgeon General Scott Dingle played in EUA product activation, legal implementation, and safety monitoring within the DoD

Commanding General U.S. Army Medical Research and Development Command and Fort Detrick

DoDI 3210.7

These instructions are provided to help maintain research integrity by explaining when and to whom research misconduct must be reported. They were derived from an agency action by the Office of Science and Technology Policy. Link: https://www.govinfo.gov/content/pkg/FR-2000-12-06/pdf/00-30852.pdf

The instructions apply to research of which the policy definition demonstrates the broad application of this DoDI. It states in part:

1) "E3.1.9.6. A requirement that the research institution immediately notify the headquarters level of the DoD Component and provide an explanation of the circumstances if:"

    a) "The public health or safety is at risk"

b) "There is a possible violation of civil or criminal law"
c) "The research community or public should be informed"

Trending 300% increase in Myocarditis post-mRNA vaccines, the committee is responsible for research activities involving COVID-19 EUA vaccines to be halted to prevent future risk to additional service members.

DoD COVID-19 EUA drug research activities have violated civil and criminal law.

Let us be reminded that the definition of research is not confined exclusively to clinical trials; instead, it is broadly applied to any activity that adds to the generalizable knowledge about the product. That activity must include a human whose private identifiable information is known. USAMRDC IRB Force Health Protection protocols mandate that every service member who receives an EUA COVID-19 vaccine have that activity recorded and any adverse reactions for study and included in their health records (research).

COURT PRECEDENT OF THE RIGHT TO REFUSE

On October 27, 2004, U.S. District Court Judge Sullivan ruled in *Doe v. Rumsfeld* ruled that:

> (1) "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." (Emphasis added.)
>
> (2) "Unless and until FDA properly classifies AVA as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver." (Emphasis added.)

COVID-19 EUA vaccines have been classified as an IND requiring 10 U.S.C. § 1107 and/or 1107(a) waivers.

HHS AGENCY PRECEDENT

On January 28, 2005, HHS issued an EUA for IND Anthrax Vaccine Adsorbed. Leadership informed service members that:

1) "Individuals who refuse anthrax vaccination will not be punished."
2) "Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice."
3) "Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination."
4) "There may be no penalty or loss of entitlement for refusing anthrax vaccination."

These instructions were not related to the formulation of the drug. Instead, they were assigned due to the drug's classification. Moreover, notice how these requirements ensured service members were not under outside pressures to participate. This guidance established adequate conditions to obtain the legally effective informed consent of the service member. https://www.govinfo.gov/content/pkg/FR-2005-02-02/pdf/05-2028.pdf

Under Secretary of Defense (P&R) CISNEROS

On September 07, 2021 USD (P&R) Cisneros issued a memorandum applicable to all individuals with credentials to access military installations on a recurring basis to include all service members. He stated, in part:

1) "Determining Vaccination Status for the Purpose of this Guidance:"

a) “An individual will be considered "fully vaccinated" when:”

i) “at least 2 weeks have elapsed after a second dose in a two-dose COVID-19 vaccine series, such as of the Pfizer-BioNTech/Comirnaty or Moderna COVID- 19 vaccines; or at least 2 weeks have elapsed after a single-dose COVID-19 vaccine, such as Johnson & Johnson's Janssen COVID-19 vaccine. The vaccine may be either authorized for emergency use or fully approved; or”

ii) “he or she has completed the recommended dose series of COVID-19 vaccines authorized for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford).”

2) "Unvaccinated" will apply to an individual who either:

a) “has not completed the full COVID-19 vaccination dose series; or”

b) “declines to attest to his or her COVID-19 vaccination status.”

Nowhere in the USD (P&R) memorandum do we find a reference to comply with DoDI 6200.02, instructions on the right to refuse EUA products or 10 U.S.C. 1107(a) legal obligations. Cisneros was under orders by SECDEF to only use full licensure drugs for mandatory compliance. Yet, Cisneros behaved as if he did not have to comply with that directive; effectively issued a waiver of informed consent; was wilfully derelict of his duty by not providing accurate guidance. The memorandum speaks for itself.

On April 04, 2022 USD (P&R) issued an update: the ‘Consolidated Department of Defense Coronavirus Disease Force Health Protection Guidance’ stating in part:

1) “Service members (members of the Armed Forces under DoD authority on active duty or in the Selected Reserve, including members of the National Guard) are required to be fully vaccinated against COVID-19,

subject to any identified contraindications, any administrative or other exemptions established in DoD policy, and any applicable court orders."

2) "Once the applicable mandatory vaccination date has passed, COVID-19 screening testing is required at least weekly for Service members who are not fully vaccinated, including those who have an exemption request under review or who are exempted from COVID-19 vaccination and are entering a DoD facility located in a county or equivalent jurisdiction where the CDC COVID-19 Community Level is high or medium."

   NOTE: This directive violates the service members' 14th Amendment rights to be treated equally since accepting or refusing are both equal options of choice. Additionally, his requirement to penalize service members not agreeing to participate in an EUA product is plainly seen by having a start date of when that punishment would begin.

3) Vaccination status is defined as:

   a) Fully vaccinated: "An individual is considered 'fully vaccinated' when at least 2 weeks have elapsed after a second dose of a two-dose COVID-19 vaccine series (e.g., PfizerBioNTech/Comirnaty, or Moderna/Spikevax vaccines), or 2 weeks after receiving a single dose of a one-dose COVID-19 vaccine (e.g., Johnson & Johnson's Janssen vaccine) that are: (1) fully licensed or authorized or approved by the FDA; (2) listed for emergency use on the World Health Organization Emergency Use Listing (e.g., AstraZeneca/Oxford); or (3) approved for use in a clinical vaccine trial for which vaccine efficacy has been independently confirmed (e.g., Novavax)."

   b) Unvaccinated: "An individual is 'not fully vaccinated' if the individual either has not completed the full COVID-19 vaccination dose series; or declines to provide his or her

> COVID-19 vaccination status and declines to provide any requested proof of that status."

Even in USD (P&R) Cisneros' consolidated memorandum, he neglects to guide Military Departments on a service member's right to refuse nor references the applicable laws and DODIs.

What should be of keen interest to the committees is the USD (P&R) method of combining licensed products with unlicensed products (e.g., "PfizerBioNTech/Comirnaty, or Moderna/Spikevax vaccines"). Combining drugs that have legal distinctions and operate under different federal laws and DoDIs is a strategic effort to obfuscate the fundamental truth that service members have the right to refuse available COVID-19 EUA products without consequence.

However, the real strategy is to maintain a backdoor to a potentially effective defense, should it be required.

Suppose USD (P&R) Cisneros is prosecuted for failing to protect the rights of service members whose finances and health have been significantly injured due to his dereliction of duty. Could he effectively argue that he did not, in fact, order anyone to participate in any EUA product?

More closely, the memo states, "An individual is considered "fully vaccinated" when at least 2 weeks have elapsed after a second dose of a two-dose COVID-19 vaccine series (e.g., PfizerBioNTech/Comirnaty, or Moderna/Spikevax vaccines)..."

Legally speaking, he said a person is considered fully vaccinated after "a" second dose, not to mean a specific dose, of either Pfizer BioNTech (EUA product) and or (/) COMIRNATY (licensed product), is received.

Therefore, his defense could be that he never ordered anyone to take the EUA product under threat of penalty since he was only following SECDEF Austin's mandate that a member is considered fully vaccinated after being

administered a mandatory/voluntary drug. His defense would be that he offered commanders the ability to utilize mandatory and/or voluntary drugs for compliance; however, it was the service member's choice of which drug to receive.

The intentional shadow banning of the legal and regulatory requirements involving EUA products reveals the malfeasance of civilian and military leadership. Additionally, we now see why SECDEF issued an order containing two paths for compliance; mandatory and voluntary. However, only the voluntary path option has been available to DoD personnel, and thus, confusion as to how they were penalized.

Civilian leaders across the more than 400 federal departments have utilized the same strategic approach demonstrating a centralized effort to weaponize the federal government against the American people and subject them to medical experimentation outside of their free will and voluntary consent.

Should the committee procure communiques from the aforementioned civilian leaders, they all contain similar language, with no mention of the right to refuse unlicensed EUA or clinical research drugs without consequence. Those directives, emails, and orders are too numerous to publish in the context of this complaint.

DEFENSE HEALTH AGENCY

The Defense Health Agency (DHA) a joint, integrated Combat Support Agency with 140,000 personnel and $11 billion in purchases, controls more than 400 DoD medical facilities and provides guidance for EUA product administration for all Military Departments.

On June 16, 2022, Lieutenant General Ronald J. Place, Director of the Health Defense Agency, issued a memorandum titled, 'Defense Health Agency Implementation of Department of Defense (DoD) Coronavirus Disease 2019 (COVID-19) Vaccination Program Implementation.' (DHA-IPM 20-004)

LTG Place was undeterred by his colleagues' willingness to abuse the rights of service members and issued guidance inferring their actions were in fact unlawful. LTG Place informed virtually the entire DoD agency that:

(1) DoDI 6200.02 applies

(2) U.S.C. 10 1107(a) applies

(3) U.S. Food and Drug Administration (FDA) Guidance, "Emergency Use Authorization of Medical Products and Related Authorities," January 2017 applies

(4) Army, Coast Guard, and Air Force regulations exempt members from medical procedures who demonstrate natural immunity

(5) "Use of vaccine products for force health protection under EUA will be executed in accordance with References (f) through (h)." The references relate to laws and regulations ensuring members have the right to refuse without consequence.

NOTE: These are virtually nonexistent references within senior Pentagon leadership and civilian appointees.

(6) "For EUA vaccines, per FDA guidance in Reference (h), vaccine recipients must be made aware of all of the following:"

a) "[Service members] have the option to accept or refuse the EUA product **and are free from any consequences of refusing administration of the product.**" He just alerted military commanders of breaking the law because all of them were applying consequences for refusing EUA vaccines, tests, and masks.

"Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the FDA in accordance with FDA-approved labeling and guidance. In accordance with Reference (o) through (q), and FDA guidance, phosphate buffered saline (PBS)-buffer Pfizer-BioNTech/COMIRNATY® has the same formulation and can be

used interchangeably with the EUA PBS-buffer Pfizer-BioNTech COVID-19 vaccine without presenting any safety or effectiveness concerns." (Emphasis added.) However, once again we see the intentional psyop writing designed to blur the legality of what drugs are under mandatory requirement.

ASD (HA) DR TERRY ADIRIM

On September 14, 2021, former acting ASD (HA) Dr. Terry Adirim issued a memorandum titled, 'Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines.' Her memo states in part:

> '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." (Emphasis added.)
>
> "Consistent with FDA guidance, DoD health care providers will use both the Pfizer- BioNTech COVID-19 vaccine and the Comirnaty COVID-19 vaccine interchangeably for the purpose of vaccinating Service members in accordance with Secretary of Defense Memorandum, 'Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members,' August 24, 2021.' (Emphasis added.)

This memorandum was the foundational blueprint for civilian appointees and rogue military commanders to violate the constitutional and federally protected rights of service members and civilian employees.

Let us compare what she appears to be stating with what she is legally saying:

1) Dr. Adirim's audience is "health care providers" and not military commanders.

2) "Use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." Why this advice? Is there a physically different method of administering an EUA vaccine from a licensed vaccine? They both require a syringe, human, and a healthcare worker. How should a healthcare worker perceive this instruction? This is doublespeak and designed to confuse healthcare workers about the legal distinction between the two drugs of which only one has ever been in circulation.

3) "As if" – one may not use an EUA drug as if it is a licensed drug because of the different set of instructions, laws, and treaties associated with their classification. This is why Dr. Terry Adirim used the word "should" to mean the decision is up to the healthcare worker but not mandatory. Pfizer was convicted of a felony (September 2009) and had to pay BILLIONS in fines for promoting a drug "as if".

4) "...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 the Secretary of Defense Memorandum."

Suppose that healthcare workers sued Dr. Terry Adirim for causing them to engage in unlawful activities, what might her defense be? Let us review her statement under the legal lens and see what she is really stating:

> Health care providers will use either the EUA product or the licensed product to fulfill SECEF's mandatory vaccine order of providing service members the option of fulfilling their legal obligation by participating in a mandatory/voluntary COVID-19 drug.

Her malfeasance was to say that healthcare workers MUST use both drugs to administer the product inferring that both are legal for mandatory administration. Since no licensed products crossed the transom of any US healthcare facility, executing her directive may have caused needless injuries requiring judicial remedy.

Dr. Adirim provided written testimony to the House Appropriations Committee, Defense Subcommittee on May 25, 2021 stating: "The Department has implemented a comprehensive outreach and communications effort to encourage all eligible persons seek out these highly safe and effective vaccines." (Emphasis added.) This statement is a violation of federal law (21 CFR 312.7) and meant to mislead the committee on the experimental nature of the drugs.

"The ASD(HA), under the Under Secretary of Defense (Personnel and Readiness), shall have primary responsibility for policy under this Instruction and is authorized to issue Instructions or other guidance for implementation of, and grant exceptions otherwise authorized by law to, this Instruction, and shall monitor implementation of this Instruction." (DoDI 6200.02 5.1) Dr. Terry Adirim and each ASH (HA) since August 24, 2021 has failed to fulfill their legal obligations under these instructions.

> **"DoD had enough licensed vaccine for all But trolls twist this…And contend some were forced to take EUA vaccines which is garbage."** — Dr. Terry Adirim, Twitter (May 15, 2022 1:22PM)

> **"I don't know the current status of this issue. When the BLA was issued, that is true. We made sure there were doses of the Comirnaty at immunization sites for those who insisted on the version with the right label."** — Dr. Terry Adirim, Twitter (July 07, 2022 9:02 AM)

The above statements are patently untrue. Service members were forced (removal by force if refused) under threat of penalty. Additionally, Pfizer publicly stated they never manufactured COMIRNATY under the original formulation nor is there an indication they manufactured the updated version for general commercial marketing. Moreover, her sarcasm of stating "for those who insisted on the version with the right label" demonstrates her failure to understand the legal ramifications of recipients who utilize an EUA medical product compared to that of a licensed product.

"Dr. Terry Adirim (a-DEE'-rim) is [currently] the program executive director (PED) of VA's Electronic Health Record Modernization Integration Office. Dr. Adirim reports directly to VA's Deputy Secretary and is responsible for leading cross-organizational and cross-functional coordination of communication and implementation strategies, to include functional, technical, and program management." (*Dr. Terry Adirim - va EHR Modernization*, 2022)

Committee members, what civilian leadership should have posted is as follows:

> SECDEF has ordered service members to receive a COVID-19 vaccine with full licensure approval from the FDA. Currently, the only mandatory vaccine available to DoD personnel is COMIRNATY. Unfortunately, Pfizer has not released a shipment date for that product. Therefore mandatory vaccination requirements are currently on hold. However, service members may volunteer for a COVID-19 EUA or WHO investigational drug without fear of consequence if they believe it will benefit their personal health goals. Commanders may not require EUA or WHO drug participation of service members, civilian employees, or contractors. Pressure to participate in an unlicensed drug violates treaty, federal law, and military regulations punishable under the UCMJ.

However, such clarity and adherence to federal law was not part of their plan.

BLA-COMPLIANT / BLA-APPROVED

The following facts demand investigation into the actions of the FDA, CDC, HHS, CBER, DOJ, and DoD.

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

> "In conjunction with the August 23 approval of Comirnaty, FDA asked

> the applicant [Pfizer] to identify available lots of vaccine that were manufactured at facilities listed in the BLA that had undergone lot release. For these lots, FDA is exercising its enforcement discretion with respect to certain labeling requirements, in that FDA is not taking enforcement with respect to vials that bear the EUA label. FDA considers these lots to be manufactured in compliance with the BLA and they are not subject to the EUA requirements when used for the approved indication Thus, the conditions in the Letter of Authorization for the EUA— including the condition requiring vaccination providers to provide recipients with the Fact Sheet for Recipients, which advises recipients that under the EUA, 'it is your choice to receive or not receive the vaccine'—do not apply when these lots are used for the approved indication. FDA worked with the applicant to develop a 'Dear Health Care Provider' letter and website to identify those lots." (Emphasis added.)

21 U.S.C. §355(a) mandates that "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."

The FDA is a person under congressional authority and must comply with this legal requirement. Moreover, Congress provides exemption from this requirement under 21 U.S.C. §360bbb-3 if the conditions for 'expanded access protocols' of that chapter are met.

Products under a Section 564 exemption must comply with the policy's "required conditions" as established by Congress. Therefore, what legal authority did the FDA use as justification to state "FDA considers these lots to be manufactured in compliance with the BLA and they are not subject to the EUA requirements?"

U.S. District Court Judge Winsor spoke directly to this issue:

> "plaintiffs [service members] have shown that the DOD is requiring

injections from vials not labeled 'Comirnaty.' Indeed, defense counsel could not even say whether vaccines labeled "Comirnaty" exist at all. ECF No. 45 at 48:5-7. (Although the DOD's response said it had an adequate Comirnaty supply, it later clarified that it was mandating vaccines from EUA-labeled vials. *See id*. at 46:22- 47:3.) In the DOD's view, this is fine because the contents of EUA-labeled vials are chemically identical to the contents of vials labeled 'Comirnaty' (if there are any such vials). According to the DOD's argument, this means service members are not required to accept 'a *product* authorized for emergency use.' 10 U.S.C. § 1107a(a)(1). Rather, the DOD argues that once the FDA licensed Comirnaty, all EUA-labeled vials essentially became Comirnaty, even if not so labeled. ECF No. 45 at 60:1-3.

Thus, the DOD argues, the 'product' injected is a chemical formulation that has received full FDA licensure—not merely an EUA—so § 1107a does not apply. *Id.* at 65:1-6. The DOD's interpretation of § 1107a is unconvincing. For starters, FDA licensure does not retroactively apply to vials shipped before BLA approval. *See* 21 U.S.C. § 355(a) …Thus, as a legal matter, vaccines sent before August 23—and vaccines produced after August 23 in unapproved facilities—remain 'product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.' § 1107a(a)(1).

Section 1107a's explicit cross-reference to the EUA provisions suggests a concern that drugs mandated for military personnel be actually BLA-approved, not merely chemically similar to a BLA-approved drug…It is difficult to see how vials that the DOD admits are not BLA-compliant—and thus could only be EUA products—could fall outside § 1107a's prohibition on mandatory administration." (*Coker v. Austin* et al (3:21-cv-01211))

Although Judge Winsor correctly applied the law, later, he was led down a path of focusing on whether or not the vials were manufactured according to the BLA-compliant process of COMIRNATY.

Manufacturing processes have no statutory bearing on the merits of this issue. A drug is under an EUA because the FDA has not licensed it for general commercial marketing for its intended use. The FDA informed Pfizer on August 23, 2021 that BioNTech COVID-19 was not approved and must submit an IND application 19736. Therefore, legally speaking, BioNTech COVID-19 Vaccine is a unique product only approved by the FDA for research purposes and MUST NOT be used for general commercial marketing under any circumstances until it receives approval by the FDA. A manufacturing process does not change this legal fact.

The FDA lacks statutory authority to ignore Congress under 21 U.S.C. § 355(a) and Section 564. Furthermore, there is no historical context the FDA can point to justify their decision. The FDA recalled (paper only) drugs in circulation and manufactured before the BLA marketing date to label them as "BLA" but refused to call them licensed products. An estimated 9 million healthcare professionals might have committed a felony due to the unethical, if not illegal, activities of officials at CBER and the FDA.

Let us review the Dear Healthcare Professional (DHP) letter sent out on the same day COMIRNATY was approved.

> "Dear Healthcare Professional,
>
> Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and <u>are therefore considered</u> "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at

cvdvaccine-us.com/resources (no longer active). For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information." (Emphasis added.)

Let us review:

(1) The word "considered" is not a definitive statement. It is a belief but not definitive. A definitive statement would have been, "these lots are BLA-approved." The word "considered" was added to provide legal cover.

(2) "Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use." A drug in circulation only authorized for emergency use was called back (on paper) by CBER and marked as BLA-compliant? For what purpose? There can be no logical reason for this decision. The opinion is that CBER, FDA, and Pfizer officials engaged in a scheme to defraud the American people by creating fake legislation that an EUA drug that shares formulation with a licensed product can be mandated if it undergoes the BLA manufacturing process. **FDA officials can not demonstrate to the committee the legal foundation for their decision to express this belief.**

(3) If Pfizer was producing BLA-compliant lots of COVID-19 Vaccines before their license to market was approved, then why has the FDA not required Pfizer to manufacture all future vials of their mRNA vaccines under the COMIRNATY label as required by 21 CFR 312.7(c)? CBER, FDA, CDC, HHS, DOJ, and the DOD all agree the two drugs share formulation. Therefore, there was a legal, ethical, and regulatory reason to require Pfizer to cease manufacturing vials under EUA status and transition only to its licensed product. However, what if the only reason FDA officials and Pfizer executives continued to manufacture under EUA status was to avoid prosecution for fraudulently marketing a drug for a legal indication real-world data can not support and to

remain under the protective umbrella of Section 564 immunity? A great question for the committees to answer is how many vials of BioNTech sharing formulation with COMIRNATY were manufactured after their initial marketing date? Those vials should have all been under their marketing label.

(4) The National Drug Code (NDC) is a FDA standard for identifying drug products marketed in the United States. Regarding Pfizer's original formulation COMIRNATY, the CDC posted: "Pfizer received initial FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. <u>These NDCs will not be manufactured</u>. Only NDCs for the subsequently BLA approved tris-sucrose formulation will be produced." The NDC codes applied to COMIRNATY's original formulation were never manufactured. Therefore, what classification did the FDA assign to those lots for regulation? According to Dr. Marks, they are classified as BLA-compliant. **However, what section of law do we call upon to understand the regulatory environment of a non-licensed, BLA-compliant drug under an EUA, but is not required to comply with Section 564 requirements?**

(5) What is the legal or regulatory definition of BLA-compliant, and how does that definition apply to the lots of EUA vials referenced in the DHP letter? Committee members should demand to see the answer in pre-existing legislation or regulation.

(6) The CDC listed the lots referenced in the DHP as being EUA products. This is documented in Bazzrea v. Austin.

RECAP:

(1) Congress informed the FDA that a drug may not be introduced into

commerce without full approval and before significant testing, trials, and submitting an application requesting that approval (BLA).

(2) Congress informed the FDA that the Secretary under Section 564 may only use drugs not approved for their intended use under a declared emergency.

(3) Congress informed the FDA that they may not license an EUA drug solely on the information obtained about that drug's use under the declared emergency.

(4) Congress informed the FDA that the Secretary must approve the manufacturing process for both EUA and BLA products. However, that process does not confer automatic approval of a drug's legal status.

(5) The DOJ fined Pfizer more than $2B for using their licensed products under "as if" conditions. FDA, CBER, DOD, and Pfizer are engaging in the same criminal activity backed by the DOJ. It is a felony to promote an unlicensed drug "as if" it is a licensed product. Legal distinctions matter and the vials under EUA were never licensed nor even claimed to be by CBER. Therefore, why the need to inject potentially criminal confusion into the marketplace?

What is the ruse and why?

Coker v. Austin (3:21-cv-01211)

On August 22, 2022, oral arguments were presented relating to BLA-approved products within the DoD and how those products impact the legal right of service members to refuse EUA products without consequence.

Judge Allen Winsor presided over the case and attorney Catherine Yang represented the DOJ.

> "THE COURT: All right. I see what you are saying, and maybe I have misunderstood."
>
> "I want to make crystal clear, the position of the military is this: If, as a

factual matter, there is no vaccine available that was made in a licensed facility, and that complies with all of the BLA requirements to make it licensed, assume for this hypothetical that none of that is available at all. And you have someone who says, I don't want to take the non-BLA compliant, and you don't have a Presidential waiver -- which would moot all of this, I guess -- the military's position is, we can make you take it consistent with 1107, make you take the non-BLA compliant?" (Emphasis added.)

"MS. YANG: Correct. Based on the FDA determination. You know -- you know, the reason being that we think that's consistent with the purpose of 1107(a)." (Emphasis added.) NOTE: The purpose of 1107(a) is to ensure service members are not required to participate in INDs. There is no debate on that particular issue nor has there ever been. The FDA informed Ms. Yang that the two drugs have legal distinctions; she is clearly avoiding this fact in a court of law.

"THE COURT: But then why would that not bring the FDA determination -- I thought the whole reason the FDA claims were justiciable is because their determinations make no difference to any plaintiff now that another vaccine is available. But it sounds like you are saying without that interchangeability determination the policy of the DoD would be different."

"MS. YANG: Well, Your Honor, I think that definitely trickles back to the point I was trying to make at the outset, which is that -- the informed consent claims are all moot because, you know, Your Honor's hypothetical asked me to accept a number of counterfactuals, but the reality is that the factual circumstances are not what Your Honor's hypothetical presented in the sense that from day one, from the very first day of the DoD mandate, August 2021, there have been BLA compliant vaccines that DoD had in its possession at that time." (Emphasis added.)

The ruse is exposed in the oral argument. The DOJ claims that the DoD had a

"BLA-compliant" vaccine on August 24, 2021 inferring those vaccines comply with SECDEF's mandatory COVID-19 vaccine order only to use full licensure drugs. Ms. Yang infers that BLA-compliant is legally the same as a full licensure drug. Factually speaking, laws not only refute Ms. Yang's errant thinking, but apply criminal penalties for their violation.

Attorney Yang injected an argument that an EUA drug identified as BLA-compliant "nullifies" SECTION 564 rights to refuse products under its authority. Ms. Yang's testimony directly conflicts with the legislation enacted by Congress under 21 U.S.C. §360bbb-3(a)(2)(a) and (b).

Using Pfizer's two mRNA vaccines as an example:

1) Pfizer BioNTech COVID-19 Vaccine under IND application 19736
2) Pfizer COMIRNATY BLA application 125742 (licensed)

Congress requires the issuance of an EUA for Pfizer's IND. It also requires the issuance of an EUA for Pfizer's BLA when COMIRNATY is used for an indication (e.g., medical condition, age, sex, contradictions) not approved by the FDA. Therefore, we clearly see that a BLA-compliant manufacturing process makes no legal difference to its EUA or licensing status.

An FDA approval board determines the legal status of a drug, biologic, or device. The board determines if the manufacturing process is BLA-compliant, but that determination does not automatically confer a legal status for licensing purposes. The FDA approval board makes that determination. This legal fact is common knowledge within the FDA and CBER, demonstrating malfeasance.

Pfizer BioNTech COVID-19 Vaccine has not been approved by the FDA. **The FDA ISSUED that notice to the entire nation under its EUA letter to Pfizer. Both Pfizer and the FDA are aware that the FDA does not consider Pfizer's EUA drug licensed for general commercial marketing and no manufacturing process changes that legal fact.**

Nowhere in SECTION 564 does it state that if the IND complies with a

BLA-compliant process, then the IND is exempt from SECTION 564 legal obligations. It states, in simple terms, that if the drug, biologic, or device "is not approved, licensed, or cleared for commercial distribution" it requires the issuance of an EUA for use under the declared emergency. (Emphasis added.)

> MS. YANG: "you know…we think with the existence of BLA-compliant doses from day one there was no standing to begin with."

This points to why Pfizer issued the DHP letter the same day the FDA granted COMIRNATY full licensure. Rogue actors planned on creating a fictitious drug classification ('BLA-compliant') having no statutory authority to intentionally confuse the judiciary into believing that an unlicensed product can be treated "as if" it is a licensed drug should it participate in an undefined "BLA-compliant" process and share formulation with a licensed product. Their goal was to misdirect the judiciary from the legal distinctions of EUA products versus licensed products having significant legal consequences for recipients.

> "THE COURT: I guess that's back to the question I was getting at before. It seems to me one reading of the record is there were some members who were ordered to get the vaccine, who had no way of getting a licensed vaccine, and were told, essentially, you are going to go down this disciplinary road because of that. Am I wrong about that? In other words, going back to the October hearing, the lawyer who was arguing said, no, we understand that the order we are litigating about we do not have the lawful authority to make someone get an unlicensed vaccine. I mean, one, you don't disagree with that statement of law; correct?" (Emphasis added.)
>
> YANG: No, I don't. No. (Emphasis added.)
>
> COURT: And there has not been a Presidential is that correct?
>
> YANG: I don't believe so.
>
> THE COURT: Okay. So then if somebody was telling an individual

service person, service member, you must get the vaccine, and I don't care if a licensed one is available or not, that would be an unlawful situation; correct?

MS. YANG: If -- I mean, well -- I mean, setting aside the argument that we have made consistently throughout this litigation, which is two-fold, even on the EUA issue. The first was that DoD relied on FDA determination that the EUA vaccine, the Pfizer EUA vaccine was interchangeable -- medically interchangeable with the Comirnaty vaccine. And the second of which was that there is a subset of EUA vaccines that are -- that are compliant with the Comirnaty BLA and effectuate under the conditions of the BLA and so are, in effect, Comirnaty. So, I mean -- I don't want to make things too complicated, but I think it is important that those two pieces are understood, because our position is that DoD was able to rely on those two pieces in requiring the vaccination even before the Comirnaty vaccine was available." (Emphasis added.)

> **"...there is a subset of EUA vaccines that are -- that are compliant with the Comirnaty BLA and effectuate under the conditions of the BLA and so are, in effect, Comirnaty."**

Committee members, attorneys who argue a legal position must do so from a position of law. They may not intentionally disregard our Republic by fabricating nonsensical claims lacking statute.

If a BLA-compliant process can effectuate a change in the legal distinction of an IND under an EUA absent the standard FDA approval procedure, then that process must be established by law. Moreover, the name COMIRNATY has more meaning than its formulation to include, but not limited to, its legal status as a drug licensed for general commercial marketing. That legal classification affects manufacturers, distributors, healthcare professionals, recipients, and courts. The legal status of a drug is no small matter. Legally speaking, no "subset" of any drug authorized for EUA is "in effect, Comirnaty." To repeat for extreme clarity: there does not exist a legal

mechanism demonstrating how a drug under EUA that undergoes a BLA-compliant process can be treated as a licensed product irrespective of the shared formulation. This argument is intentional and wilful misconduct in a court of law. The drug is either under an EUA or not, but it can not be under Section 564 immunity and governed as if it is a licensed product simultaneously. Therefore, the ONLY question Judge Windsor needed to inquire was if the drug was under EUA or full licensure status, for it can not be both.

Ms. Yang cannot point to a single line of the U.S. Code proving her position that if an EUA drug mimics the BLA-compliant process of a licensed drug, then the right to refuse that EUA drug is forfeited. Her argument is nothing less than an intentional and wilful attempt to mislead the judiciary to interfere with the well-established rights of American citizens under SECTION 564.

> 21 CFR 601.20(a) "A biologics license application shall be approved only upon examination of the product and upon a determination that the product complies with the standards established in the biologics license application and the requirements prescribed in the regulations in this chapter." (Emphasis added.) Ms. Yang's arguments do not comply with FDA's regulatory requirements.
>
> **"While FDA determined Comirnaty and Pfizer-BioNTech Covid-19 vaccine are medically interchangeable, there are legal distinctions between BLA-approved and EUA-authorized products." — Peter Marks, Director of the CBER, FDA**. ***Coker v. Austin*** et al (3:21-cv-01211)

Committee members should take note that at no time have officials at CBER, FDA, CDC, HHS, DoD, or DOJ referred to these "BLA-compliant" vials as licensed products. Instead, they misdirect with words such as "believe," "considered," "BLA-approved," "BLA-compliant," and "BLA."

Most importantly, attorneys in the DOJ argue in courts that the DoD has lots of COVID-19 vials that meet SECDEF's COVID-19 requirements. EUA products legally meet SECDEF's COVID-19 requirements under voluntary conditions, and therefore the carefully worded statement is meant to mislead the judiciary.

'BLA-APPROVED, COMIRNATY-LABELED'

This new descriptive term appeared on the scene when courts became increasingly uneasy with service members penalized for refusing EUA COVID-19 Vaccines. However, no one knows the phrase's meaning since it is a radical departure from industry norms. Does it mean the FDA licensed the vials for general commercial marketing? Or, in light of what we have learned, does it mean the vials are compliant with the BLA-approved COMIRNATY and have a COMIRNATY label attached to them but are factually vials under an EUA?

European countries allow the use of the licensed name during clinical trials and under emergency access protocols.

There are actual vials bearing COMIRNATY labels within the military, but neither the DOJ nor DoD refer to them as licensed products. This activity requires the full attention of the Committees. Due to the Feres doctrine, service members would have little recourse should these vials turn out to be actual EUA drugs instead of licensed products causing injury.

When these "BLA-approved, Comirnaty-labeled" vials appeared on military treatment facilities, not even Pfizer employees were aware of their existence in circulation. Eventually Pfizer acknowledged with the same verbiage as the DoD attorneys and stated they could only confirm they were "Comirnaty-labeled." Inquiries from service members to the DHA about the authentication of these vials went unanswered and directed to FOIA.

Army Surgeon General Scott Dingle and/or Brigadier General Anthony McQueen are obligated to know if these vials are, in fact, licensed or under an

EUA. However, the CDC previously showed these lots were under EUA status despite bearing the COMIRNATY label which should deeply concern every Committee member.

ILLEGAL ORDERS, COUNSEL, AND JAG ADVICE

Coast Guard Commandant, Admiral Karl L. Schultz, issued ALCOAST 305/21 on August 26, 2021:

> "The Secretary of Defense directed that only vaccines that have received full licensure from the Food and Drug Administration (FDA) be used for mandatory vaccination. Consistent with the Secretary of Defense's direction, all Coast Guard active duty and Ready Reserve members who are not fully vaccinated, unless they are granted an exemption or accommodation, are required to receive the Pfizer-BioNTech COVID-19 vaccine as an initial series, and subsequently as indicated, to comply with recommended vaccine schedules necessary to achieve full vaccination against COVID-19. The Pfizer-BioNTech COVID-19 was granted license by the Food and Drug Administration (FDA) on 23 Aug 2021." (Emphasis added.)

This order is illegal because ADM Schultz reiterated SECDEF's order to only use full licenced drugs and then listed a non-licensed drug "required" by Coast Guard members to receive. Thus, he ordered the Coast Guard to violate his and SECDEF's order.

Maj Gen, USAF JEFFREY T. PENNINGTON, issued a memorandum on November 01, 2021:

> "If AFRC/CC denies your religious accommodation request, you may appeal the denial. Should you appeal, I am ordering you to submit your appeal to The Surgeon General of the Air Force (AF/SG), through your

chain of command, within 72 hours of notification that AFRC/CC has denied your request…

If you do not appeal to AF/SG or if AF/SG denies your religious accommodation request appeal, then I am ordering you to receive an initial dose of a COVID-19 vaccine **with full licensure approval from the FDA** AND provide proof of vaccination by 1200 hours (noon) during your first duty day in military status…Additionally, you are ordered to receive the second dose of the COVID-19 vaccine AND provide proof no later than twenty-one (21) days after the first dose for Pfizer or twenty-eight (28) days for Moderna.

The Pfizer COVID-19 vaccine is not the only option available for complying with this order. Alternatively, you may choose to receive the two-shot Moderna COVID-19 vaccine or the single shot J&J COVID-19 vaccine. If you choose to receive the J&J vaccine, you must comply with the first deadline listed above."

This order is a psyop work of art:

(1) "The Pfizer COVID-19 vaccine is not the only option" - the deletion of "BioNTech" and the use of the lowercase "vaccine" denotes any vaccine and not a specific one from Pfizer. Pfizer's EUA drug is always listed as "Pfizer BioNTech COVID-19 Vaccine" denoting a formal name. Therefore, when he states "The Pfizer COVID-19 vaccine is not the only option" it gives the service member the impression he means a "full licensure" drug under mandatory requirement without saying mandatory. The word "option" fulfills SECDEF's COVID-19 memorandum because the EUA vaccine is under voluntary (option) conditions. Should he be called to defend his order it legally never states a requirement to participate in an EUA drug, it only gives the impression that "Pfizer COVID-19 vaccine" refers to BioNTech to mean mandatory.

(2) His order was illegal because it was physically impossible to fulfill. There were no full licensure vaccines available to USAF members under his command.

(3) Mag Gen Pennington ends his memorandum with criminal coercion stating: "Failure to comply with this lawful order may result in administrative and/or punitive action for Failing to Obey an Order under Article 92, Uniform Code of Military Justice." This order was anything but lawful.

The United States Marine Corps, Military Justice Branch, issued a Practice Advisory on September 10, 2021 stating in part:

> "The Secretary of Defense (SECDEF) mandated COVID-19 vaccination for all active duty and Ready Reserve service members via a memorandum published 24 August 2021. Pursuant to this memorandum, the Secretary of the Navy (SECNAV) published ALNAV 062/21 on 30 August 2021 with additional guidance applicable to the Department of the Navy (DON). Specifically, the ALNAV states:
>
> > 'Effective immediately, all DON active duty Service Members, who are not already vaccinated or exempted, are required to be fully vaccinated within 90 days and all Reserve Component Service Members are required to be fully vaccinated within 120 days of this issuance with an FDA approved vaccination against COVID-19.'
>
> Food and Drug Administration (FDA) licensed vaccinations are subject to the vaccination mandate. Currently, the only vaccine with a FDA license is the Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA).
>
> However, in accordance with FDA guidance available at https://www.fda.gov/vaccines-blood-biologics/qa-

comirnaty-covid-19-vaccine-mrna, doses of the Pfizer-BioNTech COVID-19 vaccine authorized under the FDA Emergency Use Authorization (EUA) produced prior to the issuance of the FDA license may be used interchangeably with doses produced post-licensing by Pfizer (Comirnaty). The Pfizer COVID-19 vaccines produced prior to and after FDA licensure have the same formulation.

Accordingly, **commanders may order an unvaccinated Marine to receive the Pfizer produced vaccine regardless of whether the particular dose of the Pfizer vaccine to be administered was produced before or after FDA licensure.** Commanders, however, cannot order a Marine to receive any other COVID-19 vaccine, even if that vaccine is approved for use under an EUA or World Health Organization (WHO) Emergency Use listing" (Emphasis added.)

This advice was criminal. Major General David J. Bligh assumed office as Staff Judge Advocate to the Commandant of the Marine Corps immediately following the publication of this Practice Advisory. He has refused to correct the criminal error.

DoDI 6200.02 clearly and conspicuously states that if a "dose" requires the issuance of an EUA for its administration then the informed consent of the service member is required in advance. The Military Justice Branch essentially issued a LEGAL opinion to Marine commanders that they "may" assume the authority of the Commander in Chief and waive the informed consent rights of Marines. Who wrote this Practice Advisory?

On September 17, 2021, the **United States Army Reserve Command**, under the authority of LTG Jody Daniels, issued COVID-19 vaccination guidance.

(1) "While the only mandatory COVID-19 vaccine is the FDA-approved Pfizer Comirnaty COVID-19 vaccine, service

members may continue to choose to voluntarily receive any FDA Emergency Use Authorized (EUA) or World Health Organization (WHO) Emergency Use Listing vaccine."

(2) "Effective immediately, commanders will vaccinate all Soldiers who are not otherwise exempt. Orders to receive the mandatory vaccine are lawful…Soldiers may at any time voluntarily receive any other vaccine approved for emergency use."

(3) "Commanders will initiate mandatory separation of Soldiers who refuse the vaccine. Failure to comply is punishable under the Uniform Code of Military Justice."

Commanders were ordered to begin vaccinations immediately even though LTG Daniels declared that the ONLY mandatory vaccine was COMIRNATY and she had not procured full licensure drugs. In addition, there is abundant instruction on punishment and no instruction on how to proceed until full licensure vaccines become available. Should the committee call LTG Daniels to testify, could she justify the punishments under her command of soldiers who did not "volunteer" for EUA or WHO Emergency Use Listing vaccines?

On September 30, 2021 **SECDEF** issued a memorandum: 'Coronavirus Disease 2019 Vaccination for Members of the National Guard and the Ready Reserve'

The memorandum required "non-federalized National Guard" members to be vaccinated or lose pay among other penalties. SECDEF required leaders to post guidance no later than December 06, 2021. SECDEF did not provide guidance on how to fulfill his order since no licensed products existed within the DoD. However, he provided backdoor legal protection by refusing to set a required date for compliance and stating, "Unless otherwise exempted in accordance with Department policy."

There are hundreds of memoranda, orders, and advisories by DoD civilian appointees, attorneys, GO/FOs, commanders, that are either illegal and or deceptive in their wording.

UNDERSTANDING THE LOSS OF DIGNITY

The following story is fictitious but correlates with nearly 9,000 actual DoD events under current civilian leadership.

Lt. John Doe has served his country for 15 years with pride, passion, and love. Every morning he rises to thank his God for the privilege of being able to honor his fellow citizens by guarding their lives with his own. He abides by a code of doing unto others as he would have them to do unto him. He asks for nothing special other than the right to honor the military profession.

He arises one day, like the thousands before, and is presented with an ultimatum by his commander to either take a vaccine with known historic adverse reactions under experimental authorization or be charged under the Uniform Code of Military Justice for disobeying a lawful order.

Lt. Doe knows that he has the irrefutable right to refuse an experimental medical product without consequence. However, his commander refuses to acknowledge that right and issues him a letter of reprimand for refusing to participate. Lt. Doe issues a legally accurate rebuttal letter informing his commander of the error of his ways. However, his commander refuses to uphold his oath of office to protect Doe's 5th, 8th, and 14th Amendment rights under the U.S. Constitution.

Lt. Doe is recommended for separation, and a Board of Inquiry (BOI) convenes. The BOI is presented with the irrefutable right to refuse by LT. Doe's licensed attorney, but the board chooses to also engage in a felony by agreeing to waive Lt. Doe's right to refuse medical experimentation without consequence.

Lt. Doe's commander applies a misconduct code on Lt. Doe's discharge papers. This misconduct code requires Lt. Doe to repay the military $12,500 for no

other reason than exercising a federally protected right held by all military personnel.

Lt. Doe is attempting to reconcile the emotions of serving his nation with honor, distinction, and joy with the lawlessness that now abounds behind a new iron curtain of censorship.

Should courts not correct the lawlessness that now abounds, history has proven the people will seek out their own remedy. We should avoid this scenario at all costs.

To Lt. Doe and others similarly situated, this document is the voice you are not allowed to have. WE LOVE YOU and will NEVER stop fighting for you!

UNDERSTANDING DoD CRIMES

Civilian appointees, senior Pentagon leadership, GO/FOs, and commanders are potentially in violation of:

(a) 45 CFR 46, 32 CFR 219, E6 Harmonization Executive Agreement, 10 USC 980, 10 USC 1107, 10 USC 1107(a), 21CFR312, 48 CFR §207,§235,§252 (DFARS Case 2007-D008), DoDI 3210.7, DoDI 3216.02, DoDI 6200.02, DoDD 5400.11-R Privacy Program
(b) Army Regulation (AR) 70-25, Use of Volunteers as Subjects of Research, Jan 25, 1990
(c) AR 40-7, Use of US Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule I Controlled Substances, Oct 19, 2009:
(d) DoD Manual 6025.18, DoDI 6025.18, DoDI 6205, DoDI 8580.02
(e) 5th, 8th, 14th Amendments
(f) Article VII of the ICCPR Treaty
(g) Federalwide Assurance - FWA00019362
(h) HQ USAMRDC DoD Assurance A20000
(i) IORG Number - IORG0003554
(j) IRB Number - IRB00007718

(k) Section 564

(l) U.S. Food and Drug Administration (FDA) Guidance, Emergency Use Authorization of Medical Products and Related Authorities (Jan 2017)

(m) DFARS 252.235-7004 Protection of Human Subjects (limited circumstances)

(n) 5 CFR §2635.101, 18 USC §1001, 18 USC §241 & §245, 18 USC §371, 21 USC §352

(o) HQ USAMRDC Institutional Review Board Policies and Procedures Reflecting 2018 Common Rule Requirements

(p) Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021

Furthermore, it is a serious constitutional violation of the 14th Amendment to require testing and masking of individuals under DoD authority solely on the basis of EUA product participation.

UNDERSTANDING THE ABUSE OF OFFICE

> **Court: "The entire point of this statute (RFRA) is that we don't want to have to get to court because we expect the government to follow the law…Is it the executive branch's position that you don't have to worry about RFRA until someone sues?"**
>
> **Government Attorney Mr. Ross: "More or less, yes."** -
> (Hunter Doster v Frank Kendall 22-3497)

This level of disregard for the Constitution, law, courts, and authorities by those in the executive branch of government is the sole reason the military is undergoing a process of being dismantled from within.

Commanders who penalized a service member refusing an EUA product committed fraud against the United States government by providing a false statement regarding the misconduct of the service member. Commanders were ordered to only use full licensure drugs but chose to rely exclusively on

experimental medical products to claim compliance with SECDEF's memorandum. This fraud has interfered with the operations of the government and is punishable with incarceration.

REMEDY

Many service members who elected not to receive the vaccine were subject to disciplinary or negative administrative actions. These actions impacted service members' ability to receive promotion, decorations, awards, assignments, and technical training or Professional Military education (PME). Many of these actions are related thereby creating a domino-effect. For example, if a member was not nominated for technical training or PME because of travel restrictions on the unvaccinated, that in-turn impacts assignments, promotions, and award nominations.

Many of the negative administrative actions are "soft" disciplinary measures. They do not qualify as punishment, are within the commander's purview, but nevertheless have a palpable impact on the service member's career progression. Moreover, each Service's Board of Military Corrections lacks the ability and mechanism to correct these soft disciplinary measures. Additionally, each service lacks a specific resolution mechanism in existing regulations or instructions to address the soft disciplinary actions that have resulted by electing not to receive the vaccine.

Consequently, an equitable remedy mechanism must be implemented within each Service to rectify the actions taken against service members that had a detrimental impact on their career progression. The mechanism must be designed to require all commanders to solicit each service member who declined to receive the vaccine asking if they want to engage in the process to potentially correct the detrimental impact. If the service member participates, the equitable remedy process would require tailoring to each action the service member received as a result of not receiving the vaccine.

For technical training or PME, any service member that had training withheld, delated, or denied will receive preferential placement into the next

available technical training or PME course commensurate with their highest-held rank.

For performance reports, the service member shall be afforded an opportunity to have any performance report written during the period of the vaccine mandate to be removed from their record. Those service members will be afforded a separate promotion board and promotion will be determined by whether the service member's record, absent any performance report during the vaccine mandate, merits promotion. Those service members opting for the separate promotion board will not have his or her record compared to the record of the lowest promoted person from the prior board. Promotion will be based upon a meets/does not meet standards for promotion. There will be no quotas or limits on the number of individuals that may be promoted.

For those who did not receive PCS orders due to being coded ineligible for PCS based upon the service member's election not to receive the vaccine, they will be provided priority in location or assignment for the next PCS cycle. These service members will be afforded the option of promotion regardless of any PSC funding budgetary restraints that may be imposed.

In instances where this wrong prevented either positional, promotional, or both opportunities, restore the service member to the rank position they would have attained within 90 days of completing technical training and/or PME.

The DoD MUST provide separated service members with the option to return to service with back pay or full payment of their unfulfilled employment contract. The DoD broke the terms of the contract, not the service member.

The DoD MUST repay all reimbursements made by service members resulting from unlawful separation to include interest.

The DoD MUST clear all negative COVID-19 mandate reports of service member records. To allow those negative reports to remain is a fraudulent act in and of itself.

CONCLUSION

SECDEF Austin, civilian appointees, and senior Pentagon leadership must comply with ratified treaties, federal law, military regulation, and court precedent. They do not have agency discretion to violate the fundamental rights of service members by writing deceptive directives void of those rights. The Committee will not be able to locate memoranda by SEDCEF, USD (P&R), ASD (HA), Secretary of the Army, and the Surgeon General of the Army providing ongoing educational communication of the rights of service members to refuse EUA products under 1107(a) U.S.C. 10 nor their obligations under DoDI 6200.02.

The lack of reference to those rights proves their intentional violation of a public officer's oath. SECDEF Austin can not plead ignorance because he gave the order only to use full licensure drugs and has since been a named defendant in several federal lawsuits. The arrogance and criminal disregard for laws by military leadership have destroyed morale, recruitment, and military readiness, representing a clear and present danger to the United States of America.

Nearly 9,000 service members were violently separated by leadership for no other reason than exercising a federally protected right. Hundreds of thousand have had their careers destroyed, payments stopped, records marred, and their dignity humiliated. 1.9M service members, civilian employees, and contractors were robbed of their legally effective informed consent rights. Some paid the ultimate price of death after being coerced into medical experimentation.

Service members, civilian employees, and contractors have the right to refuse EUA products without incurring a penalty or losing a benefit to which they are otherwise entitled. SECDEF, JAG, DOJ, FDA, HHS, CDC can not refute this statement by statute.

Crimes against individuals under DoD and Coast Guard authority continue under the leadership of Lloyd Austin, Gil Cisneros, Christine Wormouth,

Scott Dingle, Mark A. Milley, Caroline Krass, and Alejandro Mayorkas.

These individuals have dishonored the military profession and are no longer fit to command the obedience of their subordinates and must be removed from office to restore the dignity stolen from our nation's heroes.

Brian Ward
CovidPenalty.Com

Brian Ward is available for consultation, testimony, and legislative efforts.