

Space Force, Mandatory Military Vaccines, and Veteran Advocacy in the Law Friday, October 29, 2021

"COVID-19 Refusals: What Lessons Can Be Learned From The Anthrax Vaccine Immunization Program?"

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- Anthrax vaccine given to approx. 150,000 troops in 1st Gulf War
- @ 1994, Senate Report identifies anthrax vaccine as possible cause for GWS
- DoD issues Order in December 1997 that AVIP will commence in March 1998
- USS Independence/USS John Stennis "mutiny"

# 10 U.S. Code § 892 - Art. 92. Failure to obey order or regulation

- Any person subject to this chapter who—(1)violates or fails to obey any lawful general order or regulation;
- (2) having knowledge of any other lawful order issued by a member of the armed forces, which it is his duty to obey, fails to obey the order; or
- (3) is derelict in the performance of his duties;
- shall be punished as a court-martial may direct.
- (Aug. 10, 1956, ch. 1041, <u>70A Stat. 68</u>.)

- 1<sup>st</sup> Court Martial (February 1999)
  - Airman First Class Jeffrey Bettendorf, Travis AFB
  - ABC's 20/20 aired story
  - Administrative discharge, Other than Honorable
- I ultimately handled about 10-12 courts-martials
  - Five were simultaneously handled at 29 Palms in June 1999.
  - All guilty
  - Never permitted to challenge lawfulness of the order
  - Judges were unwilling to rule SECDEF was wrong

- In 1970, the National Institutes of Health ("NIH"), the agency then charged with licensing biologic drugs, licensed AVA for use against anthrax. FDA gained authority in 1972.
- After the authority to license biologic drugs was delegated to the FDA, the agency initiated a review of the safety, effectiveness, and labeling of all licensed biologics. 21 C.F.R. 601.25. The Federal Register published a proposed rule containing the results of AVA's review on December 13, 1985. In that product review, the independent Biologics Review Panel recommended that the vaccine be classified as safe, effective, and not misbranded.
- Vaccine's "efficacy against inhalation anthrax is not well documented...no meaningful assessment of its value against inhalation anthrax is possible due to its low incidence."
- The Proposed Rule published in the December 13, 1985, Federal Register was never finalized.

- On October 5, 1995, the U.S. Army Medical Research and Material Command wrote the Michigan Department of Public Health ("MDPH"), the vaccine's manufacturer, that they were enclosing a plan "to expand the indication for use to include projections from aerosol exposure to B. anthraces spores."
- The plan specifically asserts that "this vaccine is not licensed for aerosol exposure expected in a biological warfare environment." The plan proposed was to amend the anthrax vaccine license through an Investigational New Drug ("IND") application submission.

- In September 1996, AVA's manufacturer submitted an IND application to the FDA in an attempt to get FDA approval for a modification of the AVA license to demonstrate the drug's effectiveness against inhalation anthrax.
- There was no indication for inhalation anthrax on the label or in the product insert.

- In 1998, in response to concerns about the use of investigational new drugs during the 1991 Gulf War that may have led to unexplained illnesses among veterans, Congress signed into law 10 U.S.C. § 1107.
- This provision prohibits the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent. The consent requirement may be waived only by the President.

- In 1999, the President signed Executive Order 13139, pursuant to which the DoD must obtain informed consent from each individual member of the armed forces before administering investigational drugs and under which waivers of informed consent are granted only "when absolutely necessary." Exec. Order No. 13139, 64 Fed. Reg. 54,175 (September 30, 1999).
- In August, 2000, the DoD formally adopted these requirements in DoD Directive 6200.2.

### Doe #1 et al. v. DoD et al. (DDC)

- The central question before this Court is whether AVA is an "investigational" drug or a drug unapproved for its use against inhalation anthrax.
- 297 F. Supp. 2d 119 (D.D.C. Dec. 23, 2003) TRO granted
- 341 F. Supp. 2d 1 (D.D.C. Oct. 27, 2004) Permanent Injunction granted
  - "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"

### Subsequent litigation

- Rempfer et al. v. Von Eschenbach et al, 535 F. Supp. 2d 99 (D.D.C. 2008)
  - "After examining the available scientific data and interpreting the data pursuant to its regulations, the FDA applied its expertise and found that AVA is effective for immunization against anthrax, whether the infection was acquired by inhalation or cutaneously. The FDA did not act arbitrarily or capriciously. It considered the relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." The Court will not substitute its own judgment when the FDA made no clear error of judgment."
- Affirmed, 535 F. Supp. 2d 99 (D.C.Cir. 2009)

- 2 Sep 2021
- Sailors and Marines now have 90 days to get vaccinated against COVID-19 or risk disobeying a lawful order, a violation of the Uniform Code of Military Justice.
- Secretary of the <u>Navy</u> Carlos Del Toro, Chief of Naval Operations Adm. Mike Gilday, and Commandant of the <u>Marine Corps</u> Gen. David Berger told their service members that they are ordering any sailor or Marine who has not received the shots to get them now.

### What is the basis for refusal?

- Health concerns?
- Religious exemptions?
- Unlawful order?
- Political ideology? Not present with anthrax vaccine debate

- Commands should "provide counseling regarding refusal to take the COVID-19 vaccine [to] include access to a healthcare professional to answer questions regarding the risks of COVID-19 and the benefits of COVID-19 vaccinations". After that counseling, however, the person will receive a note in their service record ordering them to get vaccinated.
- Service members who remain unvaccinated after 90 days will be referred to the COVID Consolidated Disposition Authority, or CCDA.
- The new CCDA will decide what happens to sailors who refuse the vaccine. Although this new position will be able to use "the full range of administrative and disciplinary actions," "until further notice" the CCDA won't start "non-judicial punishment, courts-martial, or administrative separation in cases of Navy Service Members refusing the vaccine."
- For Marines, the process is a bit simpler: Get the shot or your commander will decide a punishment for failing to follow a lawful order.

- <u>U.S. v. Sterling (CAAF, 2016)</u>
  - Religious exercise triggers inquiry under Religious Freedom Restoration Act.
  - Court would ask whether the lawful order "substantially burdened" a "sincerely held" religious belief.
  - Sincerity inquiry will probe motives: Is the refusal really based on religion, or is it something that was simply read online?
- The Sterling court held that service members would not be "substantially burdened" as a legal matter unless they first request accommodation through their command and that accommodation is denied. Refusers will need to show that an important part of their religion was burdened by taking the vaccine.

- Chaplains in individual Navy commands will be charged with determining the sincerity of sailors' beliefs but Deputy Chief of Naval Operations for Manpower, Personnel, Training & Education will decide who gets an exemption or not.
- As part of longstanding regulations, service members seeking religious exemptions for vaccination have to write a short essay on the reasons for their opposition, then be counseled legally, medically and spiritually.
- For example, if someone seeking a religious exemption because the COVID-19 vaccines were developed with lab-replicated cells descended from aborted fetal tissue, they will have to make a case as to why they oppose this vaccine and not any others they've previously received.
  - Chickenpox, measles-mumps-rubella and hepatitis A all required to serve in the military were also created using lab-replicated cells from aborted fetal tissue.

#### But even if someone makes it past these hurdles, they still can be punished for violating the order if the substantial burden on their religious exercise is "the least restrictive means of furthering a compelling government interest."

- Doubtful any court is likely to hold that ending the COVID-19 pandemic does not constitute a compelling interest.
- But is a vaccine the least restrictive means of ending the pandemic?
  - Masks, distancing, or working from home. Workable solutions?

#### • Other administrative exemptions can be granted:

- within six months of separation from service, on leave, in the middle of a permanent change-of-station move, absent-without-leave or otherwise missing.
- Some temporary exemptions, including any for temporary leave, pregnancy, medical treatment or others, may expire before those deadlines.
- Medical exemptions can be granted for a variety of reasons, including past adverse reactions to vaccination, allergies to vaccine ingredients or a handful of conditions that the <u>CDC recognizes as high-risk</u>.

### What's Happened To Date

- Aug 2021
  - Marine Cpl. Whitney McHaffie received a general discharge under honorable conditions
    - Asserted she cannot morally take a vaccine because they are derivatives of aborted fetal tissue.
    - Did not have an explanation as to why she accepted other mandatory vaccines as part of her service, but rejected COVID-19 vaccine
- While researchers did use cell lines derived from elective abortion tissue originally created decades ago, that tissue was used to produce proteins and wasn't put directly into the vaccine.
- None of the COVID-19 vaccines approved for use in the U.S. are made with tissues taken directly from aborted fetuses.

- 2 Sep 2021
- House lawmakers have backed legislation prohibiting dishonorable discharges for troops who refuse the COVID-19 vaccine
- Legislation sponsored by Rep. Mark Green, R-Tenn., an Army veteran, requires only honorable discharges for anyone who is separated from the military over refusing to be vaccinated. It was added to the fiscal 2022 defense authorization bill, passed by the House Armed Services Committee on Thursday.

- As of Oct 18, 2021:
  - Fewer than 10 percent of the active-duty force, and 30 percent of the total force, remain completely unvaccinated.

### Litigation Against Mandatory COVID Vaccinations

- Military
- Federal Civilian
- Civilian, non-Federal

## THANK YOU FOR YOUR SERVICE!

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