

The White House

Office of the Press Secretary

For Immediate Release

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Presidential Executive Order on Reprieves, Pardons & Corrections to Servicemember records related to the Department of Defense Anthrax Vaccine Immunization Program prior to December 19, 2005

EXECUTIVE ORDER

In the best interest of justice AND by the authority vested in me as President by the laws of the United States of America, including Article II, Section 2 of the Constitution, wherein the President shall be the Commander in Chief, with the power to grant reprieves and pardons for offenses against the United States, I hereby grant reprieves for all punishments, pardons for all servicemembers and direct corrections to military service records for any and all disciplines imposed by the Department of Defense and other agencies related to the Anthrax Vaccine Immunization Program prior to December 19, 2005.

Section 1. Purpose.

Federal Courts affirmed (341 F. Supp. 2d 20) the anthrax vaccine utilized in the Department of Defense Force Protection Program was investigational, and inconsistent with Federal Regulation and law, prior to the December 19, 2005 publication by the Food and Drug Administration of a Final Rule for the Anthrax Vaccine Adsorbed (AVA) in the Federal Register (Volume 70, Number 242, page 75180-75198). Therefore, a reprieve and pardon for any Servicemember previously punished for refusing to submit to the vaccine is a just and overdue course of action, which is in the best interest of good government.

Section 2. Basis.

(a) LEGISLATIVE INQUIRY.

Multiple bipartisan Congressional Hearings resulted in House Report 106-556 in April 2000. The report found the Department of Defense Anthrax Vaccine Immunization Program (AVIP) conflicted with Food and Drug Administration regulations, and declared the anthrax vaccine investigational absent a properly approved indication for use against inhaled anthrax. The unlicensed status of the AVIP was later corroborated in Article III Federal Court rulings.

(b) JUDICIAL INQUIRY.

Federal Courts found the AVIP violated 10 U.S.C. § 1107 due to the mandate of a vaccine that was being used for a known investigational purpose absent a required Presidential Waiver or informed consent as directed in Executive Order 13139. It was not until December 19, 2005 that the AVIP received final licensure. A December 2003 preliminary injunction, and an October 2004 permanent injunction by the Federal District Court of Washington DC, enjoined mandatory Anthrax inoculations and vacated the existing rulemaking process until the vaccine's license final rule had been properly completed. The court opined regarding its "obligation to ensure that FDA follow the law in order to carry out its vital role in protecting the public's health and safety," and affirmed that "Congress has prohibited the administration of investigational drugs to service members without their consent." The Court ruled it would "not permit the government to circumvent this requirement," adding that "The men and women of our armed forces deserve the assurance that the vaccines our government compels them to take into their bodies have been tested by the greatest scrutiny of all — public scrutiny. This is the process the FDA in its expert judgment has outlined, and this is the course this Court shall compel FDA to follow." The Court vacated the Food and Drug Administration's rulemaking until the Agency classified the anthrax vaccine as "a safe and effective drug for its intended use." The Court enjoined use of the anthrax vaccine, citing 10 U.S.C. § 1107, and declared the involuntary, forced or compelled Anthrax Vaccination Program "illegal absent informed consent or a Presidential waiver." This court ruling remains undisturbed, and the District of Columbia Federal Court affirmed that the government's position regarding mandatory use of the anthrax vaccine was "not substantially justified" given the licensing was not finalized by the Food and Drug Administration until December 19, 2005 through publication of a final order for the vaccine, including approval for use against inhalation anthrax.

(c) EXECUTIVE INQUIRY.

Executive Branch review, predating the AVIP, included a Department of Defense acknowledgment that there was "no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent [Anthrax]." Additionally, the FDA issued a Notice of Intent to Revoke the Anthrax vaccine manufacturer's license in 1997, citing multiple instances of quality control deviations in 1998 & 1999. In April 2001, the White House directed the Department of Defense to review the Anthrax Vaccine program. By August 2001, an internal Department of Defense review recommended the Secretary of Defense minimize use of the vaccine. The deliberative policy process was disrupted by the Anthrax Letter attacks in September and October 2001. Following the attacks, the Department of Defense renewed anthrax vaccinations because officials unwittingly believed "The anthrax attacks in October 2001 illustrated the risk..." A preliminary report in August 2008, and a final report in February 2010, by the Federal Bureau of Investigation affirmed the perpetrator's motive in the anthrax letter attacks was "to save the failing anthrax vaccine program" by creating a "scenario where people all of a sudden realize the need to have this vaccine." The report revealed a United States Army anthrax vaccine scientist committed the crimes, and was successful in getting the failing program "rejuvenated ... within a few months of the anthrax attacks." The report disclosed that following the attacks the "FDA fast-tracked the approval process and approved the Anthrax Vaccine Adsorbed ... even though it didn't meet the original potency standards."

(d) JUSTICE.

Based on the above examples of legislative, judicial and executive inquiry, the Department of Defense discipline of Servicemembers from 1998 to 2005 for refusing to submit to mandatory anthrax vaccinations during a timeframe that the vaccine was unapproved as per investigational new drug licensure processes and incomplete FDA regulatory rulemaking deserves review. The totality of circumstances support expunging punishments meted out over anthrax vaccine. Accordingly, all disciplines for all Servicemembers over anthrax vaccine prior to December 19, 2005 warrant a reprieve.

Section 3. Policy.

(a) REPRIEVE, PARDON AND CORRECTION.

In the case of a current or former member of the Armed Forces or any similarly situated citizen who, before the December 19, 2005 publication of the final rule and order for anthrax vaccine, was the subject of any form of adverse personnel action as a result of the refusal to submit to inoculation, the Secretary of Defense, acting through the appropriate military board for the correction of military records under title 10 and 32 of the United States Code, shall:

1. Without necessity of application from the member, or representatives of former members, administratively and retroactively correct the personnel records for all adversely impacted members or former members.
2. Notify all affected current and former members of this Presidential Expungement Order causing updates to personnel records and reissue updated discharge documentation with restoration of de novo rights and privileges pertaining to their characterization of service for any and all former members.
3. Direct corrections boards to act without respect to ordinary time-bar limitations upon any applications for corrections they may in the future, or have already received, and to act upon them in the manner as set forth above.
4. Submit to the President and Congress an annual report at the end of each fiscal year regarding activities under this section until 100% complete. Each such report shall identify the specific records corrected.

(b) ADMINISTRATION.

This order shall be implemented subject to the availability of appropriations, and is not intended to, and does not create, beyond administrative corrections, any additional right or benefit, substantive or procedural, enforceable by law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP
THE WHITE HOUSE