

The Anthrax Vaccine: A Dilemma for Homeland Security

Thomas L. Rempfer

Past problems with the Department of Defense anthrax vaccine currently impact national emergency response plans approved by the Department of Homeland Security and Department of Health and Human Services. Following the 2001 anthrax letter attacks, those departments diverged from long established protocols advocating limited use of the old anthrax vaccine, also known as BioThrax®. The Executive departments procured mass quantities of the product for the Strategic National Stockpile as a prophylaxis for citizens under emergency contingencies. The departments share oversight responsibilities for the emergency stockpile's composition of vaccines and drugs based on Presidential Directives.¹ Yet a review of past oversight efforts reveals regulatory problems, ethical controversies and dubious threat assessments underlying use of the vaccine. Based on the historic controversy, and studies suggesting the majority of U.S. service members continue to object to the vaccine's use,² the government should resurvey the vaccine's suitability for American citizens. A thorough review may find that widespread use of a known antiquated product of disputed safety and efficacy in treating a non-communicable threat provides an imprudent illusion of protection for our citizens.

This article explores the Department of Defense's experience with the anthrax vaccine, and the troubling possibility that the 2001 anthrax letter attacks were a deliberate and successful effort to sustain a program that federal investigators determined was on the verge of failing. Reflection on why the mandatory military program escaped review following the federal investigation warrants deliberation. Enumerating the safety, efficacy, regulatory and legal problems encountered by the military program provides a prism to analyze future hurdles in using the vaccine on civilians. Finally, comparing past problems with current threat assessments offers an opportunity to suggest potential alternative countermeasures which minimize the negative externalities resulting from the old anthrax vaccine.

DEPARTMENT OF DEFENSE ANTHRAX VACCINE EXPERIENCE

Doctrinal debate over the current anthrax vaccine's role in biodefense precipitated initiation of the Defense Department's mandatory anthrax vaccine immunization program.³ A *Washington Post* article captured the controversy, stating that "Military leaders were initially doubtful about the need for the anthrax vaccine." The exposé revealed an inverted policy process – "starting at the top instead of trying to staff an issue from the bottom up" – adding to the program's problematic origins.⁴

The only previous mass use of the 1950s-era vaccine occurred in the 1990s, when over 150,000 soldiers received inoculations during the first Gulf War, with many later reporting illnesses of unknown origins.⁵ A decade later, the George W. Bush administration recognized the problems associated with the anthrax vaccine and Gulf War Syndrome. Officials directed a review of the program early in 2001. A memo from Presidential Advisor Karl Rove to Deputy Secretary of Defense Paul Wolfowitz⁶ resulted

in recommendations from Defense Undersecretaries Dr. David Chu and Edward Aldridge to Secretary of Defense Donald Rumsfeld.⁷ The defense officials advocated halting the mass mandatory program and continuing use of the vaccine only at a “minimum level.” They recommended purchasing biological detection devices and antibiotics to protect the soldiers “in the absence of an anthrax vaccine.”

The undersecretaries suggested a comprehensive review of doctrinal positions and development of a “coherent institutional process” for future prioritization of threats and assessments of countermeasures. The leaders also echoed a longstanding call for development of a “national long-range vaccine.” The chairman of the Joint Chiefs of Staff subsequently challenged these recommendations, insisting the vaccine was “the centerpiece of our defense against the most likely biological threat agent.”⁸ Newspaper articles captured the debate over use of the vaccine,⁹ and recent Federal Bureau of Investigation and Department of Justice revelations reignited the controversy. The Justice Department alleged the anthrax vaccine program’s “failing” status served as the stated motive in the 2001 anthrax letter attacks. By sending anthrax through the U.S. mail system, the perpetrator was attempting to create a situation where the government might recognize a renewed need for the vaccine.¹⁰

The government’s subsequent decision to continue to procure the vaccine after the letter attacks appears to discount the prior problems encountered by the U.S. military. The Department of Defense acknowledged those problems as early as 1985 in a proposal request to solicit a new vaccine.¹¹ The proposal emphasized the “requirement to develop a safe and effective product which will protect U.S. troops” from anthrax spores. Pentagon officials confirmed the military lacked a vaccine that safely and effectively protected military personnel against exposure to anthrax. U.S. Army scientists also acknowledged the product as an “experimental limited-use vaccine.”¹² Two congressional reports corroborated these findings. One report established that prior to the first Gulf War the anthrax vaccine “was rarely used,” considered “investigational,” and deemed it as “a potential cause for undiagnosed illnesses in Persian Gulf military personnel.”¹³ The other report determined the current anthrax vaccine was “experimental.”¹⁴

Safety and Efficacy Issues

Additional oversight reports cited Pentagon studies acknowledging that up to 35 percent of soldiers had adverse reactions to the anthrax vaccine, and that 6 percent of recipients reported serious complications after vaccination.¹⁵ The military studies caused authorities to alter previously low adverse reaction rates, changing warnings listed on the approved labeling.¹⁶ Despite the changes, the military continued to insist on the safety of the vaccine, while the Government Accountability Office disclosed that “a significantly large number of vaccine recipients reported experiencing adverse events.”¹⁷ Government oversight reports confirmed the long-term safety of the vaccine had not been assessed, while raising questions about ingredient alterations and problems with human efficacy testing of the vaccine.¹⁸

Recent Department of Veterans Affairs Research Advisory Committee on Gulf War Veterans’ Illnesses Scientific Findings and Recommendations validated concerns that

“studies have indicated that the current anthrax vaccine is associated with high rates of acute adverse reactions.”¹⁹ Though the report ostensibly dismissed the anthrax vaccine as a possible cause of veteran illnesses, the study acknowledged the need for further research to “analyze associations between Gulf War illness and individual vaccines, combinations of vaccines” and to evaluate “diagnosed diseases in personnel known to have received the anthrax vaccine.”²⁰ An earlier Institute of Medicine report corroborated the need for more data stating, “There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine.”²¹ A later report included additional findings that the “current anthrax vaccine is difficult to standardize, is incompletely characterized, and is relatively reactogenic [reactive].” The institute acknowledged the “long and challenging” dose regimen and determined a “new vaccine, developed according to more modern principles of vaccinology, is urgently needed.”²²

Accordingly, the government recently moved to reduce the vaccine’s cumbersome eighteen-month, six-dose regimen to five shots, and altered the route of administration in order to decrease “adverse events.” While the continued lengthy protocol seems incompatible with emergency response, the efficacy of the reduced dosage remains unproven due to pending submissions of immunogenicity response data. As a result, health officials continue to confirm “routine immunization is not recommended.”²³ The conclusions comport with pre-2001 cautions from a former commander of the U.S. Army Medical Research and Development Command at Fort Detrick concerning multiple doses and purification issues, which “argue strongly against procuring large amounts for civilian use.”²⁴

Regulatory issues

Regulatory lapses also marked troubles with past use of the vaccine, leading to a Food and Drug Administration notice of intent to revoke the anthrax vaccine manufacturer’s license based on quality control deviations.²⁵ The Government Accountability Office, in a report titled “Anthrax Vaccine Changes to the Manufacturing Process,” also revealed pre-2001 unreported production alterations that violated Food and Drug Administration rules.²⁶ The report revealed that the vaccine maker failed to notify the government about alterations to the manufacturing process in the early 1990s, and reported the manufacturer did not perform the requisite studies to confirm vaccine quality remained unaffected. The Government Accountability Office also discovered potential potency problems resulting from the unreported alterations, and documented violations of regulations in their inspection report. The analysts noted government rules where “any changes to the manufacturing that have the potential to affect the safety, purity, or potency of a biologic must be submitted and approved ... prior to implementation.” Despite this requirement, requests for approval of the alterations did not occur for up to ten years after implementation.²⁷ The problematic potency issues, and a myriad of quality control problems, ultimately resulted in government regulators deeming that the “manufacturing process for Anthrax Vaccine is not validated” as early as 1998.²⁸ Notwithstanding past problems, the government expedited manufacturing process validation for the vaccine immediately following the anthrax letter attacks in October 2001.²⁹

The problems with vaccine potency testing appeared to weigh heavily on the mind of the U.S Army scientist suspected of mailing the 2001 anthrax letters that killed five Americans. Emails released by federal investigators revealed the scientist's contention that the vaccine "isn't passing the potency test," as well as the implications of these failures. The scientist's email stated, "If it doesn't pass ... the program will come to a halt." The government's analysis of the anthrax letter attack crimes documented that the implicated U.S. Army scientist held direct responsibility for the problematic potency testing as a member of the army's anthrax potency testing team.

Additional emails quoted the scientist's concerns that "apparently Gore (and maybe even Bush) is considering making the anthrax vaccine for the military voluntary, or even stopping the program." In addition to alleging the vaccine's problems served as the 2001 anthrax letter-attack motive, the Federal Bureau of Investigation documented the coincidence of anthrax vaccine program resumption following the crimes, and the army scientist's award of the highest military honors for "getting the anthrax vaccine back into production."³⁰ The U.S. Army's Medical Research and Material Command also acknowledged the army scientist helped to get the "the anthrax vaccine back into production...working directly with the manufacturer...to determine where the problems were and resolve them so the vaccine would pass the potency test."³¹ The scientist himself acknowledged, "Awards are nice. But the real satisfaction is knowing the vaccine is back on-line."³²

Despite the known and potentially unresolved pre-2001 problems, the letter attacks succeeded in reversing the suspected cancellation of the Defense Department's mandatory program and directly resulted in significantly expanded procurement of the old anthrax vaccine for America's emergency stockpile in the years that followed.

Legal Issues

The anthrax vaccine also suffers from a troubled legal history. Federal courts affirmed the vaccine "was an investigational drug being used for an unapproved purpose."³³ Other federal courts reaffirmed this ruling, declaring the Pentagon's program as a "violation of federal law" prior to a belated, court ordered licensure of the vaccine.³⁴ The vaccine received a final Food and Drug Administration license twenty years after a 1985 proposed rule, fifty years after the vaccine's advent.³⁵ The licensing occurred after the courts ruled the mandatory military program illegal and "investigational" absent the requisite finalized license in accordance with governmental rule-making procedures.³⁶

Despite the critical judicial reviews, the government allocated over \$1.2 billion for the anthrax vaccine, adding to a long history of earlier extraordinary financial relief for the embattled manufacturer.³⁷ The latest appropriations occurred immediately after the 2008 Federal Bureau of Investigation findings, adding to more than \$50 billion allocated to bolster biological defenses in reaction to the letter attacks.³⁸ Complicating the controversy, the Food and Drug Administration acknowledged the Department of Defense served as de facto manufacturer of the vaccine due to its "continuous involvement with, and intimate knowledge of, the formulation and manufacturing processes of all of these versions of the anthrax vaccine."³⁹ Military involvement in manufacturing and altering of a vaccine, long sold to the troops and the American

people as fully approved despite the lack of required prior approvals for alterations, presents distinct legal liabilities worthy of additional examination.

THREAT ASSESSMENTS

Official threat assessments also raise questions about the need for the old anthrax vaccine in national stockpiles. The Government Accountability Office reported that the Defense Department determined “the nature and magnitude of the anthrax threat has been stable since 1990.”⁴⁰ A United Nations report substantiated past conventional wisdom about the potential threat of weaponized anthrax prior to the first Gulf War, but confirmed that the Iraqi program suffered technological hurdles in fielding dry weaponized anthrax.⁴¹ Government Accountability Office reports also noted that terrorists would find it difficult to overcome the technological and operational challenges on the road to employing a biological warfare agent.⁴² Nevertheless, in congressional testimony Pentagon leaders previously insisted that they possessed “absolutely unequivocal evidence” that Iraq had weaponized anthrax prior to the first Gulf War. Though subsequent threat assessments turned out to be “dead wrong,”⁴³ the leaders added to the vaccine imperative by insisting, “An anthrax attack is fatal if you are not inoculated.”⁴⁴

Even after the 2001 letter attacks by the Army scientist demonstrated that antibiotics successfully countered lethal exposures to highly virulent spores, military leaders continued to maintain the anthrax attacks in October 2001 justified use of the vaccine.⁴⁵ These assertions defy medical evidence and expert recommendations. According to the Monterey WMD Terrorism Database, twelve anthrax “incidents” and 472 “hoaxes” occurred in the United States since 1992.⁴⁶ For all actual infections diagnosed promptly, antibiotics successfully mitigated the resulting illnesses. As a result, government experts recommend antibiotics to combat the most lethal inhalation form of the disease. Ultimately, both the hyperbole of the threat and pronouncements of certain death absent anthrax inoculation proved to be categorically false. Regardless, the vaccine remains unapproved in “a post-exposure setting” and “not recommended for routine pre-event anthrax vaccination.”⁴⁷ As well, the Centers for Disease Control Advisory Committee on Immunization Practices recommendations maintain that “Occupational groups engaged in response activities are not routinely recommended to receive anthrax vaccine due to lack of a calculable risk assessment.”⁴⁸

Threat assessments beyond the military require review as well. Shortly after the anthrax letter attacks the Department of Homeland Security National Strategy for Homeland Security emphasized the threat,⁴⁹ as did the president’s State of the Union Address.⁵⁰ Later, references to anthrax vaccine waned entirely from the most recent Homeland Security Strategy.⁵¹ As well, the homeland security secretary conceded “there is not currently a domestic emergency involving anthrax.” The secretary confirmed “There is not currently a heightened risk of an anthrax attack” and no credible information was present to indicate an imminent threat of an attack involving bacillus anthracis.⁵² Despite this statement, the Department of Health and Human Services declared an “anthrax emergency” through 2015 based on the “significant potential for a domestic emergency.”⁵³ The emergency declaration purpose was intended to provide

product liability protection to manufacturers of stockpile countermeasures, including anthrax vaccine.

Further academic and independent analysis also refutes the severity of the anthrax threat. One example points to the Aum Shinrikyo group's unsuccessful attempts to produce and disperse anthrax. They also cited al Qaeda's unsuccessful effort to obtain anthrax and to create a microbiological research facility. They noted that the 2001 anthrax letter attacks remained the only successful "distribution of a high-quality dry-powder preparation,"⁵⁴ while the Federal Bureau of Investigation later determined that this attack originated from inside the U.S. biodefense community. A more measured, non-reactive approach also emerged from the National Academy of Sciences. Their report cautioned that society is too complex and interconnected to defend against every threat. The academy addressed the letter-attack threat as well stating "Reactions to anthrax episodes were strongly conditioned – and exaggerated."⁵⁵ Additional evidence of a growing scientific movement away from the old anthrax vaccine includes a recent report by the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. That report recommended use of "oral antibiotics" for the anthrax threat in lieu of vaccine. The congressionally sponsored report also advocated development of new classes of antibiotics against genetically modified anthrax. The commission called upon the next president to "enhance the nation's capabilities for rapid response to prevent biological attacks," but omitted any reference or recommendations to use the old anthrax vaccine.⁵⁶

CONCLUSION

This less-than-reassuring review of the military experience with the old anthrax vaccine represents an opportunity for a thorough review by the new leadership of the Departments of Homeland Security and Health and Human Services. Questions about the safety and effectiveness of the vaccine have been a constant theme since its inception, while manufacturing irregularities and legal problems nearly ended the program. The fact that the 2001 anthrax letter attacks were undertaken by the scientist in charge of vaccine potency testing for a program on the verge of failure, and that the attacks served to reinvigorate a troubled program in response to a "manufactured" crisis, creates fundamental doubts about expanding use of the vaccine.

In light of uncertain threat assessments, relying on the letter attacks as rationalization for continued use of a product with well-known problems fails the litmus test of good government and sound public health policy. Those attacks, and Defense Department "continuous involvement" with the anthrax vaccine, effectively adulterated normal procurement processes involving the old anthrax vaccine, perpetuating the troubled program beyond a normal shelf life. Documented violations of the law indelibly stain the program from a historic perspective; while safety, efficacy, and necessity questions provide pragmatic justification for pursuing alternative protections. Sound alternatives include procurement of proven antibiotics and the development of next-generation technologies to address legitimate threats.

Fortunately, current top health officials recognize the salient need for "new vaccines, especially against anthrax," and the "need to ensure that research institutions and

individual researchers keep track of the whereabouts of dangerous pathogens, handle them safely, and store them securely.”⁵⁷ Since federal investigators report “no other anthrax attacks” have occurred since the 2001 crimes, the time is right to realign current and future appropriations in the direction of modern, proven, and recommended countermeasures versus the old anthrax vaccine. At a minimum, a thorough review of the government’s use of the anthrax vaccine is in order to protect taxpayer resources in a fiscally constrained environment.

Accordingly, President Barack Obama’s appointees in the Departments of Homeland Security and Health and Human Services should commence a comprehensive review of expanded use of the vaccine early in the new administration to protect the government from adopting historically plagued policy.

Lieutenant Colonel Thomas Rempfer is a distinguished graduate of the U.S. Air Force Academy and currently serves as a graduate student with the Naval Postgraduate School’s Center for Homeland Defense and Security. He is an Air Force Command pilot, experienced in F-16s, F-117s, A-10s, and MQ-1s. His prior service included membership on the U.S. Air Force Cyberspace Task Force, as well as flight safety and operational risk management duties. LtCol Rempfer has testified twice before Congress and senior White House Office and DOD officials have enlisted his expertise regarding the anthrax vaccine issue. He may be contacted at tlrempe@nps.edu.

The author thanks Dr. James J. Wirtz, Naval Postgraduate School professor and dean of the School of International Graduate Studies, for his comments in the preparation of this paper.

The views expressed in this article are the author’s, and do not represent the official positions of the Department of Defense or the Department of Homeland Security.

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