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STRATEGY RESEARCH PROJECT

SERVICE MEMBER RESISTANCE TO THE DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM

BY

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USAWC STRATEGY RESEARCH PROJECT

Service Member Resistance to the Department of Defense Anthrax Vaccine Immunization Program

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ABSTRACT

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TITLE:

Service Member Resistance to the Department of Defense Anthrax Vaccine

Immunization Program

FORMAT:

Strategy Research Project

DATE:

19 February 2002

PAGES: 43

CLASSIFICATION: Unclassified

The current Department of Defense anthrax vaccination policy has suffered from phenomenally negative publicity, resulting in significant distrust and reluctance among military members. Criticism has come not only from Internet conspiracy theorists, but from prominent figures in government, in academia, and in the popular media. Service members fear dangerous health effects from the vaccine. Unprecedented numbers of individuals have refused to comply with the policy, either through open disobedience or by leaving military service. Serious questions about the safety and efficacy of the vaccine remain unanswered. This paper reviews the policy, the controversy surrounding it, and the historical context in order to consider options for future actions relative to the policy.

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SERVICE MEMBER RESISTANCE TO THE DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM

Once a policy has been adopted and implemented, all subsequent activity becomes an effort to justify it ...

— Barbara Tuchman

THE PROBLEM

The U.S. military is facing a public relations disaster with its current anthrax vaccination policy. Service members fear dangerous health effects from the vaccine. Unprecedented numbers of individuals have refused to comply with the policy, either through open disobedience or by leaving military service. Serious questions about the safety and efficacy of the vaccine remain unanswered. This paper reviews the policy, the controversy surrounding it, and the historical context in order to consider options for future actions relative to the policy.

NATURE OF THE ANTHRAX THREAT

Although 17 nations are believed to have offensive biological weapons programs, only Iraq and the former Soviet Union are known to have weaponized anthrax.¹ Anthrax bacillus spores are odorless, colorless, and can retain their potency for decades after dispersal as a biological weapon.² Combined with the tremendous lethality of the agent, these factors may make anthrax the agent of choice for potential users of biologic weapons. Although infection can result from skin contact or ingestion of anthrax spores, inhalation of aerosolized spores is considered the most likely threat from biological weapons.³

The lethality of anthrax was demonstrated in the former Soviet Union in 1979 after the accidental airborne release of anthrax spores from a microbiology facility into the surrounding community of Sverdlovsk. From 79 cases of anthrax infection, 68 people (86%) died of the disease.⁴ The US Congressional Office of Technology Assessment estimated in 1993 that 130,000 to 3 million deaths could be expected from a 100 Kg aerosolized release of anthrax in the Washington D.C. area: about the same number of casualties expected from a hydrogen bomb.⁵

Terrorists have used anthrax. The Japanese group Aum Shinkrikyo released anthrax aerosols on multiple occasions in the 1990s in Tokyo.⁶ Although no specific terrorist connection has been demonstrated in the multiple anthrax cases following the atrocities of 11 September 2001, suspicions persist that the anthrax letters may be the work of a terrorist group.⁷

THE ANTHRAX VACCINE IMMUNIZATION PROGRAM

INITIAL POLICY FORMULATION AND IMPLEMENTATION

In the years following the Persian Gulf War, the threat of biologic weapons became increasingly apparent. After a 2-year review, Secretary of Defense William Cohen approved in 1997 the Anthrax Vaccine Immunization Program (AVIP) for the total force, contingent on satisfaction of four conditions: supplemental vaccine testing, assured immunization tracking, approved operational and communications plans, and independent expert review of the health and medical aspects of the program.⁸ On 18 May 1998, Secretary Cohen declared that all four conditions had been met and he named the Secretary of the Army as Executive Agent with instructions to implement the program immediately.⁹

The policy called for a primary series of six doses of the vaccine administered over 18 months, with yearly booster doses thereafter—a schedule approved by the Food and Drug Administration (FDA).¹⁰ However, available supplies of the vaccine did not permit immediate immunization of all service members, and the implementation was limited initially to personnel assigned or deployed for any period of time to the high threat areas of Southwest Asia and Korea.¹¹

SCHEDULE DELAYS AND CURRENT AVIP EXECUTION

Production of anthrax vaccine at the country's only licensed manufacturing facility in Michigan was halted in January 1998 for a renovation project. An FDA inspection of the newly renovated BioPort Corporation plant in November 1999 revealed 30 deficiencies which prevented approval of the new facility. Because of these delays in vaccine production and release, the AVIP execution was slowed in July 2000 and applied only to personnel assigned or deployed on the ground in Southwest Asia or Korea for at least 30 days. For personnel not in this category who had already begun the primary series of doses, the dosing schedule was deferred pending availability of additional vaccine. Because BioPort was not able to meet FDA standards as soon as expected, the AVIP was slowed further in November 2000 to apply only to personnel in Southwest Asia, and then again in June 2001 to special mission units and research personnel only. After many delays, FDA approval for vaccine production and release from the BioPort plant was granted 31 Jan 2002.

ISSUES OF CONTROVERSY

EFFICACY OF THE VACCINE

The anthrax vaccine used in the AVIP has been licensed by the FDA since 1970. Evidence for efficacy in humans has been hard to develop because so few cases occur naturally, and because the lethality of the disease obviously complicates clinical studies with human subjects. There has been only one clinical efficacy study of an anthrax vaccine. That study enrolled a small number of subjects from goat hair mills in the 1950s and used a vaccine different from the AVIP vaccine. ¹⁹ In that study, one vaccinated subject developed cutaneous anthrax but no subjects developed inhalational anthrax. In the placebo group there were 13 cases of cutaneous anthrax and two cases of inhalational anthrax.

More extensive scientific work has been done with animal studies. A series of studies using non-human primates resulted in survival after aerosolized anthrax exposure in 62 (95%) of 65 animals vs. death in 18 of 18 unvaccinated animals.²¹ Another series of aerosolized anthrax studies with rabbits resulted in survival after exposure in 114 (97%) of 117 animals vs. death in 88 of 88 unvaccinated animals.²² Results from guinea pig studies have been less promising, showing only 20% to 26% survival in vaccinated animals after anthrax aerosol exposure.²³

Different strains of anthrax have shown different abilities to defeat the protection afforded by the anthrax vaccine produced at BioPort. More than 30 strains of anthrax have been studied in western research literature. In the most definitive study of geographically diverse strains of anthrax, survival rates varied from 63% to 89%.²⁴

SAFETY OF THE VACCINE

About 30% of vaccine recipients experience temporary local redness and tenderness at the injection site. ²⁵ Roughly 4% experience moderate levels of local redness, pain, swelling, and increased tissue temperature. Some experience a hardening of the skin and subcutaneous tissue at the injection site. A few individuals experience severe local reactions such as extensive swelling of an entire limb. ²⁶ Estimates of systemic reactions such as headache, nausea, muscle and joint aches, fever, chills, and a feeling of weariness, weakness or fatigue have ranged from as low as 0.2% ²⁷ to as high as 25% ²⁸

Adverse reactions to the anthrax vaccine are reported through the Vaccine Adverse Event Reporting System (VAERS), jointly operated by the FDA and the Centers for Disease Control and Prevention (CDC&P). As of July 1, 1999, 215 adverse reactions to anthrax vaccine were

reported to VAERS, 22 of which were considered serious.²⁹ This number represents a small proportion of roughly 350,000 people who had received about 1,000,000 vaccine doses by that time. Officials from the FDA, commenting on these adverse event rates before Congressional Subcommittee hearings in 1999, stated that these numbers "... do not signal concerns about the safety of the vaccine," and further that the "FDA continues to view the anthrax vaccine as safe and effective for individuals at risk of exposure to anthrax."³⁰ By November 2001, roughly 1,600 adverse reactions from among 2,000,000 doses were reported, a ratio characterized as "untroubling" by Dr. Tom Waytes, Vice President for Medical Affairs at BioPort.³¹

There is some evidence that negative reactions to the vaccine are increasing. In a report released in October 2001, the General Accounting Office (GAO) reported that "reactions to the vaccine spiked dramatically since the early 1990s, when a new filter and fermenter were installed at the Lansing facility." The GAO reported in a 2000 study that 85% of reserve component soldiers had some reaction to the anthrax vaccine, including 24% with systemic reactions.³³

No vaccine is risk-free. Adverse event ratios from smallpox vaccine administration may serve as normative benchmarks because of the long-term and global experience with the vaccine. Encephalitis leading to permanent brain damage or death will result in 3 people out of every 1 million receiving the smallpox vaccine.³⁴ An additional 250 people out of 1 million will experience smallpox-like symptoms that may result in death.³⁵ Experts estimate that about 400 people would die from the smallpox vaccine if all Americans received the vaccine today.³⁶

EVIDENCE OF HARM FROM THE VACCINE

Although most symptoms associated with the anthrax vaccine are mild and temporary, rare cases of severe and lasting adverse health effects can occur. One such unfortunate case was publicized in front-page stories appearing in the Air Force Times³⁷ and the Army Times³⁸ in August, 2001. The articles, under the provocative title, "How the Anthrax Vaccine Ruined My Life," told the story of former airman Tom Colosimo. The airman began having trouble after receiving his fourth anthrax vaccination dose in 1999, and he has not recovered. His symptoms include delirium, loss of balance, panic attacks, loss of bowel control, low blood pressure, sleep apnea, depression, memory loss, chronic fatigue, and loss of intellect. Steroids he takes as therapy have rendered him impotent. He was admitted to Walter Reed Army Medical Center with a diagnosis of "anthrax intoxication." He received a medical retirement from the Air Force and now needs Social Security Disability payments to make ends meet. According to the articles, the Department of Defense (DoD) has admitted that Colosimo's illness resulted from

anthrax vaccine. The Air Force Times article was a multi-page spread with photos of Colosimo holding his cane, sleeping with a respiratory assist device, and showing facial wounds from his falls.

In one recent popular media report, an "infectious disease expert" (Dr. Meryl Nass) was quoted as saying that as many as 20 per cent of those receiving anthrax vaccine will develop chronic medical problems.³⁹ Although no data were presented to substantiate this alarming claim, this type of statement by a supposed authority serves to erode confidence in the AVIP.

QUALITY CONTROL ISSUES WITH VACCINE PRODUCTION

Although some progress has been made on the list of 30 quality control deficiencies noted in the 1999 FDA inspection, persistent problems continue to prevent FDA approval of the BioPort plant. A 2000 FDA inspection report cited numerous continuing problems with the plant. Dirty air was entering the filling area and employees were noted to touch nonsterile surfaces on their way in to sterile areas. The company had also mislabeled vials with inaccurate expiration dates.

The BioPort facility encountered great difficulty trying to maintain sterility in the decanting process. Workers carrying sterile vials into the filling room shed live microorganisms, causing a contamination threat for the vaccine. Eventually the BioPort facility gave up on decanting using its own equipment, and now ships all lots to another company in Spokane, Washington for decanting. Once filled, vials with vaccine are shipped back to Michigan.⁴¹

About 800,000 doses of anthrax vaccine remain stockpiled in BioPort's quarantined reserves. These have not been released for military use because of poor test results for product quality. BioPort "assembled an expert panel to figure out what went wrong." The status of these quarantined doses is uncertain now that the plant has obtained FDA approval to resume operations.

CRITICISM BY PUBLIC FIGURES

The AVIP has come under close scrutiny during multiple congressional hearings. Representative Walter Jones (R-NC) stated that the most recent slowdown of July, 2000 "... casts doubt on the stability and integrity of this already controversial program." Representative Chris Shays (R-CT), one of AVIP's most vocal critics, stated that the entire program is based on "a paucity of science."

Representative Shays held a series of highly publicized congressional hearings in 1999 and 2000. The House Government Reform Committee endorsed Shays' highly critical report in

March, 2000, suggesting that AVIP "be suspended and made voluntary until an improved vaccine can be developed," ⁴⁵ a process that could take 7 years. ⁴⁶

Lawrence Halloran, Staff Director for the House Government Reform Subcommittee on National Security, said that the anthrax vaccine is "inherently suspect," noting that BioPort's manufacturing process uses technology from the 1950s. ⁴⁷ Halloran explained the multi-year delays in obtaining FDA approval, commenting that "[getting] BioPort licensed is like trying to get an Edsel through a modern emissions inspection ... Science has moved well beyond that technology."

Public media accounts have also been sharply critical. Dr. Linda Rosenstock was interviewed in a story about the anthrax vaccine on the CBS Evening News October 26, 2001. She stated, "But certainly we do not yet have a vaccine that I think any of us in public health would say is safe and effective enough to warrant being used in a widespread way." Dr. Rosenstock is a leading national authority on public health issues. She is the Dean of the UCLA School of Public Health and former Director of the National Institute of Safety and Health.

RELEVANCE: PROBABILITY OF PROTECTIVE SPECIFICITY

Even if there were no public doubts about the efficacy, safety or quality of the vaccine, uncertainty would remain regarding the ability of anthrax vaccination to provide protection in the face of attack with biological weapons. Most vaccines are highly specific: they work by inducing the immune system to produce antibodies against a single pathogen. Acquired immunity against the anthrax bacillus will not provide protection against other agents, or even to the same degree against variant strains of anthrax. Ken Alibek, the highest-ranking defector from the Soviet bioweapons program, warned that they had developed 2,000 strains of anthrax.

Given that dozens of biologic agents have been weaponized,⁵⁰ it is quite possible that a future attack with biological weapons will involve other pathogens or toxins for which the anthrax vaccination will provide no protection. Indeed, the AVIP may provoke the unintended effect of preferential enemy use of non-anthrax bioweapons, given the protected status of U.S. forces. Similarly, a force well-protected against conventional anthrax may perversely cause acceleration of research into genetically engineered strains of anthrax that can defeat any protection offered by vaccination or that are resistant to antibiotics. Indeed, Russian scientists have already engineered a strain of anthrax that can evade vaccine-induced protection⁵¹ and other strains that are resistant to two of the three classes of antibiotics useful in treating anthrax infections.⁵²

These uncertainties about the potential probabilities of exposure to the natural strains of anthrax give rise to a familiar dilemma. Each year the influenza vaccine is prepared to protect against only a few strains of the flu, based on predictive models developed annually by the CDC&P.⁵³ This leads some to question whether any potential risks from the flu vaccine might outweigh the benefits of protection against only a few strains, when there are dozens of strains to which a person could conceivably be exposed during a given flu season.⁵⁴

LEGALITY OF THE POLICY

The issue of legality is explicitly addressed in the Question & Answer section of the official AVIP website:

"Is there a basis to challenge the legality of an order to a military member to receive anthrax immunizations? No. Medical treatment and immunizations determined reasonably necessary to accomplish a military mission or safeguard military members may be required of military personnel. The decision of the Secretary of Defense to approve the unanimous recommendation of the Chairman and members of the Joint Chiefs of staff to vaccinate all military personnel authorizes military commanders to issue orders to receive shots. Such an order is not in conflict with any law, including any requirement of the Food and Drug Administration. It is a lawful order that a military member has a duty to obey." 55

However, the issue is not a simple one. Connecticut Attorney General Richard Blumenthal recently called for cessation of the AVIP. He stated four reasons why he believes the AVIP is illegal:

"The anthrax vaccine has not been proved safe or effective for its intended use in that [it] has never been licensed for protection against inhalational anthrax. The vaccine is not being manufactured in accordance with either its site license or product license. The vaccine is not being administered according to the license. Since the vaccine has not been tested on humans, there is no basis for concluding that it is safe and effective." ⁵⁶

ETHICS OF BIOLOGIC INTERVENTION WITHOUT INFORMED CONSENT

Most medical ethicists would agree that mandating a medical treatment without the voluntary permission of the recipient violates the Nuremburg Code. This code of research ethics grew out of the Nuremburg trials of Nazi physicians because of their notorious human experiments in the concentration camps.⁵⁷ The Nuremburg Code requires informed consent before any intervention is conducted with a research subject. This concept of informed consent pervades all aspects of medical care, and is familiar to any person who has undergone surgery in the U.S. Hospital accrediting bodies require that physicians obtain informed consent in writing before invasive procedures are performed.

The ethics of informed consent is complicated in military service, however. Good order and discipline would break down if military subordinates were allowed informed consent in many situations. The official AVIP website explains the issue in this way:

"We expect Service Members to comply with administration of this vaccine as there is [sic] for any other vaccination required before deployment to a foreign country. It is comparable to an order to wear body armor during armed engagement, or to don a protective mask in a suspected chemical or biologically contaminated environment. Any Service Member who does not comply with these measures endangers their [sic] own health, and places both their [sic] unit and mission accomplishment at risk." 58

The courts have generally supported the government's position that interventions can be imposed on military members without their consent. President Clinton further strengthened the government's ability to avoid informed consent requirements with Executive Order 13139, signed November 1999.⁵⁹ This order, entitled "Improving Health Protection of Military Personnel Participating in Particular Military Operations," specifically negates informed consent requirements for experimental vaccines and investigational new drugs for military personnel.

SERVICE MEMBER RESISTANCE

EVIDENCE OF DISCONTENT

Opinion about the AVIP among service members has not been studied systematically. However, casual conversations with soldiers, sailors, and airmen reveal a very common perception that the anthrax vaccine may be dangerous. This perception is undoubtedly fueled by the many Internet sites devoted to criticism of the AVIP. 60,61,62,63 Critics of the program also point to internal DoD documents, such as a September 1998 memorandum signed by Secretary of the Army Louis Caldera stating that the anthrax vaccine "involves unusually hazardous risks associated with the potential for adverse reactions in some recipients."

Demonstrators protested the AVIP during rallies at the Michigan state capitol and at the BioPort facility as recently as November 11, 2001, drawing media attention.⁶⁵ Protesters stated that "... the military has not done enough to investigate the vaccine's long-term effects or whether it can be given safely with other vaccines."

There seems to be a perception that the military system will not provide adequate care or compensation if a service member is injured by the vaccine. Airman Tom Colosimo reported that Air Force officials would not transfer him for definitive medical care until his mother picketed an Air Force recruiting office, drawing media attention that he credits with his transfer from Hill AFB to Walter Reed Army Medical Center.⁶⁷ Colosimo states that he had to fight to get officials

at Walter Reed to issue him a cane and a helmet to protect him when he falls. He states that he could not get a military attorney to represent him during hearings on his disability determination, and had to get a private lawyer to take his case. He states that his medical retirement pay is insufficient for his needs and that his illness prevents him from getting a job.⁶⁸

REFUSALS, COURTS-MARTIAL PROCEEDINGS, PENALTIES

Although no official tally is ongoing,⁶⁹ estimates of service members refusing the anthrax vaccine have ranged from 200 to 600.⁷⁰ One source estimated that 500 military members have been discharged from the service or punished in some way for refusing to take the anthrax vaccine.⁷¹ Punishments reported in the media have included extra duty,⁷² reduction in rank,⁷³ 50% pay for two months,⁷⁴ incarceration ranging from 25⁷⁵ to 45⁷⁶ days, \$400 fine,⁷⁷ and discharges categorized as general, bad conduct, and other than honorable conditions.⁷⁸ The number of courts-martial trials is also unknown, but several such trials have received widespread publicity.^{79,80,81,82}

Similar patterns of refusals have been reported among allied military members. Canadian soldiers, also facing mandatory anthrax vaccination, have faced courts-martial rather than submit. 83,84 In the United Kingdom, where anthrax vaccine is offered on a voluntary basis, 73% refused. 85

HISTORICAL CONTEXT

Service member resistance to the anthrax vaccine cannot be understood without considering the history of government experimentation and public health policy misadventures that have contributed to public mistrust. Army Surgeon General LTG Ronald R. Blanck acknowledged the historical basis of "the undercurrent of distrust of the Government and the military" related to AVIP refusals. General Blanck concluded, "we have a credibility problem."

This section will review experiments with nuclear detonations, the use of Agent Orange in the Vietnam War, the swine flu vaccination program of 1976, and the pyridostigmine bromide (PB) policy in the Persian Gulf War. Because of its recency and relevance, the PB policy will be reviewed in greater detail.

NUCLEAR BLAST STUDIES

The Nevada Atomic Weapons Test Site was established in 1950 near Las Vegas in response to dissatisfaction with the long supply lines⁸⁸ and exposure to Russian observation⁸⁹

associated with nuclear weapons testing in the South Pacific. Atomic Energy Commission (AEC) workers at the Nevada site were limited to a cumulative maximum radiation exposure of 3 roentgens (r).⁹⁰

By 1951 all three military services requested permission from the AEC to allow participation of military personnel in atomic weapons tests at the Nevada site. The expressed purposes were to train troops in protective measures for atomic warfare, and to study the psychological effects of atomic explosions on soldiers.⁹¹ Approval of this request resulted in the construction of Camp Desert Rock at the Nevada Test Site.

The AEC initially established a maximum cumulative radiation exposure level of 3.9r for soldiers. However, some troops were no radiation badges during the events and poor records were maintained for the amount of time they stayed at ground zero, so actual radiation exposures were unknown. Under pressure from the military services, the AEC relegated establishment of maximum radiation exposure limits to military planners, who immediately raised the limits to 6r for ground troops 4 and 25r for Air Force pilots 5 who flew through mushroom clouds to take radiation measurements.

Soldiers participating in test detonations were positioned at successively shorter distances from ground zero: first 7 miles away, ⁹⁶ then 4 miles, ⁹⁷ then 2 miles ⁹⁸, and finally just over one mile from the blast. ⁹⁹ Soldiers were initially allowed to approach to within 500 yards of ground zero about an hour after the detonation, moving from prepared positions only after AEC safety monitors had surveyed the terrain closer to the blast site and certified it as safe to proceed. ¹⁰⁰ Later, troops advanced toward ground zero immediately after the blasts, with no AEC monitors to check radiation levels. ¹⁰¹ Although soldiers were generally provided the shelter of trenches during test blasts, there were occasions when troops were ordered to "hunker down in the open and wait" for explosions as close as 2 ½ miles away. ¹⁰²

An estimated 250,000 to 500,000 military and civilian personnel were intentionally exposed to radiation from 185 nuclear test explosions between 1946 and 1953, including numbers from both the Nevada Test site and the South Pacific. Although studies are still ongoing, preliminary data suggest that leukemia rates among 3,224 exposed soldiers present in Nevada at one 48kt blast in 1957 are about twice the expected incidence. During congressional hearings on the tests in 1978, officials from the Pentagon and the Energy Department were harshly criticized for laxity in radiation safety procedures, disappearance of medical records, and suppression of scientific research linking radiation exposure to increased cancer rates. In spite of these criticisms, veterans have not been successful in pursuing legal

remedies for compensation from the government for illnesses they feel were caused by radiation. Claims have been denied based on the Feres Doctrine which states that soldiers cannot sue the government for injuries received while on active duty. 107

AGENT ORANGE

In 1962 DoD began a defoliation program in Vietnam, designed to deny protective cover to the enemy. By 1971, approximately 4.5 million acres had been sprayed with several herbicides, including 11.2 million gallons of Agent Orange (AO). Dioxin was a main ingredient of AO, a substance so toxic that the FDA has called it "100,000 times more potent than thalidomide as a cause of birth defects..." However, those dealing with the chemicals in Vietnam were given "repeated assurances that the defoliants were harmless." Vietnam veterans exposed to AO have blamed the toxin for cancer, memory loss, skin rashes, and birth defects in their children.

Presented with thousands of AO-related claims, the Veteran's Administration (VA) responded that not enough was known about the effects of dioxin on human health to support such claims. This response added to the immense frustration of many Vietnam veterans who perceived disrespect not only from the American public, but also from their own government. Many expressed beliefs that the same government that had put them in harm's way seemed now to treat their health problems with skepticism and denial rather than the compassion, care, and compensation they felt entitled to. Many veterans felt they received a hostile reception when they sought AO-related care at VA hospitals, with physicians who gave cursory examinations and referred them for psychiatric care.

As with veterans of the nuclear weapons tests, Vietnam veterans were prohibited by the Feres Doctrine from seeking legal remedy from their government. Instead, many joined lawsuits against herbicide manufacturers. Although the total number of veterans exposed to AO is unknown, one class-action lawsuit in New York asked the court to certify all 2.8 million veterans who served in Vietnam as parties to the lawsuit. 115

SWINE FLU VACCINATIONS OF 1976: GUILLAIN BARRÉ EPIDEMIC

A swine flu outbreak at Fort Dix in February 1976 led experts at the Centers for Disease Control and the Department of Health, Education and Welfare to recommend a federal flu vaccination program for all Americans. A different strain of swine flu had killed about 20 million people in the 1918 pandemic; 116 authorities were determined to avoid a similar catastrophe.

Although private insurance companies refused to accept liability for a national program, the federal government agreed to accept liability. 117

The program started in October 1976, accelerating from an initial rate of less than one million vaccinations per week to more than six million per week by mid-November. Over 40 million people were vaccinated by mid-December 1976. The program was abruptly terminated in mid-December following reports from more than ten states of Guillain-Barré syndrome (GBS) among people receiving the vaccination. Guillain-Barré syndrome is a rare neurologic disease manifested primarily by muscle weakness. Mild cases may involve flaccidity of the arms and legs only; severe cases may result in loss of bowel and bladder control and inability to breathe without a mechanical respirator. Although most patients will recover spontaneously within 3-8 months, some suffer permanent weakness. 120

By January 1977, more than 500 cases of GBS were reported; among GBS patients there were 25 deaths. ¹²¹ To make matters worse, the entire vaccination program turned out to be unnecessary: not a single case of swine flu appeared after the limited outbreak at Fort Dix. ¹²² Lawsuits resulted on the scale of hundreds of millions of dollars. The entire policy misadventure became a major political disaster for President Gerald Ford who had personally approved the vaccination program.

Neustadt and May present the swine flu program of 1976 as a case study in bad decision making that led to a public policy disaster. They suggest that decision makers, when relying on historical precedents as analogues, make a conscious effort to identify and separate the *known* from the *unclear* from the *presumed*, while setting forth *likenesses* and *differences*. Neustadt suggest that a failure among the policy planners to be explicit about their presumptions may have contributed to a policy that caused harm when it was meant to help.

THE PYRIDOSTIGMINE BROMIDE POLICY IN THE PERSIAN GULF WAR

The DoD policy to use PB during the Persian Gulf War has several parallels with the anthrax vaccination policy. Controversies surrounding the PB policy and its highly-publicized possible connection with Gulf War Syndrome have helped create a milieu of mistrust for medical force protection measures. The PB policy required troops to ingest a drug of unknown efficacy without their consent, under conditions of widely varying compliance with protocol, to protect against a suspected threat that did not actually exist. Worst of all, the drug may be responsible for devastating long-term health effects and suffering. For these reasons, the PB policy will be reviewed in detail here. This section will explore factors that led to the policy and consider alternative policies that might have been effective without reliance on PB.

In 1990, U.S. Planners for the Persian Gulf War suspected that Iraqi forces might have weaponized the nerve agent soman. Iraq was known to possess chemical weapons including sarin and had demonstrated actual use of such weapons against Iran and the Iraqi Kurds. Although there was no evidence that the Iraqis possessed soman, this nerve agent was known to be in the chemical arsenal of the Soviet Union, and planners were concerned that Iraq may have obtained soman from the former Soviets. 126

As a result of these concerns and suspicions, the DoD decided to administer PB to troops as a pretreatment adjunct in case of exposure to soman. By the end of the war, an estimated 250,000 to 300,000 troops used PB. 127

The DoD PB policy was controversial for several reasons. First, no evidence has ever materialized to suggest that Iraq possessed or weaponized soman. Second, PB was not approved by the Food and Drug Administration (FDA) for use as a pretreatment adjunct for nerve agent exposure. Rather, for the intended military use the FDA classified PB as an investigational new drug which normally requires voluntary informed consent prior to administration to research subjects. Therefore, DoD sought and received from the FDA a waiver to the informed consent requirement. Third, although FDA stipulated a waiver-related condition that all PB recipients be informed about the drug and potential side effects, there is widespread evidence that this condition was violated. Fourth, there is also considerable evidence that FORSCOM directives regarding PB use were violated, yielding great variance in dosing, frequency, and duration of PB use. Fifth, although evidence from some animal studies did suggest a reduced soman lethality with PB pretreatment, the efficacy of PB in humans is unknown. Lastly, PB is now suspected as a causative factor in the chronic negative health effects associated with Gulf War Syndrome.

Assumptions Underlying Evolution of the PB Policy

In the months leading up to the Persian Gulf War, policy makers were forced to adopt assumptions in the face of numerous uncertainties. Given Saddam Hussein's ruthless use of chemical weapons against his own people in 1987 and 1988, 134 it seemed reasonable to assume that he would not hesitate to use these agents against U.S. forces gathering in the Gulf region. Available force protection measures against chemical and biological agents included detection and warning apparatus, protective masks and clothing, and medical management. Medical management for soman consisted of pretreatment with PB before exposure and the use of two antidotes after exposure: atropine and pralidoxime chloride (2-PAM).

Although PB was suggested for use against nerve agents in the mid-1950s it was not studied seriously until the early 1970s and an investigational new drug (IND) application was not filed with the FDA until 1984. Several animal-model studies in the 1980s and 1990s suggested that PB enhanced protection against lethality with subsequent soman exposure; however, only one of these studies involved primates (rhesus monkeys) and it remains unknown whether this effect is generalizable to humans. Furthermore, animal studies of the effects of PB on other nerve agents (sarin, cyclosarin, tabun, VX) are mixed, and some demonstrate a slight *reduction* in the efficacy of post-exposure antidote treatments. Based on this limited body of literature, DoD planners accepted two assumptions: 1) that PB would enhance protection against lethality of soman exposure in humans, and 2) that PB would not meaningfully reduce the efficacy of available post-exposure treatments for other nerve agents.

The FDA classifies a drug as IND or licensed in a use-specific context. Even though PB had been licensed by the FDA since 1955 for use in patients with myasthenia gravis (a disease affecting neuromuscular synaptic transmission) and to reverse the effects of certain anesthetic agents 141, FDA approval did not pertain to the use of PB for chemical warfare agents. Despite decades of animal research, the FDA continued to classify PB as an IND for nerve agent use because PB could not meet the FDA approval criteria of safety and effectiveness. Meeting these criteria would require ethically forbidden studies of PB and lethal nerve agents with human subjects.

Despite the lack of FDA approval, Pentagon planners during Desert Shield assumed PB would be safe for military use based on two observations. First, myasthenia gravis patients had safely used PB for decades at higher doses and longer durations than those planned for military use. Second, 25 well-controlled laboratory studies of PB administration without soman exposure in five different animal species (including human) suggested no safety concerns. 143

The IND classification was a critical issue for DoD planners because of the strict regulatory and procedural limitations placed on use of any drug in this category. These FDA regulations require supervision of investigators, record keeping, reporting, and obtaining written informed consent before the drug can be administered to any person.¹⁴⁴

Securing a Waiver from the FDA for PB

Among the several regulatory implications of IND classification, the informed consent requirement raised the most serious concern for DoD policy makers. Pentagon planners concluded that obtaining informed consent from military members was not feasible. 145 Inasmuch as the FDA did not have the authority to waive the informed consent requirement,

DoD had two options: to request that the FDA obtain such authority and grant the desired waiver, or to issue its own regulations in disregard of FDA rules, based on an argument that chemical warfare threats were never considered in the development of the Food, Drug and Cosmetic Act which gives statutory authority for FDA regulations. Choosing the first option, DoD requested the FDA to establish waiver authority on 30 October 1990. In response, the FDA published an Interim Rule 21 Dec 1990 that provided a waiver mechanism. DoD then requested a waiver of the informed consent requirement for PB (and for botulinum toxoid vaccine) which was granted 08 January 1991. 146

Language from the DoD request letter, dated 30 October 1990, over the signature of Dr. Enrique Mendez, Jr., Assistant Secretary of Defense for Health Affairs, illuminates some of the core issues which became the focus of later controversy.

Our planning for Desert Shield contingencies has convinced us that another circumstance should be recognized in the FDA regulation in which it would be consistent with the statute and ethically appropriate for medical professionals to "deem it not feasible" to obtain informed consent of the patient -- that circumstance being the existence of military combat exigencies, coupled with a determination that the use of the product is in the best interests of the individual. By "military combat exigencies," we mean military combat (actual or threatened) circumstances in which the health of the individual, the safety of other personnel and the accomplishment of the military mission require that a particular treatment be provided to a specified group of military personnel, without regard to what might be any individual's personal preference for no treatment or for some alternative treatment. [italics added] . . . If a soldier's life will be endangered by nerve gas, for example, it is not acceptable from a military standpoint to defer to whatever might be the soldier's personal preference concerning a preventive or therapeutic treatment that might save his life, avoid endangerment of the other personnel in his unit and accomplish the combat mission. Based on unalterable requirements of the military field commander, it is not an option to excuse a nonconsenting soldier from the military mission, nor would it be defensible militarily -or ethically -- to send the solider unprotected into danger. 147

Critics would later suggest that the argument presented by Dr. Mendez, subsequently embodied in the Interim Rule of 21 December 1990, violated the Nuremburg Code. 148,149

The FDA waiver was conditional: DoD was exempt from the informed consent requirement but there remained strict FDA requirements to inform PB recipients of the risks and benefits of ingestion, to keep records of who received the drug, how much, and when, ¹⁵⁰ and to provide long-term follow-up on personnel receiving the investigational drugs. ¹⁵¹ Events would later show that DoD did not have procedures or personnel in place to comply with these conditions.

Unintended Consequences of the PB Policy

Although many supported the Interim Rule, the FDA and DoD came under immediate and intense criticism. Complaints took the form of harsh letters to the FDA, articles in the bioethics literature and the popular press, and litigation in Federal Court. An unnamed Desert Shield soldier and his wife (John and Mary Doe) filed suit in the U.S. District Court for the District of Columbia, naming the Secretary of Defense and the Secretary of Health and Human Services as defendants, seeking an injunction to prevent administration of investigational drugs without voluntary and informed consent. The injunction was denied and the suit was dismissed by U.S. District Judge Stanley Harris on 31 January 1999, on the basis that use of investigational drugs was a military decision and not subject to review by the courts. The plaintiffs also lost a subsequent appeal to the U.S. Court of Appeals. 153

Actual administration of the PB policy differed appreciably from DoD and FDA intent.¹⁵⁴ FORSCOM published guidelines¹⁵⁵ governing the use and discontinuation of PB, and training of medical personnel to recognize and treat side effects, but adherence to these guidelines was quite variable.¹⁵⁶ Similarly, the FDA requirements for informing PB recipients, for record keeping, and for post-treatment follow-up were not met.¹⁵⁷ These failures to comply with conditions of the FDA waiver would serve to seriously erode public trust and to question the validity of the decision for the Interim Rule.

Even greater loss of public trust would follow from the chronic symptoms reported by many Persian Gulf War veterans and the widespread perception that DoD was not sympathetic to the veterans' health complaints. In the intense and ongoing investigations related to Gulf War Syndrome, PB would emerge as one of the primary suspects as a causative factor. Pre-war assumptions about the safety of PB would later be questioned, noting that the drug's physiologic function in patients with myasthenia gravis is very different from that in healthy subjects, and that all the controlled laboratory studies failed to account for the suspected interactions of PB with numerous factors encountered on the battlefield: pesticides, heat, vaccines, stress, insect repellents, etc. Furthermore, an expanding body of research is beginning to reveal that PB can induce *permanent* disruption of the normal physiologic regulation of acetylcholine, a neurotransmitter involved with pain, muscle action, mood, memory, and sleep: functions corresponding to chronic complaints of many veterans of the Persian Gulf War. 161

Alternatives to the PB Policy

What other options were available to DoD planners given the uncertainties of late 1990? Given the desired end to minimize battlefield casualties in the event of a chemical warfare

attack with soman, an analysis of available means and alternate ways might have yielded some policy or policies other than the controversial one to mandate the use of PB.

The medical management alternative severely restricted policy options. There was no known alternative drug to PB that would give the hypothesized protection against soman. Once the decision was made for medical management, the die was cast for PB.

Other options existed, however. Protective masks and protective clothing guard against a host of chemical and biological agents. Given the unknown nature of the threat, more reliance might have been placed on training with and using the protective gear. Similarly, more reliance might have been placed on chemical detection and alarm systems that would in theory give soldiers the time needed to don protective equipment. These force protection measures are highly dependent on means, however. Shortcomings were noted in the availability, durability, and suitability of personal and collective chemical warfare protection equipment. Whether sufficient quantities of equipment could have been manufactured and fielded between August 1990 and February 1991 is unknown.

The cold war policy of massive retaliation or mutually assured destruction was evidently effective in dissuading nuclear powers from using these weapons even though they were ready and technically prepared for use on short notice. Based on that experience, pentagon planners might have placed more reliance on deterrence using the threat of retaliation with weapons of mass destruction (WMD) in the event of WMD use by Iraq. Indeed, such threats were communicated; they have been suggested as a primary reason why Iraq did not use its chemical weapon arsenal during the Persian Gulf War. 163,164

Lastly, a focus on convincing the Iraqi leadership of the unacceptable political cost of using chemical weapons may have served as an adequate deterrent. Considerations such as possible post-war prosecution for war crimes, destroying the option of a negotiated settlement to the war, and damage to long-term aspirations to become the eventual leader of the Arab world may have convinced Saddam Hussein that the risk of using chemical weapons was greater than any potential benefit.¹⁶⁵

The policy decision to order involuntary use of PB in the Persian Gulf War was controversial and as it turned out, unnecessary. A closer examination of flawed assumptions, a weighing of relative risks, and a careful examination of policy alternatives might have led to greater reliance on different force protection measures that could have avoided the unexpected and negative consequences of the PB policy.

LESSONS LEARNED FROM PAST POLICY MISADVENTURES

The first lesson learned from history is that hindsight is always better than foresight. That said, the challenge of strategic leadership is to glean lessons from the past and understand which lessons have relevance to present and future circumstances.

Perhaps the strongest message that emerges from the foregoing examples is that humility is better than hubris when dealing with issues of human health. The current body of knowledge in science and medicine is miniscule compared to the body of ignorance in those disciplines. Certainly there has been an explosion of understanding in medical and scientific fields during the past 150 years. However, the consistent experience among scientists and physicians who attain expert status in their fields is a gradual comprehension that the unknown is vastly greater than the known. This reality suggests caution when implementing interventions that can impact health.

One principle suggesting caution is that helpful intent does not guarantee helpful outcome. Indeed, because so much of human physiology is yet to be discovered, we have seen repeated examples of helpful intent resulting in great harm. That people intuitively understand this phenomenon is reflected in the saying, "the cure was worse than the disease."

Another message from human physiology is its great variability in large populations. A substance that is harmless to one individual may be fatal to another. We are not all the same.

The inevitability of unintended harm is another clear lesson to draw from the cited health policy misadventures. Strategic leaders must plan for casualties, even with interventions intended solely as health protection measures.

Finally, we must admit that a pattern of defensive bureaucratic behavior is evident from an examination of past health policy mistakes. Human nature is such that we filter out perceptions that don't fit well in our paradigms. We dismiss data that don't confirm our hypotheses. There is a tendency toward cover-ups when mistakes occur in large bureaucracies. There is an unfortunate pattern of blaming the victim when errors first begin to be revealed. Strategic leaders must recognize and protect against the innate aggressive bureaucratic tendency to justify policy at all costs. Victims must be treated fairly and compassionately in order to protect institutional integrity.

POSSIBLE FUTURE ACTIONS RELATIVE TO THE AVIP

The ongoing public controversy related to the AVIP, considered in the context of "the undercurrent of distrust" mentioned by LTC Blanck, 166 suggests a need for reconsideration of the AVIP policy. Several possible policy changes are presented below.

STATUS QUO: CONTINUATION

Continuing the AVIP as currently configured is certainly an option. Just when full implementation may resume is yet to be determined. Although FDA approval of the Bioport facility has opened the door to restore full implementation of the AVIP, the program remains limited for now. It is possible that heightened awareness of the anthrax threat due to cases of anthrax infections in the Fall of 2001 will reduce service member resistance to the AVIP.

APPLICATION ONLY FOR THOSE AT HIGH-RISK FOR ANTHRAX EXPOSURE

Given that the anthrax vaccine has acknowledged and inherent health risks, consideration should be given to restricting implementation only to those deemed to need it most when vaccine production resumes. Because of the anthrax exposures following the terrorist attacks of September 11, 2001, a redefinition of at-risk groups is needed. For example, many now believe that postal workers are at greater risk than most military members. Perhaps a policy of mandating vaccination only for those military members deploying to areas considered high risk, and offering vaccine on a voluntary basis to postal and government workers would better address current realities.

AGGRESSIVE PUBLIC RELATIONS & EDUCATION PROGRAM

The Office of the Secretary of Defense (OSD) has an impressive website with thoroughly researched and annotated information on all aspects of the AVIP. No one knows, however, what proportion of vaccine recipients have viewed the website. A more aggressive form of mass education, in the form of brochures, mailings, and "town meetings" may be needed to address fears and answer questions.

Most of the controversial issues generating reluctance among service members are addressed in the "Q&A" section of the OSD website. However, the site maintains a professional tone and avoids direct confrontation with the many prominent detractors of the program. This puts DoD at a disadvantage: AVIP detractors have no such qualms about being very direct and very confrontational. For example, Dr. Meryl Nass in her anti-AVIP website¹⁶⁸ presents point-by-point counter arguments to statements by DoD officials under such sections as "Commentary on Army Surgeon General Blanck's Op-Ed" and "LTC Randolph Puts His Spin on the News." Similarly, the National Gulf War Resource Center (NGWRC) presents uniformly negative news and perspectives on the AVIP in a section titled "Learn about the Anthrax Vaccine Immunization Program" in its website. Steve Robinson, spokesman for NGWRC, is able to speak to the media without challenge when he says, "Something is wrong with the vaccine. You don't have to be a scientist to figure it out…" 170

These Internet sites and media exposures are extremely powerful tools for AVIP's critics. Today's young service members are tightly connected to such sources of information, and are highly influenced by them. In keeping with the philosophy that the best defense is a good offense, DoD could take a more aggressive posture in answering and challenging its critics. For example, the OSD AVIP website could include a section entitled, "Open Letters to Critics," and respond point-by-point to comments and writings by such prominent detractors as Congressman Shays, Dr. Rosenstock, Dr. Nass, Attorney General Blumenthal, and Mr. Robinson. Such direct responses would inspire more confidence in service members than the current approach that is professional but seems somewhat aloof.

DAMAGE CONTROL: CARING FOR THOSE HARMED

One of the most damaging public relations failures is the perception that the military bureaucracy will respond with stonewalling and hassles rather than compassionate care when adverse events occur. It is extremely unfortunate that Airman Colosimo's complaints¹⁷¹ about the difficulty in procuring medical care, equipment, and compensation resemble so closely the complaints of earlier veterans involved with nuclear blast studies, Agent Orange, and Gulf War Syndrome. It is only natural for today's service members to read Colosimo's account in the Army Times and Air Force Times and conclude that an adverse event from the vaccine may result in abandonment by the military. This perception can only be reversed by an aggressive policy of hassle-free world-class care for those few individuals who will be injured by the vaccine. A special risk management team should be created at the DoD level to respond quickly with maximum support and maximum care for future cases of severe adverse events. If service members like Colosimo perceive that the military will make every possible effort to provide support and adequate compensation in the case of injury, DoD will have nothing to fear from the inevitable media coverage of these cases.

POSTPONEMENT PENDING FURTHER RESEARCH AND CONSULTATION

The current near-curtailment of the AVIP imposed on DoD by the shortage of vaccine offers a natural opportunity to revisit some of the issues of controversy surrounding the program. Even though the FDA has re-licensed the production of anthrax vaccine, DoD has not yet resumed full implementation of the AVIP. According to a recent press release, DoD is "undertaking a thorough review of all factors to decide its future use of the vaccine." A public symposium could be organized to allow proponents and critics of the program to come together and air differences of opinion. A neutral third party panel could serve to arbitrate the symposium. The available scientific evidence for and against vaccine efficacy and safety could

be reviewed once again, in light of the ongoing criticisms by prominent public health authorities. If the critics are satisfied by such dialogue, DoD could resume full implementation of the AVIP once vaccine is again available, having regained the advantage in public relations. On the other hand, if DoD officials feel that greater caution is warranted after such reviews and communications, the program could continue postponement until additional safety and efficacy research is completed, or until a newer vaccine is developed that puts questions of safety and efficacy to rest.

CONCLUSION AND RECOMMENDATIONS

The historic pattern of policy misadventures related to well-intended health protection measures has produced a climate of mistrust and skepticism. The current AVIP has suffered from phenomenally negative publicity, resulting in significant distrust and reluctance among military members. Criticism has come not only from Internet conspiracy theorists, but from prominent figures in government, in academia, and in the popular media.

Supply problems with the anthrax vaccine due to quality control deficiencies at the production plant have led to unintended delays in execution of the AVIP. The current pause in program execution offers a natural opportunity to reassess the AVIP and deal with the many controversial issues addressed in this paper. Only by dealing with the controversies openly and publicly, and by directly satisfying the concerns raised by the AVIP's vocal critics, can DoD allay the mistrust and skepticism now prevalent.

Although DoD is capable of resuming full implementation of the AVIP now that vaccine production has resumed, it would be a mistake to do so. Too many issues remain unresolved in public perception. An immediate redefinition of those most at risk is needed. Implementation of the AVIP should remain at the current limited level until the safety and efficacy issues are resolved. If those issues cannot be satisfactorily resolved in the public forums suggested above, the AVIP should be completely curtailed until a new vaccine can be developed.

Regardless of the timing and nature of the AVIP resumption, DoD must do a better job in educating service members and directly answering the policy's critics. We must also create a comprehensive and aggressive program to assist unintended victims of the anthrax vaccine, for those rare instances when severe adverse effects occur. We owe our service members nothing less.

WORD COUNT = 8,664

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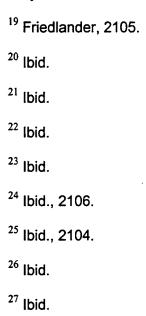
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