



## **"Anthrax immunization program: It's time for a transformation"**



**By Russell E. Dingle and  
Thomas L. Rempfer  
Special to the Air Force Times, 11 FEB 02**

**President Bush, Defense Secretary Donald Rumsfeld and Air Force Chief of Staff Gen. John Jumper - We're all present and accounted for sirs, for our debriefing on the Defense Department Anthrax Vaccine Immunization Program.**

**Let's recap the previous anthrax-vaccine mission that predates your current positions:**

- \*\* The Army funded the development of the anthrax vaccine, owns its patent, conducted all the research and is the sole customer. A review of the Army's anthrax vaccine reveals an improper license, illegal manufacturing alterations, illegal mandatory experimental use and violations of government procurement regulations.**
- \*\* A 1985 Food and Drug Administration review confirmed the anthrax-vaccine license was granted using data from a different vaccine, contrary to the law, but proposed to continue the license based on its extremely limited use. The review also revealed the vaccine "has not been employed in a controlled field trial."**
- \*\* The FDA review of the vaccine documented there has been "no meaningful assessment of its value against inhalation anthrax." In both 1985 and 1995, the Army attempted to develop a new anthrax vaccine, but abandoned this effort in 1996.**
- \*\* Inspections of the manufacturer began in 1993, garnering an FDA warning letter in 1995, a notice of intent to revoke the license in 1997 and a shutdown in 1998, the same year mandatory DoD inoculations began. For four years, the manufacturer failed additional inspections, while 500,000 service members were given more than 2 million doses.**
- \*\* The Congress, the General Accounting Office, a state attorney general and the Institute of Medicine have admonished the vaccine manufacturer, the FDA and DoD for lack of scientific data, abuse of regulatory discretion and their "illegal conduct" with the vaccine.**
- \*\* Most recently, GAO testified about unapproved adulterating manufacturing changes in the vaccine's production, the Navy reported birth defects possibly caused by the vaccine and independent studies revealed a connection to Persian Gulf War illnesses.**
- \*\* Contrary to Defense Department rhetoric, the facts have revealed improper 1970 licensure; unapproved 1990 alterations; contracts with a deviant manufacturer in violation of FDA guidelines; and willful circumvention of the law, executive order and DoD directives due to the mandatory "experimental" use of the vaccine for inhalation anthrax.**

**Gen. Jumper, your resources in the Air Force reserve components have been significantly affected, with 300 pilots and aircrew members lost due to resignations in lieu of forced vaccinations.**

**Secretary Rumsfeld, your undersecretaries reviewed the anthrax vaccine program and recommended "minimum" use of the vaccine for experiments and special bioterrorism response teams only. Their recommendations encourage the development of a future "coherent institutional process" in responding to biological warfare threats, while procuring bio-detectors, antibiotics and a modern "national long-range vaccine" for use by citizens and service members.**

**President Bush, you have the lead. The anthrax-vaccine manufacturing process remained "not validated" for four years after the immunization program began. The government is trying to methodically fix everything that's been uncovered.**

**Contrary to federal regulations, manufacturing changes were approved 10 years after implementation. It appears safety and efficacy data missing for the original vaccine - and the altered version - are being collected in the current "experimental" postal worker vaccination study, among others.**

**Mr. President, you must decide if the assessment of the former chairman of the Joint Chiefs of Staff - that the anthrax vaccine is the "centerpiece" of biological defense - is correct. Does a vaccine documented by DoD as "not licensed for aerosol exposure expected in a biological warfare environment," originating from a plant that remained closed for quality-control problems for the life of the program, fit this description? You must decide whether the rule of law is followed.**

**Mr. President, in your State of the Union address you said, "We will develop vaccines to fight anthrax." We commend your courage.**

**We look forward to a complete "transformation" on this issue: Exonerate the punished troops, rescind the dishonorable discharges and expunge the felony convictions. It's the right thing to do.**

***[The authors are USAF Reserve majors who live in Connecticut. In 1998, they were members of Connecticut Air National Guard investigative team that helped identify the legal and ethical issues surrounding the anthrax vaccine. Their views do not reflect the official position of the Department of Defense or the Air Force.]***