

Military split over anthrax shots

Point: Suspend, Review Program

By Thomas L. Rempfer and Russell E. Dingle

Baltimore Sun

January 30, 2000

America's military members remain troubled by mixed messages concerning the anthrax vaccine's safety two years after the Department of Defense announced the policy. The department's claims heralding its safety are inconsistent with statements by department personnel, medical literature, congressional oversight and Food and Drug Administration inspections.

For example, Army Surgeon General Ronald Blanck stated in 1994 that the "anthrax vaccine should continue to be considered as a potential cause for undiagnosed illnesses in Persian Gulf military personnel."

Additionally, Col. Arthur Friedlander, a chief Army biological researcher, reviewed the anthrax inoculation in the textbook, "Vaccines." He concluded: "The current vaccine against anthrax is unsatisfactory . . . composed of an undefined crude culture . . . and the presence of constituents that may be undesirable may account for the level of reactogenicity [reactions] observed." New public admissions by the Defense Department agree, noting up to 35 percent reaction rates and twice the incidence for women.

Despite these criticisms, the Pentagon initiated mass inoculations. A gynecologist from Yale, untrained in biological warfare, was selected as the "independent expert" mandated by Defense Secretary William S. Cohen to review the proposed immunizations. Not surprisingly, the doctor later explained to Congress that he had "no expertise in anthrax." Regardless, the Pentagon continues to use this gynecologist's February 1998 recommendations to justify the program.

The Food and Drug Administration inspected and refused to validate the vaccine's manufacturing process one day after the Pentagon accepted its expert's review. They found 53 deviations, substantiating a 1997 FDA threat to revoke the manufacturer's license. Recent General Accounting Office (GAO) testimony concurred, summarizing that the FDA's inspections of the facility found deficiencies that could "compromise the safety and efficacy of any or all batches."

Concurrently, vaccine production was halted while the Defense Department spent millions of dollars rebuilding the vaccine plant in hopes of obtaining a renewed FDA approval for the old licensed production methods. The FDA reinspected the facility in November, found 30 problems, and again failed to validate the manufacturing process. The plant will remain closed while attempting to correct sterility and potency problems at taxpayers' expense.

In spite of the vaccine's approval problems, the Department of Defense continues to order mandatory inoculations with stockpiles produced by the same flawed manufacturing process unearthed by the FDA. The GAO also reported that the "long-term safety of the vaccine has not yet been studied." Furthermore, congressional representatives recently warned the FDA that widespread use of this vaccine to protect the military against the biological weapon anthrax was never approved and should be optional. As a result, many service members have chosen to refuse this suspect vaccine, resulting in court-martial, dishonorable discharge and imprisonment.

Congress has mandated an unbiased safety investigation, but commanders continue to face the untenable burden of enforcing the contentious policy or sacrificing their careers. This environment only exacerbates the Pentagon's recruiting and retention dilemma. Protecting our armed forces from unnecessary risks includes protecting the troops from unsafe military medical policies that are shaky under established medical and legal standards. The troops deserve better than expedient and misguided protection efforts, promoted through the hyping of threats and the cliché of "good order and discipline." It would be irresponsible not to suspend this program immediately pending the unbiased review.

(Thomas L. Rempfer and Russell E. Dingle were pilots in a Connecticut Air National Guard team directed to research and develop questions concerning the anthrax vaccine for the chain of command. Months later, the officers were forced to transfer to nonflying assignments after refusing to be inoculated based on the findings of their research.)