



THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

OCT 19 2004

HEALTH AFFAIRS

Mr Lester Holt  
MSNBC News

Dear Mr Holt,

A number of inaccuracies have appeared recently in news reports concerning the anthrax vaccine and squalene. Four separate and independent civilian panels have investigated claims of squalene in the anthrax vaccine administered to our service members. All found the allegations without merit. Moreover, we have conducted no experiments with anthrax vaccine, as have been alleged, at Dover Air Force Base. Further, we do not, nor does anyone else, add squalene to anthrax vaccine.

Squalene is present naturally in the bloodstream of healthy people at levels in the range of 250 parts per billion. In a study report, Aug 14, 2001, one of thirty lots of anthrax vaccine tested contained measurable levels of squalene. Three samples from that lot contained squalene at 9, 7, and approximately 1 parts per billion, respectively. Use of vaccine from that lot has not been associated with elevated rates of adverse events. The Food and Drug Administration told the U.S. Congress in Oct 2000 that any trace quantities of squalene detected in lab tests should be considered "naturally occurring and safe."

To increase immune responses, as claimed in the articles, squalene would have to be present at a concentration about one million times higher than found in lab tests; the concentration would be 30 million parts per billion. Also, it would have to be in combination with other chemicals in a form called an emulsion. The Anthrax Vaccine Expert Committee (AVEC), a panel of civilian physicians and scientists, reviewed all adverse events reported after anthrax vaccination. The committee found no meaningful differences based on vaccine lot or on geographical location of the person vaccinated.

Importantly, the National Academy of Sciences' Institute of Medicine in 2002 conducted a comprehensive review of anthrax safety and effectiveness. Personnel from Dover Air Force Base contributed to the information gathered for their review. This prestigious group of independent experts concluded that trace amounts of squalene are not associated with an increase in the rates of adverse events following vaccination, and that further investigation of possible contamination is not warranted.

We understand some individuals prefer not to take vaccinations, but their numbers today in the military are extremely small. In the military, force health protection measures are necessary to ensure the entire unit's health and ability to function at all times, particularly when the unit's mission is vitally important to the national security of our nation. We have a safe and effective anthrax vaccine to protect our forces. A program to protect service members with anything but a safe and effective vaccine would not be responsible.

Sincerely,

A handwritten signature in black ink that reads "William Winkenwerder, Jr." with a stylized flourish at the end.

William Winkenwerder, Jr., MD, MBA