

BLUMENTHAL TO OPPOSE USE OF ANTHRAX VACCINE

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THOMAS D. WILLIAMS

Two former Connecticut Air National Guard pilots have convinced the state's attorney general to challenge the U.S. military's use of the anthrax vaccine because federal documents say it has never been licensed for its present use.

Attorney General Richard Blumenthal said he will present evidence produced by the two pilots to the U.S. Food and Drug Administration to try to convince the agency the vaccine isn't properly licensed. Blumenthal said he believes the irregular use of the vaccine could make Connecticut legally responsible for those who get sick from the vaccine.

It was initially federally licensed in 1970 for use by veterinarians and wool workers who touched diseased animals. The U.S. Department of Defense plans to inoculate 2.4 million armed services personnel with the vaccine to protect them from potential airborne anthrax spores used by enemy states or terrorists. The inoculations began in 1998, but in July, vaccine supplies dwindled so drastically that only those assigned to Southeast Asia are still being vaccinated.

The two Connecticut pilots, Russ Dingle and Thomas Rempfer, now Air Force Reserve majors, have also supplied Blumenthal with federal documents indicating the vaccine is inappropriate for mass inoculations because it has not been proven to be safe or effective.

Since they resigned from the Guard in January 1999 in protest over the Guard's refusal to accept their findings about the vaccine, Dingle and Rempfer have been among a dozen leaders in a national protest effort to stop the use of the vaccine.

"These documents raise profoundly serious and significant questions as to the legality of the FDA licenses, and hence the use of the vaccine," said Blumenthal. "There seems to be important flaws in licenses relating to both the product and the equipment, and these issues have never been directly addressed by the Department of Defense or the FDA."

But James C. Turner, a Defense Department spokesman, said the agency is abiding by all FDA regulations and has done the necessary animal tests to show the vaccine is safe and effective.

Lenore Gelb, an FDA spokeswoman, said: "The FDA believes that the anthrax vaccine is safe and effective protection for those individuals at high risk for exposure to [airborne anthrax spores] when used in accordance with the label. The FDA does not have legal authority to force companies to apply for new indications [uses] or to do the studies necessary to change the labeling."

However, Dingle and Rempfer recently produced a variety of military and congressional documents that show:

* U.S. Army high-level planning in 1995 to renew use of the anthrax vaccine mentioned that the vaccine needed to have a new license if it was

to protect troops against aerosol anthrax bacteria. "This vaccine is not licensed for aerosol exposure expected in a biological warfare environment," says the document prepared for the Army and sent to the manufacturer.

* And the Defense Department told a U.S. Senate committee investigating chemical and biological weapons in 1989 that the anthrax vaccine, being used today, was too risky to be safe, was not proven effective and thus was inappropriate for large scale troop inoculations.

"Current vaccines, particularly the anthrax vaccine, do not readily lend themselves to use in mass troop immunization" because they create a high level of adverse reactions and have not been proven effective, said former Assistant Secretary of Defense Robert B. Barker in a written response to Congress in 1989. "These responses [and others] clearly should have sounded very loud alarms before any of the vaccine was applied, let alone required," said Blumenthal. "They are very compelling evidence of the need to revisit and reform this entire program."

U.S. Rep. Christopher Shays, R-4th District, whose congressional subcommittee has recommended that anthrax vaccine use be shut down, said: "The subcommittee has believed since the beginning of its investigation that the Defense Department and the manufacturer should get a new license. U.S. forces should only be given a modern, well- tested vaccine explicitly approved for the purpose of providing protection against biological weapons. Throwing 1950s medical technology at a 21st-century problem won't work, and the slow collapse of the mandatory inoculation program proves it."

Blumenthal has asked state Adjutant General William A. Cugno to reinstate Rempfer, Dingle and six other pilots who resigned in protest over the vaccine almost two years ago.

Blumenthal said, "Apart from the issue of fairness to them, there is the need for their talents and skills, as well as their dedication." Rempfer praised Blumenthal for his work on the pilots' behalf. "I'm proud of Connecticut's leaders who continue to demonstrate the courage to protect the troops that protect our nation by demanding our forces get safe and effective protection, not quick fixes."