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THE DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM: UNPROVEN FORCE PROTECTION

FOURTH REPORT

BY THE

COMMITTEE ON GOVERNMENT REFORM

together with

DISSENTING AND SUPPLEMENTAL VIEWS

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Findings in Brief

1. The AVIP is a well-intentioned but over-broad response to the anthrax threat. It represents a doctrinal departure overemphasizing the role of medical intervention in force protection.

2. The AVIP is vulnerable to supply shortages and price increases. The sole-source procurement of a vaccine that requires a dedicated production facility leaves DOD captive to old technology and a single, untested company. Research and development on a second-generation, recombinant vaccine would allow others to compete.

3. The AVIP is logistically too complex to succeed. Adherence to the rigid schedule of six inoculations over 18 months for 2.4 million members of a mobile force is unlikely, particularly in reserve components. Using an artificial standard that counts only shots more than 30 days overdue, DOD tolerates serious deviations from the Food and Drug Administration [FDA] approved schedule.

4. Safety of the vaccine is not being monitored adequately. The program is predisposed to ignore or understate potential safety problems due to reliance on a passive adverse event surveillance system and DOD institutional resistance to associating health effects with the vaccine.

5. Efficacy of the vaccine against biological warfare is uncertain. The vaccine was approved for protection against cutaneous (under the skin) infection in an occupational setting, not for use as mass protection against weaponized, aerosolized anthrax.

Recommendations in Brief

1. The force-wide, mandatory AVIP should be suspended until DOD obtains approval for use of an improved vaccine. To accomplish this:

2. DOD should accelerate research and testing on a second-generation, recombinant anthrax vaccine; and,

3. DOD should pursue testing of the safety and efficacy of a shorter anthrax inoculation regimen; and,

4. DOD should enroll all anthrax vaccine recipients in a comprehensive clinical evaluation and treatment program for long term study.

5. While an improved vaccine is being developed, use of the current anthrax vaccine for force protection against biological warfare should be considered experimental and undertaken only pursuant to FDA regulations governing investigational testing for a new indication.

II. BACKGROUND

THE PROGRAM

On December 15, 1997, after what DOD described as "a detailed, deliberative process" spanning almost 4 years,[4] Secretary of Defense William S. Cohen announced a program to immunize all active duty personnel against anthrax, a bacterial disease that in

[4] *Anthrax Immunization Program,* 106th Cong., 1st sess., p. 8 (1999) (Subcommittee on National Security, Veterans Affairs, and International Relations hearing of Mar. 24, 1999, No. 106–17) [hereinafter "NSVAIR anthrax hearing (I)"] (prepared statement of Dr. Sue Bailey).