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106TH CONGRESS
1ST SESSION

H. R. 2548

To suspend further implementation of the Department of Defense anthrax vaccination program until the vaccine is determined to be safe and effective and to provide for a study by the National Institutes of Health of that vaccine.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 1999

Mr. GILMAN (for himself, Mrs. KELLY, and Mr. FILNER) introduced the following bill; which was referred to the Committee on Armed Services, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To suspend further implementation of the Department of Defense anthrax vaccination program until the vaccine is determined to be safe and effective and to provide for a study by the National Institutes of Health of that vaccine.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Department of Defense Anthrax Vaccination Moratorium Act''.

SEC. 2. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) a single force protection measure such as the mandatory anthrax vaccine immunization program should not be implemented by the Department of Defense without regard for that measure's own effects on morale, retention, recruiting, and budget; and

(2) an insufficiently proven vaccine should not be advocated as a substitute for research, development, and production of truly effective vaccines and essential antibiotics, adequate personal protective equipment, detection devices, and nonproliferation measures.

SEC. 3. MORATORIUM OF VACCINATION PROGRAM.

The Secretary of Defense shall suspend implementation of the anthrax vaccination program of the Department of Defense. After the date of the enactment of this Act, no further vaccination may be administered under the program to any member of the Armed Forces except in accordance with this Act.

SEC. 4. STUDY BY NATIONAL INSTITUTES OF HEALTH.

(a) STUDY.—

(1) IN GENERAL.—The Director of the National Institutes of Health shall require the appropriate national research institute to conduct or oversee an

independent study of the effectiveness and safety of the vaccine used in the Department of Defense anthrax vaccination program.

(2) MATTERS TO BE STUDIED.—The Director shall include in the study under paragraph (1) determination of the following with respect to that vaccine:

(A) Types and severity of adverse reactions.

(B) Long-term health implications, including interactions with other (existing and planned) vaccines and medications.

(C) Efficacy of the anthrax vaccine for protecting humans against all the strains of anthrax pathogens members of the Armed Forces are likely to encounter.

(D) Correlation of animal models to safety and effectiveness in humans.

(E) Validation of the manufacturing process focusing on, but not limited to, discrepancies identified by the Food and Drug Administration in February 1998 (especially with respect to the filter used in the harvest of anthrax vaccine, storage times, and exposure to room temperature).

(F) Definition of vaccine components in terms of the protective antigen and other bacterial products and constituents.

(G) Such other matters as are in the judgment of the Director required in order for the Director to make the determinations required by subsection (b).

(3) LIMITATION.—The Director may not use for purposes of the study any data arising from the experience of inoculating members of the Armed Forces with the vaccine studied because of the lack of informed consent and inadequate recordkeeping associated with such inoculations.

(b) REPORT.—Upon completion of the study, the Director of the National Institutes of Health shall submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate and to the Secretary of Defense a report setting forth the results of the study. The report shall include the Director's determination, based upon the results of the study, as to each of the following:

(1) Whether or not the vaccine used in the Department of Defense anthrax vaccination program has an unacceptably high systemic reaction rate.

(2) Whether or not the vaccine is effective with respect to noncutaneous transfer of anthrax.

(3) Whether or not the vaccine will be produced in a manner acceptable to the Food and Drug Administration.

SEC. 5. GENERAL ACCOUNTING OFFICE STUDY.

(a) IN GENERAL.—The Comptroller General shall conduct a study of the inoculation program referred to in section 3 and of the effect of the use of contractor-operated facilities for that program. As part of the study, the Comptroller General shall study the following with respect to the inoculation program:

(1) Effects on military morale, retention, and recruiting.

(2) Civilian costs and burdens associated with lack of military medical care and loss of civilian sick leave and work capacity for members of the reserve components who experience adverse reactions while not in military status.

(3) A system of accurately recording medical conditions of members of the Armed Forces and other patients before and after inoculation, including off-duty reactions and treatment of reserve component members and including screening for allergens

and contraindications, to include prior adverse reactions.

(b) PUBLIC COMMENT.—The Comptroller General shall publish the study under subsection (a) for public comment.

(b) GAO REVIEW.—The Comptroller General shall review the Secretary's written report and provide comments to Congress within 75 days after the Secretary files the report.

SEC. 6. BOARDS FOR CORRECTION OF MILITARY RECORDS.

The Secretary of Defense shall direct that the respective Boards for Correction of Military Records of the military departments shall, upon request by individual members or former members of the Armed Forces, expedite consideration of applications for remedies for adverse personnel actions (both voluntary and involuntary) that were a result of the mandatory anthrax vaccine immunization program, to including rescission of court-martial convictions, rescission of administrative discharges and separations, rescission of retirements and transfers, restoration of flying status, back pay and allowances, expunging of negative performance appraisal comments or ratings, and granting of physical disability certificates.

SEC. 7. CONTINGENT RESUMPTION OF VACCINATION PROGRAM.

(a) CONTINGENT AUTHORITY FOR RESUMPTION.—If the Director of the National Institutes of Health determines in the report under section 3(b) that the vaccine used in the anthrax vaccination program of the Department of Defense meets each of the criteria stated in subsection (b), the Secretary of Defense may resume the Department of Defense anthrax vaccination program. Any such resumption may not begin until the end of the 90-day period beginning on the date of the submission of the report under section 3(b).

(b) CRITERIA FOR PROGRAM RESUMPTION.—The criteria referred to in subsection (a) are the following:

(1) That the vaccine used in the Department of Defense anthrax vaccination program does not have an unacceptably high systemic reaction rate.

(2) That the vaccine is effective with respect to noncutaneous transfer of anthrax.

(3) That the vaccine will be produced in a manner acceptable to the Food and Drug Administration.

(c) REQUIREMENT FOR USE OF NEW VACCINE.—If the anthrax vaccination program is resumed under subsection (a), the Secretary of Defense may only use newly

produced vaccine for vaccinations after the resumption of the program.

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