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IS MILITARY RESEARCH HAZARDOUS TO VETERANS' HEALTH? LESSONS SPANNING HALF A CENTURY

A STAFF REPORT PREPARED FOR THE

COMMITTEE ON VETERANS' AFFAIRS

UNITED STATES SENATE

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Moss' research, but would ensure that the data were provided to DOD.[137]

Although Dr. Moss made no accusations against USDA at the Committee hearing, he has subsequently expressed his views that he lost his job at USDA because of his research findings. He also now reports that his supervisor warned him that he should not discuss his research findings with anyone. Moreover, in an internal USDA memo dated December 30, 1993, Dr. Moss stated that he was advised to "keep quiet."[138] USDA and the Johnson Wax Company are the co-inventors of DEET, an ingredient in most commercially available insecticides, such as Raid.

H. THE SAFETY OF THE BOTULISM VACCINE WAS NOT ESTABLISHED PRIOR TO THE PERSIAN GULF WAR AND REMAINS UNCERTAIN.

At a meeting with DOD officials regarding informed consent in December 1990, the FDA agreed to test the botulinum toxoid (botulism vaccine) for safety.[139] A representative of FDA's Center for Biologics Evaluation and Research explained that the existing supply of the vaccine was nearly 20 years old and consisted of three lots, stored under constant refrigeration. There was concern that the vaccine would break down into toxic products due to prolonged storage. General safety testing was performed by the FDA on all of the lots of botulinum toxoid used in the Persian Gulf; however, the FDA did not complete these tests until January 24, 1991,[140] after the war had started.

While the results of FDA's general safety testing were encouraging, the problem with adverse reactions to the vaccine were not resolved. In her review of the DOD's application for use of the botulism vaccine in the Persian Gulf, an FDA reviewer pointed out that in 1973, the Centers for Disease Control had considered terminating its distribution because of adverse reactions.[141] New lots of the vaccine were manufactured in 1971, but research was not conducted to determine whether the newer lots produced fewer adverse reactions than the older lots.[142]

Since no records were kept for most of the Gulf War soldiers who received the vaccine, there is no new information about the safety of the botulism vaccine resulting from its use by U.S. troops. Therefore, its safety remains unknown.

[137]Correspondence between Secretary Espy and Senator Rockefeller are in Committee files.

[138]Hearing, May 6, 1994; document submitted for the record by Craig Crane.

[139]Minutes of Meeting of the Informed Consent Waiver Review Group (ICWRG), Food and Drug Administration, December 31, 1990.

[140]BBIND 3723, Food and Drug Administration, memorandum from Lawrence A. D'Hoostelaere on "General safety testing of botulinum toxoid," March 2, 1994.

[141]Review by Ann Sutton, Vaccines and Allergenics, DBIND, Food and Drug Administration, to the IND record, November 14, 1990.

[142]Informational material for the use of pentavalent (ABCDE) botulinum toxoid aluminum phosphate adsorbed, U.S. Department of Health and Human Services, Centers for Disease Control, Atlanta, Georgia, Revised May 1982, protocol #392.

I. RECORDS OF ANTHRAX VACCINE ARE NOT SUITABLE TO EVALUATE SAFETY.

Although anthrax vaccine had been considered approved prior to the Persian Gulf War, it was rarely used. Therefore, its safety, particularly when given to thousands of soldiers in conjunction with other vaccines, is not well established. Anthrax vaccine should continue to be considered as a potential cause for undiagnosed illnesses in Persian Gulf military personnel because many of the support troops received anthrax vaccine, and because the DOD believes that the incidence of undiagnosed illnesses in support troops may be higher than that in combat troops.[143]

Unfortunately, medical records and shot records of individuals who served in the Persian Gulf frequently do not report the vaccines they received. In some cases, anthrax was recorded as "Vac-A." However, in many cases, veterans who believe they received anthrax vaccinations did not have them recorded in their medical records. According to testimony received at the Committee hearing on May 6, 1994, vaccines were recorded in separate vaccine records, for soldiers who had such records with them and insisted that the information be recorded.[144]

J. ARMY REGULATIONS EXEMPT INFORMED CONSENT FOR VOLUNTEERS IN SOME TYPES OF MILITARY STUDIES.

Army regulation (AR) 70-25 provides guidelines for the use of volunteers as subjects in military research. Section 3 describes three exemptions whereby military researchers are exempt from the provisions of these protective regulations (the following is a direct quote from the regulation):

> a. Research and nonresearch programs, tasks, and tests which may involve inherent occupational hazards to health or exposure of personnel to potentially hazardous situations encountered as part of training or other normal duties, e.g., flight training, jump training, marksmanship training, ranger training, fire drills, gas drills, and handling of explosives.
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> b. That portion of human factors research which involves normal training or other military duties as part of an experiment, wherein disclosure of experimental conditions to participating personnel would reveal the artificial nature of such conditions and defeat the purpose of the investigation.

[143]Briefing, Maj. Gen. Ron Blanck, Commanding General, Walter Reed Army Hospital, to Committee staff, 414 Russell Senate Office Building, Washington, DC, February 4, 1994.

[144]Hearing, May 6, 1994, testimony of the Rev. Dr. Barry Walker, Persian Gulf War veteran.