Military Human Experimentation

Congressional Committee Report 103-97

103d Congress, 2d Session - COMMITTEE PRINT - S. Prt. 103-97

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
DECEMBER 8, 1994

FOREWORD

U.S. Senate,
Committee on Veterans' Affairs,
Washington, DC, December 8, 1994

During the last few years, the public has become aware of several examples where U.S. Government researchers intentionally exposed Americans to potentially dangerous substances without their knowledge or consent. The Senate Committee on Veterans' Affairs, which I have been privileged to chair from 1993-94, has conducted a comprehensive analysis of the extent to which veterans participated in such research while they were serving in the U.S. Military. This resulted in two hearings, on May 6, 1994, and August 5, 1994.

This report, written by the majority staff of the Committee, is the result of that comprehensive investigation, and is intended to provide information for future deliberations by the Congress. The findings and conclusions contained in this report are those of the majority staff and do not necessarily reflect the views of the members of the Committee on Veterans' Affairs.

This report would not have been possible without the dedication and expertise of Dr. Patricia Olson, who, as a Congressional Science Fellow, worked tirelessly on this investigation and report, and the keen intelligence, energy, and commitment of Dr. Diana Zuckerman, who directed this effort.

John D. Rockefeller IV, Chairman

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III. Findings and conclusions

* A. For at least 50 years, DOD has intentionally exposed military personnel to potentially dangerous substances, often in secret
* B. DOD has repeatedly failed to comply with required ethical standards when using human subjects in military research during war or threat of war
* C. DOD incorrectly claims that since their goal was treatment, the use of investigational drugs in the Persian Gulf War was not research
* D. DOD used investigatory drugs in the Persian Gulf War in ways that were not effective
* E. DOD did not know whether pyridostigmine bromide would be safe for use by U.S. troops in the Persian Gulf War
* F. When U.S. troops were sent to the Persian Gulf in 1994, DOD still did not have proof that pyridostigmine bromide was safe for use as an antidote enhancer
* G. Pyridostigmine may be more dangerous in combination with pesticides and other exposures
* H. The safety of the botulism vaccine was not established prior to the Persian Gulf War
* I. Records of anthrax vaccinations are not suitable to evaluate safety
* J. Army regulations exempt informed consent for volunteers in some types of military research
* K. DOD and DVA have repeatedly failed to provide information and medical follow-up to those who participate in military research or are ordered to take investigatory drugs
* L. The Federal Government has failed to support scientific studies that provide information about the reproductive problems experienced by veterans who were intentionally exposed to potentially dangerous substances
* M. The Federal Government has failed to support scientific studies that provide timely information for compensation decisions regarding military personnel who were harmed by various exposures
* N. Participation in military research is rarely included in military medical records, making it impossible to support a veteran's claim for service-connected disabilities from military research
* O. DOD has demonstrated a pattern of misrepresenting the danger of various military exposures that continues today

IV. Recommendations

* A. Congress should deny the DOD request for a blanket waiver to use investigatory drugs in case of war or threat of war
* B. FDA should reject any applications from DOD that do not include data on women, and long-term follow-up data
* C. Congress should authorize a centralized database for all federally funded experiments that utilize human subjects
* D. Congress should mandate all Federal agencies to declassify most documents on research involving human subjects
* E. Congress should re-establish a National Commission for the Protection of Human Subjects

* F. CA and DOD should implement regular site visits to review Institutional Review Boards
* G. The Feres Doctrine should not be applied for military personnel who are harmed by inappropriate human experimentation when informed consent has not been given

Appendix -- Survey of 150 Persian Gulf War Veterans

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

I. INTRODUCTION

During the last 50 years, hundreds of thousands of military personnel have been involved in human experimentation and other intentional exposures conducted by the Department of Defence (DOD), often without a service member's knowledge or consent. In some cases, soldiers who consented to serve as human subjects found themselves participating in experiments quite different from those described at the time they volunteered. For example, thousands of World War II veterans who originally volunteered to "test summer clothing" in exchange for extra leave time, found themselves in gas chambers testing the effects of mustard gas and lewisite. (Note 1) Additionally, soldiers were sometimes ordered by commanding officers to "volunteer" to participate in research or face dire consequences. For example, several Persian Gulf War veterans interviewed by Committee staff reported that they were ordered to take experimental vaccines during Operation Desert Shield or face prison. (Note 2)

The goals of many of the military experiments and exposures were very appropriate. For example, some experiments were intended to provide important information about how to protect U.S. troops from nuclear, biological, and chemical weapons or other dangerous substances during wartime. In the Persian Gulf War, U.S. troops were intentionally exposed to an investigatory vaccine that was intended to protect them against biological warfare, and they were given pyridostigmine bromide pills in an experimental protocol intended to protect them against chemical warfare.

However, some of the studies that have been conducted had more questionable motives. For example, the Department of Defence (DOD) conducted numerous "man-break" tests, exposing soldiers to chemical weapons in order to determine the exposure level that would cause a casualty, i.e., "break a man." (Note 3) Similarly, hundreds of soldiers were subjected to hallucinogens in experimental programs conducted by the DOD in participation with, or sponsored by, the CIA. (Note 4), (Note 5) These service members often unwittingly participated as human subjects in tests for drugs intended for mind-control or behaviour modification, often without their knowledge or consent. Although the ultimate goal of those experiments was to provide information that would help U.S. military and intelligence efforts, most Americans would agree that the use of soldiers as unwitting guinea pigs in experiments that were designed to harm them, at least temporarily, is not ethical.

Whether the goals of these experiments and exposures were worthy or not, these experiences put hundred of thousands of U.S. service members at risk, and may have caused lasting harm to many individuals.

Every year, thousands of experiments utilizing human subjects are still being conducted by, or on behalf of, the DOD. Many of these ongoing experiments have very appropriate goals, such as obtaining information for preventing, diagnosing, and treating various diseases and disabilities acquired during military service. Although military personnel are the logical choice as human subjects for such research, it is questionable

whether the military hierarchy allows for individuals in subordinate positions of power to refuse to participate in military experiments. It is also questionable whether those who participated as human subjects in military research were given adequate information to fully understand the potential benefits and risks of the experiments. Moreover, the evidence suggests that they have not been adequately monitored for adverse health effects after the experimental protocols end.

Veterans who become ill or disabled due to military service are eligible to receive priority access to medical care at VA medical facilities and to receive monthly compensation checks. In order to qualify, they must demonstrate that their illness or disability was associated with their military service. Veterans who did not know that they were exposed to dangerous substances while they were in the military, therefore, would not apply for or receive the medical care or compensation that they are entitled to. Moreover, even if they know about the exposure, it would be difficult or impossible to prove if the military has not kept adequate records. It is therefore crucial that the VA learn as much as possible about the potential exposures, and that the DOD assume responsibility for providing such information to veterans and to the VA.

II. BACKGROUND

A. CODES, DECLARATIONS, AND LAWS GOVERNING HUMAN EXPERIMENTATION

The Nuremberg Code is a 10-point declaration governing human experimentation, developed by the Allies after World War II in response to inhumane experiments conducted by Nazi scientists and physicians. The Code states that voluntary and informed consent is absolutely essential from all human subjects who participate in research, whether during war or peace. The Code states:

The person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health and person which may possibly come from his participation in the experiments. (Note 6)

There is no provision in the Nuremberg Code that allows a country to waive informed consent for military personnel or veterans who serve as human subjects in experiments during wartime or in experiments that are conducted because of threat of war. However, the DOD has recently argued that wartime experimental requirements differ from peacetime requirements for informed consent. According to the Pentagon, "In all peacetime applications, we believe strongly in informed consent and its ethical foundations.....But military combat is different." (Note 7) The DOD argued that informed consent should be waived for investigatory drugs that could possibly save a soldier's life, avoid endangerment of the other personnel in his unit, and accomplish the combat mission.

More than a decade after the development of the Nuremberg Code, the World Medical Association prepared recommendations as a guide to doctors using human subjects in biomedical research. As a result, in 1964 the Eighteenth World Medical Assembly met in Helsinki, Finland, and adopted recommendations to be used as an ethical code by all medical doctors conducting biomedical research with human subjects. This code, referred to as the Declaration of Helsinki, was revised in 1975, 1983, and 1989. (Note 8) It differs from the

Nuremberg Code in certain important respects. The Declaration of Helsinki distinguishes between clinical (therapeutic) and non-clinical (non therapeutic) biomedical research, and addresses "proxy consent" for human subjects who are legally incompetent, such as children or adults with severe physical or mental disabilities. (Note 9) Proxy consent for legally competent military personnel who participate in military research is not considered appropriate under the Nuremberg Code or the Declaration of Helsinki.

On June 18, 1991, the Federal Government announced that 16 U.S. governmental agencies would abide by a set of regulations, referred to as the "Common Rule," designed to protect human subjects who participate in federally funded research. (Note 10) The provisions of the "Common Rule," first promulgated for the Department of Health and Human Services (DHHS) in 1974, described how federally funded research involving human subjects shall be conducted. However, local Institutional Review Boards (IRB's) may revise or exclude some or all consent elements if the research exposes subjects to no more than "minimal risk," meaning "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Note 11) IRB's vary greatly in their interpretation of the risks of daily life.

There are three provisions governing research funded by DHHS that are intended to protect vulnerable populations, such as pregnant women and fetuses, prisoners, and children. (Note 12) There are no special Federal regulations to protect military personnel when they participate as human subjects in federally funded research, despite logical questions about whether military personnel can truly "volunteer" in response to a request from a superior officer.

Current law prevents the Department of Defence from using Federal funds for research involving the use of human experimental subjects, unless the subject gives informed consent in advance. This law applies regardless of whether the research is intended to benefit the subject. (Note 13)

B. MUSTARD GAS AND LEWISITE

According to a report published by the Institute of Medicine (IOM) last year, approximately 60,000 military personnel were used as human subjects in the 1940's to test two chemical agents, mustard gas and lewisite. Most of these subjects were not informed of the nature of the experiments and never received medical follow-up after their participation in the research. (Note 14) Additionally, some of these human subjects were threatened with imprisonment at Fort Leavenworth if they discussed these experiments with anyone, including their wives, parents, and family doctors. (Note 15) For decades, the Pentagon denied that the research had taken place, resulting in decades of suffering for many veterans who became ill after the secret testing. According to the 1993 IOM report, such denial by the DOD continues: "This committee discovered that an atmosphere of secrecy still exists to some extent regarding the WWII testing programs. Although many documents pertaining to the WWII testing programs were declassified shortly after the war ended, others were not." (Note 16)

Based on findings from the National Academy of Sciences, the Department of Veterans Affairs recently published a final rule to compensate veterans for disabilities or deaths resulting from the long-term effects of in-service exposure to mustard gas and other agents which blister the skin (these are called vesicants). (Note 17) The final rule expands coverage to veterans exposed to mustard gas under battlefield conditions in World War I (WWI), those present at the German air raid on the Harbor of Bari, Italy (WWII), and those engaged in manufacturing and handling vesicant agents during their military service. Thus, for the first time, VA will compensate certain

veterans for illnesses which may have been caused by their exposure to vesicants over half a century ago.

C. SEVENTH-DAY ADVENTISTS

Many experiments that tested various biological agents on human subjects, referred to as Operation Whitecoat, were carried out at Fort Detrick, MD, in the 1950's. The human subjects originally consisted of volunteer enlisted men. However, after the enlisted men staged a sit down strike to obtain more information about the dangers of the biological tests, Seventh-Day Adventists who were conscientious objectors were recruited for the studies. (Note 18) Because these individuals did not believe in engaging in actual combat, they instead volunteered to be human subjects in military research projects that tested various infectious agents. At least 2,200 military personnel who were Seventh-Day Adventists volunteered for biological testing during the 1950's through the 1970's. (Note 19)

Unlike most of the studies discussed in this report, Operation Whitecoat was truly voluntary. Leaders of the Seventh-Day Adventist Church described these human subjects as "conscientious participants," rather than "conscientious objectors," because they were willing to risk their lives by participating in research rather than by fighting a war. (Note 20), (Note 21)

D. DUGWAY PROVING GROUND

Dugway Proving Ground is a military testing facility located approximately 80 miles from Salt Lake City. For several decades, Dugway has been the site of testing for various chemical and biological agents. From 1951 through 1969, hundreds, perhaps thousands of open-air tests using bacteria and viruses that cause disease in human, animals, and plants were conducted at Dugway. (Note 22) For example, antigens produced by animals that had come in contact with Venezuelan equine encephalomyelitis (VEE), a disease usually found in horses, were later found in animals around Dugway. Prior to the identification of these substances in the Dugway vicinity, VEE had only been identified in the rat population in Florida. Such a finding suggested that VEE had been used in the open-air tests at Dugway or within laboratories, and transferred to the nearby animal population. (Note 23)

In 1968, approximately 6,400 sheep died following the intentional release of a deadly nerve gas from a plane. According to a veterinarian who evaluated the sick and dying sheep, there was little doubt that the sheep had been poisoned with nerve gas. (Note 24) The sheep and other animals in the area had depressed cholinesterase levels, suggesting organophosphate nerve poisoning. Initially, the Department of Defence denied any responsibility for the accident, stating that the sheep died from organophosphate pesticides sprayed on a nearby alfalfa field. However, the nerve agent VX was identified when the poisoned sheep were autopsied, which made it clear that the deaths were not caused by pesticides. (Note 25) Eventually, the Department of Defence reimbursed the ranchers for their animals.

It is unknown how many people in the surrounding vicinity were also exposed to potentially harmful agents used in open-air tests at Dugway. In 1969, concerns were expressed at a congressional hearing about the possible public health implications of the VEE virus tested at Dugway. (Note 26)

Due to previous problems with dangerous organisms and chemicals, Dugway has developed an active program of "stimulant" testing. According to the Department of Defence, stimulants are harmless organisms or chemicals which do not cause disease. However, during 45 years of open-air testing, the Army has stopped using a variety stimulants when they realized they were not as safe as previously believed. (Note 27)

E. RADIATION EXPOSURE

ATOMIC VETERANS

>From 1945 to 1962, the United States conducted numerous nuclear detonation tests: Crossroads (Bikini); Sandstone, Greenhouse, and Ivy (Eniwetok Atoll); Castle (Bikini Atoll); Pacific Ocean 400 miles south-west of San Diego; Redwing and Hardtack I (Eniwetok and Bikini Atolls); Argus (South Atlantic); and Dominic (Christmas Island, Johnston Island, 400 miles west of San Diego). (Note 28) The main goal was to determine damage caused by the bombs; however, as a result, thousands of military personnel and civilians were exposed to radioactive fallout. Similar tests were conducted within the continental United States, including sites in New Mexico and Nevada. (Note 29) Veterans who participated in activities that directly exposed them to radioactive fallout are referred to as "atomic veterans."

Data obtained on some military personnel who were exposed to radioactive fallout were collected after these men were unintentionally exposed. However, some atomic veterans believe they were used as guinea pigs to determine the effects of radiation from various distances, including those at ground zero, on human subjects. Their suspicions are supported by a 1951 document from the Joint Panel on the Medical Aspects of Atomic Warfare, Research and Development Board, Department of Defence, which identified general criteria for bomb test-related "experiments" and identified 29 "specific problems" as "legitimate basis for biomedical participation." (Note 30)

The National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR) have prepared a series of reports to advise the U.S. Government on the health consequences of radiation exposure. (Note 31) The first of these reports was not published until the late 1980's, decades after military personnel were first exposed to ionizing radiation. For the last 13 years, the VA has provided free medical care to atomic veterans who have disorders they believe to be caused by ionizing radiation, even if there is no conclusive evidence of the cause. (Note 32) In addition, the VA provides monthly compensation to veterans who were exposed to ionizing radiation during military service, who have illnesses that are believed to be associated with their exposure. The lists of compensable diseases have been revised as more research information has become available. For example, on October 11, 1994, the VA announced that tumours of the brain and central nervous system would be considered for disability compensation for veterans exposed to ionizing radiation. (Note 33)

RADIATION RELEASES AT U.S. NUCLEAR SITES

In addition to detonation testing, radioactive releases were also intentionally conducted at U.S. nuclear sites in the years following World War II. According to the U.S. General Accounting Office (GAO), at least 12 planned radioactive releases occurred at three U.S. nuclear sites during 1948-1952. These tests were conducted at Oak Ridge, TN; Dugway, UT; and Los Alamos, NM. (Note 34) Additionally, a planned release occurred at Hanford, WA, in December 1949, which has been referred to as the Green Run test. It is not known how many civilians and military personnel were exposed to fallout from these tests.

OTHER EXPOSURES TO IONIZING RADIATION

In January 1994, the Clinton administration established a Human Radiation Inter-agency Working Group to coordinate a Government-wide effort to uncover the nature and extent of any Government-sponsored experiments on individuals involving intentional exposure to ionizing radiation. The working group represents the Administration's response to Secretary of Energy Hazel O'Leary's promise to comb Government files for information on hundreds of experiments conducted on people in the 1940's and 1950's.

To assist in identifying those people who may have been harmed by secret

experiments utilizing ionizing radiation, the Clinton administration solicited complaints from possible victims by installing several telephone hotlines. As of September 1994, 86 percent of the 21,996 callers to the radiation hotline were veterans who believed they had participated in various radiation "experiments." (Note 35)

A VA advisory committee has concluded that activities other than atomic weapons tests and occupation force activities resulted in the exposure of veterans to ionizing radiation during their military service prior to 1970. (Note 36) The committee concluded that the records for many individuals who were exposed to such activities are inadequate or inaccessible. Additionally, the committee concluded that information pertinent to military exposures is not always adequate to evaluate the health risks.

F. HALLUCINOGENS

Working with the CIA, the Department of Defence gave hallucinogenic drugs to thousands of "volunteer" soldiers in the 1950's and 1960's...

[The file ends here, with much left out...]