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THE WHITE HOUSE

WASHINGTON

July 15, 1987



MEMORANDUM FOR NANCY J. RISQUE

FROM:

RALPH BLEDSOE

A handwritten signature in dark ink, appearing to read "Ralph", is written over the printed name "RALPH BLEDSOE".

SUBJECT:

Senate Letter About Agent Orange Activities

Nancy, attached is a letter sent by Senator Daschle to a number of agencies, and a response by HHS to an OSTP inquiry about the letter. Note that Don Newman, as chairman, intends to answer Sen. Daschle on behalf of the Agent Orange Working Group members (HHS, OMB, VA, DOD). The Working Group reports to the Domestic Policy Council, but there has been no need for a meeting in recent months. (The last meeting of the DPC on Agent Orange was in November, 1985.)

I recommend this issue be handled by the Working Group, since all the necessary authority resides in the agencies represented on the Group.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

July 14, 1987

Ms. Mary Martin Gant
Executive Office of the President
Office of Science and
Technology Policy
New Executive Office Building
Room 5026
Washington, D.C. 20506

Dear Ms. Gant:

Your letter to Under Secretary Newman was forwarded to me for reply. I note you request a detailed draft response to Senator Daschle's questions by c.o.b. July 15, 1987.

Senator Daschle has sent similar letters to the Chair and members of the Agent Orange Working Group (AOWG) and to members of the Agent Orange Working Group Science Panel and to the Chair of the AOWG Advisory Committee.

Under Secretary Newman as Chairman has decided to respond to Senator Daschle on behalf of the principal members of the AOWG, the Science Panel members and the Advisory Committee other than the non-Federal scientists who are free to respond as private citizens.

This decision is to ensure consistency of response from the AOWG.

In the letter to Dr. Graham, the Senator asks for a definition of the relationship of the Office of Science and Technology Policy (OSTP) to the Agent Orange Working Group and Mr. Newman feels that such a question is best answered directly by OSTP.

An interim response to Senator Daschle's letter (July 10, 1987), has been sent and we will forward a copy of the final reply as soon as it is available.

Sincerely,

Dr. Peter E.M. Beach
Director, Office of Veterans
Affairs and Military Liaison
Executive Secretary, Agent
Orange Working Group

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Thank you very much for your assistance. I look forward to your specific responses at your earliest possible convenience.

Sincerely,


Tom Daschle
United States Senate

TAD/jl

United States Senate

WASHINGTON, DC 20510

July 2, 1987

Dr. William R. Graham
Science Advisor to the President
Office of Science and Technology Policy
360 Old Executive Office Building
Washington, DC 20506

Dear Dr. Graham:

In order that I may better understand the importance of the Air Force study of military personnel who participated in the Project Ranch Hand sprayings of defoliant during the Vietnam conflict, I would greatly appreciate your providing me with the following information.

1. Please define the White House Office of Science and Technology Policy's (OSTP) relationship to the Agent Orange Working Group.
2. During the time that the Air Force has been conducting the Ranch Hand Study, has the OSTP, as a group or through individual representatives, had any direct interaction with the principal investigators of the Study or members of the Ranch Hand Advisory Committee? If so, please describe that interaction. Has OSTP, as a group or through individual representatives, had any direct interaction with Dr. Brandt, the former chairman of the Agent Orange Working Group, or Dr. Newman, his successor? If so, please describe that interaction.
3. Please explain the management structure within the group charged with completing the Ranch Hand Study. Who has ultimate responsibility for the integrity of the scientific work? Who is responsible for ensuring that the work goes as scheduled? Who is responsible for releasing the study? Please provide a progress report on the Study.
4. Please describe the measures taken to ensure 1) scientific and intellectual freedom among the principal investigators of the Ranch Hand Study and the Ranch Hand Advisory Committee, and 2) the free flow of data regarding the Study within the scientific community? Have these measures been followed?
5. The Air Force Study (Project Ranch Hand II) Baseline Morbidity Study Results report, issued on February 24, 1984, indicated a statistically significant increase in reported birth defects in exposed cohorts (page XI-20). Have these positive self-reports of birth defects been studied by record review? Has a report concerning such study been formulated or written? Have the self-reports of no birth defects been studied? Is there a report of this work? If not, why not? If so, please provide a copy of this report.

DRAFT

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Contact: Dr. Peter E.M. Beach
(202) 245-6156**

AGENT ORANGE AND RELATED HEALTH STUDIES

Summary: More than a dozen major human health studies and related projects have been initiated examining the health status of Vietnam veterans especially to determine the possible health effects of Agent Orange. The human studies, carried out by DHHS' Centers for Disease Control, the Veterans Administration and the Department of Defense, have involved total federal spending of \$95 million through fiscal 1988, with an additional \$30 million projected through fiscal 1990. Additional related investigations are sponsored by HHS' National Institutes of Health, the Environmental Protection Agency and the Department of Agriculture. The work is coordinated under the Domestic Policy Council's Agent Orange Working Group, chaired by the HHS Under Secretary. Major human health studies are as follows:

Centers for Disease Control

VIETNAM EXPERIENCE STUDY -- Examines the long-term health effects of military service in Vietnam. Health interviews of more than 15,000 veterans and medical examinations of about 4,500 have been completed. This information will be used to compare health status of veterans who served in Vietnam with veterans of the same era who served in other countries.

Status: Findings from the health interviews and medical examinations are to be published simultaneously in mid-1988.

MORTALITY ASSESSMENT STUDY -- This is a separate part of the Vietnam Experience Study, investigating and comparing the causes of death of 446 veterans and non-Vietnam veterans who died since leaving active military service. Findings were published in February 1987 (Journal of the American Medical Association and a CDC Monograph). The report showed that the rate of postservice mortality for Vietnam veterans was 17% higher than the rate for non-Vietnam veterans. During the first 5 years after discharge, the mortality rate among Vietnam veterans was 1.45 times the rate among non-Vietnam veterans. Most of the increased mortality was from external causes such as injuries, a finding similar to results from earlier studies of men returning from combat areas after World War II and the Korean conflict.

Status: Complete.

SELECTED CANCERS STUDY -- Investigates the risk in Vietnam veterans of five cancers which have been identified in the scientific literature as possibly associated with industrial or occupational exposure to phenoxy herbicides (of which Agent Orange is one) and their dioxin contaminant. The cancers are lymphoma, soft-tissue sarcoma, nasal and nasopharyngeal cancer, and primary liver cancer. Compares the exposure histories of reported cases of these cancers with the histories of a control group of men with similar characteristics. Cases are those reported from December 1984 through November 1988 to eight tumor registries.

Status: Data collection activities will be completed in 1989 and publication of results will be in 1990.

AGENT ORANGE EXPOSURE STUDY -- Intended to evaluate possible health effects of exposure to Agent Orange by comparing the health of a group of male U.S. Vietnam veterans exposed to herbicides with the health of male Vietnam veterans not exposed.

An Agent Orange Working Group Science Subpanel determined that military records are not sufficient for identifying exposed and unexposed Vietnam Veterans without an independent method of verification. A TCDD Validation Study was conducted between October 1986 and May 1987 to validate indirect estimates of exposure based on military records by comparing such estimates with current serum 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) levels. The results of this study found no correlation between military records based estimates of likelihood of exposure to Agent Orange or self-reported exposure and serum TCDD levels. Also, the median TCDD levels in Vietnam veterans and non-Vietnam veterans in this study were identical - 3.8 ppt. The results of this study were independently reviewed by the Agent Orange Working Group Science Panel and the Congressional Office of Technology Assessment. Both groups determined that a scientifically valid Agent Orange Study is not possible.

Status: Agent Orange Exposure Study has been cancelled.

National Institute for Occupational Safety and Health

NIOSH MORTALITY STUDY OF PRODUCTION WORKERS EXPOSED TO DIOXIN -- Compares the causes of death in 7000 U.S. workers who made dioxin-contaminated products with comparable mortality rates for the U.S. male population. Special attention is given to characterizing exposure for these individuals.

Status: Finds of this study will be published in late 1988.

NIOSH MEDICAL STUDY OF PRODUCTION WORKERS EXPOSED TO DIOXIN -- compares medical examination outcomes of 400 workers who made dioxin-contaminated products with those of 400 non-exposed individuals matched for age, sex, race and neighborhood. Tests include measurement of levels of 2,3,7,8-TCDD in serum.

Status: Examinations will be completed in the spring of 1988. Findings will be published in late 1989.

Veterans Administration

VIETNAM VETERANS MORTALITY STUDY -- Designed to assess the mortality patterns and specific causes of death of U.S. veterans who served in the Army or Marine Corps during the Vietnam era. The study will determine if Vietnam era veterans who served within the borders of Vietnam are dying disproportionately from different diseases as compared with Vietnam era veterans without service in Vietnam.

Status: Completed. Findings of this study will be published in the Journal of Occupational Medicine in early 1988.

SOFT-TISSUE SARCOMA STUDY -- In cooperation with Armed Forces Institute of Pathology, this is a case-controlled study to determine if Vietnam service increases the risk of developing one of the rare types of cancer known as soft-tissue sarcoma.

Status: Completed. Published in the Journal of National Cancer Institute (JNCI 1987; 79: 693-699).

RETROSPECTIVE STUDY OF DIOXINS AND FURANS IN ADIPOSE TISSUE -- In cooperation with Environmental Protection Agency, detailed analysis is being made of tissue specimens from about 200 males of the Vietnam era age group. Specimens will be analyzed for 2,3,7,8-tetrachlorodibenzo-p-dioxin, also known as TCDD, and several other related dioxins and furans to determine if military service, especially in Vietnam, has resulted in increased levels of these compounds as compared with civilians of the same age group.

Status: Completion expected in March, 1988.

REVIEW OF SOFT-TISSUE SARCOMA CASES IN V.A. PATIENT TREATMENT FILE -- This effort, paralleling the soft-tissue sarcoma study, has involved review of soft-tissue sarcoma cases among Vietnam era veterans who were admitted to VA medical centers from 1969-1983. Review compares anatomic site, and frequency of soft-tissue sarcoma between Vietnam veterans and non-Vietnam veterans.

Status: Completed. Published in the Journal of Occupational Medicine (JOM 1986; 28:1215-1218).

SPECIALLY SOLICITED RESEARCH -- VA is funding several investigator-initiated Agent Orange research projects. These studies are designed to determine the possible adverse health effects of Agent Orange exposure.

Status: Individual research projects are in varying stages of completion.

AGENT ORANGE REGISTRY -- Identifies Vietnam veterans who are concerned about the possible health effects of Agent Orange exposure. Veterans are given a complete health evaluation. Registry data are used in reviewing the types of medical problems Vietnam veterans are experiencing, including possible relationships between herbicide exposure and subsequent health problems.

Status: Registry was established in 1978. Ensures VA contact with veterans for further testing and follow up, if needed. Over 226,000 initial examination have been performed as of October 1987.

MONOGRAPH SERIES -- VA is developing a monograph series on significant Agent Orange-related subjects for the benefit of health care professionals.

Status: Three monographs published to date: "Birth Defects and Genetic Counseling," "Cacodylic Acid," and "Human Exposure to Phenoxy Herbicides."

LITERATURE REVIEW -- VA has conducted a comprehensive review and analysis of worldwide scientific literature on the health effects on humans of Agent Orange and other phony herbicides.

Status: Ten volumes published, as well as four lay-language summaries. Plans are to produce an update of literature during calendar year 1987 with expected publication date of this update in May 1988.

WOMEN'S VIETNAM VETERANS HEALTH STUDY -- On April 7, 1986, Public Law 99-272, the "Consolidated Omnibus Reconciliation Act of 1985," was enacted. Section 19031 of that legislation mandates that the Veterans Administration (VA) provide for the conduct of a "Study of Effects of Vietnam Experience on Health Status of Vietnam Veterans."

This study will be one of the first major research efforts undertaken by any Agency to address the health concerns voiced by some women Vietnam veterans as to the possible adverse health effects resulting from service in Vietnam. Accordingly, the study will be designed as a Vietnam experience study, that is, a study which will evaluate the impact of the total Vietnam experience upon these individuals.

Status: On September 17, 1986, the VA awarded a contract for development of the study's protocol to New England Research Institute. The protocol was delivered by the contractor to the Veterans Administration's Office of Environmental Epidemiology (OEE) on June 13, 1987. The protocol is now being modified to incorporate some of the recommendations made by the Office of Technology Assessment following that Agency's review. Following preparation of an acceptable protocol, a Request for Proposals (RFP) will be issued by the VA for selection of a contractor to perform the actual conduct of the study.

Department of Defense

RANCH HAND STUDY -- A 20-year comprehensive epidemiological investigation to determine whether there is any causal relationship between health problems of Air Force air crew personnel who flew on herbicide-spraying missions (Operation Ranch Hand) in Southeast Asia and their exposure to Agent Orange. Ranch Hand group was chosen because its members were most likely to have been heavily exposed and

they could be readily identified. Study includes examinations of mortality, morbidity (disease, including birth defects in children), and follow-up (long latency of disease, e.g. cancer).

Status: Baseline morbidity report (1984) and a follow-up report (1987) baseline mortality report and two follow-up mortality reports have been issued. At this time, there is insufficient evidence to support a cause-and-effect relationship between herbicide exposure and adverse health in the Ranch Hand group. The mortality studies have not revealed any statistically significant differences in the deaths recorded in Ranch Hand and comparison groups.

Next morbidity report scheduled for release in 1989 (5-year) and thereafter at 10, 15 and 20 year points. Mortality surveillance will be reported annually.