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Report/Article Title Memorandum with Routing Slip and Attachments: from Col. George D. Lathrop to HQ USAF/SG (Maj. Gen. Dettinger) with subject Inadequate NAS Review, Project RANCH HAND II, December 20, 1979.

Journal/Book Title

Year 0000

Month/Day

Color

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Description Notes Memo outlines the USAFSAM (United States Air Force School of Aerospace Medicine) group's concerns about the conduct of the NAS's (National Academy of Sciences) review of the proposed study design of Project Ranch Hand II. Attachments include the list of members of the NAS review committee labeled "Names of People to Whom the Air Force/Herbicide Orange Protocol and Background Data Should be sent," and a letter from Robert A. Neal to George D. Lathrop explaining his withdrawal from the NAS committee, dated 19 December 1979.

ROUTING AND TRANSMITTAL SLIP		ACTION
TO (Name, office symbol or location) AFSC/SGPA		INITIALS CIRCULATE DATE COORDINATION
2		INITIALS FILE DATE INFORMATION
3		INITIALS NOTE AND RETURN DATE PERSON CONVERSATION
4		INITIALS SEE ME DATE SIGNATURE
REMARKS For your information. Letter prepared as per request of Maj. Gen. Dettinger.		
Do NOT use this form as a RECORD of approvals, concurrences, disapprovals, clearances, and similar actions.		
FROM (Name, office symbol or location) Col. George D. Lathrop USAFSAM/EK		DATE 26 Dec 79 PHONE

OPTIONAL FORM 41

AUGUST 1967

GSA FPMR (41CFR) 100-11.206

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DEPARTMENT OF THE AIR FORCE
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235

20 December 1979



REPLY TO
ATTN OF:

EK

SUBJECT: Inadequate NAS Review, Project RANCH HAND II

TO: HQ USAF/SG (Maj Gen Dettinger)

1. On 18 December 1979, Col George Lathrop, Lt Col William Wolfe, Lt Col Patricia Moynahan, Maj Alvin Young and Dr. Richard Albanese from USAFSAM attended a subcommittee meeting of the Toxicology Section of the National Academy of Sciences (NAS) in Washington, DC to present the proposed RANCH HAND II study design for the purpose of peer review. A list of the sub-committee members is provided in Attachment 1. The following represents a strong consensus of the USAFSAM group, and is provided at your request.

2. Seven major deficiencies/adverse factors affected the quality of the review.

a. Briefing format change - less than 30 minutes prior to the start of the review, the USAFSAM team was informed that it could not present their structured briefing. They were to respond to specific questions in the general areas of Mortality Study, Morbidity Study, and Follow-up Study. This format did not allow the committee members to view the study design as an integrated effort over time.

b. Time limitation - Initially, the USAFSAM team had been informed that they would have four hours to conduct the briefing, and that additional time in the evening could be available if needed. Upon arrival, they were informed that only 2-1/2 hours were allowed, so that a final report by the committee could be prepared at 1600 hours. This time limitation did not permit completion of discussion on the Morbidity Study and the follow-up aspects of the proposed design were not addressed at all. Dr. Carl Shy privately expressed the opinion that two days were needed to properly discuss the protocol. Had the USAFSAM team been permitted to follow the original format, 80-90% of the questions could have been avoided.

c. Poor preparation by the NAS committee - Despite having the protocol in their possession 18-20 days prior to the review meeting, many of the committee members were unfamiliar with even basic and fundamental aspects of the design. Their questions were often naive and reflected their lack of knowledge concerning the design. They repeatedly asked questions which were clearly addressed and answered in the protocol. Two of the seven committee members present failed to ask any questions and only four members participated significantly in the discussion.

d. Absenteeism - Dr. Alan Poland, a recognized TCDD expert and Dr. Ian Higgins, a statistician/epidemiologist (neither from John Hopkins) were not in attendance, and no explanation was offered for their absence

by the committee chairman. Their presence may have counterbalanced the bias displayed by the Johns Hopkins committee members.

e. Attendance by inappropriate individuals - a UNC Graduate student/physician from Milan, Italy attended the committee meeting at the request of Dr. Shy, his major professor. While he did not participate in the discussion, his presence at the meeting was inappropriate at best. His knowledge of the Seveso, Italy accident in 1976 was limited and the USAFSAM team's knowledge of the Seveso accident exceeded his.

f. Financial concerns - Dr. Newell of the NAS was more concerned about receiving financial payment to the NAS than he was for the scientific aspects of the protocol. His only interaction with the USAFSAM team was fifteen minutes prior to the meeting. Although he did not appear to have time for social amenities, he took time to demand that the USAFSAM team insure that payment was made to NAS before 1600 on 18 December 1979. He made no contribution to the discussion during the meeting.

g. Lack of committee leadership/non-compliance with charter - Dr. Shy, the committee chairman, did not adequately understand the charter and purpose of the meeting. He failed to clearly state the purpose of his fellow committee members. He stated that rather than a "Dog and Pony Show" as he put it, the members would ask pertinent questions thereby eliminating the need for a long session. The meeting was conducted in a manner which discouraged the peer review process, but rather simulated a student/professor relationship. One of the committee members commented later that this meeting was like a Doctoral Dissertation defense. The chairman placed more emphasis on the institutions which granted degrees to the team members than on the knowledge, degrees, positions, and experience of the team members.

3. Conflict of interest, a basis for adverse criticism - Drs Gordis and Seltser of Johns Hopkins asked essentially all of the questions and they concentrated almost exclusively on the limited size of the exposed group for the USAF Mortality Study as contrasted with the US Marine Corps population noted in the Government Accounting Office (GAO) report. They failed to perceive the Mortality Study as more than a determination of deaths as of March 1980, ignoring the planned 5-year follow-up analysis and analysis of disease patterns. The Johns Hopkins Epidemiology Department under Dr. Gordis will receive a contract from the Veterans Administration to conduct a Mortality Study of cancer in the US Marine Corps population. We perceive that Drs Gordis and Seltser considered the USAF Mortality Study as competitive with their own. They attempted to find a lever with which to invalidate our mortality effort, and displayed little or no interest in the morbidity or follow-up phases. The strengths of our study are the linkage we have between mortality, morbidity and follow-up analyses, coupled with a solid exposure index, all of which lend our study a capability that may not be obtained in the Johns Hopkins study. Dr. Robert A. Neal was scheduled to be a committee member, but he withdrew because his position as a Brigadier General in the Air Force

Reserve and his duty as a C-130 pilot could represent or be perceived as a conflict of interest. The deliberations of the NAS subcommittee would have been different if Drs Gordis and Seltser or the NAS staff had been as sensitive to conflict of interest issues, and demonstrated the level of integrity displayed by Dr. Neal (see attached letter dated 19 Dec 79 as Attachment 2).

4. Recommendations

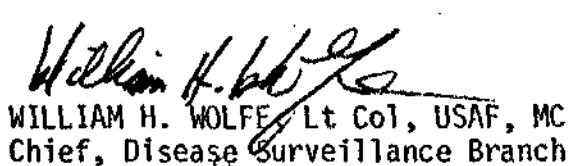
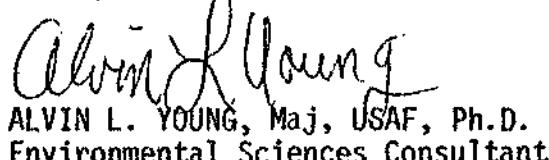
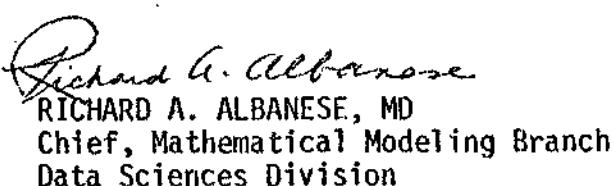
- a. In view of the political orientation of the NAS subcommittee and the inadequacy of the scientific review, Air Force, Department of Defense, and White House Domestic Policy Council should be prepared to refute any adverse criticism of the protocol leveled by the NAS. The conflict of interest issue should be clearly presented to the NAS.
- b. The Air Force should continue with the planning phase of the RANCH HAND II study, and immediately proceed with implementation of the study under Air Force or DOD direction.
- c. A consortium of university experts should be formed by the Air Force or DOD to monitor and review all aspects of the study from design, through data collection, to final analysis.



GEORGE D. LATHROP, Col, USAF, MC
Chief, Epidemiology Division

2 Atchs

1. List of panel members
2. Ltr, Dr Neal, 19 Dec 79


WILLIAM H. WOLFE Lt Col, USAF, MC
Chief, Disease Surveillance Branch
ALVIN L. YOUNG, Maj, USAF, Ph.D.
Environmental Sciences Consultant
RICHARD A. ALBANESE, MD
Chief, Mathematical Modeling Branch
Data Sciences Division

NAMES OF PEOPLE TO WHOM THE AIR FORCE/HERBICIDE ORANGE
PROTOCOL AND BACKGROUND DATA SHOULD BE SENT

Dr. Carl M. Shy
Institute for Environmental Studies
University of North Carolina
Chapel Hill, NC 27514

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Johns Hopkins School of Public Health
Baltimore, MD 21205

Dr. William Halperin
Division of Surveillance
Hazard Evaluations and Field Studies
NIOSH
4676 Columbia Parkway
Cincinnati, OH 45226

Dr. Ian T. Higgins
University of Michigan Medical Center
School of Public Health
109 Observatory
Ann Arbor, MI 48104 (313)763-3285

Dr. Leonard T. Kurland
Department of Medical Statistics
Epidemiology and Genetics
Mayo Clinic
Rochester, MN 55901

Dr. Philip Landrigan, Director
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Dr. Robert A. Neal
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School of Medicine
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Dr. Gordon W. Newell
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Dr. Raymond Seltser
Department of Epidemiology
School of Hygiene and Public Health
Johns Hopkins University
Baltimore, MD 20014

Dr. Alan T. Poland
Department of Oncology
McCardle Laboratory for Cancer Research
University of Wisconsin
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19 December 1979

George D. Lathrop, M.D., Ph.D.
Colonel, USAF, MC
Chief, Epidemiology Division
Department of the Air Force
USAF School of Aerospace Medicine (AFSC)
Brooks Air Force Base, Texas 78235

Dear Col. Lathrop:

As requested by Major Daves I am returning the protocol for the Herbicide Orange study.

A word of explanation is in order concerning my withdrawal from the NAS committee involved in the review of the protocol. I am a B/G in the Air Force Reserve (Air National Guard). I am also a C-130 pilot. As I examined my position relative to the review of the protocol, particularly in light of the criticism of the Air Force for conducting the study itself, it appeared my position on the NAS review committee could represent a conflict of interest. Therefore, I withdrew as a member of this committee.

I wish you success in the conduct of this study. It is an explosive political situation magnified by the lack of, or inconsistencies in data concerning the biological effects of TCDD.

Sincerely,

Robert A. Neal, Ph.D.
Director

RAN:cp

Encls.