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AUG 8 1990

August 7, 1990

Admiral Elmo R. Zumwalt, Jr.
1500 Wilson Boulevard
Arlington, VA 22209

Dear Admiral Zumwalt:

As you probably know, we recently filed suit against the Department of Veterans Affairs and the Centers for Disease Control over their failure to conduct the Agent Orange exposure study mandated by Congress in 1979. Enclosed for your information are copies of the complaint and some supporting documents, including two reports by the Institute of Medicine that contradict the VA and CDC claims that a cohort exposure study cannot be done.

In approximately 60 days, the VA and CDC will respond to our complaint and will most likely submit affidavits or statements from scientists of the Office of Technology Assessment or the White House Agent Orange Working Group in support of the decision to cancel the Agent Orange exposure study on the ground that it is not scientifically feasible. We must be prepared to counter those affidavits or statements with our own. I am writing to you for two reasons: (1) to inform you about the suit in the hope you can assist in any way in providing scientific opinion or other evidence that an Agent Orange exposure study - some kind of valid study, not necessarily a perfect one or the one envisioned originally by CDC - can be done, and (2) to see if you know and can serve as a reference or contact with one or more of the scientists on the Institute of Medicine's Advisory Committee on the CDC Study of the Health of Vietnam Veterans; there are 12 committee members and 3 advisors listed on the third page (unnumbered) of the enclosed Fifth Letter Report, dated June 26, 1987. The Chairman of the committee, Dr. Paul D. Stolley, has already joined in a letter (which is inaccurate) by the President of the Institute of Medicine in defense of the CDC, and we would like to find one or more members of the committee who will stand by its reports.

I realize how busy you must be and I appreciate any effort you can make to assist us.

Sincerely,

Mark A. Venuti

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VIETNAM VETERANS OF AMERICA
1224 M Street, N.W.
Washington, DC 20005,

BILL ATWELL
210 Bonita Road
St. Augustine, FL 32086,

HAROLD A. BUTLER
2624 Huntington Road
Charlottesville, VA 22901,

CAROL DELANEY-RIDOLFI
654 Little Meadow Road
Guilford, CT 06437,

MAREL J. MACKI
81 Oak Street
Dedham, MA 02026,

BEVERLY NEHMER
404 Pacheco Avenue
Santa Cruz, CA 95062,

Plaintiffs,

v.

SECRETARY EDWARD J. DERWINSKI
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, DC 20420,

SECRETARY LOUIS W. SULLIVAN
Department of Health and
Human Services
200 Independence Avenue, S.W.
Washington, DC 20201,

DIRECTOR WILLIAM L. ROPER
Centers For Disease Control
1600 Clifton Road, N.E.
Atlanta, GA 30333,

DIRECTOR VERNON N. HOUK
Center for Environmental
Health and Injury Control
Centers for Disease Control
1600 Clifton Road, N.E.
Atlanta, GA 30333,

2 AUG 1990

HARRIS, J. SSH

90 1809

Civil Action No.

COMPLAINT

and

THE UNITED STATES OF AMERICA
Serve:

United States Attorney for
the District of Columbia
Civil Division
555 - 4th Street, N.W.
Washington, D.C. 20001

and

Attorney General of the
United States
Main Justice Building,
#B-327
10th St. and Pennsylvania
Ave., N.W.
Washington, D.C. 20530,

Defendants.

COMPLAINT
FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Preliminary Statement

Plaintiffs, Vietnam Veterans of America, two Vietnam veterans, and three widows of Vietnam veterans, seek declaratory and injunctive relief relating to the failure of the defendants to conduct the epidemiological study of the long-term adverse health effects in Vietnam veterans resulting from exposure to phenoxy herbicides, including the herbicide known as Agent Orange, required by statute. The legislation requiring the study was enacted in 1979. In 1987, after spending $43 million on the study, defendants canceled the study even though it is required by statute.

One of the purposes of this study was to provide the basis

for legislation and changes in regulations related to establishing entitlement to disability compensation from exposure to Agent Orange and the development of adverse health effects. The failure to conduct the mandated study injures plaintiffs by depriving them of scientific evidence that would support entitlement to disability compensation and that would allow them to make informed decisions concerning health treatment and procreation.

In this suit, plaintiffs seek a declaration that the defendants have violated the law, and an order directing the defendants to conduct the Congressionally-mandated study.

I. JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, in that this action arises under laws of the United States, including the Administrative Procedure Act, 5 U.S.C. § 701 et seq., and pursuant to 28 U.S.C. § 1361, in that this action is in the nature of mandamus to compel an officer of the United States to perform a duty owed to plaintiffs. The relief requested is authorized by 28 U.S.C. §§ 2201-02, and 2412. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(e).

II. NATURE OF PROCEEDING

2. This is a proceeding for a declaratory judgment on defendants' obligation to conduct the mandated Agent Orange exposure study; for an order directing the defendants to conduct the study; and for any other appropriate relief.

III. THE PARTIES

The Plaintiffs

3. Vietnam Veterans of America. Plaintiff Vietnam Veterans of America (VVA) is a Congressionally-chartered, non-profit, veterans service organization that has over 35,000 members located in all fifty states who are veterans of service in Vietnam. Many of these VVA members are Vietnam veterans who were exposed to phenoxy herbicides, including the herbicide known as Agent Orange, during military service in the Republic of Vietnam. Many of these exposed VVA members currently suffer from, or are likely to contract in the future, the diseases and illnesses listed in paragraph 33 below. Many of these exposed VVA members have filed claims with the Department of Veterans Affairs (VA) for service-connected disability compensation based on exposure to Agent Orange which were denied by the VA on the ground that there is not enough scientific evidence linking their adverse health effects with exposure to Agent Orange.

4. Bill Atwell. Plaintiff Bill Atwell served as a member of the U.S. Marine Corps in Vietnam from June, 1968 to July, 1969, and was exposed to Agent Orange. After his exposure to Agent Orange, Mr. Atwell developed kidney cancer, a mass lesion on his left frontal lobe, hypertension, and psychosocial effects. Mr. Atwell's right kidney has been removed.

5. Harold A. Butler. Plaintiff Harold Butler served as a member of the U.S. Army in Vietnam from April, 1968 to April, 1969, and was exposed to Agent Orange. After his exposure to Agent Orange, Mr. Butler fathered a child with a severe birth

defect; his son Michael was born in 1974 with hydrocephalus and is severely retarded.

6. Carol Delaney-Ridolfi. Plaintiff Carol Delaney-Ridolfi is the surviving spouse of Frank J. Delaney, who served as a member of the U.S. Marine Corps in Vietnam from July, 1967 to July, 1968, and was exposed to Agent Orange. In 1984, Mr. Delaney died of acute myoblastic leukemia. Under federal law, Ms. Delaney-Ridolfi will be entitled to certain death and survivor's benefits if it is determined that Mr. Delaney's death was caused by a service-connected condition.

7. Marel J. Macki. Plaintiff Marel Macki is the surviving spouse of Richard James Macki, who served as a member of the U.S. Marine Corps in Vietnam from December, 1967 to December, 1968, and was exposed to Agent Orange. After his exposure to Agent Orange, Mr. Macki developed malignant melanoma and brain cancer, and he died of cancer in 1989. Under federal law, Ms. Macki will be entitled to certain death and survivor's benefits if it is determined that Mr. Macki's death was caused by a service-connected condition.

8. Beverly Nehmer. Plaintiff Beverly Nehmer is the surviving spouse of Daniel Nehmer, who served as a member of the U.S. Marine Corps in Vietnam from July, 1967 to August, 1968 and was exposed to Agent Orange. Mr. Nehmer died in 1978 of leukemia. Under federal law, Ms. Nehmer will be entitled to certain death and survivor's benefits if it is determined that Mr. Nehmer's death was caused by a service-connected condition.

The Defendants

9. Secretary Edward J. Derwinski. Defendant Secretary Edward J. Derwinski is the head of the U.S. Department of Veterans Affairs (VA). The VA is a cabinet-level department with responsibility under the law for various programs for veterans of the U.S. Armed Forces, including a program which provides disability compensation for veterans suffering from service-connected disabilities. Defendant Derwinski is responsible for administering the VA in compliance with law, and is responsible for the control, direction and management of the VA. Defendant Derwinski is sued in his official capacity.

10. Secretary Louis W. Sullivan. Defendant Secretary Louis W. Sullivan is the head of the U.S. Department of Health and Human Services (HHS). HHS is a cabinet-level department with responsibility for, among other things, defendant Centers for Disease Control (CDC). Defendant Sullivan is responsible for ensuring that HHS and CDC operate in compliance with law, and is responsible for the control, direction and management of HHS and CDC. Defendant Sullivan is sued in his official capacity.

11. Director William L. Roper. Defendant Director William L. Roper is the head of the Centers for Disease Control (CDC). Among other things, the CDC designs and conducts scientific research and studies. Defendant Roper is responsible for ensuring that the CDC operates in compliance with law, and is responsible for the control, direction and management of CDC. Defendant Roper is sued in his official capacity.

12. Director Vernon N. Houk. Defendant Director Vernon N. Houk is the head of the Center for Environmental Health and Injury Control of the Centers for Disease Control. This is the center of the Centers for Disease Control that was responsible for conducting the mandated Agent Orange exposure study that is the subject of this suit. Defendant Houk was responsible, pursuant to an interagency agreement with the VA, for the conduct of the mandated Agent Orange exposure study without regard to any potential effects that its conclusions might have on the liability of government or industry for adverse health effects associated with exposure to Agent Orange or other phenoxy herbicides. Defendant Houk is sued in his official capacity.

13. The United States of America. Defendant United States of America is ultimately responsible for the official policies, practices and actions of the defendants sued in their official capacities because they are officials of the government of the United States.

IV. THE FACTS

14. From 1962 to 1971, during the Vietnam war, over 11 million gallons of the phenoxy herbicide Agent Orange were sprayed in a part of Southeast Asia about the size of Connecticut in concentrations 6 to 25 times the manufacturer's suggested rate. Because until 1970 the official view of the Department of Defense was that Agent Orange was not toxic or dangerous to humans, few precautions were taken to prevent exposure to it. It has been estimated by the government that as many as 2.4 million

U.S. servicemembers were exposed to Agent Orange.

15. Agent Orange was a 50:50 mixture of 2,4-D and 2,4,5-T. 2,4,5-T contained the contaminant 2,3,7,8-tetrachlorodibenzo-para-dioxin (dioxin), which is one of the most toxic chemicals known and the most potent carcinogen ever evaluated by the Carcinogen Assessment Group of the U.S. Environmental Protection Agency.

16. Due to mounting scientific evidence of the danger of Agent Orange and dioxin to humans, on April 15, 1970, the Surgeon General of the United States issued a warning that the use of 2,4,5-T might be hazardous to "our health," and the Secretaries of Agriculture, Health, Education and Welfare, and the Interior jointly announced the suspension of its use in most areas. The Department of Defense simultaneously announced its suspension of all uses of Agent Orange. In 1979, the Environmental Protection Agency banned the domestic use of herbicides containing 2,4,5-T.

17. The Department of Veterans Affairs, formerly the Veterans Administration (VA), administers a program to compensate veterans for disabilities connected to military service, and to compensate survivors of veterans for deaths connected to military service. In the late 1970s, Vietnam veterans and survivors of Vietnam veterans began filing claims with the VA for service-connected disability and death benefits based on the allegation that their disability or death was related to the veteran's exposure to Agent Orange during service in Southeast Asia.

18. The VA denied all of these claims based on the position

that there was not enough scientific evidence to support a connection between exposure to Agent Orange and any adverse health effect except for the skin condition known as chloracne. This position was grounded on the VA's determination that (a) the overwhelming evidence from experimental animal studies of the adverse health effects associated with exposure to dioxin could not be extrapolated to humans, and (b) there were not enough scientific studies of humans exposed to dioxin upon which to base conclusions of connections between exposure and disease.

19. In 1979, Congress passed the Veterans Health Programs and Improvement Act of 1979 (Act), Public Law 96-151, 38 U.S.C. § 219 note, which, among other things, requires that the Secretary of Veterans Affairs "shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces . . . [in] Vietnam . . . as such health effects may result from exposure to phenoxy herbicides (including . . . Agent Orange) and the class of chemicals known as dioxins . . ." The Act also required that the "study . . . shall be conducted . . . in accordance with a protocol approved by the Director of the Office of Technology Assessment."

20. The reasons Congress required this study included: (1) there was mounting scientific evidence relating exposure to dioxin with numerous adverse health effects; (2) there was a growing number of Vietnam veterans manifesting the adverse health effects associated in the scientific literature with dioxin

exposure; (3) the VA was not moving forward on its own with an Agent Orange exposure study, but was at the same time taking the position that there was not enough scientific evidence to support an association between exposure to dioxin and adverse health effects for the purpose of granting claims for service-connected disability and death compensation; (4) the mandated study would provide a scientific basis for determining whether to change VA policy related to disability and death compensation due to exposure to Agent Orange; and (5) the mandated study would help alleviate the concern and apprehension of Vietnam veterans and their families concerning the relationship between Agent Orange exposure and the adverse health effects they were currently experiencing and feared they would experience in the future.

21. From December, 1979, when the statute was enacted, until January, 1983, the VA made no significant progress toward conducting the mandated Agent Orange exposure study. On September 15, 1982, the House Veterans Affairs Committee held oversight hearings concerning the mandated study. At those hearings, defendant Houk testified that CDC could design and conduct the study better and faster than the VA. On January 17, 1983, the VA entered into an interagency agreement with the CDC for the CDC to design and conduct the mandated Agent Orange exposure study.

22. A fundamental task necessary to conduct the epidemiologic study mandated by Congress is to identify for study a group or cohort of Vietnam veterans exposed to phenoxy

herbicides, including Agent Orange, for comparison to a cohort of similar veterans who were not exposed to phenoxy herbicides. There are numerous different methods by which these cohorts could be selected in order to conduct the study Congress mandated. CDC chose one of these methods: it decided to focus exclusively on a group of Army veterans who served in III Corps (one of the four regions designated by the U.S. military in Vietnam), who were not officers, who were members of infantry or artillery units, and who served only one term of enlistment. CDC could have chosen to include in its study, but did not, other groups of Vietnam veterans who were at least as likely to have been heavily exposed to phenoxy herbicides as the veterans CDC choose to study, e.g., Marine Corps veterans and veterans who served in I Corps.

23. On May 2, 1983, shortly after the VA contracted with CDC to conduct the mandated study, the VA and CDC testified during oversight hearings before the House Veterans Affairs Committee on the subject of how to determine whether a group of Vietnam veterans had been exposed to phenoxy herbicides. The VA testified: "At one time it was believed that such a determination would be virtually impossible, but subsequent diligent efforts by the Army Agent Orange Task Force [later called the Army's Environmental Support Group] under the able leadership of Mr. Richard Christian have made it likely that groups or cohorts of exposed and unexposed Vietnam veterans can be identified." Defendant Houk testified that "CDC had determined as early as the first week of October [1982] that, if

called upon and provided with appropriate resources, it could design and conduct a scientifically sound study."

24. In 1983, CDC submitted a protocol for the mandated Agent Orange exposure study to the Office of Technology Assessment (OTA), and, after CDC made revisions suggested by OTA and other reviewing groups, OTA approved the protocol.

25. In May, 1985, HHS requested the Institute of Medicine to establish a committee to assist CDC in its conduct of the mandated Agent Orange exposure study. The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of appropriate professions in the examination of policy matters pertaining to the health of the public.

26. In 1984, legislation was pending before the 98th Congress which would require the VA to review the scientific literature regarding dioxin and to conduct a rulemaking proceeding to develop regulations establishing which diseases, if any, entitle a Vietnam veteran exposed to Agent Orange to service-connected disability benefits. While this legislation was pending, the Office of Management and Budget (OMB) of the Executive Office of the President organized opposition to the legislation, stating, "[e]nactment of the bill would be a major defeat for the Administration in the toxic torts area." OMB further opined that passage of this bill "will make it far more difficult to stop broader victims compensation schemes involving hazardous wastes and substances. . . . [W]e will be in the

tenuous position of denying dioxin exposure compensation to private citizens while providing benefits to veterans for in many instances lower levels of exposure." (Emphasis in original).

27. In October, 1984, Congress enacted Public Law 98-542, the legislation opposed by OMB. The legislation required the above-described rulemaking proceeding. In addition, section 8 of the statute amended the Veterans' Health Programs Extension and Improvement Act of 1979 to require the VA Administrator (now the Secretary of Veterans' Affairs) to evaluate whether the results of the mandated Agent Orange exposure study (expected 3 to 4 years later) warrant amendments to the service-connected disability regulations issued as a result of the rulemaking proceeding required by Public Law 98-542.

28. OMB was a member of the White House Agent Orange Working Group (AOWG). The AOWG was established by the White House after the passage of Public Law 96-151 to monitor government research efforts designed to relate exposure to herbicides with long-term adverse health effects. In 1981, the AOWG included representatives from 13 government agencies or departments, i.e., the Departments of Health and Human Services, Defense, Agriculture, State, and Labor, the Veterans Administration, the Environmental Protection Agency, the General Accounting Office, the White House Offices of Science and Technology Policy and Policy Development, the Action Agency, the Office of Management and Budget, the Council of Economic Advisors, and the Office of Technology Assessment.

29. On September 20, 1984, shortly before enactment of Public Law 98-542, the Chairman of AOWG issued a directive to all of the AOWG member agencies and departments. In that directive, the Chairman stated that in order to accomplish AOWG's mission "to determine the health effects, if any, of exposure to Agent Orange of Vietnam veterans," it is essential that all documents relating to Agent Orange research studies slated for review by any person or organization outside the federal government be submitted first to the Chairman of AOWG. In October, 1985, the Chairman of AOWG recommended that the membership of AOWG be reduced from its current 13 agencies or departments to four, i.e., Department of Health and Human Services, Office of Management and Budget, Department of Defense, and the VA, "[b]ecause [with] fewer key policy persons . . . to be contacted, decisions in this volatile area could be easily and swiftly effected." This recommendation was approved by the White House Domestic Policy Council in November, 1985.

30. After enactment of Public Law 98-542, AOWG and CDC took the following actions leading to the determination that the mandated Agent Orange Exposure Study should not be conducted:

(a) AOWG and CDC changed the approved protocol to eliminate from the exposed cohort veterans who were most likely to have been exposed to phenoxy herbicides and to include in the exposed cohort veterans who were not likely to have been exposed. At the same time, CDC admitted that these changes meant that "the true magnitude of exposure and disease associations will be

underestimated." These steps were taken by AOWG and CDC over the objections of CDC scientists working on the project and the Institute of Medicine;

(b) The Institute of Medicine concluded in 1986 that the method for using military records to determine exposure to phenoxy herbicides developed and used by the Army's Environmental Support Group was satisfactory. Despite this conclusion, AOWG and CDC rejected the methods developed by the Army's Environmental Support Group resulting in an exclusion from the exposed cohort of veterans who were actually exposed;

(c) In late 1986, scientists developed a method for measuring dioxin in human blood. CDC decided to conduct a pilot study using this technology to determine whether its method for using military records to determine exposure was valid. The validity of CDC's method had been already challenged by its own scientists and the Institute of Medicine. In the pilot study, CDC measured the current level of dioxin in the blood of a subset of the veterans whom CDC had selected as the exposed cohort for the mandated Agent Orange exposure study and compared it with the current level of dioxin in the blood of a group of veterans who did not serve in Vietnam;

(d) In 1987, CDC prepared a provisional report containing its findings and conclusions regarding the pilot study, and it sent this report to the Institute of Medicine for its review. In this report, CDC concluded, among other things, that:

(1) The current level of dioxin found in an individual's blood is a suitable measure of exposure 15 to 20 years ago;

(2) The current levels of dioxin in the blood of the veterans whom CDC had selected as the exposed subset were no higher than the current levels of dioxin in the blood of the veterans who did not serve in Vietnam; and

(3) Therefore, it is not possible scientifically to conduct the mandated Agent Orange exposure study.

(e) On June 26, 1987, the Institute of Medicine issued a report of its review of CDC's provisional report. The Institute of Medicine disagreed with conclusions one and three above. The Institute stated that CDC should amend its report to state "that there exists the possibility that current [dioxin] levels may not be suitable as a measure of past exposure," and to delete the third conclusion. The Institute stated that the third conclusion "that a full-scale cohort study is not feasible goes well beyond the scope of this study, which was conducted to assess the validity of [CDC's method of determining exposure]. . . . [and] [t]he [Institute] did not find support for this conclusion in the pilot study report."

(f) CDC rejected the recommendations of the Institute of Medicine. Instead, in late 1987, AOWG and CDC decided that the mandated Agent Orange exposure study should be canceled ostensibly because it was not possible scientifically to conduct it. The decision to cancel the mandated study was affected by

the desire of the Executive Department to avoid the possibility that scientific evidence would be created that would subject the government or private industry to liability for adverse health effects related to exposure to herbicides.

31. Defendants' conclusion that it was not possible to conduct the mandated Agent Orange exposure study in a scientifically valid manner was arbitrary and capricious and unsupported by substantial evidence. Defendants either knew that their decision to cancel the mandated study was based upon scientific and medical conclusions which were unfounded, or their decision was made with reckless or at least negligent disregard for sound scientific and medical principles. When pressed at a Congressional briefing on March 29, 1990, defendant Houk conceded that an Agent Orange exposure study could be conducted in a scientifically valid manner.

32. Defendants did not seriously explore, either before or after the decision to cancel the mandated study, the feasibility of alternative means of selecting an exposed cohort of Vietnam veterans in order to conduct the mandated Agent Orange exposure study. If defendants had seriously explored the feasibility of alternative means, they would have found that the mandated Agent Orange exposure study can be conducted in a scientifically valid manner.

33. The available scientific evidence has established a relationship between exposure to herbicides containing dioxin and many adverse health effects, including chloracne and other skin

disorders, non-Hodgkin's lymphoma, soft tissue sarcoma, subclinical hepatotoxic effects, porphyria cutanea tarda, Hodkin's disease, neurologic effects, reproductive and developmental effects, leukemias, cancer of the kidney, testis, stomach, prostate, colon, hepatobiliary tract, pancreas, lip, bone, skin, lung, liver, nasal/pharyngeal/esophageal, and brain, hematopoietic diseases, multiple myeloma, psychosocial effects, immunological abnormalities, gastrointestinal ulcer, and altered lipid metabolism. The current position of the VA is that, except for chloracne and soft tissue sarcomas, this scientific evidence is insufficient for the purpose of establishing the relationship that is necessary to support service-connected disability or death compensation for veterans exposed to herbicides containing dioxin. If defendants conducted the mandated study, it would result in scientific evidence relevant to, with regard to the diseases listed in the first sentence of this paragraph, establishing the relationship that is necessary to support service-connected disability or death compensation for veterans exposed to herbicides containing dioxin.

EQUITY AND IRREPARABLE INJURY

34. The failure of defendants to conduct the mandated study injures the individual plaintiffs and many members of Vietnam Veterans of America by

(a) denying to them scientific and medical information concerning the risk of long-term adverse health effects resulting from exposure to phenoxy herbicides, thereby causing them mental

anguish, hindering their ability to take preventive action to limit the possibility of developing adverse health effects, hindering their ability to treat effectively the adverse health effects they are currently experiencing and may experience in the future, and hindering their ability to make informed decisions concerning procreation;

(b) denying them scientific evidence of the type that will allow them to convince the VA that their claims for service-connected disability and/or death compensation, based on exposure to phenoxy herbicides, including the herbicide known as Agent Orange, should be granted, and that the VA should amend its regulations governing service-connected disability and death compensation to accord service-connected status to the diseases listed in paragraph 33 above.

35. The defendants have consciously and expressly abdicated their statutory duty to conduct the Agent Orange exposure study, and plaintiffs, the intended beneficiaries of the Act, have no other adequate remedy in a court. Plaintiffs are now suffering and will continue to suffer irreparable injury from defendants' unlawful policies as set forth herein unless enjoined by this Court.

STATEMENT OF CLAIMS

36. Defendants' actions, described above, violate Public Law 96-151, 93 Stat. 1097 (as amended by Public Law 97-72, 95 Stat. 1061, and Public Law 98-542, 98 Stat. 2731), 38 U.S.C. § 219 note.

37. Defendants have unlawfully withheld and unreasonably delayed conducting the mandated study in violation of 5 U.S.C. § 706.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully request that this Court

(a) declare that defendants have violated Public Law 96-151, 93 Stat. 1097 (as amended by Public Law 97-72, 95 Stat. 1061, and Public Law 98-542, 98 Stat. 2731), 38 U.S.C. § 219 note, and 5 U.S.C. § 706 by failing to conduct the Agent Orange exposure study described therein or by unreasonably delaying the conduct of the mandated study;

(b) order defendants to conduct promptly the Agent Orange exposure study mandated by Public Law 96-151, 93 Stat. 1097, as amended by Public Law 97-72, 95 Stat. 1061, and Public Law 98-542, 98 Stat. 2731 (38 U.S.C. § 219 note);

(c) order defendant Secretary Derwinski to, after the mandated study has been completed or has provided applicable results, (i) review VA regulations relating to establishing entitlement to disability and death compensation from exposure to Agent Orange and the development of adverse health effects, (ii) make such amendments to those regulations as the study results warrant, and (iii) readjudicate the claims of veterans that have been denied but which raise issues that have been affected by the study results and/or the amended regulations.

(d) award plaintiffs reasonable attorneys' fees and other litigation costs; and

(e) grant plaintiffs such other relief as the Court deems just and proper.

Respectfully submitted,

August 2, 1990

Barton F. Stichman, Bar No. 218834
Mark A. Venuti, Bar No. 338541

National Veterans Legal Services Project
Suite 610
2001 S Street, N.W.
Washington, DC 20009
(202) 265-8305

Counsel for Plaintiffs

Selected Documents Referred to
in the Complaint Against the VA and CDC
Regarding the Failure to Conduct the Agent Orange Exposure Study

- Three Office of Management and Budget memoranda regarding the Administration's position that it must protect the government and private industry from liability "in the toxic torts area." See Complaint, pages 12-17.

- A favorable report by the Institute of Medicine on its review of the ability of the Army's Environmental Support Group to use military records to identify veterans who were exposed to Agent Orange. See Complaint, pages 12-17.

- A report by the Institute of Medicine on the CDC Pilot study which compared present dioxin blood levels of veterans CDC determined to be exposed to Agent Orange with present dioxin blood levels of veterans who were not in Vietnam. The Institute of Medicine recommended, among other things, that the CDC delete entirely its conclusion that the results of the Pilot study show that the mandated Agent Orange exposure study cannot be scientifically conducted. See Complaint, pages 12-17.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

December 6, 1983

MEMORANDUM TO: Ed Meese
Joe Wright
Jay Keyworth
Fred Fielding
M. B. Oglesby

FROM: Mike Horowitz MH

SUBJECT: Compensation for Low-Level Radiation Exposure and Related Developments

Per the request of an earlier Meese Management meeting, this memorandum summarizes recent developments involving compensation for low-level radiation exposure.

Proposals for compensating persons exposed to low-level radiation may be rapidly gaining momentum. As noted in the Stockman CCLP briefing of last May, these compensation proposals have enormous fiscal implications, potentially in the hundreds of billions of dollars.

- Without opposition, the House Veterans Affairs Committee last month adopted a Hammerschmidt amendment to the Daschle Agent Orange bill (which itself passed unanimously) that will compensate all "atomic veterans" (a population of 240,000) for three specific diseases, including leukemia. The Daschle bill passed as a result of an intense lobbying effort by key veterans groups. No notice concerning the Hammerschmidt amendment was provided to the West Wing, and the amendment was passed literally as Members were walking out of the hearings.

- By letter to Jim Baker of late September, Hatch, Laxalt, Garn, DeConcini and others, have linked the Micronesian Compact of Free Association — which provides $150 million for the espousal of all radiation-related claims against the United States -- to the downwind radiation cases. Hatch has indicated that he will place a hold on the Compact until this issue is resolved.

In addition to these developments, we can expect the following to occur in the near future.

- The Utah federal district judge in the Allens case (involving $2 billion in downwind radiation claims) is expected to issue his liability findings late this month.

- The Orphan Drug Act tables giving the probability that specific cancers are related to radiation exposure are scheduled to be issued early next year. HHS has now formally requested that Jay Keyworth organize inter-agency review of the tables prior to their publication.

- Hatch will start pushing his radiation compensation bill next year, after the Allens decision and the Orphan Drug Act tables are issued.

- Per a recent agreement with Chairman Simpson, Cranston will not seek to amend the Veteran's COLA compensation bill, in return for which he has been guaranteed floor time in late March to bring his combined Agent Orange\radiation compensation rulemaking bill before the full Senate. The bill would require complicated VA rulemaking proceedings on every disease alleged to be caused by Agent Orange or radiation -- thereby placing the VA in the untenable political position of having to conduct research and hold hearings on every asserted disease.

We will need to make some decisions soon on the Daschle/Hammerschmidt bill. For one, we will need to decide whether we will actively oppose the bill in the House. Chairman Montgomery is lukewarm to the bill, and Hammerschmidt may also have serious reservations (reportedly, Montgomery supported the bill in Committee only because he was told his Chairmanship was on the line). The bill will easily pass the House whatever we do. But unless we oppose it, the margin in the House may be sufficiently large as to make our situation in the Senate extremely difficult. We can expect considerable support for the bill in the Senate, perhaps even from conservatives such as Hatch and Laxalt who may support it because of its radiation compensation provision.

My recommendation is that we have discussions with Chairman Simpson as soon as possible to determine the best strategy for dealing with the Agent Orange/radiation legislation. Simpson thus far has strongly and publicly supported the Administration

on the compensation issue, and should be consulted on how we can best respond in the House and the Senate.

The House Agent Orange/radiation bill is our first key challenge on toxic compensation -- and it has significant ramifications for other, more costly compensation proposals. It is therefore extremely important that we organize our position and response during the current recess.

cc: John Cogan

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

January 17, 1984

MEMORANDUM TO: Dave Stockman
Joe Wright
Jay Keyworth
Fred Fielding

FROM: Mike Horowitz MH

SUBJECT: Agent Orange/Radiation Compensation Legislation

As you know, the House Veterans Affairs Committee unanimously reported out a modified version of the Daschle/Hammerschmidt Agent Orange/radiation compensation bill (H.R. 1961). The bill now provides compensation for:

- All veterans who served in Southeast Asia (2 1/2 million) who develop one of three diseases, and
- All veterans who participated in the nuclear atmospheric testing program (240,000) who develop one of three diseases, including leukemia.

The bill states that such compensation is to be awarded "notwithstanding that there is insufficient medical evidence to conclude that such diseases are service connected." The radiation portion of the bill, sponsored by Representative Hammerschmidt, literally was added by the Committee at the last moment without notice or hearings. As indicated in prior memos, the radiation component is likely to greatly complicate our prospects in the Senate, where Western conservatives are under pressure to support civilian radiation compensation.

We are now informed by the VA that the bill will be placed on the suspension calendar, that the House is expected to take it up in early to mid-February, and that it is extremely unlikely that the bill can be stopped or delayed in the House. The Senate is expected to take up the issue of Agent Orange and radiation veterans compensation in April or May, with Senator Cranston pushing for a more ambitious procedural bill which would require the VA to engage in extremely complicated and controversial rulemaking proceedings on virtually every disease alleged to be related to Agent Orange or radiation exposure.

If the bill passes the House on the suspension calendar (a two-thirds vote is needed), it may be very difficult to stop a compensation bill in the Senate, where we have the strong support of Chairman Simpson. If the bill does not, however, pass on suspension, Representative Daschle has indicated he will introduce on the floor a package of amendments adding additional diseases (on the other hand, we might be able to bottle up or stall the bill in the Rules Committee).

Enactment of the bill would be a major defeat for the Administration in the toxic torts area.

- The issue of Agent Orange and radiation veterans compensation certainly will not go away. As noted, compensation advocates such as Daschle already are pushing for additional diseases for which compensation should be mandated.

- The bill will make it far more difficult to stop broader victims compensation schemes involving hazardous wastes and substances. Dioxin -- the toxic ingredient in Agent Orange -- is a major issue in this area (Love Canal and Times Beach are largely dioxin exposure cases); we will be in the tenuous position of denying dioxin exposure compensation to private citizens while providing benefits to veterans for in many instances lower levels of exposure.

- The radiation portion of the bill will undermine the United States' position in pending radiation litigation. The Allens case, involving $2 billion in claims, is still under advisement before a Utah federal judge. As noted, the bill also will add fuel to Senator Hatch's efforts to establish a general radiation compensation system.

- The bill also will set an unacceptable precedent of providing compensation even where the scientific evidence does not support the allegations of injury. In this regard, it should be noted that the Air Force Ranchhand mortality study last year showed no higher incidence of death, and indications are that the Ranchhand morbidity study to be issued in mid-February will show no higher incidence of disease (the 1,200 Ranchhanders were by far the most heavily exposed veterans). The bill thus flies directly in the face of the best medical and scientific evidence.

The question of the position we should take on the Daschle/Hammerschmidt bill, in my opinion, should be rapidly scheduled for CCLP consideration (with the VA and the EPA invited). Since the bill is moving very rapidly in the House, we need to determine our position quickly, particularly in that we will need to do considerable work in the Senate if we are going to have a chance at defeating this legislation. Following any CCLP meeting, I believe that any decision regarding an Agent Orange/radiation veterans compensation bill may also need to be reviewed at the level of the Legislative Strategy Group.

cc: John Cogan
Mike Uhlmann

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

January 17, 1984

MEMORANDUM TO: Dave Stockman
Joe Wright
Jay Keyworth
Fred Fielding

FROM: Mike Horowitz MH

SUBJECT: Agent Orange/Radiation Compensation Legislation

As you know, the House Veterans Affairs Committee unanimously reported out a modified version of the Daschle/Hammerschmidt Agent Orange/radiation compensation bill (H.R. 1961). The bill now provides compensation for:

- All veterans who served in Southeast Asia (2 1/2 million) who develop one of three diseases, and
- All veterans who participated in the nuclear atmospheric testing program (240,000) who develop one of three diseases, including leukemia.

The bill states that such compensation is to be awarded "notwithstanding that there is insufficient medical evidence to conclude that such diseases are service connected." The radiation portion of the bill, sponsored by Representative Hammerschmidt, literally was added by the Committee at the last moment without notice or hearings. As indicated in prior memos, the radiation component is likely to greatly complicate our prospects in the Senate, where Western conservatives are under pressure to support civilian radiation compensation.

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- The bill also will set an unacceptable precedent of providing compensation even where the scientific evidence does not support the allegations of injury. In this regard, it should be noted that the Air Force Ranchhand mortality study last year showed no higher incidence of death, and indications are that the Ranchhand morbidity study to be issued in mid-February will show no higher incidence of disease (the 1,200 Ranchhanders were by far the most heavily exposed veterans). The bill thus flies directly in the face of the best medical and scientific evidence.

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cc: John Cogan
Mike Uhlmann

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

Policy/Action

MEMORANDUM July 18, 1986

TO: Debbie Steelman

THROUGH: Bernie Martin
Susan Jacobs

FROM: Sarah Ducich

SUBJECT: Agent Orange Study

This memorandum presents some additional information about the Agent Orange Working Group decision to proceed with the development of a protocol for testing the dioxin levels in blood for Vietnam ground troop veterans. HHS Undersecretary Newman may be briefing White House officials on the decision next week. We recommend that you discuss the decision and its the implications with him prior to then in order to clarify matters on next steps before CDC testifies to the Congress on July 31. In addition, attached to this memorandum are responses to the questions you raised about Agent Orange and the CDC study.

The Decision

As we discussed, the AOWG decision on the proposed CDC verification study was unclear at the end of the meeting on Tuesday. It was clear that CDC would continue its work on "Phase I," developing the test for dioxin in the blood, which they planned to complete by September 1. The decision on the second phase, the pilot study testing the blood of 400 ground troop Vietnam veterans (150 unexposed and 250 "exposed", as identified by the military records), was left up in the air. From my discussions with Dr. Al Young (OSTP) and Dr. Beach (AOWG Executive Secretary HHS), however, it appears that CDC will develop a proposal for the pilot study for approval by AOWG and by OTA by early September. Whether this is a protocol or not is still unclear.

The Implications

- Assuming that "Phase I" is successful (i.e., that the blood test can substitute for the fat test), there will be two more decision points on the future of the Agent Orange study: (1) early September on whether to proceed with "Phase II", the pilot study; and, if yes, (2) January (if CDC time estimates are correct), on whether to continue the Agent Orange study (if #1 is no, then the decision to end the AO study will come in September).

-- Both decisions will be influenced by what CDC commits to at the House Veterans Affairs Committee hearing on July 31. Representatives Edgar and Daschle have called this hearing to investigate the delay in the Agent Orange study. James Mason, the head of CDC, will be testifying as the represenative of the HHS Secretary. OTA will also testify.

-- It is important that the hearing testimony leave the AOWG with options on the future of the Agent Orange study. In particular, the testimony should point out that the blood test may only have a very limited usefulness in studying individuals with low levels of dioxin exposure.

-- The decision should take into account the legal implications of the blood test (the risks associated with testing individuals and the potential that claims against the government would be made by individuals who have higher than "normal" dioxin levels in their blood). I have discussed these issues briefly with Justice attorneys who would be available to evaluate the pilot study proposal for the legal risks. Any evaluation should be done prior to the next AOWG meeting so that the information may be used in the decision on the pilot study.

o The development of a blood test for dioxin exposure will have implications for VA in terms of requests by veterans who will want to have their blood tested for levels of dioxin. VA must be prepared to (1) respond to those requests; and (2), if they do provide veterans with the blood tests, to interpret the results. It is important that testimony and other public comments not associate the measurement of dioxin in blood with causation.

Action

We recommend that you contact HHS Undersecretary Newman and:

(1) Determine his interpretation of the AOWG decision Tuesday.

(2) Discuss the implications of the decision and the importance that the CDC testimony keep the options open on the future of the Agent Orange study.

(3) Encourage him to ensure that Mason will be explicit that developing a measure of dioxin content in blood is neither a link to cause of exposure nor proof of a cause and effect relationship between dioxin and disease.

Site Visit to the U.S. Army
Environmental Support Group

March 7, 1986
Washington, D.C.

Advisory Committee on the CDC Study
of the Health of Vietnam Veterans

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FOR CIRCULATION TO COMMITTEE ONLY
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Introduction

At the January 31, 1986 meeting of the Advisory Committee on the CDC Study of the Health of Vietnam Veterans, Mr. Richard Christian of the Environmental Support Group (ESG) invited the committee to visit his operation. The ESG is responsible for locating troops and spray paths in Vietnam. On March 7, a subset of this committee (Drs. Becker, Greenhouse and Weiss) conducted a site visit to the ESG; they were accompanied by Rita Schinnar (consultant to the Committee), Heather Miller (IOM Program Officer), and Professor Wesley Yates (University of California, Davis), an agricultural engineer and recognized expert in herbicide drift who has agreed to serve as an advisor to the committee on issues relating to herbicide spray. This report summarizes the March 7th site visit.

Those attending this site visit (hereafter referred to in this document as the subcommittee) heard a brief description of a pilot study now in progress at ESG that will be completed by early May. The objectives of the pilot study were (1) to identify problems in implementing strategies to locate troops and fixed wing sprays (Ranch Hand sprays) in Vietnam, and (2) to determine whether or not a sufficient number of veterans with possible exposure to Agent Orange can be identified using these methods.

The subcommittee was also shown a video tape of actual rotary wing and ground spray activities in Vietnam as well as Ranch Hand

operations. There was discussion about the techniques and frequency of perimeter sprays, and about the factors which affect spray concentration and, therefore, exposure (thickness of foliage, sun, wind drift, temperature, season, droplet concentration). ESG estimates (from Services Herbs and Ranch Hand Tapes) that approximately 10% of all Agent Orange used in Vietnam was applied by ground sprays, the remainder having been applied through Ranch Hand missions. Dr. Bricker of ESG estimated that only about 30% of the herbicide reached the ground when there was foliation coverage. He added that perimeter sprays applied the herbicide on previously sprayed areas where growth was sparse and ground more accessible to the herbicide.

ESG Operations

ESG has identified a total of 122 combat battalions which, between 1966 and 1969, operated in the III Corps tactical zone for at least a 1.5 year period. III Corps zone was the site of the most intensive Agent Orange spraying. From these 122 combat battalions, 65 were identified as having spent the longest period of time in that zone, and only these 65 will be included in the main Agent Orange Study (should it go forward). The main study will include 325 companies from these 65 battalions. ESG is charged with identifying the daily locations of operation for these companies from the last 3 months of 1966 through the first 3 months of 1969, using a hierarchical system of military record analysis to ascertain or infer the location of units. By relating information on unit location to information on location of Ranch Hand spraying of Agent Orange, ESG will classify the

companies as "exposed" or "not exposed" (i.e., either falling within or outside an exposure area). Finally, by reviewing military personnel files and identifying individual veterans serving in the respective companies, ESG expects to supply the CDC with the names of 8,500 subjects with "high" likelihood of exposure and 8,500 subjects with "no" or "little" likelihood of exposure. The CDC, in turn, expects to interview 12,000 subjects and conduct physical examinations on 4,000 of them.

To identify individuals with potential exposure to Agent Orange, the ESG is currently using the definition of "within 2 miles and 3 days" or "within 2 miles and 6 days" of a spray. ESG does not distinguish between "low" exposure and "no" exposure, but only attempts to determine whether or not a company was within the exposure area. The current study design calls for 2 cohorts, both to be selected from the III Corps tactical zone.

The pilot study includes 7 battalions (approximately 35 companies). These battalions were selected because they met the following criteria established by CDC:

(1) they had records available for the period October 1966 to March 1969;

(2) they had known "hits" and sizeable exposure to herbicide; and

(3) they required the least amount of record "gap" filling.

Some of the characteristics for battalions, such as "gaps" and "hits", were known from previous exercises in matching battalion locations with locations of sprays. A "gap" is defined as no location for 1 day

for 1 unit. If a unit had more than 60 gaps in a year, or if there were 30 consecutive gaps, that unit would be excluded from the study.

In the pilot study, the ESG makes reference to every military record possible to help track the locations of these companies. Each record is searched for location by grid coordinates, and each coordinate identified from records is verified by an artillery expert. The ESG told the subcommittee that its ability to make determinations on company locations has been hampered by CDC-imposed constraints. The ESG also pointed out that there is a considerable loss of numbers of veterans with potential exposure from the study because of CDC's stringent eligibility requirements. Specific examples of the ESG's objections to these requirements include:

(1) Inability to extrapolate location from non-grid data:
the ESG believes that for companies with missing grid locations or with missing dates, one can reconstruct location from careful analysis of battalion daily journals and ORLL (Operation Reports - Lessons Learned) reports. Using what is referred to as "contextual analysis," the ESG employs a fixed algorithm to fill in gaps, and feels confident in its ability to fill in the gaps by interpreting the contents of these records. ESG is using the contextual approach in the pilot study, but thus far has not been authorized to do so in the main study.

(2) Selection of subjects:
the ESG said that it could identify several cases where individuals had 10 or more exposures but were excluded from

the study because they do not meet another CDC eligibility criterion which specifies that subjects have 180 days of combat in a line unit within 1 year. If such subjects had 170 days of combat and were then moved into a headquarters unit they were not included in the study, regardless of the number of exposures which occurred prior to transfer.

(3) Selection of subjects:

All headquarters people are automatically excluded from the study. It has been presumed that one cannot keep track of the duties and activities of people on headquarters premises. However, the ESG believes (on the basis of personal observations and experiences of their personnel in Vietnam) that headquarters and firebase personnel may actually be more exposed than other field personnel due to repeated spraying of the perimeters of these bases by non-Ranch Hand operations. Ranch Hand operations were designed to drop 2-3 gallons of herbicide per acre, while perimeter sprays released 5-6 gallons per acre directly on previously sprayed areas with less dense vegetation. Perimeter sprays occurred approximately every 5 weeks. Another argument that the ESG presented which raises questions about the exposure of field troops involved the potential for exposure immediately after or during a Ranch Hand spraying. Fighter jets flew ahead of Ranch Hand planes to protect these slow, low flying aircraft from ground fire. It was well known that the fighters would occasionally have to strafe the spray path (approximately 260 feet wide, give or take 20 feet), thus decreasing the likelihood that Army

personnel would be located directly under a spray path.

(4) The ESG has instituted a quality control system. 5 percent of records abstracted in the morning and 5 percent of records abstracted in the afternoon are reviewed every day. When discrepancies or gaps were identified, a two person team worked out a solution to the problem. Because consensus among judges was used rather than assessment by a series of independent judges, the issue of interjudge reliability is moot. Quality control is also applied to gap filling and to keypunch operations. It should be noted, however, that when mistakes are corrected and gaps are filled, the ESG does not record the places or numbers of such occurrences. Hence, it is not possible to determine the proportion of data affected by quality control measures.

The following is a synopsis of the subcommittee's reactions to the pilot study and to other issues raised at the ESG site visit.

- The subcommittee is satisfied that the ESG is capable of determining locations and filling gaps using a contextual approach, and notes that the ESG exhibits a high degree of competence in recording data gathered from these activities.
- Although there is a significant amount of inference used to establish the locations of troops, the subcommittee was satisfied with the ESG's documented Standard Operating Procedure to fill in gaps, and was also satisfied with the methods used by teams or pairs to resolve questions which arose during contextual analysis.

- The subcommittee raised concerns about the degree of "blindness," on the part of individuals determining location, to a unit's level of exposure; however, they were assured by the ESG that location decisions are made independent of any information on exposure.
- The subcommittee was satisfied with the ESG's quality control program. However, they would like to see the ESG monitor the changes which occur from quality control measures in a more precise fashion.
- The subcommittee was concerned about the use of discrete categories to define exposure (e.g., exposure vs. non-exposure), and instead favors measuring exposure as a continuous variable. Indeed, the subcommittee favors the use of continuous variables whenever possible. The use of discrete categories in data collection stages essentially discards valuable information, and such data can be stratified for subsequent analyses.
- The subcommittee was perplexed about criteria established by CDC to select subjects, especially the 180 day cutoff for combat time and the exclusion of headquarters-based individuals exposed to perimeter sprays.
- The subcommittee strongly favors reinstituting the third cohort in the study (i.e., noncombat nonexposed veterans selected from areas in Vietnam outside the III Corps tactical zone) in order to have a comparison group of truly unexposed veterans. The subcommittee is less concerned about differences in samples imposed by selection of the third cohort from outside the III Corps tactical zone than it is

about the potential for exposure misclassification for individuals selected exclusively from within this zone.

- The subcommittee was impressed by several factors that were illustrated in the video tape on ground sprays. Airplanes and helicopters varied greatly in the precision of spray deposition of the herbicide. Spray from helicopters was often delivered through uneven-size holes crudely drilled into pipes attached to the helicopter or through equipment designed for insecticide application which produced much finer atomization which in turn carries a higher potential for drift. The equipment used in rotary wing sprays illustrated in the video tape represented technological improvisation - such devices were not designed for herbicide spraying; by contrast, fixed wing aircraft delivered standard size droplets (367 microns) from equipment specifically designed for this task. Leaks and crudely constructed equipment had the capacity to significantly vary the amount of herbicide delivered.
- The subcommittee was impressed by the contribution of wind to actual spray delivery. The video tape illustrated that, in the presence of wind, substantial horizontal deviation from the expected perpendicular spray path occurs. The subcommittee questioned the exposure of a person standing within 1 km of the spray path under windy conditions.
- The subcommittee was also impressed by the type of spraying that occurred from non-Ranch Hand delivery. Ground sprays used every conceivable type of vehicle and hand carried equipment. River banks, communication lines, and open

highways were regularly sprayed, as were the perimeters of headquarters and fire bases. The video tape clearly showed handlers of the herbicide who wore no protective garments, no masks, and sometimes not even a shirt. Individuals spraying from the back of trucks and men spraying from helicopters with open doors were visibly sprayed themselves as wind blew the droplets back on them. The ESG presented anecdotal data describing herbicide "spray fights," where men would hose each other down with Agent Orange or other substances just "for fun."

- The information on aborted missions also raised questions for the subcommittee. An aborted mission would dump up to 970 gallons of Agent Orange within a very small area. Data was presented on one aborted mission in which the dump occurred on a headquarters as the plane tried to land shortly after takeoff upon discovery of an engine malfunction. In at least one instance, headquarters personnel were exposed to the preponderance of 970 gallons of Agent Orange. There are 9 aborted missions on record which led to dumps plus 1 crash. The altitudes at which the dumps occurred varied from 150 feet to 5,500 feet.

The subcommittee met in closed session in the afternoon to summarize their impressions from the site visit. The subcommittee made the following observations:

* The subcommittee is concerned about the exposure which occurred though non-Ranch Hand sprays. While the Ranch Hand Study showed no significant increase in mortality or morbidity for men participating in fixed wing operations**, the subcommittee wondered about the risk for those who lived on the ground with low-dose chronic exposure from perimeter and other ground sprays. There was potential for exposure through air, water, dirt, food and "just clean fun." They expressed concern about the men who conducted the ground sprays and the ones who hosed each other for a good time. The subcommittee would like to see verification of anecdotal reports.

** [Ranch Hand Study summary from Michael Gough's "Dioxin, Agent Orange: The Facts:

The Ranch Hand Study compared the mortality statistics of the 1,269 men who participated in fixed wing Agent Orange spray missions to a cohort of other Air Force members who flew the same type of aircraft in Vietnam but who did not spray Agent Orange. To increase the power of the study, the non-Ranch Hand cohort was 5 times the size of the Ranch Hand cohort. The Ranch Hand cohort included men who shipped, handled and loaded Agent Orange, those who flew spray missions, and those who cleaned planed and equipment.

Overall death rates analyzed by race and occupation of subjects (i.e. pilot, navigator, flight engineer-enlisted, and other enlisted men) showed no statistically significant differences between the cohorts. Ranch Hand enlisted men,

who are thought to have a greater opportunity for exposure, has the same mortality rates as Ranch Hand officers. Mortality statistics by specific cause of death showed an increase in rates in Ranch Handers for homicide and digestive system disorders, but lower rates for cancer. No difference, however, was statistically significant.]

* The subcommittee expressed concern about the definitions currently used to determine exposure. Issues related to the use of continuous versus discrete variables to measure exposure as well as wind dispersion and distance covered by spray have already been discussed (above). However, there remain questions about time, including the relationship of troop location to spray location with respect to time, and the half-life of dioxin (dislodgeable from plant surfaces? on soil? in human tissue?). The committee questions how "time" and residues will be built into the determination of exposure.

* The subcommittee was impressed by the amount of information available to the ESG on issues related to spraying, including wind direction and velocity, temperature, time of spray, season, the specific substance sprayed, and type of aircraft used. However, there is some concern that such data appear "hard," and in fact, may be much "softer." It must be remembered that these data were collected under combat conditions and that accuracy remains a question.

* The subcommittee had questions about scoring individual exposures. The criteria used to define exposure and to define who will be included in the study seem arbitrary and

confusing. For example, if an individual was under a "dump" from an aborted mission, he would be coded as having a single hit. However, the actual exposure he received might be very much higher than that experienced by an individual 1 kilometer from a flight path on a windy day (who would nonetheless receive the same exposure score). If the individual experienced the dump within the confines of a headquarters base, as was the case for the aborted landing mission, he would not qualify for inclusion in the study. The subcommittee concurred with the ESG that there appear to be many exposed individuals who will be excluded from the study as it is now designed. The subcommittee questions the rationale for excluding headquarters-based companies from the study. They would like an explanation on how combat and noncombat duty relate to exposure, given that both types of duty can occur in a combat zone, and that both appear to give an individual the potential for exposure. In addition, the ESG has data on 1,100 individuals in the chemical units that were attached to each battalion. Chemical units were responsible for herbicide supply, and for herbicide distribution in non-Ranch Hand sprays. It is not clear that only chemical unit personnel were involved in ground sprays; other personnel may also have been used. However, the subcommittee concurred with the ESG that some special examination of these individuals is important. The subcommittee concluded that there appear to be different kinds of exposure, and that individuals were exposed under a variety of conditions; these issues need to be addressed

more carefully. The subcommittee finds the current definition of exposure to be inadequate.

* The subcommittee feels that the range which exists in types of exposure makes a strong argument for reinstating the third cohort (noncombat, nonexposed) in the Agent Orange study, since it appears that everyone in the combat zone had the opportunity for exposure.

* The subcommittee is under the impression that, in the main study, the ESG will only be responsible for determining the locations of companies and spray paths. Dr. Carl Keller's Science Panel of the Agent Orange Interagency Working Group is currently trying to define "exposure." The subcommittee strongly believes that the ESG should only be responsible for providing CDC with the raw data on locations. There was considerable interest expressed by individuals at the ESG in participating in modeling exposure data. The ESG has two of its employees on Keller's exposure-definition group (Christian and Bricker). The subcommittee does not feel that the ESG is qualified to conduct such analyses, and suggests that CDC should be responsible for all data analyses.

* In addition, the subcommittee, upon examination of the membership roster of Keller's Science Panel, was concerned about the thinness of expertise in certain areas. They expressed interest in knowing exactly who will be responsible for defining exposure and what criteria they will use to make this determination. Staff cautioned the subcommittee that he who finalizes the definition of exposure will be the one to determine if the Agent Orange Study will go forward. Staff

reminded subcommittee members that this is not an appropriate role for this committee.

[In response to the concern of the subcommittee regarding the panel defining exposure, and to similar concerns expressed by the CDC, staff have made an appointment with Dr. Keller to discuss the process and progress of his group in defining exposure.]

* The subcommittee would like to ask the CDC to clarify why they dropped the third cohort, why they are using cutoffs to define exposure, and how it derived criteria for eligibility.
* The subcommittee concluded that the ESG appears to be doing a reasonable job of determining locations, and the subcommittee is of the opinion that the contextual approach improves the quality of the data. However, they would like to see the ESG record the number of gaps filled in by contextual analysis, as well as the number of times disagreements are found in the data.

NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE
WASHINGTON, D. C. 20418

INSTITUTE OF MEDICINE
MEMORANDUM

TO: Dr. Samuel W. Greenhouse
Dr. Scott T. Weiss
Dr. Marshall H. Becker
Ms. Rita Schinnar

FROM: Heather Miller

DATE: February 11, 1986

SUBJECT: Site Visit to the Environmental Support Group (ESG)

At the January 31 meeting, Mr. Christian extended an invitation to the committee to visit the ESG. Another invitation was extended by Dr. Flynn of DoD. Due to time constraints at the meeting, Mr. Christian was unable to describe the methods used to locate troops and sprays. He would appreciate the opportunity to present this information to you.

The date of the site visit will be March 7, as we discussed over the phone. In order to arrive en masse, we should meet at 9:00am in my office which is in the Joseph Henry building at the intersection of 21st and Pennsylvania Avenue, N.W., Room 751. Mr. Christian is expecting us at 9:30am. Should we get separated, his office is located in Room 210, 1730 K St., N.W. and his telephone number is 653-1828.

In addition to discussions about Ranch Hand spray location methods, Mr. Christian would also like to talk about ground perimeter spraying and aerosol dispersion factors. He would like to show us a videotape of the ground spray operations. Dr. Spear, the advisor to the committee on herbicide exposure, is unfortunately not available on March 7. I am now looking into the possibility of finding another individual with his expertise (in herbicide spray drift and ground spray issues) to participate in this site visit.

Our visit with Mr. Christian will probably take up most of the morning. I would like to meet with you after lunch to discuss the important points from the morning's presentation. I feel that it is important to be able to put in writing a brief summary of Mr. Christian's presentation as well as any assessment you may wish to make. This will enable us to keep the entire committee informed of issues and concerns as they evolve. In the event that you feel that a formal statement should be made to CDC, this summary will be extremely useful in drafting such a document. I would expect that we could complete this discussion by 4:00pm.

If you would like help with hotel reservations, please call Deborah Herbert at 202-334-2453. If you have any other questons or problems, don't hesitate to call me at the same number. I am more easily reached in the morning. I look forward to seeing you March 7. In the mean time, you might want to take another look at Book 4: Exposure Assessment (brown handout book) which provides some background information on ESG issues.

INSTITUTE OF MEDICINE
Site Visit to the Environmental Support Group (ESG)
March 7, 1986

AGENDA

9:00am	Meet at the NAS, Joseph Henry Building Room 751, 21st Street, N.W. and Pennsylvania Avenue
9:30am	ESG Presentation Room 210, 1730 K Street, N.W.
12:30pm	Lunch - NAS - Joseph Henry Building
1:30pm	Deliberations, Preparation of Summary Statement NAS, JH-750
4:00pm	Adjourn