**Union Calendar No. 415**

101st Congress, 2d Session - - - - - - House Report 101-672

# THE AGENT ORANGE COVERUP: A CASE OF FLAWED SCIENCE AND POLITICAL MANIPULATION

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## TWELFTH REPORT

BY THE

## COMMITTEE ON GOVERNMENT OPERATIONS

together with

DISSENTING VIEWS

AUGUST 9, 1990.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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## LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
*Washington, DC, August 9, 1990.*

Hon. THOMAS S. FOLEY,
*Speaker of the House of Representatives,*
*Washington, DC.*

DEAR MR. SPEAKER: By direction of the Committee on Government Operations, I submit herewith the committee's twelfth report to the 101st Congress. The committee's report is based on a study made by its Human Resources and Intergovernmental Relations Subcommittee.

JOHN CONYERS, Jr., *Chairman.*

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## VIEWS

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# THE AGENT ORANGE COVERUP: A CASE OF FLAWED SCIENCE AND POLITICAL MANIPULATION

AUGUST 9, 1990.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. CONYERS, from the Committee on Government Operations, submitted the following

## TWELFTH REPORT

together with

## DISSENTING VIEWS

BASED ON A STUDY BY THE HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

On August 2, 1990, the Committee on Government Operations approved and adopted a report entitled "The Agent Orange Coverup: A Case of Flawed Science and Political Manipulation." The chairman was directed to transmit a copy to the Speaker of the House.

### I. EXECUTIVE SUMMARY

The Human Resources and Intergovernmental Relations Subcommittee conducted a year-long investigation of the studies of Agent Orange exposure and Vietnam veterans' health conducted by the Centers for Disease Control (CDC) from 1982 to 1987. The exposure study was intended to be the first comprehensive effort by the Federal Government to determine the magnitude of Agent Orange exposure to U.S. military personnel serving in Vietnam during the war years. The separate health review is the largest medical study of Vietnam veterans undertaken by the Federal Government.

The subcommittee's investigation included an extensive review of documents related to the studies at the CDC Center for Environmental Health and Injury Control in Atlanta, Georgia. Interviews

were conducted of current and former CDC employees. The records of a White House panel, the Agent Orange Working Group (AOWG), were obtained from the U.S. National Archives and the Reagan Presidential Library, and reviewed by subcommittee staff. Interviews were also conducted of military records experts, epidemiologists, and environmental authorities employed by Federal agencies, veterans service organizations, and universities.

Agent Orange, so named for the orange stripe on the 55-gallon drums in which it was stored, was a herbicide used by the U.S. military during the Vietnam War to defoliate forests that concealed the activities of the enemy. It was a mixture of two chemical ingredients, the *n*-butyl esters of 2,4-D and 2,4,5-T. One of these chemicals, 2,4,5-T, contained 2,3,7,8-tetrachlorodibenzo-*p*-dioxin. Known simply as dioxin, the chemical is considered one of the most toxic chemicals every created synthetically, and has proven to be carcinogenic in animal studies.

The study had been mandated by Congress more than a decade ago. The Veterans Health Programs Extension and Improvement Act of 1979 authorized the Veterans Administration (VA) to design and conduct a study to assess the exposure of Vietnam veterans to Agent Orange. In 1981, Congress enacted the Veterans Health Care, Training, and Small Business Loan Act, which expanded the scope of the VA study to include a health study of Vietnam veterans, using service during the war as an exposure factor, exposure to Agent Orange notwithstanding.

The CDC Agent Orange Exposure Study was canceled in 1987 when a White House panel, the AOWG, concluded that military records could not be used to assess exposure to the herbicide. The health status study was published in 1989, and a final study on selected cancers among Vietnam veterans was released in 1990.

The committee finds that the Agent Orange exposure study should not have been canceled because CDC did not document that exposure could not be assessed, nor did it explore alternative methods of determining exposure. The committee concludes that other methods of determining exposure were available to CDC, but intentionally disregarded.

The committee's report concludes that the CDC study was changed from its original format so that it would have been unlikely for the soldiers who received the heaviest exposure to the herbicide to be identified. CDC accomplished this by unjustifiably discrediting the military records provided to it by the Department of Defense's Environmental Study Group (ESG). The key alteration was CDC's decision to track troop movements using broad battalion records, which are less precise than the company-level records the Agency had originally intended to use to follow troop positions during the Vietnam War.

After restricting the study by eliminating thousands of veterans who would have been most likely to have been exposed to Agent Orange, CDC attempted to validate its flawed exposure definitions with a test to identify traces of dioxin in the blood of the veterans who had been studied. When the blood test failed to find elevated levels of dioxin in the veterans' blood, the White House instructed CDC to halt the study. The committee found that the blood test was based on flawed and manipulated estimates of the ability of

dioxin to remain in human blood 20 years after exposure. The weight of scientific evidence indicates that dioxin cannot be traced in all veterans who were exposed to Agent Orange two decades ago.

The committee also concludes that the CDC study was controlled and obstructed by the White House, primarily through its AOWG and the Office of Management and Budget (OMB), because the Reagan administration had adopted a legal strategy of refusing liability in military and civilian cases of contamination involving toxic chemicals and nuclear radiation.

The report's final conclusion is that the Federal Government has suppressed or minimized findings of ill health effects among Vietnam veterans that could be linked to Agent Orange exposure. Federal studies have found that Vietnam veterans are more susceptible to diseases such as non-Hodgkin's lymphoma and soft tissue sarcoma. Studies have also concluded that the offspring of Vietnam veterans suffer higher incidences of certain birth defects, such as cerebrospinal malformations, and that Vietnam veterans have sperm malformations and low sperm counts. The Federal Government has consistently refused to acknowledge any link between these diseases and Agent Orange, even though the maladies are known consequences of herbicide exposure in the civilian workplace.

The committee recommends that Congress mandate the creation of an accurate Agent Orange exposure index, and that the index be used, through a contract to a private organization, to conduct an independent epidemiological study of the effects of the herbicide on Vietnam veterans. The committee also recommends that the White House be barred from interfering with all Federal scientific research.

## II. Introduction

Under the House of Representatives' Rule X, 2(b)(2), the Committee on Government Operations is authorized to "review and study, on a continuing basis, the operation of Government activities at all levels with a view to determining their economy and efficiency." The committee has assigned this responsibility, as it pertains to the Department of Health and Human Services (HHS) and, its component, the Centers for Disease Control (CDC), to the Human Resources and Intergovernmental Relations Subcommittee.

Pursuant to its authority, the subcommittee conducted a two-year investigation of the studies of Agent Orange exposure and Vietnam veterans' health conducted by CDC from 1982 to 1987 and other studies of herbicides as a cause of disease. The exposure study was intended to be the first comprehensive effort by the Federal Government to determine the magnitude of Agent Orange exposure to U.S. military personnel serving in Vietnam during the war years. The separate health review is the largest medical study of Vietnam veterans undertaken by the Federal Government.

The subcommittee's investigation included an extensive review of documents related to the two studies at the CDC Center for Environmental Health and Injury Control in Atlanta, Georgia. Interviews were conducted of current and former CDC employees who worked on the studies. The records of a White House panel, the

Agent Orange Working Group (AOWG), were obtained from the U.S. National Archives and the Reagan Presidential Library, and reviewed by subcommittee staff. Interviews were also conducted of military records experts, epidemiologists, and environmental authorities employed by Federal agencies, veterans service organizations, and universities.

The subcommittee's investigation included two public hearings, which were conducted on July 11, 1989,[1] and June 26, 1990.[2] The following witnesses testified at the first hearing: Honorable Lane Evans, a Representative in Congress from the State of Illinois; Lawrence B. Hobson, M.D., Ph.D., Director, Office of Environmental Medicine, Department of Veterans' Affairs, accompanied by Donald Ivers, acting general counsel, and Fred Conway, special assistant to the general counsel; Vernon N. Houk, M.D., Director, Center for Environmental Health and Injury Control, Centers for Disease Control; Michael Kafrissen, M.D., former medical epidemiologist, Centers for Disease Control; Philip J. Landrigan, M.D., director, Division of Environmental and Occupational Medicine, Mount Sinai School of Medicine; Ellen K. Silbergeld, Ph.D., director, Toxic Chemicals Program, Environmental Defense Fund; Dennis M. Smith, M.D., former visiting scientist, Centers for Disease Control; John F. Sommer, Jr., director, National Veterans Affairs and Rehabilitation Commission, the American Legion; Jeanne M. Stellman, Ph.D., epidemiologist, American Cancer Society; Steven D. Stellman, Ph.D., Assistant Commissioner for Biostatistics and Epidemiologic Research for the Department of Health of the city of New York; and Mary R. Stout, president, Vietnam veterans of America.

The following witnesses testified at the second hearing: Richard W. Clapp, M.P.H., Sc.D., director, Environmental Health Studies, JSI Research and Training Institute; Peter C. Kahn, Ph.D., Associate Professor of Biochemistry, Rutgers University; Arnold Schecter, M.D., M.P.H., Professor of Preventative Medicine, State University of New York Health Science Center; Ellen K. Silbergeld, Ph.D., senior scientist, Environmental Defense Fund; Daniel Thau Teitelbaum, M.D., president, Medical Toxicology Partnership; Shelia Hoar Zahm, Sc.D., epidemiologist, National Cancer Institute; and Admiral Elmo R. Zumwalt, Jr., USN Ret., Special Assistant to the Secretary of Veterans Affairs.

## III. Background

Agent Orange, so named for the orange stripe on the 55-gallon drums in which it was stored, was a herbicide used by the U.S. military during the Vietnam War to defoliate forests that concealed the activities of the enemy. It was a mixture of two chemical ingredients, the *n*-butyl esters of 2,4-D and 2,4,5-T. One of these chemicals, 2,4,5-T, contained 2,3,7,8-tetrachlorodibenzo-*p*-dioxin.

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[1] Hearing before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "Oversight Review of CDC's Agent Orange Study," July 11, 1989, hereinafter referred to as "Hearing, 1989."

[2] Hearing before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "Links Between Agent Orange and Other Herbicides With Diseases," June 26, 1990, hereinafter referred to as "Hearing, 1990."

Known simply as dioxin, the chemical is considered one of the most toxic chemicals ever created synthetically, and has proven to be carcinogenic in animal studies.

According to the Office of Environmental Medicine in the Department of Veterans' Affairs, 15 different herbicides were used in Vietnam between January 1962 and September 1971. More than 80 percent of the defoliation operations used Agent Orange, which was sprayed primarily between January 1965 and April 1970. Among the other herbicides used prominently were Agent White, which also contained 2,4-D, and Agent Blue, which consisted of an organic arsenic compound called cacodylic acid. Less than 7 percent of the total acreage sprayed during the Vietnam War was covered prior to 1965. Most of the spraying occurred from 1966 to 1969. Overall, more than 20 million gallons of herbicides were sprayed upon 6 million acres. More than 3.5 million acres were sprayed more than once.

Herbicides were used for three main purposes during the Vietnam War. The principal uses were to defoliate military areas to improve observation, and to destroy crops to diminish the enemy's food supply. A third purpose was to clear vegetation around fire bases and such installations, around landing zones, and along lines of communication. Herbicide usage began in 1962, was expanded in 1965 and 1966, and peaked from 1967 to 1969. Herbicides were phased out in 1970 when it was learned that mice exposed to the chemical components of the herbicides bore offspring with birth defects.

Most of the herbicides were sprayed from fixed-wing aircraft in a project called, "Operation Ranch Hand." But herbicides were also sprayed from helicopters, trucks, riverboats, and hand applicators.

Spraying occurred in all military zones of Vietnam. The most heavily sprayed areas included inland forests near the demarcation zone, inland forests at the junction of the borders of Cambodia, Laos, and South Vietnam, inland forests north and northwest of Saigon, mangrove forests on the southern-most peninsula of Vietnam, and mangrove forests along major shipping channels southeast of Saigon. Crop destruction missions were concentrated in northern and eastern central areas of South Vietnam.

Many Vietnam veterans believe their exposure to Agent Orange has caused a variety of ailments, including cancer, birth defects, and emotional disorders linked to neurological dysfunction. Their concerns are heightened by what science has discovered about the possible effects of dioxin exposure but, also, by what is not known about the chemical's effects on humans.

Dioxin is the useless, unwanted byproduct from the production and use of chlorinated phenols. Environmental hazards have also been caused by toxic compounds related to dioxin, such as polychlorinated biphenyls (PCB's), polybrominated biphenyls (PBB's), polychlorinated dibenzofurans (PCDF's), polychlorinated naphthalenes, and polychlorinated terphenyls.

Dioxin is omnipresent, existing in household products, dust particles, and water. It has been found in significant levels across the world. Millions of people have been exposed to it through industrial accidents, fly ash from waste incinerators, herbicide spraying, manufacturing plants, and even in some edible fish.

There is no disagreement among scientists that dioxin in its pure form is the most toxic synthetic chemical in existence. Fortunately, humans are never exposed to undiluted amounts of the substance. It occurs as trace quantities in the ranges of parts per billion or parts per million as a contaminant in other products. Sometimes—in the case of fish, for example—it occurs in parts per trillion, or, in the case of water, parts per quadrillion.

Animal experiments have found dioxin toxicity to be dose-related. At low doses, there are no observed toxic effects of dioxin in animals. However, in high doses, various species have developed such diseases as hepatic necrosis and T-cell depression. Increased incidences of cancer were observed in most species exposed to dioxin during laboratory experiments.

Corresponding dose-related research cannot be legally or morally conducted on humans. However, there is some limited information about the effects of dioxin on humans as a result of inadvertent exposure from industrial accidents. A recent accident occurred in Seveso, Italy, when a cloud of trichlorophenol and dioxin spread over seven square miles of populated territory. In another accident, transformer fluid was inadvertently mixed with rice oil, affecting seven thousand people who ingested the toxic oil in Japan and Taiwan. Similar accidents occurred in West Virginia, New Jersey, and England. The most severe accidents to date occurred in West Germany and Czechoslovakia. The most well-known dioxin incidents in the United States probably were the Times Beach, Missouri, and Love Canal, NY, disasters, when dioxin from an industrial plant had seeped into the soil of residential communities.

The most serious health consequences of these accidents were neuropathy and liver damage in approximately one-third of the victims of the incidents in West Germany and Czechoslovakia. There were similar consequences of the West Virginia and New Jersey accidents. The most prevalent reaction to dioxin contamination—which may be a marker of exposure and a warning sign for disease that can take decades to develop—is the skin condition, chloracne, a painful and extremely annoying ailment, but not life threatening. Chloracne has occurred in workers and residents exposed during most industrial accidents where high levels of dioxin were released.

Some studies of industrial accidents involving dioxin have found incidences of soft tissue sarcoma, a rare form of cancer, in those exposed to the chemicals, but some in the scientific establishment consider the numbers of study subjects too small to carry the weight of significance. The U.S. Centers for Disease Control, in a recent study of Vietnam veterans, found that veterans who had served in Vietnam had significantly higher incidences of non-Hodgkin's lymphoma, another rare illness, but dismissed any possible connection to Agent Orange exposure, instead claiming it did not know why the veterans had higher levels of the disease. In March 1990, the CDC report prompted the Department of Veterans' Affairs to declare non-Hodgkin's lymphoma a monetarily compensable, service-connected disease, but the Department did not link the illness to Agent Orange exposure. In May 1990, the Department also declared soft-tissue sarcoma, a rare cancer, to be a service-connected, compensable malady for Vietnam veterans on the basis of a

report by the Department's Veterans Advisory Committee on Environmental Hazards, which found that herbicides may have caused the disease.

The rationale behind the U.S. Government's refusal to accept any causal effects between Agent Orange and all but a few diseases stems from the CDC exposure study, which was canceled when the Agency declared such a study to be scientifically impossible.

The study had been mandated by Congress more than a decade ago. The Veterans Health Programs Extension and Improvement Act of 1979 authorized the Veterans Administration (VA) to design and conduct a study to assess the exposure of Vietnam veterans to Agent Orange. In 1981, Congress enacted the Veterans Health Care, Training, and Small Business Loan Act, which expanded the scope of the VA study to include a health study of Vietnam veterans, using service during the war as an exposure factor, exposure to Agent Orange notwithstanding.

The VA's efforts to conduct the study were mired in delays. In 1982, three years after passage of the Agent Orange study legislation, the agency had not even begun the study. The House and Senate Veterans Affairs Committees decided to transfer the study from the VA to the CDC, after the Director of the CDC Center for Environmental Health and Injury Control testified at a hearing that CDC could do the study better and faster than the VA. Less than a year later, Congress passed an appropriations bill containing $54 million, to be provided through the VA's budget, for CDC to conduct the Agent Orange study. Approximately $43 million of the appropriated funds were expended before the study was canceled.

CDC, like the VA before it, had two missions. One, to design and implement a study to measure the exposure of Vietnam veterans to Agent Orange, and the second to assess the overall health of Vietnam veterans. The latter mission was divided into two studies. The first study involved conducting physical examinations of the subjects and reviewing their medical records. The second part was a study of the incidence of selected cancers among Vietnam veterans.

In January 1989, CDC published the results of the separate health assessment, called the Vietnam Experience Study (VES), in five volumes. CDC claimed the study found little differences between the two cohorts involved: veterans who served in Vietnam and veterans who did not during the same time period. In early 1990, CDC published the Selected Cancers Study, which found that Vietnam veterans were at greater risk of one cancer, non-Hodgkin's lymphoma.

The exposure study was intended to be a landmark review. For the first time, formal scientific research would be conducted to determine which soldiers were in areas sprayed with Agent Orange. The exposure assessment study was canceled in September 1987, after the White House AOWG contended that it was scientifically impossible to assess the exposure of Vietnam veterans to Agent Orange due to the inadequacy of military records. The first and only attempt by the Federal Government to determine the exposure to Agent Orange by U.S. military personnel never reached a conclusion, other than that the study was impossible to do. The question foremost in the minds of Vietnam veterans and the Congress in regard to Agent Orange has still not been answered.

## IV. FINDINGS

### A. THE CDC AGENT ORANGE EXPOSURE STUDY SHOULD NOT HAVE BEEN CANCELED BECAUSE IT DID NOT DOCUMENT THAT EXPOSURE OF VETERANS TO THE HERBICIDE COULD NOT BE ASSESSED, NOR DID CDC EXPLORE ALTERNATIVE METHODS OF DETERMINING EXPOSURE

In its November 1987 final report, *Comparison of Serum Levels of 2,3,7,8-TCDD With Indirect Estimates of Agent Orange Exposure in Vietnam veterans,* the CDC concluded:

> The findings of this study and the conclusions from the AOWG [Agent Orange Working Group of the White House] Science Sub-Panel report on exposure assessment * * * do not identify any method for utilizing military records or self-reported exposure to distinguish between U.S. Army ground combat troops who were and were not exposed to Agent Orange in Vietnam, as would be needed for a cohort study of possible health effects.[3]

This conclusion was used as the basis by the White House and CDC to cancel the study and end all Federal attempts to study the link between Agent Orange and the health problems of Vietnam veterans.[4]

The law directing the U.S. Government to assess the exposure of veterans to Agent Orange was not specific about the method of study, only that a study be conducted. The final protocol for the study was left to the discretion of CDC, with the Congressional Office of Technology Assessment (OTA) and the Institute of Medicine (IOM) serving as peer reviewers. CDC could only abandon the study if no method to assess exposure could be identified at all. CDC reached just such a conclusion. The study was canceled when CDC and the White House Panel decided that no methods of any kind existed to use military records to distinguish between exposed and unexposed soldiers who served in Vietnam.

The subcommittee's investigation of the CDC study has established that other methods existed to assess exposure of veterans to Agent Orange. Therefore, CDC erred when it reported that it could not identify any method of determining exposure. Evidence compiled by the subcommittee demonstrates that other methods were available, but were ignored or dismissed by CDC.

CDC's mistake was described by Dr. Philip J. Landrigan, one of the foremost epidemiologists in the United States, who stated that the Agency had ignored a large group of veterans who had been potentially exposed to Agent Orange. He testified that the attempt to determine Agent Orange exposure in Vietnam veterans was analogous to an earlier effort by CDC to determine exposure to

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[3] "Comparison of Serum Levels of 2,3,7,8-TCDD With Indirect Estimates of Agent Orange Exposure in Vietnam veterans," Final Report, Agent Orange Projects, Division of Chronic Disease Control, Center for Environmental Health and Injury Control, Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services, November 1987, pp. 4–5.

[4] Hearing, 1989, pp. 55–57. Letter from James O. Mason, M.D., Dr. P.H., Assistant Surgeon General, Director, Centers for Disease Control, to Don Newman, Chair, Domestic Policy Council Agent Orange Working Group, October 28, 1987.

PBB, a toxic chemical related to dioxin, following an industrial accident in Michigan.

> In response to the disaster, just as in response to the Agent Orange episode in Vietnam, a series of epidemiologic studies were undertaken. The first of these studies was an investigation that was undertaken by our group at CDC in which I was the coprincipal investigator. . . .
>
> We conducted a survey in which we did physical examinations, took blood samples on a very carefully targeted list of people in Michigan who we identified through records of contaminated farms. In theses populations of people who were very carefully targeted, we found a very high proportion who had elevated serum levels of PBB. Their levels were roughly in proportion to the extent of their exposure.
>
> At about the same time Dr. Irving Selikoff . . . took this group into Michigan and did a statewide survey to determine the proportion of people in Michigan who had been exposed to PBB. He found . . . that only a small proportion of the people whom he tested had elevated serum levels of PBB.
>
> Now, Dr. Selikoff could have said on the basis of those findings that most residents of Michigan are not exposed to PBB and that statewide records do not constitute a good basis for identifying people in Michigan who have been exposed to this toxic compound. In other words, he could have drawn conclusions that would have been parallel in their content to the conclusions that CDC drew with regard to the exposure to dioxin in Vietnam.
>
> He didn't do that, though. He recognized the possibility that there might exist a heavily exposed subgroup within the population. . . . and he urged the need for further research. And, in fact that research still continues today.
>
> * * * * *
>
> I think the analogy is obvious and I think the question that confronts us today . . . is the question of whether there might exist within the population of millions of soldiers and marines and sailors and Air Force men who went to Vietnam a heavily exposed subgroup comprising maybe 5 percent, maybe 10 percent of the total, who were heavily exposed. There are several lines of evidence which suggest that such groups exist.[5]

In its final report, CDC contended that available military records regarding troop movements and the spraying of Agent Orange were insufficient to identify veterans who had been exposed to the defoliant; the purported inadequacy of the military records was the primary reason the exposure study was canceled and termed impossible to complete. The final CDC report stated:

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[5] Hearing, 1989. Testimony of Philip J. Landrigan, M.D., Director, Division of Environmental and Occupational Medicine, Mount Sinai School of Medicine, New York, NY, pp. 221-223.

> . . . At best, available military data permit only a probabilistic assessment of *opportunity* for exposure. Accurate individual exposures to Agent Orange cannot be determined because there is limited knowledge about the initial dispersion, biodegradation, and eventual ecologic disposition of Agent Orange in Vietnam; uncertainty about the absorption of Agent Orange or TCDD in humans; and the inability to determine the precise location of individual soldiers in relation to Agent Orange applications. Because of these uncertainties, the November 1983 protocol for the Agent Orange Study indicated that further pilot testing would be needed before a decision could be made to proceed with the full-scale study. . . . military records alone could not be used to estimate possible exposure of individual men to Agent Orange. In addition, some reviewers were concerned that too few men were identified as having "meaningfully high" exposure opportunity scores to warrant proceeding with a full-scale study.[6]

The CDC conclusion that military records could not be used to identify exposed veterans has been disputed by former CDC scientists, Department of Defense records experts, and prominent private sector epidemiologists.

Dr. Jeanne Stellman of Columbia University, who conducted an epidemiologic study for the American Legion, testified before the subcommittee that available records were quite sufficient to determine exposure to Agent Orange.

> . . . We are talking about 11,197,929 gallons sprayed on Vietnam that we know the locations of pretty well. In addition, Richard Christian's [7] group then picked up an additional 13 percent of what is now the total . . . tape records of 1,593,380 gallons of herbicides given off by fixed-wing aircraft, helicopters, and ground equipment such as backpacks, and something that everybody's always referring to [as] the unknown sources, but which, in fact, only represents 20,000 gallons.
>
> So this data that you heard being disregarded and tossed out as useless to evaluate veteran's health and well-being, in fact, is the tape that was developed and used by the National Academy of Sciences . . . we have here data on more gallonage and more usage of herbicides than I would say that we have in anyplace else including all the usage in the United States which we don't have a good handle on.[8]

Dr. Dennis Smith, a scientist who worked on the CDC Agent Orange Project, was one of the people responsible for evaluating records provided to CDC by the Department of Defense. He testified that the CDC staff had developed numerous alternatives to the approach the agency used to assess exposure, and that he and others at CDC believed sufficient information existed to compen-

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[6] Op. cit., p. 9. See footnote 3.

[7] Richard Christian directed the Department of Defense's Environmental Support Group, which supplied Agent Orange spray records and military troop movement records to CDC.

[8] Hearing, 1989, p. 158.

sate for gaps in the military records transmitted by the Pentagon. But, he testified, his superiors were resistant to exploring the alternatives.

> We didn't really inform people what we were doing. We should have publicized it to a greater extent and gotten more feedback on it. We had tremendous problems with developing exposure indices but they were not in creating new indices. We had many new indices and many different things to try and experiment with. But, we had problems in selling these indices to our superiors and people at the Office of Technology Assessment.[9]

Smith also testified that he believed CDC officials blamed certain gaps of information in the military records to cover up the problems CDC was having in identifying dioxin in the bodies of Vietnam veterans.

> Considerable concern arose over the scientific problems that plagued the Agent Orange Study, and an attempt was made to divert focus from these methodological issues to other areas that had origin or direction outside of Centers for Disease Control. The first, and most useful diversion, was to the fact that improper location data would destroy the usefulness of the exposure index. Regardless of any utility the data might have, if it was not "complete" (i.e. a troop location for every single unit on every single day) then it would be the troop location data that introduced the major error into the exposure index. Previous concepts of gap-filling, imputation, verification of troop locations, obtaining locations from other sources, etc. were no longer valid; the utility contained in the data already available from ESG [Environmental Support Group of the Defense Department] was ignored, and concepts developed that initially supported the data, such as "digit preference," were now directed against the ESG data.[10]

At one point during the performance of the study, Dr. Smith sought data from outside the Environmental Support Group to buttress the military records already obtained by CDC. On May 14, 1985, he sent a memorandum to the Chief Scientist of the CDC Agent Orange Project, detailing a visit to the Military History Institute and U.S. Army War College in Carlisle, Pennsylvania.

> . . . The historical records available at Carlisle appear to be of tremendous importance to our Agent Orange Projects in respect to several aspects of our interest in the Southeast Asia conflict. To wit: (1) Troop location; (2) Herbicide Missions; (3) Medical Information; (4) Possible models of troop movement; (5) Computer operations used during the time period of interest. The records provide expanded knowledge on these areas and help facilitate an understanding of the situations in Southeast Asia that

[9] Ibid. Testimony of Dennis M. Smith, M.D., former visiting scientist, Centers for Disease Control, p. 80.
[10] Ibid., pp. 93–94.

> might affect our projects. These records are great in number and generally are not indexed: researching a particular subject may be quite time-consuming, but in my "clinical impression," may be generally productive.[11]

In 1985, officials at the Defense Department's ESG discovered that CDC was disputing the accuracy of the military records. The ESG Chief of the CDC Support Branch, who was responsible for transmitting the records to CDC, warned that CDC did not understand how to use the records and appeared to be ignoring ESG's advice. The Chief noted that gaps in military tracking records could be filled with supplementary documents, such as company morning reports. In a memorandum to the Director of ESG, the CDC Support Branch Chief described how CDC had disputed, without justification, some records provided by ESG. Quoting from a CDC internal report, the Chief wrote:

> . . . ESG claimed that additional documents exist that might help place companies on a daily basis. ESG has not *claimed* anything, this statement is fact. Who are these experts who make decisions based on a computer distance comparison? For instance, the example CDC gives for Cu Chi taken from the morning reports substantiates the accuracy of the APO's that are listed. The grid coordinate and the APO number show the location as Cu Chi. What evidence does CDC have that indicates this unit was not at Cu Chi? This information was taken from official Army archival records. It must be stated for the record, that a morning report is a company document not a brigade or division record.[12]

The memorandum also expressed concerns that CDC was ignoring ESG's advice and preparing its own, incorrect, analyses of the military records. For example, CDC had dismissed the use of company morning reports to fill in missing locations in the main data base.

The ESG memorandum states:

> . . . Our main concern is that CDC does not keep ESG advised on these types of analysis until after the fact. Our expertise is U.S. Army combat unit records and troop movements, yet we have no idea if the proper grid coordinate locations were being compared. We feel a more detailed analysis needs to be performed on this information before a decision is made not to use morning report data.[13]

Richard Christian, who directed the ESG during the CDC study, testified that he had informed CDC on numerous occasions that records were available to address all of CDC's concerns about gaps

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[11] "Site Visit Summary, Carlisle Barracks: Military History Institute and US Army War College," Memorandum from Dennis M. Smith, M.D., visiting scientist, Centers for Disease Control, to Daniel L. McGee, Ph.D., Chief Scientist, Agent Orange Projects, Centers for Disease Control, May 14, 1985, p.1.

[12] "Centers for Disease Control Report to OTA," Memorandum for the Director from Donald C. Hakenson, Chief, CDC Support Branch, Department of the Army, U.S. Army and Joint Services Environmental Support Group, October 25, 1985, p. 1.

[13] Ibid., p. 2.

in the data base. Yet, CDC reported to OTA that sufficient records were not available to complete the exposure study. Christian testified:

> . . . I was investigated by the National Academy of Sciences on two occasions. The Science Panel of the White House Agent Orange Working Group was at my office numerous times. There were visits from the OTA to look at these records and it's just inconceivable to us and to the Environmental Support Group that they could say that those records were not adequate to do an Agent Orange study.[14]

Christian's testimony raised questions about the ability of the CDC staff to sufficiently comprehend and use the military records. He testified about being astounded when he discovered that CDC was identifying enemy locations when it thought it had pinpointed U.S. sites.

> At one point, the Centers for Disease Control attempted to take over the work of ESG from the study. My staff provided the CDC with copies of daily journals. In a test of that exercise, the personnel in the Centers for Disease Control recorded the grid points from the Viet Cong locations. Certainly we were not interested in the enemy locations; we were looking for the U.S. locations and the U.S. grid points.[15]

In an interim report in 1985, CDC claimed that the ESG had not provided gap-filling information, such as morning reports. Christian testified that the interim report was false.

> . . . If we traced the record of the Environmental Support Group back to 1981, I reported to Congress that there were several collections of records that would provide company information beginning with daily journals, operational reports of lessons learned, command reports, situation reports, intelligence reports, and morning reports.
>
> Yet in that interim report No. 2 . . . they indicate . . . that I didn't tell them about morning reports. Well, I don't know what else I could have done, with testifying before Congress four times, preparing a report at the International Dioxin Conference, laying out all of those types of records with 27 meetings with the VA before the CDC took over.
>
> Certainly everyone was aware of those collections.[16]

As the study ensued, the limitations in the methodology chosen by CDC prevented the Agency from identifying Vietnam veterans exposed to Agent Orange. A further constraint on the outcome was CDC's decision to use but one approach to identify exposed veterans when others existed.

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[14] Hearing, 1989. Testimony of Richard Christian, former Director of the U.S. Army and Joint Services Environmental Support Group, Department of the Army, pp. 42–43.
[15] Ibid., p. 42.
[16] Ibid., p. 41.

The committee believes that the decision by the White House to cancel the Agent Orange study was premature, and failed to give the Agency the opportunity to explore alternative methodologies. The justification for cancelling the studies—that military records alone could not be used to conduct an Agent Orange exposure study—was misleading. Clearly, better alternatives had not been fully considered before the study was canceled.

In particular, CDC did not attempt to identify the group of veterans described in Dr. Landrigan's testimony as being highly exposed. The Government was aware of situations where soldiers had been highly exposed, but this information was not considered by CDC. For example, a highly exposed group of veterans was discovered by the White House in 1981. According to a White House memorandum:

> Newly reviewed data shows that a plane taking off from the Bien Hoa Base in Vietnam on a date certain, discovered a faulty engine, turned left to go back to the air-strip, and promptly dumped 500 gallons of Agent Orange on the base camp from a height of 2,000 feet: the "dump value rate" of the plane used was 1,000 gallons in 30 seconds and suggests a high exposure to Agent Orange by a newly defined but as yet unidentified population.[17]

The memorandum states that files in the Office of the Army Adjutant General showed that there were 87 such aborted defoliating missions in Vietnam, and that 41 of the missions involved Agent Orange.[18] The White House was aware of the missions and their locations, yet CDC did not attempt to include the unknowing veterans who received these highly-concentrated exposures in its study.

### B. THE ORIGINAL PROTOCOL FOR THE CDC AGENT ORANGE STUDY WAS CHANGED TO THE POINT THAT IT WAS UNLIKELY FOR THE HEAVIEST EXPOSED SOLDIERS TO BE IDENTIFIED

It is important to remember that the Agent Orange exposure assessment study was designed to identify soldiers who were exposed to the herbicide, not to link disease to exposure. That would have come later had the study not been canceled. The only records available to CDC were the troop movement records and the Agent Orange spray data in the files of the Department of Defense. Therefore, CDC had to design the best method of using troop location information to match against the spray records.

But from the start, CDC disregarded the records of soldiers who would have been among the most likely to have been exposed. The original protocol for the CDC Agent Orange Study contained numerous restrictions which would have the effect of arbitrarily limiting the number and type of veterans selected for the study. The protocol states:

> CDC proposes to limit this study to draftees and single-term enlistees in the non-officer ranks who served in the Army (grades E1 through E5 only); selection will be fur-

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[17] "New Information Regarding Agent Orange," The White House, Memorandum from Shannon Fairbanks to Martin Anderson, September 9, 1981, p. 1.
[18] Ibid.

> ther limited to those who had only one tour of duty in Vietnam. Exclusion of officers is based primarily on a desire to make the groups as homogeneous as possible with respect to pre-existing demographic factors which could influence health. In addition, the inclusion of officers might require substantially increased record review to assess herbicide exposure potential . . . because of multiple tours of duty in Vietnam.[19]

CDC eliminated from the study all military service branches other than the Army. It excluded all officers and anyone who served more than one tour of duty in Vietnam. The reason for these exclusions was to reduce the amount of record review. Clearly only a small percentage of available records were reviewed by CDC.

The study group selection was also limited only to veterans serving in III Corps, thus eliminating six other combat corps stationed in Vietnam during the war.[20] The study group was also limited to the time period, 1967 to 1968.[21]

Importantly, the original protocol called for soldiers to be tracked according to company records because the data is the most precise and also because companies were the smallest units for which data was available. The use of company records would have enabled CDC to track individual soldiers. CDC recognized the importance of company records and was aware early on that the records could be incomplete. Still, the Agency's scientists believed the problem could be surmounted. CDC stated in the original protocol "that it is not necessarily wise to exclude a unit simply because some of its records are missing—units with missing records could have had more or less exposure to herbicides than units with complete records." [22]

The protocol reveals that the limitations in subject selection are due to expediency, particularly to prevent lengthy record reviews. For example, in deciding to exclude Marines from the study group, the protocol states:

> The desire to omit the Marine Corps from this study can now be more easily understood. If Marines were included, the records review and other selection tasks to this point would have to be done separately for them because they were largely stationed in I Corps, and this would cause delay.[23]

The original protocol documents that CDC intended to look only at a small portion of the records available, not because the data was unusable, but because Agency officials thought looking at all the records would require too much time. Yet, based on only a limited review of available records, the study was canceled in the end because CDC found military records could not be used to identify

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[19] "Protocol for Epidemiologic Studies of the Health of Vietnam veterans," Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services, November 1983, p. 10.
[20] Ibid., p. 11.
[21] Ibid., p. 12.
[22] Ibid.
[23] Ibid., p. 14.

veterans who had been exposed to Agent Orange. The committee questions CDC's conclusion that the records could not be used because CDC did not consider all the records.

The protocol also suggests that the study would have certain limitations beyond the restrictions CDC had placed on the subjects to be selected for cohorts. "Unavoidable limitations of the proposed studies, or indeed any other studies which could be done, will preclude describing the results as 'definitive'" the protocol cautioned.[24] The protocol stated that one important limitation was the observational, as opposed to experimental, nature of the study.

> . . . Another general caveat is that it is not possible to prove a negative—that is, it will never be possible to say with certainty that herbicide exposure or some other factor connected with Vietnam service did not cause any adverse health effects.
>
> * * * * *
>
> . . . Moreover, even in the absence of exposure misclassification, the studies will have low power for rare diseases and/or low increases in risk, or for increases in risk limited to those veterans with prolonged and/or heavy exposure to herbicides or some other harmful factor. Thus, an overall finding of no increase in risk might "hide" a real increase for specific disease categories or special groups of veterans.[25]

After preparing the original protocol, with all its limitations and caveats, CDC diluted the study even further by adding more restrictions to the criteria for the inclusion of subjects. A February 1985 internal, interim report reveals that CDC made four major modifications in the original protocol. The most serious modification was that:

> . . . Battalions—rather than companies—will serve as the basis for cohort selection and unit location.
>
> * * * * *
>
> . . . Current data indicate that daily location information is not consistently available for units smaller than battalions. In other words, we believe that the location of individual battalions can be placed with reasonable accuracy for most of the 731 days but the locations of the component companies of a battalion cannot be as reliably placed due to lack of data.[26]

The effect of this change would be to severely diminish the study's ability to identify veterans most likely to have been exposed to Agent Orange. The interim report admits as much. ". . . because battalions are larger, more dispersed units than companies, the location of men in relation to herbicide applications will be known with less precision than envisioned in the protocol." [27]

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[24] Ibid., p. 37.
[25] Ibid.
[26] "Agent Orange Projects Interim Report: Agent Orange Study Exposure Assessment: Procedures and Statistical Issues," Agent Orange Projects, Center for Environmental Health, Centers for Disease Control, February 1985, p. 4.
[27] Ibid., p. 1.

CDC's decision to use battalion data was based on its conclusion that the military records were not accurate for the purpose of tracking companies. OTA concurred in this decision at the time. However, as noted previously, testimony and documents provided to the subcommittee indicate that CDC's decision was disputed, not only by the Department of Defense, which had greater expertise in evaluating military records, but by scientists working on the Agent Orange Project itself.

The second major change in the protocol was that the ". . . Ranking of unit exposure likelihoods will not determine selection of men into the study." [28] Originally, CDC planned to rank 125 companies according to time and distance proximity to herbicide applications, before any individuals from the units were selected for the study. The interim report states this approach was abandoned because CDC had identified numerous transfers of soldiers between companies in III Corps.[29] Therefore, unit exposures would not necessarily correlate to individual exposures.

The committee finds this change to be another example of CDC's dilution of the study for reasons of convenience and expedience. The individual soldiers could have been tracked, adjustments made for transfers, but because of the amount of time and work involved, and due to its own perception that the study had to be completed post-haste, this more precise method of tracking individual companies and soldiers was disregarded. The committee recognizes that pursuing alternatives would have been a complicated and arduous task; however, it was feasible. Because CDC diluted the study without doing the necessary work to compensate for tracking problems, the committee finds no support for the final conclusion that the Agency could not identify any method for using military records to assess exposure.

The interim report discussed two additional changes in the original protocol: Individual military records would be used to buttress unit morning reports to track troop movements and the study would be restricted to men serving only in infantry or artillery units. In explaining the reason for the latter alteration, CDC revealed that many soldiers likely to have been exposed were arbitrarily eliminated from the study because their backgrounds might not conform to the backgrounds of the study comparison group who did not serve in Vietnam. According to the interim report:

> . . . For the Agent Orange Study, our goal is not to select a "representative" sample of Army men in III Corps, but rather to select men from III Corps who are as *comparable* as possible, except for differing likelihoods of Agent Orange exposure. We believe that men serving in artillery and infantry battalions will resemble each other more closely in terms of baseline characteristics and general military experience than they would resemble men from cavalry, armor, and engineering units.[30]

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[28] Ibid., p. 6.
[29] Ibid.
[30] Ibid., p. 9.

The effect of these modifications on the study was noted in the interim report.

> . . . because unit exposure likelihoods do not appear to correlate highly with individual men's exposure likelihoods, we will not be able to exclude men from units with intermediate exposure likelihoods from the study; therefore the spread or range of exposure likelihoods between the groups being compared will likely be reduced.[31]
>
> [Further,] The misclassification of Agent Orange exposure inherent in this study means that the true magnitude of exposure-disease associations will be underestimated.[32]

By the end of 1985, CDC scientists realized that the restrictions in the criteria described previously had so limited the scope of their research, they were unable to identify enough subjects for inclusion in the study. To compensate, CDC changed the criteria again, allowing a larger number of soldiers to be included, but reducing the numbers of soldiers with the greatest likelihood of exposure to Agent Orange. On December 8, 1985, new criteria were established in a second, interim report.[33] First, CDC reduced the number of days served in combat companies for selection in the study from 9 months to 6 months. The Agency also broadened the time period for study subjects from veterans who served only in the time period, 1967–1968, when the herbicide spraying was heaviest, by adding an additional six months.[34]

The Director of the CDC Center for Environmental Health and Injury Control testified that the reduction in number of days served eliminated veterans who had greater opportunities for exposure to Agent Orange. The following exchange occurred between the Subcommittee Chairman and the Director.

> Mr. WEISS. If you reduced that 9-month number, you would be eliminating the veterans with the greatest opportunity for exposure, would you not?
>
> Dr. HOUK. If we reduced the number, right.
>
> Mr. WEISS. The 9-month number.
>
> Dr. HOUK. If we had made it 6 months?
>
> Mr. WEISS. Yes.
>
> Dr. HOUK. We would have less likelihood of exposure.
>
> Mr. WEISS. That's right.
>
> Dr. HOUK. Right.[35]

In addition to its complaints about the Defense Department's troop movement records, CDC also questioned data it had received regarding the dispersion of the Agent Orange after being sprayed. The December 8, 1985, interim report discussed test missions flown over a sampling grid in 1970.

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[31] Ibid., p. 1.
[32] Ibid., p. 2.
[33] "Exposure Assessment for the Agent Orange Study, Interim Report Number 2, Supplemental Information," Agent Orange Projects, Division of Chronic Disease Control, Center for Environmental Health, Centers for Disease Control, December 8, 1985.
[34] Ibid., p. 5.
[35] Hearing, 1989. Testimony of Vernon N. Houk, M.D., Director, Center for Environmental Health and Injury Control, Centers for Disease Control, p. 47.

> . . . While many conditions such as the spray system, altitude, and aircraft were similar to those which prevailed in Vietnam for the Ranch Hand missions, other conditions (e.g. the number of aircraft used and vegetative cover) were different, so that results can only be used as rough estimates of herbicide dispersion. In a crosswind, the concentration decreased . . .
>
> . . . unfortunately estimates of dose would depend on knowledge of bioavailability, absorption rates, clothing worn, as well as behavioral factors such as amount of time spent in contact with vegetation, soil, and grasses, and consumption of local food and water. Data are insufficient to estimate dose.[36]

At the time CDC was diluting the study, using the rationale that the Defense Department's records were inaccurate or missing, a team of expert scientists from the National Academy of Sciences' Institute of Medicine (IOM) made a site visit to the Department's Environmental Support Group (ESG). The scientific team found the ESG records important and useable, and was critical of CDC's performance. The IOM final report stated that they were "satisfied that the ESG is capable of determining locations and fillings gaps using a contextual approach, and notes that the ESG exhibits a high degree of competence in recording data gathered from these activities." [37] The IOM also said it 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 . . . satisfied with the ESG's quality control program." [38]

ESG personnel informed the IOM team that ESG's "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." [39] ESG identified numerous cases of veterans who had received 10 or more exposures to Agent Orange, but had been excluded from the CDC study. For example, ESG pointed out, because CDC has eliminated all headquarters personnel from the study, if a veteran "had 170 days of combat and . . . then moved into a headquarters unit they were not included in the study . . ." [40]

After reviewing the work of ESG, the IOM team concluded that CDC had wrongly restricted the study. For example, the team stated that it 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 . . . whenever possible. The use of discrete categories in data collec-

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[36] Op. cit., p. 17. See footnote 33.
[37] "Site Visit to the U.S. Army Environmental Support Group," Advisory Committee on the CDC Study of the Health of Vietnam veterans, National Academy of Sciences, Institute of Medicine, March 7, 1986, p. 6.
[38] Ibid., pp. 6–7
[39] Ibid., p. 4.
[40] Ibid., p. 5.

> tion stages essentially discards valuable information, and such data can be stratified for subsequent analyses.[41]

The IOM team also said it "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."[42] The team also found, "the criteria used to define exposure and to define who will be included in the study seem arbitrary and confusing" and concurred with ESG "that there appear to be many exposed individuals who will be excluded from the study as it is now designed."[43]

The IOM experts were also concerned that a scientific panel of the White House Agent Orange Working Group (AOWG) "is currently trying to define 'exposure' " and noted "the thinness of expertise in certain areas" of the individuals serving on the panel.[44] In conclusion, the scientific team reported 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 [IOM] subcommittee finds the current definition of exposure to be inadequate."[45]

The IOM findings were not reported to the White House. Therefore, the White House AOWG was misinformed when its Science Panel held a meeting three months after the IOM site visit to ESG, and reported:

> Pertinent military records have been used appropriately to locate all known herbicide spraying operations and military units and to identify individuals who may have had opportunities for exposure to Agent Orange. Limitations on the assessment of exposure opportunities are due to limitations in the records themselves.
>
> * * * * *
>
> There is unanimous agreement that an epidemiological study of ground troops' possible exposures to Agent Orange disseminated by Operation Ranch Hand fixed-wing aerial spraying, based solely on military records, does not appear to be scientifically feasible.[46]

In reaching this decision, the AOWG Science Panel noted that it "did not bring in independent evidence or experts." In light of the evidence compiled since the cancellation of the study, the committee finds that the White House's final decision was based on incomplete and erroneous information, and that pertinent information was purposefully withheld by CDC. The committee further concludes that the dilution of the study was unnecessary, was based on arbitrary criteria established by a panel controlled by the White House, and directly led to the study's collapse. The Agency Orange Exposure study failed as a result of its own design.

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[41] Ibid., p. 7.
[42] Ibid.
[43] Ibid., pp. 11-12.
[44] Ibid., p. 13.
[45] Ibid., pp. 12-13.
[46] "Minutes of the Meeting on June 17, 1986," Science Panel of the White House Agent Orange Working Group.

C. THE BLOOD SERUM ANALYSIS, WHICH WAS USED AS PROOF BY CDC THAT AN AGENT ORANGE EXPOSURE STUDY COULD NOT BE CONDUCTED, WAS BASED ON ERRONEOUS ASSUMPTIONS AND A FLAWED ANALYSIS

Using its criticism of the ESG records as its excuse, CDC and the AOWG were inclined against proceeding with the study. However, before a decision to cancel or go forward could be reached, CDC needed to test the exposure definition it had developed. The method it considered to validate the definition involved testing Vietnam veterans for traces of dioxin. At first, this was not considered feasible. Although the measurement of dioxin in humans had been achieved through the use of gas chromatography/mass spectrometry to identify the contaminant in fatty adipose tissue, Federal scientists believed there were two obstacles to using this process in the Agent Orange study. First, there was the difficulty of obtaining adipose tissue, which required surgical extraction, a procedure considered too invasive and unwieldy for a study of this sort. Second, the half-life of dioxin in animal studies proved to be less than a year, which, if extrapolated to humans, would mean the dioxin had been eliminated from the bodies of Vietnam veterans long before 1986.[47]

During a meeting of the AOWG Science Panel on June 17, 1986, representatives of CDC proposed using dioxin levels in blood serum as a surrogate for Agent Orange exposure. The minutes of the meeting indicate that the Science Panel was divided on the proposal; some thought it should be done, while others did not think it was feasible. The panel concluded:

> There is no agreement at this time whether a feasible and accurate method for validation of individual exposure status can be devised, and the science panel cannot recommend attempting a verification study.
>
> * * * * *
>
> There is unanimous agreement that if a well-designed exposure verification study fails to validate individuals' exposures as determined from military records, the Agent Orange Epidemiological Study should be discontinued.[48]

CDC overcame the difficulties of obtaining adipose tissue by developing, for the first time, a method of identifying dioxin traces in human blood. This left the second obstacle, the short half-life of dioxin, as the sole impediment. This was also overcome, according to CDC:

> The second problem of expected short half-life was changing as studies on human 2,3,7,8-TCDD exposure yielded results more compatible with a half-life much longer than 1 year. Results from a few persons in Missouri

[47] "Estimates of the Half-Life of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin in Vietnam veterans of Operation Ranch Hand," James L. Pirkle, Donald G. Patterson, Donald L. Phillips, and Larry L. Needham, Centers for Disease Control, and William H. Wolfe, Joel E. Michalek, Judson C. Miner, and Michael R. Peterson, U.S. Air Force School of Aerospace Medicine, Journal of Toxicology and Environmental Health, Vol. 26, 1989, p. 166.

[48] Op. cit., p. 2. See footnote 46.

> . . . and an occupationally exposed worker in Germany . . . suggested, on the basis of last known exposure determined by history, that 5–8 years was a more reasonable estimate of 2,3,7,8-TCDD half-life for humans. In another study . . . an individual who ingested radiolabeled 2,3,7,8-TCDD and tracked his urinary and fecal excretion of the radiolabel estimated the half-life at 5–8 years.[49]

The exposure examples cited by CDC to justify a new half-life of dioxin involved situations totally unlike Agent Orange spraying in Vietnam. Yet, based on this new evidence, CDC, in collaboration with the U.S. Air Force, tested the blood of Ranch Hand veterans, as well as veterans whom CDC had selected in its exposure study. Using a half-life estimate for dioxin of 7.1 years, the blood of 646 Vietnam veterans was tested. According to CDC, only 4 percent of the non-Ranch Hand subjects had elevated levels of dioxin in their blood, and there was no correlation between exposure and dioxin in the blood.[50] CDC reached no conclusions about exposure on the basis of the study and, without further evaluation, found there was no other method to assess exposure. The final report on the blood testing found:

> The findings of this study and the conclusions from the AOWG Science Sub-Panel report on exposure assessment . . . do not identify any method for utilizing military records or self-reported exposure to distinguish between exposed and nonexposed Vietnam veterans, as would be needed for a cohort study of possible health effects.[51]

CDC's conclusion that the half-life of dioxin in the human body is 7.1 years was reached in disregard of warnings from CDC's own scientists and the peer review committee at IOM that there was not sufficient evidence to support the longer half-life. IOM informed CDC that, because of the incorrect assumptions about the half-life of dioxin, the conclusions of the blood study were not supportable. IOM informed CDC of its concerns:

> [The IOM site team has] substantial reservations about the conclusions and recommendations presented in the CDC pilot study report. The committee believes that the *conclusions* as they are now stated are not fully supported by the evidence provided in this report.
>
> Moreover, the committee urges that the *recommendations* as currently stated in the CDC pilot study report be deleted; they appear to reach well beyond the data presented and to incorporate information that goes beyond the scope of the current investigation.[52]

The IOM report criticized CDC's assumption about the half-life of dioxin. The IOM was concerned that the study was based on blood drawn 20 years after exposure to Agent Orange. The report advised

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[49] Op. cit., pp. 166–167. See footnote 47.
[50] Op. cit., p. 43. See footnote 3.
[51] Ibid.
[52] "Review of Comparison of Serum Levels of 2,3,7,8-TCDD with Indirect Estimates of Agent Orange Exposure in Vietnam veterans," Fifth Letter Report, Advisory Committee on the CDC Study of the Health of Vietnam veterans, Institute of Medicine, June 26, 1987, pp. 17–18.

that "There are several possible conditions that could have occurred between 1967 and 1987 that might result in the TCDD levels observed today." [53] The report stated that the veterans studied could have had different ranges of exposure, which due to decay of dioxin in the body, could result in the same background levels of dioxin 20 years later, or that they could have been equally exposed, but dioxin decayed in their bodies at different rates, due to physical and environmental variables.[54]

The IOM committee was particularly critical of the conclusion by CDC and the White House that the blood tests proved a complete exposure study was impossible.

> The 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 indirect indices of exposure. If such an expansive statement is offered, it certainly warrants argumentation and documentation. The committee did not find support for this conclusion in the pilot study . . .[55]

The IOM panel was also concerned that blood was not available for a significant portion of the cohort studies: 52 percent of the veterans who did not serve in Vietnam and only 68 percent of the veterans who did serve in Vietnam.[56] The IOM team asked CDC to provide alternative explanations for the lack of correspondence between the indirect measures and current dioxin levels, and in regard to fears about Agent Orange, concluded:

> . . . it is not clear that the findings presented in this pilot study warrant complete abatement of concern. Little can be said with certainty about the TCDD levels in men 20 years ago. Moreover, background levels detected some years later do not provide assurance that no health effects will ultimately surface. Given the insufficiency of data relating the level of exposure to health outcome in humans, delayed effects of low or high doses could become apparent years after exposure occurred.[57]

IOM's comments, which were largely disregarded in the final blood serum assay report, served to remind CDC that the purpose of the blood tests was to validate the exposure definitions and scores developed by the agency and the AOWG, not to actually assess exposure. It should have come as no surprise to CDC that there was no correlation between the blood tests and exposure scores, because the scores were based on a diluted protocol that eliminated from the study the veterans who would have been the likeliest to be exposed. The Director of the CDC Agent Orange Project was aware of this problem, and warned the Director of CDC on March 17, 1986:

> If only weak correlations are found between residual TCDD levels and the exposure opportunity scores (e.g.,

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[53] Ibid., p. 11.
[54] Ibid.
[55] Ibid., p. 19.
[56] Ibid., p. 15.
[57] Ibid., pp. 19–20.

there is no difference between the "high" and "low" exposure opportunity scores), it will be unknown if the failure to find a difference was due to limited Agent Orange exposure in Vietnam or to misclassification of the scores.[58]

The same memorandum also stated that, while the blood serum assay was a legitimate tool for validating CDC exposure methodology, "it should be noted that current TCDD levels could bear an imperfect correlation with exposure to Agent Orange because of individual variability in both the metabolic half-life of dioxins and in post-service exposure to dioxin containing compounds." [59]

More than a year earlier, in January 1986, the senior statistician on the Agent Orange Project expressed serious reservations about using dioxin measurements to validate exposure. The statistician warned that a TCDD analysis had a substantial likelihood that there will be essentially no correlations:

> . . . there is a great danger of very poor correlation in adipose measurements separated by a long period of time. Thus, there is a substantial chance that we will find at best a very weak relation between exposure score and the adipose measurement . . . we are asking for trouble if we do TCDD measurements.[60]

The Director of the Center for Environmental Health and Injury Control stated that the senior statistician did not know what he was talking about. Dr. Houk testified, "I think he has been proven to be wrong and I discussed with him that it would be inappropriate for a senior laboratory scientist to comment on the inadequacies of a very elegant statistical design and analysis." [61] Dr. Houk's criticism is curious, given that he had selected this same statistician to direct the analysis of the study's results.[62]

The evidence is compelling that CDC was aware that the blood test study could not be the final word on the Agent Orange study. In 1987, the scientists working on the blood serum study cautioned in a provisional report:

> The study reported here measured TCDD levels as a *marker* of prior exposure to Agent Orange. It was *not* designed to detect "biologically meaningful" differences in serum TCDD levels because:
>
> 1. Levels of TCDD in man at which adverse health effects become manifest are not known;
> 2. Even if toxic levels of TCDD were known, the tissue half-life of TCDD in man is not precisely known, so that it would be difficult to extrapolate current

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[58] "Evaluation of residual dioxin levels in Vietnam veterans as a validation of Agent Orange exposure opportunity scores," Memorandum from Peter M. Layde, M.D., M.Sc., Acting Director, Agent Orange Projects, to James O. Mason, M.D., Dr.P.H., Director, Centers for Disease Control, March 17, 1986, p. 3.

[59] Ibid.

[60] "Trip Report on Meeting with Tavia Gordon, Max Halperin, and Shelby Stanton," Memorandum from John M. Karon, Senior Statistician, Agent Orange Project, to Dan McGee, Director, Agent Orange Project, January 9, 1986, p. 6.

[61] Hearing, 1989, p. 67.

[62] Ibid., p. 68.

levels in veterans back 20 years to when exposure may have occurred; and

3. The component of Agent Orange that may have been responsible for adverse health effects is not known. Although attention has focused on the TCDD contaminant, the two active Agent Orange ingredients, 2,4-D and 2,4,5-T, also may cause adverse health effects. . . . Different components of Agent Orange may have been responsible for different manifestations.[63]

One of the scientists on the Agent Orange Project testified that CDC, despite its public claims to the contrary, "had no idea about its [dioxin's] half-life. We had some conjectures about the half-life of dioxin but we didn't have anything certain." [64] He added:

> Also, we weren't certain about the dosage that would produce an effect. No one knew the relative importance of the various routes of exposure. We didn't know much at all about the distribution of dioxin within the body. There's an assumption that it stores itself in fat tissue 11 times more frequently than in serum but this sort of information, I think, is very questionable.[65]

CDC had already diluted the study protocol to the point it would not identify the veterans most likely to have been exposed, to avoid a lengthy document review. The decisions to dilute were made for reasons of expediency. With its manipulation of the half-life of dioxin, CDC seemed to be trying to justify an intentionally flawed exposure assessment methodology with the blood serum analysis. The blood assay test was more a method of convenience than an exhaustive scientific approach. As Dr. Smith testified:

> We damned the historical records with overemphasis on minor problems with ESG. We ignored other sources of records and relied too much on unreliable, anecdotal reports. We played with the half-life of dioxin using only those studies and reports that would advance the concepts of what the model which we wanted to use would say at the time. . . .
>
> We ignored most of the medical literature on dioxin. We had some excellent references but we only focused on a few papers, especially when the adipose tissue proposal came along. The focus was only on a few papers that supported what we had in mind, or, what we had ultimately come to.[66]

Dr. Michael Kafrissen worked on the Agent Orange Projects and had been asked by CDC to evaluate the half-life of dioxin in the human body. Although he said there was some preliminary evidence indicating a half-life of 7.1 years for dioxin in humans in

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[63] "Comparison of Serum Levels of 2,3,7,8-TCDD with Indirect Estimates of Agent Orange Exposure in Vietnam veterans—Provisional Report," Agent Orange Projects, Division of Chronic Disease Control, Center for Environmental Health, Centers for Disease Control, July 1987, p. 18.

[64] Hearing, 1989. Smith testimony, p. 81.

[65] Ibid.

[66] Ibid., p. 82.

some situations, he stated, "I don't believe at this time there is sufficient information to say that this number obtains for all men at all times under all physical circumstances." [67] Dr. Kafrissen also testified that "We did not know all of the critical levels—and I don't believe we now know—of dioxin that is going to effect a problem in humans. For that reason, we were concerned with the possibility that men may have been affected, may have been exposed and that we would no longer be able to judge that based on these laboratory specimens." [68]

The assumption that dioxin had a longer half-life in the human body than previously believed was based on studies of individuals who were directly exposed to high doses of dioxin in laboratory accidents, one study of a scientist who ingested dioxin in high doses to evaluate half-life, and tests conducted of veterans who worked in Operation Rand Hand, directly spraying and handling Agent Orange in large amounts. These subjects cannot be compared to Vietnam veterans who had less direct exposure, possibly over longer periods of time. The large, short-term exposure to undiluted chemicals as the result of industrial accidents is quite different from the possible long-term exposure to Agent Orange in which the contaminants were diluted with other substances. Obviously, dioxin exposure is different in these subjects and the elimination of dioxin traces would be entirely different than in the subjects mentioned earlier. While studying the half-life of dioxin in highly exposed veterans and workers was relevant to the CDC Agent Orange Study, the committee finds the conclusion that the 7.1 years half-life in highly exposed individuals can be extrapolated to all Vietnam veterans to be unsupportable.

Even the method by which CDC determined the half-life—called first order kinetics—may not have been the correct way of assessing dioxin elimination from the human body. The scientists who conducted the half-life study cautioned:

> With just two serum 2,3,7,8-TCDD values per veteran, it is not possible to definitively state that a first-order kinetic model is appropriate to describe the decline in serum 2,3,7,8-TCDD concentrations over time or that a more complex model is needed.[69]

Based on the complete record of the CDC Agent Orange Studies, the committee believes there was a two-part course selected by the Agency that guaranteed the eventual cancellation of the study. First, CDC ignored the military records experts at the Pentagon, created its own use of the records to establish exposure, and then diluted the study to the point that numerous veterans who were most likely to have high exposure were eliminated from the study. Second, using the flawed exposure definition it had developed, CDC then attempted to justify it with the blood serum assay, which, itself, was based on false assumptions about the chemical's half-life in the human body. Unsound assumptions about the half-life of

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[67] Ibid. Testimony of Michael E. Kafrissen, M.D., former epidemiologist, Centers for Disease Control, p. 107.
[68] Ibid., pp. 106–107.
[69] Op. cit., p. 170. See footnote 47.

dioxin were used to validate badly-designed exposure assessments. Given these restrictions, it would have been impossible to validate exposure.

The committee also finds that, in adopting these courses of action, CDC disregarded or ignored the warnings from its own scientists, Defense Department officials, and the expert committee assembled by the IOM.

### D. THE WHITE HOUSE COMPROMISED THE INDEPENDENCE OF THE CDC AND UNDERMINED THE STUDY BY CONTROLLING CRUCIAL DECISIONS AND GUIDING THE COURSE OF RESEARCH AT THE SAME TIME IT HAD SECRETLY TAKEN A LEGAL POSITION TO RESIST DEMANDS TO COMPENSATE VICTIMS OF AGENT ORANGE EXPOSURE AND INDUSTRIAL ACCIDENTS

The subcommittee's review of Executive Branch records demonstrates that two components of the White House, the Agent Orange Working Group (AOWG) and the Office of Management and Budget (OMB), monitored and controlled the CDC Agent Orange Project. Top administration officials such as Attorney General Edwin Meese and White House Chief of Staff James Baker had ultimate decisionmaking authority for approving and eventually canceling the exposure study, but the nuts and bolts of the work were handled by the AOWG and OMB.

While Agent Orange was the impetus for the establishment of the White House advisory committee under President Carter, the panel's mandate was not limited to the war-time defoliant. Its purview included the effect of herbicide contaminants in addition to Agent Orange.

The first responsibilities of the White House panel were to instruct the Air Force to conduct the study of Ranch Hand personnel and to oversee both the Ranch Hand study and the epidemiological study of Agent Orange.[70]

In June 1983, the Reagan Administration decided to revise the charter of the White House panel by eliminating its mandate to explore the effects of all herbicides and contaminants and concentrating the work of the group only on Agent Orange. In a memorandum from Robert B. Carleson, Special Assistant to the President, to White House aide Jack Svahn, it was decided:

> . . . the task of the Working Group on Agent Orange be concentrated so that its work can be completed in a timely manner. Therefore, please ensure that your working group deals only and specifically with the possible long term adverse health effects of exposure to Agent Orange and Vietnam veterans.[71]

The AOWG was the successor to the White House Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. The origi-

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[70] Memoranda to the Secretary of Defense and the Administrator of Veterans Affairs, from Stuart E. Eizenstat, Assistant to the President for Domestic Affairs and Policy, September 16, 1980.

[71] "Task Assignment of the Working Group on Agent Orange," Memorandum from Robert B. Carleson, Special Assistant to the President, to Jack Svahn, Chairman, Working Group on Agent Orange, June 2, 1983.

nal advisory committee was established on December 11, 1979, in a memorandum drafted by Stuart E. Eizenstat, Assistant to President Jimmy Carter for Domestic Affairs and Policy. The advisory panel's mission was to assure that all Federal research into herbicides and contaminants provide reliable data, and to provide technical support to Federal agencies working on the research.[72]

The original mandate to focus the White House panel on the effects of all herbicides was abruptly altered by the Reagan White House. By focusing the work of AOWG on Agent Orange only, the administration laid the groundwork for manipulating the study to the point of uselessness.

A possible reason that the White House chose this path is revealed in confidential documents prepared by attorneys in OMB. The White House was deeply concerned that the Federal Government would be placed in the position of paying compensation to veterans suffering diseases related to Agent Orange and, moreover, feared that providing help to Vietnam veterans would set the precedent of having the United States compensate civilian victims of toxic contaminant exposure, too.

These concerns were included in a series of memoranda prepared by an OMB attorney about pending legislative proposals to compensate victims exposed to Agent Orange and nuclear radiation. These proposals, OMB warned, "have enormous fiscal implications, *potentially in the hundreds of billions of dollars.*"[73] In discussing H.R. 1961, a bill pending in the House of Representatives that would provide compensation to veterans exposed to Agent Orange and nuclear radiation, OMB called the legislation "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 . . .[74]

The ramifications feared by the White House were delineated in a second memorandum. A major worry was that the legislation, if passed, would make it hard for the White House to prevent compensation to victims of other types of contaminants:

> 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.*[75]

The White House also feared that passage of the legislation would damage its efforts to prevent compensation for claims involv-

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[72] Charter, Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants," as amended May 1984.

[73] "Compensation for Low-Level Radiation Exposure and Related Developments," Executive Office of the President, Office of Management and Budget, Memorandum to Ed Meese, Joe Wright, Jay Keyworth, Fred Fielding, and M.B. Oglesby, from Mike Horowitz, December 6, 1983, p.1.

[74] Ibid., p. 3.

[75] "Agent Orange/Radiation Compensation Legislation," Executive Office of the President, Office of Management and Budget, Memorandum to Dave Stockman, Joe Wright, Jay Keyworth, and Fred Fielding, from Mike Horowitz, January 17, 1984, p. 2.

ing nuclear radiation. "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." [76]

A subsequent memorandum reiterated these concerns and expanded upon them. In regard to nuclear radiation, OMB warned:

> Many residents near the test sites received cumulative exposures far in excess of the single doses to which veterans were exposed. These residents will undoubtedly demand compensation for these far greater levels of cumulative exposure. . . . There is understandable concern at Justice that H.R. 1961 will effect the outcome of that case.
>
> The bill will certainly be used by anti-nuclear extremists as providing credibility for their alarmist claims on the dangers to the public from nuclear weapons facilities, nuclear reactors, transportration of nuclear materials, underground testing, etc. This may have serious national security ramifications.[77]

So strident was the administration in its belief that the Federal Government should not be liable for exposure to toxic chemicals that the Justice Department ordered the Defense Department not to assist the Special Master overseeing the legal settlement between the manufacturers of Agent Orange and Vietnam veterans. On May 22, 1986, the Director of the Defense Department's ESG asked the Justice Department if he could assist the Special Master in the evaluation of herbicide spray and troop movement records already provided to the Special Master. The assistance, the director wrote, would "prevent duplication, delay, misinterpretation and costs against the funds set-aside for Veterans' awards." [78]

The Justice Department ordered the Defense Department not to cooperate with the Special Master, advising that "government employees not be made available to render advice and assistance concerning the allocation of settlement fund proceeds." [79]

A month later, the Director of ESG was asked to testify before a subcommittee of the House Committee on Veterans Affairs about the results of the work of the Agent Orange Working Group. In a memorandum to the Defense Department Adjutant General, the Director reported that much of his testimony was "deleted by OMB. . . . Such results are neither forthright or responsive. . . . the testimony has been rewritten and its guts torn out. . . ." [80]

In light of these confidential actions by the Justice Department and OMB, and given the White House's legal concerns that the Federal Government could be liable in toxic contaminant law suits, it is apparent why the charter of the AOWG was revised and limit-

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[76] Ibid.

[77] "H.R. 1961, Agent Orange and Atomic Veterans Relief Act," Executive Office of the President, Office of Management and Budget, Memorandum to Ed Meese, Jack Svahn, Jay Keyworth, and B. Oglesby, from Mike Horowitz, February 6, 1984, p. 2.

[78] Letter from Robert C. Longstreth, Trial Attorney, Torts Branch, Civil Division, Department of Justice, to Richard S. Christian, Director, U.S. Army and Joint Services Environmental Support Group, June 3, 1986. (Letter cites Christian letter of May 22, 1986.)

[79] Ibid.

[80] Memorandum from Director, Environmental Support Group, to The Adjutant General, July 30, 1986.

ed to Agent Orange only. At the time of the revision, numerous Federal research projects were being conducted of domestic and civilian worker exposure to herbicides.[81] By revising the charter to ignore the dozens of Federal studies dealing with herbicides other than Agent Orange, the White House forced the AOWG to overlook a wide range of issues, not only related to Agent Orange, but vital to the health of civilian workers, as well. Thus, the White House would not have to deal with potential liabilities involving herbicides other than Agent Orange.

The committee believes that, given the White House's predisposition against compensating victims of toxic contamination, White House officials should have recused themselves from involvement in the deliberations about the CDC Agent Orange Studies and that the AOWG should not have been given the authority to approve or

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[81] The following studies were reported to the Agent Orange Working Group in a document, "Federally Sponsored Human Studies Related to Agent Orange," April 11, 1983, National Institute of Occupational Safety and Health (NIOSH), Investigation of Leukemia Cluster in Madison County, Kentucky, Allegedly Associated with Pentachlorophenol Treated Ammunition Boxes; Centers for Disease Control (CDC), Birth Defects and Military Service in Vietnam Study; NIOSH Dioxin Registry; National Institute of Environmental Health and Safety (NIEHS), Establishment and Maintenance of an International Registry of Persons Exposed to Phenoxy Acid Herbicides and Contaminants; NIOSH Soft Tissue Sarcoma Investigation, National Cancer Institute (NCI), Case Control Study of Lymphoma and Soft Tissue Sarcoma; NCI Study of Mortality Among Pesticide Applicators from Florida; CDC Epidemiologic Study of Ground Troops Exposed to Agent Orange during the Vietnam Conflict; Veterans Administration (VA), Vietnam veterans Mortality Studies, Vietnam veteran Identical Twin Studies, Survey of Patient Treatment File for Vietnam veteran In-Patient Care, Agent Orange Registry Examinations, TCDD in Body Fat of Vietnam veterans and Other Men, Retrospective Study of Dioxins and Furans in Adipose Tissue of Vietnam Era Veterans; Department of Defense (DOD), Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicide Orange, Armed Forces Institute of Pathology Agent Orange Registry of Vietnam veteran Biopsy Tissues; Environmental Protection Agency (EPA), Report of Assessment of a Field Investigation of Six-Year Spontaneous Abortion Rates in Three Oregon Areas of Relation to Forest 2,4,5-T Spray Practices, National Pesticide Monitoring Project of Human Adipose Tissue; Department of Agriculture (DOA), A Case Control Study of the Relationship Between Exposure to 2,4-D and Spontaneous Abortions in Humans, Exposure Measurements of Mixers, Loaders and Applicators of 2,4,-D on Wheat, Exposure of Forest Workers to Ground Applications of 2,4-D; Department of Health and Human Services (HHS), Bioassay of Octachlorodibenzo-p-dioxin, Carcinogenesis Bioassay of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in Swiss Webster Mice, Carcinogenesis Bioassay of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in Osborn-Mendel Rats and B6C3F1 Mice, Bioassay of a Mixture of 1,2,3,6,7,8- and a Mixture of 1,2,3,6,7,8-Hexachloro-dibenzo-p-dioxins for Possible Carcinogenicity, Comparative Species Evaluation of Chemical Disposition and Metabolism of 2,3,7,8-Tetrachlorodibenzofuran in Rat, Monkey, Guinea Pig and Two Strains of Mice, Neurotoxicity of 2,4,-D in Rodents, Studies of the Chemical Disposition and Metabolism of Octachlorodibenzodioxin, Effects of Agent Orange Components on Male Fertility and Reproduction, Mutagenicity Studies of TCDD, Implications of Low Level Exposure of Dioxins, Mechanisms of Toxicity of the Chlorinated p-dioxins, Research Toward Understanding the Molecular Level Mechanisms of Toxicity of TCDD and Related Compounds; Synthesis of Selected Tetrachlorodibenzo-p-dioxins and Related Compounds as Analytical Standards, Matrix Effect and Sub Parts-per-billion Quantitative Analysis of TCDD by Mass Spectrometry—With Special Reference to Milk, Toxic Actions of Dioxins, Xenobiotic Induction of Pleiotropic Responses in Liver, Molecular, Biochemical Actions of Chlorinated-p-dioxins, Mechanisms for Toxicity of Chlorinated Dibenzo-dioxins, Modular basis of Dioxin toxicity in Keratinocytes; EPA, Evaluation of Large Scale Combustion Sources, Evaluation of Municipal Waste Combusters, Bacterial Decomposition of TCDD, Investigation of Bioavailability to Fresh Water Fish of TCDD's in Fly Ash, Analysis of Environmental Samples for PCDD's and PCDF's, DOA, Survey of Phenoxy Herbicide Use by Agricultural Commodity, Survey of Phenoxy Herbicide Literature, Photolysis of 2,4,5-T, Biological and Economic Assessment of 2,4,5-T and Silvex, TCDD Residue Monitoring in Deer; DOD, Environmental Chemistry of Herbicide Orange and TCDD; VA, Review of Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins, Urinary 6-Hydroxy Cortisol: Physiological and Pharmacologic Studies, Effect of TCDD on Lipid Metabolism, Mechanisms of Dioxin Inducted Toxicity Using the Chloracne Model, Behavioral Toxicity of An Agent Orange Component of 2,4-D, Effects of 2,3,7,8-Tetra-chlorodibenzodioxin on Hepatobiliary Function in Animals, Mechanism of TCDD Absorption and Toxicity on Lipid and Lipoprotein Metabolism, Metabolism of the Herbicides Present in Agent Orange and Agent White, TCDD Exposed Rhesus Monkeys: Effects on Behavior and Stress Hormones, Neuromuscular Toxicity of Agent Orange, Effects of Low Dose TCDD on Mammalian Chromosomes and Liver Cells, Mechanism of Porphyria Caused by TCDD and Related Chemicals, Effects of Agent Orange on Sleep.

disapprove CDC's activities. The potential to wrongly influence the outcome of the CDC studies inherent in this conflict of interest was realized when White House officials directly interceded in the decision that steered the study in the wrong direction, and ultimately resulted in its failure.

A July 18, 1986, OMB memorandum provides evidence that it was the White House, not CDC, that was making decisions during possibly the most crucial phase of the Agent Orange exposure study. It was a time when the military records were considered unsuitable for use in the study, and the entire project was in danger of being canceled. The cancellation was averted when CDC proposed testing the blood of Vietnam veterans for dioxin traces. The memorandum presents information about the White House AOWG's "decision to proceed with the development of a protocol for testing the dioxin levels in blood for Vietnam ground troop veterans." [82] The memorandum states that the decision on whether to cancel the study will be influenced by CDC's public testimony before the House Veterans Affairs Committee on July 31, 1986. According to the memorandum, "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." [83]

The memorandum contains an admission that the final decision was based on the Federal Government's legal culpability, not necessarily the independent work of scientists.

> 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.[84]

So fearful was the White House that it might have to compensate Americans exposed to contaminants, it pressured CDC to refute the blood serum test as a measure of exposure to Agent Orange, even before it commenced. To avert possible future claims for compensation from veterans, the memorandum states, *"It is important that testimony and other public comments not associate the measurement of dioxin in blood with causation."* [85] The memorandum recommended that the White House contact the Director of CDC and encourage him to "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." [86]

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[82] "Agent Orange Study," Executive Office of the President, Office of Management and Budget, to Debbie Steelman from Sarah Ducich, July 18, 1986, p. 1.
[83] Ibid., p. 2.
[84] Ibid.
[85] Ibid.
[86] Ibid.

The memorandum also represents evidence that the CDC study was doomed to failure by the White House, long before its final cancellation. Why else would the conclusions be reached that the blood dioxin measurement cannot be linked to Agent Orange, even before the test began? Perhaps most instructive of the White House's attitude is that it was its panel, the AOWG, that canceled the Agent Orange study, not CDC.

When the blood test, which the White House had allowed but classified as inconclusive even before it began, was finally completed in 1987, apparently showing no higher levels of dioxin in the blood of Vietnam veterans, the AOWG moved quickly. On August 27, 1987, the Chairman of the AOWG informed the Chairman of the White House Domestic Policy Council, "it has been concluded that military records cannot support a valid epidemiological study of the health effects of Agent Orange exposure on Vietnam veterans . . . I advise you to recommend to the Domestic Policy Council that the Agent Orange exposure study be cancelled." [87]

Two months later, the Director of CDC acknowledged the instructions to cancel the study. ". . . AOWG has instructed CDC to begin the process of cancelling the contracts and closing out all activities related to the Agent Orange Exposure Study." [88]

The AOWG had been riding herd over CDC from the beginning of the study. The AOWG had ordered that all Federal research be submitted to the White House panel prior to public release. On September 20, 1984, the panel ordered 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 Chair, AOWG." [89] After the study was canceled, the White House maintained its insistence on controlling any Federal scientific efforts related to Agent Orange. On April 1, 1988, the Chairman of the AOWG sent a memorandum to members of the panel, advising them that the future release of any information related to Agent Orange must be cleared by the AOWG.

> The release of any report, without the review mandated by the Agent Orange Working Group procedures, could constitute a serious breach and may undercut our credibility. Any premature release could cause embarrassment to the government.
>
> Research findings and conclusions must be submitted to the AOWG 48 hours prior to release for review, comment and clearance before going to Congress or the public.[90]

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[87] Letter from Don M. Newman, Chair Pro Tempore, Domestic Policy Council Agent Orange Working Group, to Edwin Meese, Chair Pro Tem, Domestic Policy Council, The White House, August 27, 1987.

[88] Hearing, 1989, pp. 55-56. Note to Don Newman, Chair, Domestic Policy Council Agent Orange Working Group, from James O. Mason, M.D., Director, Centers for Disease Control, October 28, 1987.

[89] "Accomplishing the AOWG Mission," Memorandum From Edward N. Brandt, M.D., Chair, Pro Tempore, to Members, Cabinet Council Agent Orange Working Group, September 20, 1984.

[90] "Clearance of all studies and press releases by the Domestic Policy Council Agent Orange Working Group," from Don M. Newman, Chairman, Domestic Policy Council Agent Orange Working Group, to Members, Domestic Policy Council, Agent Orange Working Group (DPC/AOWG), April 1, 1988.

## E. THE FEDERAL GOVERNMENT HAS SUPPRESSED OR MINIMIZED FINDINGS OF ILL HEALTH EFFECTS AMONG VIETNAM VETERANS THAT COULD BE LINKED TO AGENT ORANGE EXPOSURE

The Agent Orange Exposure Study was one of three parallel projects assigned to CDC involving the health of Vietnam veterans. The other two were the Vietnam Experience Study (VES), to determine the health status of veterans of Vietnam, and the Selected Cancers Study, conducted to determine if Vietnam veterans had been susceptible to a group of rare cancers. The key to the White House's legal strategy of not paying compensation for any type of toxic contamination was the cancellation of the exposure study. Once the exposure phase of the studies was canceled, on the premise that assessing exposure was scientifically impossible, Federal scientists were able to dismiss any link between diseases and maladies they discovered and Agent Orange.

Two examples involve the CDC's findings regarding birth defects involving the offspring of Vietnam veterans and the semen analysis conducted of the Veterans in the VES. CDC found that Vietnam veterans were more likely than non-Vietnam veterans to report birth defects. The study also concluded that Vietnam veterans reporting exposure to herbicides are at even greater risk of reporting miscarriages, birth defects, serious health problems, and infant mortality.[91]

Any possible link between herbicide exposure and the reported birth defects was dismissed by CDC because of the cancellation of the exposure study.

> The findings from a recent study in which current dioxin . . . body burdens in Vietnam and non-Vietnam veterans were assessed suggest that self-reported herbicide exposure may not be a valid estimate of actual herbicide exposure. Among Vietnam veterans, there was no evidence of elevated serum dioxin levels, and no correlation between average dioxin levels and self-reported exposure to herbicides in Vietnam. Thus, the herbicide exposure index used here may reflect the level of concern and anxiety Vietnam veterans have about the impact of Agent Orange on their health and health of their children.[92]

CDC's review of birth records found that the offspring of Vietnam veterans were twice as likely to have digestive system birth defects and were also twice as likely to suffer early neonatal death.[93] The birth records' review also indicated that the offspring of Vietnam veterans were more susceptible to cerebrospinal malformations, such as spina bifida, anencephaly, and hydrocephalus. CDC explained this problem as an underreporting of the birth defects among non-Vietnam veterans, rather than an excess among Vietnam veterans.[94] CDC's semen analysis of Vietnam veterans also found problems:

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[91] "Health Status of Vietnam veterans, Volume V, Reproductive Outcomes and Child Health," Vietnam Experience Study, Centers for Disease Control, January 1989, pp. 21-29.
[92] Ibid., pp. 41-42.
[93] Ibid., pp. 72-73.
[94] Ibid., pp. 84-85.

> Mean sperm concentration was 20% lower for Vietnam veterans than for non-Vietnam veterans.
>
> * * * * *
>
> Specimens from Vietnam veterans had a lower mean proportion of morphologically "normal" sperm than did speciments from non-Vietnam veterans . . . specimens from Vietnam veterans were more likely to contain larger and more tapered sperm. . . . Both the mean cell perimeter and the mean length of the major axis of the sperm cells were significantly larger for Vietnam than for non-Vietnam veterans.[95]

Although CDC could not explain definitively why Vietnam veterans had low sperm counts and altered sperm shapes, it quickly concluded there was no link to Agent Orange:

> The possibility that exposure to dioxin-containing herbicides may have affected the sperm of Vietnam veterans is a potential concern. However, this explanation seems unlikely, since in a recent study we found that few Army ground troops were heavily exposed to dioxin-containing herbicides.[96]

The committee finds CDC's conclusion derived from the canceled exposure study that few ground troops were exposed to Agent Orange to be a false and misleading interpretation of its own study. The exposure study found that CDC could "not identify any method for utilizing military records or self-reported exposure to distinguish between U.S. Army ground combat troops who were and were not exposed to Agent Orange in Vietnam . . ." [97] The study did not find that few ground troops were exposed, the reason used to dismiss any relation between birth defects and low sperm counts by CDC.

"We never did an Agent Orange study. The Agent Orange exposure component was deemed not to be feasible based upon the validation study and that study of TCDD exposure was never done," admitted Dr. Vernon Houk, Director of the CDC office which conducted the study.[98]

The canceled CDC study, the study "we never did," according to Dr. Houk, had become a convenient way for the Federal Government to dismiss any link between Agent Orange and health problems among Vietnam veterans, and deny liability for claims involving the herbicide. CDC's own Vietnam Experience Study contained preliminary indications that the liability could be large. CDC's findings showed that psychological problems such as Post Traumatic Stress Disorder, depression, anxiety, and psychopathology were more prevalent among Vietnam veterans than non-Vietnam veterans. Vietnam veterans were more likely to have histories of hospitalizations, hypertension, benign growths, chloracne, ulcers, hepatitis, liver conditions, urinary tract problems, and fertility difficul-

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[95] "Health Status of Vietnam veterans, Volume III, Medical Examination," Vietnam Experience Study, Centers for Disease Control, January 1989, p. 207.
[96] Ibid., p. 220.
[97] Op. cit., p. 4. See footnote 3.
[98] Hearing, 1989. Houk testimony, p. 44.

ties. They were more prone to abnormal clinical findings, such as possible left ventricular hypertrophy, hearing loss, peripheral neuropathy, evidence of past hepatitis B infection, and abnormal laboratory findings, such as gamma-glutamyl transferase, fasting glucose, thyroid-stimulating hormone, and occult stool blood.[99]

CDC was also aware of other clinical effects that were assumed to be related to exposure to the chemical constituents of Agent Orange. Studies of workers exposed to dioxin found a host of effects.

TABLE OF CLINICAL EFFECTS ASSOCIATED WITH EXPOSURE TO THE CONSTITUENTS OF AGENT ORANGE [100]

Dermatological: Chloracne, porphyria cutanea tarda, hyperpigmentation and hirsutism, contact dermatitis.

Hepatic: Liver damage ( . . . mild fibrosis, fatty changes, hemofuscin deposition, parenchymal-cell degeneration), increased serum hepatic enzyme levels.

Other internal: Disorders of fat metabolism, disorders of carbohydrate metabolism, cardiovascular disorders . . . elevated serum cholesterol levels, abdominal pains and diarrhea, pancreatic disorders.

Respiratory: . . . SMR for lung cancer, dyspnea. . . .

Genito-urinary: Hemorrhagic cystitis, hematuria proteinuria, SMR for malignant neoplasms of the genito-urinary organs and the bladder.

Neuro-muscular: Asthenia, fatigue, headaches, sleep disturbances, sweating, irritability, confusion, peripheral neural damage, polyneuropathies, delayed peripheral nerve conduction, encephalomyelitis sensorial impairments. . . . Hyperesthesia, impotence . . . lassitude and weakness, vertigo, ataxia, hyporeflexia, rigidity, myotonia, pain in the extremities, joint pain, severe aches in the lower extremities, difficulty in muscular and mental coordination, profound muscular weakness, neuroarthropathy.

Other: Loss in body weight, thymic atrophy, decreased immune competence.

At the time the Agent Orange exposure study had been canceled, CDC's reputation for objectivity and accuracy was beyond reproach. Thus, its false interpretation that few ground troops had been exposed to Agent Orange was accepted as gospel by the scientific community. Other Federal agencies, particularly the VA, were quick to parrot CDC's work and apply it to other research. For example, a 1987 report by the VA on soft tissue sarcoma and military service in Vietnam found that subgroups of ground troops studied who appeared to have higher opportunities for exposure to Agent Orange were at greater risk of contracting the rare cancer, and

[99] Ibid. Testimony of Dr. Steven Stellman, pp. 178–179.

[100] "Observed Clinical Effects of 'Agent Orange,'" Memorandum from Dennis Smith, Visiting Scientist, Agent Orange Projects, Centers for Disease Control, to Dan L. McGee, Ph.D., Senior Statistician, Agent Orange Projects, January 30, 1985, pp. 1–2.

that Army veterans who served combat missions showed a 2.6 times elevated risk of soft tissue sarcoma, as compared to veterans who did not serve in combat.[101]

The study concluded that "the possibility of a modestly increased risk of STS associated with Agent Orange exposure in Vietnam among select groups of Vietnam veterans can be neither confirmed nor ruled out in this study. Additional studies using better characterization of exposure are needed to answer this question." [102] The researchers had planned to conduct such a study. "Initially, an elaborate computer matching of troop location to recorded aerial spray missions . . . was planned. However, an expert government panel has subsequently determined that military records alone could not be used to locate troops with enough precision to allow a scientifically valid estimate of the likelihood of exposure to herbicides." [103] The expert Government panel to which the researchers referred is the AOWG, which based its conclusions on the CDC exposure study.

The VA also downplayed the findings of a mortality study it conducted of Army and Marine Corps veterans of Vietnam. The study found that Marines serving in Vietnam had statistically significant higher elevations of lung cancer and non-Hodgkin's lymphoma, two diseases associated with exposure to phenoxy herbicides.

> The veterans who served in the Marine Corps in Vietnam were seen to have a statistically significant . . . excess of non-Hodgkin's lymphoma when compared with Marines who did not serve in Vietnam.
>
> * * * * *
>
> Non-Hodgkin's lymphoma has been associated with exposure to phenoxy herbicides, arsenicals, dapsone, and certain viruses. The men who served in Vietnam had the potential for exposure to all of these agents. Agent Blue, a herbicide used in Vietnam, was an organic arsenical compound and dapsone, a sulfone, was used as an antimalarial drug by some of the troops in Vietnam. Dapsone has been shown to cause lymphomas in laboratory animals. Dapsone was given mainly to troops stationed in I Corps and the central highland areas of Vietnam where falciparum malaria was prevalent. Most of the Marines in Vietnam served in I Corps.[104]

Dr. Lawrence Hobson, the Director of the VA's Office of Environmental Medicine, testified that the study did not find significantly higher levels of non-Hodgkin's lymphoma and lung cancer. He contended that a "greater proportion" of the subjects studied died from those diseases.[105]

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[101] "Soft Tissue Sarcoma and Military Service in Vietnam: A Case-Control Study," Han Kang, Dr. P.H., Franz Enziger, M.D., Patricia Breslin, Sc.D., Michael Feil, M.S., Yvonne Lee, M.S., and Barclay Shepard, M.D., JNCI, Vol. 79, No. 4, October 1987.

[102] Ibid.

[103] Ibid.

[104] "Proportionate Mortality Study of US Army and US Marine Corps Veterans of the Vietnam War," Patricia Breslin, ScD, Han K. Kang, DrPH; Yvonne Lee, MSc; Vicki Burt, ScM; and Barclay M. Shepard, MD, Journal of Occupational Medicine, Vol. 30, No. 5, May 1988.

[105] Hearing, 1989. Testimony of Lawrence Hobson, M.D., Director, Office of Environmental Medicine, Veterans Administration, p. 138.

> It isn't fair to say that you had more deaths among the marines or a higher rate of death or a higher incidence of death from soft tissue sarcoma among those marines.
>
> The only thing you can say is that more of the ones who died seemed to have died from soft tissue sarcoma than from say heart disease or lung disease or some other form of cancer.[106]

Dr. Hobson's attempt to minimize the VA's finding that Marines were at greater risk of certain diseases obfuscates the facts uncovered by the Agency's research. The committee believes that Federal scientists have an obligation to use pertinent information regarding the health of Vietnam veterans as a tool for further exploration of the risks associated with service in Vietnam. Instead, the VA has consistently attempted to dismiss the relevance of the information to allay the concerns of Vietnam veterans.

Admiral Elmo R. Zumwalt, former Chief of Naval Operations, and more recently a special advisor to the Secretary of Veterans Affairs on Agent Orange, testified before the subcommittee of a conspiracy to withhold the truth about the herbicide from the public.

> The sad truth which emerges from my work is not only that there is credible evidence linking certain cancers and other illnesses with Agent Orange, but that government and industry officials credited with examining such linkage intentionally manipulated or withheld compelling information of the adverse health effects associated with exposure to the toxic contaminants contained in Agent Orange.[107]

Dr. Daniel Thau Teitelbaum, a toxicologist who, through litigation involving herbicide manufacturers, has reviewed their internal records, testified that the companies had withheld information about toxic contaminants in their products. He said the contaminants, called xanthen-9-ones, are toxic in animal species and are contained in 2,4-D, a chemical prevalent in herbicides, including homeowner's weed killers.[108] Dr. Teitelbaum testified that the presence of these contaminants had not been reported to the Environmental Protection Agency or State registration agencies.[109]

An epidemiologist with the National Cancer Institute, Dr. Shelia Hoar Zahm, testified that a recent study she conducted, scheduled for publication in September 1990, has proven 2,4-D to be a carcinogen in agricultural workers who use herbicides with that ingredient.[110]

2,4-D was a major ingredient of Agent Orange, but has not been explored in Federal research regarding the effects of the herbicide on Vietnam veterans.

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[106] Ibid.
[107] Hearing, 1990. Prepared statement of Adm. Elmo R. Zumwalt, Jr., p. 4.
[108] Ibid.
[109] Ibid.
[110] Ibid.

## V. Recommendations

### A. Congress should require the Department of Defense to create an Agent Orange exposure index

In light of the committee's determination that the CDC Agent Orange Exposure Study was flawed and canceled based on erroneous information, the committee believes that an exposure index, matching troop movement records to spray data, still needs to be and can be developed. The committee believes that the Department of Defense has the expertise and resources to conduct such an exposure index—provided adequate, independent peer review is provided by expert bodies not associated with the Department—and recommends that Congress mandate the development of an index.

### B. When an adequate exposure index is developed, the Federal Government should contract through the National Academy of Sciences for a private, independent epidemiological study matching the health outcomes of Vietnam veterans against the exposure index

The development of an exposure index would be only the first part of a study determining the association or non-association of illness to Agent Orange exposure. Given the bias demonstrated by Federal agencies in the past, the committee believes veterans would be better served by an epidemiological study prepared by objective scientists. Using the index developed by the Department of Defense, it is suggested that a private organization be awarded a contract, to be administered by the National Academy of Sciences, to conduct a proper epidemiological study.

### C. All scientific research conducted by Federal agencies should be done without interference from Federal components outside their respective agencies

The White House made crucial decisions affecting the course of CDC's Agent Orange research, and the outcome. This kind of political interference is inappropriate and casts doubts on the integrity and credibility of Federal research. While components of the Federal Government should be free to make policy determinations based on Federal research, they must not be allowed to have policy determine the outcome of such research. The committee recommends that all scientific research conducted in the future by Federal agencies be done independently from the White House or other political organizations. If regulations do not already require such independence, then each agency should promulgate rules to prevent political interference.

## DISSENTING VIEWS OF HON. RICHARD K. ARMEY, HON. FRANK HORTON, HON. HOWARD C. NIELSON, HON. J. DENNIS HASTERT, HON. JON L. KYL, AND HON. CHUCK DOUGLAS

Agent Orange is a highly emotional and controversial issue with strong political pressure for answers. We have deep sympathy for veterans and their families who believe their suffering is due to Agent Orange exposure, and we want the record to be clear that we remain committed to compensating American veterans for service-connected disabilities.

Regrettably, however, instead of advancing the debate on Agent Orange in a positive direction, the Human Resources Subcommittee has abused this issue in order to launch an ideological assault upon a Republican White House with which it has never agreed. Consequently, constructive suggestions for further review and detached review of science are given a back seat to unsubstantiated charges of a political coverup, and the Committee Report seems more concerned with writing the President out of the Constitution than it does with evaluating the science surrounding Agent Orange. Our view is buttressed by the Subcommittee Chairman's steadfast refusal to rethink his charges against the White House and work with us to develop an Agent Orange report that all members of this Committee could support. In fact, the draft report was already printed in final galley form by the Government Printing Office before minority members were ever given a copy.

Our concerns are not limited to procedural grounds, however, and we have many specific reservations with the report. In addition to being highly emotional and controversial, studying Agent Orange is also an extraordinarily complex task, and these enormous complexities cannot be as readily dismissed as they were by the Committee Report. The fact is that while CDC was charged with studying the exposure of Vietnam veterans to Agent Orange, determining exposure is just not as easy as it sounds. For example, when we refer to exposure, do we mean opportunity for exposure or actual exposure to Agent Orange. The distinction is crucial.

If we're referring to actual exposure, several additional factors come into play. What was the quantity of the exposure? How long was the veteran exposed? Was exposure on the skin or clothes? How long did exposure occur after spraying? Was the exposure repeated? The answer to these questions were important factors in the National Cancer Institute studies cited by the Committee Report to substantiate the link between herbicides and certain cancers. Good science suggests that these questions should not have been ignored in the Agent Orange study. Furthermore, the answers to these questions are extraordinarily difficult to ascertain twenty years after actual exposure. Consequently, when we recognize that the CDC study was premised upon determining actual exposure,

and after CDC made several attempts to accurately determine exposure, CDC's conclusion that a scientifically valid exposure study could not be done is not as dubious or devious as some would suggest.

Conversely, if you're conducting an exposure opportunity study as the Committee Report implies the CDC should have done, you invite serious misspecification errors which could render further study useless. Misspecification means that we identify persons as exposed when they were not exposed and vice versa. CDC was reluctant to use this approach because it believed it would be a disservice to veterans to measure the existence or non-existence of health effects on persons who could not be conclusively determined to have been exposed to Agent Orange.

While proponents of an exposure opportunity study readily admit that this approach creates an opportunity for misspecification, they downplay this concern by asserting that these errors will cancel each other out; however, this is not an acceptable response. Epidemiologists who argue that misspecification errors will cancel each other out are guilty of using the statistician's equivalent of the punt. There is no scientifically justifiable explanation for asserting that misspecification errors are random, and the cancelling out argument is nothing more than a convenient way to dismiss errors that can't otherwise be explained away.

The bottom line is that any study put together by CDC would be subject to legitimate attack for its shortcomings. In fact, we suspect that if CDC conducted an exposure opportunity study concluding that there is no relationship between exposure to Agent Orange and adverse health effects, the Human Resources Subcommittee would be the first in line to attack the very model it now supports because of its misspecification weaknesses.

The Committee Report's author would probably seek to refute our arguments by pointing to the independent National Academy of Sciences' (NAS) Institute of Medicine (IOM) report which raises the same criticisms as the Committee Report regarding the CDC's handling of troop data. However, this report is mischaracterized in the Committee Report and is inappropriately used to support the Human Resources Committee's political conclusions.

On July 19th, Institute of Medicine President, Samuel Thier, responded by letter to an article appearing in the July 23rd issue of Time Magazine (Time reaches the newsstands before its published date) entitled "A Cover-Up on Agent Orange." This article reported similar coverup and manipulation charges as those raised in the Committee Report. However, in his letter, Dr. Thier says that the Time article,

> incorrectly says CDC suppressed a 1986 report from the Institute of Medicine (IOM) of the National Academy of Sciences. The document in question was actually an internal report . . . [and] the report did not criticize the CDC study; it was about the Defense Department, not the CDC.

More important, however, Dr. Thier asserted that the report concluded,

> [The] Defense Department was capable of handling troop data, *but also expressed concerns that these might not be accurate measures of exposure to Agent Orange.* [Emphasis ours.]
>
> The 1987 IOM pre-publication review of CDC's Agent Orange Validation Study was critical of the CDC's work because the committee was explicitly asked to critique the agency's draft report. However, *the IOM report also states that the CDC design, methods and analyses were well conceived, appropriately executed, and clearly presented.* [Emphasis ours.]

Unfortunately, the Committee Report does not end with its criticisms of the CDC study, but chooses to extend its outrageous accusations of coverup to the Reagan White House.

After subpoenaing virtually every imaginable document prepared, reviewed or witnessed by the White House regarding Agent Orange, the most the Committee Report can tell us is that the White House opposed legislation which presumed that simple exposure alone to Agent Orange constituted a service-connected disability meriting compensation. We are then asked to conclude that this opposition provided the impetus for its plot to cover up the truth about Agent Orange. This conclusion is simply not supported by the facts.

First, we need to acknowledge that compensating veterans for simple exposure to Agent Orange is a political decision, not a scientific one. Scientific information made available to the White House, from both inside and outside of government, has failed to establish any supportable conclusive link between simple exposure to Agent Orange and adverse long-term health effects. Therefore, the practical effect of the White House's legislative position was to oppose spending billions of tax dollars to compensate for an event that virtually no scientist has linked to long-term disabilities.

Consequently, we find it highly ironic and extremely troublesome that while the White House is repeatedly attacked in the Committee Report for ignoring science and using political manipulation, when the White House makes a decision clearly supported by science, this decision is seized upon by the majority as the key evidence supporting a political coverup. We wonder who's the real one playing politics.

Next, we find it totally implausible for the White House to mastermind a coverup on its own when Congress was intimately involved in the Agent Orange proceedings since their inception. The Office of Technology Assessment (OTA) and the House Veterans Affairs Committee under the able leadership of its Chairman Sonny Montgomery had either participated in or had overseen the progress of the CDC study, and both supported the CDC's activities and conclusions.

In a House Veterans Affairs Subcommittee press release dated March 29, 1990, Chairman Montgomery is quoted,

> Agent Orange has been and remains an emotional and controversial issue, but the findings of [the CDC] and all reputable studies are convincing: There is nothing to show

> decisively that there are long-term adverse health effects as a result of exposure to Agent Orange.

Regarding the report prepared by Admiral Zumwalt and relied on so extensively by the Human Resources Subcommittee, the OTA had this to say in a July 23rd, 1990 letter from John Gibbons to Congressman Montgomery,

> The report seems to take the form more of a legal brief than of a scientific review of evidence. . . . Based on a review of the areas in which OTA has been involved, we conclude that many of the assertions made in the report supporting a conclusion that Agent Orange is responsible for a wide range of health problems among Vietnam veterans, are incorrect. These are not mainly matters of differing opinion, but matters of fact—what did or did not happen. For those aspects about which OTA staff have detailed knowledge, it appears that Admiral Zumwalt's arguments are based, in many instances, on faulty information or incorrect interpretation of data.

Therefore, the Committee Report cannot accuse the White House of engineering a coverup without also implicating Congress and several highly respected members of this body, and we refuse to do so. Charging Members of Congress for a coverup is simply ludicrous, and so is charging the White House as well.

We suspect that the real motivation behind the Human Resources Subcommittee Chairman's zealous attack on the White House is to lay the groundwork for his final recommendation and real goal: writing Republican Presidents out of the Constitution. By recommending that all scientific research conducted in the future be done independently from the White House or other "political" organizations, this goal is made clear.

However, the last time we looked, Article II, Section I of the Constitution of the United States still vested executive power in the President of the United States. Notwithstanding the desires of the Committee Report's authors, we are unaware of any Constitutional Amendments to change this "political" office.

This final recommendation of the Committee Report is most troubling because it highlights an ongoing double standard applied by the Human Resources Subcommittee regarding the work of scientists, both inside and outside of government. The implications of this double standard are clear: If you're a scientist who agrees with the political conclusions of the Human Resources Subcommittee Chairman, your views will be put forth as gospel, and no one has a right to question them. On the other hand, if you're a scientist who disagrees with the Chairman's political conclusions, you'll either be lucky enough to be ignored, or you'll face the unfortunate prospects of having your views attacked and your integrity questioned before a publicly held Congressional hearing.

We are simply tired of seeing Administration officials constantly dragged through the Human Resources Subcommittee wringer under the banner of science over politics, when the Subcommittee is the one so clearly guilty of playing politics itself.

Veterans deserve much better than what this report seeks to offer.

RICHARD K. ARMEY.
FRANK HORTON.
HOWARD C. NIELSON.
J. DENNIS HASTERT.
JON L. KYL.
CHUCK DOUGLAS.

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