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SCIENTIFIC COMMUNITY REPORT ON AGENT ORANGE

HEARING

BEFORE THE

SUBCOMMITTEE ON
MEDICAL FACILITIES AND BENEFITS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

SEPTEMBER 16, 1980

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SCIENTIFIC COMMUNITY REPORT ON AGENT ORANGE

TUESDAY, SEPTEMBER 16, 1980

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON MEDICAL FACILITIES AND BENEFITS,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The Subcommittee on Medical Facilities and Benefits met pursuant to notice, Hon. David E. Satterfield (chairman) presiding.

Chairman SATTERFIELD. This morning we will continue our hearings on agent orange—this being the fourth in a series of hearings—to receive testimony on the latest and most current scientific information dealing with possible long-term health effects of exposure to dioxin by humans.

In keeping with my previous opening statements at hearings on this subject, I want to say again that this subcommittee wants to obtain the truth about agent orange and to do so as soon as objective and thoroughly scientific findings are possible. Nothing less than the facts will satisfy this committee nor should anything less satisfy the American public or the Vietnam veteran. We know that there may be no quick answers or rapid resolutions to the many differences of opinion about how best to conduct and coordinate the numerous ongoing scientific investigations; however, we do seek to encourage and develop the means whereby we can find the answers to the problem as soon as possible.

In December 1979, you will recall, the President formed an interagency work group to study the possible long-term health effects of phenoxy herbicides and contaminants and to coordinate all Federal research efforts regarding agent orange and other herbicides. That group, which is directed to report to the public on a regular basis its findings relative to results and implications of this research, includes distinguished representatives of the Department of Health and Human Services, the Department of Defense, and the Veterans' Administration. Also participating as observers are highly qualified personnel of the Environmental Protection Agency, the Departments of Agriculture and Labor, the White House Office of Science and Technology Policy, and the Congress Office of Technology Assessment.

This morning we will receive testimony concerning recent activities of the scientific panel of the interagency work group in regard to the agent orange issue. We will also receive from the Veterans' Administration its latest findings with regard to scientific evidence thus far compiled and evaluated by it as well as a summary of the VA in-house education efforts and the situation regarding current claims alleging agent orange causation.

In line with the interagency work group's panel recommendation that the Air Force proceed with its planned study of Operation Ranchhand personnel that is, the Air Force personnel who prepared the aircraft for or who were involved in the spraying of herbicides in Vietnam—we will receive testimony from the Air Force concerning its progress in identifying the population which was thus exposed to agent orange as well as its progress to date in planning that study of the population whose nature and extent of exposure to agent orange can plausibly be documented with any degree of reliability. We will also hear from the American Council of Science and Health regarding its recent research into the effects of dioxin exposure.

I now recognize the distinguished ranking minority member of the subcommittee, the Honorable John Paul Hammerschmidt.

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman. I would like to commend you once again for holding these hearings. I consider them to be vital for two reasons. First, we on this subcommittee have a duty to monitor the progress of the research taking place with respect to agent orange. The fact that you have scheduled three oversight hearings during this session alone speaks well for how seriously you and others have taken this duty. Second, we have a responsibility to those who may have been exposed to agent orange in ways that could be harmful. This responsibility extends beyond merely monitoring the research and providing for these veterans in the event that research shows that they were indeed harmed. We also have a responsibility to keep them fully informed, to help allay fears caused by sensationalistic publicity, and to give them the assurance that we are doing all we can.

These hearings which are open to the public and to the press are helpful, I hope, in doing just that. I have read the testimony we will hear today, and I suppose the best capsulization would be that the process of examination and study of possible harmful effects will be a long one. I bring this out at the opening of our hearings, Mr. Chairman, because I would like very much for all of our witnesses to begin thinking of suggestions for interim measures that might be effective in helping potential recipients of VA benefits.

It seems to me that we have three possibilities emerging from the research at least in its present state. First, many disorders may have been the result of exposure to agent orange and be provable as such. Second, disorders may have been the result of such exposure and never be provable. Third, they may be totally unrelated.

I am not suggesting at this point, Mr. Chairman, that any of these three possibilities is the one research will eventually come up with. I am merely wondering how those of us on this committee might feel 8 or 10 years from now if it is firmly established that a causal connection exists and large numbers of our Vietnam veterans have been suffering without help during that period. Is an interim remedy available in order to prevent irreparable harm and without inviting unwarranted claims?

I look forward to hearing the recommendations of our witnesses. Thank you, Mr. Chairman.

Chairman SATTERFIELD. Thank you, Mr. Hammerschmidt. Our first witness this morning is Dr. Philip Handler, president of the

National Academy of Sciences. We welcome you. I understand that you are accompanied by Robert Tardiff, also of your group. I would like to point out to my colleagues that Dr. Handler has an important engagement at 11:30 and I have assured him that we would do what we could to see that he may meet that appointment without having to rush. Dr. Handler, we welcome you this morning. We will be happy to receive your testimony. Your written statement will appear in the record.[1]

STATEMENT OF DR. PHILIP HANDLER, PRESIDENT, NATIONAL ACADEMY OF SCIENCES

Dr. HANDLER. Thank you very much, Mr. Chairman. I am very pleased to be here, pleased to have your invitation to present some information to your committee. I am accompanied, sir, by Dr. Robert Tardiff, who is the executive director of our Board on Toxicology and Environmental Health Hazards and I hope that he will be useful to the committee at your pleasure.

What I would like to do, if I might, is to trace some of the history of the relationship of the Academy to the entire problem of agent orange and its principal contaminants and their possible health effects as we have witnessed these.

The compound 2,3,7,8-tetrachlorodibenzo-para-dioxin, usually abbreviated TCDD, is an obligate contaminant of 2,4,5-T, the herbicide which is the material which is used for its own purposes. And as best we know them today, most, if not all, of the effects which have been attributed in the past to 2,4,5-T have actually been the result of the presence of this contaminant, particularly in agent orange.

Let me assure you, Mr. Chairman, that the Academy recognizes the urgency of establishing a firm scientific base for the resolution of the health issues surrounding agent orange and, with my colleagues, we, too, congratulate you on conducting this set of hearings.

In the last decade, the phenoxy herbicides, including 2,4-D and 2,4,5-T, have been receiving much attention with respect to their potential health effects. 2,4,5-T was examined in a substantial testing program under the National Cancer Institute in the middle sixties, and at that time a particular sample tested was found to induce birth defects in experimental animals. That observation led to an extensive investigation by a panel of the President's Science Advisory Committee (PSAC), of which I was then a member, as well as by the Academy. During that review, a suspicion emerged that the major cause of teratogenicity might reside not in the 2,4,5-T itself but in a contaminant, one of the dioxins. A sample that had been used in that original test was recovered, rechecked for its teratogenicity in laboratory animals, and also analyzed for the presence of dioxins. The analytical methods available at the time were less than adequate but they served the purpose. Much better methods are available today. And at the time the sample was found to contain 27 parts per million of a dioxin. The meaning of that was not entirely apparent at the time.

It was also possible to prepare highly pure 2,4,5-T and to secure the dioxin as a pure compound; each of these was then tested separately for its teratogenicity. The study showed not only that

[1] See p. 11.

the dioxin was highly teratogenic, but also that 2,4,5-T itself had some residual teratogenicity, albeit at rather high doses. It has been in the time since that there has been much attention given to this matter.

The matter became a public issue particularly because 2,4,5-T was used in the Vietnam war as a defoliating agent by our forces. It should be noted that much of the 2,4,5-T used in agent orange at that time contained substantially more dioxin than does any current production. There has been concern about possible teratogenic effects on the Vietnamese population as well as concern about possible effects on military personnel involved in the dispersal of 2,4,5-T during that war. At present, the 2,4,5-T sold in the United States is highly pure, containing less than 0.05 part per million of dioxin. There remains, then, continuing concern even for this highly purified 2,4,5-T. Dioxin is an extremely potent toxicant to the reproductive systems of female laboratory animals, although not, to our knowledge, in male laboratory animals. In addition to its teratogenicity, it has been found to be carcinogenic. The above findings led to severe restrictions in the permitted use of 2,4,5-T in the early seventies and to an emergency suspension, this past year, on the use of 2,4,5-T on forests and rights of way. That suspension resulted from an alleged increase in the number of spontaneous abortions in an area in Oregon where 2,4,5-T had been used as part of forestry practices. We at the Academy have not reviewed the basis for that charge, and I can make no comment.

Involvement of the Academy in the evaluation and understanding of the health risks of agent orange goes back approximately a decade. I hope it will be helpful to outline the pertinent highlights of our past and present studies and the reviews undertaken by the Academy on behalf of the Government and then to describe for your consideration areas of possible investigation which may in the future contribute to the resolution of the perplexing problem of delayed sequelae from exposures to dioxins. In that regard, the resources of our National Research Council are available to assist the Nation in developing a strategy to gain increased understanding of the nature and the degree of chronic risk, if such there be, to exposed individuals.

In late 1970, the Congress directed the Department of Defense to arrange with the Academy for a study of the ecological and physiological effects of the widespread military use of herbicides in South Vietnam. This extensive investigation developed an inventory of the areas sprayed by the herbicide. We took aerial photographs of those areas and examined such areas as we could on the ground, but most of them were denied to us by the military circumstances at the time. We reviewed the effects caused to all sorts of vegetation, studied the persistence of herbicides in the soil and in the streams, looked at the effects of herbicide orange on animal populations in the estuaries of Vietnam, and attempted to identify effects of the defoliant on resident populations that we thought had been exposed to agent orange. And, sir, this is a copy of the summary of that study. The study itself is a foot-long shelf of documents which emerged at the time. They were submitted to the Congress and to the Department of Defense and this is simply the summary and conclusions.

Chairman SATTERFIELD. If you will give it to this committee——

Dr. HANDLER. We would be very pleased to do so, Mr. Chairman, along with several relevant working papers associated with the study.

Chairman SATTERFIELD. If so then, without objection, it will be admitted into the file of these hearings.

Dr. HANDLER. At the time that report was issued, I foresaw the serious implication of dioxin on human health. In a letter to then Secretary of State Kissinger, I noted: "* * * The hazard could well be serious and indeed is so regarded by knowledgeable individuals in this country as well as in Southeast Asia * * *." Many of those issues are more sharply focused today than they were at the time.

The rather limited data which we were able to collect failed to indicate any direct damage by herbicides to human health in Vietnam. However, there were consistent but secondhand reports from certain areas of the country, among the montagnards, of acute and occasionally fatal respiratory distress, particularly in children. There were also reports of severe irritation to the eyes and the skin as well as digestive disturbances. No physician saw any of those persons, so the secondhand information we received did not even come from physicians who had seen these alleged victims. No independent medical studies of these exposed populations were available, and it was impossible to confirm or deny any of these reports.

While considerable attention was paid by the committee to the possibility of birth defects induced either by herbicides or by contaminants in herbicide preparations, no evidence to substantiate the occurrence of herbicide-induced defects was obtained, and I will return to that in a moment.

The committee noted that over 10 million gallons of agent orange were used in South Vietnam, suggesting that about 200 to 300 pounds of dioxin had been released over South Vietnam and that no serious sequelae in human beings had been identified.

However, at the time, that committee did not study or review the effects of herbicides on U.S. military personnel who were serving in South Vietnam; no reason to do so had been called to their attention. That they neglected to look at those who participated in Ranch Hand, I think in retrospect, was a very serious defect; but it was not called to anyone's attention at the time.

The final report of that Academy study recommended that the medical data collected at the Barsky Unit of the Cho Ray Hospital in Saigon be evaluated. That is a very large pediatric hospital to which a large fraction of all children born in South Vietnam with birth defects were brought for examination and sometimes surgery. We thought this was a possible place to pick up any information that might correlate the incidence of birth defects with whether children so affected lived in areas that had been sprayed. This was an attempt to determine whether there might be a relationship between exposure and the development of congenital malformation.

Later, when records of the herbicide spray missions were linked with the patients' home addresses, there appeared to be no statistically significant association between probable exposure to the herbicide of the mother during the first trimester of pregnancy and the proportion of patients with birth defects. But in view of the

invariable nature and less than total reliability of the clinical data, as well as the impossibility of gathering additional information from Vietnam, an exhaustive and conclusive report of their data was not possible. In the hope that such data as there are may be helpful in adding to our knowledge, we hope shortly, to complete a brief report on that evaluation. It has never previously been published but it has just been completed and will shortly be made available. I can only say that the data proved to be equivocal at best; if, indeed, agent orange caused any birth defects in South Vietnam, the absolute number must have been quite small, and they cannot be detected by statistical procedures.

The second area of Academy activity was initiated in the middle of last year when the Air Force requested the Academy to conduct an extensive peer review and evaluation of a proposed epidemiological study to be undertaken by the Air Force itself of its personnel who had been stationed in Vietnam and involved in the spraying of agent orange between 1962 and 1971.

Specifically, the Academy was asked to consider whether the study was adequately designed to address various issues such as: toxicity, epidemiology, statistics, data collection, and overall health effects. The Air Force also requested that consideration be given to additional ways in which the scientific validity of the study might be improved, other techniques that might be included in the study, as well as additional statistical procedures which might clarify any detected associations from exposure to agent orange.

An Academy panel reviewed the Air Force protocol and completed its report early this year. That report states that the proposed study of Ranch Hands, is designed, is unlikely to achieve its scientific goals because of the relatively small sample size and because of the limited followup period that was planned. The panel then recommended redesign of the study to include longer followup and more careful selection of its end-points. At the time, the panel also asked the Air Force to review the selection of the group that was intended to perform the study, namely Air Force personnel themselves, with respect to the public's perception of credibility of a study so conducted. It is my understanding that the Air Force is attempting to modify its protocol in keeping with our recommendations. We would, of course, be pleased if we were asked by the Air Force to assist in some further review of their next generation protocol.

As a result of questions raised in earlier hearings of the Senate Committee on Veterans' Affairs, the Academy undertook at that committee's request a brief informal review of the Veterans' Administration's so-called fat study. This review was to examine the persistence of dioxin in the fatty tissue of veterans who might have been exposed. The Academy's reviewers found methodologic difficulties so substantial as to make untenable any conclusions correlating exposures to dioxin and agent orange in Vietnam and possible health risks to date. In addition, it was pointed out that a basic fallacy had crept into one of the underlying premises concerning the longevity of dioxin in human adipose tissue. As I understand it, all that means is that, from what one knows about the behavior of dioxin in fatty tissue in other species, there is little reason to believe that veterans who genuinely had been exposed to dioxin

during their time in Vietnam would today continue to carry that dioxin. It should have been gone by now.

As you also may know, earlier this year Chairman Roberts requested the Academy to review five epidemiological studies conducted outside the United States of individuals exposed occupationally to phenoxy herbicides and to dioxin and to comment on the methodology, the findings, and the conclusions of these studies. At that time our staff provided a preliminary brief review. In my reply I noted that the studies provided very little substantive data about the association, and even less about causation, of cancer by the phenoxy herbicides and their contaminants because of the methodologic weaknesses of these studies. At best, these studies point to some association between occupation and cancer, but it is unlikely that attribution can be established with respect to exposure to any particular specific chemical. I should add that such data serve better as stimuli to broad-gaged investigations whose design favors the generation of data sufficiently sensitive to discriminate among various chemicals in the environment than as the basis for substantive conclusions.

Our National Research Council has also been extensively involved in the medical followup studies of one of the more noted chemical disasters: namely, the widespread exposures to dioxin that occurred in Seveso, Italy. In July 1976 at Seveso, a reaction vessel in a chemical manufacturing plant accidentally vented trichlorophenol containing highly toxic dioxin as a contaminant. The resulting cloud of chemical was carried southward by the wind for several kilometers, exposing humans, animals, and plant life. At the time when we at the Academy were so informed, while deeply regretting the incident, it occurred to us that we might look at it as an opportunity. As you may know, Mr. Chairman, the Academy has, ever since the end of World War II, managed, conducted, operated the laboratories of the Atomic Bomb Casualty Commission at Hiroshima and Nagasaki, and we have been responsible for all that has been learned about what has happened to those who survived those two bombs. That information is the basis for everything we currently understand about the effects of radiation on human beings, particularly the dose/response relationships. It occurred to us that that Seveso incident might again be an experiment we would never conduct, but, having occurred, we should use it to get as much information as possible. So, the Academy offered, on its own, to cooperate with the Italian Government and the scientific community there to study the effects of that accident.

An Academy National Research Council team visited in Italy in early 1977 and recommended:

> The development of a continuing relationship of U.S. scientists with their Italian counterparts to exchange scientific and technical information, to encourage the conduct of complementary research, organize workshops and conferences as appropriate, and to aid in coordinating visits of scientific experts and the exchange of scientists.

In response to those recommendations, the Committee on Response Strategies to Unusual Chemical Hazards was established within our National Research Council to interact with an Italian counterpart committee which was established for the purpose. In the first phase, the binational group met to define the needs and

the opportunities for study of the after effects of the Seveso incident through various mechanisms including a series of workshops.

As a result of those interactions, our committee arranged an international workshop which met in March of 1980 concerning plans for clinical and epidemiological followup after area-wide chemical contamination. The human exposures to dioxin both in Italy and in our country figured prominently in this program. Specific attention was addressed to the dermatologic, reproductive, neurologic, immunologic and mutagenic effects of dioxin as well as the potential for carcinogenesis. The major effects which have been seen to date are the skin lesion, which is called chloracne, and certain neurological deficits which persist to this time, albeit without associated behavioral changes. We hope to have the proceedings of this workshop edited and published for general use in the next few months. We will continue with that program and we trust that it will, in due course, serve the purposes to which it is intended as a basis for illuminating the effects of dioxin on human beings.

Despite the existence of much evidence from laboratory experiments concerning the adverse health effects of 2,4,5-T and dioxin, many issues remain to be resolved through careful studies of past human exposures and by dispassionate evaluation.

In my opinion, efforts of the research community should be structured around two types of investigations.

First: Evaluation of the health status of humans accidentally exposed to high levels of dioxin. And the second, intensive controlled studies of human surrogates; that is, laboratory animals and certain kinds of cell systems to be studied apart from whole animals.

Occupational and accidental exposures have been identified in many areas of the world. In general terms, concentrations and the duration of exposure are known for numerous individuals. Careful studies of such highly exposed groups of persons are most likely to identify the adverse long-term health consequences of dioxin in humans. Combining the data from such experiences, rather than examining in isolation small, select populations, will greatly enhance our capacity for analysis. It is our understanding that a step toward this objective has been undertaken by the National Institute of Occupational Safety and Health (NIOSH) which is developing a registry of persons exposed to dioxin in the United States. That effort can be extended internationally, perhaps with the assistance of the World Health Organization (WHO). Investigations of that larger cohort might, hopefully, generate far more definitive data on any cause-effect relationship for dioxin in man.

Before embarking on such a large-scale effort, we have suggested that a feasibility study be undertaken by the Academy in cooperation with WHO to identify the sources of data, particularly those outside the United States. Such registries would be particularly useful in the evaluation of risks of chronic diseases, particularly cancer, cardiovascular disease, and neurologic impairment. It is well recognized that chronic diseases such as cancer often take many decades to develop after initial exposure. Thus, if risks exist for populations such as those at Seveso, Italy, or the Vietnam veterans, the expression of those risks may not be forthcoming for

many years hence. This argues, of course, for an immediate and comprehensive evaluation on a worldwide basis of the substantial number of industrial workers exposed to dioxin over the past several decades. In addition, it also calls for a long-term commitment on the part of Government to pursue clinical and epidemiological studies of those exposed to dioxin.

Laboratory evidence attributes to dioxin two serious adverse effects: (*a*) Deleterious influence on the female—but not the male—reproductive system, including birth defects; and (*b*) carcinogenesis. More emphasis must be placed on defining the ways in which dioxin exerts its detrimental effects on experimental animals and in what manner, if any, it may constitute risk to humans. To this end, laboratory studies investigating the generation of reproductive deficits and birth anomalies and those evaluating potential carcinogenesis would be particularly appropriate. A noteworthy example of a reproductive study was recently reported by the investigators of the National Institute of Environmental Health Sciences. The principal author thereof is in the room, sir. The study carefully pursued the possibility of birth anomalies in the offspring of exposed males, a study question which has rarely been pursued, I am sure that Dr. Moore will be pleased to tell you about this. Continued experimentation of this nature is heartily endorsed.

Some recent experimental evidence suggests that dioxin adversely effects both the immune and the nervous systems of exposed animals. Since these studies are amenable to investigation in humans by a variety of physiologic and biochemical methods, their study should be encouraged where feasible in the case of persons exposed to high levels of dioxin.

Those are some of the avenues that can be pursued by appropriately qualified scientists. It is our understanding that the Government has convened an interagency group to develop strategies to investigate the many health questions related to agent orange, 2,4,5-T, and dioxin. We endorse such intensified and consolidated approaches. We look forward to their reports.

In areas of scientific uncertainty and public debate, the resources of the Academy and the National Research Council are often called upon to assist Federal decisionmakers in developing appropriate research strategies. Our Board on Toxicology and Environmental Health Hazards has had an active interest in performing a comprehensive evaluation of the health effects associated with exposures to the chlorinated dibenzo-dioxins and their highly toxic chemical cousins, the chlorinated dibenzo-furans. For both classes there appears to be substantial human exposure as well as extensive toxicological data to warrant such an evaluation. Review of the significance of these agents with respect to the health of the Nation should include a dispassionate, rigorous analysis of the existing scientific information. To be helpful in this respect, we have prepared a study proposal for consideration of the VA, the EPA, and the National Institute of Environmental Health Sciences. We currently await their response. The anticipated benefits of such an evaluation would accrue to veterans, workers, and the general population. We would be pleased to be of assistance to the Subcommittee on Medical Facilities and Benefits in reaching reasonable, equitable solutions to the problems which have been generated by

the attribution of diverse health problems in veterans to exposures to herbicide orange while in service.

Mr. Chairman, I appreciate the opportunity you have provided for me to outline those activities of the Academy that have been part of the national effort to improve our understanding of dioxin exposure experienced by our Vietnam veterans. Dr. Tardiff and I will be pleased to respond to any questions you may have, sir. Thank you very much.

Chairman SATTERFIELD. Thank you, Dr. Handler.

Testimony
of
Philip Handler, President
National Academy of Sciences
National Research Council
Washington, D.C.

Thank you, Mr. Chairman, for your invitation to the National Academy of Sciences to present information to your Subcommittee. I am Philip Handler, President of the National Academy of Sciences and Chairman of the National Research Council. I am accompanied by Dr. Robert Tardiff, Executive Director of our Board on Toxicology and Environmental Health Hazards.

Let me remind you that the National Academy of Sciences is a private organization of some 1,300 scientists, chartered in 1863 by the Congress to provide advice to the federal government on matters of science. The National Research Council, the operating arm of the Academy, has at present, about 700 committees and 7,500 committee members endeavoring to provide objective scientific judgements on subjects ranging over the full spectrum of science, medicine, and engineering. The Academy speaks primarily through the published reports of the studies conducted by these committees.

Today I will discuss the findings of several Academy reports that bear upon the question of the potential risks associated with exposure to the herbicide 2,4,5-T and its obligate dioxin contaminate, 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD), with emphasis on the dioxin present as a contaminant in Herbicide Orange. In addition, my colleague and I are prepared to comment on this question from the base of our individual scientific expertise.

Let me assure you, Mr. Chairman, that the Academy recognizes the urgency of establishing a firm scientific basis for the resolution of the health issues surrounding Herbicide Orange.

Background. In the last decade, the phenoxy herbicides, including 2,4-D and 2,4,5-T, have been receiving much attention with respect to their potential health effects. 2,4,5-T was examined in a substantial testing program under the National Cancer Institute in

the middle sixties, and a particular sample tested was found to induce birth defects in experimental animals. This led to an extensive investigation by a Panel of the President's Science Advisory Committee (PSAC) and by the National Academy of Sciences-National Research Council. During the review by the PSAC a suspicion emerged that the major cause of teratogenicity might reside not in the 2,4,5-T, but in a contaminant, one of the dioxins. A sample used in the original test was recovered and rechecked for its teratogenicity in laboratory animals and also analyzed for the presence of the dioxins; it was found to contain 27 parts per million (ppm) of TCDD. It was also possible to prepare highly pure 2,4,5-T and to secure TCDD as a pure compound; each of these were then tested for teratogenicity. The studies showed not only that TCDD was highly teratogenic, but also that the 2,4,5-T itself had residual teratogenicity albeit at rather high doses. Subsequently, there has been much publicity and intensive additional study. The matter has become a public issue particularly because 2,4,5-T was used in the Vietnam war as a defoliating agent by U.S. forces. (It should be noted that much of the 2,4,5-T used in the herbicide "Agent Orange" at that time contained substantially more TCDD than does current production.) There has been concern about possible teratogenic effects on the Vietnamese population as well as concern about possible effects on the military personnel involved in the dispersal of 2,4,5-T during the Vietnam war. At present, 2,4,5-T as sold in the United States is highly pure containing less than 0.05 ppm of TCDD. There remains, however, continuing concern for even this highly purified 2,4,5-T. TCDD is an extremely potent toxicant to the female reproductive system of laboratory animals and, in addition to its teratogenicity, has been found to be

carcinogenic. The above findings led to severe restrictions in the permitted use of 2,4,5-T in the early seventies, and to an emergency suspension this past year on 2,4,5-T for use on forest and rights of way. This suspension resulted from a purported increase in the number of "spontaneous" abortions in an area in Oregon, where 2,4,5-T had been used as part of forestry practices.

Academy Studies. Involvement of the Academy in the evaluation and understanding of health risks from 2,4,5-T (a component of Herbicide Orange) and its obligate contaminate TCDD goes back approximately a decade. I suggest that it would be helpful to outline the pertinent high-lights of past and present studies and reviews undertaken by the Academy on behalf of the government and to describe for your consideration areas of possible investigation which may contribute to the resolution of the perplexing problem of delayed sequelae from exposures to TCDD. For the record I would like to add that the resources of the Academy's National Research Council are available to assist in supporting the nation's strategy for increasing understanding of the nature and degree of chronic risk, if any, to exposed individuals.

In response to public concern about the extensive use of herbicides in the Vietnam war, Congress--in late 1970--directed the Department of Defense to arrange with the Academy for a study of the ecological and physiological effects of the wide-spread military use of herbicides in South Vietnam. This extensive investigation developed an inventory of the areas sprayed by the herbicide, reviewed the effects caused to vegetation, studied the persistence of herbicides in soil, looked at the effects of Herbicide Orange on animal populations in estuaries of Vietnam, and attempted to identify effects of the defoliant on resident populations exposed to Herbicide Orange.

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At the time the NAS report was issued, I foresaw the serious implications of dioxin on human health. In a letter to Secretary of State Henry Kissinger, I noted: "...The hazard could well be serious and indeed is so regarded by knowledgeable individuals in this country as well as in Southeast Asia..." Many of these issues are more sharply focused today.

The perhaps limited data collected by the committee failed to indicate direct damage by herbicides to human health. However, there were consistent, although mostly "second-hand" reports from certain areas of acute and occasionally fatal respiratory distress, particularly in children. There also were reports of severe irritation to the eyes and skin, as well as digestive disturbances. However, no independent medical studies of exposed populations were available from the time of spraying, to confirm or deny these reports.

While considerable attention was paid by the committee to the possibility of birth defects induced either by herbicides or by contaminants in herbicide preparations, no evidence to substantiate the occurrence of herbicide-induced defects was obtained.

The committee noted that over ten million gallons of Herbicide Orange were used in South Vietnam, suggesting that perhaps 200-300 pounds of TCDD had been released over South Vietnam, and that no serious sequelae had been identified.

However, at the time, that committee did not study or review the effects of herbicides on U.S. military personnel who served in South Vietnam, nor had any reason to do so been called to their attention.

The final report of that NAS study, "The Effects of Herbicides in South Vietnam," recommended that the medical data collected at

the Barsky Unit of Cho Ray Hospital in Saigon be evaluated to determine whether there might be a relationship between exposure to herbicides and the development of congenital malformations.

Later, when records of the herbicide spray missions were linked with patients' addresses, there seemed to be no statistically significant association between probable exposure to the herbicide during the first trimester of pregnancy and the proportion of patients with birth defects. In view of the variable nature of the clinical data, and the impossibility of gathering additional information from Vietnam, an exhaustive and conclusive report of their data was not possible. In the hope that what data there is may be helpful in adding to our knowledge we shortly hope to complete a brief report on this evaluation. I can say, however, that the data proved to be equivocal at best; if, indeed, Agent Orange caused any birth defects in South Vietnam, the absolute number must have been quite small.

A second area of Academy activity was initiated in mid-1979 when the United States Air Force requested the Academy to conduct an extensive peer review and evaluation of a proposed epidemiological study by the U.S. Air Force of its personnel stationed in Vietnam and involved in the spraying of Herbicide Orange during 1962-1971.

Specifically, the Academy was asked to consider whether the study was adequately designed to address various issues such as: toxicity, epidemiology, statistics, data collection, and over-all health effects. The Air Force also requested that consideration be given to: additional ways in which the scientific validity of the study might be improved, other techniques that might be included in the study, as well as additional statistical procedures which might add to the clarity of any detected associations from exposure to Herbicide Orange.

An Academy panel reviewed the Air Force protocol and completed its report early this year. The report concluded that the proposed study of "Ranch Hands," as designed, was unlikely to achieve its scientific goals because of the relatively small sample size and limited follow-up period. The Panel then recommended a re-design of the study to include longer follow-up and more careful selection of end-points. The Panel also asked the Air Force to review the selection of the experimental group with respect to the public's perception of credibility. It is my understanding that the Air Force is attempting to modify its protocol in keeping with our recommendations. We would, of course, be pleased if asked by the Air Force to assist in a further review of their next generation protocol.

As a result of questions raised in earlier hearings of the Senate Committee on Veterans Affairs, the Academy undertook at the Committee's request a brief informal review of the VA's so-called "Fat Study". The Academy's reviewers found methodologic difficulties so substantial as to make untenable any conclusions correlating exposures to TCDD and Agent Orange in Vietnam and possible health risks today. In addition, it was pointed out that a basic fallacy had crept into one of the underlying premises concerning the longevity of TCDD in human adipose tissue.

As you also may know, earlier this year Chairman Roberts requested the Academy to review five epidemiologic studies conducted outside the U.S., of individuals exposed occupationally to phenoxy herbicides and to TCDD and to comment on the methodology, findings and conclusions of these studies. At that time our staff provided a preliminary and brief review. In my reply, I noted that the studies provided very little substantive data about the association--and

even less about causation--of cancer by the phenoxy herbicides and their contaminants because of methodologic weaknesses. At best these studies point to an association between occupation and cancer but it is unlikely that attribution can be established with respect to exposure to any particular chemical. I should add that such data serve better as stimuli to broad-gauge investigations whose design favors the generation of data sufficiently sensitive to discriminate among various chemicals in the environment than as the basis for substantive conclusions.

The Academy's Research Council also has been extensively involved in medical follow-up studies of one of the more noted chemical disasters: namely, the wide-spread exposures to TCDD at Seveso, Italy. In July 1976, at Seveso, Italy, a reaction vessel in a chemical manufacturing plant accidently vented trichlorophenol containing highly toxic TCDD as a contaminant. The resulting cloud of chemical was carried southward by the wind for several kilometers, exposing humans, animals, and plant life. The Academy offered to cooperate with the Italian government and scientific community to study the effects of the accident. An NAS/NRC team that visited Italy in early 1977 recommended:

> "The development of a continuing relationship of U.S. scientists with their Italian counterparts; 1) to exchange scientific and technical information, 2) to encourage the conduct of complementary research, 3) to organize workshops and conferences as appropriate, and 4) to aid in coordinating visits of scientific experts and the exchange of scientists."

In response to those recommendations, a Committee on Response Strategies to Unusual Chemical Hazards was established within the

NRC to interact with the Italian counterpart committee. In the first phase, the binational group met to define the needs and opportunities for study of the after-effects of the Seveso incident through various mechanisms including a series of workshops.

As a result of interactions with the Italian committee in 1979, our NRC Committee arranged an international workshop for March, 1980, concerning plans for Clinical and Epidemiologic Follow-up After Area-wide Chemical Contamination. The human exposures to TCDD in Italy and the United States figured prominently in this program. Specific attention was addressed to the dermatologic, reproductive, neurologic, immunologic and mutagenic effects of TCDD as well as the potential for carcinogenesis. While information about specific effects are important, general principles were developed to facilitate rigorous investigations of wide-spread exposures and their impacts on human health. We hope to have the proceedings of this workshop edited and published in the next few months.

Recommendations for Additional Studies. Despite the existence of much evidence from laboratory experimentation concerning the adverse health effects of 2,4,5-T and TCDD, many issues remain to be resolved through careful studies of past human exposures and by dispassionate evaluation.

In my opinion, efforts of the research community should be structured around two types of investigations: the first, evaluation of the health status of humans accidentally exposed to high levels of TCDD; and, the second intensive and controlled studies of human surrogates (i.e., laboratory animals and some *in vitro* systems).

Occupational and accidental exposures have been identified in many areas of the world; in general terms, concentrations and duration of exposure are known. Careful studies of such highly

exposed groups of persons are most likely to identify the adverse health consequences of TCDD in humans. Combining the data from such experiences, rather than examining in isolation small select populations, will greatly enhance our capacity for analysis. It is our understanding that a step toward this objective has been undertaken by the National Institute of Occupational Safety and Health (NIOSH). NIOSH is developing a registry of persons exposed to TCDD in the U.S. If this effort can be extended internationally, perhaps with the assistance of the World Health Organization, investigations of that larger cohort might, hopefully, generate far more definitive data on any cause-effect relationships for TCDD in humans.

Before embarking on such a large-scale effort, we have suggested that a feasibility study be undertaken by the Academy in cooperation with the World Health Organization to identify the sources of data, particularly those outside of the United States. Such registries would be particularly useful in the evaluation of risks of chronic diseases particularly cancer, cardiovascular disease and neurologic impairment. It is well recognized that chronic diseases such as cancer often take many decades to develop after initial exposure. Thus, if risks exist for populations such as those at Seveso, Italy, or the Vietnam veterans, the expression of those risks may not be forthcoming for many years hence. This argues, of course, for an immediate and comprehensive evaluation on a world-wide basis of the substantial number of industrial workers exposed to TCDD over the past several decades. In addition, it also calls for a long-term commitment on the part of government to pursue clinical and epidemiologic studies of those exposed to TCDD.

Laboratory evidence attributes to TCDD two serious adverse effects: (a) deleterious influence on the female reproductive system, including birth defects, and (b) carcinogenesis. More emphasis must be placed on defining the ways in which TCDD exerts its detrimental effects on experimental animals and in what manner, if any, it may constitute a risk to humans. To this end, laboratory studies investigating the generation of reproductive deficits and birth anomalies and those evaluating potential carcinogenesis would be particularly appropriate. A particularly noteworthy example of a reproductive study was recently reported by investigators of the National Institute of Environmental Health Sciences (NIEHS). The study carefully pursued the possibility of birth anomalies in offspring of exposed males--a study question rarely pursued. Continued experimentation of this nature is heartily endorsed.

Some recent experimental evidence suggests that TCDD adversely effects both the immune and nervous system of exposed animals. Since these systems are amenable to investigation in humans by a variety of physiologic and biochemical methods, their study should be encouraged where feasible in the case of persons exposed to high levels of TCDD.

Those are but some of the avenues that can be pursued by appropriately qualified scientists. It our understanding that the government has convened an inter-agency group to develop strategies to investigate the many health questions related to Herbicide Orange, 2,4,5-T, and TCDD. We endorse such intensified and consolidated approaches and look forward to their reports.

In areas of scientific uncertainty and public debate, the resources of the Academy and the National Research Council are often called upon to assist federal decision-makers in developing

appropriate research strategies. The National Research Council's Board on Toxicology and Environmental Health Hazards has had an active interest in performing a comprehensive evaluation of the health effects associated with exposures to chlorinated dibenzo-dioxins and their highly toxic chemical cousins the chlorinated dibenzo-furans. For both classes of agents, there appears to be substantial human exposure as well as extensive toxicologic data to warrant such an evaluation. Review of the significance of these agents with respect to the health of the Nation should include a dispassionate and rigorous analysis of the existing scientific information. To be helpful in this respect we have prepared a study proposal for consideration of the Veterans Administration, the Environmental Protection Agency, and the National Institute of Environmental Health Sciences; and we await their response. The anticipated benefits from such an evaluation would accrue to veterans, workers, and the general population of our country. We would be pleased to be of assistance to the Subcommittee on Medical Facilities and Benefits in reaching reasonable, equitable solutions to the problems generated by the attribution of diverse health problems in veterans to exposures to Herbicide Orange while in service.

Mr. Chairman, I appreciate the opportunity you have provided for me to outline the activities of the Academy and its National Research Council that are part of the national effort to improve our understanding of dioxin exposure experienced by our Vietnam Veterans. Dr. Tardiff and I will be pleased to respond to any questions that you may have with regard to these matters.

Chairman SATTERFIELD. Mr. Edwards?

Mr. EDWARDS. Dr. Handler, you state on page 4 that 200 to 300 pounds of TCDD had been released over South Vietnam and that no serious consequences had been identified, and on page 5 you say that: "indeed, if agent orange caused any birth defects in South Vietnam, the absolute number must have been quite small." How many people did you send to South Vietnam to make this study?

Dr. HANDLER. About 50, sir, I don't know the exact number.

Mr. EDWARDS. About 50?

Dr. HANDLER. Yes; and they were there for months. They made repeated visits. They spent time out in the field under difficult condition. For example, the chairman of the study was in a helicopter that was almost shot down; it returned full of bullet holes. They did all that one could ask of investigators under those circumstances. But they could not get to much of the sprayed area which was in the hands of the North Vietnamese forces at that time.

Mr. EDWARDS. When was this extensive study by the 50 experts made?

Dr. HANDLER. Our report was issued in 1974 but the period of the study was from 1970 to 1973. There were several teams of investigators who made many trips. There were panels of physicians, of sociologists, of botanists, of foresters, of soil experts, and so forth. The chairman of the group was a distinguished scientist from Michigan State who indeed was one of the individuals who was responsible for the original idea that compounds like 2,4-D can be used as herbicides. Originally, he found that they were plant hormones.

Mr. EDWARDS. And do the Vietnamese agree with the conclusions of this study?

Dr. HANDLER. There was a small amount of disagreement at the time the report was released. There were two Vietnamese scientists on the central committee, and they agreed with the study itself. There were certain persons from South Vietnam who indicated that our people had not seen the affected personnel; however, the report said that the committee had never seen those alleged affected personnel. In the report, we have acknowledged that all we have are secondhand accounts and that no Vietnamese physician had seen the affected persons. So we never knew what to do with this hearsay evidence.

Mr. EDWARDS. Thank you. In other words, Dr. Handler, your testimony is that there is nothing more to be done in South Vietnam, that the——

Dr. HANDLER. No, sir.

Mr. EDWARDS [continuing]. Examination had been made by the 50 experts who went——

Dr. HANDLER. No; I wouldn't say that, Mr. Edwards. Those studies were done very shortly after the spraying itself. If indeed dioxin has delayed sequelae, South Vietnam is the place to look. Certainly there were large numbers of South Vietnamese who must have been exposed in varying degree. However, we will never know exactly the dose to which they were exposed. But the place to look for adverse effects is surely in South Vietnam. In our study we were looking for the acute early effects, and the one we reposed most confidence in our ability to study was the evaluation of possi-

ble birth defects because those children had only recently been through Cho Rey Hospital in Saigon.

Mr. EDWARDS. Thank you.

Chairman SATTERFIELD. Mr. Hammerschmidt?

Mr. HAMMERSCHMIDT. Thank you, Dr. Handler, for your very expert testimony. We appreciate your being here. You mention on page 9 of your testimony that combining the data from the various experiences relating to occupational and accidential exposures might enhance the capability for analysis. I am wondering if a different combination of data might also enhance our understanding of the potentialities in this matter. In other words, what of examining the effects of other chemicals used in Vietnam, both sprayed and ingested? Is it conceivable that, for instance, the Dapsone malaria tablet, which was discontinued after it proved toxic to a number of soldiers, might have worked in concert with other chemicals to be harmful?

I ask that question because this is the gist of several recent articles and I wonder about the credibility of that speculation.

Dr. HANDLER. Mr. Hammerschmidt, I regret we have not looked into that question, and I personally am not qualified to venture a guess.

Mr. HAMMERSCHMIDT. Is that an area that your studies would eventually pursue?

Dr. HANDLER. Yes, sir; we could do so.

Mr. HAMMERSCHMIDT. What is the significance of the exposures to chlorinated benzo-dioxins? Is this the same thing as a dioxin in agent orange?

Dr. HANDLER. Yes; the very same thing.

Mr. HAMMERSCHMIDT. One other item. On page 8 you discussed the Italian study and the damage over there and the possible neurologic damage which you said is continuing, and then you made some other comment related to that. Would you elaborate a little bit more on what you said about the neurologic effects which are persisting?

Dr. HANDLER. These were the immediate effects, sir. The examinations were conducted as soon as possible after those persons were exposed and they were followed up for weeks, perhaps a few months thereafter. During that period the initial adverse effect was the skin lesion which is called chloracne. There were also various neurological deficits, that is delayed transmission of nerve impulses, but there were no behavioral changes, no changes in their central nervous system which were leading to, call it, psychopathy.

Mr. HAMMERSCHMIDT. I see. I want to ask you a question that you may not be in a position to respond to, but if you can, I would like to get your evaluation. As I mentioned in my opening remarks, I am curious about reaching an interim solution pending the outcome of conclusive medical research. If there ever is any conclusive evaluation, it would appear that it will be many years before all medical research is finished. Do you consider the state of medical research to be such that at this point it would be equitable to allow veterans suffering from certain severe disorders, arguably related to agent orange, to receive service-connected medical treatment for such disorders?

Dr. HANDLER. If such treatment exists, sir, the Veterans' Administration is prepared to be of as much assistance as it can and that is independent of the causality. We owe it to them and should provide it to the best of our ability. It is independent of whether or not we can establish causality in consequence of exposure to agent orange.

Mr. HAMMERSCHMIDT. I guess the point I am getting to—let's take chloracne, which seems to be the easiest thing to find as we have listened to witnesses here——

Dr. HANDLER. There isn't much that can be done about chloracne. It will subside in some and persist in others.

Mr. HAMMERSCHMIDT. The VA is now, I guess, treating that as a service-connected disorder if it is causal to exposure to agent orange.

Dr. HANDLER. Yes.

Mr. HAMMERSCHMIDT. Thank you very much, Doctor.

Dr. HANDLER. It is treated symptomatically. There is no specific drug which has any curative properties under those circumstances.

Mr. HAMMERSCHMIDT. Thank you very much.

Chairman SATTERFIELD. Dr. Handler, I know that I assured you that you would be leaving in time to make your 11:30 appointment. What time will your departure from here be?

Dr. HANDLER. I could take certainly as much more time as you require, Mr. Chairman, until about 11:15 if need be.

Chairman SATTERFIELD. Could you go that long?

Dr. HANDLER. Yes.

Chairman SATTERFIELD. All right, I just wanted to mention it because if we do run too long I would assume you would not object to members submitting questions to you so that you may respond directly.

Dr. HANDLER. We would be very pleased to do so, sir.

Chairman SATTERFIELD. Next I recognize Mr. Edgar. I might point out, incidentally, that in accordance with the rules of this committee, I will be recognizing members in the order in which they appeared this morning. Mr. Edgar.

Mr. EDGAR. Thank you, Mr. Chairman. I will try to be quick in the questions that I have. I am a bit confused about the tone of your testimony this morning, and I would like to try to examine your testimony versus the testimony we heard earlier on July 22 or thereabouts from Dr. Samuel Epstein.

On page 12 of his testimony and several other places throughout that testimony he made a number of references to the level and strength of this particular component that makes up agent orange. On page 13 of his testimony he makes this statement, and I would like to know whether you agree with it or not. "TCDD is the most toxic synthetic chemical compound known." Is that true or false?

Dr. HANDLER. Synthetic, that is made by man. TCDD will come close, if it isn't exact, sir. By that is meant that the consequences become evident at doses that are lower than for other toxic compounds, not that the consequences are more violent than those of others. However I suspect that bacteria toxices really have us licked; they are much more toxic gram for gram.

Mr. EDGAR. Dr. Epstein and Steve Stellman, Ph. D., and his wife, Dr. Jean Stellman, spent a great deal of time reviewing the fact

that studies on agent orange have been conducted for the last 15 years. In your testimony you make little or no reference to some of the chemical companies who have made studies, including Dow Chemical Co., as I understand it, who has made a study of birth defects that they have not published. It seems to me from reviewing the literature that the toxicological effects of agent orange are generally known to have impact not only in laboratory mice but in human beings exposed, The Oregon case, some problems that occurred in Italy, some plantsites that have occurred, and also the large number of veterans who are coming to our offices and indicating, for example, that they cut a barrel in half and used it as a habachi and this barrel was used to hold the chemical agent orange, are suffering not only chloracne but also some cancer and other effects.

It seems strange to me that after all of these studies and all of these reports and all of these reviews that we can't at least at this point, knowing that additional studies should come, at least at this point say that agent orange is a chemical compound serious enough to cause medical problems in human beings and that the Veterans' Administration ought to (*a*) identify a process of evaluation of all the veterans who may have been exposed, and (*b*) that we ought to move quickly to some legislative or administrative remedy.

How do you react to the fact that we have had studies, and we have known about the toxicological effects of this substance since the late forties. It is not something that is new. It has caused enough alarm to have it banned and force the reduction in the quantity and content of its use when it is used. How do you respond to that?

Dr. HANDLER. With difficulty, Mr. Edgar. But I made no attempt to review the whole literature. As I said at the outset, all I was going to do was review our—the Academy—relationship to this problem, the events which have transpired, and the manner in which we have attempted to be helpful.

Your statement is, of course, true. It is known that these compounds are indeed toxic under certain circumstances, and it is known what some of the consequences are. I didn't think that was the problem. We are not attempting to indict dioxin or agent orange in some broad way. There are many dangerous chemicals which are in use in our society, some of which are invaluable to us. The question of importance is: can we learn to live with beneficial but hazardous chemicals?

The problem, I thought, for your committee and the Veterans' Administration is to make the specific association between the medical complaint presented by a veteran who was in Vietnam and may or may not have been exposed and the degree of exposure and establish causality. That, sir, has turned out to be very difficult, as I understand it. There will be some instances in which—I can assume for example, the gentlemen you named—anyone who got his hands in the material, used it liberally and was heavily exposed, will constitute almost prima facie evidence that adverse effects are likely to happen. The problem is: Although it is said that TCDD is the most toxic compound known, that still doesn't tell you whether the lesions or the illness or discomfort in a given individual can be traced to what might have been a minute level of

exposure to TCDD. Similarly, one cannot conclude that all persons exposed in any dosage will today show effects.

Mr. EDGAR. Doctor, you are an expert in studies and preparing proposals and analyzing the process at which we look at things. Does it strike you at all interesting that we have not come up with a cross check between the areas of spraying and exposure in Vietnam, that is taking a look at the specific grids used by the Air Force and others to spray the defoliant, and the names and addresses of the veterans who served in those areas? Why hasn't someone used computers and other things to overlay those who served in the areas that received the largest amount of exposure? Wouldn't it be possible as part of a study for the Air Force, Defense Department, and the Veterans' Administration jointly to survey all the Vietnam era veterans in a specific questionnaire outlining the specific areas and theaters in which they served, cross checking that with the military data, and then putting that in a computer with the spraying flights and trying to get some sense as to whether or not there is any direct relationship of exposure? Does that make any sense at all?

Dr. HANDLER. It is feasible to attempt such a study, but I assure you that it is extraordinarily difficult. The data which tell you where a given soldier was on a given day are not terribly reliable, and even the soldier may not know because he doesn't keep a diary in those forms. The grid maps for the sprayings are all available. They are in our report. There is a package of maps in the back of the Academy report which shows the spraying and the dates.

Mr. EDGAR. Let me change my question a bit.

Dr. HANDLER. But to establish who was where and then to establish what the exposure level really was will prove to be very, very difficult indeed. In general, as you know, sir, our spraying was conducted where there were no American troops on the occasion of the spraying. In general, but not invariably.

Mr. EDGAR. It is my experience that they used it as a way to clear the area where the encampments were made and some of the veterans used it to spray around the tents. But let me change the question and look at it more in focus.

Let's just take the physicans in the VA hospital system. It is my understanding that a comprehensive questionnaire asking for detailed information about exposure and symptoms and health effects is not presently in practice, that there is a questionnaire that is used that asks some vague questions, but the medical teams within the hospitals of the VA system do not have a comprehensive questionnaire to begin to gather data on exposure. Do you think that would make sense?

Dr. HANDLER. If it were addressed with an open mind to see what would come out of it, yes, sir. But with no sense that necessarily that will get you what you really want to know. The difficulty is that most of the problems which we can trace to human exposure to dioxin components of agent orange are diseases which come about in other ways. One-fifth of all Americans die of cancer, and it is very difficult to know in the case of a given individual whether any exposure to anything was contributory or the extent of contribution. That is the impetus of the problem.

Mr. EDGAR. But don't you think it is the failure of our system not to have some way of checking as to whether there is a higher level of incidence of Vietnam era veterans? If we don't have an adequate way of gathering that information, we will never be able to make that statement.

Dr. HANDLER. We may establish a gross correlation, but the problem is to decide about any individual as he presents himself to the VA.

Mr. EDGAR. Finally, there is no way in your studies or knowledge of testing skin, the blood, the human system for its levels of——

Dr. HANDLER. Not this long after the exposure, sir. By now, from what I understand of the kinetics of this process in laboratory animals, and that those levels can be projected into human physiology, then the dioxin to which individuals were exposed would now be gone and one couldn't find it. However, it could have caused its effects and now be gone but it wouldn't be there as a tag.

Chairman SATTERFIELD. Mr. Deckard?

Mr. DECKARD. Thank you, Mr. Chairman. Dr. Handler, I would first like to make reference to a question posed earlier by Mr. Edwards with respect to a study that took place in South Vietnam involving approximately 50 people and you mentioned that a number of those were botanists, soil experts, and so on. How many were biologists qualified to make empirical studies regarding toxic, genetic, and carcinogenic effects of dioxin in human beings?

Dr. HANDLER. There was a team of physicians, although I cannot tell you exactly how large that team was. They weren't looking for genetic effects. It would have been very difficult to find genetic effects at that time. We also had some physical and cultural anthropologists in the group. They did their very best to trace down such information as they could get. I can't say that we simply have to accept their findings as being determinative, but I think those who went were qualified to do what they had come to do, sir. They could not examine the whole population of South Vietnam or all of the American forces during that period, but I am not sure there was any need to, either. They could and did look at the population going through the South Vietnamese hospitals. They went into village after village on foot, examining children and adults, looking for anything they could find. It was really a very thorough, serious study, sir. All I can say is that, with respect to effects on humans, they came away almost emptyhanded. However, they never got up into the hills where the Montagnards were living and from whom came the stories of acute distress immediately following spraying missions.

Mr. DECKARD. On page 10 of your testimony you indicate that laboratory evidence attributes to TCDD two serious adverse effects, deleterious influence on the female reproductive system, including birth defects, and carcinogenesis. On the basis of that, would you, as you seem to allude earlier, attribute prima facie evidence insofar as cancer is concerned to those who have been exposed to agent orange in Vietnam?

Dr. HANDLER. I repeat my earlier statement, Mr. Deckard. Almost 20 percent of all Americans develop cancer and die of it. For any given individual, dying of one of the more common forms of cancer, it is very difficult to associate that fate with some

previous exposure. If an unusual form of cancer were involved, or if numerous exposed persons develop identical lesions, then such a prima facie case might not seem unreasonable.

Mr. DECKARD. On the same page you make reference to a study conducted by the National Institute of Environmental Health Services, a reproductive study pursuing the possibility of birth anomalies in offspring of exposed males, a study rarely pursued. Can you give us the results of that study?

Dr. HANDLER. The author of that report is in the room, Dr. Moore. I would much prefer that you ask him directly, since it is his study.

Mr. DECKARD. Thank you very much. Thank you, Mr. Chairman.

Chairman SATTERFIELD. Mr. Daschle?

Mr. DASCHLE. Thank you, Mr. Chairman. I would like to ask you first, Dr. Handler, if you would not agree with the statement that there are really two ways of determining the history of carcinogenity and that is either through epidemiology studies, such as the ones that you have discussed this morning, or through the two sects, two rodent species work that is done as you described or alluded to in your study which usually involves mice and rats. Are those the two approaches that are most commonly held in the scientific community for considering the effects of chemicals?

Dr. HANDLER. Those are the two general techniques that are available to us; namely, epidemiological studies and experimental animal studies. We don't perform such experiments on human beings.

Mr. DASCHLE. The point I am getting to, I guess, is that we have seen in the case of those studies done in the two sects, two rodent species, area that ample evidence seems to exist that carcinogenity does occur with the application of this dioxin in those animals, or in those rodents, is that not correct?

Dr. HANDLER. In the animals, yes.

Mr. DASCHLE. In the animals.

Dr. HANDLER. Yes.

Mr. DASCHLE. Let me ask if you agree with the statement presented to me by the Occupational Safety and Health Administration and I quote here, this is their cancer policy:

> The validity of qualitatively extrapolating animal test results to humans is firmly based on substantial empirical evidence in the record, not only of experiments in tests of mammalian animals given positive carcinogenic test results for every compound known to cause cancer in humans except arsenic and perhaps benzene, but although there may be wide variations in the susceptability of various species to cancer, evidence exists that a substance that causes cancer in one mammalian animal species is likely to do so in most other mammalian species tests. Substantial evidence and scientific data in the record indicate that some laboratory animals are suitable test models for determining the cancer-causing potential of toxic substances to humans.

That is the OSHA cancer policy. Would you advocate that we accept this policy as an across-the-board policy with regard to carcinogenity in other areas, such as agent orange in the Veterans' Administration?

Dr. HANDLER. I don't think it was a statement of policy, Mr. Daschle. I think it was a philosophical conclusion, a kind of scientific conclusion, but it is not a policy.

Mr. DASCHLE. Let me clarify this. It says directly prior to the quote I just read, "As stated in the notice of rulemaking on OSHA

cancer policy, the following holds true." It seems to me that they are drawing a very clear policy determination in regard to the correlation they draw between animal tests and human carcinogenicity.

Dr. HANDLER. I accept the scientific part of that, with few exceptions known to us, compounds that are carcinogenic in species A are very highly likely to be carcinogenic in any other species, assuming both species are mammals. That is the scientific part of their statement I fully accept. What they omit to discuss is that important concept, the dose/response relationship; and that, as we also know, can be highly variable. OSHA would take the statement that they made and then go further by indicating that from the human environment should be removed, to the best of our ability, all traces of any material which can be shown to be carcinogenic in any species. That, sir, is probably not feasible for a great variety of carcinogens. Our task is to establish first what level of feasibility is available to us, to remove a given carcinogen effectively, and, second, if we can't quite remove it, what are the consequences of the level that remains?

Mr. DASCHLE. Then do you disagree with the application of rulemaking that has occurred already in EPA and OSHA with regard to the handling and, in some cases, the removal of certain chemicals from the shelf? We have already set that dose relationship in regard to rulemaking. I guess what I am wondering is why we seem to or appear to have a double standard.

Dr. HANDLER. The Supreme Court has just noted that there was no basis for the rule with respect to benzene as it applied to a specific concentration. It was the dose and the hazard associated with the dose which was in question, not the generality that benzene having been shown to be carcinogenic in species A was probably carcinogenic in humans. That concept is accepted. And that there is a responsibility to use reasonable available technology to control a hazardous substance is acceptable philosophy of the country. The question then turns on the quantitative aspects of risk.

Your line of argument is: "Is agent orange carcinogenic under some circumstances?" The answer is yes. Do I accept that in all likelihood that which is carcinogenic in rats and mice, in this case agent orange and dioxin, is carcinogenic in man? My answer is yes. However, I would hold that they are not carcinogenic at all levels of exposure. I don't believe that one molecule will give you cancer. By contrast, I do not know how much is required to give you cancer, and there lies our dilemma.

Mr. DASCHLE. I guess no one would ask you to make that proposal, but I think that the evidence is clear that there is that connection. And there also is evidence that the dosage levels used in Vietnam were well and beyond the level of human acceptability.

Dr. HANDLER. I don't know what you mean by that.

Mr. DASCHLE. I think the dosage level, as I have understood it to be, was 10 times the recommended level used today in certain parts of Vietnam and——

Dr. HANDLER. Ten times per acre?

Mr. DASCHLE. Per acre, that's correct. And given that high level, one could make some very, not easy, but very seemingly acceptable

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correlations between the dose level given in laboratory animals and the dose level received by those in certain areas in Vietnam.

Dr. HANDLER. I am not sure you are correct. All of this argument would disappear if we really could do what you just said. But we cannot do the calculation that you just proposed.

Chairman SATTERFIELD. Dr. Handler, the time has approached and we promised to get you out of here so that you could make that 11:30 appointment. I hate to cut off this line of questioning, but for any member who wishes to submit a question in writing, Dr. Handler has consented to entertain it and to respond on the record. He does have a very important appointment and we had promised him in the beginning that we would make certain he could keep it. Thank you very much, Dr. Handler and Dr. Tardiff.

Dr. HANDLER. Thank you. We will provide copies of this report.

Chairman SATTERFIELD. Thank you very much. Our next witness this morning is Lt. Gen. Paul Myers, who I understand is accompanied by Maj. Alvin Young. General Myers is the Surgeon General, Department of the Air Force. I see you have some additional people with you. If you would identify them for the record, we would appreciate it very much.

General MYERS. Mr. Chairman and members of the subcommittee, good morning. I am Lt. Gen. Paul Myers, the Air Force Surgeon General. With me today are Dr. Carlos Stern, on my right, who is the Deputy for Environment and Safety, Office of the Assistant Secretary of the Air Force—Manpower, Reserve Affairs and Installations—and Maj. Alvin Young, Ph. D., who has been actively involved in the herbicide orange program in the Air Force for the past 12 years. And may I, for the committee's, reference just state that Dr. Young obtained his bachelor of science degree in agricultural science and his master of science degree in crop physiology. His first assignment with the U.S. Air Force in 1968 was as a project scientist assigned to investigate the ecological impact of repetitive applications of phenoxy herbicides. I think it would be helpful to the committee, Mr. Chairman, if we asked Major Young to give a briefing on the use of herbicide orange and then I will follow with a status report on the Ranch Hand study.

Major YOUNG. Thank you, Mr. Chairman. I have some slides I would like to show you. I need to turn the lights off, however, to do this. I am sorry for the inconvenience.

There has been a lot of discussion of how herbicides were used in Vietnam. I have been asked to give you an overview of that use. So what I would like to do by the use of slides is take you back in time to Vietnam and show you the use of herbicides.

There are exceptions to everything, as you well know. I am going to try to give you the general picture as we experienced it and as we have written in many military reports.

As you are all aware, the phenoxy herbicides were developed in the early 1940 time period and extensively used in the fifties and early sixties within the United States. We developed the use of herbicides as a technology for removing vegetation. This slide shows a prime example of the use of herbicides. Here is a brush infected right-of-way in the United States. This is the same right-of-way 1 year after a 2-pound-per-acre application of 2,4-D and 2,4,5-T. It was the proposed use of this technology that was brought

to our attention in solving the problems in Vietnam. There, the vegetation was so dense that the problem of ambush was paramount. The enemy could come with impunity to the lines of our communication and to the perimeters of our bases, and launch attacks upon our people and then withdraw. We never saw him come, we never saw him go, but he would inflict severe damage on our installations and troops.

It was this idea, that we could control vegetation by the use of chemicals, that prompted us to take chemicals to Vietnam, especially the defoliants, the phenoxy herbicides.

The program began January 9, 1962. It was approved by President Kennedy, and I would just point out that many Presidents after that continued to approve its use up until 1970. The project consisted of sending 55-gallon drums of herbicides to Vietnam. These were variously painted with stripes for the simple reason of keeping our personnel informed of what herbicide they contained. It was good to have a code ring around them. If you mixed orange with white, for example, a percipitant was developed and this could cause severe problems in terms of handling, in terms of logistics, since it clogged the aircraft spray nozzles. So it was important that we have a color code. Although these materials were formulated commercially in the United States, we color coded them only for our convenience in Vietnam.

The chemical arrived in 55-gallon containers, was put on flat bed trucks and transported to the units that were responsible for spraying. Here is a slide of a pumping operation transferring the herbicide to what we call the F-6 trailer. Please note the ground around these F-6 trailers you will see a great deal of indication of herbicide spill.

This is another slide. The herbicide could not all be placed into the F-6 trailer. That which remained was simply stacked in rows. The drums that were pumped into the F-6 trailer were then drained. There was always a little bit of residue left in them. They were drained and that drained material was frequently used by our personnel to control the vegetation around the base perimeter camps. Most of the residual orange that would have been used in the base perimeter operations would have been for those perimeters where Ranch Hand squadrons were located.

This is a slide of a drum disposal site or storage site at Bien Hoa, and indeed we have heard many comments about how the barrels disappeared and were used in various ways. Most of those barrels went into runway construction and bunker construction. It is certainly conceivable that those barrels could have gone elsewhere, too.

Here is a picture of the aircraft at Bien Hoa where herbicide activity was taking place. There were crews handling hoses running from the trailers into the aircraft. The principal aircraft was the C-123. This is called the Provider. It was the workhorse for Ranch Hand.

I have a picture here of "Patches." This is one of the most famous aircraft, having received thousands of bullet holes in its years of spraying herbicides in Vietnam. This particular picture was taken in 1978. I show it to you for a number of reasons. First, I want you to get a feel for what the aircraft looked like and, second,

to see the cargo space. Into that cargo space we placed a 1,000-gallon spray system, called the internal modular spray system. It had a console unit in front of it. As you can see, when it was installed within the aircraft, there was very little room for movement of personnel. Indeed, in the back of the aircraft behind the tank, the console operator that ran the system was located.

Underneath each of the wings were spray booms. These were 22 feet long, containing 16 nozzles. Likewise, behind the cargo door we had another spray boom.

In 1963 there were three aircraft spraying herbicides. In 1965 we increased the number to seven. In 1966 it went to 17 by December of that year. By 1967 we were at 19 and by the first of 1968 we were at full strength, 30 aircraft spraying herbicides plus 3 that were used for insecticide operations by that time period.

A typical mission consisted of anywhere from 3 to 4 aircraft early in the conflict to as many as 12 later in the conflict. The crews of the C-123's consisted of officers in front, a pilot and a copilot. In the lead aircraft, a navigator was also located up front. He was also an officer. In the back of the aircraft was an enlisted man that ran the console unit. The individual in this picture is sitting in a metal box which was in a typical situation. We had to provide protection from ground fire for all of our personnel in the aircraft. This was one of the reasons why there were very few visitors flying along with the Ranch Hands. It was a very hazardous occupation simply because of ground fire.

The individual and the console were placed inside a metal box. Likewise, underneath the pilot and copilot were one-half inch steel plates to protect them.

The aircraft encountered so much ground fire on defoliation missions that the Air Force decided to provide fighter support for every mission that took place after the middle of 1966. And indeed, for fighter recognition, an orange band was placed across the wing, not necessarily signifying that it was carrying herbicide orange, but rather that it was a Ranch Hand aircraft.

We are on our way down now into the jungles of Vietnam. This is a picture of spraying. Spraying took place primarily in the morning or in the evening. There were three reasons for that. The first reason was in terms of the meteorological condition. There were very few winds. That allowed the herbicide to fall quickly upon the vegetation. Second, the vegetation is very sensitive at that time period. It is one of the most sensitive times when the vegetation is most susceptible to the herbicide. And the third reason is a tactical one; coming in from the direction of the Sun allowed our crews a few extra seconds of safety.

I want to show you the amount of hostility that we encountered from ground fire. This picture shows a fighter aircraft flying ahead of the Ranch Hand aircraft dropping ordinance on weapons ground fire. On a typical mission, anywhere from 10 to 40 hits were received by the aircraft over target. That is an incredible number. There were more Purple Hearts awarded to the personnel in Ranch Hand squadrons than to any squadron its size in Vietnam. The esprit de corps of this unit had to have been fantastic to have gone day after day into such hostile areas.

Here is a picture of a swamp with the herbicide coming down. Here is a picture taken in 1968. You can see that a lot more aircraft are involved in the mission. These aircraft flew very close to the vegetation, as you can see here with the three aircraft diving down. As a matter of fact, one of the problems was if we didn't pull up in time the consequence should be obvious. Amazingly enough, we lost very few aircraft in actual combat instances like this. Here is an aircraft flying right at the top of the vegetation, pulling up just in time to miss the trees.

In the background in this picture you see an area that had been previously defoliated. It took anywhere from 3, to 4, to 5 weeks for the vegetation to drop most of its leaves so that we had a visibility increase of about 80 percent. These particular aircraft are spraying an area that had not previously been sprayed.

Here is a picture taken in 1964 of a roadway. A single aircraft is widening an area previously sprayed some 3 weeks earlier. In terms of the parameters, the aircraft typically flew at 150 miles per hour and about 150 feet off the ground. When you consider that sometimes this altitude was the height of the vegetation, you can see how close they were. A 1,000-gallon tank permitted about a 3- to 4-minute spray time, a total distance of about 8.7 statute miles which equals about 340 acres treatment per aircraft with a deposition rate of about 3 gallons per acre.

Here is one of the important things that you should remember, the particle size. When one disperses insecticides, you want very small particles. When you disperse herbicides, you want a larger particle and you want that particle to fall straight down so you put it right where you want it. Indeed, this 100- to 500-micron range for most of the herbicide particles meant that they fell within 1 minute. Indeed, this left very little available for drift and volitalization.

This slide shows the chrome coat cards that were placed underneath an actual herbicide mission. This slide was taken during our test program at Eglin AFB, Fla., where I was extensively involved. This shows you the droplet dispersal from the kind of dispersing system used in Vietnam.

This was a picture taken 22 miles southeast of Saigon. It was taken about 1½ months after defoliation. Enemy troops built literally whole cities with these soil bunkers. There is a tunnel network that you see in the slide. There were actually ships placed by the enemy in the mangrove swamps. From these floating bases, they would go out in the evening and raid the countryside, attack the RVN and US bases and the people. It was only through the process of defoliation that we were able to uncover these kinds of hidden installations. This meant that we did not have to send our troops in there to flush them out. By simply removing the vegetation, our bombers then could pinpoint those little towns of enemy concentration, and could remove the threat they presented.

I am sorry this picture doesn't focus too well, but it was taken from an aircraft flying in the high mountainous regions of Vietnam, an area we defoliated because the trails coming in from North Vietnam and Cambodia were used by the enemy to transport weapons and so on down into South Vietnam. This is a very important picture for you to see, too, because this shows one of the

major problems we had in defoliating jungles. The triple canopy jungle in Vietnam, which is very nicely addressed in Dr. Handler's report, prevented the herbicide from penetrating to the ground. If you notice, there are some bare branches at the top. That was due to the first application of herbicides. Notice there are some brown vegetation beneath. That was due to the second application some weeks to months later. Yet beneath that zone there is still a significant amount of green vegetation. Our studies, not only in Vietnam but elsewhere, showed that approximately 94 percent of the herbicide never penetrated to the bottom canopy. It was tied up by the very tops of those trees. This was a major problem. This meant that many times we had to go back and respray. If we could open up the canopy enough to expose the roads and transport networks, fine. But, if not, we had to respray.

The n-butyl esters, which was the major formulation of herbicide orange in Vietnam, was a formulation that is readily absorbed by the vegetation. We were able to spray this during the wet season in Vietnam simply because it was so rapidly taken in by the vegetation. It was rapidly absorbed within some 30 minutes.

Here is a picture of a spray swath made by 12 mission aircraft which had gone through this region about 3 weeks earlier. The swath is about 8.7 statute miles long. As you can see, the effects of defoliation are now beginning to appear. Notice the straight lines of demarkation suggesting that, indeed, the material drifted very little.

Likewise, this photograph of a mangrove. This was taken about 2 weeks after the spraying occurred and you can see a very straight line of demarkation. Our aircraft pilots were a very proficient group.

If you notice here, they started spraying just as they flew over the little canal. There is hardly any evidence of vegetative damage to the left of that canal, but all along the river where they were trying to defoliate you can see the distinct band of defoliation.

The Rung Sat special region was the region we probably hit harder with herbicides than any region in Vietnam. The reason, of course, is because of the tremendous concentration of enemy troops that carried on hostile action out of those mangrove swamps. Indeed, the herbicide was extremely effective against mangrove. The greatest vegetative damage done in Vietnam was done to the mangrove swamp, as can be seen here.

There were other uses for herbicides, of course, other than defoliation; crop destruction is one. On the left was an area sprayed with cacodylic acid in 1968. Cacodylic acid, or if you would prefer, herbicide blue, was extremely effective against rice at very low concentrations. Fifty percent of blue was sprayed on crops and the remaining 50 percent of blue was sprayed around base perimeters. Most herbicide sprayed around base perimeters was cacodylic acid, or blue. It was done primarily by helicopters or by ground vehicles with sprayers mounted on them.

This photograph shows a helicopter with a 200-gallon tank. The tank could be installed within about 3 to 4 minutes. While the Ranch Hand population was assigned to a specific mission, that is defoliation, helicopter pilots did not have that same designation. Whatever helicopter was available, whether it was an Army, or

Navy, or Marine, or an Air Force, and the base commander wanted to control vegetation, then that helicopter was brought into action. So there were many personnel that probably were exposed to herbicides in this operation that we have no way of identifying.

Here is a typical picture of a helicopter spraying herbicide blue on elephant grass, vegetation that would grow 1 foot a day and within a month would be 30 feet tall and almost impenetrable. Only by spraying with blue could we kill back that vegetation—which would regrow, by the way, in about 60 days—and give us a clear line of sight, as evidenced here.

Orange was also sprayed from helicopters. This is an area near the demilitarized zone and those are chopper swaths through the middle. The bomb craters are the result of an action from the B-52 aircraft.

This photograph, ladies and gentlemen, was what we were trying to obtain. This is an area not far from Saigon. It was a road that was made safe for our convoys to pass because we could now see if the enemy was out there in that vegetation. This type of open site saved, I am sure, many, many American lives.

Frequently troops would come into areas that had the canopy opened up by the use of herbicides. They could flush out what was left of the residual forces of the enemy.

There were four major installations in Vietnam where the Ranch Hand squadrons were located. In the 1962-65 period, near Saigon at Ton Son Nhut, was the Ranch Hand headquarters and the major operating location. In late 1965, early 1966, the operation transferred to Bien Hoa, which is in III Corps. Two operating locations were then opened up, one at Da Nang in 1966, the other at Phu Cat in II Corps in 1967. From there locations missions throughout the entire range of Vietnam could be reached. There was no base location for a squadron, by the way, in IV Corps which was really where the crop production area for the Vietnamese people took place.

Each one of those regions is called a combat tactical zone and these data show you that indeed the bulk of herbicide orange was sprayed in region III, primarily in the Rung Sat special region zone, an area of high enemy concentration.

Ninety percent of herbicide orange was used in forest defoliation, in those areas where tall, very complex triple canopy jungle was found. Eight percent was used in crop destruction and approximately 2 percent was used around base perimeters and catch sites. For example, that site I showed you near Saigon.

There were other chemicals sprayed in Vietnam. Probably, the most important was malathion, an insecticide. This photograph shows the silver bug birds; they were not camouflaged. They did receive a few bullet holes but very few, primarily because everyone recognized the importance of these aircraft. They controlled disease-carrying insects. The interesting thing that many people do not know is that in the time period from 1966-1972 these aircraft treated approximately 6 million acres of land in Vietnam. They were commonly seen around bases, around cities, and just prior to military operations. It would have been very common for these silver bug birds to come in at the time our troops were landing in helicopters and spray for control of malaria-carrying mosquitos.

Chairman SATTERFIELD. Major, may I ask you a question?

Major YOUNG. Sir, I have just concluded my briefing. I would be very happy to answer any questions.

Chairman SATTERFIELD. The insecticide you sprayed contained dioxin?

Major YOUNG. No, sir, malathion is an insecticide currently used in the United States and throughout the world today. It does not contain dioxin. It is sprayed at a very low rate. We are talking about a fraction of a pound per acre.

STATEMENT OF LT. GEN. PAUL MYERS, SURGEON GENERAL, U.S. AIR FORCE

General MYERS. Mr. Chairman, members of the committee, I appreciate the opportunity to appear before you to review Air Force activities to date in the epidemiologic investigation of health effects of Ranch Hand personnel as they may relate to exposure to herbicide orange.

As we have heard, various herbicides were used in Vietnam by the Air Force in support of tactical military operations from 1962 until 1970. The major herbicides used during this period were the phenoxy compounds, 2,4-D ((2,4-dichlorophenoxy) acetic acid) and 2,4,5-T, ((2,4,5-trichlorophenoxy) acetic acid) which were both registerd by the U.S. Department of Agriculture. There two herbicides were used under four code names, the most prominent of which was herbicide orange. Herbicide orange was a defoliant consisting of a 50:50 mixture of 2,4-D and 2,4,5-T.

The component 2,4,5-T contained the contaminant TCDD—dioxin—which developed during the manufacturing process and is highly toxic in its pure form. The name herbicide orange, as we have just learned, came from an identifying orange stripe painted on the 55-gallon drum.

During the period 1962 to 1970, 44 million pounds of 2,4,5-T contained in approximately 11 million gallons were disseminated over 6.5 percent of the land mass of Vietnam. This was carried out under the code name "Ranch Hand." The missions were generally conducted in remote or enemy-controlled areas as a result of the military need to improve observation of enemy activity, to reduce the potential for ambush, and to destroy the enemy food supply.

In October 1969, the Department of Defense restricted the use of herbicide orange to areas remote from population. This action was prompted by the National Institutes of Health report that 2,4,5-T could cause malformations and stillbirths in mice. In April 1970, the Department of Defense suspended further use of herbicide orange in Vietnam. All remaining stocks of herbicide orange were incinerated at sea in 1977.

In late 1977, the Veterans' Administration began receiving complaints from veterans who felt that their medical problems may have been caused by exposure to herbicides in Vietnam. These problems included cancer, birth defects in offspring, fatigue, and nervousness, among others.

Because of increasing public concerns, the Air Force made a commitment to the Congress and to the public in October 1978 that it would assess the health of Ranch Hand personnel exposed to

herbicide orange. These airmen were selected because of likely heavy exposure and they could be readily identified.

Air Force medical scientists developed an extensive protocol for an in-depth epidemiological investigation. The results would hopefully determine whether a causal relationship could be established between exposure to herbicide orange and changes in the long-term health status of the individuals involved. There are three integrated elements in the investigation: (1) a mortality study, (2) a morbidity study—to include birth defects in offspring—and (3) a followup study. As initially conceived, the investigation was to be a 6-year project with options to extend based on results obtained during that period.

The protocol was subjected to extensive scientific review. The Air Force wanted to be certain that it would make the best scientific effort possible. The first submission for review was in June 1979, to the University of Texas School of Public Health at Houston. Subsequently, it was submitted to and reviewed by the Air Force Scientific Advisory Board made up of civilian scientists; the Armed Forces Epidemiological Board, again made up of civilian scientists; and lastly, the protocol was submitted to the National Academy of Sciences. The report from the National Academy was received in May of this year. Each report from the peer review groups raised a number of technical issues with respect to the proposed Air Force protocol. In addition, the National Academy of Sciences review expressed concern over public perception of credibility if the Air Force conducted the study but did not question the ability of the Air Force investigators to do the study.

The concern about credibility led to a referral of the Academy's recommendations, along with the other peer review observations, to the Interagency Work Group to Study the Possible Long-term Health Effects of Phenoxy Herbicides and Contaminants for a determination of how the study should be conducted and by whom. The merits and the methods of the study were reviewed by the interagency work group beginning June 17, 1980. A recommendation was made by that group on August 1, 1980, to the Assistant to the President for Domestic Affairs and Policy that the study be done by the Air Force.

In summary, the work group recommended that the Ranch Hand study, with appropriate protocol modifications and with outside peer review and monitoring, be commenced by the Air Force as soon as possible. These recommendations are a matter of public record. On September 10, 1980, these recommendations were reaffirmed by the interagency work group to the Air Force.

The following actions on the Ranch Hand study have already been taken: (1) Extensive research of the scientific literature has been conducted. (2) Contact has been made and maintained with leading herbicide orange experts in the country. (3) Extensive interagency coordination has been accomplished with the Veterans' Administration, the Department of Defense, and other governmental agencies with interest in this issue. (4) The Ranch Hand organization has been briefed and endorsed the study. (5) 15 million Air Force personnel records have been screened. (6) Basic statistical formats and data repository fundamentals have been established. (7) 1,198 Ranch Hand members have been identified and addresses

obtained. Currently 245 of the Ranch Hand members are on active duty—134 officers and 111 enlisted. (8) The process of matching the control group to the Ranch Hand participants is underway and a review of the records of approximately 30,000 potential controls has begun. The participants will be matched by age, job, time in Vietnam, and race. (9) The mortality study is ongoing. To date, there have been 49 deaths in the Ranch Hand group and 57 percent of these were from aircraft accidents or hostilities in Vietnam. To be specific, 20 crewmen were killed in action and 8 others died in a single unfortunate, tragic accident. (10) The questionnaire is being refined to include the major points addressed by the peer review agencies. The procurement process has begun to acquire the assistance of a recognized health survey organization for the purpose of administering the expanded and more comprehensive health survey instrument. A similar procurement plan will be followed for the physical examinations. (11) Drafts of the initial contact letters to the Ranch Hand study participants are being refined. (12) A fact sheet is being developed for each participant explaining the purpose and general content of the study and the role of the participant. (13) Privacy Act statements have been prepared. (14) The informed consent form has been reviewed by the Air Force legal staff.

This is a brief overview of progress in the development of the Ranch Hand study.

I plan to attend the Ranch Hand organization meeting next month to give them a progress report. I will, on behalf of the Air Force, extend a personal as well as written invitation to participate in this study and answer any questions that may be asked by the Ranch Hand group.

Mr. Chairman, I shall be happy to answer any questions that you and the committee may have and I would ask, sir, your indulgence for a moment. We have prepared some charts which will very quickly give a resume or a precis of this Ranch Hand problem and the herbicide orange difficulty.

Chairman SATTERFIELD. We would be very happy to receive those charts, and since the question has come up, I wonder if it is possible to have those charts previously presented on slides available for submission and inclusion in the record.

Major YOUNG. Yes, sir.

Chairman SATTERFIELD. Without objection, all of these charts will be admitted in the record.

[The information referred to follows:]

HISTORICAL BACKGROUND

- Phenoxy Herbicides Developed nearly 40 years ago
  - 72 million pounds used annually in U.S.
- Use in Vietnam, 1962 - 1970
  - 56 million pounds of 2,4-D
  - 44 million pounds of 2,4,5-T contained in approximately 11 million gallons

1969 - National Institutes of Health Sponsored Study
  - Bionetics Research Laboratories
  - Birth defects in laboratory mice

1970 - DOD suspended use of "Orange"

1972 - Herbicide Orange removed from Vietnam

1977 - AF incinerated remaining supplies of Herbicide Orange at sea

1978 - AF Deputy Surgeon General testimony to this committee
  - AF to do a questionnaire

1979 - White House letter to Department of Defense
  - DOD draft a work plan for the proposed agency study on Herbicide Orange

REVIEWS

	AF Presentation	Report
- University of Texas, School of Public Health	Jun 79	July 79
- Air Force Scientific Advisory Board	Aug 79	Sept 79
- Armed Forces Epidemiological Board	Aug 79	Oct 79
- National Academy of Sciences, National Research Council, Board of Toxicology and Environmental Health Hazards	Dec 79	May 80
- Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	Jun 80	Aug 80

STUDIES

1949 - Nitro West VA
  - Accident
  - Population 121 workers having chloracne
  - No excess of cancers or cardiovascular disease

1976 - Seveso, Italy
  - Accident in trichlorophenol production facility involving dioxin
  - 187 cases of chloracne
  - Nerve conduction decrement

1979-1980 - Four Swedish and 1 West German report
  - Exposure of workers
  - Interagency work group, scientific panel concluded
    - Despite the studies limitations, they show a correlation between exposure to phenoxy acid herbicides and an increased risk of some forms of cancer

1980 - Male mouse study
  - No effect on offspring after exposure of sires to dioxin

1980 - National Cancer Institute Animal Bioassay
  - Results confirm earlier reports that TCDD is carcinogenic in laboratory animals

SYMPTOMS AND LAB FINDINGS REPORTED

FROM LITERATURE REVIEW

Symptoms	Findings
Digestive nausea vomiting diarrhea abdominal pain excess gas loss of appetite	Digestive liver dysfunction
Cutaneous chloracne (skin rash) porphyria (retention of blood products) increased pigmentation increased body hair loss of scalp hair	Cutaneous chloracne porphyria
Neuromuscular weakness numbness muscle pain walking difficulty dizziness decreased learning ability nerve tingling depression fatigue sleeplessness	Neuromuscular diminished reflexes nerve conduction defects
Genitourinary impotence decreased libido reproductive problems	Genitourinary protein in urine degeneration of filtering and collecting system
Circulatory rapid pulse slow pulse missed heart beat	Circulatory increased cholesterol slow or fast heart rate irregular heart rhythm
Alleged cancers in all systems	
Alleged birth defects	

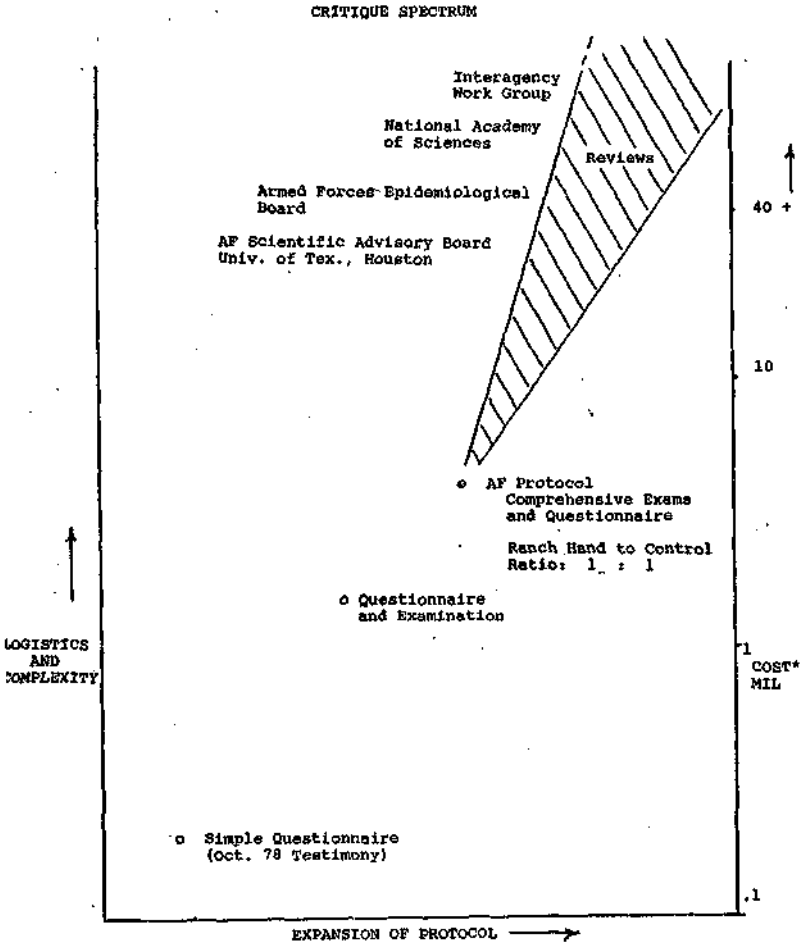
AIR FORCE PROTOCOL

- 3 phase study
  1. mortality
     - to include autopsy
     - 49 Ranch Hands deceased
     - 57% killed in action or in aircraft accidents
  2. morbidity
     - questionnaire
     - physical examination
  3. follow-up
     - up to 20 years

- Data analysis
  - initial mortality study
    - results 1-2 years

  1st questionnaire
    - results 1 1/2-2 years

  1st physical examination
    - results 2-3 years
  - follow-up
    - results up to 21-22 years



*order of magnitude

USE OF HERBICIDES IN SOUTH VIETNAM, 1961-1971*

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Herbicides used in support of tactical military operations in South Vietnam from 1961 to 1971 are today, ten years after the last herbicide mission, the center of intense scientific debate involving not only medical but also legal, political and ecological issues. This paper reviews the historical and operational concepts and some potential human exposure considerations involving the military use of herbicides in the Southeast Asian Conflict.

Herbicides Used in South Vietnam

Synthesis technology, efficacy data, and field application techniques were developed for the two major phenoxy herbicides, 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (24,5-T) during World War II at Fort Detrick, Frederick, Maryland. Following World War II, the commercial use of these two "synthetic" organic herbicides revolutionized American agriculture. In 1950, more than 10 million pounds of these materials were used annually for weed and brush control in the United States. By 1960, in excess of 36 million pounds were used.

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*A synopsis of Information from Chapters I and III of The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and Its Associated Dioxin, Air Force Technical Report OEHL-TR-78-92, USAF Occupational and Environmental Health Laboratory, Brooks Air Force Base, Texas. (Authors: A. L. Young, J. A. Calcagni, C. E. Thalken, and J. W. Tremblay). 1978.

In May 1961, the Office of the Secretary of Defense requested the Fort Detrick personnel to determine the technical feasibility of defoliating jungle vegetation in the Republic of Vietnam. By early fall, 1961, 18 different aerial spray tests (defoliation and anticrop) had been conducted with various formulations of commercially-available herbicides. The choice of these herbicides was based upon the chemicals that had had considerable research, proven performance, and practical background at that period in time. Also, such factors as availability in large quantity, costs and known or accepted safety in regard to their toxicity to humans and animals were considered. The results of these tests were that significant defoliation and anticrop effects could be obtained with two different mixtures of herbicides. The first was a mixture of the n-butyl esters of 2,4-D and 2,4,5-T and the iso-butyl ester of 2,4,5-T. This mixture was code-named "Purple." The second "military" herbicide was code-named "Blue" and consisted of the acid and sodium salt of cacodylic acid. The colored bands which were painted around the center of the 55-gallon drums served as aid to the identification by support personnel.

The first shipment of Herbicides Purple and Blue was received at Tan Son Nhut Air Base, Republic of Vietnam, on 9 January 1962. These were the first military herbicides used in Operation RANCH HAND, the tactical military project for the aerial spraying of herbicides in South Vietnam. Two additional phenoxy herbicide formulations were received in limited quantities in South Vietnam and evaluated during the first two years of Operation RANCH HAND. These were code-named Pink and Green. By January 1965, two additional military herbicides,

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code-named Orange and White, had been evaluated and brought into the spray program. Herbicide Orange replaced all uses of Purple, Pink, or Green, and eventually became the most widely used military herbicide in South Vietnam. The composition of the three major herbicides used in South Vietnam were as follows:

1. Herbicide Orange

Orange was a reddish-brown to tan colored liquid soluble in diesel fuel and organic solvents, but insoluble in water. One gallon of Orange theoretically contained 4.21 pounds of the active ingredient of 2,4-D and 4.41 pounds of the active ingredient of 2,4,5-T. Orange was formulated to contain a 50:50 mixture of the n-butyl esters of 2,4-D and 2,4,5-T. The percentages of the formulation typically were:

n-butyl ester of 2,4-D	49.49
free acid of 2,4-D	0.13
n-butyl ester of 2,4,5-T	48.75
Free acid of 2,4,5-T	1.00
inert ingredients (e.g., butyl alcohol and ester moieties)	0.62

2. Herbicide White

White was a dark brown viscous liquid that was soluble in water but insoluble in organic solvents and diesel fuel. One gallon of White contained 0.54 pounds of the active ingredient of 4-amino-3,5,6-trichloropicolinic acid (picloram) and 2.00 pounds of the active ingredient of 2,4-D. White was formulated to contain a 1:4 mixture of the triisopropanoamine salts of picloram and 2,4-D. The percentages of the formulation were:

triisopropanolamine salt of picloram	10.2
triisopropanolamine salt of 2,4-D	39.6
inert ingredient (primarily the solvent triisopropanolamine)	50.2

3. Herbicide Blue

Blue was a clear yellowish-tan liquid that was soluble in water, but insoluble in organic solvents and diesel fuel. One gallon of Blue contained 3.10 pounds of the active ingredient hydroxydimethyarsine oxide (cacodylic acid). Blue was formulated to contain cacodylic acid (as the free acid) and the sodium salt of cacodylic acid (sodium cacodylate). The percentages of the formulation were:

cacodylic acid	4.7
sodium cacodylate	26.4
surfactant	3.4
sodium chloride	5.5
water	59.5
antifoam agent	0.5

As previously noted, not all of the herbicides used in South Vietnam were used throughout the entire 10 years (1962-1971) encompassed by the Department of Defense defoliation program. In addition, 2,4,5-T formulations used early in the program are believed to have contained higher levels of the toxic contaminant TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin or "dioxin") than did the formulations used in the later years. The three time periods

shown in Table 1 can be differentiated on the basis of specific herbicides used and the mean dioxin content.

TABLE 1. THE DIFFERENTIATION OF THREE TIME PERIODS DURING THE US MILITARY DEFOLIATION PROGRAM IN SOUTH VIETNAM AND MEAN DIOXIN CONTENT

Period	Herbicides Used (Code Names)	Mean Dioxin Content (parts per million)*
January 1962-June 1965	Purple, Pink, Green	~32**
	Blue	0
July 1965-June 1970	Orange	~ 2+
	White, Blue	0
July 1970-October 1971	White, Blue	0

*Found only in 2,4,5-T containing formulations.
**Value based on analyses of five samples.
+Value based on the analyses of 488 samples.

Herbicide Orange was the most extensively used herbicide in South Vietnam. Orange accounted for approximately 10.7 million gallons of the total 17.7 million gallons of herbicide used (Table 2). It was used from mid-1965 to June 1970. However, as noted in Table 2, Orange was not the only 2,4,5-T containing herbicide used in the defoliation program. Small quantities of Purple, Pink, and Green, all containing 2,4,5-T were used from 1962 through mid-1965. In subsequent sections of this document, the term "Herbicide Orange" will refer to all of the 2,4,5-T containing herbicides used in Vietnam (Purple, Pink, Green, and Orange).

TABLE 2. NUMBER OF GALLONS OF MILITARY HERBICIDE PROCURED BY THE US DEPARTMENT OF DEFENSE AND DISSEMINATED IN SOUTH VIETNAM DURING JANUARY 1962 - OCTOBER 1971

Code Name	Herbicide	Quantity	Period of Use
Orange	2,4-D; 2,4,5-T	10,646,000	1965-1970*
White	2,4-D; Picloram	5,633,000	1965-1971**
Blue	Cacodylic Acid	1,150,000	1962-1971**
Purple	2,4-D; 2,4,5-T	145,000	1962-1965
Pink	2,4,5-T	123,000	1962-1965
Green	2,4,5-T	8,200	1962-1965
	Total	17,705,200	

*Last fixed-wing mission of Orange 16 April 1970; last helicopter mission of Orange 6 June 1970.
**Last fixed-wing mission 9 January 1971; all herbicides under US control stopped 31 October 1971.

Use Patterns of Individual Herbicides

Each of the three major herbicides (Orange, White, and Blue) had specific uses. Ninety-nine percent of Herbicide White was applied in defoliation missions. It was not recommended for use on crops because of the persistence of Picloram in soils. Because the herbicidal action on woody plants was usually slow, full defoliation did not occur for several months after spray application. Thus, it was an ideal herbicide for use in the inland forests in areas where defoliation was not immediately required, but where it did occur it would persist longer than if the area were sprayed with Orange or Blue.

Herbicide Blue was the herbicide of choice for crop destruction missions involving cereal or grain crops. Approximately 50 percent of all Blue was used in crop destruction missions in remote or enemy controlled areas with the remainder being used as a contact herbicide for control of grasses around base perimeters.

Ninety percent of all Herbicide Orange was used for forest defoliation and it was especially effective in defoliating mangrove forests. Eight percent of Herbicide Orange was used in the destruction of broadleaf crops (beans, peanuts, ramie, and root or tuber crops). The remaining 2 percent was used around base perimeters, cache sites, waterways, and communication lines.

Table 3 shows the number of acres sprayed with herbicides in South Vietnam within the three major vegetational categories.

TABLE 3. THE NUMBER OF ACRES TREATED IN SOUTH VIETNAM, 1962-1971, WITH MILITARY HERBICIDES WITHIN THE THREE MAJOR VEGETATIONAL CATEGORIES

Vegetational Category	Areas Treated*
Inland forest	2,670,000
Mangrove forests	318,000
Cultivated crops	260,000
Total	3,248,000

*Areas receiving single or multiple coverage.

Certain portions of South Vietnam were more likely to have been subjected to defoliation. Herbicide expenditures for the four Combat Tactical Zones of South Vietnam are shown in Table 4. These data were obtained from the HERBS tape (a computer listing of all herbicide missions in South Vietnam from 1965 through 1971). Total volume is in close agreement with the actual procurement data shown in Table 2.

TABLE 4. US HERBICIDES EXPENDITURES IN SOUTH VIETNAM, 1962-1971: A BREAKDOWN BY COMBAT TACTICAL ZONE*

Combat Tactical Zones		Herbicide Expenditure (gallons) Orange	White	Blue
CTZ I		2,250,000	363,000	298,000
CTZ II		2,519,000	729,000	473,000
CTZ III (includes Saigon)		5,309,000	3,719,000	294,000
CTZ IV		1,227,000	435,000	62,000
	Subtotals	11,305,000	5,246,000	1,127,000
	Grand total			17,678,000

*Source: HERBS tape

In addition to the herbicides, numerous other chemicals were shipped to South Vietnam in 55-gallon drums. These included selected fuel additives, cleaning solvents, cooking oils, and a variety of other pesticides. The insecticide Malathion was widely used for control of mosquitoes and at least 400,000 gallons of it were used from 1966 through 1970. In addition, much smaller quantities of Lindane and DDT were used in ground operations

throughout the war in Southeast Asia. The distribution of the herbicides within Vietnam after their arrival did not occur randomly. About 65 percent was shipped to the 20th Ordnance Storage Depot, Saigon, and 35 percent was shipped to the 511th Ordnance Depot, Da Nang.

Military Aircraft and Vehicles Used in the Dissemination of Herbicides

Numerous aircraft were used in the air war in Vietnam, but only a few of these aircraft were used for aerial dissemination of herbicides. The "work horse" of Operation RANCH HAND was the two-engine aircraft C-123/UC-123 called the "Provider." This cargo aircraft was adapted to receive a modular spray system for internal carriage. The module (the A/A 45 Y-1) consisted of a 1,000-gallon tank, pump, and engine which were all mounted on a frame pallet. An operator's console was an integral part of the unit, but was not mounted on the pallet. Wing booms (1.5 inches in diameter, 22 feet long) extended from the outboard engine nacelles toward the wing tips. A short tail boom (3 inches in diameter, 20 feet long) was positioned centrally near the aft cargo door. Each aircraft normally had a crew of three men: the pilot, co-pilot (navigator), and flight engineer (console operator). During the peak activity of RANCH HAND operations (1968-1969), 33 UC-123K aircraft were employed. The "U" designated modification for aerial spraying and the "K" designated modification with jet boosters. However, many other squadrons of non-RANCH HAND C-123 aircraft were routinely used throughout South Vietnam in transport operations.

The control of malaria and other mosquito-borne diseases in South Vietnam necessitated an extensive aerial insecticide application program in order to control these vector insects. From 1967 through 1972, three UC-123K aircraft were used to spray Malathion, an organophosphate insecticide. These aircraft could be distinguished from the Herbicide-spraying aircraft because they were

not camouflaged. These aircraft routinely sprayed insecticide adjacent to military and civilian installations, as well as in areas where military operations were in progress, or about to commence.

Approximately 10 to 12 percent of all herbicides used in South Vietnam was disseminated by helicopter or ground application equipment. Generally, helicopter crews were not assigned to herbicide spray duties on a full-time basis and rotated the spraying duties with other mission requirements. The military UH-1 series of helicopters, deployed by the Air Force, the Army, and Navy units, generally sprayed the herbicides. The most common spray system used was the AGRINAUTICS unit. This unit was installed in or removed from the aircraft in a matter of minutes because it was "tied down" to installed cargo shackles and aircraft modifications were not required for its use. The unit consisted of a 200-gallon tank and a collapsible 32-foot spray boom. The unit was operated by manual controls to control the flow valve and a windmill brake. Generally, each helicopter had three crew members.

A summary of the aircraft used in herbicide and insecticide operations is shown in Table 5.

TABLE 5. US MILITARY AIRCRAFT USED IN THE DISSEMINATION OF HERBICIDES AND INSECTICIDES IN SOUTH VIETNAM

Aircraft	Camouflaged	Chemical Disseminated
UC-123K	Yes	All Herbicides
UC-123K	No	Malathion
Helicopter		
Air Force UH-1 Army UH-1B/UH-1D Navy UH-1E	Yes	Orange, Blue

Various ground delivery systems were also used in South Vietnam for control of vegetation in limited areas. Most of these units were towed or mounted on vehicles. One unit that was routinely used was the Buffalo turbine. It developed a wind blast with a velocity up to 150 mph at 10,000 ft^3/minute volume. When the herbicide was injected into the air blast, it was essentially "shot" at the foliage. The buffalo turbine was useful for roadside spraying and applications of perimeter defenses. The herbicides of choice in these operations were Blue and Orange.

Exposure Considerations: Applications and Environmental Parameters

There were relatively few military operations that involved the handling of herbicides by military personnel. A review of operations involving Herbicide Orange in South Vietnam from January 1962 to April 1970 revealed that there were essentially three groups of US military personnel potentially exposed to Herbicide Orange and its associated dioxin contaminant. These three groups were:

1. "Operation RANCH HAND" personnel actively involved in the defoliation program. This group included aircrew members and maintenance and support personnel directly assigned to the RANCH HAND squadrons.

2. Personnel assigned to selected support functions that may have resulted in exposure to Herbicide Orange. This group included, for example, personnel who sprayed herbicides, using helicopters or ground application equipment; personnel who may have delivered the herbicides to the units performing the defoliation missions; aircraft mechanics who were specialized and occasionally provided support to RANCH HAND aircraft; or, personnel who

may have flown contaminated C-123 aircraft, but were not assigned to RANCH HAND (e.g., during the Tet Offensive, all RANCH HAND aircraft were reconfigured to transport supplies and equipment, and were assigned to non-RANCH HAND squadrons).

3. Ground personnel who may have been inadvertently sprayed by defoliation aircraft or who, during combat operations, may have entered an area previously sprayed with Herbicide Orange.

The total number of US military personnel exposed to Herbicide Orange is not known. Approximately 1,200 RANCH HAND personnel were exposed in direct support of the defoliation operations; however, there are no data on the number of non-RANCH HAND personnel who may have been exposed. The actual number of people may be in the thousands since at least 100 helicopter spray equipment units were used in South Vietnam, and most military bases had vehicle-mounted and backpack spray units available for use in routine vegetation control programs. The number of military ground personnel who may have inadvertently been sprayed by RANCH HAND aircraft, or who may have entered areas recently sprayed with Herbicide Orange during combat operations is not known. Approximately 10 percent of South Vietnam was sprayed with herbicides, and most of this area was contested and/or controlled by enemy forces. Most areas sprayed were remote, unpopulated and forested. Because of the dense canopy cover, the target of the defoliation operation, the amount of herbicide penetrating to the forest floor would have been small. The exposure of personnel could have occurred by essentially three routes:

1. Percutaneous absorption and inhalation of vapors/aerosols by direct exposure to sprays.

2. Percutaneous absorption and inhalation of vapors by exposure to treated areas following spray application, and

3. Ingestion of foods contaminated with the material.

The chemical and physical characteristics of Herbicide Orange and the spray, as it would have occurred following dissemination from a UC-123K, are important factors in assessing relative exposures to the Herbicides and TCDD.

Table 6 reviews the pertinent chemical and physical characteristics of Herbicide Orange. Table 7 reviews both the application parameters of the spray system used in the UC-123K aircraft and the characteristics of the spray itself. Generally, herbicides were sprayed in the early morning or late afternoon, so as to minimize the effects of air movement on particle dispersion.

TABLE 6. PERTINENT CHEMICAL AND PHYSICAL CHARACTERISTICS OF HERBICIDE ORANGE

Formulation Concentrated	(8.6 lb ai/gal)*
Water Insoluble	Density = 1.28
Vapor Pressure	3.6×10^{-4} mm Hg at 30°C
NBE** 2,4-D : 1.2×10^{-4}	
NBE 2,4,5-T : 0.4×10^{-4}	
TCDD : 1×10^{-4}	
Viscous	40 centipoises at 20°C
Noncorrosive to metal	
Deleterious to paints, rubber, neoprene	
Long shelf life	

*Pounds active ingredient (2,4-D and 2,4,5-T) per gallon.
**NBE - Normal Butyl ester

TABLE 7. APPLICATION PARAMETERS AND SPRAY CHARACTERISTICS OF THE UC-123K/ AA 45 Y-1 INTERNAL SPRAY SYSTEM

Aircraft speed	130 KIAS*
Aircraft altitude	150 feet
Tank volume	1,000 gallons
Spray time	3.5-4 minutes
Particle size:	
<100 microns: 1.9%	
100-500 microns: 76.2%	
>500 microns : 21.9%	
87% impacted within 1 min	
13% drifted or volatilized	
Mean particle volume	0.61 microliters
Spray swath	260 ± 20 feet
Mean deposition	3 gallons/acre
Total area/tank	340 acres

*Knots indicated air speed

Ground combat forces normally would not have been expected to have entered a previously treated area for several weeks after treatment, during which time numerous environmental factors would have reduced the potential for exposure to military personnel. An indepth review of the environmental fate of Herbicide Orange and TCDD concluded the the vast majority of the phenoxy herbicides would have impacted forest canopy, the intended target.

Rapid uptake (e.g., within a few hours) of the ester formulations of 2,4-D and 2,4,5-T would have occurred. Most of the herbicide probably would have undergone rapid degradation (weeks) within the cellular matrix of the vegetation. However, some of the herbicide may have remained unmetabolized and would have been deposited on the forest floor at the time of leaf fall. Soil microbial and/or chemical action would likely have completed the degradation process. Herbicide droplets that impacted directly on soil or water would have probably hydrolyzed rapidly (within hours). Biological and nonbiological degradative processes would have further occurred to significantly reduce these residues. Some violatilization of the esters of 2,4-D and 2,4,5-T would have occurred during and immediately after application. The volatile material most likely would have dissipated within the foliage of the target area. Photodecomposition of TCDD would have minimized the amount of biologically active volatile residues moving downwind of the target area.

Accumulation of phenoxy herbicides in animals may have occurred following ingestion of treated vegetation. The magnitude of this accumulation would have likely been at nontoxic levels. Herbicide residues in animals would have rapidly declined after withdrawal from treated feed.

Most TCDD sprayed into the environment during defoliation operations would have probably photodegraded within 24 hours of application. Moreover, recent studies suggest that even within the shaded forest canopy, volatilization and subsequent photodecomposition of TCDD can occur. Since translocation into vegetation would be minimal, most TCDD that escaped

photodegradation would probably have entered the soil-organic complex on the forest floor following leaf fall. Soil chemical and microbial processes would have further reduced TCDD residues. Bioconcentration of the remaining minute levels of TCDD may have occurred in liver and fat of animals ingesting contaminated vegetation or soil. However, there are no field data available that indicate that the levels of TCDD likely to have accumulated in these animals would have had a biological effect.

The environmental generation of TCDD from 2,4,5-T residues, through thermal or photolytic processes, would have been highly unlikely and of no consequence.

SUMMARY

The choice of herbicides used in South Vietnam in Operation RANCH HAND, 1962-1971, was based upon those herbicides that had been widely used in world agriculture, shown to be effective in controlling a broad spectrum of vegetation, and proven safe to humans and animals. The major herbicides used in South Vietnam were the phenoxy herbicides 2,4-D and 2,4,5-T. These two herbicides were formulated as the water insoluble esters and code-named by the military as Purple, Orange, Pink and Green. A water soluble amine formulation of 2,4-D was used in Herbicide White. Two other herbicides were extensively used by the military, picloram (in White) and cacodylic acid (in Blue).

An estimated 107 million pounds of herbicides were aerially-disseminated on 3 million acres in South Vietnam from January 1962 through October 1971.

Approximately 94 percent of all herbicides sprayed in Vietnam were 2,4-D (56 million pounds or 53 percent of total) or 2,4,5-T (44 million pounds or 41 percent of total). The 44 million pounds of 2,4,5-T contained an estimated 368 pounds of the toxic contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD or dioxin). Ninety-six percent of all 2,4,5-T was contained in Herbicide Orange; the remaining 4 percent in Herbicides Green, Pink and Purple. However, Herbicides Green, Pink and Purple contained approximately 40 percent of the estimated amount of TCDD disseminated in South Vietnam. Green, Pink and Purple were sprayed as defoliants on less than 90,000 acres from 1962 through 1964, a period when only a small force of US military personnel were in South Vietnam. Ninety percent of all the Herbicide Orange (containing 38.3 million pounds of 2,4,5-T and 203 pounds of TCDD) were used in defoliation operations on 2.9 million acres of inland forests and mangrove forests of South Vietnam.

The handling, transport and storage procedures employed for the herbicide generally precluded physical contact with the herbicides by most military personnel. However, personnel assigned to the RANCH HAND squadron and to individual helicopters responsible for the dissemination of herbicides were the most likely military personnel exposed to the herbicides.

The methods employed in spraying the herbicides, the geographical areas designated for dissemination of the herbicides, and the action of the environment on the herbicides generally precluded direct physical contact with the herbicide by military personnel assigned to other military programs.

Chairman SATTERFIELD. General, Mr. Daschle has a question about that chart.

Mr. DASCHLE. General, would you go back to that chart for just a second? I am wondering, at any time between that period and before 1970 did Dow Chemical or any one of the chemical companies inform the Air Force of the toxicity studies that they had done and the carcinogenity that they had found?

General MYERS. I will refer that question, if I may, to Major Young.

Major YOUNG. Let me say that I have reviewed all the records that I could find. I have reviewed thousands of reports for that time period. I found nothing to that effect. However, I think you must realize that at that time period we did not know either about the teratogenic aspect or the carcinogenic aspect of dioxin. So I don't think Dow knew that.

You will recall that Dow had an industrial accident in 1964. As a consequence of that industrial accident there was the appearance of chloracne in many of its workers. Following that, efforts were taken to reduce whatever it was that caused the chloracne. We really did not know for sure that it was TCDD, as I understand, at that point in time, although there were some thoughts that it might be. So what I am really saying is that Dow notified, as we understand, a lot of other companies that were making herbicides and a significant reduction, in fact, did occur in the amount of dioxin in the herbicides we purchased. The mean concentration of the early material was 32 parts per million, as best we can determine from archive samples. But after 1964, the mean concentration of dioxin was two parts per million.

Mr. DASCHLE. But it was not until 1970 that you learned that agent orange even contained the chemical dioxin, is that not correct?

Major YOUNG. Identified as dioxin. There was a lot of information known about the presence of chloracnigen, or something that would cause chloracne. The rabbit ear test screened for that.

Chairman SATTERFIELD. Mr. Danielson?

Mr. DANIELSON. What is a teratogen?

Major YOUNG. The ability to cause birth defects. We are talking about a laboratory situation; namely the Bionetics Report that General Myers referred to.

Mr. GUYER. Could I interpolate a question there? When you decide to use these defoliants, do you accept the industrial recommendation? You have no chance to really do indepth studies, do you? In other words, the companies involved, I believe Monsanto has some suits on their hands right now as well as perhaps Dow, and I do not know the depth of profundity to which they go before it becomes usable. Do you know anything about that?

Major YOUNG. We normally set military standards for products that we purchase in the service. The military standards are well known for the phenoxy herbicides. They specify the active ingredient that must be present and the amount of nonactive material. You must realize that the ability to detect TCDD at those very low levels just did not exist up until 1970.

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Mr. GUYER. Could I ask the general, you mentioned 57 percent of the fatalities were from operational causes but you didn't say what the others were from.

General MYERS. There are 11 known deaths. We have no information——

Mr. GUYER. You have no way of knowing whether they are related or nonrelated.

General MYERS. I don't.

Mr. GUYER. I see, that's all.

Chairman SATTERFIELD. General, you may proceed with your charts, please.

General MYERS. Thank you. I would just add parenthetically as a part of the answers given about the levels of detection of TCDD in orange, that the Air Force Occupational and Environmental Health laboratory has been involved with and helped develop state-of-the-art technology in order to characterize the quantities of this contaminant found in the herbicide, soils, and water.

These charts present a process of events. The peer review process was lengthy. It began in June 1979. I have reviewed that for you. Each of these organizations who are composed of distinguished scientists all had some critique to make and the protocol became modified as we moved along.

This chart reflects studies that have been done: The Nitro accident in West Virginia where 121 workers all had chloracne. The Seveso, Italy, accident has been discussed. There are now four Swedish and one West German report of exposure of workers with some relationship apparently to what we call soft tumors or lymphomas. In 1980, the John Moore mouse study, which has been referred to, and then the National Cancer Institute animal bioassay results confirmed earlier reports that TCDD is carcinogenic in laboratory animals.

Mr. EDGAR. Would the gentleman yield at that point? There was some testimony and some studies done at Fort Drumm in New York in 1959. Do you have any indication of that?

General MYERS. I have none personally.

Mr. EDGAR. Let me just read from the testimony. On page 4 of Samuel Epstein's testimony it says, "The effectiveness of the compound as a herbicide was first demonstrated in 1949 in Beltsville and Fort Derrick, Md. This was immediately followed by extensive military research, including aerial spray tests. By 1951 tests at Fort Derrick determined that the herbicide of choice was an equal mixture," and it lists that. And then it says, "The effectiveness of this formulation was established in 1959 in defoliation studies over 4 square miles of Fort Drumm, N.Y." I don't see that listed on your study and there are some other studies that aren't listed there.

Major YOUNG. Dr. Epstein took that from my publications. Indeed, I described those in the "Toxicology Environmental Fate and Human Risk of Herbicide Orange." Copies have been provided to the committee. In that 247-page document, I detailed those early studies.

That Fort Drumm study was important from the aspect of application technique development, equipment, and particle size stud-particle size in terms of what we spray. It was a very limited study,

however. We only looked to see if defoliation occurred. It was not a toxicological effects study.

General MYERS. Mr. Edgar, I prefaced the chart presentation with words that we were giving a precis and didn't hope to cover every item.

Chairman SATTERFIELD. If you will proceed with your charts, General, we will try to withhold questions, unless they pertain to the chart, until you complete your presentation.

General MYERS. What I have done here is show for the subcommittee's consideration the symptoms that are listed by each of what we call a system; that is, the digestive system. And then on the other side are the positive findings that one can get through some kind of test. So even though there may be a whole spectrum of symptom complaints which can be seen in many difficulties that people may have, what we would look for in a TCDD problem would be some kind of liver dysfunction which has to be measured by doing sophisticated liver function tests in the laboratory. Now we turn to the cutaneous manifestations of rashes and porphyria, which is a breakdown of the pigment in the blood cell. This results in some blistering on the skin or the rash which is similar to juvenile acne. That is the only thing we see other than some increased pigmentation or increased body hair or loss of scalp hair.

As we move on through the neuromuscular symptoms that we referred to, we see those which can be found in many disorders and diseases. The findings so far in TCDD are diminished reflexes and diminution of what we call nerve conduction, a way of measuring the rapidity with which an impulse travels along a nerve fiber.

Chairman SATTERFIELD. You say general findings; findings by whom?

General MYERS. Sir, I am sorry, I couldn't hear your question.

Chairman SATTERFIELD. By whom are those findings? Air Force?

General MYERS. No, these are the results of some of the studies in the literature. Under genitourinary, there have been allegations of impotence, decreased libido, and reproductive problems. But what we see when we are looking at human beings are protein in the urine and some degeneration in both the filtering and collective parts of the kidneys. There have been complaints about rapid pulse and slow pulse and missed heartbeats. Those are shown objectively on EKG. And then there are the allegations of cancers in all systems as well as alleged birth defects for which we have no laboratory data.

Mr. DASCHLE. General, if I could ask you, but you are referring strictly to human testing——

General MYERS. That is exactly it.

Mr. DASCHLE [continuing]. Not animal testing.

General MYERS. No, those are all human systems. And here on these charts, just very quickly, are the three phases of our Air Force protocol: Mortality, morbidity, and followup, as well as the data analysis and the predictions when we should have some information. From our initial mortality study, we will be getting data at the end of a year and a half to two. We are well into that. Data from the first questionnaire is about 2 years out and from the first physical examination, the same. And then, as the National Acade-

my had recommended, our followup goes from 6 years out to 20 years.

This last chart is merely an attempt to show how the dynamics of the study relate in protocol complexity, in the logistics of its application, to cost. And what we see here is a relatively simplistic questionnaire which can be given very easily. It is not complex and it is at low cost. But as one develops the increasing science that is required to do an indepth program, we move on to this part of the chart. This is where we have had the input from our various peer review groups. We are looking at a ratio of not 1:1 here but a 1:5 Ranch Hand to control group for the mortality phase and a very exhaustive questionnaire as well as an extensive physical examination.

Mr. Chairman, that completes the charts and the presentation, sir.

Chairman SATTERFIELD. Thank you, General. There are at least two or three questions I would like to ask right at the inception because I think it might put your testimony in the proper frame of reference. You referred to the epidemilogical study that the Air Force is beginning. You also referred to the fact that the National Academy of Science had made some recommendations. According to Dr. Handler this morning, two of those recommendations had to do, if I recall correctly, with the timeframe of your study and the size of the test group.

You indicated that your study would be 6 years with follow-on depending on what was ascertained. Is that in accordance with the recommendations of the National Academy?

General MYERS. The National Academy made the recommendations that you referred to, Mr. Chairman, when they questioned the scientific validity because of the small sample size. Second, they recommended that the study be conducted over a much longer period of time.

Chairman SATTERFIELD. My question is what that longer period of time is more than 6 years?

General MYERS. Yes, sir, 20, and we have included that in the protocol. So reviews will be done at 1, 3, 5, 10, 15, and 20 years.

Chairman SATTERFIELD. So in effect you have changed then your protocol to one of 20 rather than 6 years.

General MYERS. Yes, sir. There is no way, however, to alter the sample size because the Ranch Hand population is fixed at 1,198.

Chairman SATTERFIELD. Just to make everything abundantly clear, I deduced from your statement that an attempt would be made to conduct this study with respect to all 1,198 rather than just the 245 you have on active duty.

General MYERS. Oh, yes, sir. When we talk about the Ranch Hand group, we are talking about the entire group. I merely said the 245 remained on active duty.

Chairman SATTERFIELD. I just want to make clear that you are trying to get those who are not on active duty to participate.

General Myers. Yes, sir, and we have the names and addresses of all of those individuals.

Chairman SATTERFIELD. I only have one other question with respect to these charts. You showed two in which you listed and referred to review of literature, and on one column you had "com-

plaints." I am not sure what was meant in that second column. I asked the question and I am still not sure I have got the answer. Where have you listed findings, what kind of findings?

General MYERS. Mr. Chairman, when one investigates a medical problem, the patient presents with a series of symptoms and findings. The symptoms are what the patient says he perceives as his problem. For example, numbness and tingling, headache, low back pain, or weakness. The findings are what one sees on the examination, either by feeling or looking. And findings also are included in what one perceives on an X-ray with some special kind of technique in a laboratory to measure a given value.

Chairman SATTERFIELD. In other words, a physical manifestation of the allegation.

General MYERS. Exactly.

Chairman SATTERFIELD. But nevertheless, both columns refer to allegations and not to conclusive findings.

General MYERS. The symptom complexes would be more accurate.

Chairman SATTERFIELD. All right, sir. I just wanted to get that clear.

General MYERS. Yes, sir.

Chairman SATTERFIELD. Mr. Edgar?

Mr. EDGAR. Thank you, Mr. Chairman. General Myers, if you were to contemplate any major changes in your working protocol or any major things you would have liked to have seen covered that have not been covered, what might they be?

General MYERS. We are quite satisfied. Having been through 5 peer review processes with 28 eminent scientists in the United States analyzing the data, we have reached a point where we are comfortable with the protocol. It is quite obvious that if that protocol is exposed to more scientists, one can get both increased input and advice to decrease some of the indices. At the moment, we are quite certain that that peer review has been exhaustive and extensive. So in the interests of getting the study moving, we feel that we have done what we have had to do.

Mr. EDGAR. The Ranch Hand group that you are using as your control group, which has to stay fixed, was basically a group of veterans who manned the airplanes; is that not true?

General MYERS. The Ranch Hand group are the individuals that Major Young referred to who were involved in the spraying.

Mr. EDGAR. Is there any interest on the part of the Air Force in trying to make contact with random sampling of people who had extensive exposure in the field after or shortly after the actual spraying took place and spent time using the water for cooking and that type of thing?

General MYERS. That had been recommended and I would refer to the statement by Ms. Bernstein before the Senate committee on September 10 that the interagency work group having considered all the data, felt that there was not enough ability to identify ground personnel and advised us to proceed with the Ranch Hand study as the protocol called for.

Mr. EDGAR. I would like to pursue that a little bit. A number of Vietnam veterans have come to my attention who know of its use, who entered areas shortly after the spraying, and it seems to me

that that response is totally inadequate. We are not measuring the prolonged involvement of troops in weeding out and having operations in the field where these sprayings took place. Manifestations of problems that you may see in the Ranch Hand group might not impact the kind of level of intensity of exposure that others may have had on the ground in operations.

As was indicated by Dr. Handler's testimony, there obviously are grids that Ranch Hand group used in doing its spraying. You have pictures that you showed in your slide presentation so you would know where they were taken. I think that some investigation could be made of veterans who served with particular units in particularly high exposure areas of Vietnam to see whether or not a like number of random sampled group of people who had extensive exposure on the ground and in the field and using the vegetation and water as part of their involvement might also have impact from agent orange.

General MYERS. I think there are a number of ways to answer your question. The first of these is that we know very well who the Ranch Hands are. They are identified. And we also know that more than likely, and Major Young can present the evidence to back this up, that the Ranch Hand exposure is many, many times over what could have been the exposure of any serviceman on the ground. I think in some of the presentations where he showed particle size and the degradation of dioxin because of the sunlight it is obvious that we have a population which was at far greater risk than anyone on the ground.

Mr. EDGAR. I am not questioning the risk that the Ranch Hands had. What I am questioning is that there is another aspect to the impact and that is that veteran who was on the ground for 4, 5, 6, 7, 8, 9, 10 months or longer in areas that were heavily exposed to agent orange use and your defoliation activities took place in that area. While they did not handle the material using the pumps and the pipes and the equipment, they may have lived with the substance over a period of time, and some definitive analysis of that group seems to me to be necessary.

General MYERS. That was considered. If I may just quote from Ms. Bernstein's testimony. Because of our difficulty with this as we developed our protocol, we referred it to the interagency work group panel and the science panel "agreed with other peer review groups that the size of the cohort the Air Force proposes to study does impose limitations on the statistical power of the study (that is, the study's ability to detect the relatively rare health effects); however, the panel agreed that adding to the cohort ground troops whose exposure to agent orange was clearly significantly less than that of Ranch Hand personnel, and although not documentable, would dilute the cohort and therefore further diminish the likelihood of detecting adverse health effects."

Mr. EDGAR. Let me ask one other question. The Department of Defense study will show what ailments occur at higher than normal levels in those with the heaviest level of exposure to agent orange, the Ranch Hand group. Will these results be of any value in setting the presumption of causality for lesser levels of exposure?

General MYERS. I would be hard-pressed to answer that question one way or another at this time. Dr. Stern.

Dr. STERN. We see the Ranch Hand study as but one study in a matrix of many other studies that the interagency work group will be responsible for coordinating. Whether that composite picture would serve the issue you asked about, we can't say. Our study is one element in that large picture. It cannot by itself answer the full range of——

Mr. EDGAR. Let me ask one final question, and I apologize for taking the time. Is the task force group planning to redo the medical questionnaire used in the VA medical system as a result of any of these studies that have already been completed?

General MYERS. I can't answer your question about what the Veterans' Administration intends. We have in the Air Force modified our protocol significantly based on the input that we have had from peer review groups. In fact, it has become essential for us to get people in that kind of business so that the questionnaire suffers no credibility at all. The development and the pretesting and the administration of that questionnaire will be as scientifically sound as possible using civilians with expertise in those areas.

Mr. EDGAR. Wouldn't your experience, though, be helpful to the task force group so that they don't start from scratch?

General MYERS. Indeed, and it is the intent of the interagency work group monitoring portion of that organization to be right along every minute looking to see if we are on the right track.

Mr. EDGAR. Thank you. I yield back.

Chairman SATTERFIELD. Mr. Sawyer.

Mr. SAWYER. Thank you, Mr. Chairman. I have listened now to the better part of a couple of panels on this. Would it be a fair statement that as of now there is no established evidence of any causality between agent orange and any of these myriad of reported symptoms?

General MYERS. I think one could say with great definition, Mr. Sawyer, that we know exposure to herbicide orange can produce chloracne. We have seen it in industrial accidents. There may well be some veterans who have chloracne or have had it. I don't believe there is any clearcut evidence at the moment to imply that any other disorder that may be seen can be absolutely related to herbicide orange exposure.

Mr. SAWYER. Is this chloracne a transient thing or does it leave any residual problem? I understand what acne is, but I am not clear about chloracne.

General MYERS. It is relatively self-limiting. Like juvenile acne, it does leave scarring.

Mr. SAWYER. But I presume it is a transient thing, it isn't a permanent condition, is it?

General MYERS. It can leave scarring as a result of the acne process. There have been a few reports of continued chloracne problem.

Mr. SAWYER. And other than the epidermal scarring, there isn't any further health damage as far as is known?

General MYERS. As best I can answer, no.

Mr. DASCHLE. Will the gentleman yield. If I could just clarify one statement. I don't think you would dispute this, General, but there

are very definitive studies that show a causal relationship between dioxin and the carcinogenity the dioxin in animals. There are two ways of testing, this is what we were talking about earlier, either through epidemiology studies or through laboratory testing. In laboratory testing that distinction now has been drawn. Thank you.

Mr. SAWYER. I assume, though, that the question of whether any alleged carcinogen produces tumors in specially bred K22 mice that are cancer-prone to begin with and are bred for that purpose doesn't necessarily establish a linkage with the ability to cause it in a human being. Other than the chloracne, I presume there is no established etiology or impact of agent orange except for a wide assortment of, as I look at the list, varying complaints. We will lay aside the chloracne question.

General MYERS. That is true.

Mr. SAWYER. I was particularly interested because a panel we had here before suggested or recommended legislation imposing absolute liability on producers. Regardless of the merits or demerits of that, or even the constitutionality of it, it seems to me that even with absolute liability causation is required. You can't have absolute liability unless you cause some damage. So I was particularly interested in whether there was anything yet on that.

General MYERS. I would prefer to stay away from that particular problem.

Mr. SAWYER. Thank you, General.

Chairman SATTERFIELD. We are going to have a series of votes in a very short period of time. Many of the members who were here earlier have told me that they had to leave because of prior commitments at lunch. I wonder if perhaps you all could return at 2 o'clock so that we might pursue these questions?

General MYERS. Yes, sir.

Chairman SATTERFIELD. Fine. The subcommittee then will stand adjourned until 2 o'clock.

[Whereupon, at 12:15 p.m. on September 16, 1980, the subcommittee recessed, to reconvene at 2 p.m. the same day.]

AFTERNOON SESSION

Chairman SATTERFIELD. The subcommittee will come to order. We will continue with the testimony of the Air Force. We had begun questioning of our witnesses. The next gentleman to be introduced for questions is Mr. Daschle. If you will proceed, Mr. Daschle.

Mr. DASCHLE. Thank you, Mr. Chairman. General, I would like to clarify again, if I could, when you first found out that agent orange contained the deadly contaminant dioxin.

General MYERS. My perception of that is that the Department of Defense became aware of that 1969 study which was shown on the chart and that use was suspended then in 1970.

Mr. DASCHLE. So it was in 1969 that you became aware of it. Were you ever notified by the producers of agent orange that they had done any tests prior to 1970 with regard to the contaminant? In other words, at the time that you made the decision to use it, were you provided any material which showed that it might cause health hazards?

General MYERS. I would ask Major Young if he would respond.

Major YOUNG. Not in regard to the dioxin. We conducted our own toxicological tests animal tests with the early formulations used in Vietnam. We have a publication on purple, a 2,4-D/2,4,5-T formulation, which is a toxicological evaluation. There were a number of publications also put out during the Vietnam period on the toxicology of 2,4-D and 2,4,5-T. The issue of TCDD, however, did not come about until 1969. We saw no report prior to that. At least the records reflect that of those that I have seen.

Mr. DASCHLE. Major Young, in going through your reports of the history of the use of this, did you have any records where the herbicide was dumped at a time when perhaps they were under attack or had to flee a given area? Was the 1,000 gallons ever dumped on a given area?

Major YOUNG. Indeed, anytime that the crew found that it was necessary because of any number of circumstances, but usually the aircraft was in danger of crashing, they then would jettison the tank. Jettison the herbicide not the tank itself. They would have to file a report and those reports are available. They have been maintained. We have them on microfiche so we know how many times the herbicide was jettisoned due to complications in flying and we know approximately where. Many times it took place outside of Da Nang and was actually dumped in the ocean. I think it occured on about 11 occasions.

Mr. DASCHLE. Do you know what the total number of jettisoned incidences was during this period of time?

Major YOUNG. That can be provided. I believe the figure is 21, but I am not absolutely certain.

Mr. DASCHLE. Twenty-one cases were——

Major YOUNG. Yes.

Mr. DASCHLE. The 1,000 gallon tank or parts of it thereof were actually dumped.

Major YOUNG. It took 20 seconds to jettison the entire load.

Mr. DASCHLE. Twenty seconds.

Major YOUNG. Yes.

Mr. DASCHLE. And so that jettison material fell over an area the size of what? Could it be said that it falls pretty directly below the aircraft so most likely that would have fallen in a very concentrated form on a given area?

Major YOUNG. Exactly. It would just be like pouring it out of a bucket.

Mr. DASCHLE. You poured it out of a bucket.

Major YOUNG. The hose was 6 inches in diameter. You can imagine how quickly it poured out?

Chairman SATTERFIELD. Will the gentleman yield at that point.

Mr. DASCHLE. Yes.

Chairman SATTERFIELD. May I ask a question? When that occurred, what altitude level would it normally be?

Major YOUNG. Typically on the way to a mission and returning from a mission they would fly about 1,000 to 1,500 feet. Of course, it would depend on what kind of terrain they were going over. If they were over a very hostile area, they would fly at least 3,000 feet in elevation, altitude above the ground.

Mr. DASCHLE. I would like to then go back to a question that was asked this morning in regard to testimony provided by Ms. Bern-

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stein. I haven't seen this testimony, but it is my understanding that the thrust of what she said was that those people who actually handled the material in operation Ranch Hand were probably more susceptible to the effects of it than were those on the ground. Is that a correct interpretation of what she was stating?

General MYERS. I think that is incorrect.

Mr. DASCHLE. How would you rephrase that?

General MYERS. They weren't more susceptible. They had greater exposure.

Mr. DASCHLE. That is even more along the lines of what I was saying. They had more exposure. Prior to the time that they were actually employed for the purpose of dispensing the agent orange, were they given any classes or any kinds of education on how it should be used?

Major YOUNG. We generally provided information to the supervisors relative to the handling of the herbicide. I can personally say that aprons were provided, at least during some periods of time. I wore an apron on many of the occasions when I was loading the aircraft. But that wasn't always true. One of the problems was that despite the fact that aprons, special boots, and even goggles and gloves, may have been provided, the temperature at the time when these operations were taking place was very hot and it was a very uncomfortable thing, I can assure you, to have a lot of clothes on trying to do a lot of heavy work. The attitude was these materials were harmless.

Mr. DASCHLE. You used some precautions in the way you used these?

Major YOUNG. Yes, we had them available, at least during some periods. Whether they were always used, you can't say because of the environment.

Mr. DASCHLE. By and large, you were trained, No. 1; No 2, you wore aprons.

Major YOUNG. The supervisor was aware. Now, was he effective in always telling the crews that handled it? We don't really know that.

Mr. DASCHLE. As a rule, you were trained and you were provided equipment to wear in the dispensation of this——

Major YOUNG. During some periods, but it wasn't always worn.

Mr. DASCHLE. But it wasn't always worn.

Major YOUNG. Loading crews frequently wore teeshirts, sometimes only shorts.

Mr. DASCHLE. In your presentation this morning you said that oftentimes you avoided ambushes through the use of this spraying of the herbicide. Obviously, being concerned about ambushes you were concerned about our own people in the area being ambushed, is that not correct?

Major YOUNG. Well, any time that we had to go into an area that was hostile, where we knew the hostilities were going on.

Mr. DASCHLE. I guess the point I am trying to lead up to here is that on the one hand you had people who were trained, who were given protective gear, whether they used it or not, using this chemical——

Major YOUNG. In the concentrated form.

Mr. DASCHLE [continuing]. On the other hand, you had people who had no training, who in some cases were coming into an area very directly following the spraying of the herbicide, who in some cases may even have gone into an area where the whole thing was dumped in concentrations the likes of which we have no idea. Which leads me to come to the conclusion that the Bernstein conjecture here that indeed those Ranch Hand operatives had greater exposure, may not be entirely accurate. In fact, I think one can draw the conclusion that those people on the ground had greater exposure, at least to the extent that they were not given the same kind of protection given those people actually implementing the spraying of the herbicide.

Major YOUNG. I would disagree from my own experience. I can tell you this. When you are handling the concentrated form, all the chemicals, and we are talking about thousands and thousands of gallons on a daily basis, one perhaps would take more precautions then as compared to talking about a teaspoon or a cupful that might fall in a small area, or three gallons dispersed over an entire acre. There is a tremendous difference in exposure. You can put your hands in a drum and you are massively exposed. But I stood under many an aircraft as it was flying over, and I can tell you you could hardly feel the mist. That is a big difference. I think that has to be taken into consideration.

Also, I would point out that it was our policy to not let troops go into an area until about a month afterwards simply because the whole concept of defoliation was to remove the vegetation. If we were going to send our troops in, my God, why spray, just send the troops in.

Mr. DASCHLE. But in prior testimony on the first hearing we had you indicated, or someone indicated, that we had no way of guaranteeing that the troops were not in the areas where they were sprayed. In fact, we had no knowledge of where troop locations actually existed in every instance. So there is no guarantee at all that indeed we prevented spraying on our own people. In fact, we have ample testimony from others in the form of letters and such that these people were sprayed on. I would be happy to provide that again for the record.

Major YOUNG. I think you misunderstand. On almost every mission there were a series of coordinated actions that were required. You must realize that on a typical Ranch Hand mission, we sent our aircraft out a couple of days beforehand to be sure they knew where the target was actually located. Those aircraft stayed at 3,000 feet while they located and defined the target. Our targeting officer then went back and briefed the mission. Typically 24 hours before that mission was run, they contacted the commanders on the ground, if there were commanders with troops in those areas. That has been reported many, many times. The exceptions, however, are the free spraying zones.

The GAO report focused on the free spraying zones, the demilitarized zone, and the zone around Khe San. Their 1979 report focused on the free spraying zone where, in fact, we were not able to coordinate with the commander. Had the GAO tried to do the same workup in an area of III Corps, they would not have been able to do it. It is that simple.

Mr. DASCHLE. Well, exposure, of course I don't accept that, but even if I did, there was other forms of exposure, including the use of the drums for other purposes, including the fact that many of these soliders, as they have testified before us, actually drank from the water which was sprayed with the herbicide, whether it was in a free zone or not. The kinds of exposure are very diversified, and there is no way of saying that in every instance you prevented our people from having that kind of exposure. In fact, during the earlier testimony, you indicated that perhaps some of these drums were used. So, of course, we have the effect there of that exposure having been provided.

I want to follow up with one other question and I will then turn my time back. Earlier the general indicated that Ms. Bernstein had said that it would be impossible to do any kind of a ground troop study, but it is my understanding that her judgment on that study was based on information provided her by the Air Force which had indicated that indeed the study would be very difficult, if not impossible, to do. Do you not find yourself in a position of saying she said it can't be done but we told her that it can't be done, so you have a chicken and an egg thing here where you are following your own tail.

I guess the question would be on what other basis has she made the decision that a study can't be done other than the information provided her by the Air Force?

General MYERS. We can thoroughly track the location by time also and duration of exposure of the Ranch Hand personnel. We have them identified and have addresses. That is an identifiable population against which we can match a control group at the rate of 5 to 1. There is not that kind of concrete data for any ground troop concentration that we have been able to detect which would allow us the same kind of science as applied to this control epidemiological study. That is a known fact. So, obviously, as we were trying to produce the best scientific protocol that we could come up with that would pass the peer review process, it became necessary for us to purify it to the point where it would have some meaning. And if that cohort group had been diluted with others who had been on the ground against whom it would be almost impossible to match a control, we would destroy, I think, some of the scientific credibility of the study that we are trying to now push through to completion. Maybe Dr. Stern would like to speak to that.

Dr. STERN. I would like to just augment what General Myers said. By control, we mean a group that is similar in every respect except almost certainly not exposed to that particular agent. So not only would you have to locate GI's on the ground who were probably exposed and somehow reconstruct their exposure, but you would have to identify a similar group that almost certainly was not exposed and then compare them. That is the challenge. And in a sense that can be done in a discrete and separable way from the Ranch Hand study. There is no benefit to linking the two studies and holding the one up.

The other point I wanted to make is there is no good way for a soldier on the ground to know that he was being sprayed with agent orange. The probability was many times greater that he was being sprayed with insecticide.

Mr. DASCHLE. Dr. Stern, I would have to disagree. Those planes were very well marked and there is a big difference. I don't recall the designations of the planes, but there is a clear distinction in the kind of plane used.

Dr. STERN. Exact same airplane?

Mr. DASCHLE. Oh, no. The one was camouflaged with a big orange line across the top of the wing.

Dr. STERN. But there is no way a soldier on the ground would have seen it.

Mr. DASCHLE. Coming from a distance, I would respectfully disagree. I think you could tell. And besides that, the silver plane and a camouflage plane are obviously two different, very distinctively differently painted planes.

Dr. STERN. Flying just at the top of the canopy at 150 feet coming out of the Sun?

Mr. DASCHLE. Oh, they are always coming out of the Sun?

Dr. STERN. Well, that was the whole idea, that they should not be easy to see and not easy to spot. That doesn't make it that clearcut. And now you are relying on someone's memory of many years back that he remembers being sprayed by that particular airplane. If he is wrong, then you are looking at a totally different epidemiologic study, maybe still important but a different one.

Mr. DASCHLE. Mr. Chairman, I know that there are a lot of witnesses and I apologize for taking more time than I should.

Chairman SATTERFIELD. Thank you, Mr. Daschle. Mrs. Heckler.

Mrs. HECKLER. Thank you, Mr. Chairman. Major Young, as I understand it, you have been involved with this whole question of agent orange from the very beginning in the sense that the first memo that raised the issue was to have been a report on a conversation in which you defined agent orange as being very toxic and carcinogenic. And as I understand it, Maude deVictor, who was the claims processor at the VA hospital in Chicago, when she encountered a number of claimants, veterans who seemed to have the same symptoms and tried to find an answer, she ultimately was directed to call you. As a herbicide expert in the Air Force you were asked for your opinion, and it was the basis of that opinion, as she reported it in this memo, that the issue has really been developed.

Since that time, it is my understanding that you have contradicted the contents of that memo. Could you explain to me exactly what happened here and how is it that a claims processor who was interested enough in the question of agent orange and the problems of the veterans and who sought out your advice, could possibly misrepresent your conversation with her to the point where you now refute almost all the contents of the memo? Is that a correct statement? Is it in fact true that you do refute the contents of the memo?

Major YOUNG. Of course. I thank you for the opportunity to respond. I have been very concerned about that anonymous memo. In my own conversation with Maude de Victor in 1977, we, in fact, discussed many of the points that were in the memo. We did not discuss it the way that memo described it, however.

Mrs. HECKLER. I am only interested, first of all, in the scientific accuracy and the——

Major YOUNG. The memo was very poorly distorted, that is the bottom line.

Mrs. HECKLER. In other words, are you standing behind the scientific content of the memo?

Major YOUNG. Oh, of course not. Maude de Victor did not——

Mrs. HECKLER. This whole agent orange issue was discovered by this one claims processor who identified it formally at the VA. She was, as you know, reassigned to another location and subjected to some serious problems in her job as a result of this memo and as a result of her involvement with the issue of agent orange. I would like to have you give me your side of the involvement with Maude de Victor, how it arose, what your conversations with her were about, what the scientific content of the conversations, not the use of a memo, et cetera, what the scientific content of the conversations involved.

Major YOUNG. I would be pleased to do that. Maude de Victor called me in 1977. She said that a sergeant whose records she was reviewing had died of cancer and she wanted to know if, in fact, agent blue, which contains an arsenical, could have caused the cancer in this sergeant who had died. The wife of the sergeant had claimed that he, the sergeant, recalled many times being involved in spray actions around bases and that he had sprayed agent blue. So she asked me could it be that agent blue is a carcinogen. I pointed out to her that our knowledge of cacodylic acid was, in fact, extensive enough to say that cacodylic acid was probably not a carcinogen at all. And it was highly unlikely, from what we knew at that time, that blue could have been the cause.

She asked me then are there any other chemicals used in Vietnam, and I talked to her about white and how it persists in the soil, but the fact that toxicologically it is essentially nontoxic. We talked about 2,4-D and 2,4,5-T as it is found in orange. I pointed out the same thing to her. Then I mentioned to her that indeed there had been the accusation by the North Vietnamese scientist, T. T. Tung, that Vietnamese who alleged exposure said they had cancer. I said that to our knowledge those are the only reports we have ever heard that TCDD is a carcinogen. Mind you, there were no animal data available at all showing that TCDD was a carcinogen. We only knew that it was a teratogen. We did not know it was a carcinogen.

Maude de Victor asked me if I would send her some publications, and I sent her three; two dealing with the science as we knew it in terms of the chlorinated hydrocarbons, and one article by Dr. Tung. It was a very pleasant conversation. I never communicated again with Maude de Victor. When the anonymous memo came out, I understood that Maude de Victor was asked if she had prepared that anonymous memo and she said she did not. I don't know who prepared that anonymous memo with that information. That information is not what I had given Maude de Victor.

Mrs. HECKLER. What information in the memo would you refute or contradict?

Major YOUNG. Interestingly enough, the memo follows very much the general topics, but the information that I would certainly refute is that the Air Force was not critically following it or the Department of Defense. We knew it wasn't an issue at that point

and we had just finished disposing of orange. No one was aware that there was a veteran issue because there wasn't one. I never stated that TCDD was a mutagen. Quite the contrary. We didn't know anything about mutagenesis. I didn't say that blue was a carcinogen. Quite the contrary. We didn't know that blue was a carcinogen. We still don't.

Mrs. HECKLER. What would you say about TCDD now?

Major YOUNG. Today, in laboratory studies, animals that have ingested TCDD repeatedly for a long period of time do show carcinogenesis. But that information was found after that memo. Where the information came from in that anonymous memo I don't know, but I think it was probably very intentional. And if Maude de Victor was——

Mrs. HECKLER. In what way do you feel it was intentional?

Major YOUNG. I think coming out at a press conference means that it was quite intentional because that was how the anonymous memo was released. The only name in it was mine.

Mrs. HECKLER. And the memo followed the general conversation that you had with——

Major YOUNG. With Maude de Victor of that date. The memo was dated the day of the conversation, which is very interesting to me because the publications I sent her which were noted in the memo could not have been given to Maude until after that date because I sent them in the mail. I suggest the memo was probably written some time after I had done it and perhaps Maude had had a conversation with somebody that used the information and then doctored it up accordingly. I don't know. I am as mystified as you.

Mrs. HECKLER. She, of course, as you know, raised the issue of whether or not claims would be recognized by the Veterans' Administration——

Major YOUNG. I think that was very valid.

Mrs. HECKLER. That was valid?

Major YOUNG. Of course.

Mrs. HECKLER. That was her job as a claims processor.

Major YOUNG. That was her job. I had a very pleasant conversation with Maude de Victor. I offered to do everything I could do to help. I said I would be glad to send literature and I did.

Mrs. HECKLER. The Air Force changed its rules in terms of the—rather, the Department of Defense—in terms of its use of agent orange. Earlier, according to your own films, agent orange was sprayed more liberally and later it was limited to unpopulated areas. Is that correct?

Major YOUNG. We sprayed the herbicide in areas that were contested. I showed you a picture taken only 22 miles from Saigon in a very highly contested area. Obviously, there were a lot of people, if nothing more than just the enemy, down on the ground. But because the enemy often infiltrated the villages, it was certainly possible that spraying could have occurred near a village. OK, after the October suspension we were directed not to spray where there were any people at all. That was the whole point. In terms of native Vietnamese. That was the difference. So instead of spraying 22 miles near Saigon, now we were restricted much, much farther away in more remote regions.

Mrs. HECKLER. What was the date of your telephone conversation with Maude de Victor?

Major YOUNG. The 12th of October.

Mrs. HECKLER. In what year?

Major YOUNG. 1977.

Mrs. HECKLER. 1977. And the Department of Defense had decided that it would curtail spraying to the more remote areas which were less populated in what year?

Major YOUNG. In 1969, October 1969.

General MYERS. And discontinued completely in 1970.

Major YOUNG. Yes.

Mrs. HECKLER. Was there a suspicion on the part of the Department of Defense that this was a highly toxic substance for humans——

Major YOUNG. No.

Mrs. HECKLER [continuing]. And was that the reason that a population of those in the sprayed area was a factor in determining where the spraying would be targeted?

Major YOUNG. The allegation was being made in 1969. There were a number of Saigon newspapers that were reporting items about birth defects. Interestingly enough, those articles appeared at the same time as the Bionetics Report was appearing. I imagine that you can visualize the pressure that must have gone throughout the entire community over such allegations. That probably was the major reason why orange was restricted.

Mrs. HECKLER. Were allegations in the Vietnamese papers of birth defects?

Major YOUNG. Yes, there were.

Mrs. HECKLER. Those are the same allegations that the Vietnam veterans are making today, those that fear that they have been the victims of agent orange.

Major YOUNG. Yes, I realize that. Yes, T. T. Tung made those very allegations in 1968.

Mrs. HECKLER. And those are the same allegations that EPA took into account in terms of the Oregon situation because when the herbicide was used containing the same ingredient they found that women in the area had spontaneous abortions and there were reproduction——

Major YOUNG. The same allegations that Dr. Handler addressed, one of the reasons why we sent that team of scientists to Vietnam. The difference was he was never able to show, the team was never able to show that those allegations were true, as you have heard Dr. Handler state this morning.

Mr. DASCHLE. Will the gentleman yield just a second? I would only add that the reason they weren't able to show it is that by his own testimony he was unable to go into those areas where the greatest application of agent orange was applied.

Major YOUNG. Twenty-two miles from Saigon isn't far.

Mr. DASCHLE. By and large, as he said this morning, the bulk of that area was inaccessible to those experts who were providing the study.

Major YOUNG. The Montagnard population, sir, that was the population of concern he was suggesting.

Chairman SATTERFIELD. Will the gentlelady yield at that point?

Mrs. HECKLER. Yes.

Chairman SATTERFIELD. I have a question that may be a guess at this point. It was my understanding that Dr. Handler also testified to the fact that there was a showing that where females are exposed to dioxin there is a reproductive problem. But my recollection was that he also said that there is a need for further study to ascertain whether or not only males who are exposed result in some problem with their offspring, is that correct?

Major YOUNG. Sir, I know of no scientific study that shows that human females exposed to 2,4,5-T, have had reproductive problems.

Chairman SATTERFIELD. But the point I am making is that the incidences you referred to earlier were incidences in which women were exposed right along with men in any event.

Major YOUNG. You mean the allegations out of the Saigon newspapers?

Chairman SATTERFIELD. That's right. So there still is the question of trying to ascertain through research whether or not exposure of males, assuming that the conclusion with females is correct, there is still the question as to whether or not——

Major YOUNG. Exactly, sir, it is.

Chairman SATTERFIELD [continuing]. The male as the sire also results in a problem?

Major YOUNG. I think Dr. Moore will be addressing some of that.

Mrs. HECKLER. It seems to me along those same lines that we don't have to wait for a study to determine in part the impact of this exposure, that the EPA in its very unprecedented act was actually acting on the basis of actual experiences of women in the area in which the herbicide had been used.

Major YOUNG. The Alsea Oregon report, and I know one of our speakers is going to comment more on this——

Mrs. HECKLER. That was not an academic study. I mean, that was a report that——

Major YOUNG. That was an academic study. It was a Ph. D. dissertation at Colorado State University.

Mrs. HECKLER. Based on experiences in the area.

Chairman SATTERFIELD. That is the second bell, so we are going to have to recess momentarily to go over to the floor and vote. We will come straight back. The subcommittee will stand in recess until we return.

[Brief recess.]

Chairman SATTERFIELD. The subcommittee will reconvene. Mrs. Heckler.

Mrs. HECKLER. Thank you, Mr. Chairman. Major Young, I have since gotten a copy of this report and the reference to Maude de Victor's statement as a memo was incorrect. I have a copy that was written in her own hand. This is a "Report of Contact," usual means of communicating within an agency, any agency, reporting in her own hand the message. She reports that she contacted Capt. Al Young and goes on to describe the statement as she understood it in terms of your conversation. And she talks about the two basic types of defoliants used in Vietnam, agent orange and agent blue. She discusses agent orange. And this is more or less a report of a person working in the Veterans' Administration based on information that has come to her.

In this report, the source of the information comes from the person contacted, which would be you. And she comments on its documented toxicity, it is quite high. The range is considered 150,000 times more toxic than organic arsenic. That an indication that a person has received this exposure but not at a lethal level is the clinical manifestation of chloracne, which is the severe acne. This report of contact also recommends, "Consequently, the entire medical file on this person should be evaluated." And then it states, "The following resource material will assist the VA in establishing and implementing criteria for assessing severe connection benefits."

She then quotes this Dr. Tung and R. M. Oliver, toxic effects, and goes on then to describe agent blue.

This is the contact form that she signed and that she filled out in her own hand, which was later revealed publicly. Have you seen this document?

Major YOUNG. No, I have not.

Mrs. HECKLER. Were you aware that she had simply reported your conversation with her in this ordinary routine way and in what was the usual manner, in fact her required manner, for making note for the record of official contacts?

Major YOUNG. Certainly, I do the same thing.

Mrs. HECKLER. You do?

Major YOUNG. Yes.

Mrs. HECKLER. So you must have assumed that Maude de Victor had written a report of this kind, is that right?

Major YOUNG. I did, because I maintain one myself of every conversation.

Mrs. HECKLER. So, in other words, Maude de Victor, at her press conference when she did make this public, was revealing nothing more than she had ordinarily reported and contained in this interoffice statement and what you seem to imply is that she had other motives and so forth.

Major YOUNG. No, ma'am, I am sorry, I didn't mean to imply that.

Mrs. HECKLER. You have said that you contradict the——

Major YOUNG. The memo I am talking about is a different memo.

Mrs. HECKLER. There is another memo?

Major YOUNG. Yes, ma'am. There is the memo that has no signature on it.

Mrs. HECKLER. So you do not contradict this memo?

Major YOUNG. I haven't seen that one, but I am referring to one that is typed, and was distributed in March 1980.

Mrs. HECKLER. Do you have a copy of that memo?

Major YOUNG. Not with me but it is available.

Mrs. HECKLER. Can you supply it for the subcommittee?

Major YOUNG. Yes.

Mrs. HECKLER. Mr. Chairman, I am going to ask that the Maude de Victor report of contact and the second memorandum which was made public, both be introduced in the record.

Chairman SATTERFIELD. I was just checking with staff. The memo that is not signed, is that the memorandum that is already in the record in these hearings previously? And you are asking that we admit this one?

Mrs. HECKLER. That we also include this one.

Chairman SATTERFIELD. First of all, this particular memorandum hasn't been properly identified for introduction. I have no idea whatever of who wrote it, or under what circumstances it was written.

Mrs. HECKLER. This is a case file. This is the original of claims processor case file memo that originally——

Chairman SATTERFIELD. May I see it?

Mrs. HECKLER. Certainly instigated the whole question of the Veterans' Administration responsibility for the Vietnam veterans who might have been subject to agent orange and who might have developed cancer or other disabilities, and she mentions the possibility of liver dysfunction as a result of it. It was this memo and this particular caseworker who really began the total investigation of the question of agent orange within the VA.

Chairman SATTERFIELD. The first thing that bothers me, and I don't know for what purpose it might be admitted, but at this moment, at least, it is hearsay and certainly the content of this, if she did indeed write it, would be her product, but it does nothing whatever to establish the proof or accuracy of what she is saying.

Mrs. HECKLER. No, no, it does not establish the proof. However, this is a report of contact by a woman who was a claims processor concerned with a veteran who had come to her with serious health problems, and the question was the liability of the Veterans' Administration. And as a result of her contact with the veteran, she then pursued the expert information and contacted the known knowledgeable person in the field who was at that time Captain Young. And this is a report of her communications with him, which was the first official request on the part of a claims processor in the Veterans' Administration in 1977 on the question of agent orange and its linkage to the Veterans' Administration and the Veterans' Administration liability to the veteran.

Chairman SATTERFIELD. At the present time, I think it would be proper only to accept this statement in the files of these hearings. Whether or not they become a part of the hearings themselves would have to be predicated upon properly establishing the authenticity of this photostatic copy and the fact that this indeed is Maude de Victor's signature. Perhaps we really ought to interrogate her before it is admitted into the record from the standpoint of establishing those things which are here and authenticate them. I think that is the minimum that would be necessary.

Mr. DASCHLE. I would certainly, for the record, Mr. Chairman, ask that we insert it in the record. I think we can demonstrate the authenticity of that signature because I had something to do with obtaining it.

Chairman SATTERFIELD. I am going to admit it into the file at this time on condition that upon proper authentication of it and establishing that this is indeed a document that Maude de Victor wrote and reflects her own views, then we would perhaps admit it to the record. But without that kind of linkage, I do not think it is proper just to admit a photostatic copy of something that purports to be a report. That is just a fundamental problem. We will admit it to the file with the condition that upon proper establishment we would consider moving it into the record.

Mr. DASCHLE. If the gentleman would yield. I can assure you we can make that authentication.

Chairman SATTERFIELD. It will be available so that can be done. The other report that we are talking about, which you are asking that it be admitted into the record, I don't even know what we are talking about.

Mrs. HECKLER. This is the memorandum which Major Young has.

Chairman SATTERFIELD. Do you have a copy of it, Major Young?

Major YOUNG. Of the one that I mentioned?

Chairman SATTERFIELD. Well, I don't know whether the one you are talking about is the one we are talking about.

Major YOUNG. I haven't seen a handwritten memo, sir.

Mrs. HECKLER. We would be very happy to supply that for you. I would ask for the copy of the anonymous memo be made available to the committee.

Chairman SATTERFIELD. How do we identify the anonymous memo?

Mrs. HECKLER. Major Young, you have referred to it at length so certainly you must have a copy of it in your possession at some point, in your office or something.

Major YOUNG. Yes; we have it.

Mrs. HECKLER. And you are willing to make it available to the committee?

Major YOUNG. Mr. Daschle should have a copy of it.

Chairman SATTERFIELD. Frankly, I have let this question go on on the assumption that both parties were talking about the same unidentified and anonymous memorandum. I don't know whether we are or not, but if a copy of it can be produced, here again, we will admit that to the file with the condition that we will move it into the record upon proper authentication and identification.

Mrs. HECKLER. I certainly will accept that, Mr. Chairman, but I will say that I don't think we are talking about two different things substantively. We may be talking about two different pieces of paper, but I think the substance of the issue is the same. The point to be made is that the response which you gave, Major Young, earlier on the question of agent orange revealed a knowledge of the subject, of course, as of 1977, and I think that the problem that the hearing today addresses or does not address the weakness of all of the testimony is the fact that the issue is never resolved, that while we had a caseworker, a claims processor in Chicago who brought this issue to the attention of the VA, who sought your advice, to which you responded, and raised the issue which has very rightfully induced grave concern in the minds of Vietnam veterans who served where this defoliant was used, that despite all of the evidence that the problem existed, that the correlation was at least suspect. In 1970 we find that the issue is still at the level of placing a study upon a study, a layer upon a layer, and there is no resolution. Meanwhile, the tension and anxiety and the physical problems of the Vietnam veterans mount.

Chairman SATTERFIELD. Will the gentlelady yield?

Mrs. HECKLER. Yes, I will.

Chairman SATTERFIELD. I am at a loss at this moment to know precisely how we are to use this document and I don't know whether it is being introduced for the purpose of contradicting Major

Young who stated his position today or for some other reason. I think in all fairness we ought to ascertain what the overall import is. I haven't read the report. If it is indeed for the purpose of establishing or goes to the veracity of what Major Young has said, then certainly we would reserve to him the right, at such time as we would consider putting it in the record, to also testify. I don't know—just looking at it offhand, at best the written memorandum would be something that was written by the individual who signed it and it might reflect her own understanding. But as far as fact, to impute that statement to someone else I think would be highly questionable.

Mrs. HECKLER. Mr. Chairman, I think that the purpose of the hearing is to search for the truth.

Chairman SATTERFIELD. Absolutely.

Mrs. HECKLER. And get to the bottom of this. And what we have done for so long is simply postpone asking the hard questions and reconciling contradictory statements. Is there a contradiction? I am not certain that there is a contradiction. But certainly there appears to be and I think that in the mission of this subcommittee, in fairness and concern for the veterans, we owe it to the Vietnam veterans to have all of these questions reconciled as quickly as possible.

Chairman SATTERFIELD. I could not agree with the gentlelady more, but I think in attempting to reconcile things we cannot go on hearsay evidence or on documents, the purport and validity of which is not established. And that is the only point that I am making.

Mr. DASCHLE. Will the gentlelady yield?

Mrs. HECKLER. I would be happy to yield.

Mr. DASCHLE. I would only make this point, and I think the chairman raises a very valid question about what worth this memo might have. If indeed we can authenticate its veracity and if indeed Mrs. de Victor actually did write that, I think one of the most telling statements in that whole memo regards the comments made regarding the culpability of the Air Force and the Veterans' Administration. I say that only because in private I have had other officials indicate to me that one of the chief concerns of the Veterans' Administration is whether or not they can handle the volume of people who would come in. In fact, I quote the "barrage of people" that they would get if this were made a presumptive disability. If indeed that is a genuine concern, as reflected in the memo and in private conversations outside of public testimony, then I think that this would add to the public record because, indeed, then we go beyond the whole question of scientific evidence to the real question of policymaking which, as you have stated many times, is really the purview of the Congress and not the Veterans' Administration in the first place.

Chairman SATTERFIELD. Will the gentleman yield?

Mr. DASCHLE. I would be happy to yield.

Chairman SATTERFIELD. Absolutely. It is the purview of the Congress, and I am confident that this Congress will react properly. My only point is that I think we must establish exactly what the parameters of these statements are. Just to let them in because they are here really doesn't solve the problem. I think we should

certainly get all the contradictions. As far as I am personally concerned, I think everybody in the Federal Government initially dragged their feet on this and it is unfortunate that studies were not begun voluntarily earlier. But that doesn't cure the situation that confronts us today. We still need answers.

I do not mean to deprecate the suggestion of these statements that they might have some impact on what we are trying to do, but I think in all fairness to the subcommittee, as well as all the parties involved, that we establish exactly the circumstances on which such a document was transcribed and preferably have the individual here who can answer questions with respect to it. I think that is the very least that we can do.

Mrs. HECKLER. I think this is true. I would agree with you. I think that the author of the documents should certainly be invited to testify if they want to pursue that question. But I think it is also important to realize that our first priority is to serve the needs of the veterans and the Vietnam veteran. What this hearing is all about and what we are seeking to do is to find out whether or not the military and the Veterans' Administration have done everything possible to discover the truth in terms of the causation and the linkage between these symptoms and physical disabilities which Vietnam veterans have experienced and exposure to agent orange.

The issue was actually initiated by this very memo and by this particular claims processor. We will have the opportunity to ask the Veterans' Administration later in this hearing about their role in this and whether or not they are aware of the memo. I have only the desire to seek the truth, but I really feel that it is in the public interest to have some reconciliation of policy and statement so that we will know what the facts are so that this issue can be resolved.

Apparently, you contradict another memo. You have not seen this memo ever before, is that right, Major Young?

Major YOUNG. No, I haven't. This is the first time I have seen a handwritten memo. It doesn't follow the same information. What she quotes in here is not exactly what I talked with her about. But that is not surprising. I mean, when you discuss something very complex and highly technical, it is very easy for people to misunderstand. I am sure that if I were to go into an expose about how 2,4,5-T works at the cellular level that there will be many people in this room that might not totally understand, and asked 15 or 20 minutes from now to write it down, who knows what they might write down.

Mrs. HECKLER. I think that might be the case and there is also the other possibility, a claims processor who has spent a great deal of time on the problem of a veteran with unusual symptoms and which raised very, very deep suspicions in her mind in terms of linkage, that a claims processor with that kind, with that level and degree of concern, who would consult you as an expert, would also want to be faithful in writing a report. I would assume that she would write a report that actually followed in substance the conversation. Since she turned to you as an expert, she would follow a substantial outline of the conversation and make this a part of her report. This is something to be determined later, but I do feel that

the reconciliation between your version and hers is relevant and there is a second point of reconciliation that I think also has to be addressed.

[The following document pertaining to the foregoing exchanges about the anonymous memo was introduced into the record:]

DEPARTMENT OF THE AIR FORCE,
OFFICE OF THE ASSISTANT SECRETARY,
Washington, D.C., May 15, 1980.

Hon. THOMAS A. DASCHLE,
House of Representatives,
Washington, D.C.

DEAR MR. DASCHLE: This is in reply to your joint letter of March 18, 1980, with Congressman Bonior, to the Secretary of the Air Force, concerning Herbicide Orange.

In your letter and concurrent press conference on the same subject, you and Congressman Bonior expressed your doubts about the ability of the Air Force to deal with the problems of Herbicide Orange in a forthright manner. You further expressed concern that "material unfavorable to the position of the Air Force has been withheld." You seem to base both of these views on the existence and contents of an anonymous, unaddressed memorandum of two and a half years ago which you released at the press conference and enclosed in your letter but which the Air Force had never before seen.

Let me state at the outset that the Air Force has not knowingly withheld, and will not withhold, health information on the subject of Herbicide Orange or any other herbicides used by the service. All of our scientific files on the subject (with the exception of the Ranch Hand protocol which will be made public at an appropriate future time) are open and we have cooperated and will continue to cooperate with all responsible groups and individuals interested in studying the issue. I know of no instance when the Air Force failed to share its knowledge fully and in good faith both through scientific channels and through political forums such as Congressional Hearings. Air Force representatives have testified at three such hearings and in numerous open scientific and governmental forums, and our scientists have published many technical reports, including the comprehensive literature review entitled "The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and its Associated Dioxin," of October 1978 (Attachment 1).

The October 12, 1977, memorandum which raised your concern makes reference to a telephone conversation with USAF Captain (now Major) Alvin L. Young. On the same date as that appearing on the memorandum, Major Young was called by a Veterans' Administration employee, one Maude DeVictor. Major Young made contemporaneous notes of that conversation (Attachment 2) and the following day wrote a letter to Ms. DeVictor (Attachment 3) enclosing three professional reports—the same three referenced in the memorandum at issue—as requested by Ms. DeVictor. Major Young has provided a more thorough account of his recollection of the telephone conversation (Attachment 4) in response to the inquiry triggered by your letter. Examination of this documentation from Major Young should clearly demonstrate that the memorandum in question could not have drawn its conclusions from what Major Young said in his telephone conversation with Ms. DeVictor.

We have no idea who wrote the anonymous memorandum, nor what data the author relied upon to reach the conclusions asserted therein. However, even if we assume that the author was a person capable of assessing complex, technical health information, it is reasonably clear that different responsible scientists may interpret differently the results of health-effects studies. It is rare that such research will produce unequivocal results; rather, the results more likely will produce inferences subject to differing interpretations. And of course it is necessary for a determination of their reasonableness that anyone drawing conclusions from such a study be prepared to justify on the basis of the weight of evidence then available, the detailed basis for his position, and why other possible hypotheses were rejected. This is especially important in the area of health-effects research, where it is virtually impossible to prove that a given exposure is absolutely safe.

I am satisfied that the Air Force, in establishing its official position regarding the likely health effects of Herbicides Orange and Blue, has accepted the judgment of its senior experts and that it has been willing to defend the underlying scientific information on which its position is based. General Dettinger's testimony of October 11, 1978, must be understood in that context. It was supported by the comprehensive literature survey previously referred to and then provided to the Congress and

personal discussions with scientists in this country and in Europe, to mention just a few sources.

The statement of General Dettinger which you quoted ("The tumorgenicity, teratogenicity, or mutagenicity of dioxin have not been substantiated in humans * * *") remains, in the Air Force's scientific judgment, as true today as when it was originally stated. As mentioned, the Air Force has never before seen the anonymous memorandum you sent. The three reports it cites, namely the ones Major Young sent to Ms. DeVictor the day after the memorandum was dated, do not in our view support the memorandum's conclusions that Herbicide Orange is carcinogenic, teratogenic and mutagenic, nor, as stated earlier, does what Major Young said in his conversation with Ms. DeVictor support the memorandum's conclusions. Perhaps the memorandum's author drew the conclusion regarding catastrophic health effects from the Tung report, but we do not regard that study as a valid scientific study, as indicated in our technical report of October 1978, at page VI-23.

Regarding your reference to "Air Force herbicide policy," I would like to address this perhaps semantic, but nonetheless significant, statement in your letter. The Air Force has only one herbicide policy, and that is to use only those items and procedures officially approved by the Environmental Protection Agency (EPA). We do not and will not use any herbicide not sanctioned by EPA. At the time Herbicide Orange was used in Vietnam, and in fact until 1979, the ingredients of Herbicide Orange had the official approval of the U.S. Department of Agriculture and the EPA and were registered in a variety of formulations and for a variety of general uses. To the best of our knowledge, the constituents of Herbicide Blue are still approved for general use by EPA.

One other issue addressed in the memorandum which you provided needs to be clarified. Herbicide Blue does not contain either 2, 4-D or 2, 4, 5-T, as the memorandum asserts on page 1. It contains cacodylic acid, an organic arsenical (as the memorandum states on the second page). To the best of our knowledge, there have been no published scientific studies showing that cacodylic acid may be a carcinogen. The basis for our position is summarized in a paper prepared on this subject by the Air Force in response to your inquiry (Attachment 5). We are certainly unaware of any studies available in 1977 on which the author could have based the Herbicide Blue findings as noted in the October 12, 1977, memorandum.

Your letter also asked several questions concerning our position on the hazards of dioxin as contrasted with the positions you ascribe to EPA and the Department of Health and Human Services. Rather than address those issues, I believe it more appropriate for the Air Force to refer these important and complex concerns which you have to the newly created Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. The President established the work group precisely so that the administration could speak with one voice, and the Air Force will accept the findings and policies established by this body. Therefore, I am forwarding a copy of your letter and this response to the work group through its Department of Defense representative.

With regard to your question concerning studies which may directly bear on the health-related impact of herbicides, our health experts confirm that no previous human studies have been conducted by the Air Force. Our proposed Ranch Hand study would be the first. Information which may indirectly bear on your concerns may be found in the complete set of Government documents pertaining to Herbicide Orange now being assembled by the Department of Justice in response to discovery requests made in the lawsuit captioned Products Liability Action re: Agent Orange, No. MDL 381 (Eastern District of New York). The Air Force, as the executive agent for responding to such discovery for the Department of Defense, is a major contributor of materials. The comprehensive collection of information, to be maintained in a repository known as the Agent Orange Document Center, is under the control of Civil Division, Torts Branch, Department of Justice (Ms. Joan Bernott, 724-6808). The Center is expected to contain in excess of 1.5 million documents in an indexed and cross-referenced manner. I am advised that the Center will be open to all interested persons under procedures to be established by the Department of Justice.

I deeply share your concern for the welfare of all our Vietnam veterans, including those who may have been exposed to Herbicide Orange. I hope the information provided herein is helpful to you.

A similar letter is being provided to Congressman Bonior.

Sincerely,

JOSEPH C. ZENGERLE,
Assistant Secretary of the Air Force,
(Manpower, Reserve Affairs and Installations).

Attachments (5).

Mrs. HECHLER. As I understand it, and I think I heard you earlier this morning talk about the fact that there were no ground troops in the area where agent orange was sprayed, is that correct?

Major YOUNG. Not generally. There were ground troops of the enemy. We know that because of the hits we took when our aircraft were flying over the target.

Mrs. HECKLER. We are not talking about enemy ground troops. We are talking about American ground troops.

Major YOUNG. I only know of a few cases where commanders contacted the Ranch Hand squadrons afterwards and said that they were in the area when the flyover did occur.

Mrs. HECKLER. So you would say largely and substantially that there were almost no ground troops in the area where the spraying occurred. That was your statement this morning?

Major YOUNG. That is correct.

Mrs. HECKLER. All right, now, that directly is contradicted by the statement of Maj. Gen. William S. Augerson, who testified before this committee on February 25 and who referred in his testimony to the GAO study in which he says, "The agent orange concentrated (1) when and what military units were in or near areas sprayed with herbicide orange, and (2) what precautions were taken to prevent ground troops and others from exposure. The GAO determined to their satisfaction that a large number of U.S. Army and Marine Corps ground troops were in or close to sprayed areas during and shortly after spraying." There is a great chasm of difference between your statement and this GAO statement.

Major YOUNG. Earlier I mentioned to you the free spraying zone the GAO did their report on. But they also considered the worst conditions. For example, they made no consideration as to the limitation of the drift. They suggested that the drift could go many, many kilometers in either direction and therefore anyone within the distance of all that drift could be affected. We actually know from spray equipment studies that 2,000 feet would have been the absolute maximum. There are the studies that we conducted from 1964 through 1968.

The GAO did not give consideration to environmental fate at all. They also did not look at the issue of the recordkeeping. Certainly there are inadequate records below the battalion level. Ten percent of the troops in a battalion were located at battalion headquarters. The GAO noted in one instance that herbicide orange may have been sprayed on a battalion headquarters. They concluded that all of the troops were at battalion headquarters. But, of course, that is not what happened in Vietnam. Ninety percent of the troops were not at battalion headquarters, they were out in the field.

So the numbers the GAO reported are, in my view, exaggerated.

I don't think any of us have ever denied that it was possible for anyone to have been sprayed in Vietnam. I think it is possible, it was possible. A war was going on and it wasn't always possible to keep track of where everyone was at. It wasn't even possible for us to always know where our Ranch Hand aircraft were. So it is a "gimme." I think it is possible the troops were sprayed. But I think the occurrence was probably quite rare, rather than the common situation.

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Mrs. HECKLER. Then you directly refute and you contradict the statement of the GAO which said that a large number of U.S. Army and Marine Corps ground troops were in or close to sprayed areas during and shortly after spraying.

Major YOUNG. I don't think the GAO had all the information when they did their report. Had they, I think they would have come up with a different conclusion.

Mrs. HECKLER. In other words, you feel that the GAO, which is the investigative arm of the Congress, was not competent in doing their report?

Major YOUNG. Oh, no, I don't wish to question competence at all. I simply say that when you talk about a very complex issue, you ask somebody to make a report, and you give them 1 month, the results are limited. They don't have time to check all the records. I have spent 12 years just reviewing records on the subject. It takes a long time to go over all the thousands and thousands of records on this issue. There are lots of things that I haven't had a chance to completely review yet. It is a very complex issue. I wish there was an easy way to resolve it.

Mrs. HECKLER. I think, Mr. Chairman, that if we are going to have a subsequent hearing on this subject that we should have the GAO come and describe their methodology. The whole Congress funds the GAO generously and relies on them for very complex investigative reports, upon which the vast majority of public policy decisions are made. If this study of the Vietnam veteran and agent orange is based on preliminary data or a rush job that did not have in-depth consideration of all of the factors, then I think that the GAO should answer to the Congress for that.

Mr. DASCHLE. Will the gentlelady yield?

Mrs. HECKLER. Yes, I will.

Mr. DASCHLE. I think it is really very interesting that as the evidence just continues to mount, I mean it is the de Victor study first, the GAO study, the scientific study, and the five European studies, every single one of them, the pile continues to get higher and higher and we see constant refutation on the part of the major. I really find it somewhat interesting that they are all wrong and he is correct and it is our decision, I guess, to sort out the truth from fiction.

Mrs. HECKLER. And all of the evidence to the contrary is insufficient, all the evidence to the contrary delays a decision. Meanwhile, the Vietnam veteran continues to suffer with the problems and with the suspicions and with the anxiety, and nothing changes. We simply begin to authorize another study and we then contradict and refute all the other studies, et cetera.

Chairman SATTERFIELD. Will the gentlelady yield? May I ask what study we are talking about now that gets to the issue of whether or not exposure to agent orange produces a health effect?

Mrs. HECKLER. We have had a number of studies on that qustion.

Chairman SATTERFIELD. I know, but the line of questioning that you have been exploring, somehow I don't get the impression that it goes to the heart of that point. If it does, we ought to set the record straight.

Mrs. HECKLER. I think that the whole issue that was raised by this little Maude de Victor report of contact——

Chairman SATTERFIELD. That is a question of whether the people were exposed to agent orange more than anything else, is it not?

Mrs. HECKLER. No, the memo discusses the impact of——

Chairman SATTERFIELD. We will get to Maude de Victor——

Mrs. HECKLER. Right.

Chairman SATTERFIELD [continuing]. I think we need to get her qualifications in order to weigh the validity of what she said, but the point I am getting at, I think the main reason for the hearing today is to see whether or not we can find out, in the shortest amount of time, whether or not there is a health defect from exposure to agent orange. I think Major Young, in all fairness, is giving his viewpoint to the extent of his knowledge. One can't expect him to have more than that with which he is personally acquainted. There obviously can be areas of disagreement based on different experiences. The point is, I don't see where your questioning gets to the issue before us today.

Mrs. HECKLER. The question is how many troops and how many veterans were subjected to agent orange as well as the linkage between agent orange and cancer and other physical disabilities. The first question that has to be determined, or at least a necessary question that must be answered, is the number of troops who were subjected or exposed to the problem and there is a very serious contradiction between what Major Young has said in terms of the amount of exposure and the GAO report which was submitted to the Congress.

Mr. EDGAR. Would the gentlewoman yield at that point?

Mrs. HECKLER. I would be glad to yield.

Mr. EDGAR. I would like to ask Major Young a specific question relating to the comment you just made. I want to understand whether I understood your comment regarding the defoliant dropping straight down. You referred to the fact that only the people under that defoliant within, did you say, 200 yards?

Major YOUNG. Six-tenths of a kilometer or 2,000 feet.

Mr. EDGAR. You are clearly not talking about it getting into the water system, you are not talking about it getting into with any air condition, wind condition, or anything like that making it travel any further?

Major YOUNG. We haven't even brought those questions up in the last little while. Then you are asking about the environmental fate.

Mr. EDGAR. No, I am trying to understand your answer to one of Mrs. Heckler's questions in terms of exposure and it sounded to me as though you were saying, as a result of your slide presentation, as a result of your words just a few moments ago, that one of your criticisms of the GAO report was that they took a too-wide view of military people who could be affected because they weren't directly under the spraying area. Is that what I heard you say?

Major YOUNG. It depends on the time element that is involved here, that is true. If you are talking about actual application directly on them, then at time zero if you were to say that you flew over the battalion headquarters, my comment was that generally only 10 percent of the battalion people were located at headquarters, 90 percent were away. But if you based your calculations on how many were under there and you said the entire battalion was

sprayed, then you have distorted the figures. You have added too many.

If you are asking me how many people could have walked into the sprayed zone after spraying, I have no way of knowing that. Could they have been exposed once they got in there? Our data on triple canopy jungle suggests that 94 percent of the herbicide was still up above on the canopy. Perhaps 6 percent was down below, near ground level. That is a tremendous amount of difference between exposure, you see, up on top and down below. Was it in the water?

Mr. EDGAR. Some of it you came back and sprayed two times, three times.

Major YOUNG. But not on the same day, months later. Months later. And battalions were always moving.

Mr. EDGAR. What is the evidence that you have that the toxic nature of the chemicals disappeared within a short period of time?

Major YOUNG. We have excellent degradation data on 2,4-D, 2,4,5-T, and excellent photodegradation data on dioxin. Environmental fate is a major issue in terms of exposure. Within 24 hours in sunlight and even in shade, dioxin rapidly disappears. If troops came in after that, the likelihood of them encountering the same level as if they had been right there at the time of spraying would be tremendously different. That is all I am saying. We have a great deal of science on what happens to dioxin in the environment. I have been studying it for 10 years. We have numerous publications on it, well accepted by the scientific community and verified by the Italians.

Mrs. HECKLER. I would like to ask a final question or series of questions on this issue of locating the Vietnam veterans who might have been subject to a serious physical problem as a result of exposure to agent orange. At this moment the level of concern is so prevalent among this group of veterans that I think that at least identifying those who would be in the suspect area could diminish what is becoming a comprehensive anxiety.

You have poured over the records, you say, Major Young, for 12 years. Isn't it possible through the computer listings that you must have at the DOD of all spray missions to plot them out on a map with a chronology and match them with the areas of operation of ground troops?

Major YOUNG. It is very easy to take the headquarters, battalion headquarters where we know they were at and match against our HERBs tape, a computer printout. That can be done. That is no problem. The problem is where was any given individual, that is the issue. The problem of misclassification in an epidemiological study makes all the difference about whether it is a good study or a bad study. If the individual was not there where and when the spraying occurred but he claims that he was, then you see you could actually dilute whatever health effects that might have occurred. If you say that the individual was not sprayed since the records don't confirm that and yet the individual was actually sprayed and had a health problem, you have also hurt the study. So our problem is to be able to say that this individual was in fact sprayed. Would the individual know that he was sprayed? I can tell you from my own experience in triple canopy jungle, I think it

would have been very difficult. To have smelled the herbicide or insecticide doesn't necessarily say that we have got a toxic dose or much of an exposure at all. The smell can be transmitted for a long way. The smell does not necessarily have to be the inactive ingredient, that is the interesting part.

Mrs. HECKLER. Are you saying that it would be impossible to identify those most likely to have been in the exposed area? That it would be impossible?

Major YOUNG. No, I am simply saying that we would not know for sure that they were exposed or whether they were not exposed. We could give a likelihood.

Mrs. HECKLER. I think that the likelihood and the degree of likelihood are important factors. And if there is indeed a scientific correlation, and several separate studies have found a significant relationship between exposure to 2,4,5-T and cancer or reproductive disorders, these studies have indicated a significant relationship. Under those circumstances, the significant chance of a certain veteran to have been exposed to this chemical is a very important medical fact and certainly the military has it within their capacity to make that determination.

Major YOUNG. The Veterans' Administration, I hope, will be able to use the HERB tapes and the location of the headquarters to help set up their study. That is what we are hoping for. I am sure the VA has given serious consideration to that. Perhaps when a study design is done, they will be able to use the data we have to identify populations with a higher risk of exposure versus those with a lower risk of exposure.

Mrs. HECKLER. What role do you see the Air Force playing in this kind of study?

General MYERS. May I answer that, please, ma'am?

Mrs. HECKLER. Yes, sir.

General MYERS. I would like, if I could, to refer to the National Academy report, which says that "the limitation in study design and the size of the exposed population gives rise to the question of whether other exposed populations can be identified and whether they can be integrated into the coordinated study that has any reasonable expectation of producing meaningful results within a few years." The Air Force took that into consideration as it was planning or refining its protocol. Because we were faced with a dilemma and reasonably rapid startup, the question was relegated to the interagency work group.

The work group with its scientific panel as an inclusive body within that group said back to us that the panel agreed with the Air Force that adding to the cohort ground troops whose exposure to agent orange was clearly significantly less than that of Ranch Hand would dilute the cohort and therefore further diminish the likelihood of detecting adverse health effects.

We also took into consideration the added time that would be required to set up the control groups and felt that we had in hand a working protocol with an identifiable group. We had enough data. In our mortality study we were well along. The timeliness and scientific creditability of the Air Force study would drive us to not include ground troops whose identification would be very difficult for dose relationships, time exposure, and control.

Mr. EDGAR. Would the gentlelady yield?

Mrs. HECKLER. Yes.

Mr. EDGAR. That goes to the heart of a question I asked earlier. What independent information was available to the task force to make the decision that you have just outlined? It sounds like they have accepted not only the Department of Defense but the Air Force recommendations without any independent judgments as to whether or not ground troops should be considered.

General MYERS. I would offer as a partial answer the exhaustive review of the literature, but I hope that the interagency work group itself could answer that question.

Mr. EDGAR. I intend to ask the question of them, but I have some information that over on the Senate side when the task group was reporting to the Senate that they made some comment about the fact that they accepted the Department of Defense statement. Are you aware of that?

General MYERS. I have read Mrs. Bernstein's testimony.

Mr. EDGAR. Yes, and what did she say on that occasion, do you remember? On that issue?

General MYERS. I quoted from it just a moment ago.

Mr. EDGAR. She basically agreed with the Department of Defense and the Air Force's decision.

General MYERS. The interagency work group which she chaired was concerned about beginning the study, and it was felt that we would not increase the scientific validity by diluting the cohort population and that——

Mr. EDGAR. But isn't it true that it was your recommendation, Department of Defense and the Air Force recommendation, not to dilute the study and the task force just accepted that?

General MYERS. No, it was the Air Force recommendation that we go on our protocol. Peer review groups had suggested the——

Mr. EDGAR. Peer review groups had suggested that we needed the other type of evaluation.

General MYERS. The National Academy.

Mr. EDGAR. The task force basically accepted your recommendation?

General MYERS. Yes.

Mrs. HECKLER. General, I just have one final question. How would you characterize the bottom line now for the Vietnam veteran who is concerned about agent orange? When will the resolution of the issue come and what is the outlook on that? We have studied it for years and EPA has acted quite decisively when confronted with similar problems. Nonetheless, the studies have not been completed, the military studies. The VA studies have not been conclusive. Vietnam veterans are developing and reporting more symptoms and certainly exhibit enormous concern which is becoming a very serious problem for the Veterans' Administration, for the credibility of the Government. What would you say is the bottom line? When do you see a light at the end of the tunnel? Or do you?

General MYERS. That is hard to answer and it is a complex answer that I am going to give. I wish that the problems that our veterans are experiencing were as simple as perhaps yellow fever and we could identify a mosquito carrying an organism and say that was the cause and this was the effect. But that is not the case.

We are dealing with a complex set of symptoms and an even more complex set of developments which may take years to unfold.

The Ranch Hand study is merely a part of this puzzle that is going to be unraveled. So ongoing at the present time are the Veterans' Administration study, the Ranch Hand study, the birth defects study that the Center for Disease Control has undertaken in Atlanta, and there are ongoing research projects involving laboratory animals. So all of these will contribute, we hope eventually, to unscrambling the problem. We are almost faced with the same kind of dilemma as determining what is the cause of cancer.

Mrs. HECKLER. And we are going to have to wait as long for the answer on agent orange as we do on the question of what causes cancer.

General MYERS. Our protocol calls for reviews at 1, 3, 5, 10, 15, and 20 years. At each one of those milestones we would be hopeful that there would be some indicator to give us an idea of how we should proceed, how we should perhaps reorient the research, or move in a different direction. But we are not going to get anywhere unless we begin in a very timely way and that is exactly what the Air Force is trying to do now.

Mrs. HECKLER. It sounds to me like we are looking for the proverbial "needle in the haystack" and if we are, what hope do we have to offer to this whole group of veterans who have most unusual problems?

General MYERS. We owe them a great obligation. We owe them an intensity of purpose and an intensity of study. But we would do them a gross disservice if we struck off quickly and came up with meaningless information which would wreak havoc and perhaps lead to things that would take years to undo. We are trying to unscramble in a logical, progressive way a most difficult scientific question.

Mrs. HECKLER. General, I would like to ask one other question, and that is, since the scientific question remains open in the eyes of many who have testified, nonetheless, the medical problems of the Vietnam veterans continue to mount. It would be useful to have some kind of a temporary response to the veteran, not providing compensation but certainly medical care. In order to provide medical care for the symptoms of exposure to agent orange for the disabilities that these veterans experience without determining the actual causation and the actual liability of the VA for compensation, for purposes of providing military medical benefits in the short run while awaiting this final answer, it would be necessary to establish the parameters, those who were exposed. It would be necessary to acquire that data because if they did not have the exposure, then there would be no basis for VA treatment for the disabilities.

General MYERS. We are faced, as I tried to point out, with an incredibly complex problem. Not the least of this is the fact that between the ages of 2 and 35, cancer is the leading cause of death, without herbicide orange being even a player. How does one dig all that information out? How do you scientifically put together a protocol that will withstand the test of time? We have asked our best scientists in the country to help us with this. We think we are on the right track. I am not ducking your question with reference

to what the VA should do, but I would respectfully submit that the VA would respond to that.

Mrs. HECKLER. On the other hand, if the military could provide the identification data that would allow at least a beginning for the development of classification information so that medical treatment could be made available.

General MYERS. I think the answer is we have a group of individuals that we can identify as to location and exposure, which we estimate to be 1,000 times greater than any other group. We would like to study those people now. Regarding the identification of other individuals in Southeast Asia who may have had some exposure, there are so many variables in that that it would be very difficult to put together a timely protocol and move out quickly on it.

Mrs. HECKLER. Thank you.

Chairman SATTERFIELD. I would like to pursue this line of questioning because, first of all, I am not going to be here in Congress after this year and I do have an observation along with a series of questions.

I served in World War II on an aircraft carrier, and recently a book was written entitled "Hellcat," an aircraft I flew. Very serious, deep studies were made in the Navy Department and Department of Defense, and it turns out that one of the engagements that my air group was in, there is no record of us ever having been there, including the carrier from which we flew. I only mention that because I think that it is probably indicative of the kind of reports that one tries to gather after the fact when one is engaged in combat. I believe it has always been that way.

Recognizing that, and recognizing that we as members of Congress are going to have to traverse this inadequacy, I would like to ask this question: If I am correct, you have stated that you know the dates that spraying of agent orange took place, and we have maps that show where that spraying took place. Are there records that would show which units were in the general area? Not necessarily where the spraying took place, but adjacent to them.

Major YOUNG. I don't know that they are complete, but there are records, yes.

Chairman SATTERFIELD. But you know which units were in Vietnam.

Major YOUNG. Oh, yes.

Chairman SATTERFIELD. Is there a source at this moment where individuals assigned to those units could be identified as being with those units within certain dates?

Major YOUNG. I would have to refer that to the people that are currently doing the searching of those records within the Department of Defense, but I think it is certainly possible.

Chairman SATTERFIELD. It should be available, should it not?

Major YOUNG. Certainly.

Chairman SATTERFIELD. It occurs to me that we may very well get to that point, that if examining the group which was part of Ranch Hand and obviously heavily exposed, if a causal connection between that exposure and some physical infirmity is established, then the question of attempting to establish which veterans were exposed and at which levels, it seems to me, is ultimately going to

be a question that we in Congress are going to have to address and to determine how we would handle the situation by blanket legislation.

I mention that because it seems to me that the No. 1 question before us at this time, and the reason that we are having these hearings, is an effort to establish the first thing that must be established and that is whether exposure to dioxin produces a health effect. If it is found that it does, then I think it is the purview and probably the responsibility of this committee and Congress to fashion the kind of legislation that would say who and under what conditions would qualify for coverage under the VA laws and the benefits that flow therefrom.

I only mention this because I think this is really why we are here today. I hope that we can get on with unwinding that one all-encompassing question and that is the connection between exposure while on military duty and some health defect.

Mr. ABDNOR. Will the chairman yield?

Chairman SATTERFIELD. I would be happy to.

Mr. ABDNOR. Along your line of questioning or comment, it went through my mind, how long has 2,4-D and 2,4,5-T been produced? How many years have we used them?

Major YOUNG. The first commercial production of 2,4-D occurred in 1946. The first commercial production of 2,4,5-T occured in 1947.

Mr. ABDNOR. I was just wondering before the days of our safety regulations and precautionary warnings, what is the history in the plant itself where some of these people work with the raw chemical without any dilution whatsoever? Do they have anything on the record to show if employees have had any similar happenings?

Major YOUNG. One of the real difficulties is that there are very few documented cases of problems. I actually have from my own search of the literature about 14 cases of documented problems after being exposed to 2,4-D, but only 7 in terms of commercial use of 2,4,5-T. There are, then, 21 case histories, documented case histories, spanning over 35 years of use of two of the major agricultural chemicals used on this planet. I can't tell you how many millions and millions and millions of pounds of these materials have been used, or how many millions of people have used them.

Mr. ABDNOR. Did those 21 cases happen to appear in the earlier years of production or have they all——

Major YOUNG. There are many cases of housewives who came down with severe rashes or nausea from spraying herbicides on the weeds in their backyard. There are cases of farmers or pilots exposed while spraying in the field.

Mr. ABDNOR. I can assure you I reacted to a very mild mixture when I was spraying weeds in my field. I mean it is a very, very strong chemical even when it is greatly diluted. I just couldn't imagine what it would be like to be around it if you were using it in the raw form or producing it. I just thought there might be some cases where there were results.

Major YOUNG. I believe the USDA is giving consideration to studies of agricultural happenings.

Mr. ABDNOR. I wasn't so much that, but I was well aware of how strong this is when it is greatly diluted. I just wondered if somebody was around it all the time, day after day, in the raw chemical

itself, if you had any similar cases to those we are witnessing today from our veterans. This is a serious thing, as we are all saying. I know in my dealing with veterans, this is not even those who haven't been affected or afflicted by this yet. It is a very emotional thing. They wonder what could happen to them. I think it behooves us all to try to come to some kind of a solution. I know you have got to do it carefully, but it just can't go on forever because of the strain these people are under and the results we have already seen does cause us to have to certainly do everything we can to get all the facts together. That is all there is to it. Thank you, Mr. Chairman.

Chairman SATTERFIELD. Thank you. General, I know we have made you miss one train, I hope you will make the one that you have scheduled now. I appreciate very much your being before us today and giving us your time. And Major Young and Dr. Stern as well. No doubt we will be in touch with you again. We thank you very much for appearing today. Incidentally, Dr. Young, I do want you to know that these two memorandums that have been introduced and accepted in the file, if there is any further action with respect to them and if you are involved, in all fairness this subcommittee will certainly give you an opportunity to respond in any fashion which you feel may be necessary.

Major YOUNG. Thank you, sir.

General MYERS. Thank you, Mr. Chairman, thank you very much.

Chairman SATTERFIELD. Our next witness today is Mr. Richard Main with the American Council on Science and Health. Mr. Main, if you would come forward, we would be more than happy to receive your testimony.

STATEMENT OF DR. ELIZABETH M. WHELAN, PRESENTED BY RICHARD MAIN, AMERICAN COUNCIL ON SCIENCE AND HEALTH

Mr. MAIN. Thank you, Mr. Chairman. I am here today representing Dr. Elizabeth Whelan, the executive director of the American Council on Science and Health. We have two separate presentations actually to give today. The first part was prepared by Dr. Whelan and she would like to apologize for not being able to be here, but I would like to go ahead and read the first part of the testimony.

The American Council on Science and Health is a national consumer education group directed and advised by a panel of some 70 scientists from a variety of disciplines. Its purpose is to provide scientifically balanced evaluations of the relationship of chemicals and the environment to human health.

The American Council achieves its purpose by testifying and publishing detailed overviews of the health risks and benefits associated with public health and environmental issues that confront our society. These position statements are based on extensive reviews of the most current and relevant literature on a specific topic and are supplemented by consultations with leading specialists from the fields of public health, medicine, nutrition, toxicology, genetics, and the environmental sciences.

Today, our society with its almost desperate search for causes for human disease is using litigation to pin the blame on "environmental" factors, particularly if they are associated with industry and technology. The court dockets are increasingly crowded by numerous suits involving the alleged relationship between products of modern society and human health. While the specific decisions of these legal battles differ, "environmental" factors can be judged guilty without the benefit of scientific fact and the long range implication to the consumer frequently is the same: higher prices, decreased product availability, and declining innovation due to hampered research and development.

Health related litigation has become a way of life in the United States. It is becoming increasingly difficult to pick up a newspaper and not read about some party suing a manufacturer for damages such as birth defects, miscarriages, or cancer which are claimed to result from the exposure to a manufacturer's product or its contaminants. More often than not, chemicals are blamed for the misfortune.

The sums of money sought are astronomical; they often total billions of dollars, especially when more than one plaintiff is involved. What is even more devastating from a scientific point of view, however, is that many of the cases go to court lacking documented scientific proof of their charges. Legal principles such as the burden of proof and reasonable doubt no longer seem to have much bearing. Why has this ominous change taken place?

For one thing, today more than ever before, we as a society have an increasingly strong desire to explain the cause of all human illnesses. Everytime one of us utters the words, "If only I had done this" or "If only that hadn't happened," we in effect are trying to rationalize our misfortune.

Whether it is right or wrong, perhaps we gain some sort of consolation in naming a cause. We are no longer content to attribute illness to an "Act of God." Instead, we have become so health conscious that we see an infringement on our well-being as a personal insult that demands some sort of explanation and restitution. This is most apparent in environmental litigation.

Dr. Whelan told me a story which she asked me to relate, and I will read it as follows:

> An associate of mine, (meaning an associate of Dr. Whelan's) was recently diagnosed as having kidney cancer. For three weeks he asked me the same questions, 'What caused it? Why me? What did I do wrong? Whose fault is it?' The conversations we have had have been tragically frustrating with my answer always the same, "We have no information on what causes kidney cancer. We simply do not know." He posed the same questions repeatedly to his physician. A few weeks ago the doctor gave in to his pleadings, telling my friend that his use of saccharin might be the cause. Presumably, the physician knows that even the darkest picture ever drawn on this issue of saccharin's safety has never implicated the sweetener as a cause of kidney cancer. But the doctor was attempting to fulfill a need; my friend desperately wanted to identify a cause and the saccharin explanation satisfied him, allowing him to place the blame somewhere: on the saccharin manufacturers and on himself for using it. My associate's experience is characteristic of a major change in attitude we have noted during the 1970's.

Another example of this type of attitude recently occurred. A man in the midwest was arrested for drunken driving. In his pleadings before the judge he explained that while he was in Vietnam he was exposed to agent orange and that more than the

alcohol accounted for his erratic driving pattern. The judge released him without penalty.

Between 1962 and 1970, the American military forces sprayed the jungles of Vietnam with a chemical called agent orange in an attempt to defoliate the region and to destroy food crops. Agent orange, a combination of the herbicides 2,4-D and 2,4,5-T has recently been the subject of a class action suit filed on behalf of over 4,000 U.S. Vietnam veterans. The veterans claimed that they have suffered adverse health effects, such as cancer, that their wives have suffered miscarriages and that their children have been born with birth defects all because of their exposure to the herbicide. This suit seeks judgment in excess of $40 billion to establish a trust fund to be administered by the court as compensation for the alleged victims. Animal studies have demonstrated that dioxin, an unavoidable toxic contaminant of 2,4,5-T, has caused cancer, birth defects, and miscarriages in laboratory animals when administered in sufficient doses.

However, these same studies have also shown that these effects do not occur when the dose is sufficiently small. In addition, all human studies to date on 2,4,5-T, dioxin, 2,4-D, and agent orange have failed to document a causal relationship between the chemicals and either cancer, birth defects, or miscarriages.

We have come a long way in understanding some of the environmental causes of today's major killers. But the fact remains that we simply do not have all the answers. Diseases and deaths still occur for reasons unknown to us. Human beings remain mortal. Death and disease are still natural processes. It is unconstructive to blame ourselves in these instances. And it is economically disastrous for a society if government agencies ban substances or require corporations or taxpayers to compensate victims of disease if there is no established cause and effect relationship. When a cause of a disease is established, action should be taken, but we cannot afford to make regulatory decisions or make awards to plaintiffs on the basis of an emotional reaction. The search for cause should be a scientific one, not a witch hunt.

Now, the remainder of this testimony, Mr. Chairman, is my testimony and not that of Elizabeth Whelan. But I am still representing the American Council on Science and Health.

Chairman SATTERFIELD. If you are reading from a prepared statement, I would appreciate it if you could make a notation on that so that we will be abundantly certain in the transcript of these hearings that we are now proceeding with your own remarks. You may proceed.

Mr. MAIN. All right.

Mr. DASCHLE. Mr. Chairman, in the interest of time, I would like to ask unanimous consent that the text of his statement be inserted into the record and that we ask him to summarize, if he so could, the thrust of what his testimony would be.

Chairman SATTERFIELD. Would you be in a position to do that, Mr. Main, or would you prefer to read your remarks? I will leave that with you.

Mr. MAIN. I would like the entire remainder of this prepared statement to be part of the record.

Chairman SATTERFIELD. We could do that, and if you would like to extemporize, that would be all right as well. Or, I would comply with your wishes if you would rather read what you have prepared. We would permit you to do that, too.

Mr. MAIN. I would like to summarize it as rapidly as possible because I think that we would move this whole hearing along if I was able to answer some specific questions.

Chairman SATTERFIELD. That is what we have in mind. Without objection then, your entire written statement will be admitted at this point.

Mr. MAIN. Thank you.

[Written statement follows:]

PREPARED STATEMENT OF RICHARD W. MAIN, AMERICAN COUNCIL ON SCIENCE AND HEALTH

Over the past decade, manufacturers and users have spent millions of dollars defending the herbicide 2,4,5-T from a continuous onslaught of emotional criticism. Often these attacks have been totally political in nature with science the ignored consideration.

At issue in the 2,4,5-T case, as well as with Agent Orange, is the presence of TCDD (dioxin) in the herbicide. Scientists, on the basis of data from laboratory research and actual product use experience, believe that 2,4,5-T does not present an unreasonable human health hazard as normally utilized in agriculture and vegetation management.

Science is the best and proper judge of the human health hazards of products introduced into commerce in this country. Hazard evaluations must be insulated from the politics of the day. Use of the product should be regulated by what scientific research has determined about its effects.

Much of the phenoxy herbicide and agent orange hysteria is based on EPA's 1978 Alsea II study which alleged that there was a seasonal cycle of abortions reaching a peak number in June and a significant correlation between the number of abortions and the amount of herbicide used in the area.

The point is: bad science, typified by the EPA's Alsea II report, must always be challenged. It cannot be the basis for scientific conculsions or Government regulatory actions. At issue is whether government agencies should rely on validated scientific data or emotional and anecdotal allegations in deciding the fate of a chemical product.

An Oregon State University task force has concluded the federal study of herbicide use in relation to miscarriages suffered by women in the Alsea area is so seriously flawed that its conclusions cannot be supported.

In a 92-page critique of the EPA study released by OSU's Environmental Health Sciences Center, the task force reports:

Our critique does not support any of the three conclusions. If there is a relationship between herbicide use and miscarriages in the Alsea Basin and its surrounding area, it is not apparent and cannot be tested using the data from the Alsea II study.

Virgil Freed, director of the center, said the work on the critique began in June 1979. "We took a look at the problem because there was so much excitement about it," he said.

The study was undertaken because the center in Corvallis is close to the Alsea area and has expertise, Freed said.

The center is financed by National Institutes of Health grants, and Freed estimated that between $10,000 and $12,000 in staff time was used to complete the study.

The critique adds information to the EPA data, particularly on patterns in the area, Freed said. It also has a "much better statistical analysis of the data."

He said conclusions by the task force are similar to those by researchers in other countries who have examined the EPA study.

Members of the task force which wrote the OSU report are Sheldon L. Wagner, a toxicologist; James A. Witt, environmental toxicologist; Logan A. Norris, environmental chemist in forestry; and James E. Higgins, Alan Agresti and Melchoir Ortiz Jr., statisticians.

There have been numerous conflicting reports in the news about agent orange and 2,4,5-T. Not to be ignored is the American Farm Bureau's policy which states that the farmers favor the use of agricultural chemicals unless the risk of using those chemicals outweighs the benefits.

The American Farm Bureau Federation is a voluntary, nonprofit, nongovernmental, general farm organization with members in 49 States and Puerto Rico. Their 3,200,000 members represent more than 85 percent of all farm and ranch owners and operators in the United States.

Agricultural chemicals, which include pesticides, herbicides, fertilizers, and antibiotics, have been widely used in the United States since the early 1900's. Agriculture in America has become the world's miracle in food and fiber production because of three basic elements: technological know-how, skillful management and agricultural chemicals. Take away any one of those elements and the miracle of American agriculture will cease. A ban on the use of pesticides would raise the cost of food by 50 to 80 percent, remove some foods (such as rice) from the marketplace, and cause a dramatic increase in diseased, insect-infected, low-quality food and fiber products.

Farm Bureau decided that they had to find out what the risks of using 2,4,5-T and what the benefits are. Stated another way, they set out to compare the risk of using 2,4,5-T to the risk of not using it.

Farm Bureau does not want to be responsible for spraying chemicals which would cause birth defects, cancer, spontaneous abortions, or any other health problems. It is their members, the farmers, ranchers and their families who are the most highly exposed individuals in our society to these chemicals. They work with these chemicals almost daily.

Farm Bureau organized a conference which they term a "Scientific Dispute Resolution Conference on 2,4,5-T." They brought in scientists from seven countries, plus the United States. The scientists were world experts on the toxicology, biochemistry, and carcinogenicity, mutagenicity, teratogenicity, use and environmental fate; most had worked with 2,4,5-T for many years. Environmental groups were invited to send qualified scientists.

Farm Bureau invited all the environmental groups they could think including the Sierra Club, Friends of the Earth, Audubon Society, Izaak Walton League, Environmental Defense Fund—(EDF)—and so forth. Special care was taken to invite all of the groups that have been protesting the use of phenoxy herbicides to participate in this meeting and to send their scientists so there could be peer reviews. All of the environmental groups declined. The EDF even went so far as to say that "they would not touch the Dispute Resolution Conference with a 10-foot leafy tree." Others said they did not have any technical expertise on the subject. They did not send any scientists to participate in the workshops. Another category of individuals were invited to this meeting known as observers; and many of the environmental groups did send observers to the meeting.

The scientists sat in workshop sessions and reviewed the known scientific data on 2,4,5-T and dioxin. The unanimous conclusion was that 2,4,5-T could not be documented as the cause of any of the alleged health risks, including abortions. Not one related abortion could be documented anywhere in the world, even in Vietnam or Seveso, Italy. If this country is to survive and prosper, scientific facts must prevail over political fiction and emotionalism.

The towering structure of America rests primarily on the production of food and fiber. It is the basis of our standard of living and our national prosperity. Even during the recent recession, with the highest unemployment level since the Great Depression of the 1930's, America is still the most fortunate land on Earth for the vast majority of its citizens.

The abundance, quality and availability of U.S. industrial equipment and supplies, public services and facilities, housing and furnishings, education and training, medicine and public health, communications and transportation and, above all, food and fiber far surpass those of any other nation on Earth since history began.

The efficiency of our farms is such that our burgeoning population is more than adequately nourished by the land labor of less than 5 percent of our people. We, thereby, release 95 percent of our work force to advance our industry, public works, education and research, and to enrich our culture and maintain our defense.

Countries like China and the U.S.S.R. still bind over 50 percent of their people to the toil of the soil and yet are unable to produce the bare necessities of food and fiber for their people. It is not particularly remarkable to learn that Russia, with its government-directed production programs, has recently announced via Pravda that for the 68th consecutive year they have failed to meet their agricultural production goals because of "unusual weather." They have to appeal, periodically, to America to supply the deficiency.

For the first time in the history of man's long, and often frustrating, struggle against want, America has found how to banish hunger, exposure and destitution from the Earth.

This is, by far, the greatest victory that democracy and the political philosophy of freedom of choice and enterprise has won. It constitutes the fundamental fulfillment of our civilization upon which all other national accomplishment necessarily rests.

At the beginning of the Industrial Revolution in the 19th century, gangs of workmen known as Luddites roamed England systematically destroying machinery. To their compatriots in the Netherlands, we owe the word "sabotage" how to sabot, which is the heavy wooden shoe that Dutch workmen threw into the grinding gears of new technology. An error common to both the Luddite activists of the early 1800's and the new Luddites of today is that both confuse cause and effect. Both value motion over results. Both offer simplistic solutions to complex social and economic problems. Like the mythical bird that flies backward, they are more interested in where they have been than where they are going.

Attacks on corporations because of size alone is part of the neo-Luddite movement resulting in product boycotts and proposals for divestiture and for Federal chartering and control of corporations.

Guised as social concern and rallying under the banner of "big is bad," this Luddite thinking has been accepted as valid by many writers, editors, and broadcasters.

Our society now abounds with so-called experts who deal in half-truths and play on human fears or suspicions to further their own special interests. Many have come to realize they can make names for themselves by scaring the public through the news media. The media, in search of exciting news, encourages the embellishment and sensationalization of facts. Since tough facts are often bland and hard to market as news, the public gets a distorted picture of environmental matters. We face a danger that public policies in technology will be determined by the media and single-interest groups.

Luddites seem to be involved in many of the environmental issues. There is a big movement throughout this country and abroad—Brazil, New Zealand, Australia, Canada, and Europe—to ban agricultural chemicals. The American Farm Bureau's policy states that "We favor use of agricultural chemicals unless the risk outweighs the benefit of using these materials." Not only do we look at it from a risk-benefit evaluation, but we prefer to look at it as the risk of using these materials compared to the risk of not using these compounds. The present alternative to not using agricultural chemicals is hunger, disease, and death. That is a risk not to be taken lightly.

I attended a meeting a few weeks ago in the Chicago area put on by Citizens Against Toxic Sprays and a group called Vet Line-Hot Line to organize the Vietnam veterans and nonveterans to file into a class action suit against the manufacturers of phenoxy herbicides and the Federal Government and possibly the world. Claims amount to $45 billion. Individuals organizing this suit have said that their goal is not so much to help the veterans, it is not so much to ban phenoxy herbicides, but to redistribute the wealth of this country. The settlement would be greater than that of the manufacturers and would put them out of business, say these Luddites. Most of the information that you hear by the media and by these groups not only is misinformation but, in most cases, is out-and-out lies. Unfortunately, there are not enough experts in these subjects to be at all of the meetings to confront the news media, to straighten out this misinformation and to inform the public of the facts.

This meeting in Chicago was led by a psychiatrist who had worked for the Veterans' Administration. For 3 hours he stood before the audience and said, "I know how everyone in this room feels. When your alarm goes off in the morning, you are too tired to get out of bed. You feel weak. You do not want to go to the office. You are all suffering from the symptoms of Agent Orange." He went on to say, "We want you to sign up for this suit. We want you to have an exam, and do not be discouraged by the doctors if they cannot find anything wrong with you, because there is no scientific way that the medical profession can prove that you are not suffering from the following symptoms." And he went over them again, and again, and again. This should give you an idea of what we are up against.

The rise of science and technology in the three centuries since Galileo directed the minds of men from superstition into an era of enlightenment is the most distinctive and constructive feature of modern civilization. The use of science—observation, deduction, experiment, and induction or prediction—is the one feature which differentiates our culture from all those of the past. Without technology and the scientific approach to the resolution of myriad natural problems that have always, do now, and ever shall beset mankind, our civilization would and/or will fade into oblivion as did those of Egypt, Greece, Rome, India, China, or Eurasia and also those of Central and South America, the Mayan, Toltec, Inca, and Aztec cultures of a millenium ago.

There is nothing uniquely sacred about our modern way of life. If the basic necessities of food, energy, fiber, shelter, health, education, and economic necessity are effectively impaired, it is just as subject to political, social, economic collapse as were those which have preceded us.

Yet despite the munificence that scientific technology has evolved to support our way of life, there is a rising crescendo of opposition to its application.

The enemies of science are numerous. In high echelons of Congress and State legislatures, in positions of prominent responsibility in both Federal and State administrative offices, are people trying to curb the works of science. This, of course, is another form of the belief that the way to advance the slow is to hobble the swift.

But with alarming frequency, bogus science prevails. A mountain of sound evidence, in regard to a produce or process, compiled by the most reputable researchers, and proven up to and beyond the hilt in actual practice, may be set aside in an instant. The current actions being taken against agent orange, the herbicide 2,4,5-T, and other important chemical production tools graphically illustrates this point. A public official, keenly aware of the politically expedient course, can ignore all favorable evidence and issue a restriction or outright ban on no better basis than a shallow and inaccurate publication written to cater to some fallacy already made popular by inflammatory reports by media or special interest groups with Ludditist dogma.

This procedure is, of course, Lysenkoism. It can only lead to the calamitous decline of those scientific disciplines affected here in America, just as it destroyed genetics and related agricultural sciences in the U.S.S.R. Lysenko set back Russian agriculture for at least 50 years and forced the country with the most extensive wheat lands in the world to come, hat in hand, to America and Canada for wheat to feed its people. Similar disaster can happen here, and before the end of this century.

If we could mold our research to fit political expediency, it will fail to resolve the problems which beset us; progress will become regress; and our Nation will descend to third world status.

From these dire predictions, which surely must be obvious to all perceptive and intelligent people, there are certain simple conclusions one can draw:

First, education must propagate the facts and truth as they are known to exist at the time. There can be no compromise with this for momentary political advantage.

Second, science in the form of research, development, and application must be pursued on the basis of objective experimental evidence regardless of where the chips may fall. Efforts to compromise so-called scientific evidence to meet the ephemeral moods of the body politic will inexorably result in a total collapse of the system: social, economic, political.

Third, scientific evidence must be impartially presented to the people whether it agrees or disagrees with their current tenets and opinions. All scientific knowledge should be given equal exposure at all times, so that the public cannot so easily be misled by pseudo-scientific demagoguery.

Fourth, scientific decisions are not amenable to the democratic process and there is no such things as truth by referendum.

Fifth, removal or restriction in the use of a technical product must be based on all available scientific data and not selected evidence to fit a preconceived notion of those in appointed authority and their clamorous supporters. Such judgments must weigh the technical, economic, social and environmental benefits versus risk on an equal and impartial basis.

Sixth, it must become recognized, not only by scientists, administrators, educators, and industrialists, but by the general public that has the vote, that science and all its ancillary disciplines have become an integral component of our present socio-political-economic system, in our civilization. If we abandon science now, then we automatically will have to abandon our civilization, as there is no way we can feed, clothe, shelter, educate, and protect the health of the present human population without science. We have already passed the point-of-no-return.

STATEMENT OF RICHARD W. MAIN, AMERICAN COUNCIL ON SCIENCE AND HEALTH

Mr. MAIN. Over the past decade manufacturers and users have spent millions of dollars defending the herbicide 2,4,5-T from a continuous onslaught of emotional criticism. Often, these attacks have been totally political in nature with science an ignored consideration.

At issue in the 2,4,5-T case, as well as with agent orange, is the presence of TCDD, dioxin, in the herbicide. Scientists, on the basis

of data from laboratory research and actual product use experience, believe that 2,4,5-T does not present an unreasonable human health hazard as now normally utilized in agriculture and vegetation management.

Much of the phenoxy herbicide and agent orange hysteria is based on the U.S. Environmental Protection Agency's 1978 Alsea II study which alleged that there was a seasonal cycle of abortions reaching a peak number in June and a significant correlation between the number of abortions and the amount of herbicide used in the area.

The point I would like to make here is that bad science typified by EPA's Alsea II report must always be challenged. An Oregon State University task force has concluded that the EPA study of herbicide use in relation to the miscarriages suffered by women in the Alsea area are so seriously flawed its conclusions cannot be supported.

A 92-page critique of EPA's study released by Oregon State University's Environmental Health Science Center states, "Our critique does not support any of the three conclusions." I have brought with me today a summary of that Oregon State University's critique which I would also like to request that it be made part of the record.

Chairman SATTERFIELD. Without objection, that will also be admitted in the record at the conclusion of your remarks.

Mr. MAIN. Thank you. If anyone is interested, they may write to Oregon State University's Environmental Health Science Center and obtain the entire 92 page critique.

There have been numerous conflicting reports in the news about Agent Orange and 2,4,5-T. Not to be ignored is the American Farm Bureau's policy which states that farmers favor the use of agricultural chemicals unless the risks of using those chemicals outweigh the benefits.

The American Farm Bureau Federation is a voluntary, nonprofit, nongovernmental general farm organization with members in 49 States and Puerto Rico. Their 3,200,000 member families represent more than 85 percent of all the farm and ranch owners and operators in the United States.

The American Farm Bureau feels that its members are the most highly exposed individuals in the United States to the herbicide 2,4,5-T. Farm Bureau members have used 2,4,5-T and 2,4-D and mixed together for well over 30 years. The exposure that Farm Bureau members have is far greater than that which any Vietnam veteran could have experienced. We have the names and addresses and phone numbers of all of these Farm Bureau members who have applied these chemicals for well over 30 years. In the beginning, the mixtures of 2,4-D and 2,4,5-T that the farmers used contained the same high concentrations of dioxin that could be found in agent orange in Vietnam.

The American Farm Bureau Federation participated in the Environmental Protection Agency's regulatory program. The Environmental Protection Agency issued what is known as a rebuttable presumption against registration on the herbicide 2,4,5-T. The members of the American Farm Bureau are quite concerned about the health hazard of this chemical. The farmers do not want to be

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responsible for spraying a chemical out into the environment which could cause birth defects, miscarriages, cancer, or any other health-related problem. It is their families and their children again who are the most highly exposed.

So, in an attempt to find out the truth about 2,4,5-T, dioxin and 2,4-D, the American Farm Bureau Federation last year convened a Scientific Dispute Resolution Conference which was held here in Washington, D.C. in June of 1979. The Farm Bureau invited all of the environmental groups that they could think of, including the Sierra Club, Friends of the Earth, Audubon Society, Isaak Walton League, Environmental Defense Fund. Special care was taken to invite all the groups that have been protesting the use of phenoxy herbicides to participate in this meeting and to send their scientists so that there could be peer review. All of the environmental groups declined.

The Environmental Defense Fund went so far as to say that, and I quote, "They would not touch the Dispute Resolution Conference with a ten foot leafy tree." Others said they did not have any technical expertise on the subject. So none of the environmental groups sent any scientific representatives to the conference, although there was another category known as observers. These individuals were invited to the meeting and many of the environmental groups did send observers. The scientists sat in workshop sessions and reviewed the known scientific data on 2,4,5-T and dioxin. The unanimous conclusion of well over 100 scientists from 8 different countries was that 2,4,5-T could not be documented as the cause of any of the alleged health risks, including abortion. Not one related abortion could be documented anywhere in the world, even in Vietnam or Seveso, Italy.

I brought copies of the summary of this Scientific Dispute Resolution Conference and I am requesting that that summary also become part of the hearing record.

Chairman SATTERFIELD. Without objection, it will be included in the record at the end of your testimony.

[The information referred to follows:]

DISPUTE RESOLUTION CONFERENCE ON 2,4,5-T

Background:

The Dispute Resolution Mechanism – A method for arriving at a consensus, or at least a workable compromise, on a complex scientific, social-political question. It requires that proponents of all viewpoints on an issue meet to debate the merits of their positions and then derive a set of conclusions satisfactory to all concerned. This specific conference on 2,4,5-T addressed only the scientific issues.

Organization – Individual "workshops" are conducted on separate aspects of the issue and workshop recommendations or conclusions are submitted to the assemblage as a whole.

Sponsorship – The Research Foundation of the American Farm Bureau Federation, using member- and industry-contributed funds, provided financial support for this conference. No scientist was paid for his participation.

Focus on 2,4,5-T – The herbicide 2,4,5-T was selected as the topic for this first conference because it is currently the center of governmental legislative activity and media attention. Workshop topics and chairmen were: Carcinogenicity – Dr. Jesse Steinfeld, former U.S. Surgeon General; Teratogenicity – Dr. E. Marshall Johnson, Jefferson Medical College; Ecological Effects – Kenneth Kamlet, National Wildlife Federation; Chemistry – Dr. Philip Kearney, Science and Education Administration (USDA); Human Exposure – Dr. Donald Austin, California Health and Welfare Agency; Benefits – Dr. John Schaub, Economist USDA.

Conference co-chairmen were Dr. F. H. Tschirley, Michigan State University and Dr. T. C. Byerly, former USDA Administrator.

MAJOR CONCLUSIONS[1] OF THE WORKSHOPS:

Carcinogenicity — Mutagenicity

- "2,4,5-T is not a carcinogen nor mutagen in animal test systems studied to date.
- TCDD[2] is carcinogenic for rats and mice.
- TCDD is a mutagen in two bacterial reverse mutation systems, but no *in vivo* correlates of mutagenicity have been found.
- Phenoxy herbicides containing TCDD have not been shown to be carcinogenic in humans in retrospective epidemiologic studies to date.
- Based upon the most definite animal carcinogenesis study, the working group felt that extrapolation from the high dosages of the test chemical should be made to dosages that might possibly be encountered in the environment during continuous lifetime exposure."

Teratogenicity

Effect of 2,4,5-T on Reproductive Parameters in Animals:

- "A review of early studies in animals revealed that high doses of 2,4,5-T containing 0.1 ppm of TCDD or less produced cleft palate (mouse only) or embryo lethality in a number of experimental species (mouse, rat, hamster, sheep, monkey, rabbit). A recent three-generation reproduction study in rats was available for examination by this

June, 1979

Arlington, VA

[1] *All conclusions represented a group consensus; there were no minority reports filed.*

[2] *TCDD is 2,3,7,8-tetrachlorodibenzo-p-dioxin.*

group. Neonatal survival was decreased in a dose-related manner, and the no-adverse-effect dose level in the species most sensitive to 2,4,5-T, the mouse, was 20 mg/kg/day.

Effect of TCDD in Reproductive Parameters in Animals:

- Studies in rats and mice for teratogenic and embryo-toxic effects revealed the highest no-effect dose level in rats to be 0.03 $\mu g/kg/day$ (teratogenicity). At higher doses, cleft palates, intestinal hemorrhage, kidney changes, or embryofetal lethality was observed.

  In studies conducted in rats and monkeys, the apparent no-effect level in rats was 0.001 $\mu g/kg/day$, a level of 10X below the demonstrated no-effect level in Rhesus monkeys.

Effects of 2,4,5-T and TCDD on Reproductive Parameters in Humans:

- Alsea Study—The miscarriages reported in this study were not demonstrated to result from the spraying of the forests with 2,4,5-T.
- Analysis of available data[1] leads this group to the conclusion that no adverse effects on human reproduction have yet been demonstrated after exposure to 2,4,5-T or TCDD."

Human Exposure

- "Sufficient evidence exists to date to conclude that chloracne in humans is the most frequently manifested consequence of exposures to TCDD and may occur without other evidence of toxicity.
- The group found no evidence for an abortifacient[2] effect of TCDD in the human.
- The group considered the Alsea, Oregon data and reached a consensus that such serious deficiencies existed in the data that no conclusions were possible regarding possible abortifacient effects of 2,4,5-T.
- In regards to the data on TCDD exposure in Seveso, the group concluded that evidence of no manifest teratogenic effect in Seveso over the time period of observation exists.
- The group concluded that there was no evidence of an association between birth defects of the neural tube and exposure to 2,4,5-T in either the New Zealand or Victoria, Australia investigations.
- The group agreed that the available data cannot be interpreted as providing either positive or negative evidence of a carcinogenic effect in the human.
- TCDD was not found in the urine of personnel who applied 2,4,5-T sprays in the forest. Based on a TCDD concentration of 0.04 ppm in the formulated product, 2.9×10^{-4} $\mu g/kg/work\ day$ is the maximum amount that could have been absorbed."

Ecological Effects

- "2,4,5-T *itself*, relative to TCDD as a contaminant, is of minimal ecological concern subject to several qualifications as to conditions of use.
- TCDD degrades rapidly on leaves, in water, and on the soil surface through the action of sunlight. However, once incorporated in soil, measured half-lives have ranged from 1 to 3 years or more.
- In terms of levels of TCDD entering the top few inches of soil, routine right-of-way applications in the United States represent about 1/13,000th the level of contamination that was initially associated with the Seveso, Italy episode, and about 1/1000th of that currently remaining from 2,4,5-T applications (experimental equipment calibration) at Eglin Air Force base in Florida about 15 years ago.
- The highest environmental residues of TCDD from approved 2,4,5-T application that can currently be documented (based on a single sample) is 60 ppt in one beef fat sample.
- Although the available analytical data provide little evidence that TCDD is accumulating in the environment as a result of normal domestic use of 2,4,5-T, larger numbers of samples must be analyzed with even more specific methods before this can be established.
- The major area of uncertainty concerns the questions of whether such levels could be expected to result in detectable (immediate or delayed) biological effects. Although no known biological effects in connection with routine 2,4,5-T use have been documented over a 30 year period, we cannot say with total assurance that such effects cannot, do not, and will not occur.

Chemistry

- "It was agreed that no levels of TCDD in the ppm or ppb range have been detected in the environment exclusive of waste disposal or spills. It was further agreed that levels at 100 ppt or above have not been detected in any environmental sample associated with the normal use of 2,4,5-T, i.e., fish, beef or mothers' milk. Below this level, specific substrates and studies must be considered separately:

  Mothers' Milk—Based on three separate studies conducted up to January, 1979, no validated TCDD residues above 1 ppt have been detected based on analyses of 44 mothers' milk samples. *There are no confirmed*[1] *detected levels of TCDD in mothers' milk.*

[1] *Data from the USA, Sweden, New Zealand, Australia, Vietnam and Italy were studied.*

[2] *Causing abortion.*

Beef Fat—Out of 85 samples (including 20 controls) there was only one sample of beef fat confirmed at 60 ppt of TCDD and two apparent but unconfirmed samples at 20 ppt. The remainder of the samples were below the detection limits of 10 ppt. These data were obtained from the EPA "Dioxin Implementation Plan."

In a separate published study in 1976 by one laboratory, 24 samples of beef fat from animals known to have grazed on 2,4,5-T treated forage were analyzed at a level of sensitivity of 6 ppt. None of the samples showed a residue of TCDD at or above the limit of detection[2].

Beef Liver—Of the 43 beef liver samples from cattle grazed on 2,4,5-T treated rangeland (EPA "Dioxin Implementation Plan"), no confirmed TCDD residues were present at a level of sensitivity of 4-8 ppt.

Bovine Milk—One laboratory has reported in the scientific literature a study based on work done in 1974 with lactating cows grazed on 2,4,5-T treated foliage. No milk sample from these animals showed a residue of TCDD above the detection limit of 1 ppt.

Fish—A published scientific report on the analyses for TCDD in fish taken from waters adjacent to areas of regular 2,4,5-T use (in Arkansas and Texas) in 1975 showed no detectable TCDD at a sensitivity of 10 ppt.

Wildlife—In connection with normal patterns of use of 2,4,5-T, few studies of TCDD residues in wildlife have been done. The largest study used inadequate analytical methodology and did not yield sound quantitative data. A later unconfirmed small study did not detect TCDD in livers of a large native rodent species collected in forest spray area.

(1) Confirmed = Detection by more than one laboratory at 2.5 x signal-to-noise ratio using the agreed analytical method.

(2) A finding of a residue equal to or less than the limit of detection should not be considered positive.

Environment, General

Is 2,4,5-T the sole source of 2,3,7,8-TCDD in the environment?

No. There are other sources such as combustion of certain chlorinated organic compounds whether in industrial or municipal waste. There are indications that other combustion sources are implicated as well. It is impractical to attempt to eliminate all of these sources at the present time.

Concern has been expressed regarding the persistence of 2,4,5-T and TCDD in the environment. Extensive studies with 2,4,5-T over many years have shown it to break down quite readily. The half-life of 2,4,5-T in soil at normal rates of application will range from two weeks to four months. Temperature, moisture, fertility, and soil type may modify the rate of disappearance, but the half-life of 2,4,5-T rarely exceeds four months.

TCDD, on the other hand, while rapidly degraded by light, appears much more persistent in soil and aquatic systems. At the extremely low concentration that would accompany the normal application of 2,4,5-T, it is probable that the half-life is not in excess of one year. However, in laboratory experiments or chemical accidents where greater amounts have gotten into the soil, the half-life appears to be significantly longer. One possible explanation of this is that the biological activity of TCDD is so high that at saturation concentrations in soil solutions, the chemical or biological mechanism responsible for its disappearance is inhibited, thus resulting in longer persistence."

Benefits

"Given the data available, the majority of the work group concurred with the conclusion that significant economic losses would occur if 2,4,5-T were not available for use in forestry. Higher costs would occur in the control of brush in rights-of-way and losses in production from pasture and range would result. Given current production practices, losses would be sustained in rice production. However, several members questioned the extent of the rice production losses because of lack of documentation of data and assumptions.

For further information contact: American Farm Bureau Federation, 225 Touhy Avenue, Park Ridge, IL 60068.

Mr. MAIN. Thank you. In all of these issues one important aspect is to consider the risk versus the benefit. I would like to say that the present alternative to not using such chemicals in agriculture is hunger, disease, and death. This is a risk not to be taken lightly.

I would like to briefly relate a description of a meeting which I attended in Chicago a few weeks ago. This meeting was put on by Citizens Against Toxic Sprays and a group called Vet Line-Hot Line to organize the Vietnam veterans and nonveterans to file into a class action suit against the manufacturers of phenoxy herbicides and the Federal Government claims amounting to $45 billion. Individuals organizing this suit said that their goal is not so much to help the veterans, it is not so much to ban phenoxy herbicides, but to redistribute the wealth of this country. The settlement would be greater than that of manufacturers and would put them out of business. Most of the information that you hear by the media and by these groups not only is misinformation but, in, most cases, it is out and out lies. Unfortunately, there are not enough experts in these subjects to attend all of the meetings and to confront the news media to straighten out this misinformation and to inform the public of the facts.

This meeting in Chicago is led by a psychiatrist who at one time had worked for the Veterans' Administration. For 3 hours this individual stood before the audience and said, "I know how everyone in this room feels. When your alarm goes off in the morning, you are too tired to get out of bed. You feel weak. You do not want to go to the office. You are all suffering from the symptoms of agent orange." He went on to say, "We want you to sign up for this suit. We want you to have an exam. And do not be discouraged by doctors if they cannot find anything wrong with you because there is no scientific way that the medical profession can prove that you are not suffering from the following symptoms," and he went over those symptoms again and again. This should give you a pretty good idea of the things that we are up against on this issue.

Chairman SATTERFIELD. We have a vote on the floor and we are going to have to go and answer the roll. How much longer do you feel your statement will take?

Mr. MAIN. I could quit at this time and take questions.

Chairman SATTERFIELD. We are trying to get through, if we can, this afternoon. We have got your whole statement in the record. If we can adjourn or recess right now, we will go vote and come back. If you do not mind waiting, we can address questions to you then if any of the members have questions.

Mr. MAIN. I would be more than happy to wait.

Chairman SATTERFIELD. The subommittee will recess for a few minutes while we go vote.

[Brief recess.]

Chairman SATTERFIELD. The subcommittee will come to order. Mr. Main, I appreciate your suspending your statement to us. As I mentioned, the entire statement will be in the record and, although many members are not here now because of business elsewhere, they will all read it in due course. Mr. Daschle, do you have any questions?

Mr. DASCHLE. Mr. Chairman, I am going to withhold questions, but in the interest of the record I might just say that my lack of

questions at this time is only in the interest of time and not in the interest of pursuing some of the statements made in the testimony. I would like to do that at some later date, perhaps for the record.

Chairman SATTERFIELD. Very well. I am confident that Mr. Main and also Ms. Whelan, who could not appear, would be happy to respond to questions in writing. Thank you for your attendance today. We appreciate your coming.

Mr. MAIN. Thank you.

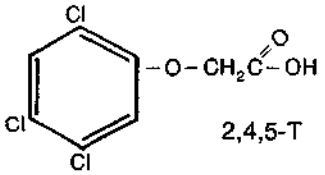
[Submitted information follows:]

(SUMMARIES)

A SCIENTIFIC CRITIQUE OF THE EPA ALSEA II STUDY AND REPORT

with

the November 16, 1979 Supplement



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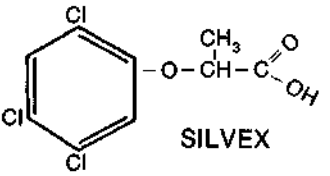

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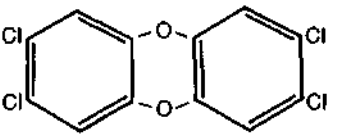

TCDD

Oregon State University

ENVIRONMENTAL HEALTH SCIENCES CENTER

OCTOBER 25, 1979

A SCIENTIFIC CRITIQUE OF THE EPA ALSEA II STUDY AND REPORT

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October 25, 1979

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FORWARD

Health is a very precious possession of the human. It should not be needlessly jeopardized but rather protected by every rational means. Increasingly, we have been concerned with chronic effects produced by environmental agents — physical, biological, and chemical. In recent years, much attention has been focused on chemical agents in the environment, *particularly the man-made chemicals that, by one means or another, find their way into the* environment. The Environmental Health Sciences Center at Oregon State University, established over a decade ago, has as its primary mission the study of the toxicology of environmental chemicals in order to assess possible hazards and provide a basis for developing strategies to prevent these hazards. The Center, supported by Oregon State University and grants from the National Institute of Health, pursues this mission through research, training, and a number of other activities. From time to time, special problems arise calling for study and evaluation by interdisciplinary task forces. Such task forces bring their expertise to bear on the problem of collecting and analyzing the relevant information and then preparing a report for public use.

For some years, the use of the herbicide 2,4,5-T has been under serious challenge by some segments of the public and the scientific community. Many studies using laboratory animals and doses above that experienced in the environment have been carried out on the toxicology of 2,4,5-T and its low level contaminant, TCDD. However, some individuals have claimed to have suffered ill effects from exposure to 2,4,5-T in the environment. One such claim involving spontaneous abortions resulted in the Environmental Protection Agency "Alsea II Study." The results of this study played a prominent role in the Agency's decision to suspend the use of 2,4,5-T in forestry.

A number of individual scientists and groups, not only in this country but in other countries as well, challenge the study and its conclusion. Consequently, because of this sharp difference of opinion and the familiarity of staff members and associated investigators of the Environmental Health Sciences Center with the area and the problem, it was felt that the Center should undertake its own independent study. Accordingly, an interdisciplinary task force to study this problem was formed. It was composed of Sheldon L. Wagner, M.D. (toxicologist); James M. Witt, Ph.D. (environmental toxicologist/hazard assessment); Logan A. Norris, Ph.D. (environmental chemist/forestry); James E. Higgins, Ph.D. (statistician); Alan Agresti, Ph.D. (statistician); and Melchor Ortiz, Jr., Ph.D. (statistician). After detailed study, consultation with many colleagues and the development of new information, this task force prepared the following report. We believe that it adds substantive new information that would be of wide interest of those concerned with the problem.

V. H. Freed, Ph.D.
Director, Environmental Health
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A SCIENTIFIC CRITIQUE OF THE EPA ALSEA II STUDY AND REPORT[1]

by

Sheldon L. Wagner, James M. Witt, Logan A. Norris
James E. Higgins, Alan Agresti, and Melchor Ortiz, Jr.

SUMMARY

In 1978, women living near Alsea, Oregon, a forested area in which 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) is used seasonally, noted an apparent temporal relationship between their spontaneous abortions and the use of this herbicide on adjacent land. A two-part investigation of this incident was conducted by the U.S. Environmental Protection Agency (EPA). The first part (Alsea I) did not find a relationship between spraying and abortions. In the second part (Alsea II) EPA reported (a) the abortion rate was higher in the Study area than in either the Control or Urban area (b) there was a seasonal four-month cycle of abortions with an outstanding peak in June in the Study area and (c) there is a significant cross-correlation between the spontaneous abortion index and the pattern of 2,4,5-T use in the Study area. Our critique does not support any of the three conclusions from EPA's Alsea II study.

This critique shows that EPA reached erroneous conclusions from the Alsea II study because of: (1) failure to account for differences in the characteristics between the Study area and the Rural and Urban control areas, (2) inaccuracies in the collection of data on spontaneous abortions, (3) failure to account for marked differences in the medical practice among areas, (4) incomplete and inaccurate data on 2,4,5-T use, and (5) failure to recognize that the magnitude of the monthly variations in rates of hospitalized spontaneous abortions (HSAb) in all three areas is not greater than would be expected due to random variations. When corrections for some of these problems are applied, we find the rate of spontaneous abortions in the Study area does not appear to be related to the use of 2,4,5-T.

Retrospective studies such as the Alsea II study are exceedingly difficult to conduct. The net effect of attempting a comparison among several poorly identified populations is to obscure the potentially significant data by the mass of other data containing no information. When poorly done, these studies confuse rather than clarify issues, in this case the risks from using agricultural chemicals in our country. The original contention of the women from Alsea, Oregon, namely that there is a relationship between herbicide use and miscarriages, is not suported by the data in EPA's Alsea II Report.

[1] Includes contributions by Scott Overton, Ph.D., Professor, Department of Statistics, Oregon State University, Corvallis, Oregon.

ANALYSIS OF ASSOCIATION BETWEEN 2,4,5-T EXPOSURE AND HOSPITALIZED SPONTANEOUS ABORTIONS

Supplement To:

A SCIENTIFIC CRITIQUE OF THE EPA ALSEA II STUDY AND REPORT

November 16, 1979

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ANALYSIS OF ASSOCIATION BETWEEN 2,4,5-T EXPOSURE AND HOSPITALIZED SPONTANEOUS ABORTIONS[1]

by

Alan Agresti, Ph.D.

SUMMARY

This supplement describes statistical analyses that have been conducted using the hospitalized spontaneous abortion (HSAb) data for the EPA Alsea II Study area. These analyses were done after the completion of the "Scientific Critique of the EPA Alsea II Study and Report," when it was found to be possible to disaggregate the data temporally to monthly units and spatially to zip code units. For each pregnancy which resulted in a live birth or HSAb during the period 1972-1977, a woman was classified as "exposed" or "unexposed" according to whether or not 2,4,5-T was sprayed in the zip code of her residence during certain months. *No significant differences in HSAb rates were observed between the "exposed" and "unexposed" groups, and there was no detectable tendency for the HSAb rate to increase as the potential exposure level to 2,4,5-T increased.*

[1]The author is grateful to Scott Overton, James Witt, and Logan Norris for their comments and suggestions.

Chairman SATTERFIELD. Fine. We appreciate that very much. I am sorry that the constraint of time is such that we do not have more members here or questions, but we very well may submit some to you in writing. Thank you very much for your attendance today, We appreciate your coming.

The next witnesses we have, and we regret for having kept you gentlemen here all day, Dr. David Rall and Dr. John Moore, the National Institute of Environmental Health Sciences. Dr. Moore, incidentally, chairs the Interagency Advisory Group. Dr. Rall is director of the National Institute of Environmental Health Scientists. This is a panel and we would like to hear the statements from both of you gentlemen and then we will ask questions.

I might say in the interests of time that if you feel it advisable, you may submit your written statements in the record and extemporize or summarize them. We will be happy to receive your statements any way which you would care to deliver them. Dr. Rall, perhaps you would lead off.

Dr. RALL. May I suggest, Mr. Chairman, that Dr. Moore, who will deal with more issues than I, might lead off and leave simply the issue of the animal carcinogenicity studies and I will then summarize them.

Chairman SATTERFIELD. That will be fine. Then, Dr. Moore, if you would lead off, we would appreciate it.

Dr. MOORE. Thank you, Mr. Chairman. I am John Moore, a toxicologist, Deputy Director of the National Toxicology Program and I chair the Science Panel of the Interagency Work Group. I ask that my prepared statement be entered into the record along with that of the whole statement of chairman of the Interagency Work Group, Joan Bernstein, which I believe was provided earlier to the committee.

Chairman SATTERFIELD. Yes.

Dr. MOORE. If that is possible, I would then like to briefly summarize a couple of points that I think have come out during the day that I am sure I will be asked anyway.

Chairman SATTERFIELD. Without objection, Dr. Moore, your written statement will be admitted at this point in the record.

[The following was received for the record:]

WRITTEN STATEMENT OF DR. JOHN A. MOORE, DEPUTY DIRECTOR, NATIONAL TOXICOLOGY PROGRAM, DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND CHAIRMAN, SCIENTIFIC PANEL, INTERAGENCY WORK GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

Mr. Chairman and members of the subcommittee, I am John A. Moore, a toxicologist, Deputy Director of the National Toxicology Program and chairman of the Scientific Panel of the Interagency Work Group to Study the Effects of Possible Long Term Health Effects of Phenoxy Herbicides and Contaminants. I wish to utilize this opportunity to appear before the committee by describing several scientific activities that I believe are of relevance to Vietnam veterans. The testimony of Ms. Bernstein, chair of the full Interagency Work Group, describes the group's activities in a more comprehensive manner.

The activities of the scientific panel can be categorized in four broad areas: (1) Identification of research activities being conducted or funded by the Federal Government including current status and targeted completion dates; (2) identification of areas in which additional research is required; (3) reviewing proposed research; and (4) review and interpretation of research results for relevance to the concern of Vietnam veterans that they are or may be at increased risk of suffering a variety of health impairments.

Future activities of the scientific panel will also include monitoring the progress of these research activities.

In an issue of this type, the preferred course of gathering scientific knowledge is to identify an exposed population and conduct the appropriate medical studies. Attempts to identify a population from among those ground troops who served in Vietnam have not been successful. This completely frustrates any study whose objective is to define what risk, if any, is associated with herbicide orange exposure. Without accurate knowledge as to who was actually exposed, you are likely to misclassify the study population and, as a consequence, erroneously interpret the study results.

The Air Force ranch hand personnel, who applied herbicide orange, are the only population whose frequency and duration of exposure are known. The degree of exposure may equal or even exceed that of people involved in the more intensive domestic uses of these types of herbicides. The Interagency Work Group has recommended that studies of the health status of this group be conducted since the detection of adverse health effects would provide an indication as to the type of health effects that may occur in other (ground troop) personnel. I feel obliged to caution the committee there are definite limitations in the extent to which the results of this will be applicable to the total Vietnam veteran population. Two major limitations are that the small size of the Ranch Hand population restricts the level of confidence that can be placed on a failure to detect an increased incidence of a variety of health effects; second, the detection of a health effect in this study would not permit the establishment of a quantitative health risk for ground troops since the Ranch Hand exposure is estimated to have been much greater.

It remains the opinion of the scientific panel that certain health decrements may be present in the veteran population that are a consequence of Vietnam service and are not directly associated with herbicide orange exposure. I suspect that any attempt to specifically and accurately identify who might have been exposed to other chemicals—which may include herbicides, insecticides, or drugs—or agents that may be peculiar to the Vietnam environment—such as fungal toxicants—would prove to be a most formidable, if not impossible, task. In view of these circumstances, coupled with the uncertainty of identifying personnel exposed to herbicide orange, the scientific panel suggests that a prudent approach to determining if Vietnam veterans are suffering health impairment is to design and conduct studies that would indicate if service in Vietnam is the causal factor.

Two possible health effects which are worrying many Vietnam veterans are birth defects and cancer.

The principal issue is that veterans allege and fear that they are at an increased risk of siring malformed children years after exposure to herbicide orange. It is known that exposure of female rates and mice to 2,4,5-T or 2,3,7,8-TCDD—a constituent and contaminant of herbicide orange, respectively—can produce malformed offspring, fetal toxicity or fetal death. One cannot predict male effects from results obtained through studies of female exposure. Logic dictates that the ability to sire malformed offspring years after herbicide orange exposure could plausibly occur only if there was permanent genetic damage—mutation—to the spermatogonial cells. Current data on the mutagenicity of the herbicide orange components, 2,4-D, 2,4,5-T, and 2,3,7,8-TCDD, are judged to be inadequate. These chemicals are being retested using the best current techniques. The first results are now emerging and more will be forthcoming next year. The scientific panel will begin reviewing available data in the next 2 months.

A direct method of securing relevant toxicology data is through the administration of the constituents of herbicide orange to male laboratory animals and examining their sperm, ability to fertilize untreated females, as well as examination of their offspring for viability and malformations. The National Toxicology Program performed such a study in mice and reported its results in August. The study reported that there was no evidence of germ cell toxicity or adverse effects in the development and survival of offspring as a consequence of paternal exposure to simulated mixtures of herbicide orange. This report is now being reviewed by the scientific panel.

A third approach is to study and evaluate human birth records data. The scientific panel evaluated the potential utility of a birth defects registry that has been maintained since 1968 in the metropolitan Atlanta area. The panel recommended that a case control epidemiological study be conducted using this registry. The panel felt that such a study would have a good probability of determining if Vietnam veterans are siring children with an increased incidence of specific malformations. Detailed planning of this study is underway at the Center for Disease Control. A detailed protocol for this study was recently submitted to the scientific panel, and will be reviewed September 25. While it will be useful as a means of determining if

service in Vietnam resulted in an adverse health consequence, the study is unlikely to be able to indicate that herbicide orange was the factor responsible for increased incidence of malformations, should such a phenomenon exist.

Veterans are concerned that cancer, death, illness, or increased risk is associated with herbicide orange exposure.

Previously published studies had reported 2,3,7,8-TCDD—the contaminant in herbicide orange—to be a carcinogen in rats. Two additional animal cancer bioassays were recently completed by the National Cancer Institute and National Toxicology Program (NTP). The draft reports were reviewed for the National Toxicology Program by a group of independent scientists in June. This group of scientists concurred in the reports' findings that TCDD was carcinogenic in rats and mice. The recent study in rats confirmed the previously published reports; the mouse study extends the observation that 2,3,7,8-TCDD is a carcinogen to a second animal species.

The scientific panel also reviewed several case control epidemiology studies that were conducted by Swedish scientists. The panel concluded that in spite of the reservations associated with case control epidemiology studies, the studies show a correlation between exposure to phenoxy acid herbicides and an increased risk of some forms of cancer. They also were of the opinion that independent verification would further validate these studies.

While these studies do establish a cancer risk from TCDD and possible phenoxy acid exposure, the data do not lend themselves to the establishment of a quantitive risk for veterans exposed to herbicide orange. To determine if risk is resulting in tumor occurrence, the veteran population should be studied directly. A valid scientific criticism of such a study conducted at this time is that the study may be premature and prone to a false negative result given that the time elapsed since exposure in Vietnam is less than the 15 to 20 years that is typically required for excess cancer incidence to become manifest. However, the perception of cancer risk is a current concern and, in some instances, excess cancer may appear in a population 10 years after exposure. Therefore, such a study should be initiated. The rationale for this recommendation is:

One, a negative finding would allay the current and possibly increasing fear that herbicide orange exposure or Vietnam service already is resulting in excess cancer deaths.

Two, a positive finding would establish service connection and permit appropriate policy decisions with respect to service connected disability and right to compensation.

Three, a positive finding would identify the types of cancer for which there is increased risk and the medical community could focus attention on specific surveillance for early detection of tumors with a possible attendant increase in successful treatment.

Four, an appropriate cohort will have been registered that can and must be resurveyed at appropriate time periods to detect changes in major morbidity or cancer incidence.

Such a study could easily be included as part of the congressionally mandated Veterans' Administration epidemiology study. Since results from this study are not expected for several years, other mechanisms will continue to be explored. The proposed Air Force Ranch Hand study will study cancer incidence; however, the limitation of study size dictates that a larger study also be planned.

In conclusion, I am not optimistic that scientific studies will provide unequivocal data as to the significance of herbicide orange exposure to the health of Vietnam veterans. It is plausible that studies can determine if various health effects are associated with Vietnam service. The principal studies needed to provide such data may require several years to complete.

I would be happy to answer any questions the subcommittee may have.

Chairman SATTERFIELD. You may proceed.

STATEMENT OF DR. JOHN A. MOORE, DEPUTY DIRECTOR, NATIONAL TOXICOLOGY PROGRAM, DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CHAIRMAN, SCIENTIFIC PANEL, INTERAGENCY WORK GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

Dr. MOORE. The science panel of the work group, I think, has been involved in a variety of activities, a couple of which I think I

would like just to briefly touch upon. One of the issues is the fact that in order to conduct a study on possible health effects as a consequence of agent orange one must have a population identified in order to conduct the study. And indeed, as has been mentioned several times earlier today, with the exception of the Ranch Hand personnel or the Air Force personnel, we have been unsuccessful to date in identifying any population of ground troops who one can say with some reasonable degree of assurance were exposed. That is not to infer that we don't think that one should give up on that effort.

As is mentioned in the work group progress report, as well as in my testimony and that of Joan Bernstein, that the science panel has met with members of the Department of Defense who are trying to follow two battalions, one in the Army and one in the Marines, during a heavy period of exposure by chasing all the records that they feel are available to them. We have been briefed by them as to the approach, have seen some of the types of records they were looking at. Their report, I believe, is close to being finished on those two battalion searches.

I might also mention that I do know they have held counsel quite closely with GAO during the design of this approach, I think in part stimulated by the GAO report which identified Marine records and maybe more specifically some Marine battalions as possibly being sprayed, and one could document their exposure. But until we have a report, we really can't review it and comment on it. This is maybe some of the concerns that Mr. Edgar had mentioned earlier, that we have not reviewed the report. The report isn't available. We fully intend to review the report when it is available. And indeed, still hope that we can identify a population of ground troops whose exposure can be reasonably documented so that we don't have to totally rely on just the 1,150-odd Ranch Hand personnel. That does not suggest that if such a population can be found that one should not also study Ranch Hand.

Chairman SATTERFIELD. Do you feel optimistic that it may be identified?

Dr. MOORE. No. The other point I would like to touch upon is the area of birth defects and cancer. There are a number of activities that have either recently been completed or are in progress that I think are very germane to the Vietnam agent orange issue. One was a study recently completed in mice in which male mice were exposed to various formulations of agent orange with varying degrees of dioxin contamination. That study was released August 1, it is in the process of being completely reviewed by the scientific panel for its credibility and opinion. That should be available, I would believe, in the next several weeks.

Also germane I think is a study that the panel reviewed back in April and recommended that it should be conducted, and that is a study of malformations as have been recorded in the Metropolitan Atlanta area. They have had a registry there since 1968 in which a case control type of epidemiology study is to be done in which they hope they will be able to see if they can establish any correlation between having been a Vietnam veteran and an increased incidence of malformation of children that are already born. They are

projecting to survey birth record data between 1968 and up to and maybe including 1980.

In the area of cancer, the relevant animal data that is available I will leave to Dr. Rall to discuss. I think it is the panel's opinion, at least, that the studies that are available do establish a cancer risk from TCDD and possibly phenoxy acid exposure. However, the data do not allow them to establish a quantitation of that risk. And indeed, it is, I think, the opinion of the panel that the best way one is going to be able to address an increased incidence of cancer or certain forms of cancer within the Vietnam veteran population is to study the Vietnam veteran population or some portion of the population. One doesn't have to study all 2.5 or 2.8 million of them. And we feel that it is appropriate that this should be done and should be done now even though there is some concern, some legitimate concern, on the part of some people that indeed the time that has elapsed since Vietnam exposure to agent orange in 1980 is too short for cancer to have become manifest in a population. Given that it is a current concern, we feel that a study should be done without any great delay because I think a negative finding would greatly allay the current and possible increasing fears of many veterans that they already are at risk of cancer.

Another reason we think the study should be done if it is a positive finding, one would have established service connection and permit appropriate policy decisions to emanate therefrom.

Also, a positive finding would identify the types of cancer that may be present, and indeed alert the medical community as to what types of cancer should be surveyed for with the possible attendant increase in successful treatment if indeed it is found to occur.

The other this is even if one proposes to do a study today, we would certainly suggest that a study of the same population should be followed up 5, 10, 15 years later and you would have that population registered and just go back to the same population.

With that, Mr. Chairman, I think I will be available for questions.

Chairman SATTERFIELD. One question concerning your suggestion about Vietnam population generally. I take it that you are talking merely about the Vietnam veteran and not necessarily those exposed to agent orange?

Dr. MOORE. That is correct, Mr. Chairman. I think the quandry that one faces, if one cannot identify veterans who were possibly exposed or possibly not exposed, you run the risk of amalgamating them together in a study with the attendant problem that you have misclassified people. People who were not exposed you put in the exposed group, and with the inevitable outcome being that you end up with confounding data which will be misinterpreted one way or the other.

Chairman SATTERFIELD. I recognize that problem and that is why I asked the question because it would seem to me, then, that if you established a pattern of high incidence among Vietnam veterans we might be on the course of establishing some sort of service-connected cause without necessarily tying it to agent orange or anything else.

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Dr. MOORE. Right. Our feeling is that, at least as I perceive the issue, the issue from a VA standpoint should be whether the problem that may be present is service-connected? As a scientist, I would like to know what would be the cause of that service-connection.

Chairman SATTERFIELD. I think we are pretty much in that same position although we are in the position, at least, or have the capability of being a little less precise in deciding which Vietnam veterans or which veterans might be entitled to what benefit. But it does seems to me that there still has to be the establishment of some health effect that is reasonably attached to service, enough that we would infer cause and effect.

Dr. RALL. With your permission, Mr. Chairman, I would like to submit my full statement for the record and very briefly summarize the salient features.

Chairman SATTERFIELD. Without objection, the entire statement will be admitted at this point in the record.

[The following was received for the record:]

WRITTEN STATEMENT OF DR. DAVID P. RALL, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. RALL. Mr. Chairman, my name is Dr. David P. Rall. I am a pharmacologist and physician. I am Director of the National Institute of Environmental Health Sciences of NIH. I am also director of the PHS National Toxicology Program. I am pleased to testify before this subcommittee this morning on the cancer-causing potential of the herbicide agent orange. My associate, Dr. John A. Moore, will discuss the broader toxicological issues involved with agent orange.

It is estimated that between 1962 and 1971, the period of the greatest application, more than 100 million pounds of agent orange were used in Vietnam. With such heavy application, it is inevitable that an unknown number of American troops were exposed at an unknown concentration to the substance. The question I will attempt to clarify is, do some of these Vietnam veterans now face an increased risk of developing cancer as a result of that exposure?

There are two ways by which scientists can determine whether a substance will cause cancer in humans. First, they can use epidemiology, the study of the increase of disease in human populations. Epidemiology is a very useful tool for finding associations between exposures and disease in human populations. Unfortunately, toxic substances such as agent orange are unlike the infectious diseases with which science is more familiar. These new agents of environmental disease may not leave identifiable markers in the body. It is also difficult to isolate all the other factors that could cause an increase in a particular type of cancer and to focus on the causal agent. None of us lives in a sterile environment. We are all exposed to a multitude of agents that may cause cancer. These occur in the air, in the water and in our food. Thus, each of us faces some risk of developing cancer from these exposures. Risk is also increased by lifestyle factors such as smoking and drinking, as well. As a result, looking at humans to identify the cause of a disease like cancer is not a simple proposition.

In cases where epidemiology has been used to determine specific cancer-causing agents such as the discovery that those working with vinyl chloride experienced an increase in angiosarcomas was well above the norm, so that the increase in these cancers was easily detected in these relatively small populations. Were this not the case, the increase would have been missed. And second, angiosarcomas are such a rare tumor to begin with that when one sees even four or five new cases, one immediately realizes something unusual has occurred.

The smallest excess in cancer risk that has been directly observed in a group of exposed individuals due to a particular exposure is the 30 percent excess risk of childhood leukemia due to radiation exposure in utero in the last trimester of pregnancy. And, in fact, it took some 20 years to establish this fact.

Perhaps the most important difficulty in relating exposure to human disease is the long latency period experienced from the time of exposure to the disease initiator and the manifestation of cancer. The typical time period involved is 20 to 40 years.

Thus, if the maximum exposure to agent orange in Vietnam occurred between 1962 and 1970, and if the cancer risk resulting is large enough to be detectable, we would not expect to see the impact of the herbicide spraying until the 1980's and 1990's or, depending upon its latency period, we will have to wait for our evidence until the turn of the century when the exposed veterans will be in their fifties and sixties.

I think we would all agree that it would be tragic if we discover that these men, while acting in the service of their country, survived the war only to face the prospect of cancer in the prime of life. So, the question arises, if it is desirable from a public policy standpoint to know whether they have been inadvertently exposed to cancer-causing agent, is there any way to determine this without waiting until we can actually see the results in the exposed population?

The answer is yes, there is; the standard scientific tool for determining whether a given substance represents a carcinogenic risk for humans is the two-sex, two-rodent species lifetime bioassay. In the National Toxicology Program, we usually use rats and mice uniformly bred for laboratory purposes. After years of experience with testing on such animals, scientists have a fair understanding of the reactions of the test animals to toxic chemicals.

Both the rat and the mouse have been shown to be reasonably susceptible to the carcinogenic action of a wide variety of compounds. Many of those substances which cause cancer in humans were first detected in rodentcoal tar, polycyclic hydrocarbons. DES and vinyl chloride are examples. There is little basis to assume that there is any carcinogen which is specific only to one species, although the sensitivity of different species to various carcinogens and the specific organs in which cancer may appear may differ.

Thus, I believe that the results of experimental tests on animals can be used to predict whether a given substance may cause cancer in humans with an acceptable degree of certainty. Within the last 2 years, the principle that well-conducted studies on laboratory animals can be used to predict carcinogenicity in humans has been endorsed by the Interagency Regulatory Liaison Group, the Federal Regulatory Council, and the National Academy of Sciences.

The International Agency for Research on Cancer—(IARC)—a WHO component, which the National Cancer Institute helped to establish and continues to support, has developed criteria for "sufficient evidence of carcinogenicity." These criteria require an increase in malignant tumors: One, in multiple species or strains of animals; and/or two in multiple experiments, routes of exposure and/or levels; and/or three, to an unusual degree.

IARC also publishes monographs reviewing the scientific evidence available on studies of various compounds. In August 1977, IARC's Monograph 15 included reports on animal studies of the two ingredients which were mixed together on a 1 to 1 basis to form agent orange, 2,4-D and 2,4,5-T. In general, these are old studies, not well performed by today's standards. I'd like to briefly describe the results of these tests.

For 2,4-D, IARC reported the results of three different studies. The first test involved the administration by gavage—stomach tube—of 2,4-D to both sexes of two strains of groups of 25 mice. The increases in tumors among the dosed animals were not statistically significant when compared to the controls.

The second was a feeding study involving groups of 25 male and 25 female rats. In this study, only the males receiving the highest dose had a substantially significant increase in tumors when compared to the controls.

In the third study, groups of 18 male and 18 female rats were injected with 2,4-D. There was no statistically significant increase in tumors in any of the animals when compared to the controls.

Now I would like to review the results of the studies IARC reported on the second ingredient of agent orange, 2,4,5-T. There were three different studies reported. The first involved groups of 18 male and 18 female mice of two strains for 78 weeks. There was no statistically significant increase in tumors.

The second study involved the feeding of 20 male and 19 female mice with water containing 2,4,5-T for 2 months. There was no statistically significant increase in tumors noted. A second group of 22 male and 25 female mice of a different strain were similarly fed with treated water. In this group there was a statistical difference in tumor incidence in the females compared to the controls but not in the males.

In the final study, groups of 18 male and 18 female mice were administered 2,4,5-T subcutaneously, under the skin. Here there was no statistically significant difference in tumor incidence.

IARC judged these studies to be inadequate. None constitutes good evidence for or against the carcinogenicity of these two components of agent orange. In a standard

NTP bioassay, groups of 50 animals of two species, usually rats and mice, are used. None of the test studies I have just reviewed included more than 25 animals per group. These studies also appear to have been rather short-term studies—8 weeks—as opposed to the 103 and 104 week studies used by the NTP.

Furthermore, these tests were of two of the ingredients of agent orange, not the product itself, nor of its highly-toxic contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin—TCDD.

Agent orange surplus stocks have been examined for TCDD content. On the average, 1.86 parts per million—ppm—have been found in the herbicide with as much as 47 ppm in one sample. Thus, it is important to look at the TCDD which we already know to be one of the most toxic compounds known to determine its carcinogenicity .

This has been done. In a study by Kociba and others from Dow Chemical, groups of 100 rats were fed diets containing doses of TCDD for 2 years. Liver cancer and carcinoma of the lung, hard palate and nasal turbinates were observed. An increased incidence of squamous cell carcinoma of the tongue, hard palate, and nasal turbinates also was observed in the male rats. A study by Van Miller, Allen, and others, using fewer animals, is in qualitative agreement with the Kociba study. An increased incidence of hepatic and lung neoplasms is shown in both studies. These two studies show that chronic administration of TCDD causes an increased incidence of cancer in animals. The NTP also has tested TCDD for carcinogenicity. Results of two studies, one involving dermal exposure and the other involving gavage, were reviewed by the NTP Board of Scientific Counselors this June. These results will be published shortly.

One study, which involved painting the skin of one species of mouse for 3 days a week for 104 weeks, found the increase in fibrosarcomas in the integumentary system of the female mice to be statistically significant. However, NTP's Board of Scientific Counselors was critical of some aspects of the study, which was designed and performed on contract several years ago. The board's conclusion regarding this first study is that the results cannot be interpreted.

A second study was also reviewed by the NTP board in June. In this 104 week gavage study of TCDD, a larger number of male and female mice and rats in each group was used. At the conclusion of the study, the male rats developed thyroid tumors and the female had liver cancer. Both the male and female mice developed liver tumors and the females had an excess of thyroid cancers and other dose-related tumors as well.

The board found this to have been a well-conducted study. Under the conditions of the test, the board concluded that TCDD was carcinogenic for both rats and mice.

In summary, we have evidence reported by IARC in female mice for 2,4,5-T and in high dose male rats for 2,4-D, the two components of agent orange. Although both of these studies can be criticized for being too brief and for using too few animals, nevertheless these studies are nonetheless cause for concern.

Although judged inadequate, we have also positive evidence of the carcinogenicity of TCDD in the NTP dermal study and in the Kociba and Van Miller studies. But we have positive results for two species in the well-conducted NTP gavage study of TCDD using an adequate number of animals for an adequate amount of time.

Although IARC has not considered this evidence, it is my own judgment that the analysis of the data from all of these studies meets the IARC standard for sufficient evidence of the carcinogenicity of TCDD, the most toxic component of agent orange. Using the established principles of the Interagency Regulatory Liaison Group and the Regulatory Council, we must presume that agent orange is a human carcinogen. In other words, exposure may cause an undetermined number of human cancers.

The final question is the most difficult and that is, what sort of a threat does agent orange actually represent? Unfortunately, this is a question for which science has no adequate answer at this time. There are all sorts of confounding factors which do not permit us to extrapolate directly from animals to man.

First, there is no precise way to take the animal evidence and then use a formula that will predict how strong a carcinogen a substance may be. We would have to assume that the median human response to agent orange is equivalent to that of the laboratory animals. But this ignores the fact that our laboratory animals are specially bred so that they are genetically similar. Human beings, however, are genetically heterogeneous. Their response to toxic agents differs greatly. We know that the human population includes some highly susceptible subgroups which further confounds our ability to relate our experiences in animals to that in man.

Second, unlike laboratory animals, people are exposed to many carcinogenic substances in their daily environment. These carcinogens, which we eat, drink, and breathe and which are also absorbed through the skin, interreact with one another, sometimes in ways which suggest multiplier rather than merely additive effects.

One of the best known examples is lung cancer in asbestos workers who smoke. Their risk of cancer is far greater than those who do not smoke. The same synergistic effect occurs with smoking and exposure to radiation.

Finally, there is the problem of range of detection. Even a weak carcinogen can cause tragic results if enough people are exposed.

In conclusion, let me say that the science of toxicology is very young. Regrettably, we have too few answers. At the present time, all that we are able to do is to raise concerns about the possible hazard from substances like agent orange. It is up to you, our lawmakers, to determine what society should do to protect itself from these real threats which are as yet unquantifiable.

I would be happy to take any questions.

Chairman SATTERFIELD. You may proceed.

STATEMENT OF DR. DAVID P. RALL, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. RALL. I would like to summarize very briefly the animal findings with respect to the carcinogenicity of 2,4,5-T, 2,4-D and of dioxin and try to spend a few moments explaining what I think these findings mean.

With respect to 2,4-D and 2,4,5-T, there have been a number of studies. These are essentially negative, they are not recent studies, and they have certain lack in the number of animals tested and the length of time they are followed. The results, therefore, are not conclusive.

With respect to dioxin or TCDD, there are at least three studies. The first study was by Kociba and his colleagues at Dow Chemical reported in 1978. Second, a small study reported from the University of Wisconsin, same time. And finally, the National Cancer Institute, national toxicological program study which has been presented in preliminary form, is under review and will be published probably in early 1981.

All these studies are in essential agreement. At a dose range of about a 10th of a microgram per kilo per day in both rats and mice, there is an increased incidence of liver cancer, thyroid cancer, and possibly lung and nasal cancer. This represents a total dose for the rats of about 25 micrograms per lifetime, and for the mice, about 2.5 micrograms per lifetime. Thus, I would conclude that TCDD is a confirmed animal carcinogen.

Now, to understand what this means, I would like to just briefly review three facts that we know. First, with possibly a single exception, all chemicals that cause cancer in humans cause cancer in properly designed animal experiments. Second, many chemicals that have later been shown to cause cancer in humans were first detected in laboratory animal studies—vinyl chloride, diethyl, stilvesteral or DES, dischloralmethyl ether, others. Third, based on five or six examples, all that could be found in the literature, the amount of a chemical on a weight basis that causes cancer in a laboratory animal is in the same order of magnitude the same that causes cancer in human population. This is a conclusion of a recent NAS/NRC study. Based on what I think these three facts are telling us, it appears to me in summary that we therefore have the situation that there were some unknown number of veterans exposed to some unknown amount of dioxin in the years between 1962 and 1970. Since dioxin is carcinogenic in laboratory animals, past experience would suggest that some 20 to 30 years after that exposure, and that is from about 1982 to the year 2000, there may

be an increase in cancer incidence in these exposed veterans due to the dioxin exposure. But we must admit as scientists that we do not know.

I would also be pleased to answer your questions.

Chairman SATTERFIELD. Mr. Daschle.

Mr. DASCHLE. Mr. Chairman, I have been here all day, as you know, and as far as I am concerned the testimony just presented is some of the most informative and helpful that the committee has heard. I want to thank both of you. I have had the opportunity of meeting Mr. Moore before. I would just ask, I guess, Dr. Rall, if you could, based on what you have just said, which in my opinion is very significant, what would your recommendation be in terms of the way in which Congress pursues providing for medical care? Can one go, given the information that we now have and the correlation there appears to be between animals and humans, can one make a presumption of disability with regard to the medical problems now being experienced by some of our veterans? Is one out of bounds by making a direct presumption that given the fact that they were in Vietnam and are now suffering some of these consequences, is that presumption out of order?

Dr. RALL. It is a very difficult question you are asking. It has many implications. First, exposure in Vietnam does not necessarily mean exposure to dioxin. That is one of the problems we are struggling with. The second, we don't know whether it will be a very tiny fraction of those exposed because, in fact, they were exposed to relatively small amounts, that are likely to develop cancer or whether it is a large fraction. So that, it seems to me, is a question that we as scientists can't answer.

As I indicated, I think it is likely there will be some effect. Whether that will be 100ths of a percent, 10ths of a percent, or 1 percent I don't know. I am afraid, Mr. Congressman, that that decision has to be in your hands. As a scientist, I have said about as much as I can and still stay being a scientist.

Mr. DASCHLE. There appears to be a question of the burden of proof. That is really what we are getting down to. The burden of proof is now on those victims, if I can be so liberal with that term. The veteran is in a position at this point of having to prove that first he was there, that second there has to be some direct connection, and third that he is in need of some kind of treatment. It seems to me that based on the scientific evidence that exists today, given the fact that you have some conditions under which that evidence can be used, it seems to be overwhelming that the burden of proof should now be shifted from the veteran to the Veterans' Administration.

But again, in the interests of time, Mr. Chairman, I would defer any questions, but I would like to submit some in writing to both of you gentlemen, if I could.

Chairman SATTERFIELD. Would you gentlemen respond if that were done?

Dr. MOORE. We would be delighted.

Dr. RALL. Happy to.

Chairman SATTERFIELD. That would be very helpful.

Dr. RALL. Could I make one statement that I think might help the subcommittee a little bit. There has been much talk of the

desirability of epidemiological study to try to understand what has happened to the people, the veterans. I am very much in favor of epidemiology. I think it is an absolute cornerstone of the structure that is necessary to solve this sort of problem. But let me remind you all that between the time there was the first reasonably good study linking cigarette smoking with lung cancer to the time that that link was considered established in the medical community was 20 years and took 15 separate studies. I think that is something that should worry us all.

Mr. DASCHLE. I think the point is very well taken. We have a choice, as you outlined in your excellent formal statement here, of going two different routes when it comes to scientific research. One is the epidemiology work, the other is that work done with laboratory animals. If the preponderance of information from laboratory animals indicates that there is a connection that can be drawn, it seems to me that we have at least evidence enough to provide for that presumption as long as the epidemiology study at some point doesn't overturn the evidence provided by the laboratory study with animals. From that point of view, I think we can make a very strong case. Thank you, Mr. Chairman.

Chairman SATTERFIELD. I just have two questions. First of all, I have wholeheartedly endorsed the concept of an interagency advisory group as it seems to me that we have different levels and kinds of exposure to dioxin which really ought to be investigated. Is there any general epidemiological study or whether one is even possible in terms of exposure to this toxic agent to the general population in the United States?

Dr. MOORE. Let me answer that a little broader than you asked it, Congressman. One thing that is clear that has occurred over the past years, a number of industrial accidents where exposure was very great. Fortunately, all of these accidents involved rather small numbers of people, with the possible exception of Seveso, Italy, where the numbers are in the thousands. This probably represents our oldest exposed population and also may be our most heavily exposed population, at least from the dioxin standpoint. And indeed it was mentioned earlier today, there is an attempt by the National Institute of Occupational Safety and Health to assemble a U.S. registry of all these workers who were exposed. We are also trying to work with the International Agency for Research on Cancer, which is part of the World Health Organization, to make that an international registry since a number of our more dramatic exposures occurred outside of this country.

There also has been planned, and in fact some are underway, studies with more generally exposed populations or worker populations, applicators, pesticide applicators, in this country, looking for possible effects of birth defects.

Chairman SATTERFIELD. I know you are talking about specialized and specially identified groups, but is there or is there not a danger that the vast majority of the people in this country have been subjected to some level of exposure simply by the general use of dioxin in pesticides and herbicides?

Dr. MOORE. This is indeed a compounding factor that is legitimately raised, that any time you try to look at a group and then

say you are going to look at a control group, that indeed the specter is the control group has also been exposed to phenoxy acids.

Chairman SATTERFIELD. The next question that I am leading to is the one that has bothered me a little bit. If that may be a fact, then in attempting to identify the health effects of specific exposure in Vietnam, we are really looking for something that would increase the exposure of the general population in the first place, which I assume would make it just that much more difficult?

Dr. MOORE. Doesn't make it any easier.

Chairman SATTERFIELD. Because those people in Vietnam have also been exposed as part of the general population of the United States both before and after.

Dr. MOORE. Right. There is some consideration to looking at some populations in this country whose exposure may be, quote, fairly clean. If you go to a typical chemical company, they have been exposed to this, but they have also been exposed to 17 other things and, if you find an effect, you don't know what it is due to. There is some possibility that wheat farmers in this country are very heavy and somewhat exclusive use of 2,4-D and indeed they may be a population to look at and see if indeed more domestic use may be the cause.

Chairman SATTERFIELD. I just have one question of Dr. Rall. I think you testified that there have been some animal tests and three cancer tests particularly with mice. You also said that in those cases where you find a cause of cancer or carcinogen in humans that invariably that same carcinogen shows up in animal studies. I noticed in reverse that you stated that in many cases where cancer is found in animals, it is also found in humans where the chemical was on the same order of magnitude, animal to human. I would like to ask this question. You mentioned that in one of the studies that TCDD appeared apparently in levels of 25 micrograms over a lifetime, and I don't remember what animal that was.

Dr. RALL. That was a rat.

Chairman SATTERFIELD. A rat contracted cancer. I wonder if you could tell me, in making the magnitude conversion to the human, what would this be tantamount to exposure on the part of a human and for how long a period?

Dr. RALL. My view is that the conversion factor from rat to man should be about 6, so that would be 125 micrograms. There are some people who say it would be much higher.

Chairman SATTERFIELD. That would be every day during his life?

Dr. RALL. That is the total exposure over a life.

Chairman SATTERFIELD. Over a lifetime. The reason I asked the question, I remember we had a somewhat similar question raised in the rat study on saccharin and the conversion there was astronomical.

Dr. RALL. This is probably not.

Chairman SATTERFIELD. I thank you very much, gentlemen. We appreciate very much your coming and giving us the benefit of your views. We would appreciate your answers. Thank you very much.

Our final witness today, and again I am very sorry to have kept him waiting so long, is Mr. Guy McMichael, General Counsel,

Veterans Administration. Mr. McMichael, we are glad to see you again and welcome you.

Mr. McMichael. Thank you very much. It has been a long day and in the interest of trying to expedite the situation, I will submit my entire statement for the record and let me just make a few general remarks.

Chairman Satterfield. Without objection, your statement will be admitted at this point in the record.

[The following was received for the record:]

Prepared Statement of Guy H. McMichael III, General Counsel, Veterans' Administration

Mr. McMichael. Mr. Chairman and members of the committee. Good morning. I am pleased to have this opportunity to appear before you today to update you concerning the progress of the Veterans' Administration in dealing with the complex issue of agent orange and other phenoxy herbicides utilized as defoliants during the period of conflict in Vietnam.

With me today are Dr. Barclay Shepard, Special Assistant to the Chief Medical Director, Mr. John Wisniewski, Deputy Director, Compensation and Pension Service and Dr. William Jacoby, the Deputy Chief Medical Director.

Mr. Chairman, since we last appeared before you in February 1980, the agent orange issue has continued to generate a great deal of public concern regarding the possible health impact of this defoliant upon our Vietnam veteran population and their families. This concern is genuine and is evidence of the real fears of many of those who believe they may have been exposed to this chemical agent. I wish to assure this subcommittee that the Veterans' Administration is fully cognizant of these concerns and fears and of the need to find answers as soon as possible. As you know, the problems are many and often their solutions are elusive and extremely complex. There is much we still do not know about the adverse health effects of the components of agent orange upon a human population, and it should be recognized that we may never be able to clarify completely the entire matter of the long-range health effects of agent orange. We are committed, however, to the rigorous pursuit of a resolution of this complex issue in a forthright and scientific manner.

Today, I would like to describe to the committee the several agent orange related activities in which we have been engaged since our most recent testimony in February. The VA, of course, is only one of many bodies that are working to resolve this issue. Our activities have involved us in establishing a closer working relationship with other Federal and non-Federal agencies and scientific institutions, as well as with individual scientists and researchers who are working in this area. We have been in contact with the Governments of Australia and New Zealand, nations which also participated in the Vietnam conflict, whose veterans have also expressed fears and concerns about their exposure to agent orange. In my testimony today, I will update you on the activities of the Veterans' Administration and explain our role relative to the activities of other Federal agencies.

When the issue of agent orange first surfaced, it was difficult, if not impossible, to foresee the level of activity in which we would ultimately be engaged. At first, the task of coordinating agent orange activities was given to our Assistant Chief Medical Director for Professional Services within the Department of Medicine and Surgery—D.M. & S. as one of his many areas of responsibility. With the increased level of interest and activity, it became apparent that a centralized control point within D.M. & S., exclusively devoted to handling the heavy demands of the agent orange program, was necessary. To provide this essential administrative control, the Office of Special Assistant to the Chief Medical Director for Herbicide Orange Affairs was established in April 1980. Dr. Barclay M. Shepard was selected to serve in that position. It is the responsibility of that office to: One, respond to agent orange inquiries; two, recommend policy to the newly formed Policy Coordinating Committee, about which I will comment in a moment; three, direct the activities of the VA's Advisory Committee on health-related effects of herbicides; four, establish liaison with other Federal and non-Federal agencies and institutions; five, oversee the agent orange functions of the 180 environmental physicians in our 172 VA medical centers and 8 independent outpatient clinics; six, coordinate the conduct of special agent orange studies; and, seven, serve as special adviser to the Chief Medical Director on all matters concerned with the agent orange issue.

The tasks assigned to the office are many and varied. It is an office which we believe will best serve the needs of this agency in responding to the agent orange

problem and ultimately, serve the needs of our Vietnam veteran population and their families.

The magnitude and complexity of the agent orange issues have also dictated the need to establish a high-level policy coordinating body for the entire agency. Consequently, in June 1980, a special Agent Orange Policy Coordinating Committee (PCC) was established. This committee serves as the central coordinating point to review all aspects of agent orange activities within the VA and to develop and establish new policy initiatives. The Administrator has appointed me to chair this committee. Members are selected because of their relationship to, or knowledge of, the agent orange program and represent a base of expertise essential to the mission of the committee. This committee generally oversees the activities of the Special Assistant to the Chief Medical Director and maintains a close liaison with that office and the day-to-day activities for which it is responsible. The relationship is one of mutual support in implementing policy developed by the PCC and carrying out the medical aspects of that policy by the Office of the Special Assistant. We anticipate that this newly formed committee will prove useful in coordinating the many and diverse agent orange activities with which the Veterans' Administration is involved.

The Advisory Committee on the Health-Related Effects of Herbicides has continued its valuable role in providing for the exchange of scientific information concerning herbicides and their possible adverse health effects, advice to the VA on future courses of action, including appropriate research efforts, and coordination among the various agencies represented. This committee's function remains that of assembling and analyzing the information which the VA needs in order to formulate policy and implement procedures in the interests of our Vietnam veterans. The committee, in this regard, has a factfinding advisory role and may on occasion recommend policy for consideration by the Agency. We believe that the committee membership is balanced and reflects a broad range of scientific and medical expertise, as well as representing various veterans groups who are concerned with the agent orange issue.

The advisory committee holds quarterly meetings which are open to the public. The committee has held five meetings since June 1979, the most recent being held August 6, 1980. We encourage the submission of questions by representatives of the public or private agencies and by concerned individuals who may be in attendance at these meetings. In accordance with the provisions of the Federal Advisory Committee Act, a formal transcript of these meetings is prepared and is made available to various Government offices and interested individuals.

The committee has acted on several significant agent orange related issues including the following: (1) Considered the various aspects of an epidemiological study of Vietnam veterans exposed to agent orange; (2) recommended that VA closely monitor epidemiological studies performed on other population groups exposed to the chemical components of agent orange in conjunction with agriculture and forest management as well as exposure resulting from industrial accidents; (3) discussed the effects of agent orange on the male reproductive system; (4) discussed the variables involved in attempting to define a threshold level of exposure to dioxin which might result in toxic effects in humans; and (5) explored the types of animal studies that might be performed in order to define the effects of human exposure to agent orange.

Copies of the recent study of male mice exposed to the components of agent orange were provided to members of the advisory committee for their review and analysis at the August 6 meeting. We are now in the process of assembling and reviewing the comments on that study which have been submitted by the committee members. Copies of the Swedish and West German studies on workers exposed to dioxin have also been distributed to advisory committee members with a similar request for their analysis and comment regarding the significance of each study.

In this regard, Mr. Chairman, I am aware of your continuing interest as expressed in a recent letter concerning our current views of these studies. Pending a report from the advisory committee, I can state that the Veterans' Administration supports the views expressed by the scientific panel of the Interagency Work Group, on which the VA is represented, and by the Office of Technology Assessment. We fully agree that these studies provide credible and valuable leads in the scientific pursuit of the health effects of exposure to phenoxy acids. We do not believe, however, that they answer the question as to whether there exists a causal relationship between exposure to phenoxy acid herbicides as used in Vietnam and the appearance of various types of malignancies. We note the use of the term "correlation" by the scientific panel in commenting on the Swedish studies. I am informed that when used in the scientific context, the term means "coexistence" of two factors, not a "cause and effect" relationship.

The advisory committee on the Health-Related Effects of Herbicides will continue to function as an important focal point of our efforts to find answers to the questions about adverse health effects resulting from the use of phenoxy herbicides in Vietnam or elsewhere and to communicate with the public concerning these matters.

In addition to seeking advice and recommendations from our own advisory committee, we have actively participated in the efforts of the Interagency Work Group To Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants which was established by the White House in December 1979. The Interagency Work Group (IWG) is responsible for monitoring and coordinating Federal research effects of herbicides such as agent orange and is charged with reporting to the White House the results and implications of these efforts as well as recommending policy to the White House. The work group is chaired by Joan Z. Bernstein, General Counsel of the Department of Health and Human Services. It includes representatives of the Department of Health and Human Services (DHHS), Department of Defense (DOD), and the Veterans' Administration. Representatives of the Environmental Protection Agency, the Departments of Agriculture and Labor, the White House Office of Science and Technology Policy and the Congress Office of Technology Assessment also participate as observers. The IWG, which meets on a monthly basis, utilizes the services of its scientific panel to review, analyze, and comment on research activities already underway or being planned by Federal agencies and non-Federal research organizations.

We believe that the efforts of the IWG and of its scientific panel have been extremely helpful to us and we look forward to continued active participation and cooperation.

The agent orange registry was initiated in 1978 shortly after the VA became aware of the serious nature of the herbicide issue. It was one of the early steps taken by the VA to attempt to evaluate the magnitude of the problem. The purpose of the registry was to identify those veterans who were concerned about the possible health effects resulting from exposure to herbicides in Vietnam and to document baseline medical information on individual veterans who might later develop illnesses which could be related to earlier herbicide exposure. The information was derived from the answers to the questionnaire, a physical examination and a set of baseline laboratory tests. It should be clearly understood that it was never the intent that the registry would serve in any way as a portion of a research study. It was intended to be and remains simply a catalog of a self-selected group of Vietnam veterans with some baseline medical information relating to them.

To date, approximately 30,000 veterans have been examined and the data from approximately 12,000 have been entered into the computer. We have, of course, been curious as to what insight an analysis of this information might yield. To assist us in the evaluation of the information contained in the registry, a data analysis task force has been established. This group of individuals with special expertise in the areas of biostatistics and automated data processing technology as well as familiarity with existing VA computer files, has been carefully examining various aspects of the registry in order to evaluate its current and future usefulness. The task force is currently reviewing the available information and is developing a data retrieval system which will provide a description of some of the health problems being experienced by those veterans who are enrolled in the registry. The registry continues to remain a useful mechanism for identifying concerned Vietnam veterans, for providing some medical information concerning these individuals, and for assisting us in maintaining contact with all participants. We are now developing a followup plan to reassure all individuals in the registry that we will make every effort to maintain contact with them and keep them informed on any new developments relating to the agent orange issue.

As was indicated in our testimony in February, chloracne has been the only long-term finding which has been consistently recognized as resulting from exposure to dioxin, a contaminant of agent orange. A diagnosis of chloracne is based upon the distribution and type of lesions and a history of exposure to dioxin. However, it is not always easy to distinguish between chloracne and other more common forms of acne. In response to concerns expressed before this committee and in order to take advantage of the best possible expert advice, a special chloracne task force was recently assembled. This group, which consists of four distinguished dermatologists, has been given the responsibility of designing a protocol for chloracne examinations and of preparing special educational materials to be utilized for the training of other dermatologists and our environmental physicians. The task force has also been given the responsibility of identifying a larger group of dermatologists who could serve as special consultants for chloracne cases as well as aiding in the adjudication of such cases by the VA. We are now in the process of reviewing

previous adjudications in this area to assess the validity of our earlier findings. Some educational materials have already been prepared by the task force and are currently being reviewed. It is our goal to make these materials available to our physicians in the near future.

Public Law 96.151 mandates the conduct of two major efforts by the VA relative to agent orange: An epidemiological study of Vietnam veterans exposed to phenoxy herbicides and a review and analysis of the world's literature on phenoxy herbicides.

The Veterans' Administration is undertaking to contract with an epidemiologist from outside the Federal Government to design the protocol for the required epidemiological study. We have utilized an open, competitive bidding process. The proposals which we received have been critically reviewed and evaluated by a panel of experts, the majority of whom came from outside of the Veterans' Administration. The membership of this panel included: Dr. Robert Hoover, Assistant Chief, Environmental Epidemiological Branch, National Cancer Institute; Dr. Gilbert Beebe, Clinical Epidemiology Branch, National Cancer Institute; Dr. Joyce Lashoff, Assistant Director, Health and Life Sciences Division, Office of Technology Assessment; and Dr. John Kurtze, Chief, Neurology Service, Washington, VA Medical Center. Also serving on the panel as a nonvoting member was Dr. Lawrence Hobson, who at that time was Deputy Assistant Chief Medical Director for Research and Development. A recommendation has been made by the panel and negotiations for a contract will be initiated in the near future.

The process of selecting a contractor has been impeded somewhat by actions taken by the National Veterans Law Center. In May of this year the center attempted to obtain a temporary restraining order to preclude the Veterans' Administration from opening any proposals for a contract for the design of the epidemiological study. The basic contention of the center was, and continues to be, that in their view the solicitation would not result in a proper and adequate protocol for the mandate study. Further, it was contended that the Veterans' Administration should not carry out the study but rather the responsibility for conducting the study should be given to some unbiased and independent organization.

Judge Harold Green of the U.S. District Court for the District of Columbia denied the center's motion for a temporary restraining order stating that the complaints made by the center were premature since it could not be determined that the ultimate study design would be deficient or defective until after it was prepared and subjected to careful review and analysis. The court retained jurisdiction of the case and advised the parties that if, after the development of the protocol, the center still believes it has been harmed in some fashion, it could again seek a preliminary injunction.

Subsequent to the denial of the motion, the National Veterans Law Center filed a protest with the General Accounting Office alleging irregularities or violations of procurement laws, rules, and regulations committed by the Veterans' Administration in the procedures utilized to select a contractor. We are unable at this time to forecast when a final resolution by the General Accounting Office will be achieved. We are, therefore, somewhat constrained from proceeding with the mandated epidemiological study at this time.

Once a contract has been awarded, a study design will be prepared and will be submitted to several groups for their review and comments. These reviews will include the Veterans' Administration Advisory Committee on Herbicides, the Interagency Work Group To Study the Possible Long-Term Health Effects of Phenoxy Herbicides, and the Congressional Office of Technology Assessment. Additionally, we are planning to request the National Academy of Sciences to select a panel of epidemiologists to review the proposed protocol. Once the protocol has been approved, a determination will be made as to what organization will actually carry out the study. In arriving at that decision, we will be seeking the advice of many parties, not the least of which will be our oversight and appropriation committees in Congress. Consensus will also be sought from the Interagency Work Group on this issue.

It is hoped that this study will be underway by late 1981. It should be emphasized that although some early findings and conclusions may be reported, more definitive answers will not be available for at least a decade or more. While this is frustrating to all who want quick answers to this complex issue, the fact remains that any possible long-term adverse effects on human health must of definition wait for a sufficient passage of time. We can reasonably expect some conclusions resulting from a study of this magnitude, but should not expect that this, or any other study, will provide all the answers we might want to obtain. In any event, on both a short- and long-term basis, the VA will vigorously seek answers to this most complex issue. Nevertheless, some basic information about the health status of Vietnam

veterans should be available in a few years. That data should enable us to make those informed governmental policy decisions that will need to be made.

The second major effort mandated by Public Law 96-151 is a review and analysis of the world's literature on phenoxy herbicides. The Veterans' Administation has already undertaken an extensive review of the literature and is aware of much of its content. The goal of the mandated study is the preparation of bibliography with an annotated review and analysis of the literature on phenoxy herbicides and of the contaminant, dioxin or TCDD.

In view of the large volume of the literature and technical complexity of the subject matter, it was decided that this task would best be accomplished by contract. A number of proposals have been submitted and a panel of experts will soon begin its review of them.

The provisions of Public Law 96-151 require that a report on the literature review and analysis be submitted by the VA to Congress by December 20, 1980. It is currently anticipated that completion of this review and analysis will require approximately 9 months from the date the contract is awarded.

Many research activities by other agencies concerned with the toxicity of phenoxy herbicides were described in the previous hearings in February. The VA continues to monitor with interest the progress of these studies.

Earlier this year the Center for Disease Control (CDC) proposed a study to determine if Vietnam veterans have a greater than normal risk of fathering children with birth defects. This question has been the source of considerable concern among our Vietnam veterans and their wives. We believe that a carefully designed and conducted study of this type would shed considerable light on this vexing and emotional issue. The CDC has received preliminary approval of the study from the Interagency Work Group and the protocol is currently in the review process. It is anticipated that the study will be jointly funded by HHS, DOD, and VA.

We are also continuing our active cooperation in the agent orange registry at the Armed Forces Institute of Pathology—(AFIP)—for pathologic materials from veterans with possible exposure to herbicides during the Vietnam war. Currently, there are 79 cases entered in this registry. An analysis of these cases is being conducted as material is submitted. Although the number of cases is still very small, to date there is no evidence to suggest any increase in prevalence of a disease or group of diseases above the expected incidence. In order to expand the number of cases submitted, the VA has requested the AFIP to increase its efforts to encourage both civilian and Federal hospitals to submit case material whenever appropriate. The VA has been given every assurance that the AFIP is willing and able to comply with this request.

The VA is likewise monitoring with interest the progress of the ranch hand study. Because of the unique nature of this study cohort with regard to known exposure to agent orange, this effort has peculiar and significant importance. The VA strongly endorses this study and has recommended that it be given full support.

Mr. Chairman, we are cognizant of the concerns of Congress and of our responsibility to inform concerned individuals of our activities regarding agent orange and of keeping them abreast of the latest developments concerning the agent orange issue.

Some of our more significant activities in this area have included an education conference on agent orange which was held in Silver Spring, Md., on May 26-28, 1980. This follow-up conference to the one held in Washington, D.C., on September 27, 28, 1979, was attended by our 180 environmental physicians and 54 adjudication staff from our Department of Veterans' Benefits. Presentations were given by several of the country's leading experts on herbicides and included discussions of current knowledge regarding: One, the chemistry, toxicology and metabolism of agent orange in experimental animals. Two, the manner in which herbicides were used in Vietnam. Three, the environmental fate of agent orange constituents. Four, known and suspected human health effects of agent orange constituents. Five, approaches to the epidemiological study of the effects on humans of agent orange. Six, how Vietnam veterans view the agent orange issue. Seven, latest VA agent orange initiatives and policies. Eight, the need for compassionate service to veterans concerned about agent orange.

In our continuing effort to keep our Vietnam veterans advised concerning agent orange activities, an information pamphlet "Worried About Agent Orange?" has been prepared and distributed to 172 VA medical centers, 8 independent outpatient clinics, 91 Vet outreach centers, 58 VA regional offices, Members of Congress, State veterans' affairs offices, veterans service organizations, and to other concerned agencies and individuals. The pamphlet, prepared in cooperation with the Interagency Work Group, provides a concise overview of agent orange.

Additionally, we are in the process of preparing two educational films on agent orange, the first of which will further inform veterans concerning what is known about agent orange and advise them of the agent orange registry. The second film will soon be initiated and will serve as a training device for VA physicians and administrative personnel. Both films will be available for general public use upon request.

We will shortly begin publication of a newsletter which will serve to provide information and guidance to 180 environmental physicians and other VA medical staff concerning agent orange related activities. We will continue to review our education and information program on a regular basis and make such modifications as warranted by the situation.

In conclusion, the Veterans' Administration continues to be concerned about the agent orange issue and is striving to resolve it as expeditiously and reasonably as possible. As we have become more involved in the pursuit of answers to this problem, we have come to appreciate more fully the complexity of the many variables which impact on the agent orange controversy. The seriousness of the issue and the very real concerns of Vietnam veterans and their families are a constant motivating force for responsible and effective actions and programs. Unfortunately, we cannot provide all the answers to the many questions being raised today nor will we be able to do so in the immediate foreseeable future. As was indicated at the time of our last appearance before this committee, the scientific inquiry process necessary to produce accurate reliable information does not lend itself to quick answers. We hope that the epidemiological study, the literature analysis, and all other research endeavors concerned with agent orange will assist us in providing definitive, scientifically valid answers. It must be stated that this process will take many years with no guarantee that all the answers will be found. We only guarantee that our search for answers will be supported by the full energy and resources at the disposal of the Veterans' Administration.

I cannot state in strong enough terms that in the interim it has been and will be the stated policy of the Veterans Administration that no eligible veteran will be denied medical care and treatment by the VA because the answers are not in. Our goal remains to provide compassionate and understanding service. This is a responsibility that we take very seriously.

Chairman SATTERFIELD. Before you begin, I wonder if you could identify the gentlemen with you so that it can be reflected in the record.

STATEMENT OF GUY H. McMICHAEL III, GENERAL COUNSEL, VETERANS' ADMINISTRATION

Mr. McMICHAEL. Yes, I would be happy to. Dr. Barclay Shepard, who is Special Assistant to the Chief Medical Director, dealing with issues of agent orange. And Mr. John Wisniewski, Deputy Director, Compensation and Pension Service. I also have a number of people from the agency to help respond to possible questions you might have.

This has been a long day but I think it has been an illuminating one in many respects. I would like to offer a couple of general observations. First, I think it is obvious from a variety of perspectives that there is genuine concern about this issue. I know there is genuine concern on the part of the committee and I would hope that you would grant the Veterans Administration the same presumption that there is genuine concern on the part of the Veterans Administration at getting to the bottom of this question.

I think it is also fair to say that we could have done more sooner. Perhaps we didn't recognize the seriousness of this issue as soon as we should have. I do think we are now trying as expeditiously as possible to proceed on as many routes as possible to find answers. And it is clear that we all want answers now and no one would desire to find those answers right now more than the Veterans' Administration. At least our concern is equal to that of this committee.

It seems to me that the central concern that faces the Veterans' Administration, and I think this committee in its jurisdiction, is really the question, "Are Vietnam vets suffering health problems that are either qualitatively or quantitatively different from their non-Vietnam veteran peers?" It seems to me that is the central question. What caused that health difference, if in fact there is a health difference, is really of less concern to us right now than whether, in fact, we can find out if there is some kind of health problem.

In attempting to find the answers to this, it seems to me that we have two competing objectives; both of those objectives are worthwhile but they tend to conflict with each other. The first is that we would like to get the answers as quickly as possible. There are a lot of people out there who are genuinely concerned and want prompt answers. At the same time, we want a competent study done. The very factors that lead into doing the kind of competent study, one that stands up to scrutiny, one that can't be criticized that it was hasty, that it did not take this or that into consideration, obviously requires some time. It has to be recognized that there are tradeoffs and, if we are going to do a competent study, it is in fact going to take some time. We have yet to be able even to issue a contract to have someone help design a protocol. If and when that is done, the so-called protocol that will then be designed by the contractor will then be subjected to an intensive review by a number of bodies. I think this is good. I think we need that kind of——

Chairman SATTERFIELD. Would you yield for a moment? Would you mind telling us why you have not been able to contract?

Mr. MCMICHAEL. We were first sued by the National Veterans Law Center seeking a temporary restraining order. The temporary restraining order was denied, but a bid protest has been filed with the General Accounting Office and, until that bid protest is resolved, we are constrained from going forward.

Chairman SATTERFIELD. So you are in a position where you cannot proceed even though you may wish to?

Mr. MCMICHAEL. That is correct. So we are going to have a long review of the protocol. I hope we can try to get this done as quickly as possible, but I would be less than candid if I didn't say that in order to get the kind of protocol that everyone agrees is a fair and complete one is going to take some time.

There has been a lot of talk today about what the scientific evidence shows, whether we have enough information to make the policy decisions. And it seems to me there is a difference here. Final scientific answers, the sort of answers that are satisfactory to the scientific community, fully in consort with the scientific method, are obviously going to take a long, long time before we get those definitive answers. At least the evidence today would seem to suggest that they are going to take a long time.

On the other hand, it may take less time to obtain enough information in order for Congress to make a rational policy decision. The question today and the one in which there seems to be some difference of opinion is do we have the kind of baseline data now to make those basic policy decisions? We don't believe we have that kind of baseline data today. We think we are going to be able to get some of that, and we hope we will be able to get it within the

next 2 to 3 years. Certainly the CDC study will be of great interest. And if we get some basic information about the health status of Vietnam veterans and how that health status compares to non-Vietnam veterans in terms of rates of cancer or what have you, it seems to me this committee will have the kind of information it needs to make basic policy decisions, but I don't believe you have it today.

With that, I will be happy to answer questions.

Chairman SATTERFIELD. Thank you.

Mr. Daschle.

Mr. DASCHLE. Could you guess as to when you might have the protocol? I mean, you know what the legal ramifications are at this point with the GAO.

Mr. MCMICHAEL. Assuming that we can issue a contract within a relatively quick period of time, I don't know exactly when that bid protest will be resolved, but assuming it is resolved in the next month or so, I would hope that we would have, and maybe Dr. Shepard could comment on it because he is probably more familiar than I am. I would hope we would have a protocol—at least we have the ranch hand experience which ought to help us in terms of developing it—which has been reviewed by a number of bodies within a year.

Mr. DASCHLE. Within a year?

Mr. MCMICHAEL. Yes.

Mr. DASCHLE. Let me ask you this, have you changed the status of chloracne as a disability in regard to whether it is considered now service-connected or non-service-connected?

Mr. MCMICHAEL. I think there has been some confusion about this and let me try to state it as best I understand it and maybe Mr. Wisniewski can add to it. If a veteran presents himself to the VA with a claim of a disability and the claim of disability is chloracne, if we can ascertain that he in fact has chloracne, and can relate the onset of that chloracne to some period of his military service, then we will service-connect that.

Mr. DASCHLE. You will service-connect it?

Mr. MCMICHAEL. Yes.

Mr. DASCHLE. On what basis? Obviously there is nothing on his medical record to show that he had chloracne because it was acquired after his date of separation. So it is using his word that obviously, you don't have to take his word that he has it, you can see that, but the fact was that he served in Vietnam, he has now developed chloracne and to you that is good enough.

Mr. MCMICHAEL. It would depend on when they had the first manifestation. If a veteran walks in to our claims office and says, "I was discharged in 1968 and for the first time last week I had an outbreak of chloracne," I believe the scientific evidence would not be able to relate at the present time the first outbreak of chloracne 12 years following service, that period of service. If, however, he came in and said, "I have chloracne, and although not in my service record I can present evidence that shows that that chloracne developed in service or within a reasonable period following service," then I believe we can service-connect him.

Mr. DASCHLE. Do you base that decision that the VA has now made on the scientific evidence that is presented that shows a

relationship between his time in Vietnam perhaps and the causal effect that he has now with the symptoms of chloracne?

Mr. McMichael. I am not sure I understand your question.

Mr. Daschle. I guess I don't know why there has been a shift in policy, so to speak?

Mr. McMichael. I don't believe there has been a shift in policy. It may be that we have been inarticulate in expressing it.

Mr. Daschle. You have always considered chloracne as a service-connected disability?

Mr. McMichael. We take someone who comes to us with a disability, the first thing we have to do is establish that, in fact, they have some form of disabling condition. Then if we can relate the onset of that disabling condition, its occurrence, to a period for which military service occurred, then we can service-connect his disability. This has always been our policy with respect to disability claims.

Mr. Daschle. What do you base the service connection on? I guess I don't understand that.

Mr. McMichael. If, in fact, someone developed either chloracne or acne, for that matter, for the first time in service, if one develops flat feet for the first time in service, we can service connect those flat feet simply——

Mr. Daschle. But you have no record of his developing that on most of these medical reports.

Mr. McMichael. We may or we may not. I am not sure what you base your——

Mr. Daschle. What I have understood this policy to be now is you will provide service-connected medical care to chloracne cases that had not been established on medical records prior to the date of separation.

Mr. McMichael. We provide service connection in a variety of situations for disabling conditions independent of whether or not it was noted in a person's military records.

Mr. Daschle. But as I understand it now, in this case, chloracne hasn't been one of those service-connected disabilities that you have been providing care for and that this is now somewhat of a change.

Mr. McMichael. I do not believe that there has been a change in policy.

Mr. Daschle. Are we under the second bell already, Mr. Chairman?

Chairman Satterfield. We will recess for a moment and we will try to vote.

[Brief recess.]

Chairman Satterfield. The subcommittee will come to order. Mr. Daschle, I believe you had the floor.

Mr. Daschle. Thank you. I want to follow up now with a question that relates to a statement that you made earlier. You said that you have other means of establishing service connection other than the veteran's service record. What other means are there that the VA uses?

Mr. McMichael. I would like Mr. Wisniewski to respond to that.

Mr. Wisniewski. There are a variety of ways by which service connection can be established. Of course, the easiest and principal

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way is the service records that are kept by the military, treatment records, and the separation examination report which describes disabilities. But subsequent to service a man may, for example, get a disability which has a known incubation period, such as poliomyelitis, and if this disability occurs within that incubation period, we can hold by the application of sound medical principles that the disability must have had its inception during military service and thereby is service connected. That is one way. Then we have presumptive service connections. Presumptive service connections are utilized where you have usually a chronic constitutional disease, there is nothing in the service records to show it, the disease has a vague subclinical way of beginning.

Mr. DASCHLE. You now have 40 presumptive diseases that are——

Mr. WISNIEWSKI. Yes, we have 40 presumptive conditions, most of them are chronic constitutional conditions. Most of the presumptive periods are 1 year and in some cases——

Mr. DASCHLE. Seven.

Mr. WISNIEWSKI. In one case we have 7 years, that is multiple sclerosis, and that is because multiple sclerosis is a condition which is very insidious in its onset, in the early years has transient symptomatology which is not readily recognized by even physicians when a person reports for treatment, and it is usually fairly well advanced before it is affirmatively diagnosed. Sometimes this may take years. For that reason, the Congress set up a 7-year presumptive period in this particular instance.

Tuberculosis has a 3-year presumptive period. In only one case are we more generous than that and that is in the case of POW's nutritional deficiencies and in those cases for POW's those kinds of conditions, avitaminosis, pellagra, and so forth, we have an open-ended presumption. So service connection may be presumptively established.

Mr. DASCHLE. Are you going to use presumptive disability for the 850 Vietnam veterans that you are going to reexamine who may have skin conditions that resemble chloracne? In other words, you obviously can't use the first criteria you just mentioned. Obviously you would have to use the presumptive.

Mr. WISNIEWSKI. No, we don't have to use the presumptive. For example, in the several instances, the herbicide area being one of them, the others are radiation and asbetosis, if we had an exposure during service for instance in radiation, we know that a man got a certain dosage of radiation, then 20 or 30 years later he developed the type of a carcinoma that the medical profession can tell us is probably due to that radiation dosage during service, we have a cause-and-effect relationship. The cause was incurred in service. If the cause was incurred in service, we can directly service connect that condition and we can do that for herbicides.

We are conceding in most cases now, except where it is highly improbable that a man had some exposure to herbicides during Vietnam service, and that being the case, if he subsequently develops a disability and the medical profession tells me that this disability is the likely effect of herbicide exposure, we can service connect and we will.

Mr. DASCHLE. When you say disability, you are only talking about chloracne at this point.

Mr. WISNIEWSKI. At this point the only disability that I know of that is directly relatable to the type of herbicide exposure that veterans had in Vietnam, would be chloracne. In this case we have service connected. We have only had 22 claims, incidentally, of chloracne to date, specifically alleging chloracne. On a medical examination we were only able to confirm three cases. Those three cases have been service connected.

Mr. DASCHLE. I still have to ask, because it seems to me that what you are telling me represents a change in policy.

Mr. WISNIEWSKI. Not really.

Mr. DASCHLE. When was the last time prior to 1976, arbitrarily selected, that you provided that kind of compensation and medical treatment for herbicide exposure?

Mr. WISNIEWSKI. For herbicide exposure per se, we don't provide treatment and we don't provide disability compensation. No more than we provide compensation and treatment for exposure to bullets. We provide compensation and treatment for the end result, if there is one, the disability that results.

Mr. DASCHLE. There is a big difference between service connected and nonservice connected and you now categorize chloracne as a service-connected disability. Even though you have no way of knowing where that service-connected disability originated, you are using this presumptive disability criteria that you outlined, is that correct?

Mr. WISNIEWSKI. It is not really a presumptive, it is a cause and effect.

Mr. DASCHLE. We don't know what cause it was.

Mr. WISNIEWSKI. We are conceding that if a man served in Vietnam, he has exposure to herbicides. And having done that, if he develops chloracne within a very reasonable period after the service or during service, it doesn't matter what caused it. We will service connect any condition that is coincidental in point of time with military service except conditions that are congenital or conditions that are caused by willful misconduct of some kind. But other than that, if they are developed during service, we don't care what the cause is. We will service connect them and pay compensation for them if they are disabling to any compensable degree.

Mr. DASCHLE. What about the carcinogenity, the cancers that have now been linked in these studies and liver dysfunctions, are they considered service-connected disabilities?

Mr. MCMICHAEL. I don't think the evidence has established a cause/effect relationship here.

Mr. DASCHLE. We are talking about presumptive, which is what he was talking about earlier with chloracne.

Mr. MCMICHAEL. No, we are talking about cause and effect and of the likelihood of the exposure occurring during a period of service. In the case of the Swedish and West German studies, what you have seen so far is a correlation but not a cause and effect.

Mr. DASCHLE. What about laboratory animals?

Mr. MCMICHAEL. That is not an established cause and effect with relation to disabilities that have been claimed so far.

Mr. DASCHLE. May show a cause and effect, but what you are saying is that cause and effect in laboratory animals cannot be transferred to humans, is that what you are saying?

Mr. MCMICHAEL. No, I am not saying that. I am saying the fact that I drink saccharin doesn't establish that if I develop cancer that that cancer is the result of my having ingested saccharin.

Mr. DASCHLE. First of all, you are not denying that there is a cause and effect in laboratory animals.

Mr. MCMICHAEL. Oh, yes, there is a cause and effect in laboratory animals.

Mr. DASCHLE. OK, and what you are saying then is that you would disagree with the policy that I outlined earlier, articulated by the Occupational Safety and Health Administration, that where that cause and effect exists a presumption can be made with regard to its effect on humans.

Mr. MCMICHAEL. It would seem to me that it depends on the purpose for which you are making presumptions. If you are making presumptions with respect to allowing future exposure, prospective exposure, a standard of extreme cautiousness is called for—whether that same standard ought to apply in determining whether or not a given disability is likely to have been caused by exposure is another matter.

Mr. DASCHLE. I have one more question. What is wrong, I mean if you truly are concerned about the veteran himself, what is wrong with saying, Look, we don't know whether or not that will forever be a cause-and-effect relationship on which we can presume a disability, but until it is disproven, we are going to accept the fact that we will take the burden here and treat it as a presumptive disability in which a cause and effect shown in laboratory animals can be correlated with the same effect in humans? What is wrong with taking that approach and, who knows, in 20 years being disproven by an epidemiologcal study? Than saying, wait a minute, we are going to wait until all the facts are in and you are going to have to worry about that and find some other kind of care. What is wrong with taking that approach?

Mr. MCMICHAEL. Again, as I said earlier, I think that the difference between when the final scientific evidence is in and having enough information to make a policy judgment may differ. The question is whether you have enough information now to make a policy judgment. I want to be very specific in terms of what you are suggesting. If in the case of disability compensation, for example, if I understand it, you are suggesting that if a veteran presents himself and says, "I have a disability and I believe that disability was a result of my service in Vietnam," if you are suggesting the policy ought to be that until we disprove that any disability was not, in fact a result of his service in Vietnam, that would be a departure from the standard way in which disability compensation has always been established. Now, if you want to do that——

Mr. DASCHLE. Could I interrupt for just a half a second? I would say not a disability, but the disabilities that are shown in laboratory animals that show that cause-and-effect relationship.

Mr. MCMICHAEL. All right, I just want to make sure what the proposal is. Are you suggesting that any case of cancer that any

Vietnam veteran develops should be presumed to be connected with his service in Vietnam?

Mr. DASCHLE. If he served in Vietnam in those areas that can be shown were sprayed by the herbicide——

Mr. MCMICHAEL. Then any case of cancer ought to be presumed service connected.

Mr. DASCHLE. That is right.

Mr. MCMICHAEL. That is a judgment for Congress to make. It would seem to me a substantial portion of the population is going to develop cancer in any event, independent of their service in Vietnam, you are suggesting a fairly significant departure from the traditional way in which——

Mr. DASCHLE. Not really. You have got 40 presumptive disabilities already: multiple sclerosis, tuberculosis. How in the world can you trace that back to service in——

Mr. MCMICHAEL. There you are talking about incubation periods, and I assume that you are suggesting that there is a definite latency period for the development of cancer that relates back to the period of service?

Mr. DASCHLE. That is correct, and until proven otherwise, that is what we are saying. Sure it represents a departure. What I am asking is what is wrong with that departure? I don't understand from your point of view if you are concerned about the veteran, why that departure is so significant.

Mr. MCMICHAEL. I think if we had evidence suggesting, for example, that there were cancer rates among Vietnam veterans that were qualitatively or quantitatively different from veterans, peer group non-Vietnam veterans, that type of presumption, independent of how we could prove cause or effect, might very well be the first judgment Congress would want to make. But you don't have that information. When and if you get that information, then it seems to me the kind of suggestion you are making is one that Congress ought to consider seriously.

Mr. DASCHLE. We are right back to square one because that kind of information may not be available for 20 years. And what we are asking is, is the VA willing to depart from its standard procedure and base the information on the other equally as reliable information, as Dr. Rall testified, in laboratory animals? If you can make that presumption, not for an indefinite period of time, but for a period of time until——

Mr. MCMICHAEL. Presumably, any veteran then who drank saccharin, put saccharin in his coffee or drank it in diet colas, presumably we would make the same presumption?

Mr. DASCHLE. I am glad you bring that point up because that now has been disproved, so obviously would no longer be a presumptive disability. I am saying——

Mr. MCMICHAEL. It has been disproved that it causes it in animals?

Mr. DASCHLE. It is disproved that it causes it in humans, and that is what the epidemiology studies would either prove or disprove.

Mr. MCMICHAEL. I thought you were suggesting that the importance was that the animal studies would be presumptive.

Mr. DASCHLE. I am, I am saying that, and I am saying that up until then I have no objection to the fact that if we would have treated saccharin-related cancer patients that we would have been out anything. We would have given them the benefit of the doubt, and that is what I am saying we ought to do for agent orange.

Mr. MCMICHAEL. That is a policy decision that I think Congress has to make. I would suggest, though, that it is a substantial departure from the traditional way of doing it, and I would have some difficulty in distinguishing this particular set of disabilities from others that I think I could conjure up that an equally convincing case ought to be made.

Mr. DASCHLE. The point is whether you want to handle this in a bureaucratic fashion or whether you really want to get down to what I think is some kind of a compassionate handling of the situation. I don't see any——

Mr. MCMICHAEL. Presumably the highest compassion would be to provide any veteran, simply by virtue of his military service, service connection and disability payments for any disability he develops simply by virtue of the fact that he served in the military. That, I guess, would be the ultimate compassion. If you are not willing to do that, then you have to start drawing some distinctions.

Chairman SATTERFIELD. Mrs. Heckler.

Mrs. HECKLER. I understand that there have been six recent studies which found a significant relationship between exposure to 2,4,5-T and cancer or reproductive disorders in human populations. There is a study by Swedish scientists, Hardell and Sandstrol, in 1979, who found that forestry, sawmill and pulp workers in northern Sweden exposed to these chemicals contracted a rare and unusual cancer, a soft tissue sarcoma at a rate five times greater than unexposed persons.

There is another group of Swedish scientists in 1979 who found that persons exposed to these same chemicals, 2,4,5-T and 2,4-D, contracted cancer in general at a rate seven times greater than unexposed persons. Another group of Swedish scientists as early as 1974 found that railway workers exposed to 2,4,5-T and 2,4-D 10 years earlier suffered an incidence of stomach cancer that was six times greater than the rate of incidence in the general population.

West German scientists Thiess and Frentzel-Beyme in 1977 determined that workers exposed to dioxin in an industrial accident had an incidence of stomach cancer five times greater than the general population. There are other studies. I could go on and on.

What I am wondering is, we are doing this study of Vietnam veterans in general and the correlation between exposure and various disabilities, would you separate out Vietnam veterans and compare the rate of cancer in the Vietnam veterans with that of the same population group——

Mr. MCMICHAEL. That is one of the things that we are attempting to do.

Mrs. HECKLER. That is not a difficult thing to do. We are compiling excellent statistics on cancer in general in our country, so it would seem to me a very easy statistical analysis to decide whether or not there was a correlation, if there is a higher rate or not.

Mr. McMichael. There are a number of things that seem to me when I ask about them to be quite easy that I find to my despair to be somewhat more complex than I had assumed. I do think we do have good mortality records in the United States on cancer deaths, and we are attempting right now to try to get some baseline data on mortalities. We have less valid——

Mrs. Heckler. I think mortality would be an easier standard to certify and a much harder standard than needs to be applied in this particular case.

Mr. McMichael. I am informed that we have much less reliable information on morbidity, but as to mortality we do have some pretty good information in terms of cancer registers and so on, and we are attempting to get some baseline data there. Your suggestion is an excellent one. We are attempting to do it. I would only suggest that it is not quite as simple as it would appear to be on its face.

Mrs. Heckler. I would like to know what mechanism you are using to get this data. Who is in charge of this and the project at the VA?

Mr. McMichael. The Interagency Work Group has been discussing this matter, and Dr. Shepard has also participated.

Mrs. Heckler. So it is not the exclusive investigation of the VA? You are not doing it with in-house?

Mr. McMichael. No.

Mrs. Heckler. Dr. Shepard, would you comment on this?

Dr. Shepard. Yes, ma'am. One area that we have been engaged in actively is the agent orange registry that the VA has put together. We currently have examined approximately 30,000 Vietnam veterans. This is a self-selected group of individuals who are concerned about the possible health effects of agent orange. Of those 30,000, we have approximately the data on 12,000 in our computer file. We are now putting together a process by which we can extract that information, examine it, and hopefully in the very near future come up with some baseline raw data that will look at some of the areas that have been alluded to, some of the symptomatology that has been presented, and make some kind of preliminary judgments as to the prevalence of malignancies in this route.

Mrs. Heckler. Are you looking just at the question of malignancies or are you looking at other disorders and also the question of reproductive problems, malformations, and defects?

Dr. Shepard. Part of the data is generated by means of a questionnaire and on that questionnaire there are specific questions relating to reproductive disorders and a whole host of other problems.

Mr. McMichael. In addition, as I mentioned earlier, we are participating with the Center for Disease Control in a study of the offspring of Vietnam veterans to see if we can come up with any evidence with respect to higher incidence of birth defects in Vietnam veterans as opposed to the population as a whole.

Mrs. Heckler. You are doing this as part of the Interagency Task Force or the Center for Disease Control?

Mr. McMichael. We are sharing the funding with HHS and DOD and it is being conducted by CDC.

Mrs. HECKLER. I see, you are channeling funding and they are conducting the study?

Mr. MCMICHAEL. Yes.

Mrs. HECKLER. Dr. Shepard, you are the VA medical coordinator for agent orange. Do you have any background with herbicides or with chemical agents specifically?

Dr. SHEPARD. My medical background? No, ma'am, not specifically.

Mrs. HECKLER. What about other members of the task force. Do they have more specific background in this field?

Dr. SHEPARD. Are you alluding to the Interagency Work Group?

Mrs. HECKLER. Yes.

Dr. SHEPARD. Yes, ma'am. There are a number of scientists, both on the larger committee and on the scientific panel which is a subcommittee of that group, which is also augmented by people with specific expertise in the area of epidemiology, toxicology, and other related scientific expertise.

Mrs. HECKLER. Is there a specific targeted time frame in which you hope to get some results or have some tentative findings? Is this an endless open-ended study that could go on for the next 20 years?

Dr. SHEPARD. No; I think we already have some evidence in the area of reproductive effects in the male mouse study that Dr. Moore coauthored, and I think there is very persuasive evidence that in terms of male mice being exposed to the constituents of agent orange there was no detectable difference in fertility and in the production of birth defects and any sperm abnormalities in male mice. So that is one study that has been completed which I think is a piece of a larger puzzle.

Mrs. HECKLER. What about female mice?

Dr. SHEPARD. I am not aware of any recent similar studies relating to female mice. I am sure there has been laboratory evidence to suggest that there may be some problems resulting from exposure to these chemicals. But the important thing is the male mice. We need to distinguish between male mice and female or any laboratory animal, I suppose.

Mrs. HECKLER. Has the VA granted any disability rating to a veteran claiming agent orange poisoning or any other type of chemical poisoning arising out of service in Vietnam?

Mr. MCMICHAEL. Again, I think the importance is that we grant service-connected disability based on someone presenting themselves to us with a disability. Whether they claim it is caused by agent orange or not is less important than the fact that we determine first whether or not they have a disabling condition, and second, if we can relate that disabling condition to his service in the military.

There has been a great deal of talk, for example, of skin conditions. We have service connected for Vietnam era veterans some 217,000 skin cases. So it is kind of a misleading sample to figure out who is complaining of agent orange. What we are principally concerned about are people who say, "I have a disability and I believe that disability is related to my service."

Mrs. HECKLER. I would like to understand your answer a little bit more definitely. Has the VA granted any disability rating to a

veteran claiming agent orange poisoning or any other type of chemical poisoning arising out of service in Vietnam?

Mr. McMichael. Mr. Wisniewski, I think, can respond.

Mr. Wisniewski. We may have but we haven't kept any statistics or haven't done any research in that area to see. We normally do not catalog the causes of disability. We catalogue and take account of the disabling effects, the residuals, and we have that in our system of records. But we don't have the causes. Only in three areas now have we gone to that extent of looking for causes because those are areas that the Congress and the public is specifically interested in. One is herbicides, the other is radiation, and the third one is asbestosis.

Mrs. Heckler. We are very interested in all three of them, that is true. How far are you going to go in terms of this question of disability ratings? Isn't it possible for you to analyze your records, your Vietnam veteran records, and be able to determine whether or not that has been a claim for which a disability has been granted.

Mr. McMichael. Let me say that we are rapidly attempting to get that kind of data. We have not normally collected it in that form. We are aware of the concern about this. Wherever someone expresses concern about agent orange, thinks something may be due to agent orange, we are now attempting to catalogue that and place that veteran on the agent orange registry so we can follow up on him and can also cross-check with our patient treatment files to see whether or not such veterans have been treated in VA hospitals. So we are attempting now to get the kind of information you are asking. A lot of it is in less than perfect form. Our original computer program, I think, was not well designed. We are attempting to rectify that, and I would hope we would have more information of the type that you are particularly concerned with in the near future.

Mrs. Heckler. It is very hard to understand how the VA would not have a better computer system and not be able to produce these answers with some degree of rapidity. I mean, these are statistical questions, they are not policy questions.

Mr. McMichael. This committee, I think, is well aware of some of the computer problems the Agency has had and it is too painful for me to recount all of them.

Chairman Satterfield. If the gentleman will yield. I recall right now $5 million that was flatly turned down that we needed.

Mr. McMichael. Yes, sir. I must admit, I am as mystified as you are at times when I ask for information that would appear to be readily available particularly when you see the amount of information the Federal Government collects about people and the complaints you got about the information we do collect. When you go and ask for some specific form of information and it isn't available, it is as frustrating for me as I think it is for you. We think that the information ought to be available and when we are told that we just don't collect it that way or we can't pull it out easily, I become as frustrated as you. We are attempting to get——

Mrs. Heckler. It is very hard to understand because the regulators of this society in the same Government are able to collect all kinds of data and act on it quickly. We are all hearing from our

constituents about this strangulation by overregulation. They have the computers and all the agencies of the Government do have the computers. It is really difficult to reconcile these things, in the same Government with the same computer allowances and so forth how one system can overburden the population by going too far and the other cannot be able to provide basic answers. That is very difficult. Are you upgrading your computer system?

Mr. McMichael. We are attempting to, yes.

Mrs. Heckler. I hope that in the process of doing it that you will give special attention to the collection of data relating to all aspects of the Vietnam veteran problem and especially agent orange.

Mr. McMichael. Yes. I might add that we are going to have, within a month or so, information collected by the Census Bureau, what we call the "Survey of Veterans II." That information should be very valuable. It will enable us, for example, to break out information between the Vietnam era and the Vietnam theater, something that our records don't normally do. It will present some information about health status of Vietnam theater veterans, and I look forward to that as being additional information we might be able to provide the subcommittee which will aid it in making its decisions.

Mrs. Heckler. Isn't it possible for the VA to contact the Department of Defense and get the names of those who were in the Vietnam theater versus the Vietnam era fairly quickly? Don't tell me that the Department of Defense computers are not capable of this kind of programing. I would just find that incredible.

Mr. McMichael. Part of the difficulty results from the fact that the data is collected consistent with congressional programs, and that congressional programs, laws dealing with veterans in general, do not make distinction between area of service. Because of that, we have not as a routine matter collected information other than by period of service.

Mrs. Heckler. Then it would seem a clear congressional mandate for this committee to draft a law that will require the Veterans' Administration to do what I think is just ordinarily required anyhow in terms of common sense in dealing with the problems of the Vietnam veteran. If you need a legislative mandate, we certainly should give it to you. Then provide this information in terms of the era and theater and the disability claims relating to agent orange, and so forth.

About that memorandum of Maude de Victor. This is a report of contact. Are you familiar with this?

Mr. McMichael. I believe I am, if it is the one I have seen, a report of contact in handwriting by Maude de Victor. Let me try, if I can, to place this in perspective. A press conference was held in which a typed memorandum was presented. The allegations reported in the press were that somehow this was evidence that the VA knew of all kinds of serious health consequences and had been hiding it. We were asked whose memorandum is this and who wrote it. The memorandum appeared in many ways to track language that was in a report of contact written by one Maude de Victor recounting her version of a telephone conversation she had with Captain Young. We asked Maude de Victor with respect to the typed memorandum, "Is this your memorandum? Are you the

author?" She indicated to us that she was not the author of that memorandum. She has indicated that she is the author of the handwritten report of contact——

Mrs. HECKLER. She has signed this copy that we received from the Veteran's Administration so I don't see that——

Mr. MCMICHAEL. Yes; and in our response to inquiries about that we indicated that we thought that she was the author of the typewritten memorandum but that we could not be sure and that, in fact, she had denied that she was the author.

Mrs. HECKLER. All right, will you tell me what happened to Maude de Victor in terms of her employment at the VA? I understand that she was reassigned as a result of the furor that was created over agent orange, that she was at least for a period of time reassigned to another function.

Mr. MCMICHAEL. I don't believe that she was reassigned to anything other than at her own request, but I would be happy to provide a full report. She is employed at the VA. She has been regularly receiving pay increases. At one point I understand she did not want to work on new target terminals because she believed that they emitted radiation which was harmful to her. At her request, we took her off of the terminals and brought in a scientific team to try to examine whether or not those tubes were emitting radiation.

Mrs. HECKLER. Yes; now it is my understanding that Maude de Victor herself had been a cancer patient.

Mr. MCMICHAEL. That is my understanding as well.

Mrs. HECKLER. So she has already had cancer and was very cautious about where she worked.

Mr. MCMICHAEL. Yes; I can appreciate her concern.

Mrs. HECKLER. Mr. Chairman, I would hope that we will have an opportunity to have Maude de Victor's report of call memorandum introduced because I think it can be a very historic document.

Chairman SATTERFIELD. I am sure we will pursue it. I would like to ask a question along that line, though. You talked about terminals, that she was afraid might contaminate her. What kind of terminals are we talking about?

Mr. MCMICHAEL. Those are the target terminals.

Chairman SATTERFIELD. Are you talking about computers?

Mr. MCMICHAEL. Yes; cathode ray tubes.

Chairman SATTERFIELD. Is she a scientist?

Mr. MCMICHAEL. Not to my knowledge.

Chairman SATTERFIELD. We can get into those questions later. I would just like to find out if I understand correctly what you all have been saying. Let's say that I am a Vietnam veteran and all of a sudden I have a physical problem. I come to the VA and say, "I have a physical problem and I believe it resulted from exposure to agent orange in Vietnam." You discover the fact that this is a problem which you have given service connection to in the past and recognize that it may come from some totally different source, that the incubation period or whatever you might say is all in order, and so you give me service connected disability but not necessarily for agent orange. Is this what you have been saying, in essence, that you have been doing and why there is no specific

cause assigned because it is something that you automatically accept as a disabling service connected?

Mr. McMichael. I have been attempting to say that. Perhaps I was not quite as articulate.

Chairman Satterfield. That is the reason then that this information is not readily available. Assuming that we had the computers, it may not even have been on the computers.

Mr. McMichael. Yes; but it certainly is our policy now that if someone presents themselves either to a medical facility or to a disability compensation claim and says, "Somehow I think this is related to agent orange," we are taking that and we are attempting to put that in the registry.

Chairman Satterfield. In other words, what we are saying then is that if the complaint is something that has not been normally recognized as a health problem that could be service connected, and the allegation is made that there was exposure to agent orange, that this is the area where we are trying to seek information as to whether or not there is a cause and effect between that specific complaint and the exposure in Vietnam to agent orange. Thank you very much. Any other questions?

Mr. Daschle. Mr. Chairman, I just have one last one. The Senate recently passed the Heinz-Cranston amendment requiring rulemaking. What is the position of the VA with regard to that amendment?

Mr. McMichael. We are currently developing our official position but we don't have it yet. I can tell you that in general we support the idea of giving us authority to expand the study and certainly are not adverse to reporting to the Congress within a given period of time what we found and proceeding in a public manner to develop rules. I might add that if we are talking about presumptions, it has been invariably the practice of the Veterans Administration to seek explicit statutory authority from Congress rather than to do this administratively.

I might just add that I have been doing some research on presumptions recently. I thought you would be interested, Mr. Chairman, that in a treatise on evidence Professor Morgan is quoted as saying, "Every writer of sufficient intelligence to appreciate the difficulties of the subject matter has approached the topic of presumptions with a sense of hopelessness and has left it with a feeling of despair."

Mr. Daschle. Thank you, Mr. Chairman.

Chairman Satterfield. Gentlemen, we thank you very much, especially for having waited so long today. We do appreciate your patience and your testimony and thank you very much for appearing.

I would like to state at this time that I am in receipt of a letter from Mr. Donald Frayer of Dow Chemical in which he has written concerning two points raised in our hearings on July 22, one dealing with their reproductive study and I think providing some information that will be helpful to this committee. And the other with respect to whether or not there was a communication with the Department of Defense with respect to dioxin and I believe that this response also bears information which ought to be helpful to this committee.

I was requested by the writer of this letter to admit this response to the record of our July 22 hearings and unless I hear objection otherwise, I intend to do so. Without objection, then this letter will be admitted into that hearing.

There is no other business to come before the committee at this time. It stands adjourned.

[Whereupon, at 6:20 p.m., on September 16, 1980, the hearing was adjourned.]

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