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OVERSIGHT HEARING TO RECEIVE TESTIMONY ON AGENT ORANGE

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HEARING

BEFORE THE

SUBCOMMITTEE ON MEDICAL FACILITIES AND BENEFITS

OF THE

COMMITTEE ON VETERANS' AFFAIRS HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

FEBRUARY 25, 1980

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OVERSIGHT HEARINGS TO RECEIVE TESTIMONY ON AGENT ORANGE

MONDAY, FEBRUARY 25, 1980

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

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 334, Cannon House Office Building, Hon. David E. Satterfield III, (chairman) presiding.

Chairman SATTERFIELD. The subcommittee will come to order. Our hearing this morning has been scheduled to receive testimony from officials of the executive branch in order to inform this subcommittee of their efforts and the results of their efforts to determine whether there is a connection between the exposure to Agent Orange and a health problem.

As you know, some Vietnam veterans have alleged that exposure to the herbicidal defoliant, Agent Orange, during the Vietnam conflict had resulted in service-connected health problems and disabilities. This committee feels, and has felt for some time, that there is a crying need to ascertain whether these allegations are correct.

Our hearing today is for the express and sole purpose of oversight to receive reports from those government agencies which testified before this subcommittee on October 11, 1978. We are especially interested in what has been done and what has been learned since those hearings. I think it is only proper to state that our subcommittee considers this problem to be a very serious one which raises very serious issues.

Clearly, it is one which has received an unusual amount of public attention. It is an issue which lends itself to emotionalism. There have been both explicit and implicit charges that Government is insensitive to the needs of our veterans who served their country in Vietnam and that it has attempted to ignore a problem of great magnitude for reasons of indifference and bureaucratic inertia.

I wish now to reiterate something I said at a previous Agent Orange hearing. The purpose of these hearings in not to inquire into the propriety of the use of defoliants in Southeast Asia. Rather, it is to determine whether or not exposure to those defoliants, specifically the herbicide Agent Orange, had any adverse effect upon the health of our veterans. If a problem does exist with regard to certain Vietnam veterans, we on this committee want to know it. If, on the other hand, no problem exists, we want to know that as well.

Whatever the result of our inquiries into this matter, we want the Vietnam veteran to be fully advised of testimony received here for two reasons. First: To alleviate his trepidation if in fact such fears

are unwarranted; and Second: To provide health care and/or indemnification if indeed there is a causative link between exposure to Agent Orange and any medical problems.

Expressed otherwise, the subcommittee wants to get at the truth about Agent Orange, and we want to get at it as soon as is reasonably possible on an objective, thoroughly scientific basis. Nothing less will satisfy this committee, nor should anything less satisfy the American public or the Vietnam veteran.

No member of this subcommittee is under any illusion that the end of this hearing today will bring with it a conclusion to the Agent Orange controversy. Far from it. So little is presently known about the human health effects of this herbicide that it may be several years before a proper accounting of suspected hazards can be rendered.

Now, Congress and the Federal Government have responded to the serious allegations of Agent Orange and that issue. In the last session of the 96th Congress, the House and Senate passed H.R. 3896, now Public Law 96–151, which required the VA to conduct a full-scale epidemiological Agent Orange study. Prior to that, the VA on its own had already convened an advisory committee to collect and collate all relevant medical and diagnostic information on veterans' claims of dioxin related illnesses.

Further studies are now ongoing under the authority of the Public Health Services Act within the Department of Health, Education, and Welfare. The Environmental Protection Agency is conducting its own study, as is the Department of Defense.

In December 1979, the President's Assistant for Domestic Affairs and Policy ordered the establishment of an interagency work group to study the long-term health effects of exposure to this class of chemicals. This group will coordinate all ongoing investigations and the results of those investigations.

I believe that the Government is sincerely and vitally concerned about getting to the bottom of these questions. The hearing today will elicit testimony on these efforts and the present and future progress in scientific inquiry.

I understand that some individuals or groups have inquired about the possibility of testifying today at this hearing. I would like to emphasize that the purpose of it is oversight. As such, we have elected on this particular day to limit the hearings, as I have stated previously, to those agencies in the executive branch of the Government which are charged with the responsibility to conduct and which are conducting the legitimate investigations we need.

I would like to say, as a followup to that statement, that the question of cause and effect really is not one for this committee to determine. That determination requires scientific and medical expertise which this committee does not possess. We are not equipped to make that kind of a decision. Some have indicated that this committee should act anyway. I would remind those who feel this way that it is the province of this committee to administer the entire VA program and to provide veteran indemnification, treatment or other services, when there is a legal requirement that it be done.

In this regard, I think I should remind those who have made such a suggestion that this committee has authority and jurisdiction to determine first the definition of veterans who are entitled to benefits under VA law, and, second, to provide for the treatment of veterans with health problems or disabilities.

In this regard, I would point out that when we talk of the effects of dioxin and whether or not there is a health problem, two factors are involved. The first and the overriding question is whether or not the exposure to dioxin creates a health problem. And the second, if found that it does, whether or not veterans exposed to it are entitled to indemnification, compensation and other benefits.

This committee is not involved in the answers to either of these two questions. They are questions which must be answered by experts on the basis of scientific inquiry and then upon fact on a case by case basis, whether or not a veteran was exposed to dioxin while on active duty.

This committee does have a responsibility, and I have no doubt that it will continue to exercise that responsibility to the fullest extent in order to make certain that veterans who have been harmed in any way or who have a health problem as a result of serving this country will be properly cared for and properly indemnified for whatever ills they may have suffered as a result.

Having said that, I hope I have explained to some degree the parameters of the hearing today. I would say to those others who would like to testify that it is my intention at some later date to hold further oversight hearings so that all groups will be given an opportunity to come before this committee to express their views and to present whatever reports they have. I hope that we can properly do this in the not too distant future.

I now recognize the ranking minority member of the committee, the Honorable John Paul Hammerschmidt, for any remarks that he may care to make.

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman. I am pleased that we finally have a law which focuses on this most important issue. I would like to commend you at the outset, Mr. Chairman, for scheduling this early hearing to allow our subcommittee to monitor both the new law and the progress of the agent orange issue as a whole.

I would like to take a few quick moments before we begin the hearing to express my hope that both sides of this very emotional issue will exercise restraint as we develop enough data through the study that we have mandated in Public Law 96–151.

In the first place, there should be no such thing as "sides" on a question such as this. There has been some talk of frivolous claims by Government officials, and there has been some talk of Government foot-dragging by concerned veterans. We don't need anyone, especially the Government, to act as adversaries when it comes to the well-being of those who have served.

I have read the testimony that we are to receive and, quite frankly, the defensiveness of much of it perplexes me. All of us who will take part in today's hearings are agents of our Government, and as such we are the Government on this issue. We as a government found the use of Agent Orange to be essential to the use of our military operations for many years. When it became evident that such use was potentially harmful, we as a government ceased it. Now, in the face of evidence that the use of Agent Orange may have harmed those of our citizens who were honorably carrying out our declared military policy, we as a government have a sworn and serious duty to do everything in our power to determine whether or not a causal nexus existed between the use of Agent Orange and the difficulties our veterans are talking about.

If there was such a nexus, we must provide for our countrymen who trusted us and did their duty. Any less, in this or any other case, dishonors and cheapens the notion of combat service to the United States of America.

It is with this premise, Mr. Chairman, that I hope we will conduct the hearings today. Thank you.

Chairman SATTERFIELD. Thank you, Mr. Hammerschmidt. I think I should point out that there is the possibility of a vote on the floor today which, if passed will bring about a secret session of the House. Should that occur, I am sure all of the members of this committee would want to be present. Accordingly, in an effort to try to expedite this session without shutting anybody off, I have asked the three groups that are scheduled to testify today to consent to appearing before us as parts of a panel so that we might hear each of them and defer members' questions to the entire panels.

I think in this way everyone will have a chance to discuss whatever he wishes without unduly delaying the hearing. I wish to thank those who are going to testify this morning for agreeing to this procedure.

I would like now to recognize the first panel, for the Veterans' Administration, the Honorable Max Cleland, Administrator, and Dr. Donald Custis, the VA Medical Director; for the Department of Health, Education, and Welfare, Mrs. Joan Z. Bernstein and Dr. John Moore; and for the Department of Defense, Maj. Gen. William F. Augerson and Maj. Gen. Murphy A. Chesney.

Gentlemen and lady, we appreciate your appearance here this morning. If there are others in your group that you would like to have recognized as being present, I would ask you to state their names so that our reporter can reflect their names in the record.

Mr. Cleland, we are delighted to have you again this morning. Your written statement will appear in the records at this point.

[Statement follows:]

PREPARED STATEMENT OF MAX CLELAND, ADMINISTRATOR OF VETERANS' AFFAIRS

Mr. Chairman and Members of the Committee: Good morning. I am happy to appear before you today to give you a detailed appraisal of what progress the Veterans Administration has made to date with respect to the problem of the possible adverse health effects experienced by American service personnel as a result of exposure to herbicides used in Vietnam.

With me today are Dr. Donald L. Custis, Chief Medical Director; Ms. Dorothy Starbuck, Chief Benefits Director; Mr. Guy H. McMichael III, General Counsel; Dr. William Jacoby, Deputy Chief Medical Director; Dr. Paul Haber, Assistant Chief Medical Director for Professional Services; Dr. Lawrence Hobson, Deputy Assistant Chief Medical Director for Research and Development; and Mr. Charles Peckarsky, Director, Compensation and Pension Service, Department of Veterans Benefits.

I would like to give you an indepth look at the Agent Orange issue, with particular attention to the activities of the Veterans Administration since we appeared before you in October 1978.

I will also report to you information on Agent Orange that has been uncovered since that time.

Let me say at the outset that the Veterans Administration is committed to resolving any doubts that veterans may have concerning the possible adverse health effects of exposure to Agent Orange. Regrettably, there is much we still do not know and we cannot provide final answers at this time. We are working as diligently and as expeditiously as possible to resolve the difficult scientific issues this problem presents. While that process is going on, however, and I want to strongly emphasize this point, any veteran who believes that he or she may have incurred some ill effects as a result of exposure to Agent Orange and seeks help or examination at a VA Medical Center or Outpatient Clinic will receive

the full scope of health care for which he or she is eligible, without regard to causation. I want to assure you that no one is currently suffering from a lack of treatment because of a lack of knowledge as to whether there are any long-term adverse health effects resulting from exposure to Agent Orange.

In my testimony today, I will provide a brief summary of the circumstances surrounding the use of Agent Orange and then I will discuss for you the VA's activities under four major categories: (1) what we have learned; (2) what we have been able to share with our health care facilities; (3) the record we are building; and (4) the research that we and other Federal agencies have done or are contemplating doing in order to resolve the many difficult questions surrounding the controversy over Agent Orange.

HERBICIDE USE IN VIETNAM

I would like briefly to review for you the circumstances surrounding the use of Agent Orange in Vietnam. Herbicides were first used in 1962 to deprive the enemy of jungle and forest cover and to destroy food crops so as to prevent their use by the enemy.

Agent Orange was one of a number of chemical herbicides utilized in Vietnam, which were given code names including White, Purple, Pink, and Green. By 1965, the use of defoliants other than Agent Orange was largely discontinued.

Agent Orange is a reddish-brown or tan-colored liquid which is insoluble in water It is composed of a one to one mixture of two chemicals, 2,4-D and 2,4,5-T.

Although I do not mean to dismiss the use of the other herbicides, our attention today and in the investigations that we are conducting focuses primarily upon Agent Orange because it was the principal defoliant used in Vietnam. The toxicity of the two individual components in Agent Orange was extensively studied for two decades before their use in Vietnam. It was concluded that these chemicals had very limited toxicity for either animals or man. The problem, however, stems from the fact that a contaminant substance also found in Agent Orange, which was formed during the manufacture of 2,4,5-T, is an extremely toxic substance. This contaminant is TCDD (2,3,7,8 tetrachloro-dibenzo-paradioxin) or "dioxin."

The Department of Defense (DoD) has informed us that between 1965 and 1971 there were 2,961 herbicide spraying missions that covered about 3½ million acres of South Vietnam. During this time, Agent Orange constituted 94 percent of the herbicide utilized. Nearly 11 million gallons of Agent Orange was sprayed containing 170 pounds of herbicides. These missions reached their peak in the years 1967 and 1969, when approximately 3.25 million gallons were sprayed annually. In 1970, the spraying fell off to about a million gallons and, in 1971, the use of Agent Orange was discontinued.

Most of the Agent Orange was sprayed from fixed wing aircraft (C-123) in what was then called "Operation Ranch Hand", a code name for the spraying mission. A relatively small amount of Agent Orange was sprayed from helicopters and from portable containers.

The spraying missions usually occurred at dawn or at dusk, at a time when U.S. field troops were not likely to be active. Efforts were made by the Air Force to inform ground troop commanders of the occurrence of spraying missions before they actually took place. During the latter part of the war, the spraying missions were accompanied by fighter aircraft which strafed the ground in advance of the actual spraying. At these times, special efforts were made to assure that U.S. troops would not be in the sprayed areas.

The DoD also informs us that efforts were made to permit a period of time to elapse before the troops entered a sprayed area. However, a recent report from the General Accounting Office (GAO) entitled "U.S. Ground Troops in South Vietnam were in areas sprayed with Herbicide Orange" (November 16, 1979) indicates that at times some Marine troops entered such an area within hours or days after the spraying mission had taken place.

In April 1970, the Secretaries of Agriculture, Health, Education, and Welfare, and the Interior suspended the use of 2,4,5,–T a component of Agent Orange. This suspension resulted from published studies which revealed the 2,4,5–T, had toxic effects in animals. This toxicity was subsequently tied to the contaminant TCDD. The Department of Defense then suspended the use of Agent Orange in Vietnam.

DoD also reported to us that efforts were made to reduce the opportunity for exposure of ground troops to Agent Orange. Also, we were further informed that it is unlikely that dioxin was incorporated into the food chain as the toxic effects of the herbicide destroyed crops, fruits, and vegetables very quickly and made them unfit for human consumption.

Animals may have ingested some dioxin after grazing on areas that were sprayed but we are advised that it is unlikely that such animals made more than a minimal contribution to the diet of American troops.

OVERVIEW OF THE AGENT ORANGE PROBLEM

Despite intensive scientific investigation over the last several years, much remains to be learned about the toxicity of Agent Orange. For instance, we do not know if there is a delayed syndrome of Agent Orange toxicity nor, if it occurs, how much exposure is required to produce it.

One of the most vexing issues in the Agent Orange area is the problem of how much exposure individual troops received. The war was a fluid combat experience with many small units involved and no fixed battle lines. We are informed by DoD that they do not possess accurate information on the disposition of many of the 2.6 million troops who served in Vietnam. This circumstance makes it very difficult to determine precisely whether any individual might have been exposed. The GAO has reported that we do have some information about the movements of Marine troops, particularly in the I Corps Area, although it is unclear to what extent the amount of exposure to Agent Orange can be determined even with this group.

Still another difficulty relates to the fact that even if an individual veteran does have toxic symptoms at this time, it is frequently impossible to determine whether these symptoms are related to exposure to chemicals experienced in civilian life after returning from Vietnam or whether they were indeed due to exposure to Agent Orange in Vietnam. For example, there are many known examples of toxic exposures of human population following industrial accidents. In addition, there is the possibility of damage from a range of universal environment contaminants such as PCB and PCP.

The symptoms alleged by veterans as a result of exposure to Agent Orange are multitudinous and many of them occur so frequently among all segments of the population that it is impossible at this time to attribute these symptoms specifically to Agent Orange. Such common symptoms include restlessness, lethargy, headaches, confusion, dizziness, loss of srength, loss of libido, impotence, infertility, abdominal pains, sweating, tremor, pallor, change of personality, irritability, insomnia, and difficulty in concentration.

Two other problems are of significant concern to us, but their relationship to exposure to Agent Orange has not been proven. I refer to the occurrence of malignancies of various sorts and to the production of abnormal children with birth or congential defects. Although there have been allegations of both occurrences by many Vietnam veterans, there is an absence of validated scientific information to relate these occurrences to human exposure to Agent Orange.

There are a number of reasons why it is difficult to get to the root of this problem. First, there are a large number of unknown factors, some of which I have already discussed. Second, the current scientific conclusions are largely based on animal experiments. Whereas there are a number of reports of human exposure to Agent Orange constituents from industrial settings and accidents which I will share with you, the only clearcut health related finding is that such exposures may be followed by the development of a skin condition known as chloracne. However, there are no scientifically validated data yet available to show increased frequency among Vietnam veterans of this or other diseases or of any deaths attributable to long-term toxicity of Agent Orange constituents. Third, the data with respect to the extent of individual exposures to Agent Orange is extremely difficult to obtain. Fourth, there is no single test yet available for determining exposure to Agent Orange.

REPORTED STUDIES ON AGENT ORANGE

Let me turn now to a brief review of the studies reported on Agent Orange effects.

Scientific work on the physicological effects of the herbicides found in Agent Orange on animals has been pursued since the 1940's when 2,4–D and 2,4,5–T were first prepared. Studies on TCDD have also been pursued for over 30 years, even though its presence in Agent Orange was not widely appreciated until the late 1960's.

Aminal studies of the effects of 2,4–D, 2,4,5–T and TCDD are helpful in suggesting the potential for toxic actions of these chemicals in human beings. However, the animal studies can only be regarded as suggestive since no clearcut relationship has been established between the response of humans to these chemicals and that of other animal species. Accordingly, the only way to reach definite conclusions about the effects of Agent Orange constituents on humans is

through studies of exposed human populations. Since many types of studies that can be performed with these chemicals in aminals are precluded in humans, the necessary data has to be obtained through epidemiological studies of individuals accidently exposed to these chemicals.

It might be valuable to review briefly the experimental studies of the toxic properties of all three Agent Orange constituents in animals. Several animal species have been used in these studies including rats, mice, hamsters, rabbits, guinea pigs, chickens, dogs, cats, sheep, cattle and monkeys. These studies show that the toxicity of the compounds varies according to the species of animal utilized, the dose of the compound administered and the method of administration. However, the following general conclusions have been reached:

1. If given in large enough quantities, all three compounds can be fatal for all species studied.

2. Administration of these chemicals through "artificial" portals, such as by injection, is more rapidly and uniformly harmful than if the compounds are ingested or inhaled.

3. The major effects of these compounds consist of interference with the normal functioning of one or more of the following organs and body systems: liver, kidneys, lungs, nervous system, blood-forming organs, and the reproductive system.

4. The compounds are capable of inducing an increased rate of abortions among exposed pregnant females in some animal species and of early death and abnormal development among their offspring. There are, in contrast, no studies yet reported on the effect of Agent Orange constituents on the male reproductive system, or on the progeny of exposed male subjects.

5. Cancers are seen with increased frequency among study animals. Those reported most commonly are sarcomas and cancers of the liver and lung.

6. Changes in immune systems and in chromosomal composition have also been demonstrated in several animal species following exposure to these chemicals.

Of the three compounds, TCDD is by far the most toxic to animals. In fact, it has been considered by some scientists to be one of the most potent toxic substances known. In experimental studies on animals, TCDD has demonstrated a potential for producing chronic toxic effects such as liver damage, decreased blood counts and growth retardation.

Let me now review the reported studies of human exposure to Agent Orange constituents.

The relationship between accidental human exposure to Agent Orange constituents and the development of long-term illnesses other than chloracne remains speculative at present. However, data resulting from careful follow-up studies on the victims of some of these accidents are slowly beginning to accumulate. The most notable of these results is the report by Judith Zack and Raymond Suskind on the mortality rates of workers exposed to TCDD in the Nitro, West Virginia accident in 1949. Their article published in the Journal of Occupational Medicine for January 1980, focused attention on those 121 workers who had developed chloracne. The conclusions of this study were that in comparison with individuals of the same age and sex in the U.S. population there were fewer deaths among the exposed workers and that their death rates from cancer and cardiovascular disease were not increased.

The accident at Nitro, West Virginia was the first reported industrial accident involving Agent Orange. A total of 228 people were exposed to a chemical mixture including TCDD. The next major industrial accident involving TCDD occured in 1953, at a factory in West Germany (Ludwigshafen) where 55 workers were exposed. There were a series of TCDD occupational exposures in Czechoslovakia between 1965–1969 involving 78 people. Finally, in 1976, the largest industrial accident to date occurred in Seveso, Italy during which up to 10,000 people were exposed to TCDD.

Studies of these and of a number of smaller industrial, laboratory, and other accidents have revealed the following: First, acute effects were common and included such symptoms as dizziness, nausea, headache, nervousness, fatigue, weakness, muscle aching, loss of appetite and abdominal pain. These symptoms seem to be reversible although long-term follow-up data on most of the individuals involved are not available. Second, TCDD exposure was capable of producing the skin lesion, chloracne, which was found to persist for prolonged periods of time. In fact, chloracne has been the only long-term finding which could be consistently associated with exposure to Agent Orange constituents. Third, other significant long-term effects attributed by some observers to exposure to one or more of the Agent Orange constituents, and especially the contaminant TCDD, include porphyria cutanea tarda, liver abnormalities, depressive states and peripheral neuropathy. The proof of these relationships remains elusive.

Several other recent studies of Agent Orange effects on humans have been published. One of these was the ALSEA study conducted by the Enviromental Protection Agency in 1978. It is concluded in this study that there was a connection between an increased rate of spontaneous abortions in women living in the Alsea area of western Oregon and the use of 2,4,5,–T in the adjacent forests. It was on the basis of this study that the EPA subsequently issued a Rebuttable Presumption Against Registration of 2,4,5–T.

It is of interest to note that the results of this study have been contested by a number of scientists in this country and elsewhere. For example, the staff of the Environmental Health Sciences Center at Oregon State University issued a critique of the ALSEA Report in October 1979. This critique concluded that the connection drawn in the EPA study between a presumably augmented abortion rate and the use of 2,5,4,–T was not supported by the data presented.

HUMAN EXPOSURE TO AGENT ORANGE

A number of reports in the press have suggested that Vietnam veterans exposed to Agent Orange have developed a variety of chronic illnesses manifested by a wide variety of symptoms. Included in these reports are several types of cancers and other diseases as well as the persistence of such non-specific symptoms as nervousness, irritability and problems with interpersonal relations.

Dr. Ton-That Tung of Vietnam has echoed these findings on the basis of his own observations. He has reported that residents of what was the South Vietnam exposed to Agent Orange had a higher incident of liver cancer than those who had not been exposed. Among women who were exposed, there was a higher incidence of abortions and children with birth defects than among unexposed women. Unfortunately, the validty of his data cannot be confirmed by independent observers due to lack of appropriate scientific access to Vietnam.

In contrast to these reports is the report of the National Academy of Sciences entitled "The Effects of Herbicides in South Vietnam." This 1974 report, which represents a very exhaustive review of all available data through 1974, concluded that there was no definitive evidence of lasting damage to human health from the herbicides utilized in Vietnam.

In a monograph published by The International Agency for Research on Cancer in 1977 entitled "Evaluation of the Carcinogenic Risk of Chemicals to Man," it was concluded that the available evidence did not permit any firm conclusions to be drawn as to the cancer-causing potential of 2,4-D, 2,4,5-T or TCDD.

The Air Force published a technical report in 1978 entitled "The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and its Associated Dioxin." We believe that this report is the most comprehensive review of the scientific literature relevant to Agent Orange yet produced. It was concluded that the available scientific evidence does not support the contention that Agent Orange has a permanent adverse effect on human health.

VA ACTIVITIES ON AGENT ORANGE

I would now like to inform you as to what the Veterans Administration has specifically done about the Agent Orange issue.

First of all, we have gathered scientific information about Agent Orange and its constituents. This has been accomplished through an ongoing review of the world's literature by my staff and by obtaining position papers from the VA Advisory Committee on the Health-Related Effects of Herbicides in response to questions which we have submitted to it.

On April 12, 1978, very shortly after the VA learned of the growing concern about Agent Orange, the first VA-sponsored ad hoc interagency meeting on herbicides was held in Centeal Office. The committee membership was expanded to widen its expertise for the subsequent meetings held on July 7, 1978, and September 25, 1978. The primary goals of this ad hoc committee were to exchange information on what was know up to that time about herbicides and their possible adverse health effects, to advise the VA on future courses of action (including possible research), and to minimize duplication of effort among the various agencies represented.

The committee was successful in making progress toward the accomplishment of these goals. However, to comply with the Federal Avisory Committee Act, the VA requested and received approval from the General Services Administration for the establishment of the current VA Advisory Committee on Health-Related Effects of Herbicides in April 1979. This committee's role is to assemble and analyze the information which the Veterans Administration needs in order to

formulate appropriate medical policy and procedures in the interests of the involved veterans. The committee has an entirely fact-finding and advisory role and will notbe requested to develop policy. After careful review of nominations for membership from a wide variety of groups and individuals, a balanced committee representative of most of the varied public and private sector elements involved in the herbicide controversy was selected. A list of the membership and their institutional affiliations may be found in Attachment A.

The committee has thus far held meetings on June 11, 1979, September 24, 1979, and December 12, 1979. The fourth meeting is planned for April 1980 These meetings are open to the public. There has been a considerable sharing of information among the Committee members about the multiple activities and experiences of their agencies and organizations. In addition, the Committee has been given a series of questions submitted by both the VA and the public and has been requested to prepare answers to them in the form of position papers. These questions cover the entire spectrum of concerns in the Agent Orange area.

A summary of the more significant aspects of the committee's responses to date are as follows: First, the committee listed the components of an epidemiological study of Vietnam veterans exposed to Agent Orange. Stress was placed on defining as precisely as possible the exposure of each veteran included in the study to Agent Orange as well as to other environmental toxins. The Committee also recommended that epidemiological studies be performed on other population groups such as those exposed to Agent Orange constituents as the result of industrial or agricultural pursuits. Second, potential diagnostic procedures for Agent Orange toxicity recommended by the Committee for careful consideration include measurement of dioxin levels in fat, and studies of immune system alteration, chromosomal changes, and liver enzymes induction. It was pointed out that none of these procedures has yet been proven to have diagnostic value.

Third, the effects of Agent Orange exposure on the male reproductive system were described as being unknown at present and requiring further indepth study. The great difficulties involved in carrying out such a study were specified.

Fourth, the problems of defining the precise exposure of Vietnam era veterans to Agent Orange was recounted and the considerations involved in defining the probability of such exposure were outlined.

Fifth, the types of animal studies that might be performed in order to clarify human exposure to Agent Orange were outlined with those on nonhuman primates being assigned particularly high priority.

A more detailed summary of these position papers are provided in Attachment B.

In addition to working with an Advisory Committee, we are also actively participating in the efforts of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. That work group, which is chaired by the General Counsel of the Department of Health, Education, and Welfare, was established in December 1979, at the request of the White House. The work group is charged with the responsibility of coordinating the activities of the various Federal agencies with program responsibilities in the areas of phenoxy herbicides and the effects of exposure to them. It is our intention to cooperate fully with the work group and to seek their advice and counsel from time to time as we proceed in our various research, treatment, educational, and informational activities iu this area.

The Committee had its first meeting on February 1, 1980 and has submitted a report to the White House summarizing the research activities of the Federal government in this area.

VA AGENT ORANGE EDUCATIONAL ACTIVITIES

The next major activity which I would like to describe to you is our effort to educate our health care personnel on the latest scientific and clinical information on Agent Orange.

The first information that we provided to our hospitals and clinics was contained in a conference call with them in March 1978. This conference call indicated that it is VA policy to provide examinations, and where appropriate, treatment to all eligible Vietnam veterans claiming exposure to defoliants.

Following this, a teletype was sent to all VA facilities on May 18, 1978, which further defined current VA policy and guidance on the Agent Orange issue. (Attachment C)

VA Circular 10–78–219, which was published on September 14, 1978, established the formal protocol for the examination of veterans who may have been exposed to herbicides during the Vietnam War and for processing of the data obtained from these examinations for the VA's Agent Orange Registry. (Attachment D)

VA Circular 10–78–234, which was issued in September 1979, explained the establishment of the Armed Forces Institute of Pathology (AFIP) Registry for specimens from Vietnam veterans exposed to Agent Orange. (Attachment E).

A conference was held on September 27 and 28, 1979 in Washington, D.C. for those physicians in each VA medical facility who are in charge of examining veterans who may have been exposed to Agent Orange. They heard presentations on the following topics from some of the country's leading experts on herbicides:

a. The chemistry, toxicology, and metabolism of Agent Orange constituents in experimental animals.

b. The way in which Agent Orange was employed during the Vietnam War.

c. The environmental fate of Agent Orange constituents.

d. Known and suspected human health effects of Agent Orange constituents.

e. Approaches to the epidemiological study of the effects on humans of Agent Orange.

f. How Vietnam veterans view the Agent Orange issue.

On February 4, 1980, an initial meeting was held at the St. Louis, Missouri VA Regional Medical Education Center to discuss the production of an educational videotape relating to Agent Orange. The program, which is being prepared with input from a variety of sources within the VA, will be designed to educate and inform veterans, the general public, and VA physicians and administrative personnel on the Agent Orange issue. Among the items that will be addressed in the videotape are the proper handling and treatment of veterans claiming Agent Orange exposure; what is known concerning the health effects of exposure to Agent Orange; what research is currently ongoing, will soon commence, or is under consideration in this area; and the perspective of Vietnam veterans concerning the issue.

COMPILATION OF DATA

A third VA activity relevant to Agent Orange is our effort to build a record of the medical data obtained from examination of Vietnam veterans. The goal of this effort is to gain additional knowledge about potential effects of exposure to herbicides on human health. With that knowledge we can then offer these veterans the most appropriate health care services.

The major component of this activity was initiated in May 1978 when we established a program for the medical examination and long-term follow-up of veterans who had served in Vietnam during the years that herbicides were used there (i.e., 1962–1971).

The objectives of this program are: (1) to detect disease among these veterans and to provide appropriate treatment for those eligible for VA health care benefits; (2) to develop statistical data on any health abnormalities which might conceivably be related to exposure to Agent Orange; and (3) to provide education and counseling to our veteran patients on the known effects of Agent Orange on human health.

The data obtained from these examinations will all be entered into a central computer where they will form the basis for our "Agent Orange Registry." The data will be steadily augmented through a series of repeat examinations performed by the VA over a period of years on all of the veterans included in the Registry. In addition, information concerning the health care which these veterans receive during this interval will also be included in the Registry.

The data in the Registry will be analyzed periodically in order to detect significant trends in the health of the veterans included in it, and to determine if any particular diseases are occurring with an unusual frequency among the veterans examined. These findings may prove to be very useful in suggesting where future scientific studies of Agent Orange effects on human health might be most profitably direct.

The Registry will also permit the VA to keep in contact with Vietnam era veterans potentially exposed to Agent Orange so that these veterans may promptly benefit from any relevant discoveries made concerning the diagnosis and treatment of any adverse health effects arising from such exposure.

In order to make this data most useful, the VA will work with the Department of Defense in an attempt to define the extent of Agent Orange exposure for each veteran entered into the Registry. However, this task will be extremely difficult, if not impossible, to accomplish because of the incomplete nature of the records maintained on troop movements during the Vietnam War.

The veterans' response to this program has been brisk and it is estimated that approximately 10,000 of them will have been examined under it by March 31, 1980.

We are also actively participating in the "Special Registry at the Armed Forces Institute of Pathology for Pathological Materials from Veterans with Possible

Exposure to Herbicides During the Vietnam War." This Registry was established on September 29, 1978. Its purpose is the collection and review of all types of tissue material obtained by the VA from veterans claiming exposure to herbicides. These materials are evaluated and diagnosed at the AFIP and a report of the findings is submitted to the VA. The tissues examined are then retained at the AFIP so that they may be utilized for further studies.

The diagnostic conclusions reached on the tissues submitted to the AFIP Registry will also be available for incorporation into other studies relevant to Agent Orange that may be undertaken in the future. Among such studies that are being considered by the AFIP are the following: (1) the detection of unusual or unique tumors; (2) the search for an unusually high incidence of a tumor from a particular anatomic site or occurring at an unusually young age; and (3) the discovery of a cluster of similar cases of a disease in particular military unit.

Another aspect of our efforts to build a record concerns the claims we have received for disability compensation based on Agent Orange exposure. Before providing an analysis of the claims which the VA has adjudicated thus far, I would like briefly to discuss the problems with regard to the adjudication of claims which the Agent Orange issue has posed and to place them into prespective for you.

The major difficulty here concerns the matter of relating what is currently known about the effects of exposure to Agent Orange to the VA's adjudication process. Establishing a connection between occurrences in service and subsequent disability is, of course, less difficult when the underlying disease or injury can be documented during service. When a chronic disease becomes manifest to a degree of 10 percent disabling within one year following service, it is by law presumed to have had its inception during service. Likewise, where a disease process is in a state of pathological advancement from which it can be reasonably inferred that its origin was in service, even if first detected more than a year thereafter, service connection will be found. Also, when service medical records contain clues such as subtle blood or urine chemistry changes indicating the possible incipient stages of a disease, establishing a connection is made easier.

Determinations of the sort just described do not require that the adjudicator form or offer an opinion as to the causative agent or event. So long as the precipitating injury or disease was incurred or aggravated in the line of duty, the law permits compensation for resulting disability. Two compensation claims based upon chloracne, a known health consequence of dioxin, have been granted by VA but because the presence of this skin disease was verified in service, it was unnecessary to inculpate any causative agent.

More vexing is the resolution of claims in which it is contended that disabilities first appearing n any years post-service are attributable to service incidents, such as exposure to toxic agents. It is known, for example, that humans receiving ionizing radiation in certain forms and in sufficient doses face an increased likelihood of contracting "radiogenic" forms of cancer, perhaps several years hence.

Unless or until some such latent effects of Agent Orange or its derivative components are scientifically documented, there are intrinsic limitations as to the VA's authority to allow these claims under current law. Though I cannot emphasize enough our policy to resolve reasonable doubt as to service incurrence of disabilities in favor of claimants, there is currently no medical basis upon which adverse health effects of late-post-exposure onset can be reasonably tied to Agent Orange.

It is VA policy to assist claimants in the development of pertinent facts in order that every benefit supported in law can be granted. A Department of Veterans Benefits circular dated April 25, 1979 (Attachment F) reminded adjudicators and benefits counselors to notify Agent Orange claimants of the availability of the special medical examination and treatment program which could help them document the existence of disabling conditions. Claimants are encouraged to submit any evidence, lay or medical, which could support entitlement, and assistance in acquiring this evidence is provided upon request. Claimants are also advised of their right to avail themselves of the administrative hearings to which they are entitled at any time.

In April, 1978, the Adjudication Divisions of the regional offices were instructed to begin routinely sending to Central Office copies of all decisions involving claims for disability benefits based upon exposure to defoliants in Vietnam (Attachments G and H). Through January 31, 1980, 1,233 of these decisions were received. Because the potential health problems associated with use of defoliants in Southeast Asia have received wide publicity only relatively recently, it is believed that the 1,233 decisions represent the majority of claims filed and adjudicated to date.

The table in Attachment I depicts, by disability type, the number of physical and mental disorders claimed and found in these 1,233 cases, and the disposition of the claims at the regional office level. As can be seen, the 1,624 disorders claimed

due to Agent Orange span the spectrum of physical and mental maladies. In 286 claims, no specific disability has been alleged. The existence of the disabilities claimed was not documented by clinical examination or treatment records in the great majority of cases.

In 21 instances, the disorders claimed to be due to Agent Orange exposure were held to be service-connected. In none of these 21 was it necessary to determine whether Agent Orange was or was not a causative factor. These decisions also show that among Agent Orange claimants, 53 disorders not alleged to be due to Agent Orange but clinically documented were held to be service-connected on the basis of evidence evinced during processing of the Agent Orange claims. These 53 do not include disorders previously held to be service-connected based upon prior claims.

The Board of Veterans Appeals has, since July 1978, dispatched 65 appellate decisions in cases involving contentions of Agent Orange-caused disability. Of these, 47 have been remanded for further evidentiary development. Five appeals have been allowed, although again it has been unnecessary to assign a cause-effect relationship between herbicide exposure and the disabling condition. The five involve 3 different forms of cancer, one case of arthralgia and one case of anxiety neurosis.

Analysis of the 1,233 originating agency decisions showed that in 202 of the denied claims, a VA examination had not been performed. In each of these cases, there was insufficient probability of a valid claim to warrant scheduling a compensation examination or the claimant did not avail himself of the opportunity. The Department of Veterans Benefits will soon issue an instruction to all field stations to review the claim folders of previously unsuccessful Agent Orange claimants and, where there is no record of the special VA examination for inclusion in the Agent Orange Registry, to remind the veteran of the availability of these examinations and VA health care.

Within the confines of current law and available scientific data, the VA has made every effort to adjudicate fairly these claims. Given the considerable uncertainties as to deposition of the defoliant in Southeast Asia and troop positions at pertinent times, we will accept in the absence of positive evidence to the contrary a Vietnam veteran's contention of exposure. The crux of the problem is that some veterans are concerned that they have experienced delayed impairment of health as a result of exposure, and there is no scientific evidence at present that this has occurred.

As previously discussed, there is currently no scientific evidence that Agent Orange can induce sperm cell damage which can be transmitted to the detriment of fetuses. No Agent Orange claims have been filed by female veterans. Title 38 presently permits payment of compensation only in cases of disabilities experienced by veterans themselves. Should it be learned that injuries to reproductive cells suffered by either male or female service members can be transmitted to the detriment of the health of their offspring, the remedies available for redressing these "secondary" injuries would require careful reassessment.

VA AGENT ORANGE RESEARCH ACTIVITIES

The fourth area of VA emphasis which I wish to discuss today is that of research. We have been conducting studies in several areas relevant to the Agent Orange issue. For example, we have made an effort to find out whether it is possible to detect and measure dioxin in the body fat of veterans exposed to Agent Orange. We utilized the following protocol in doing this project: 20 veterans who reported that they were exposed to Agent Orange in Vietnam, some of whom have symptoms which they attribute to that exposure, volunteered to allow a surgeon to remove fat from their abdominal wall for the test. In addition, three Air Force officers who have worked extensively with Agent Orange but who have no ill effects, similarly volunteered. Another 11 veterans of the Vietnam era who were not exposed to Agent Orange agreed that surgeons could take a sample of their fat as "control" when they performed a needed operation. All these veterans gave informed consent for the fat biopsy procedure.

The 34 fat samples were tested by an independent, university-based chemist who used the most sensitive method known to detect and measure dioxin. The method, known as gas chromatography with high resolution mass spectrometry, is still experimental and difficult to use.

The results of the analysis show that seven of twenty veterans with Vietnam service had dioxin in the small amounts of 3 to 89 parts per trillion in their fat. Six others in this group had even smaller amounts and seven had no detectable dioxin at all. The three Air Force officers who have worked extensively with

Agent Orange had 3 to 4 parts per trillion in their fat. One of the eleven controls with no known exposure to Agent Orange had 3 parts per trillion, three others had less, and seven had none at all.

Environmental Protection Agency scientists using a different testing procedure on eight duplicate samples have confirmed these results.

We can say then that there is a method to detect and measure small amounts of dioxin in body fat but that it is difficult to perform. Further, it requires an operation to obtain the fat sample. Accordingly, this test, while a potentially valuable research tool, is not a practical routine diagnostic procedure.

We are presenting the results of this study to the VA Advisory Committee on Health-Related Effects of Herbicides, to the Interagency Workgroup on the Toxic Effects of Phenoxy Herbicides, National Academy of Sciences and Office of Technology Assessment for their critical review and comments. When that review is completed, the VA plans to submit the results of the study for publication in a recognized scientific journal. We will submit a preliminary report of this study to the committee upon completion of this review.

Public Law 96–151 mandated that the Veterans Administration undertake two projects: (1) an epidemiological study of Vietnam veterans exposed to phenoxy herbicides and (2) a review and analysis of the world's literature on phenoxy herbicides.

The VA will contract with an epidemiologist from the private sector to design the required study and to analyze and interpret its results. The epidemiologist will be selected by a process of open competitive bidding. The successful bidder will be an individual with an impeccable scientific reputation who has successfully conducted epidemiological studies of a major scope in the past. This individual will also not be publicly associated with a partisan position on the human effects of Agent Orange so as to avoid bias in the design and analysis of the epidemiological study.

It is expected that the use of a distinguished outside epidemiologist to design the VA's study will help assure its objectivity and scientific appropriateness. In addition, the designer would be expected to develop a methodology for monitoring the quality and objectivity of the data gathered.

In order to further assure that the study is designed in the scientifically appropriate manner, it will be reviewed prior to its initiation by several prestigious scientific groups. It is currently, anticipated that one of these groups will be a panel of epidemiologists selected by the National Academy of Sciences. Other groups involved in the review will include our Advisory Group on Herbicides, the Office of Technology Assessment and the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides.

It is our intention that the medical and demographic data for the study will be collected in selected VA medical centers by a staff specifically trained in the techniques specified by the study's designer. This arrangement appears to be the most effective method for gathering the necessary data. Attempts to duplicate the staff and facilities required for this purpose outside of the VA would, we believe, be both inordinately expensive and logistically impractical.

The present schedule calls for selection of the contract exidemiologist to be completed by the middle of March 1980. In addition, it is anticipated that the study will be initiated by October, 1980. If this schedule is met, the first results of the study should be available by December, 1981.

Although tentative conclusions from the study will undoubtedly be reported on a regular basis commencing in 1981, its final results may not be available for as long as a decade. This delay in completion of the study is actually a reflection of the fact that any toxic effects which Agent Orange might have on human health may not become apparent for several decades after initial exposure.

The review and analysis of the literature on phenoxy herbicides required by Public law 96–151, will also be performed by a distinguished and ojecetive scientist from outside the federal government who will be retained by an open bid contract. Once again, the purpose for conducting the project in this manner is to help assure its objectivity.

The body of literature pertaining to the Agent Orange issue is large and complex, and it is growing at a rapid rate. However, the identification and collection of this literature will be expedited by the fact that several extensive bibliographies on herbicides (i.e., those prepared by DoD and EPA) will be available for use in this project.

It is anticipated that the contract will be awarded in April, 1980 and that the entire project will be completed by January, 1981.

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In its efforts to resolve the Agent Orange issue, the VA is maintining close liaison with the several government agencies with an interest in and a responsibility for investigating certain facets of the herbicide problem. We are following their research and other herbicide-related activities closely and coordinating with them whenever possible.

This effort at coordination is significantly enhanced by the fact that we are actively participating in the efforts of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants which I referred to earlier, and the VA's own Advisory Committee on Health-Related Effects of Herbicides.

OTHER RESEARCH ACTIVITIES

I understand other agencies will be presenting testimony on their research activities in the area of dioxin toxicity. However, I would like to give you a brief review of those activities. I would preface my remarks in this regard by saying that thousands of experiments have been done and the literature searches performed by the National Academy of Science and the Air Force list many of them. In fact, one of the most important efforts of our Advisory Committee on Health-Related Effects of Herbicides has been to learn of additional experiments and to interpret their meaning for us.

Currently, HEW's research deals with many aspects of the problems of the toxicity of 2,4-D, 2,4,5-T, dioxins and other possible contaminants. For example, HEW is supporting or conducting epidemiological studies of workers exposed to these compounds in Nitro, W. Va., Jacksonville, Ark., and Sauget, Ill. Results of these studies should yield information on the possible human health effects of chronic dioxin exposure. Further, HEW is establishing a registry of workers involved in the formulation or synthesis of 2,4,5,-T and is exploring through the World Health Organization International Agency for Research on Cancer the development of an international registry of such workers.

HEW is studying methods for improving the analysis of the dioxins and the preparation of pure samples of certain dioxins and dibenzofurans for analytical standards and for toxicological studies.

NIH has initiated a study to determine if treatment of male mice with mixtures of pure 2,4-D, 2,4,5-T and dioxin can cause birth defects and other damage to offspring as has been reported by veterans. Mutagenesis tests for these chemicals and neurobehavioral tests for 2,4-D are also scheduled.

A National Cancer Institute (NCI) study of 4,000 Florida pest control operators is being conducted. The causes of death in this group from 1965 to the present will be compared with normal life expectancy corrected for age and sex.

The National Health Examination Survey performed by PHS/DHEW will provide additional data on veterans exposed to Agent Orange.

One of our Advisory Committee members has pointed out that veteran claims of birth defects must be examined with full recognition of the fact that in the normal course of pregnancy fifteen percent abort spontaneously and about two percent of surviving fetuses have some developmental defect. Furthermore, six percent of the abnormal births relate to environmental factors and at least 20 percent have a major genetic etiology.

The Communicable Disease Center's exhaustive study of birth defects in the Atlanta area may provide valuable data relevant to possible effect of Agent Orange on reproduction. In order to help clarify the influence of exposure to herbicides in Vietnam on birth defects, we are preparing a formal request to the Secretary, DHEW, that the CDC's thirteen page questionnaire on birth defects include information on the parents' service in Vietnam. This information can then be correlated with birth defects among the offspring of Vietnam service personnel.

Information is being made widely available from the toxicology/carcinogenesis efforts of the National Center for Toxicology Research (NCTR) in North Carolina. NCTR compiles voluminous information on the many HEW agencies (e.g., FDA, NCI, NIOSH) involved in (a) screening chemicals for possible toxicity; (b) salmonella assays; and (c) fruit fly studies for genetic changes. We intend to keep abreast of the many chemicals in their testing cycle, but particularly the dioxins and related compounds. We note that TCDD is near the end of its carcinogenicity testing cycle. Furthermore, it is possible that a technical report on TCDD will be released to the public this year—potentially an important step in determining the hazard to veterans exposed to Agent Orange.

Much of the automated library information established, or to be established, by the National Library of Medicine at the request of NCTR will assist BA.

This includes TOXLINE, CHEMLINE, the Toxicology Research Projects Directory, and the epidemiology Projects Research Directory.

The National Toxicology Program involving the National Cancer Institute of NIH, the National Institute for Environmental Health Science the National Institute for Occupational Safety and Health, and the National Center for Toxicological Research has developed a plan for implementation in 1980 which specifies agency roles in a number of studies of TCDD to ascertain fetotoxicity teratogenecity, carcinogenicity and other effects of these chemicals.

The Department of Defense is pushing its plans to conduct an epidemiological study of the Ranch Hand members. These individuals, the pilots and crews who worked in intimate contact with Agent Orange, are among the few service members whose exposure to this material is fully documented.

The National Forest Products association has performed a study of exposure of forest orkers to 2,4,5-T, one of the components of Agent Orange.

The U.S. Department of Agriculture is conducting a study of cancer deaths in which Forestry Service employees exposed to herbicides will be compared to a cohort group of employees not at risk.

There is a joint State of California/NCI followup of 9,000 pesticide poisoning patients treated in emergency rooms. The earliest date for significant information from this study is probably 1987.

CONCLUSION

In conclusion, I believe that the VA is conducting a well-organized and broadly based program for helping to resolve the issues of Agent Orange effects on human health. In addition, we are providing medical diagnostic and treatment services to eligible veterans who claim ill effects from herbicides. We are coordinating these activities with complementary efforts being conducted by other federal agencies and outside groups.

Despite these efforts, the final resolution of all of the issues concerning Agent Orange may not be completed for many years. It is impossible to estimate precisely when we will complete our several Agent Orange-related projects because of the numerous imponderable factors involved. However, the following tentative schedule of project milestones can be given:

The epidemiological study, mandated by Public Law 96–151, will be initiated by October, 1980 and its first tentative results will be available by January, 1982.

The review and analysis of Agent Orange literature, also mandated by Public Law 96–151, will be completed by December 1980.

The VA's Agent Oragnge Registry will contain data from 10,000 Vietnam era veterans by April, 1980. Analysis of this data will be issued on a regular basis beginning in mid 1980.

The VA's Advisory Committee on Health-Related Effects of Herbicides will issue a set of recommendations for future VA approaches to the resolution of the Agent Orange issues by September, 1980. These recommendations will be periodically updated in the future.

The VA will conduct or support research in a number of basic biomedical areas which appear to be relevant to the diagnosis of Agent Orange effects on human health. Among these areas being considered are: chromosomal effects, immune system competence and effects on liver enzymes.

Studies of the relative statistical frequency among Vietnam veterans of diseases alleged to be caused by Agent Orange exposure will be pursued beginning this year. These will include studies of cancer, liver and kidney disease, infertility and birth defects.

During 1980 the VA will further regularize its liaison with other groups and individuals who are actively involved in some aspect of the Agent Orange issue. It is expected that this process will permit the VA to benefit from the experience and insight of others studying the issue and, in turn, to provide them with accurate information on what the VA is doing in this area. It is also possible that these liaisons will permit the participants in the Agent Orange effort to resolve some of their major methodological and technical differences so that future efforts can proceed in a more productive fashion.

During 1980 the VA will continue to develop educational materials on Agent Orange for dissemination to the staff of its health care facilities and for the veterans it serves.

Mr. Chairman, everyone wants to know immediately the definitive answers to the questions posed by Agent Orange. Unfortunately, the scientific inquiry process necessary to provide accurate reliable information does not always lend itself to

immediate answers. I want you to know, as one who has a personal stake in this question, that we at the Veterans Administration, including the 39,000 Vietnam veterans who are employed by the Veterans Administration, are committed to obtaining and disseminating accurate information as soon as humanly possible. In the meantime, we shall continue to provide every eligible veteran we examine, and find to be in need of treatment, appropriate medical care reg rdless of causation. We owe them no less.

ATTACHMENT A—ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

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ATTACHMENT B

The Executive Summary of the first 13 position papers prepared by the Advisory Committee in response to the specific questions put to them by the Veterans Administration.

Question No. 1. a. Do the available data on exposure of Vietnam veterans to herbicides permit the performance of scientifically valid epidemiological studies on the long-term health effects of herbicides in this group?

b. 2.4 million veterans reportedly may have been exposed to Agent Orange. Is reliable information on subsequent health of these individuals available? Might it be useful?

Answer. The necessary components of a valid epidemiological study of Vietnam veterans exposed to Agent Orange (A/O) was outlined. These components are: (1) precise data on the quantity of A/O applied, and the specific times and places of its application; (2) identification of the veterans exposed to A/O with quantification of the extent of their exposure; (3) selection of a control group of veterans which match the exposed group in relevant parameters; (4) inclusion as the endpoints of the epidemiological study such factors as mortality experience and reproductive effects and (5) definition of the exposure of the control and study groups to other environmental toxins.

Question No. 2. What are the best human population groups in which to study the long-term effects of herbicides on health, and how may these studies best be conducted?

Answer. Those population groups exposed to A/O over a long period of time are the ones that should be the focus of epidemiological studies of A/O effects on human health. In addition to the Vietnam veterans with A/O exposure, other population groups which might be studied include industrial and agricultural workers who have had significant contacts with A/O.

Question No. 3. Of what diagnostic value are the following procedures in assessing possible herbicide toxicity: levels of dioxin in fat pad biopsies; study of immune factors; study of chromosomal patterns; and study of liver microsomal enzymes? What additional diagnostic procedures should be considered?

Answer. Studies in experimental animals have suggested that certain types of studies might be useful in the diagnosis of A/O toxicity. Among these are: dioxin levels in fat biopsies, alteration in immune factors, chromosomal changes, and activity of liver microsomal enzymes. However, it appears that many people in the United States may have detectable levels of dioxin in their tissues yet most of them are asymptomatic. In contrast, the absence of detectable dioxin levels does not rule out exposure.

Experimental evidence that dioxin alters the immune system and chromosomal integrity in experimental animals has not been confirmed in man.

TODD, the principal toxin in A/O, has been shown to be a potent stimulator of the liver microsomal enzyme aryl hydrocarbon hydroxylase. However, there is no evidence that harmful effects of TODD can be correlated with abnormalities in the activity of the enzyme.

In conclusion, none of the physiological alterations currently associated with A/O exposure can be utilized as the basis for definitive diagnostic tests for such exposure. However, the results of such tests might be helpful in establishing a diagnosis of dioxin "intoxication" in some patients when utilized along with clinical data.

Question No. 4. Is it possible for herbicides to have long-term adverse effects on the male reproductive system?

Answer. It is possible that such effects might occur, but there is no convincing evidence that they do occur. However, speculation as to the nature of such effects might include the following possibilities: (1) A/O's constituents could exert a direct deleterious effect on male spermatogenesis causing infertility; and (2) A/O could damage the genetic components of the sperm and result in abnormalities in the embryo formed from a union with these sperm.

Detection of the effects of possible A/O-induced sperm defects and proof that such effects are related to wartime exposure will be very difficult to achieve. For example, detection of "poor reproductive outcomes" would require study of very large numbers of individuals since these outcomes may be very subtle and difficult to detect. Even if these defects are detectable, they must be shown to occur in a much higher frequency among exposed Vietnam veterans than in controls. This might also pose significant difficulties in study design and execution.

Despite these methodological difficulties, it is clear that efforts should be made to study the effects of A/O on the male reproductive system in a scientific, meticulous fashion.

Question No. 5. What topics should be included in the educational curricula being developed to upgrade knowledge of potential herbicide toxicity among VA staff members?

Answer. An outline was provided of an approach to educating VA health care professionals in the methods of detecting herbicide toxicity. Attention to animal

and industrial studies as models is recommended. In addition, it is suggested that specific forms and procedures be designed to be used in the training programs for collection of the relevant clinical data from veterans.

Question No. 6. What sort of animal studies would make the most important contributions to understanding the potentially toxic effects of herbicides in humans?

Answer. The ideal animal model would be one which responds to A/O constituents in a manner similar to that of the human being. The rhesus monkey is recommended as one species that might meet the requirements of the ideal model. It is suggested that male rhesus monkeys be exposed to mixtures of A/O similar to those to which American troops were exposed in Vietnam for similar amounts of time. These animals should then be observed for clinical abnormalities including those in the psychological and reproductive areas.

The carcinogenic potential of A/O can not be conveniently assessed with the use of the rhesus monkey model, since the latent period of toxin-induced cancers in this species is very long. Accordingly, the use of rates and mice for such studies is recommended because of the rapidity with which these species develop such cancers.

Other potentially relevant studies are as follows: (1) separate toxicological studies on call cultures since they may render feasible the solution of many complex investigative problems which have defined studies in intact animals; and (2) studies of the persistence of TCDD in the fat of nonhuman primates may clarify this matter in humans.

Question No. 7. What additional data should be included in the VA's herbicide registry over that currently collected?

Answer. The data being collected on Vietnam veterans participating in VA's A/O examination program is considered adequate at this time.

Question No. 8. What are the known facts on the persistence of dioxin and the herbicides used during the Vietnam War in water, soil and the atmosphere? Can these media serve as a source of human exposure to dioxin and herbicides?

Answer. The available data on persistence in soil, air and water under several conditions of temperature and humidity of the herbicides used during the Vietnam War and of TCDD were summarized.

The potential routes of human exposure to TCDD include: skin absorption, inhalation and ingestion. Skin and inhalation exposure from aerial application undoubtedly occurred in Vietnam but are very difficult to quantitate under the conditions which A/O was sprayed there. Ingestion exposure, in contrast, probably did not occur, since TCDD apparently does not enter the food chain. Therefore, it may be very difficult, or even impossible, to specify which military troops were exposed to A/O, much less the extent of any exposure which occurred.

Question No. 9. What medical tests should be utilized to help establish diagnosis of chronic herbicide-induced toxicity among Vietnam veterans?

Answer. The difficulty of separating lesions due to TCDD from those related to other invironmental toxins was emphasized. In addition, it was pointed out that since there are no known lesions specifically associated with A/O, there are no diagnostic tests specific for A/O toxicity. Accordingly, any approach to the search for evidences of A/O toxicity must be in a research mode.

A detailed list of the types of tests that should be undertaken and a sequential protocol in which they should be applied is provided. It starts with a review of the medical records of the study participants during their terms of military service in Vietnam. Next, emphasis would be placed on the following body systems in the medical examination: skin, hematopoietic-immunologic system, liver, reproductive system and central nervous system (neurological and psychological aspects). Efforts would also be made to document sources of exposure to environmental toxins other than A/O utilized in Vietnam.

Question No. 10. Can criteria be established for determining the level of exposure of military personnel to dioxin during the Vietnam war based on spraying tapes and unit histories?

Answer. There are no data available which will allow determination of a precise level of exposure of a Vietnam veteran to Agent Orange. Accordingly, the best assessment of such exposure is one based on "relative probabilities." These probabilities would be constructed on the basis of a model which considered the following factors: (1) the inclusive dates during which the individual was in Vietnam; (2) the jobs he performed; (3) the way in which the exposure occurred; (4) the type of aircraft/vehicle involved in the exposure; and (5) the individual's circumstances during the spraying exposure.

The following data on A/O use must be considered in calculating the probability of exposure of a given individual at a specific time.

Area 1.—(a) A/O and other TCDD-containing herbicides were utilized in Vietnam between 1962 and 1971. A/O was the most heavily utilized of these herbicides (i.e., 10.7 million gallons of Orange out of 17.7 million gallons total used).

(b) The dioxin content of A/O which was utilized between 1965 and 1971 was apparently much lower than that of the herbicides utilized between 1962 and 1965.

Area 2.—(a) The exposure of military populations to A/O was highly variable, ranging from the close with it experienced by the 1,200 Ranch Hand group through the more indirect type of contact of ground troops entering a defoliated area one month or more after herbicide application.

(b) It appears that the vast majority of U.S. troop contacts with A/O would be of the indirect and delayed type.

Area 3.—(a) The precise job which an individual performed and his geographical situation at the time of spraying will approximately correlate with his chances of coming in contact with a TCDD-containing herbicide.

(b) A/O, for example, was utilized primarily on mangrove and island forests *and in combat* Tactical Zone III.

Area 4.—The military aircraft utilized for most A/O spraying was the C–123/UC–123. However, some A/O was sprayed by helicopter pilots and the C–123 was also used extensively for pesticide spraying.

Area 5.—(a) Exposure to A/O might have occurred via direct percutaneous absorption, inhalation of vapors/areosols; indirect percutaneous or inhalation absorption; and ingestion of contaminated foods.

(b) The known facts of the environmental fate of A/O constituents would suggest that these constituents are decomposed rather rapidly and that they do not enter the food chain to a significant extent.

In conclusion, the paper recommends that exposure must be investigated on an individual basis utilizing the five areas mentioned in the paper as the framework on which the investigation should be based.

Question No. 11. Will it be possible to develop standards and criteria which define the precise relationship between herbicides and dioxin with chronic adverse effects in humans? Can these criteria also specify the reasonable limits between the time of exposure to herbicides and the development of disease?

Answer. At the present time it is not possible to develop standards and criteria which define the precise relationship between exposure to herbicides and dioxin with chronic adverse effects in humans. Such criteria can only be developed as the result of epidemiological studies based on sound scientific principles.

Question No. 12. To what extent is information potentially available on the effects of Agent Orange on the indigenous Vietnam population?

Answer. The amount of data available in this area is very limited and expansion of its contents will depend upon whether the government of Vietnam will permit scientific access to the appropriate geographical area and population groups. In the meantime, the 1974 study by the National Academy of Sciences (i.e., "The Effects of Herbicides in South Vietnam") remains our sole source of information on the health experience of the population of South Vietnam exposed to A/O. Unfortunately, that study has a significant limitation scientifically because it lacks data on long-term follow-up of exposed populations.

Question No. 13. What is the UN doing concerning possible Agent Orange exposure of UN troops that served with U.S. forces in Vietnam?

Answer. The Administrator sent a letter on August 28, 1979 to the Honorable Kurt Waldheim, Secretary General of the United Nations, requesting information on any activities that the UN might be undertaking related to the Agent Orange issue. As of February 15, 1980, no reply had been received to this letter.

ATTACHMENT C

Directors, VA hospitals, domiciliary, outpatient clinics, and regional offices with outpatient clinics.

Subject: Potential exposures of Veterans to chemical defoliants during the Vietnam War.

1. During the Vietnam War, herbicidal war chemicals were utilzed for defoliation of vegetation. Recently concern has developed among some scientific and other groups that these chemicals may be capable of producing adverse health effects on individuals who were exposed to these herbicides. Because of their potential impact on a segment of the veteran population, the VA is attempting to develop accurate information on the health-related effects of the defoliants utilized during the Vietnam War.

2. The four defoliants utilized regularly were picloram, cacodlic acid, 2,4-D and 2,4,5-T. These were mixed in variable proportions and placed in color-coded storage drums which were identified as "Agent Orange", "Agent White", "Agent Blue", and "Agent Purple." A large number of studies performed on man and several animal species have demonstrated that the four herbicides have a low level of toxity, both individually and when mixed. Furthermore they appear to be rapidly absorbed and completely excreted in both the human and the animal.

3. Humans exposed repeatedly to these agents may experience temporary and fully reversible neurlogical symptoms; however, the only chronic condition definitely associated with such exposure in humans is chloracne. Comprehensive animal studies performed under experimental conditions have demonstrated that very massive doses of these agents produce fatty degeneration of solid organs, gastrointestinal disturbances and thymic atrophy, all of which were reversible after withdrawal of the chemicals.

4. These studies have failed to confirm the suggestion in the Vietnamese medical literature that liver cancer, frequent abortions, and fetal birth defects occur among those exposed to the defoliants. In addition, no confirmation has been obtained for the experimental studies of one scientists who found that hepatic and pancreatic cancers followed prolonged exposure to one of the chemicals.

5. In contrast to the apparent low toxicity of the four defoliants, evidence has been adduced that a contaminant called dioxin found in some of the storage drums has a significant potential toxicity. Although its concentration of dioxin was variable in different drums, it was always found in minute quantities. Experimental evidence from animal studies indicates that this chemical is eliminated from the body fairly rapidly and that it produces its toxic effects rather promptly. All available data suggests that it is not retained in tissues for prolonged periods of time. Accordingly, the recent suggestion by some observers that dioxin might still be detected in the fat tissues of Vietnam veterans exposed to it appears to be implausible.

6. Despite the generally negative results of human and animal studies of the toxicity potential of the Vietnam defoliants, a great deal of concern has been engendered among veterans and their families by media presentations on these agents. The VA is responding to these concerns by working collaboratively with appropriate experts from the Federal and private sectors in order to more adequately define the potential human toxicity of the defoliants for humans. You will be periodically informed concerning the results of these efforts.

7. Meanwhile, we request that all VA staff who are called upon to deal with veterans who are concerned about toxic effects from a possible exposure to the defoliants adhere to the following protocol:

A. Every veteran who alleges defoliant exposure must receive prompt courteous, compassionate consideration.

B. If the veteran has no objective symptoms or signs, simple reassurance should be offered. The veteran should be told that a record of the medical examination will be kept for future reference, but that if the veteran does not now have symptoms and did not previously experience any, the likelihood of herbicide poisoning is virtually zero.

C. If the veteran presents with symptoms and signs which are not clearly explicable in terms of definable disease, a detailed history should be recorded on the VA form 10–10m, including such details the veteran may remember concerning his exposure to defoliant agents. This information can be checked against military data, if indicated.

D. In view of the remaining uncertainties on the long-term effects of the defoliants, all VA personnel should avoid premature commitment to any diagnosis of defoliant poisoning. Similarly, entries in medical records should not contain statements about the relationship between a veteran's illnesses and defoliant exposure unless unequivocal confirmation of such a connection has been established. Accordingly, veterans in whom defoliant poisoning is suspected should be admitted to a VA hospital for appropriate work-up.

E. If there is evidence suggestive of defoliant agent poisoning, pertinent data must be forwarded to the ADCMD for operations (11), VACO.

F. No veterans other than those referred by DVE should be called in for the express purpose of having them examined for possible defoliant poisoning.

G. All VA forms 10–10m indicating that the veteran or the physician has material concern about the possibility of defoliant poisoning, should be preserved until further notification.

H. A 3 x 5 locator card should be developed by MAS so that VA forms 10–10m can be swiftly retrieved if the need develops. MAS staff have received instructions on how to develop these cards. Significant administrative problems may be reported to VACO MAS (136D).

I. If a patient who already is hospitalized intimates that he or she may have been exposed to defoliants, a statement to this effect should be entered in the medical record. If there are symtoms or signs which cannot be explained in terms of well known medical entities these should be appropriately investigated.

J. Many agricultural and horticultural agents contain the same herbicidal chemicals as were incorporated in the Vietnam defoliants. Whenever there is suspicion of chemical poisoning, therefore, inquiry should be directed to other sources of intoxication as well as the allegations concerning the Vietnam episodes. There also are many industrial sources of chemical intoxication whose manifestations are similar to the syndromes ascribed to the defoliants. A careful occupational history therefore is necessary.

K. Staff of field HCF's who may be called upon to make public statements concerning the defoliants should not do so before reviewing their proposed expositions with the ACMD for professional services, whose staff will provide the needed technical guidance.

7. We trust that the foregoing guidance will be sufficient. If new information indicated a change of policy, additional directives will be issued. Should any problem arise which is not covered by this policy statement additional clarification may be sought by calling VACO Medical Service (Dr. Gerrit Schepers, ext. 389–2550). Any freedom of information request should be coordinated with VACO. 11/10A

ATTACHMENT D

Circular 10–78–219

SEPTEMBER 14, 1978.

VETERANS ADMINISTRATION,
Department of Medicine and Surgery
Washington, D.C.

To: Directors, all VA hospitals, domiciliary, and outpatient clinics.
Subject: Possible exposures of Veterans to herbicides during the Vietnam War, RCS 11–49.

1. The purpose of this Circular is to provide supplemental information to the teletype directive dated May 19, 1978, on the above subject, and instructions for documentation in the medical record. It is essential that all concerned personnel be given copies of the teletype directive and this Circular.

2. Recent publicity in the news media about illness among persons who were exposed to herbicidal agents used in Southeast Asia, may result in veterans presenting themselves at VA health care facilities for evaluation. It should be understood that there is no positive evidence for deleterious effects on the health of individuals exposed to these herbicides which is of a permanent nature. However, it is widely agreed that it is necessary to provide such individuals with meticulous medical follow-up for prolonged periods of time in order to obtain definitive answers about the health related effects of herbicides.

3. Accordingly, VA policy is to examine thoroughly all veterans who claim toxic effects from exposure to herbicides during the Vietnam War and to maintain appropriate records on them so that any late complications due to these agents can be determined and treated.

4. All Vietnam Era veterans who currently are being treated in a VAHCF, and those who apply for such care will be asked to identify their previous military occupational code number, and asked whether they were exposed to herbicidal sprays or bulk chemicals during their periods of service in Vietnam. The military occupational code number will be entered on the VA Form 10–10 (April 1978) Application for Medical Benefits, in item 13, Military Service.

5. If a veteran states that he/she was exposed to defoliant sprays or bulk chemicals, he/she will be asked the questions appearing on the initial data base, possible exposure to toxic chemicals, part I, of the regular medical history for an examination (attachment A).

6. In eliciting the medical history and performing the physical examination (Attachments B & C), particular attention should be given to those organs which are most commonly affected by chemical intoxicants: nervous system, immune system, blood-forming system, liver, kidneys, thyroid, adrenals, gonads, skin, and lungs. Evidence concerning the following symptoms/conditions should be ascertained: an altered sex drive, sterility, frequent abortions, congenital deform-

ities among children, repeated infections, and neoplasia. Particular attention should be directed to the detection of chloracne, a skin condition which has been associated with acute exposure to herbicide mixtures containing the toxic chemical, Dioxin. It is important when the first manifestation of these symptoms/conditions occurred and the details of any treatment provided.

7. Appropriate diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and signs. Performance of non-routine diagnostic studies such as sperm counts may be appropriate if suggested by the workup. Any surgical, cytologic or other similar tissue removed in conjunction with any diagnostic, operative or other procedure should be processed and reported in the usual manner. All slides, blocks, and tissues will be retained for inclusion in a special tissue registry, the location and operation of which will be described in a separate circular.

8. There is controversy among experts regarding the diagnostic value of measuring levels in body fat of Dioxin, a toxic contaminant of the herbicides utilized in Vietnam. In order to help resolve this controversy a study will be conducted, under VACO auspices, which will measure Dioxin levels in fat tissue taken from VA patients with a history of exposure to herbicides and from an unexposed control group. Until this study is completed, no VAHCF should attempt to measure tissue Dioxin levels in any of its patients without prior concent from VACO (11F).

9. Whenever a veteran seeks evaluation at a VAHCF for possible toxicity due to herbicides, the Medical Administration Service should be notified of this fact promptly. Following notification, that Service will initiate the procedures listed below:

(1) The patient data card will be used to imprint a 3 x 5 card.

(2) The 3 x 5 card will be filed alphabetically in a special file, which will be retained indefinitely.

(3) The file will be labeled "Possible Toxic Chemical Exposure File".

(4) In Item No. 17 of VAF 10–10, "Do you believe the need for care is" the following statement will be entered in the blank space: "Possible Toxic Chemical Esposure".

(5) For extra control purposes—insert at the top of VAF 10–10m, (Medical Certificate and History) the following statement: "The veteran states he/she has been exposed to chemical defoliant".

10. For all Vietnam veterans for whom these 3 x 5 cards are generated, it is essential that uniform recording of the initial data base discussed in paragraph 4 be provided. The following medical record forms will contain the data as illustrated on Attachments A, B, and C: Progress Notes (SF 509 or VAF 10–7978i) and Physical Examination (SF 506 or VAF 10–7978e). The heading, "Initial data base–possible exposure to toxic chemicals (part I, II or III)" will be placed at the top and bottom (including reverse side of each form) to insure proper identification and easy retrieval. If a Vietnam veteran is currently hospitalized, the illustrated progress notes form (parts I and II) will be completed and, in addition, the current physical examination form, already completed, will be stamped with the heading "Initial data base—possible exposure to toxic chemicals—part III."

11. When the VAF 10–10 involving a potential chemical exposure and the Initial Data Base are completed and there is no indication for hospitalization or outpatient treatment, the forms will be placed in an existing or newly created veteran's Consolidated Health Record (CHR) rather than being placed in the rejected VAF 10–10 file. The placement of these forms in the CHR will insure that the record is retained for historical, clinical, statistical and research purposes.

12. A quarterly report, beginning with the quarter ending September 1978 will be submitted to reach the Associate Deputy CMD for Operations (11) by the 8th workday of the month following the close of the quarter. Negative reports are to be submitted. The report will contain the following information:

(a) Total number of Vietnam Era veterans claiming symptoms related to possible exposure to chemical defoliants or bulk chemicals during their tours of service in Southeast Asia.

(b) Of the total number of veterans alleging symptoms in subparagraph a above, the number of veterans with symptoms professionally attributed to exposure to chemicals defoliants.

(c) Copies of Attachments A, B, and C, with copies of pertinent laboratory data and consultations, completed for each veteran included in subparagraph b will accompany the quarterly report.

Color-coded month tags should be placed on the 3 x 5 cards to provide the data required by subparagraph a. Local controls should be established to provide subparagraph b data.

13. We recommend that consideration be given to the designation of one or two clinical staff members as "environmental health physician(s)" to provide clinical management of veterans claiming exposure.

14. Questions concerning VACO's position on possible exposures to herbicides should be referred as follows: policy questions to Dr. Paul Haber (11) at extension 2213 or Dr. Richard Levinson (11F) at extension 3556, clinical questions to Dr. Gerrit Schepers (111) at extension 2550; and administrative questions to Medical Administration Service (136B) at extensions 2933 and 3468.

HERBERT M. BAGANZ, M.D.,
Acting Deputy Chief Medical Director.

Attachments.

Circular 10-78-219
September 14, 1978

RCS 11-49
Attachment A

MEDICAL RECORD	PROGRESS NOTES
DATE	INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

A. Date _____ Current Status of Veteran: ____ Outpatient ____ Inpatient

B. Branch of Service:
Military or Civilian Unit Designation:

C. How many exposures does the veteran allege?

D. What was the nature of each exposure?

E. When and where did these exposures occur? (Specify dates, military field bases, and length of exposure.)

F. Define severity of the exposure - circle or check, as appropriate.

Severe Direct Repeated Prolonged
Short Mild Indirect

G. At time of exposure - what was the veteran's job in service?
(Field participation, rear echelon, administration, etc.)

H. How directly was the veteran brought in contact with chemicals? (Check one)

____ Veteran was member of headquarters personnel and far removed from site of chemical exposure.

____ Veteran was in field.

____ Veteran operated apparatus used for chemical spraying or handled bulk chemicals in such a manner that gross exposure was possible.

I. If, in field, was veteran undercover (building, trench, foxhole, etc.) or out in open? Was he in a vehicle at the time?

(Continue on reverse side)

(SEE OTHER SIDE)

PATIENT'S IDENTIFICATION (Use typed or written name plus Name—last, first, middle; grade; rank; name hospital or medical facility)

REGISTER NO | WARD NO.

PROGRESS NOTES STANDARD FORM 509 (Rev. 11-77) Prescribed by GSA/ICMR. OMB (41 CFR) 101-11.206-5 509-109

INITIAL DATA BASE-POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

Circular 10-78-219
September 14, 1978

Attachment A
(Reverse Side)

PROGRESS NOTES

DATE

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

J. How long was veteran present at site of chemical exposure?

K. Was veteran issued protective gear? ___Yes ___No
If "yes" - did veteran wear this gear? ___Yes ___No
Describe gear:

L. Did veteran enter areas where chemicals previously had been sprayed or spilled - or did veteran eat from utensils or drink water contaminated by chemicals? Does veteran remember chemical names? Describe in detail.

M. What steps were taken to remove chemicals from veteran or the environment?

N. Has veteran been exposed to other potentially toxic chemicals:
(1) Prior to military service: ___Yes ___No
(2) During military service: ___Yes ___No
(3) After military service: ___Yes ___No IF "YES" DESCRIBE

O. (1) What is veteran's military occupation code number? _____
(2) Veteran possesses a copy of DD 214, Report of Separation-Active Duty?
___Yes ___No IF "YES" ENCOURAGE VETERAN TO BRING A COPY.
(3) Veteran possesses a copy of Service health/medical record?
___Yes ___No IF "YES" ENCOURAGE VETERAN TO BRING IN A COPY.
(4) Has veteran received VA Care?
___Yes ___No IF "YES", STATE LOCATION.

GPO . 1977 O-PC-2[illegible]

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

Circular 10-78-219
September 14, 1978

RCS 11-49
Attachment B

MEDICAL RECORD	PROGRESS NOTES
DATE	INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II
	REVIEW DATA ON PART I
	A. Pertinent Medical History - include symptoms at time of exposure, or later - attributed by the veteran to exposure - (continue on another Part II if needed)
	B. Pertinent Physical Examination (PE) - (check one).
	___Physical Examination to be done (Use SF 506 or VAF 10-7978f) "Initial Data Base - Chemical Exposure, Part III."
	___Repeat Physical Examination is indicated (a prior PE has been done within six months and has been reviewed).
	___Repeat PE is not indicated (a prior PE has been done within six months and has been reviewed).

(Continue on reverse side) (SEE OTHER SIDE)

PATIENT'S IDENTIFICATION (Use typed or written name plus home—last, first, middle; post; rank, rate, badge# or medical facility)

REGISTER NO. WARD NO

PROGRESS NOTES (STANDARD FORM 509 (Rev. 11-77) Prescribed by GSA/ICMR 509-110) INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II

B-1

Circular 10-78-219
September 14, 1978

Attachment B
(Reverse Side)

PROGRESS NOTES

DATE

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II

Check if following examination ordered:

C. Yes No

___ ___ Complete blood count including differential
Chest X-Ray (if no chest X-Ray within six months)

___ ___ Liver Function Profile

___ ___ Renal Function Profile

___ ___ Sperm Count

___ ___ Referral to a Dermatologist

D. Other Comments:

1. Evidence of Neoplasia: Present ___ Absent ___

Family History of:

Neoplasia Related Factors (e.g., cigarette smoking, radiation exposure, etc.)

2. Evidence of - Veteran and/or Family:

Infertility: Present ___ Absent ___

Abortions: Yes___ No ___

Teratogenesis: Yes ___ No ___

If "yes", Describe:

3. Were veteran's spouse or children in Vietnam? Yes ___ No ___
If "yes", give details.

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II

Circular 10-78-219
September 14, 1978

RCS 11-49
Attachment C

CLINICAL RECORD	PHYSICAL EXAMINATION					
DATE OF EXAM.	HEIGHT	WEIGHT			TEMPERATURE	PULSE	BLOOD PRESSURE

INSTRUCTIONS.—Describe (1) General Appearance and Mental Status; (2) Head and Neck (General); (3) Eyes; (4) Ears; (5) Nose; (6) Mouth; (7) Throat; (8) Teeth; (9) Chest (General); (10) Lungs; (11) Cardiovascular; (12) Abdomen; (13) Hernia; (14) Genitalia; (15) Rectum; (16) Prostate; (17) Back; (18) Extremities; (19) Neurological; (20) Skin; (21) Lymphatics.

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART III

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle; Grade; Date; Hospital or medical facility)	REGISTER NO.	WARD NO.

68-365 O - 80 - 3

Circular 10-79-83

April 16, 1979.

Veterans Administration
Department of Medicine and Surgery,
Washington, D.C.

To: Directors, VA Medical Centers, Medical and Regional Office Centers, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics.

Subject: Possible exposure of veterans to herbicides during the Vietnam War, RCS 11-49.

1. This represents a revision of circular 10-78-219, dated September 14, 1978.

2. A number of individuals from the public, scientific, medical and journalism communities have recently raised the issue of possible adverse effects of herbicides utilized during the Vietnam War on the health of the veterans exposed to these chemicals.

3. The VA shares this concern and has reviewed the most recent studies on the toxicilogy of these herbicides. These studies indicate that transient symptoms and signs of disease may appear shortly after exposure to the herbicides, but they do not provide evidence of any lasting deleterious effects in human beings.

4. The VA will provide an appropriately detailed medical examination and follow-up of all Vietnam veterans who come to VA health care facilities claiming herbicide exposure in order to obtain further information regarding any possible long-term health-related effects of these agents.

5. In pursuance of this goal, it is VA policy to provide thorough medical evaluations of all veterans in its patient population who claim exposure to herbicides during the Vietnam War and to follow them over a period of years so that any long-term complications resulting from these chemicals can be detected and treated. Data on all veterans examined for possible herbicide toxicity in the VA system will be entered into a registry maintained in VA Central Office. Follow-up of the veterans entered into the registry will be monitored and supervised by the Office of the ACMD for Professional Services.

6. It is to be emphasized that at this time VA medical centers will refrain from efforts to induce veterans who are not currently part of their patient population to undergo an examination for possible health-related effects of herbicides. Should the medical evidence being gathered reveal a relationship between herbicide exposure in Vietnam and long-term effects on health, an effort will be made to reach all possible exposed veterans for appropriate study.

7. All Vietnam Era veterans who currently are being treated in a Veterans Administration medical center, and future applicants for VA health care, will be asked if they were exposed to herbicidal chemicals during their service in Vietnam. Those claiming exposure will be requested to identify their military occupational code numbers. These numbers will be entered on the VA form 10-10 (April 1978), "Application for Medical Benefits," under item 13, "Military Service."

8. Veterans who claim exposure to herbicidal chemicals during the Vietnam War, will receive a thorough examination which covers the specific areas indicated in Attachments A, B and C of this circular. Each VA medical center will record results of these examinations in the formats illustrated in these attachments. This information must be collected for both inpatients and outpatients.

9. Veterans who report exposure to herbicidal chemicals will be asked the questions listed on the initial data base, possible exposure to toxic chemicals, part I, which is presented in attachment A.

10. In eliciting the medical history and performing the physical examination (in accordance with Attachments B and C) particular attention will be given to those organs which are most commonly affected by chemical intoxicants, namely, nervous system, immune system, blood-forming system, liver, kidneys, thyroid, adrenals, gonads, skin and lungs. Particular attention will be paid to the detection of chloracne, a skin condition which has been associated with acute exposure to herbicide mixtures containing the toxic chemical, Dioxin. Evidence will also be sought concerning the following potentially relevant symptoms or conditions: altered sex drive, sterility, congenital deformities among children, repeated infections, neoplasia, and for female veterans, difficulties in carrying pregnancies to term. In gathering these data, it is important to determine when the first manifestation of the potential symptoms or conditions occurred, their intensity, the degree of physical incapacitation at the time of exposure, and to note the details of any treatment received for them.

11. In conjunction with this workup, Appropriate diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and signs. Non-routine diagnostic studies, such as, sperm counts should be performed

only if suggested by the workup. Surgical or cytologic specimens obtained during any diagnostic, operative or other procedure performed during the workups should be processed and reported in the usual manner. However, the slides, blocks and tissue specimens are to be retained for inclusion in a special tissue registry, the location and operation of which is described in DM & S Circular 10–78–234, dated September 29, 1978, Subj: Special Registry at the Armed Forces Institute of Pathology for Pathological Material from Veterans with Possible Exposure to Herbicides During the Vietnam War.

12. There is controversy among experts regarding the diagnostic value of measuring levels of dioxin in body fat. In order to help resolve this controversy, a VA-supervised study will be conducted which will measure dioxin levels in fat tissue taken from VA patients with a history of exposure to herbicides and from an unexposed control group. Until this study is completed, no VA medical center will attempt to measure tissue dioxin levels in any of its patients without prior consent of VACO (11F).

13. When a Vietnam veteran who claims herbicide exposure is examined at a VA medical center, the center's Medical Administration Service must be notified. Following notification, that Service will initiate the procedures listed below:

(a) The patient data card will be used to imprint a 3 x 5 card.

(b) The card will be filed alphabetically in a special file, labeled "Possible Toxic Chemical Exposure File," which will be retained indefinately.

(c) In item No. 17 of VAF 10–10, "Do you believe the need for care is" the following statement will be entered in the blank space: "Possible Toxic Chemical Exposure."

(d) For extra control purposes—insert at the top of VAF 10–10m, Medical Certificate and History, the following statement: "The veteran states he/she has been exposed to herbicidal chemicals."

(e) A duplicate copy of the examinations recorded as directed in paragraph 8 through 11, above, will be forwarded to VACO (11F) as part of the medical center's quarterly report as directed in paragraph 15 below.

14. The original records of all examinations performed on Vietnam veterans for possible herbicide toxicity are to be retained in the veteran's Consolidated Health Record (CHR). If a CHR does not already exist for a veteran examined for herbicide toxicity, one will be established, and the results of the examination for herbicide toxicity is to be enclosed in his/her CHR.

15. A quarterly report will be submitted to VACO Professional Services (11F) by the 8th workday of the month following the close of each quarter, beginning with the quarter ending December 31, 1978. Negative reports are required. The data submitted will be reviewed by a multidisciplinary committee composed of VACO staff members.

16. This report will contain the following information:

(a) A legible copy of all of the data obtained on Vietnam veterans who claim herbicide exposure as directed in paragraphs 8 through 11 in this circular and recorded in the format provided in Attachments A, B, and C. Examinations recorded in any other formats are not accpetable. Pertinent laboratory data and consultations obtained as part of these examinations will accompany this report.

(b) Copies of all medical record documents prepared as a result of follow-up of Vietnam veterans already reported during previous quarters. These documents will be identified with a statement indicating that their submission is a follow-up of a previous report.

17. One or two clinical staff members will be designated as "environmental health physician(s)" and assigned responsibility for the examination and follow-up of veterans claiming herbicide exposure. The names of the physicians selected for this responsibility will be submitted to VACO by May 1, 1979.

18. Questions concerning VACO's position on possible exposures to herbicides should be referred as follows: policy questions to Dr. Paul Naber (11) at extension 2213 or Dr. Richard Levinson (11F) at extension 3560; clinical questions to Dr. Gerrit Schepers (111) at extension 2550; and administrative questions to Medical Administration Service (136B) at extensions 2933 and 3468.

19. VA Form 10–20681(NR), APR 1979, attachment A,B, and C may be reproduced at each medical center in quantities needed.

20. Rescission of circular 10–78–219.

DONALD L. CUSTIS, M.D.,
Deputy Chief Medical Director.

Attachments.

Circular 10-79-83
April 16, 1979

RCS 11-49
Attachment A

MEDICAL RECORD | PROGRESS NOTES

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

A. Date ______ Current Status of Veteran: ____ Outpatient
Inpatient

B. Branch of Service:
Military or Civilian Unit Designation:

C. How many exposures does the veteran allege?

D. What was the nature of each exposure?

E. When and where did these exposures occur? (Specify dates, military field bases, and length of exposure.)

F. Define severity of the exposure - circle or check, as appropriate.

Severe	Direct	Repeated	Prolonged
Short	Mild	Indirect	

G. At time of exposure - what was the veteran's job in service? (Field participation, rear echelon, administration, etc.)

H. How directly was the veteran brought in contact with chemicals? (Check one)

____ Veteran was member of headquarters personnel and far removed from site of chemical exposure.

____ Veteran was in field.

____ Veteran operated apparatus used for chemical spraying or handled bulk chemicals in such a manner that gross exposure was possible.

I. If, in field, was veteran undercover (building, trench, foxhole, etc.) or out in open? Was he in a vehicle at the time?

(Continue on reverse side) (SEE OTHER SIDE)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle; grade; rank; rate; hospital or medical facility) | REGISTER NO. | WARD NO.

PROGRESS NOTES INITIAL DATA BASE-POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

VA Form 10-20681(NR) A-1
APR 1979

Circular 10-79-89
April 16, 1979

Attachment A
(Reverse Side)

PROGRESS NOTES

DATE

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

J. How long was veteran present at site of chemical exposure?

K. Was veteran issued protective gear? ____Yes ____No
If "yes" - did veteran wear this gear? ____Yes ____No
Describe gear:

L. Did veteran enter areas where chemicals previously had been sprayed or spilled - or did veteran eat from utensils or drink water contaminated by chemicals? Does veteran remember chemical names? Describe in detail.

M. What steps were taken to remove chemicals from veteran or the environment?

N. Has veteran been exposed to other potentially toxic chemicals:
(1) Prior to military service: ____Yes ____No
(2) During military service: ____Yes ____No
(3) After military service: ____Yes ____No IF "YES" DESCRIBE

O. (1) What is veteran's military occupation code number? _____
(2) Veteran possesses a copy of DD 214, Report of Separation-Active Duty?
____Yes ____No IF "YES" ENCOURAGE VETERAN TO BRING A COPY.
(3) Veteran possesses a copy of Service health/medical record?
____Yes ____No IF "YES" ENCOURAGE VETERAN TO BRING IN A COPY.
(4) Has veteran received VA Care?
____Yes ____No IF "YES", STATE LOCATION.

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART I

Circular 10-79-8
April 16, 1979

RCS 11-49
Attachment B

MEDICAL RECORD | PROGRESS NOTES

DATE

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II

REVIEW DATA ON PART I

A. Pertinent Medical History - include symptoms at time of exposure, or later - attributed by the veteran to exposure - (continue on another Part II if needed)

B. Pertinent Physical Examination (PE) - (check one).

___Physical Examination to be done (Use SF 50 or VAF 10-7978i) "Initial Data Base - Chemical Exposure, Part III"

___Repeat Physical Examination is indicated (a prior PE has been done within six months and has been reviewed).

___Repeat PE is not indicated (a prior PE has been done within six months and has been reviewed).

(Continue on reverse side) (SEE OTHER SIDE)

PATIENT'S IDENTIFICATION | REGISTER NO. | WARD

PROGRESS NOTES

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II

Attachment B
(Reverse Side)

PROGRESS NOTES

DATE

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART II

Check if following examination ordered:

C. Yes No

___ ___ Complete blood count including differential
Chest X-Ray (if no chest X-Ray within six months)

___ ___ Liver Function Profile

___ ___ Renal Function Profile

___ ___ Sperm Count

___ ___ Referral to a Dermatologist

D. Other Comments:

1. Evidence of Neoplasia: Present ___ Absent ___

Family History of:

Neoplasia Related Factors (e.g., cigarette smoking, radiation exposure, etc.)

2. Evidence of - Veteran and/or Family:

Infertility: Present ___ Absent ___

Abortions: Yes ___ No ___

Teratogenesis: Yes ___ No ___

If "yes", Describe:

3. Were veteran's spouse or children in Vietnam? Yes ___ No ___
If "yes", give details.

RCS 11-49
Attachment C

CLINICAL RECORD		PHYSICAL EXAMINATION					
DATE OF EXAM.	HEIGHT	WEIGHT			TEMPERATURE	PULSE	BLOOD PRESSURE

INSTRUCTIONS.—Describe (1) General Appearance and Mental Status; (2) Head and Neck (General); (3) Eyes; (4) Ears; (5) Nose; (6) Mouth; (7) Throat; (8) Teeth; (9) Chest (General); (10) Lungs; (11) Cardiovascular; (12) Abdomen; (13) Hernia; (14) Genitalia; (15) Rectum; (16) Prostate; (17) Back; (18) Extremities; (19) Neurological; (20) Skin; (21) Lymphatics.

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART III

(Continue on reverse side)

PATIENT'S IDENTIFICATION (Use typed or written name and/or Social Security No., date of birth, grade, date, hospital or medical facility)

REGISTER NO. | WARD NO.

INITIAL DATA BASE - POSSIBLE EXPOSURE TO TOXIC CHEMICALS - PART III

PHYSICAL EXAMINATION

VA Form 10-20681(HR), APR 1979

ATTACHMENT E

Circular 10–78–234

SEPTEMBER 29, 1978.

VETERANS ADMINISTRATION,
Department of Medicine and Surgery,
Washington, D.C.

Subject: Special Registry at the Armed Forces Institute of Pathology for Pathological Material from Veterans with Possible Exposure to Herbicides During the Vietnam War

To: Directors, Medical Centers, Medical Regional Office Centers, Domiciliary, Outpatient Clinics and Regional Offices with Outpatient Clinics

1. Attention is directed to IM&S Circular 10–78–219, RCS 11–49 dated September 14, 1978 Possible exposures of veterans to herbicides during the Vietnam War with particular reference to paragraph 7. This paragraph states that a special tissue registry will be established for central collection of surgical, cytologic and autopsy material from veterans included in this category.

2. This Circular announces the establishment of this special registry in the Environmental and Drug Induced Pathology Department at the Armed Forces Institute of Pathology (AFIP).

3. All pathological material (surgical, cytologic or other similar tissue) from veterans with possible exposure to herbicides during the Vietnam War will be examined and reported in the customary manner at each medical facility. In addition, a duplicate set of slides, blocks and representative wet tissue will be forwarded promptly to the AFIP with the case clearly marked as "Possible Exposure to Herbicides-Vietnam War." Information will also be placed on SF 513, Tissue Examination in the patient's medical record noting that pathological material has been sent to the AFIP for inclusion in the special registry.

4. The material for shipment to the AFIP will be packaged in the normal manner and addressed to the Director, Armed Forces Institute of Pathology, Attention Environmental and Drug Induced Pathology Department, Washington, D.C. 20306.

5. Any questions in this connection should be directed to Dr. Paul C. LeGolvan, Deputy Director, Pathology Service (113), extension 2348.

HERBERT M. BAGANZ, M.D.,
Acting Deputy Chief Medical Director.

ATTACHMENT F

DVB Circular 21–79–6

DEPARTMENT OF VETERANS BENEFITS,
Veterans Administration,
Washington, D.C.

APRIL 25, 1979.

ASSISTANCE TO AGENT ORANGE EXPOSURE CLAIMANTS

1. *Purpose.*—This issue specifies assistance to be given veterans claiming disabilities resulting from exposure to herbicide orange.

2. *General.*—The Department of Medicine and Surgery in their Circular 10–79–83 provides for thorough examinations of all veterans who claim toxic effects from exposure to herbicides during service in Vietnam, and the maintenance of records on them so that any late complications due to these agents can be determined and treated.

3. *Procedures.*—a. *Veterans Assistance Service.*—(1) Occasionally, veterans will phone the VA or come in expressing concern about the health effects upon them from their exposure to herbicide orange while serving in Southest Asia, but alleging no disability. In such cases, the individuals will be informed of the hospital examination and treatment program available to them at the VA health facility in their area.

(2) Other veterans, in addition to expressing their concern over the health effects of herbicide orange, will allege a disability which they feel is etiologically related to their exposure to that chemical. In addition to assisting these veterans in the filing of their claims, they will be also informed of the hospital examination and treatment program, and be encouraged to contact the VA health facility in their area for examination and treatment, if indicated.

b. *Adjudication Division.*—When a claim for exposure to herbicide orange is received in the Adjudication Division for processing, the information pertaining to hospital examination and treatment, if not already made available, will be conveyed in the initial correspondence directed to the claimant.

DOROTHY L. STARBUCK,
Chief Benefits Director.

ATTACHMENT G

APRIL 17, 1978.

RATING PRACTICES AND PROCEDURES DISABILITY—VIETNAM DEFOLIANT EXPOSURE

Claims contending relationship between defoliant exposure and disability.—Claims for service-connected disability benefits are being received from veterans who claim disability incurred through or aggravated by exposure to defoliants used during the Vietnam War.

Except for a skin condition known as chloracne, there are presently no firm date to incriminate the herbicides as causative agents of any other known category of disease or chronic symptom. However, a contaminant Dioxin, found in small quantities in defoliants is toxic.

No special procedures will be initiated for these claims. Instead, each case will receive a thorough development of all available evidence. This will include a request to both the veteran and the service department to furnish verification of exposure to herbicides, the extent and duration thereof and the dates on which such exposure occurred.

All other required development will be done concurrently with the request for verification of exposure to defoliants, and each case will be extended the same consideration given any other claim for service connection.

Where no disability is claimed but only exposure to herbicide is alleged, the claim will be administratively disallowed and the veteran advised that mere exposure itself is not a disease or disability. The claimant will be advised that specific disabilities must be claimed. This should be accompanied by evidence of the earliest manifestation of symptoms together with evidence of continuity.

A veteran's claim alleging herbicide related genetic damage based upon damage or defect in the veteran's child will be administratively disallowed since Title 38 U.S.C. makes no provision for such a claim.

Copies of all ratings involving defoliants will be submitted to the Compensation and Pension Service (211C). There should be no hesitancy in submitting cases, appearing to have merit, but not meeting current criteria for service connection, to the Compensation and Pension Service (23B/211C) for advisory opinion.

ATTACHMENT H

AUGUST 31, 1979

(3) *For the medical activity.*—(a) When a medical center requests a determination of service connection for hospitalization on treatment purposes, an extra copy of the rating will be prepared for release to the approparite Medical activity. (See par 30.02c.)

(b) A copy of each rating decision granting service connection for tuberculosis will be transmitted to the Chief of Medical Administration of the Medical Activity concerned.

(c) Regional offices will furnish a copy of each rating decision initially establishing service connection to the clinic of jurisdiction. Ratings submitted will include zero percent evaluations and cases disallowed due to receipt of retired pay.

1. The veteran's full name and address (including ZIP code) will be annotated in the upper right of the narrative section of VA Form 21-6796.

2. The veteran's social security number will be added to the rating unless that number is also the VA file number.

3. Copies of the rating decisions will be batched each day and forwarded to the appropriate clinics of jurisdiction with a VA Form 3230 indicating "For Priority Patient Data Card Purposes."

(4) *For the Veterans Services Officer.*—When payments are being made to the guardian for an incompetent veteran, a copy of any rating establishing the veteran as competent will be prepared for transmittal to the appropriate VSO (See par. 54.01d(1).)

(5) *Special Law Code 10 cases.*—In each disability case, when the award is authorized under special law code 10, a copy of the rating will be prepared for direct transmission to Compensation and Pension Service (213B), VA Central Office, simultaneously with the release of the batch transmittal to the Hines DPC containing this input date. (See par. 15.20a(10)(a).)

(6) *Ionizing Radiation Involved.*—(a) An extra copy of the rating decision will be prepared in the case of the initial grant, disallowance or reestablishment of service connection or the initial denial, establishment, or reestablishment of a permanent and total rating for pension purposes in cases in which injury from ionizing radiation is shown or claimed. For this purpose, ionizing radiation will include X-rays and emanations from nuclear explosions and radioactive substances. Laser beam and solar ray injury cases will not be included.

(b) The copy of the rating will be transmitted direct to the Compensation and Pension Service (211C), Central Office.

(7) *Herbicide exposure in Vietnam.*—Copies of ratings involving exposure to defoliants in Vietnam will be submitted to the Compensation and Pension Service (211C).

(8) *Ratings involving asbestos.*—Copies of ratings involving asbestos-related diseases will be submitted to the Compensation and Pension Service (211C).

b. *Date of claim.*—Entry will be the date of receipt of the application or of the claim for increase (including report of examination or hospitalization–VAR 1157), or any request requiring the rating decision being made. This date will not be determined by consideration of the rating board dicision of the effective date of an evaluation for service-connected disabilities or the date of permenent and total disability for pension. (See also par. 15.24b.)

Veterans Administration

Agent Orange Claims Experience - Agencies of Original Jurisdiction

Through January 31, 1980

	Chloracne	Other skin disorders	Neuro-psychiatric, including nervousness, headaches, fatigue, insomnia	Neurological (paralysis, numbness)	Gastrointestinal	Genitourinary (except sexual dysfunction)	Sexual dysfunction (impotence, sterility, abnormal menstrual damage, loss of libido)	Malignancies (leukemia, lymphoma, myeloma excl	Eye, ear, nose and throat pathology	Pulmonary	Cardiovascular (including hypertension)	Myocarditis[2] by vote	Peripheral collapsing (including Raynaud's)	Other	Total
Number of physical and mental disorders claimed due to Agent Orange[1]	7	502	313	143	122	34	92	127	87	73	59	5	32	28	1624
Of above disorders, number clinically documented (diagnosed)[2]	2	117	53	20	13	8	8	99	11	16	14	—	—	5	366
Of disorders claimed due to Agent Orange, number deemed service connected (cases allowed)[3]	2	17	—	—	—	—	—	2	—	—	—	—	—	—	21
Of disorders claimed due to Agent Orange, number deemed not service connected (cases denied)	5	486	313	143	122	34	92	125	87	73	59	5	32	28	1603
Number of other disorders among above claimants for which service connection has been granted	—	15	4	3	3	—	—	2	4	1	3	—	—	18	53

[1] In 286 claims, no specific disability is alleged (merely that there was exposure)

[2] Sources of these diagnoses: 48 from service medical records;
131 from VA examination or treatment records;
186 other medical records

[3] In the allowed cases it has been unnecessary to attribute the disabilities to Agent Orange

STATEMENT OF HON. MAX CLELAND, ADMINISTRATOR, VETERANS' ADMINISTRATION

Mr. CLELAND. Thank you very much, Mr. Chairman. Let me just second the remarks that you made about the objectives of this hearing. Particularly, I would like to echo your comment about getting to the bottom of the questions surrounding Agent Orange, particularly as you put it: "The truth about Agent Orange through laying a basis of fact and evidence through valid and objective scientific inquiry." It seems to me that that is something that should be kept in all of our minds.

I might say, Mr. Chairman, that at the outset I would like to state that this is the most perplexing, complex issue with which I have had to deal as Administrator. I would also like to say that I have a personal stake in the outcome of the questions surrounding Agent Orange. I was on the ground in Vietnam in 2 of the 3 peak spraying years. The peak spraying years were 1967, 1968, and 1969. I was on the ground a little more than 10 months in 1967 and 1968, both in the Central Highlands and up in I Corps, along the coast and along the DMZ and out near Khe Sahn.

I was personally exposed to Agent Orange at least twice. Dr. Custip who is now the Chief Medical Director was on the ground for a year in a third of those peak spraying years, 1969. So between us, we covered in our own personal experience 3 peak spraying years in regard to the spraying of Agent Orange. We may both have been exposed. We both have a personal stake in the outcome of this inquiry.

Mr. Chairman, I would like to introduce a couple of other distinguished people with the Veterans' Administration: Dr. Jacoby, who was with the Department of the Navy before he came to the Veterans' Administration and is now the Deputy Chief Medical Director; Dr. Paul Haber, Chief of Professional Services; and Mr. Guy McMichael, the General Counsel.

Mr. Chairman, I would like to provide you and the committee today a feel for some information that we have learned about the Agent Orange issue since our last appearance here in October 1978.

First, what have we learned? The Department of Defense has informed us that Agent Orange constituted some 94 percent of the herbicides used in Vietnam between 1965 and 1971 in order to deny the enemy of protective forests and deny them food crops.

The use of Agent Orange was terminated in 1971, as you stated, Mr. Chairman, when it was discovered that it contained the contaminant called dioxin or TCDD which is known to be a highly toxic chemical.

The other two constituents of Agent Orange namely 2,4-D and 2,4,5-T, were not known to be toxic. Even though the presence of TCDD or dioxin in Agent Orange was not recognized until several years after its initial use, DOD further informs us that efforts had already been made—had always been made to insure that U.S. troops had minimal direct exposure to all herbicides used in Vietnam.

Although we have extensive information on Agent Orange spraying missions, we lack precise data on U.S. ground troop movements in Vietnam during the time when spraying was occurring. As a result, our information on the exposure of any particular to agent orange is often very limited.

We have endeavored to obtain information on the results of past and present research on the toxic effects of dioxin. Its appears that

most of the available data has been obtained from animal experiments. Although the experiments reported are by no means complete or definitive, it appears that TCDD or dioxin can produce harmful and even fatal effects in animals if given in high enough doses over a sufficiently long period of time.

These harmful effects are manifested in several organs and body systems including the liver, kidneys, and the nervous system. Adverse effects on growth and reproduction are seen and the young of treated animals may suffer birth defects.

Cancers are also reported in increased incidence. The relevance of these animal studies to humans is unclear at the present time. The only way to determine their relevance is through meticulously designed, long-term epidemiological studies of humans exposed to TCDD at industrial laboratory accidents or in this case, possible exposure in Vietnam.

The available human studies on TCDD exposure are very limited in size and do not resolve the outstanding questions concerning human toxicity.

However, thus far, no study has shown any evidence for a delayed syndrome of toxicity of any Agent Orange constituent encountered under accidental conditions. In fact, the only long-term disease in humans clearly associated with such exposure is a skin condition called chloracne.

Therefore, there is not now any proof that a definitive Agent Orange syndrome exists in our Vietnam veterans.

Mr. Chairman, I would like to turn now to what the VA has done about the Agent Orange issue.

First: We formed an advisory committee made up of internationally recognized experts from outside the VA who are very knowledgeable about herbicides.

The committee has provided us with information on the latest relevant experiments and has advised us on how we can most productively proceed on Agent Orange in the future.

Second: We have developed informational and instructional materials for our health care staff on the most current knowledge concerning Agent Orange. This material has been presented thus far in the form of circulars, conference calls and educational conferences.

We are currently developing additional and more effective formats such as video tapes and pamphlets. Some of this new material is directed mainly toward the veteran himself.

In developing all of these new materials, we seek to incorporate scientifically validated data with a concern for the veterans' viewpoint and how it might apply to them.

Third: We have been building a data base on the potential health effects of Agent Orange among the Vietnam veterans. The major component of this effort is the operation of an Agent Orange registry which will contain the data from medical examinations performed by the VA on the Vietnam veterans who believe that they were exposed to Agent Orange.

These examinations, which have been performed on nearly 10,000 veterans since the initiation of this procedure in July 1978, will be repeated on the same individuals over a period of years.

The data obtained from them are expected to provide clues as to definitive studies that might be undertaken to uncover any effects of Agent Orange on human health.

They will also be utilized to help the VA's ability to deliver appropriate health care to these veterans.

Complementing this activity is a program in which we submit tissue specimens from Vietnam veterans treated in our hospitals to a special registry at the Armed Forces Institute of Pathology for preservation and detailed pathological study.

I would like to point out that our Department of Veterans Benefits has been processing claims for compensation on the basis of presumed Agent Orange toxicity while the investigation efforts are proceeding.

Thus far, 1,233 claims have been decided at the regional office level. In 21 instances, the disorders claimed to be due to Agent Orange exposure were held to be service-connected.

In none of these 21 cases was it necessary to determine whether Agent Orange was the causative factor. Mr. Chairman, I think that that is an interesting point. Under the law we are allowed to service connect a disability without actually knowing the cause, as long as we can determine that the disabling disease or injury was incurred in service.

Fourth, we have been conducting research in areas pertinent to Agent Orange. For example, we have recently completed a study of the levels of dioxin in the fat of veterans exposed to Agent Orangec ompared to a control group of veterans with no known exposure.

In this study we showed that small amounts of dioxin could be found in the fat of some but not all of the veterans included in the study who were possibly exposed to Agent Orange in Vietnam.

However, we discovered that dioxin could also be found in the study participants with no known exposure. This suggests that Vietnam veterans could be exposed to dioxin outside of Vietnam.

At any rate, no correlation could be established in this study between fat levels of dioxin and the occurrence of disease.

Dr. Custis can correct me if I am wrong, but I think we are now submitting that study to other governmental agencies, including the Office of Technology Assessment, which is an arm of the Congress.

Mr. DASCHLE. Mr. Cleland?

Mr. CLELAND. Yes, sir.

Mr. DASCHLE. I would like to interrupt for just a second. I was trying to follow this as you went through it quickly. I would like to have you cite that page in testimony. What page is that?

Mr. CLELAND. I have a prepared statement that is about 100 pages long. I am attempting to really summarize it——

Mr. MCMICHAEL. We have a summary that we will be happy to provide.

Mr. CLELAND [continuing]. I have almost concluded my summary.

Chairman SATTERFIELD. Mr. Cleland, since you are summarizing in the interest of time, without objection your full statement and indeed the statements of all of our witnesses today will be admitted into the record of these hearings in their entirety. If any of you do decide to summarize as Mr. Cleland has done, we would be happy for you to do so.

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

Mr. DASCHLE. That is all. He is going to give me the summaries.

Mr. CLELAND. The VA is currently involved in an epidemiological study of possible agent orange health effects in Vietnam veterans as mandated by the law passed by the Congress that the Chairman referred to Public Law 96–151.

In order to insure maximum objectivity, the study will be designed and its data analyzed by distinguished epidemiologists from the private sector. In addition, the studies designed will be reviewed by a series of review panels composed of expert scientists outside the VA, including the Office of Technology Assessment and the interagency work group to study the possible long-term health effects of phenoxy herbicides and contaminants. That is the White House interagency group.

We are exploring the possibility of undertaking or supporting additional research in a number of areas. Among those under consideration are studies of alterations in liver enzymes, immune systems and chromosomes among the Vietnam veterans exposed to Agent Orange.

The VA has endeavored at all times to coordinate its Agent Orange programs with those conducted in other Federal agencies. Our own advisory committee provides one of two major mechanisms for this coordination. The other is through our membership on the interagency work group which the President recently created.

In conclusion, Mr. Chairman, I would like to point out that despite major efforts by many agencies and individuals, it remains unclear whether Agent Orange constituents have any long-term effects on human health.

It is clear to me that the only way in which this matter can ever be resolved is through properly designed scientific studies which are very carefully performed.

Mr. Chairman, I would like to assure you that the Veterans' Administration will conscientiously and expeditiously perform those Agent Orange studies which are within its scientific competence. We will encourage others to undertake those studies we cannot reasonably perform.

I also wish to emphasize, Mr. Chairman, that Vietnam veterans claiming illness as a result of exposure to Agent Orange are currently being given the full scope of health care in our facilities for which they are eligible.

Now, Mr. Chairman, we took the step of appointing an agent orange coordinator at our hospitals and outpatient clinics in order to make sure that we were providing the appropriate examinations and treatment.

Mr. Chairman, no veteran is or will be denied his VA health care benefits because of our lack of information about Agent Orange health care effects.

The point is, Mr. Chairman, that while the question of causation of disability or disease is still at issue, the question of treatment of that disease or disability is not at issue.

We are prepared to treat and will examine veterans with agent orange complaints.

Mr. Chairman, let me just take a few moments to read from my prepared statement, from page 14. I would like to highlight something that is of concern to me.

A number of reports in the press have suggested that Vietnam veterans exposed to Agent Orange have developed a variety of chronic illnesses manifested by a wide variety of symptoms.

Included in these reports are several types of cancers and other diseases as well as the persistence of such nonspecific symptoms as nervousness, irritability, and problems with interpersonal relationships.

Dr. Ton-That Tung of Vietnam has echoed these findings on the basis of his own observations. He has reported that residents of what was then South Vietnam exposed to Agent Orange had a higher incidence of liver cancer than those who had not been exposed.

Among women who were exposed there was a higher incidence of abortion and children with birth defects than among unexposed women. Unfortunately, the validity of his data cannot be confirmed by independent observers due to lack of appropriate scientific access to Vietnam.

Mr. Chairman, I might also say that we have talked with this physician personally.

In contrast to these reports is the report of the National Academy of Sciences entitled "The Effects of Herbicides in South Vietnam." This 1974 report which represents a very exhaustive review of all available data through 1974, concluded that there was no definitive evidence of lasting damage to human health from the herbicides in Vietnam.

In a monograph published by the International Agency for Research on Cancer in 1977, entitled "Evaluation of the Carcinogenic Risk of Chemicals to Man," it was concluded that the available evidence did not permit any firm conclusions to be drawn as to the cancer-causing potential of 2,4-D, 2,4,5-T or TCDD.

The Air Force published a technical report in 1978 entitled "The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and its Associated Dioxin."

We believe that this report is the most comprehensive review of the scientific literature relevant to Agent Orange yet produced. It was concluded that the available scientific evidence does not support the contention that Agent Orange has a permanent adverse effect on human health.

Mr. Chairman, I would now like to turn to the top of page 18 and make a comment. I mentioned earlier, Mr. Chairman, that we had formed an advisory committee in the VA on this question.

A summary of the more significant aspects of the committee's responses to date are as follows: First, the committee listed the components of an epidemiological study of Vietnam veterans exposed to Agent Orange. Stress was placed on defining as precisely as possible the exposure of each veteran included in the study of Agent Orange as well as other environmental toxins.

The committee also recommended that epidemiological studies be performed on other population groups such as those exposed to Agent Orange constituents as the result of industrial or agricultural pursuits.

Second, the potential diagnostic procedures for Agent Orange toxicity recommended by the committee for careful consideration include measurement of dioxin levels in fat, and studies of immune system alteration, chromosomal changes, and liver enzymes induction.

It was pointed out that none of these procedures has yet been proven to have diagnostic value.

Third, the effects of Agent Orange exposure on the male reproductive system were described as being unknown at present requiring further indepth study. The great difficulties involved in carrying out such a study were specified.

Fourth, the problems of defining the precise exposure of Vietnam-era veterans to Agent Orange was recounted and the considerations involved in defining the probability of such exposure were outlined.

Fifth, the types of animal studies that might be performed in order to identify the effects of human exposure to Agent Orange were outlined with those on nonhuman primates being assinged particularly high priority.

A more detailed summary of these position papers are provided in Attachment B.

Mr. Chairman, I don't want to complete the long and lengthy official statement. But I wanted to say that the Agent Orange Advisory Committee has been working hard and some appendixes to my

statement testify to some of their responses to some key questions surrounding Agent Orange.

Mr. Chairman, I think that I will stop now and allow others to make whatever points they would like to make. And I would be happy to be available for questions.

Chairman SATTERFIELD. Thank you, very much, Mr. Cleland. Our next witness is Joan Bernstein, Department of HEW.

We certainly welcome you here this morning. You may wish to introduce for the record those who have accompanied you. And we would be glad to receive that as well as your statement.

Mrs. BERNSTEIN. Thank you, Mr. Chairman. As you said, I am Joan Bernstein, General Counsel of HEW and I chair the Interagency Work Group to study the "Possible Long-Term Health Effects of Exposure to Phenoxy Herbicides and the Dioxin Contaminants."

I would like to introduce the group from the scientific community of HEW who are with me here today. On my left is Dr. John Moore, Deputy Director of the National Toxicology Program and chair of the Work Group's Scientific Panel.

In addition, Dr. David Rall, Director of the National Institute of Environmental Health Sciences, is with me. Dave, would you stand?

[Whereupon, Dr. Rall stood briefly.]

Mrs. BERNSTEIN. Also here are Dr. John Froines, Deputy Director of the National Institute for Occupational Safety and Health, and Dr. Patricia Honchar, Chief, Dioxin Study and Registry at NIOSH.

Dr. Froines is representing Dr. Anthony Robbins, the Director of NIOSH, who is unable to be here today. Dr. Rall and Dr. Robbins are assisting Dr. Moore in supervising the work of the Scientific Panel.

I will briefly summarize my full statement if I may and ask that the rest be inserted in the record.

Chairman SATTERFIELD. Without objection, so ordered. We will be happy to receive your shorter statement now.

[Material follows:]

STATEMENT BY JOAN Z. BERNSTEIN, GENERAL COUNSEL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, BEFORE THE COMMITTEE ON VETERANS' AFFAIRS

Mr. Chairman and Members of the Subcommittee: I am Joan Z. Bernstein, General Counsel of Health, Education, and Welfare and Chair of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. I appreciate this opportunity to appear before the Subcommittee in my dual capacity to report on the Federal Government's current and planned efforts to study the possible long-term adverse health effects on humans of exposure to these chemical compounds.

Because of the Subcommittee's concern about health problems experienced by Vietnam veterans, I will review the status of HEW and work group efforts to study the effects on humans of phenoxy herbicides and dioxins, and will focus particularly on our examination of the phenoxy herbicide known as Agent Orange.

With me today are several members of the HEW scientific community who are very much involved in this effort. They are Dr. John Moore, Deputy Director of the National Toxicology Program; Dr. David Rall, Director of the National Institute of Environmental Health Sciences (NIEHS); Dr. Anthony Robbins, Director of the National Institute for Occupational Safety and Health (NIOSH); and Dr. Patricia Honchar, Chief of the Dioxin Study and Registry at NIOSH. Dr. Moore is the Director of the Scientific Panel of the interagency work group and is being assisted in that endeavor by Drs. Rall and Robbins.

The subject under discussion today is surrounded by controversy and emotion. There is much that is already known about the effects of human exposure to phenoxy herbicides and dioxins, but much that remains in doubt. Accordingly, I believe that we at the Federal level must recognize and fulfill our responsibility to the American people for a thorough, objective, scientifically impeccable, and timely examination of this subject. We must complete such an examination and accounting for the Vietnam veterans, their families, and their offspring because we owe them nothing less. We must complete it, also, because we as a society must face the full impact on our physical environment of the chemicals we use. In the most literal sense, our claim to a healthful environment demands such action.

I believe the Chairman and Members of this Subcommittee share my view concerning the need to avoid emotionalism and alarm, or the creation of false expectations, in connection with the Agent Orange studies. Secretary Harris, my colleagues from HEW and other agencies here today, and I all share your firm commitment to a full examination and a complete and accurate accounting of the truth on this subject. We make this pledge both for the Vietnam veterans and others who have been working so hard to bring this matter to the country's attention, and for the public at large.

As most of you know, for many years chemical herbicides have been used widely throughout this country and the rest of the world for a variety of farming, forest management, and similar purposes. An important group are the phenoxy acid herbicides. Two of these, 2,4–D and 2,4,5–T, constitute Agent Orange, a herbicide that was widely used for forest defoliation and destruction of crops during the Vietnam conflict.

The chemical reactions that produce 2, 4, 5–T unavoidably contaminate it with trace amounts of a chemical referred to as TCDD (2, 3, 7, 8-tetrachlorodibenzo-*p*-dioxin), which has been shown in laboratory studies to be one of the most toxic chemicals known. Although TCDD is but one of a family of dioxins, much of the concern as to the alleged health effects of Agent Orange and other dioxins has centered on this contaminant.

In addition to its use in Agent Orange, 2, 4, 5–T has been extensively applied in the United States. The Environmental Protection Agency temporarily banned major uses of 2, 4, 5–T in 1979 because of concern as to toxic human effects. Hearings on whether permanently to ban 2, 4, 5–T are now in progress. Herbicides using 2, 4–D are still in wide current use.

The Department of Health, Education, and Welfare and a number of other governmental and private entities and individuals, here and abroad, have been concerned for some years about the potential long-term health effects of exposure to phenoxy acid herbicides and dioxin contaminants. Indeed, HEW has actively conducted or sponsored more than 50 studies relating to phenoxy acid herbicides, TCDD, and other dioxins for more than ten years. The results of this research represent much of our collective current medical and scientific knowledge on this subject.

In January, 1978, concern about the long-term health hazards of TCDD and other dioxins led to the Department's co-sponsoring, with the International Agency for Research on Cancer of the World Health Organization (WHO), the development of a report that assessed available knowledge on the effects of dioxins and future needs for information. Much of the current research in this field is designed to address the major recommendations developed at that meeting. Further, the Department established a group in the summer of 1979 to coordinate its research activities germane to the Agent Orange and dioxin issues.

From a government-wide perspective, during the past two years, the Administration has given increasing attention to the potential adverse human health effects resulting from exposure to the phenoxy herbicides and dioxins. Various Federal agencies have been involved in the collection of scientific information, the review and evaluation of existing animal and human exposure data on the toxicity of dioxins (especially TCDD), and the support of related research.

The Administration is supporting studies to be conducted by the Department of Defense, by the Veterans Administration, by the Center for Disease Control and the National Institutes of Health, both within HEW, and by other Federal agencies. In addition, members of the Domestic Policy Staff and the Office of Science and Technology Policy of the White House have reinforced the efforts of various agencies to conduct well-designed, valid, objective, and peer-reviewed laboratory and epidemiological studies concerning the potential toxic and adverse health effects of dioxins.

The Air Force has made a commitment to conduct a study of possible health effects in Air Force personnel who were involved in aerial herbicide missions in Vietnam (the RANCH HAND study). This commitment has led to the development of a protocol which has incorporated the recommendations of outside expert peer review groups. This revised protocol has been transmitted to a Committee of the Assembly of Life Sciences of the National Academy of Sciences for their review. This study, to be elaborated on and discussed further by the Air Force, is one of several epidemiological studies which are being planned, currently in progress, or nearing completion.

On December 11, 1979, the President's Assistant for Domestic Affairs and Policy, Stuart Eizenstat, asked the Secretaries of Defense and Health, Education, and Welfare, and the Administrator of Veterans Affairs, to establish an interagency work group to facilitate, coordinate, and monitor agency studies of the possible long-term health effects of phenoxy herbicides and their contaminants. This work group, chaired by HEW, is charged with assuring that the protocols and methodology of current and proposed federally funded research and studies are scientifically sound. This interagency group also will ensure that all relevant research findings, whether publicly or privately financed, are promptly made available to the public and the Congress, in a comprehensible and comprehensive manner.

Although the formal work group held its first meeting on February 1, 1980, the real interagency effort began two years ago. Thus, the work group represents the formalization of a number of informal working relationships among the various agencies involved in dioxin studies rather than the starting point of such efforts.

This same concern about phenoxy herbicides and dioxins is clearly shared by the Congress and has resulted in the passage of legislation to spur adequate research and to assure its quality and objectivity. As you know, one of these bills, S. 2096, was disapproved by the President. It was the President's conviction that one provision of the bill encroached on functions vested by the Constitution in the Executive Branch and that the activities it required were already under way.

No doubt the members of this Subcommittee and I could spend several interesting hours in debate over the separation of powers issues presented by the disapproval. However, rather than engage in such a dialogue, I would rather focus on the salient point of the veto message: the President's strong support of the effort to investigate the health effects of dioxin exposure and his commitment to continue and complete that investigation.

With that in mind, I'd like to discuss where we are and where I believe we are going in this investigation. HEW's own research over the past decade has encompassed a combination of laboratory investigations and studies of people who have been exposed to TCDD or phenoxy acid herbicides in their occupational environment or by accidental exposures.

Research with animals has indicated that TCDD, a dioxin contaminant in Agent Orange, is one of the most toxic agents known. These animal studies have already established that TCDD can cause cancer, birth defects and fetal toxicity when pregnant female animals are exposed, and can also cause depression of the immunological systems and increased susceptibility to infectious agents.

Animal toxicity tests have served us well in reliably predicting toxic effects in man. Thus, the animal studies which show TCDD to be highly toxic are extremely important. Epidemiologic studies will help to define the full nature and expression of the toxicity of TCDD and other dioxin contaminants in man.

It is widely accepted, though obviously unfortunate, that occupational groups often are instructive populations in which to explore questions about the effect of a particular chemical or substance upon human health. Workplace exposures to particular materials are often well documented, and records are frequently available describing the work histories of industrial populations. Documented incidents of heavy exposure to dioxin due to industrial accidents have produced some information about its immediate effects in humans, but less is known about its long-term effects. In this setting, NIOSH has initiated an epidemiologic study designed to examine long-term effects of human exposure to TCDD.

NIOSH is assembling a registry of all workers in the United States who have been involved in making 2,4,5-T, one of the components of Agent Orange which is contaminanted with TCDD. This study is designed to monitor the health of workers who have been exposed to dioxins. Because 2,4,5-T has been synthesized in this country since the 1940s by a number of industries, there may be a large enough group of workers who have been exposed to dioxin for a long enough period of time, to answer questions about the long-term effects of dioxins on humans. The study should assist in answering key questions about dioxins posed by Vietnam veterans and others.

Assembling the registry and determining how well it will answer questions or confirm animal toxicity results will take time. The first step, already completed, has been to ascertain which U.S. industries have ever made 2,4,5–T. Through confirmation of lists of suppliers and registrants of 2,4,5–T provided by the Air Force and the Environmental Protection Agency, a final list of the industries which have synthesized this material has been compiled. Contacting each industry to explain the NIOSH study and the information needed from them is under way.

Also in progress is the collection of worker records and other information from the industrial users. To determine precisely how long ago and for how long workers have been exposed to 2,4,5–T, NIOSH must gather the work histories of the people involved. Together with detailed information about the exact process used to manufacture 2,4,5–T, this approach will allow the best determination of exposures which the workers have received. Additionally, any medical records which employers have maintained for their workers may provide more clues about the effects of exposure.

A critical step in this study will be tracing the health of workers exposed to 2,4,5–T. To do this, demographic information such as name, Social Security number, and last-known address for each individual must be obtained from the industry. Through Social Security records, a determination can be made of the vital status of each 2,4,5–T worker. For those no longer living, the cause of death will be determined through State death certificates.

Ascertaining vital statistics and cause of death may require some time past the point when all records are accumulated from the industries. The final data analysis then will aim at determining, by total time of exposure, whether the mortality experience of these 2,4,5–T workers differs significantly in any way from that of the general population.

Because the records of 2,4,5–T workers are currently being collected, it is still not possible to say with certainty just how definitive results from the NIOSH registry will be. The ultimate value of the registry in answering questions about health effects will depend on the number of workers registered, the adequacy of the records obtained from the industries, and the success of tracing these workers historically.

All of these activities are time consuming, but HEW believes that the NIOSH dioxin registry is a pursuit which holds promise for providing reliable information about the effects of exposure to dioxins on the workers who have been involved in the manufacture of 2,4,5–T, and on other groups such as Vietnam veterans exposed to Agent Orange. At a minimum, the registry should make possible an objective evaluation of morbidity and mortality patterns, including cancer incidence.

Another current occupational study involves a health examination of workers at a Nitro, West Virginia, plant that has been involved in the production of 2, 4, 5–T since the 1940s. Heavy exposure of some of these workers to TCDD occurred in 1949 from an industrial accident. Other studies involving workers exposed to 2, 4, 5–T and TCDD are under way in Arkansas and New York. Additionally, studies of workers exposed to other dioxins are under way in Illinois and Kentucky. Taken together, these studies represent one part of an overall effort to gather the data most relevant to the specific concern that Agent Orange exposure may have caused long-term adverse health effects in Vietnam veterans.

Another part of the scientific effort that is directly relevant to the veterans' concerns is the group of studies being conducted to ascertain whether TCDD, 2, 4–D or 2, 4, 5–T produce genetic damage or induce alterations in males that may result in their fathering malformed offspring. This is especially important because research is clearly establishing that other members of the dioxin family of chemicals can produce toxic manifestations that are indistinguishable from those produced by TCDD. Studies of some occupationally exposed populations are consistent with these laboratory findings. Thus, what is learned about one dioxin is extremely important in adding to our knowledge about them all.

Animal toxicity studies have predicted and occupational studies have confirmed that skin lesions (chloracne) in humans are associated with TCDD exposure. There is also evidence of other toxic effects in humans, including: liver effects as indicated by enlargement and abnormalities in clinical tests of liver function; alterations in lipid (fat) metabolism; and, more recently, a modest decrease in the ability of peripheral nerves to transmit impulses.

Despite the great amount of insight that we already have, important gaps in our knowledge still exist. The symptoms that are known to be associated with dioxins or phenoxy acids often have not been shown to represent a unique disease pattern. Therefore, studies to determine whether there is a relationship between these chemicals and a specific disease pattern in veterans exposed to them are imperative.

The interagency work group has appropriately begun by focusing on scientific information that is already available or under development about health effects in order to establish an action agenda for getting done that which remains undone. We must, however, recognize some of the problems involved in this scientific effort.

Despite all the current and contemplated research, it may be that although Agent Orange is the cause of some disease, the disease is also attributable to other agents. If so, the most that a study can tell us is that exposure to the chemical increases the disease's frequency. This limitation is especially acute in studying the effects of Agent Orange on the health of American troops in Vietnam. The time and concentration of their exposure is not known. Also, it is already known that the more serious illnesses claimed to be caused by phenoxy herbicides and dioxins can be caused by a variety of agents.

In the face of these problems, the work group has decided to set the following priorities for the gathering of information:

First, to attempt to correlate the incidence of illness and disease among Vietnam veterans with their exposure in Vietnam to Agent Orange, in part by determining, insofar as practical, if Vietnam veterans as a class are as healthy as other relevant population groups.

Second, to study the broader implications for public health in the United States and elsewhere raised by the continued use of substances containing dioxins.

The mission of the work group is essentially scientific. It may discover that members of the Armed Forces who served in Vietnam run a greater risk than other groups of contracting serious diseases. But it may also find that the origin of any such diseases is not peculiar to a given chemical or to the Vietnam experience.

If these are the findings, they will not tell us at what elevation of risk a veteran's illness should be deemed service-connected, or if the United States should assume responsibility for compensating the Vietnam veteran or his survivors for illness should the increased risk be very small.

They will not assist us in adjusting the equities between those Vietnam veterans and non-Vietnam veterans who contract similar ailments, or between veterans and other members of the public.

Finally, they will give only tenuous guidance on the role that government should play in ameliorating the adverse consequences of dioxins to the health of the public at large.

I do not raise these difficult questions in order to answer them. I raise them because I am concerned that the intense public discussion to date about the design, objectivity and timeliness of research on this subject may be creating or contributing to an erroneous impression. Because of the controversy, many may have come to believe that once an optimal research agenda is established and carried out, the research results will provide definitive, incontrovertible scientific information about the health effects of phenoxy herbicides and their contaminants.

I believe this is an unfortunate view because even the best effort of which our scientists are capable may not produce such conclusive results. In short, we may be left, after the research is done, with many of the same social policy issues we face today. Nevertheless, we believe the research being carried out or planned is important and valuable. We hope it will help all of us formulate a fair and humane social policy. But it will not and cannot by itself answer questions that seem to us to be fundamentally ones of broad social policy that both the Administration and Congress must soon confront.

The timetable for a definitive report by the work group and the development and review of its scientific findings will be established within the relatively near future. In the coming months, as the work group holds additional meetings, we will keep this Subcommittee apprised of current or planned research. We will also try to keep you and the public fully informed on our progress at each stage along the way.

In that regard, I have attached to this statement, and ask that it be considered a part of my testimony, a copy of the work group's first report to Stuart Eizenstat. The report provides additional details on a number of points I have discussed briefly and explores many additional and related features of the overall effort. We will be happy to answer any questions the Subcommittee may have. Thank you.

THE SECRETARY OF HEALTH,
EDUCATION, AND WELFARE,
Washington D.C., February 19, 1980.

Hon. STUART EIZENSTAT,
Assistant to the President for Domestic Affairs and Policy,
The White House, Washington, D.C.

DEAR MR. EIZENSTAT: I am forwarding the initial report of the formal Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants established in response to your memorandum of December 11, 1979. The report sets forth the interim membership of the work group and its research and other work plans developed to date. The report also contains brief summaries of significant research in this area which is currently in progress or being planned by Federal agencies participating in the work group. The report was prepared under the direction of Dr. John Moore, Deputy Director of the National Toxicology Program and Chair of the group's scientific panel, based upon information supplied by member agencies.

As noted in the report, the full work group held its initial meeting on Friday, February 1, 1980, under the direction of Joan Z. Bernstein, General Counsel of this Department and group Chair. At that session, it was agreed that the full work group would meet monthly. Specific steps to keep the public informed of our progress will be considered at the next meeting. Additionally, the scientific panel will be holding meetings throughout the coming months to assure that the scientific aspects of the work group's mission are carried out in a competent and efficient manner, and are coordinated with the work of other groups such as the Veterans' Administration Advisory Committee. We will address the group's activities in detail in our upcoming reports, which will be sent to you monthly following each meeting of the full work group.

Your December 11 memorandum asked that the group consider and include in its initial report any recommendations for additional agency representation on the work group. The group has reserved that matter for the time being but will keep you informed should additional agency involvement appear desirable.

I am gratified at the cooperation of all work group participants and look forward to our being able to report, in the near future, real progress toward completing the work group's most serious mission on behalf of the Nation.

Sincerely yours,

PATRICIA ROBERTS HARRIS.

Enclosure.

INTERAGENCY WORK GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HEBRICIDES AND CONTAMINANTS

PROGRESS REPORT

February 15, 1980

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INTERAGENCY WORKING GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

SUMMARY OF ACTIVITIES

The Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants met for the first time on February 1, 1980. The Interim Research Agenda attached at Tab B was prepared pursuant to discussions at that meeting.

Discussion at the meeting focussed on the first priority, allegations of health affects resulting from possible exposure to Agent Orange in Vietnam veterans. The Work Group believes that the most pressing need is for the design and conduct of studies that will determine if there is an increase in certain relevant diseases among Vietnam veterans and their offspring. If there is an increased prevalance of these diseases, the group should attempt to identify the possible association between phenoxy herbicides, dioxins or other related contaminants and these diseases. This course is to be taken because the alleged health effects encompass a broad variety of symptons, many of which can be associated with a variety of agents. Although other agents may be responsible in whole or part for these diseases, this work group will focus only on the chemicals identified above.

It should be noted that conclusive results are not likely, at least in a short period of time. Any attempt to correlate a cause-effect relationship between Agent Orange (whose definite time and concentration of exposure to U.S. troops is not accurately known) and an alleged pattern of illness that is nonspecific in nature is a tenuous undertaking. Most of the current activities listed separately in this report are directly applicable to the Agent Orange issue. Our plan is to complete the list of activities and commerce evaluation to determine their current status and completion schedules and insure that the total effort is comprehensive. Of immediate interest is the proposed Operation Ranch Hand Study currently under review by the National Academy of Sciences, the VA's design of an epidemiology study, the current status of analytical methods for dioxin analyses, toxicology experiments that assess effects of an Agent Orange mixture on male mice and their progeny, and mutation experiments.

The Working Group has also proposed to commit itself to the a program that assesses the significance of dioxin contaminants on public health. To properly address this objective, all sources of dioxin exposure must be considered. Dioxins that contaminate phenoxide acid herbicides are a current major concern; other sources of dioxin exposure may be of equal or greater concern. Another family of chemical contaminants, the dibenzofurans, will also be considered since they are often found in products that contain dioxins and, based on toxicologic and medical evidence, the pattern of disease produced by the toxic members of these two chemical classes is similar, if not identical.

INTERAGENCY WORKING GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

INTERM RESEARCH AGENDA

I. Sources of Exposure:
   1. Identify chemicals known to be contaminated with TCDD, TCDF, other dioxins and dibenzofurans.
   2. Determine the stages in the production process at which contamination occurs.
   3. Quantify the magnitude of contaminant levels.
   4. Consider the significance of other means of dioxin or dibenzofuran formation.

II. Chemical Analyses:
   1. Determine the quantitative and qualitative reliability of methods, including human tissue analysis.
   2. Estimate the quantitative limits of detection required in analyses of selected samples.
   3. Determine the analytical standards required and procedures for their procurement.

III. Human Health:
   1. Accidental or Occupational Exposures:
      A. Evaluate the adequacy of ongoing or completed studies in assessing toxicities associated with exposures.
      B. Attempt to obtain more current information on health status of individuals imvolved in previous U.S. and foreign exposures.
   2. Characterization of the Disease:
      A. Determine the symptomology and clinical findings consistently associated with exposure.
      B. Identify the toxicity parameters that may be associated with exposures.
      C. Adduce the time frame from exposure that toxic symptoms appear and persist.

D. Consider whether dose response parameters can be developed.

3. Vietnam Veterans:
   A. Collate the alleged disease parameters.
   B. Assure that epidemiology study designs will assess possible increases in alleged disease patterns, disease parameters associated with occupational or accidental exposures and selected toxicity parameters identified in laboratory toxicity experiments.
   C. Review ongoing or completed activities, i.e., Ranch Hand; selection of appropriate ground troop population; tissue analyses, etc.
   D. Determine the most reliable or acceptable means of presuming herbicide exposure.
   E. Consider the significance of herbicide and contaminant exposure of military personnel not stationed in Vietnam.

IV. Laboratory Toxicology:
1. Collate the comparative toxicity data for the dioxins and dibenzofurans; identify data gaps.
2. Consider comparative studies that correlate dose and duration of exposure with sequential development of toxic symptoms.
3. Reevaluate chemical disposition data as to adequacy.

DEPARTMENT OF AGRICULTURE

STUDIES ON PHENOXY ACIDS, DIOXANS OR RELATED CONTAMINANTS

1. Epidemiology Study

The Office of Safety and Health Management (OSHM) is planning a feasibility study on U.S. Forest Service employees that have been exposed to phenoxy herbicides (2,4-D, 2,4,5-T and silvex) in forest management practices. Some of these employees have been exposed to phenoxy herbicides for close to 30 years. The study will begin with a review of job descriptions of various employees to document exposure. Depending on the results of this feasibility study, a larger morbidity and mortality survey may be undertaken.

Contact Person: DAVE GRAHAM.

Estimated date of completion: June 1, 1980.

2. Human Exposure Studies

The Science and Education Administration-Agricultural Research will conduct a human exposure study of pesticide applicators engaged in spraying 2,4-D under actual farm conditions. Participants will be selected from the Fargo, North Dakota and Pullman, Washington area where 2,4-D is used extensively for weed control in wheat. Exposure will be assessed by measuring 2,4-D residues in dermal, inhalation and urine samples. The urine data will be put into a pharmacokinetic model to calculate the actual dose received during spray operations. Both ground and aerial applicators will be examined.

Contact PERSON: Dr. P. C. KEARNEY.

Estimated date of completion: Fall-Winter 1980.

3. TCDD Residues in Wildlife

An experiment is being conducted on 8 deer placed in an enclosure and treated with 2,4,5-T for conifer release programs. Samples of liver, fat and muscle tissues were taken from the deer at different time intervals after spraying. The tissues are now being analyzed for TCDD residues by the University of Nebraska using gas liquid chromatography—mass spectrometry methods.

Contact Person: DR. DAVE GRAHAM.

Estimated Date of Completion: Summer 1980.

DECEMBER 8, 1979.

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

DEPARTMENT OF DEFENSE (DOD) HERBICIDE ORANGE STUDY UPDATE

This is to follow up our meeting of December 4, 1979, and provide an update on all DOD study efforts to evaluate the long-term human health effects of herbicide orange.

The Air Force Ranch Hand study is our only ongoing human health effect effort. Since your last meeting with the Assistant Secretary of the Air Force (Manpower, Reserve Affairs and Installations), a number of previously discussed activities have now been accomplished:

The formal protocol review tasking of the National Academy of Sciences (NAS), together with a $10,000 transfer of funds, was made on December 4, 1979;

A protocol incorporating the comments and recommendations of the three previous peer review groups, the University of Texas at Houston, School of Public Health, the Air Force Scientific Advisory Board, and the Armed Forces Epidemiological Board, has been transmitted to the membership of the Herbicide Orange Sub-Committee of the Committee of Toxicology, Assembly of Life Sciences, NAS, for their review prior to the formal review meeting;

NAS has established the date of December 18, 1979, for the Air Force formal presentation and the beginning of NAS sub-committee's collective consideration of the protocol;

The Air Force has written to the NAS expressing its desire to have additional follow-on participation of the Academy in the study, and

The Air Force has established contact with the Internal Revenue Service in order that former Ranch Hand members who separated from the service may be located. These individuals will probably be contacted and examined after the active duty and retired personnel.

A related activity to the Air Force Ranch Hand study is the DOD participation on the Veterans Administration Advisory Committee on Effects of Herbicides.

We will continue to keep you informed of our activities regarding the long term health effects of herbicide orange and look forward to being a participant on the Interagency work group.

GEORGE MARIENTHAL,
Deputy Assistant Secretary of Defense
(Energy, Environment and Safety).

FEBRUARY 1980.

ENVIRONMENTAL PROTECTION AGENCY

RESEARCH ACTIVITIES RELATED TO PHENOXY HERBICIDES AND THEIR DIOXIN CONTAMINANTS

I. Chemical Analysis:

A. Methods Development (dioxins):

A multiple-lab participation system of analysis has been developed to obtain validated analyses of environmental samples contaminated with TCDD at very low levels. Current work is directed toward attaining the capability of analyzing samples from a wider range of environmental origins. At the same time efforts are underway to distinguish between the various TCDD insomers and to lower the size of the sample that is required for study.

B. Studies in progress:

1. Special studies (TCDD):

The system referred to in A is being applied to specific samples derived from water, stream sediments, wildlife, dump sites, etc.

2. Monitoring (phenoxy herbicides).

a. EPA's National Surface Water and Sediment Residue Network regularly obtains samples from the naton's major drainage areas and monitors them for concentrations of certain phenoxy herbicides.

b. In association with activities of the National Center for Health Statistics, EPA is analyzing urine samples from the general population in the U.S. for the presence and amount of certain herbicides.

II. Investigation of combustion as a potential source of dioxin contamination:

A study has been initiated to investigate the hypothesis that dioxins may be routinely formed during common combustion processes, such as those at power plants and incinerators.

FEBRUARY 1980.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STUDIES ON PHENOXY ACIDS, DIOXINS OR RELATED CONTAMINANTS

I. *Epidemiological Studies:*

1. Establishment of a Dioxin Registry:

NIOSH is establishing a registry of U.S. workers who have been exposed to dioxins and certain dioxin contaminated herbicides. The techniques used in establishing the registry will conform to those used by the World Health Organization so that results of the studies can be compared with those from other countries. The registry will allow an evaluation of the morbidity and mortality trends and attempt to identify any excess disease pattern associated with these exposures.

2. Occupational Surveys:
   (a) Health Evaluation of 2,4,5–T workers in Nitro, West Virginia;
   (b) Health Evaluation of 2,4,5–T workers in Jacksonville, Arkansas;
   (c) Health Evaluation of pentachlorophenol workers in Sauget, Illinois.
3. Discussion in progress between NIEHS, NIOSH and International Agency for Research on Cancer, WHO, about update of 1978 report on Long Term Health Effects of Chlorinated Dibenzodioxins and Dibenzofurans.

II. *Methods of Chemical Analysis:*

1. Development and validation of methodologies for tissue analysis of TCDD and related compounds.
2. Synthesis of analytical standards for dioxins and dibenzofurans DHEW Research Grant:
   Project No.—5N01CP85945–01;
   Title—Polychlorinated Dibenzo-*p*-Dioxin and Dibenzofuran Synthesis.

III. *Animal Toxicology Studies.*

1. "Agent Orange":
   (a) Effects of "Agent Orange" components on Male Fertility and Reproduction. A probe study in male mice using large doses of the constituents of Agent Orange to determine effects on fertility and ability to sire normal offspring. Estimate initial report, July 1980.
   (b) Reevaluation of the mutagenic potential of components of Agent Orange. Studies of 2,4–D, 2,4,5–T, TCDD in microbial and *Drosophila* systems are in progress.
2. 2,3,7,8–Tetrachlorodibenzo–*p*–dioxin (TCDD):
   Evaluation of the Carcinogenic Effects of TCDD in Rats and Mice. Studies include groups with oral or skin exposure throughout lifespan. Estimate draft report available for peer review March 15, 1980.
   DHEW Research Grants:
   Project No. and *Title*
   5R01DE04333–03—PCB and TCDD Orofacil Teratogenesis in M Multatta;
   5R01ES01330–03—Implications of Low Level Exposure to Dioxins (Rats, Monkeys);
   5R01ES01552–03—Mechanism(s) of Toxicity of the Chlorinated *p*-dioxins (Rats, Mice, Guinea Pigs);
   5R01ES01884–03—Toxicology of Chlorinated Dibenzo-*p*-dioxins (Mice);
   5P01CA22484–02—Biochemical Studies in Chemical Carcinogenesis.
3. Hexachlorodibenzo-*p*-dioxins (HCDD).
   Evaluation of the Carcinogenic Effect of HCDD in Rats and Mice. Studies include groups with oral or by skin exposure throughout lifespan. Estimate peer review of draft report March 1, 1980.

4. Octachlorodibenzo-*p*-dioxin (OCDD).
   (a) Review of previous toxicology studies. Estimate completion March 30, 1980.
   (b) Studies of chemical disposition and metabolism of OCDD. Estimate completion September, 1980.
5. 2,3,7,8–Tetrachlorodibenzofuran (TCDF).
   (a) Comparative species evaluation of chemical disposition and metabolism of TCDF in rat, monkey and guinea pig. Estimate completion June 1980.
   (b) Teratology Evaluation of TCDF in rats or mice. In planning stage; estimated—third quarter fiscal year 1980.
6. 2,4–Dichlorophenoxyacetic Acid (2,4–D): Neurotoxicity of 2,4–D in rodents. Study planning stage.

FEBRUARY 1980.

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The Occupational Safety and Health Administration is very concerned about the known and potential adverse health effects of workers exposed to phenoxy herbicides and 2, 3, 7, 8,-tetrachlorodibenzo-*p*-dioxin (TCDD) contaminants. The significant animal toxicity of TCDD makes careful exploration of the human toxicity of these materials mandatory.

To date, OSHA has been involved in several inspections where dioxin and TCDD contamination have occurred. Sampling has occurred during each of these inspections and has brought to our attention the analytical difficulties in quantitating dioxin contamination as well as the difficulty in separating TCDD from other tetrachlorodibenzo-dioxins. OSHA along with NIOSH has participated in the development of personal protective clothing and equipment recommendations for workers involved in a dioxin clean-up operation at a corporation in Jacksonville, Arkansas. The Department of Labor has also recently submitted a proposal to HEW to review and assess the problems and potential adverse health effects of dioxins.

OSHA recognizes that more information is needed on the long term health effects of dioxins and TCDD in humans as well as the adverse human health effects of low level exposures before an effective regulatory program can be achieved. OSHA welcomes the opportunity to participate on the Interagency Work Group to study the possible long term health effects of phenoxy herbicides and contaminants and the scientific panel to be headed by Dr. John Moore, to help achieve this goal.

DECEMBER 1979.

VETERANS ADMINISTRATION

ACTIVITIES WITH REGARD TO HERBICIDES, PARTICULARLY AGENT ORANGE

Under the Administrator's direction, the Veteran Administration performed following activities with regard to the issue of possible health related effects of exposure to herbicides, particularly Agent Orange, in Vietnam veterans.

1. *Information Gathering.*—In order to assure that the VA has available the highest level of expertise on herbicides, an official Advisory Committee was chartered on April 20, 1979. It consists of representatives from Government and non-Government agencies who are actively involved in scientific activity related to herbicides. Supplementing this, the VA has made contacts with the DOD, EPA and HEW in order to stay knowledgeable on their heribcide related research.

2. *Dissemination of Information.*—Formal efforts have been made to inform VA professional staffs about the latest information on herbicides. These efforts have included: (a) An educational "White Paper" discussing herbicides; (b) Conference telephone calls to all VA medical facilities discussing the current medical and administrative aspects relating to the evaluation of Vietnam veterans possibly exposed to herbicides; (c) Written instructions to the VA medical centers (Circular 10–78–219) for the medical evluations and reporting of veterans possibly, exposed to herbicides in Vietnam; and (d) An educational conference in Washington, D.C. on herbicides for physicians representing each VA medical center.

The VA provided testimony in reference to herbicides and the VA medical programs to the Subcommittee on Medical Facilities and Benefits of the Veterans Affairs Committee of the House of Representatives.

An information conference was conducted in VA Central Office for representatives of the Service Organizations.

Individual veteran's correspondence and telephone calls have been replied to in an effort to answer specific questions and educate the veterans on current knowledge in relation to herbicides.

The Veterans Administration has participated in TV programs discussing the topic of herbicide exposure as it relates to the health status of the Vietnam veterans.

3. *Performance of Research.*—The VA has set up a central registry which contains data obtained from performance of comprehensive medical examinations on Vietnam era veterans claiming exposure to herbicides. This registry will be utilized in the performance of a formal epidemiological study on the possible health related effects of herbicides in Vietnam veterans. The VA also is performing a pilot study of the feasibility and diagnostic usefulness of determining dioxin levels in the fat of veterans exposed to herbicides.

In addition to performing its own research, the VA has stimulated appropriate research efforts by other Federal agencies in areas where its expertise was limited. In this regard the VA Administrator has made written requests to DOD and HEW to engage in studies of herbicides outside of the VA's scope of expertise. Both requests have resulted in positive responses.

4. *Provision of Health Care Services.*—Vietnam veterans were provided medical care for any illness, regardless of the etiology, which may have been uncovered during the course of an examination performed in relation to the herbicide program.

5. *Processing of Compensation Claims for Herbicide Exposure.*—The VA processed some 750 claims for compensation arising from possible exposure of veterans to herbicides. Thus far, two claims have been adjudicated as being possibly related to herbicide exposure. These two veterans demonstrated evidence of a skin condition, chloracne.

INTERAGENCY WORKING GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

ATTENDEES-FEBRUARY 1, 1980 MEETING [1]

Department of Health, Education and Welfare:

Jodie Bernstein; David Andrews; Leslie Platt; Harold Margulies; Pat Honchar; Peter E. M. Beach; J. A. Moore; David Rall; Anne Cohn; Jacky Simon; Marian Troyer; and Doug Hussey.

Department of Labor:

Stephen Mallinger; and Patricia Breslin.

Department of Defense:

William S. Augerson; Peter Flynn; and Jerome G. Bricker.

Veterans Administration:

Paul Haber; W. J. Jacoby, Jr.; Guy McMichael; and Frederic Conway.

Department of Agriculture: P. C. Kearney.
Environmental Protection Agency: Donald Barnes.
Office of Science and Technology Policy: Richard H. Adamson.

STATEMENT OF JOAN Z. BERNSTEIN, GENERAL COUNSEL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mrs. BERNSTEIN. My full statement reviews the status of efforts by HEW and the Inter-Agency Work Group with special emphasis on our research concerning this phenoxy herbicide know as Agent Orange.

Agent Orange, as you have heard used extensively for several years, is composed of phenoxy herbicides: 2,4-D and 2,4,5-T.

In the chemical production of 2,4,5-T the herbicide is contaminated with the highly toxic chemical called TCDD. Concern surrounding the health effects of Agent Orange are largely focused on this contaminant.

Today, while much is known about the biological effects of phenoxy herbicides and contaminants there are still important gaps in our knowledge. The work group is attempting to fill these gaps in order to enable us better to assess the risks of these chemicals to man.

[1] Final membership list being developed.

Various Federal agencies have been involved for some time in their own efforts to further own current knowledge of this subject. Activities have included the collection of scientific information, the review and evaluation of existing data and supportive research.

For approximately the last 10 years, HEW itself has conducted or sponsored more than 50 studies relating to phenoxy acid herbicides and dioxins. Our efforts have encompassed both laboratory investigations and epidemiological studies of people who have been exposed to TCDD or phenoxy herbicides in their occupational environment or by accidental exposure.

HEW's laboratory studies have made valuable contributions to our knowledge about dioxins. Our laboratory animal toxicity studies have shown that TCDD is one of the most toxic agents known, capable of causing a number of adverse animal health effects. Animal studies have also established that other dioxins can produce disease manifestations identical to those produced by TCDD. These animal studies are especially significant because animal toxicity tests have been reliable predictors of toxic effects in man.

To help refine and expand our knowledge of the human health effects of exposure to phenoxy herbicides and dioxins, HEW is currently sponsoring or conducting several epidemiological studies. NIOSH is currently assembling a registry of all workers in the United States who have been involved in making 2,4,5-T. This effort involves collecting the workers' records and other information and gathering the workers' social security records. From the completed registry, NIOSH will attempt to determine and analyze the rates of sickness and death to 2,4,5-T workers.

In addition to this nationwide study, other occupational studies are underway in West Virginia, Arkansas, New York, Illinois, and Kentucky. To date, our occupational studies have definitely linked one human defect, chloracne, to dioxin exposure and have provided evidence of other adverse effects such as liver and nervous system impairment.

To assure a coordinated interagency effort in this area, an interagency work group has been established under the leadership of HEW. The work group is responsible for reviewing the protocols, methodologies, and status of all federally funded research and all other activities on the subject. It will also insure, we hope, that the public and the Congress are promptly and accurately informed of all relevant research findings. This work group represents the formalization of a number of informal working relationships among the various agencies involved in dioxin studies rather than the starting point of such efforts.

At our first meeting on February 1, the work group set priorities for the gathering of information. The work group will attempt to correlate the incidents of illness and disease among Vietnam veterans with their exposure in Vietnam to Agent Orange, in part by determining, insofar as practical, if Vietnam veterans as a class are as healthy as other relevant population groups.

In studying this priority, the work group is recognizing that many of the symptoms articulated by Vietnam veterans could be associated with a number of causes. The group also will study the broader public health implications raised by the continued use of substances containing dioxins.

The efforts of HEW and the interagency work group will take time and may not provide us with definitive information regarding the linkage of Agent Orange to the adverse health effects reported by the Vietnam veteran. In short, as we have pointed out in the full HEW statement, we may be left after the research is done with many of the same social policy issues we face today. However, the interagency work group is committed to completing thorough and objective scientific examination as well as a complete and accurate accounting on this subject.

My colleagues and I will be happy to answer whatever questions you may have following the panel discussion. Thank you.

Chairman SATTERFIELD. Thank you, very much. The next witness is from the Department of Defense. Do both of you have statements?

General AUGERSON. Yes, sir.

Chairman SATTERFIELD. We will be glad, then, to receive yours, General Augerson, first.

STATEMENT OF MAJ. GEN. WILLIAM S. AUGERSON, DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH RESOURCES AND PROGRAMS)

General AUGERSON. Thank you, Mr. Chairman. I am General Augerson, Deputy Assistant Secretary of Defense for Health Resources and Programs.

You seemed to have convened an Army Corps reunion here. Mr. Cleland and I just discovered that we were up in the same piece of Haicor at the same time.

Others have summarized the history and background very well. Orange was used as a result of the Presidential decision. It was used to protect Americans. It was assumed to be safe due to its extensive civil use of similar compounds.

Ten percent of Vietnam was sprayed. Most of it was remote from population areas. When the dioxin problem surfaced or appeared the use was stopped and the U.S. stocks were subsequently destroyed in 1977. We have records on computer tape of U.S. Air Force spray missions but we do not have files on the use of Herbicide Orange by helicopters, off of trucks or in ground use.

The problem at hand which is common to many of our other chemical servants consists of three questions: Is dioxin toxic to humans at low doses, were U.S. ground troops exposed and to what extent, and what has this exposure—has this exposure led to ill health to these men or their children.

These are difficult questions and prodigious work will be necessary to resolve them. The Department of Defense is determined to cooperate fully in the necessary work to solve this problem.

The Air Force project to evaluate carefully a large number of personnel known to be exposed substantially to Herbicide Orange, to us seems to be an important way to evaluate the potential problem.

Major General Chesney on my right will report in some detail on that Air Force study.

Because of the concern about this subject, the action office within the Department of the Defense has changed to—from the environmental office to my office, the Office of the Assistant Secretary of Defense for Health Affairs.

I am prepared to answer your questions.

Chairman SATTERFIELD. Thank you.

General AUGERSON. And by the way, sir, I have submitted a rather long formal statement.

Chairman SATTERFIELD. Without objection, your full statement as well as the statements of all of the other members of the panel will be admitted to this record.

[Material follows:]

STATEMENT OF MAJOR GENERAL WILLIAM S. AUGERSON, DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH RESOURCES AND PROGRAMS), BEFORE THE SUBCOMMITTEE ON MEDICAL FACILITIES AND BENEFITS, COMMITTEE VETERANS' AFFAIRS, HOUSE OF REPRESENTATIVES

Mr. Chairman, Gentlemen and Ladies: It is a pleasure to appear before the Committee to discuss the Department of Defense's use of the mixture of herbicides known as "Orange". Our discussion will include: its application in Vietnam; the controls which were utilized in the operational missions; and the evolution of the state of knowledge concerning the possibility of toxic responses due to a small concentration of a contaminating substance known as 2, 3, 7, 8-tetrachlorodibenzo-para-dioxin, usually referred to as either TCDD or simply dioxin; subsequent curtailment of herbicide operations; and the eventual destruction of all remaining stocks of the herbicide. I recognize your concern about possible health effects in Vietnam service personnel. The Air Force presentation will cover our effort to evalute possible health effects in a group known to be exposed.

We, in the Department of Defense, prefer to refer to the equal mixture of 2, 4–D and 2, 4, 5–T as *Herbicide* Orange, rather than as it has been referred to in other publications as "Agent Orange". The action of these substances, as was first and widely demonstrated in commercial agricultural applications here in the United States and in other countries, was to selectively destroy or defoliate brush and other woody plants. Their combined action was selective, and in the true sense they are herbicides. The use of the word "agent" has the connotation that the substance has an anti-personnel or anti-animal effect and is deliberately employed against such targets. This was not the case. When the initial selection and decision to use these herbicides in defoliation and selective crop applications was made, both substances were considered to have no human toxicity.

Herbicide Orange and the other herbicidal compounds utilized in Vietnam derived their names from the use of a 3-inch, color-coded band which was painted around the center of the ICC 17C 55-gallon, 18-gauge, steel drums, used for shipment of the compound from the manufacturing plant in the United States to the operational utilization points in Vietnam. Other herbicide formulations had containers which were marked with white, blue, pink, purple and green bands for easy identification.

The initial decision to use herbicides in Vietnam was made by the President of the United States at the request of the Republic of Vietnam. Approval of initial targets was the subject of inter-agency review, and early research and development efforts in 1962 were restricted to remote areas in the Ca Mau peninsula and along Route 15, northwest of Saigon. These missions were accompanied by information leaflets, loudspeaker warnings and avoided all populated areas. Following these tests, extensive evaluation of effectiveness was made by a technical team. In fact, over the period from 1963 to 1968, there were at least eight major evaluation programs and reports. A list is included as Appendix 1. Few of these considered the health effects, since information available at that time did not indicate high toxicity, mutagenicity or any significant human health effects. Only in October 1969, as a result of a Department of Health, Education and Welfare study performed by Litton Bionetics, did concerns arise. These were, of course, evaluated in the later contract effort with the National Academy of Sciences, complete reports of which were submitted to the Congress in February 1974.

Herbicide Orange, the defoliant in question, consists of a 50:50 mixture of the *n*-butyl esters of 2, 4–D ((2, 4–dichlorophenoxy) acetic acid) and 2, 4, 5–T ((2, 4, 5–trichlorophenoxy) acetic acid). Each gallon of Orange contains 4 pounds of 2, 4–D and 4.6 pounds of 2, 4, 5–T on an acid-equivalent basis. Each of these herbicides was registered by the EPA, and have been in commercial use in U.S. agriculture since the mid-1940's. The outstanding effectiveness of these two herbicides in controlling the growth of broad-leaved plants and weeds, coupled with their ap-

parently low mammalian toxicity and low application rates, resulted in their rapid acceptance and spread in world agriculture. As a result, 2, 4–D production went from 14,000 pounds in 1950 to 36 million pounds by 1960. During the 1960's, approximately 78 million pounds of 2, 4, 5–T was applied within the United States for agricultural purposes.

I would like to describe now how Herbicide Orange was used in Vietnam. Defoliation operational approval consisted of a rigorous process which required approval by both Republic of Vietnam officials and U.S. officials, even up to the U.S. Ambassador. This dual-approval chain operated regardless of whether the request was initiated by Republic of Vietnam (RVN) or U.S. Force commanders. On the RVN side of the chain, authorization review and approval for missions started with the Province Chief and was then sent through the Regional Vietnamese Army Commander to the RVN Armed Forces General Staff to what was called the "202 Committee;" the request was also sent to the American Division Commander for the area in which the province was located, and then on to the Senior Advisor of the Military Region and to the U.S. Mission to the "203 Committee". In this approval process, the Vietnamese Province Chief was required to provide an analysis of the target area, which included intelligence, civic affairs evaluation, including number of people in and near the target areas, the creation of refugees, and the psychological-warfare aspects of the operation. The Province Chief also had to guarantee a pledge of indemnification for damage to "friendly" crops. On the American side of the approval process, the Senior Advisor had to consider the same factors as the Vietnamese Province Chief, plus other problem areas, such as the effects on pacification operations, community development and economic effects, in consultation with other specialized advisors such as the Agricultural Advisor.

Proceeding up the American line of approval, the "203 Committee" considered the proposal from the standpoint of intelligence, planning, USAID aspects and the American Embassy. If all of the lower authorities had granted approval, the proposal for a spraying operation was then forwarded to the MACV Commander and the American Ambassador. Disapproval by either the RVN or American chain of commands stopped the proposed mission. As a further precaution, forty-eight hours before each flight mission, final approval had to be sought from the Province Chief and from all ground commanders having a responsibility in the target area to be sprayed. These involved approval procedures were mandatory for all operations involving destruction of crops and for all fixed-wing, aircraft defoliation missions. Defoliation missions conducted by helicopter or on-the-ground spraying were delegated for approval to the Mulitary Region Commander on the part of the RVN and the American Forces.

Post-mission reports had to be submitted to MACV Headquarters. These reports had to include: project and target number, date of mission, number of sorties scheduled and number accomplished, reasons for non-successful sorties, number of gallons of agent used, and type of mission (defoliant or crop destruction), hits from ground fire received by aircraft, and map coordinates of actual spray run.

We now have in the Department a computer listing of all such spray missions for the period from 1965 to the end of spraying in 1971, which is believed to be complete. This print-out shows the date, time, agent used, gallons of agent dispensed, the map coordinates and the area covered by the mission. A detailed computer presentation is not available for the period before 1965. Very recently, another computer report has been obtained which provides information on post-1965 spray missions in each of the provinces of Vietnam, and provides the same mission profile data as described earlier.

In order to verify that these review and approval procedures were being followed with respect to all fixed-wing aircraft spray missions, a special task force from MACV and the American Embassy reviewed the project and mission files and issued a report in May of 1968. In general, the report found that policies and procedures were followed; however, it noted that there had been serious damage to "friendly" crops. Steps were outlined to further improve the management of herbicide operations. One major report recommendation was, in accordance with the wishes of the RVN government, to limit further operations to "low population density" areas, defined as those areas with no more than 7 persons per square kilometer.

It should be mentioned that from August 1965 through February 1971, 90 percent of all of the Herbicide Orange disseminated over South Vietnam was for forest defoliation. Crop destruction missions, during the same time period, accounted for 8 percent of amount sprayed; and the remaining 2 percent was used around base perimeters, cache sites, waterways and communications lines.

Much of this protective perimeter spraying was done by ground vehicles or by the use of small helicopters with limited capacity tanks. These perimeter defoliation operations helped to maintain clear fields of fire and protected our troops from infiltration through the dense cover. Areas around our fire bases and camps were also routinely sprayed with insecticides both from the air and by ground dissemination methods to reudce mosquitos and thus help to control malaria. Some of these numerous insecticide control flights by helicopters may have been mistaken as defoliation runs. The insecticide most commonly used was malathion, which is commonly used here in the States.

The primary purpose of defoliants in South Vietnam was to deny the Viet Cong the advantages of the dense, jungle-foliage cover which enabled them to ambush our forces with sometimes disasterous results and high casualties. The dense, tri-level jungle growth also permitted the enemy forces to assemble large forces, develop supply dumps and operate with relative immunity from aerial observation and strikes. Therefore, the aerial spraying operations using various herbicides were initiated to reduce casualties among our forces, and hence were directed at enemy-controlled territory. From an area standpoint, herbicides were sprayed on approximately 10.3 percent of the inland forests of South Vietnam, 36.1 percent of the mangrove forests, and 3 percent of the cultivated lands. Total area estimates sprayed for all of South Vietnam range from 8.6 percent to approximately 10 percent of the land mass. During the period from January 1962 through December 1964, when relatively few American forces were in the field in South Vietnam, approximately 281,200 gallons of defoliants were sprayed on hostile areas. At the end of 1962, approximately 12,000 personnel were assigned. By January 1965, this number had increased to 23,000 and by the end of 1965, approximately 181,000 personnel were present in South Vietnam. In the period from January 1965 to February 1971 when American forces were augmented, approximately 11.3 million gallons of Herbicide Orange were sprayed. Much of the herbicide was deposited on the dense jungle canopy in remote areas occupied by enemy forces. The typical spraying mission was flown at an altitude of 150 feet and released the herbicide at the rate of 3 gallons per acre, with a flight speed of 130 knots. The spraying time was about 3.5 to 4 minutes in a spray line 14 kilometers long (8.7 miles) by 260 to 280 feet wide.

In canopy penetration studies with phenoxy herbicide formulations similar to Orange, it was found that, on the average, only 21 percent of the spray penetrated the top canopy of the dense forest growth and only about 6 percent penetrated to the ground level. As would be expected, the percent spray penetration through forest canopies was inversely related to the canopy density. In a typical, initial spray mission, nominally 1,000 gallons of Herbicide Orange would be applied over 346 acres of forest, thus 94 percent or 940 gallons would come to rest on the forest canopy and be trapped and absorbed in the foliage. The remaining 60 gallons would penetrate to the ground level and be deposited either on the soil or the underbrush. The actual ground-level deposit rate would likely be about .17 gallon per acre or 1.4 pounds of 2,4–D/2,4,5–T mixture per acre. In comparison, mixtures of such herbicides have been routinely applied in the United States at the rate of 2.0 pounds per acre. Our military forces moving through Orange-treated forests would have encountered the same amount of phenoxy herbicides as a person would encounter in walking through defoliated brush-infested ranch land here in the United States.

Going back to the total amount of 2,4,5–T sprayed over all of South Vietnam from January 1962 through February 1971, it amounted to 44 million pounds or 41 percent of the total weight of 2,4–D and 2,4,5–T. It has been estimated the herbicide contained 368 pounds of the contaminant 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, the Herbicides Green, Pink and Purple contained approximately 40 percent of the estimated amount of dioxin sprayed in South Vietnam. Herbicides Green, Pink, and Purple were sprayed as defoliants on less than 90,000 acreas from 1962 through 1964, when we had only a small force of our military personnel in South Vietnam. Therefore, we have remaining an estimated 203 pounds of dioxin in a total of 38.3 million pounds of 2,4,5–T which was sprayed over 2.9 million acres of inland forests and mangrove forests. Thus, we find that each acre of jungle forest (43,560 sq. ft.) would receive, assuming uniform distribution, 7/100,000 of a pound of dioxin. However, this is distributed over the top of the forest canopy; and earlier studies have shown that only 6 percent of this deposit would likely reach the ground. Taking this factor into consideration, the amount of dioxin ever reaching the forest floor would be four millionths of a pound per acre without assuming any photo or chemical degradation of the chemical. The 4 millionths of a pound of dioxin per acre converts to 1.9

milligrams per acre or .04 micrograms of dioxin per square foot on either the soil or deposited in the underbrush. This would be the concentration of dioxin from Herbicide Orange immediately after a spray mission; however, one should also consider that many of these forests had trees which were 150 feet tall, and that there may be as high as 300 tons of vegetation per acre on which this small quantity of dioxin fell.

Under tropical conditions, the effects of Herbicide Orange sprayed at the rate of 3 gallons per acre were not seen for a period of one to two weeks when leaf browning and discoloration took place. However, leaf drop did not occur until one to two months after application, reaching a maximum in two to three months. Since the denial of cover to the enemy did not take place until at least a month after application, generally our forces did not operate in these areas until the cover was eliminated. Inevitably, in any operation as vast as the Vietnam War, some military persons may have entered regions before defoliation and some few may have been exposed to spray. Hence, an environment decay factor also acted to further reduce the minute initial dioxin concentrations. A 1978 study of the fate of dioxin in plants, soil, water and air of a microagroecosystem using tritium-labeled dioxin at concentrations of 44 or 7,500 parts per billion applied to bluegrass found that the dioxin concentrations was initially 20 parts per trillion (10^{-12}g/g of grass) but after 4 weeks, the concentration was at or below 1 part per trillion. The half-life was approximately six days. The investigators concluded that volatization (about 10 percent) of dioxin was a major pathway of dissipation from their microagroecosystem chamber. Once the dioxin was volatilized, it was dechlorinated in the direct sun and apparently even in the shade (as we might have under the jungle canopy) and even without the presence of ultraviolet light.

Another study, a year earlier, found that herbicide formulations (including Orange) which contained known amounts of dioxin and exposed to natural sunlight on leaves, soil and grass, lost most of the dioxin in a single day, due mainly to photochemical dechlorination. Despite the known soil persistence of the pure form of dioxin, it was not stable as a contaminant in thin herbicide films exposed to outdoor light.

As a result of the National Institute of Health report that 2,4,5-T could cause malformations and stillbirths, the Department of Defense in October 1969 restricted the use of Herbicide Orange to areas in Vietnam which were remote from population concentrations concurrent with civilian actions. In April 1970, the Department ceased all operations involving the use of Herbicide Orange. This was done because of its possible teratogenicity and the now recognized contamination with minute concentrations of the highly toxic dioxin or TCDD. At the time of the suspension of all spray operations there were 1.37 million gallons of Herbicide Orange in storage in South Vietnam, and another .85 million gallons sorted at the Naval Construction Battalion Center in Gulfport, Mississippi. In September of 1971, the Department directed that all of the Herbicide Orange in Vietnam be returned to the United States and that the entire 2.2 million gallons be disposed of in an environmentally safe manner. The Herbicide Orange from Vietnam was moved in April 1972 to Johnston Island in the Pacific Ocean for later disposal. During the period between 1971 and 1977, several methods of disposal and reprocessing to remove the contaminant dioxin were researched. In March 1977, the Air Force requested the EPA to approve the destruction of stored herbicide through high temperature incineration on-board of a specially designed incineration vessel on the open sea, West of Johnston Island. This was approved and was accomplished. A total of three herbicide loadings were required, one from Gulfport and two from Johnston Island to eliminate the entire stored DoD stock of Herbicide Orange.

During the land based operations involving removal of the herbicide from the storage drums and transfer to the incineration ship, air sampling was conducted on a continuing basis; and the levels of 2,4-D and 2,4,5-T vapors were at least two- and in most cases three, orders of magnitude below the acceptable, threshold, limit values for these substances. Dioxin was not detected in any air samples at either site. Approximately 200 personnel carried out the removal from storage drums and transfer activities at the two locations. Comparisons of available pre- and post-operational medical examinations of military personnel involved have revealed no apparent physical effects as a result of these transfer operations with Herbicide Orange.

As a result of an April 10, 1978 letter from the late Ralph H. Metcalfe to the General Accounting Office, in which he expressed concern about the possible long-term adverse health effects on individuals that were exposed to Herbicide Orange in Vietnam, the GAO began the investigation which produced the report

entitled, "Health Effects of Exposure to Herbicide Orange in South Vietnam Should Be Resolved", published on April 6, 1979. This report pointed out that since 1977, Vietnam veterans have been contacting the Veterans Administration about health problems which they believe were caused by exposure to herbicides in Vietnam. Problems in identifying personnel exposed to herbicides and determining the possible health consequences of such exposure had hindered the Veterans Administration efforts to resolve the concerns posed by these veterans. The report made the recommendation that the Department of Defense, with the assistance and guidance of an appropriate interagency group, conduct a survey of any long-term medical effects on military personnel who were likely to have been exposed to herbicides in South Vietnam. It also recommended that the Secretary of Defense provide guidance to ensure that Air Force, Army, and Navy medical facilities are uniformly monitoring and evaluating possible herbicide-related concerns of personnel who served in Vietnam. Information thus developed in Defense medical facilities should be coordinated with the Veterans Administration.

Our Department did not agree with the recommendation that the DoD undertake a comprehensive interagency study of the long-term medical effects on military personnel who might have been exposed to Herbicide Orange in Vietnam. It was our position that a retrospective epidemiological study of that population would not produce reliable results because: (1) About 17 years have elapsed since the beginning of herbicide operations in Vietnam, and during this interim period any number of other influences on health may have supervened; (2) There are generally no data on exposure concentrations and exposure items; and lacking a reliable estimate of exposure, the interpretation of the results would be highly unreliable; and (3) Identifying an appropriate control group would be virtually impossible. For any group to serve as an appropriate control, it would be necessary to show that these people were not exposed to Herbicide Orange, and that they have, essentially, the same shared influences on their health as those of the exposed group. The Department, as an alternative, proposed to support the then-current effort of the National Academy of Science's Committee of Toxicology to study, in cooperation with the Italian Government, the health effects of the release of large amounts of TCDD into the environment from an industrial accident in Seveso, Italy. We believed this would be a better study than that recommended by GAO because the concentration of TCDD was determined, known exposures are documented, and prompt medical follow up was achieved.

Subsequently, in response to a letter of May 21, 1979 from Senator Percy, the GAO continued their study of the use of Herbicide Orange in South Vietnam. The GAO concentrated on determining (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. They did not determine the names and last known addresses of Marines assigned to these units. Also, Army personnel could not be identified by name because the Army records were found to be incomplete. During the time of the spraying operations up to 1979, Herbicide Orange was not considered to be toxic or dangerous to humans, and few precautions were taken to prevent expsoure to the substances.

The GAO could not document from available records whether ground troops were actually exposed or the degree of exposure to Herbicide Orange. The GAO recommended that Congress direct DoD, VA, HEW or EPA to determine whether a study is needed on the health effects of Herbicide Orange on the ground troops that were identified in their analysis.

The Department of Defense, through the Military Departments, have now issued guidance to their medical facilities concerning Herbicide Orange health effects to ensure uniform monitoring and evaluation. The Department of Defense still believes that an extensive, retrospective epidemiological study of the ground troops in Vietnam, a truly prodigious undertaking, is very unlikely to uncover causality between exposure to Herbicide Orange and subsequent ill effects on health.

With respect to our Department's interest in other studies currently underway, we are actively participating as a member of the recent established interagency working group which was initiated by the Office of the President to facilitate, coordinate, and monitor studies sponsored by the participating agencies to determine possible long-term health effects of phenoxy herbicides and their contaminations including the dioxins. This Working Group, chaired by the General Counsel, D/HEW will have our full support and technical assistance whenever needed.

In addition, we intend to continue to work with the Veterans Administration in an effort to be responsive to their data needs in consonance with our available resources. Many of the Executive Department agencies involved in this new interagency working group have for a couple of years been interacting in a cooperative effort to resolve these problems.

The Department of Defense particularly supports the Air Force Ranch Hand Study as it is directed at a defined population who had repeated and known exposure to Herbicide Orange which is the substance of concern to our Vietnam veterans. The study will consider a locatable population which can be followed for an extended period of time to determine any significant directions in expected morbidity, mortality, or general health status. Further, the Air Force personnel who will be involved in this study as well as the control group will have been exposed to many of the in-country environments as other veterans who served in Vietnam. However, any study of this magnitude and scope will take time to accomplish in a thorough manner. We believe by the end of 1986 that the study will provide significant data to help resolve whether there are long term health problems related to exposure to Herbicide Orange in this military population.

An other study of particular interest to us is the investigation of the industrial accident which took place in Serveso, Italy in 1976 in which a defined population was exposed to gross contamination. The Department of Agriculture and the Board of Toxicology of the National Academy of Sciences have been closely following this accidental exposure in cooperation with the Department of State and the Government of Italy.

As to your inquiry about studies in the private sector, the Department has recently received a report on the mortality experience of workers exposed to TCDD in a tricholophenal process accident at the Monsanto Chemical plant in Nitro, West Virginia in 1949. One-hundred twenty-one male workers who developed chloracne resulting from this accident were selected and followed up. The study has shown no apparent excess in total mortality or in deaths from malignant neoplasms or diseases of the circulatory system in a group of industrial workers with a high peak exposure to TCDD over a follow-up period of 29 years. Caution as to any conclusiveness of the findings is, however necessary as the number of workers is limited and the number of deaths observed is rather small (32) for this 29 year period.

We intend to follow two other herbicide related studies. These particular studies have been mentioned because of their relevancy to the effects of high exposures of these substances to defined and traceable populations.

Many Federal agencies, e.g., Environmental Protection Agency, National Cancer Institute are sponsoring research relevant to Herbicide Orange and prepared by private organizations. We will follow such work but defer to the relevant agencies for any comment about their result: (1) A Dow study on the mortality analysis of employees engaged in the manufacture of 2, 4, 5-T, and (2) the Vertac health effects study on 200 workers manufacturing 2, 4, 5-T at Jacksonville, Arkansas.

We are, committed, however, to do whatever we can to help resolve this troublesome concern for the Government and for those who served in Vietnam. In this regard, cognizance for matters concerning health effects of Herbicide Orange have now been moved into the Office of the Assistant Secretary of Defense (Health Affairs), from the Office of the Assistant Secretary of Defense (Manpower, Reserve Affairs and Logistics) (Energy, Enviroment and Safety).

Thank you.

APPENDIX 1

An Evaluation of Chemical Corp Destruction in Vietnam, Betts and Denton, (AD–779 790, $5.25) October 1967.

A Statistical Analysis of the US Corp Spraying Program in South Vietnam, Russo (AD–779 791, $5.25) October 1967.

Research and Analysis Study ST67–003, Evaluation of Herbicide Operations in RVN (AD–779 792, $4.75) 12 July 1966.

Report on the Herbicide Policy Review, 28 August 1968 (AD–779 794, $10.00).

Evaluation of Herbicide Operations in the Republic of Vietnam, September 1962-September 1963 (Declassified from SECRET) (AD–779 795, $5.75) 10 October 1963.

A Review of the Herbicide Program in South Vietnam, William F. Warren, Scientific Advisory Group, Working Paper No. 10-68, CINCPAC, August 1968. (Declassified from Confidential) Less Appendices A and C (AD-77, 797, $6.50).
Crop Destruction Operations in RVN during 1967. Warren, Henry and Johnson. CINCPAC Scientific Advisory Group, Working Paper No. 20-67, CINCPAC, December 23, 1967. (Declassified from Secret) Less Appendices A and C and noted deletions. (AD-779 798, $5.25).
Assessment of Ecological Effects of Extensive or Repeated Use of Herbicide, MRI, 1 December 1967.

Chairman SATTERFIELD. General Chesney?

STATEMENT OF MAJ. GEN. MURPHY A. CHESNEY, DIRECTOR OF MEDICAL PLANS AND RESOURCES, OFFICE OF THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

General CHESNEY. Good morning, sir. I have with me today Col. George D. Lathrop, M.D. Ph. D., chief of the Division for Epidemiology for the U.S. Air Force, crew of air space medicine, Brooks Air Force Base, Tex.; and Maj. Allen A. Young, Ph. D., consultant, in the Environmental Health Sciences in the Epidemiological Division at the school.

Now, in October 1978, the Air Force Deputy Surgeon General testified before your committee concerning Herbicide Orange. As part of that testimony the Air Force advised that we plan to survey the Ranch Hand personnel to determine the status of that group.

Because of increasing concern with Congress and the public concerning possible health hazards associated with Herbicide Orange, the Air Force decided to expand the questionnaire into a comprehensive epidemiological study of the Ranch Hand group.

I would like to quickly review for your group our activities to date in the development and the implementation of this study.

The study is designed to see "Have there been, are there now and will there be in the foreseeable future any adverse health effects among the Ranch Hand personnel?"

The study is composed of three integrated elements: A mortality study, a morbidity study, and a followup study which will address the health issues through a 24-hour timespan beginning in 1962 through 1986.

The mortality and morbidity study elements will be conducted almost simultaneously by use of study methods that include personnel tracking procedures and medical/personnel records reviews to pinpoint mortality patterns; extensive baseline telephone questionnaires to ascertain current and past symptoms of health events; comprehensive physical examinations to determine exact health status and to provide a baseline data platform with which to correlate the symptoms; and additional questionnaires and physical examinations to be conducted periodically during the phase.

We have reviewed more than 2,500 scientific articles and where appropriate have incorporated those into our study.

Contact has been made with leading Herbicide Orange experts in the country; and we have also looked at at least six epidemiological investigations going on around the world.

We have made contact with the various Department of Defense and other Government agencies concerning their activities in this area. Fifteen million Air Force personnel records have now been computer processed and 37,000 others have been processed by hand.

The Ranch Hand group has been identified. The baseline questionnaire has been identified. The mortality study is well underway; and we are at work now with our statistical format and our repository fundamentals have been established.

In addition to the above action, a control group has been identified and individual controls will be selected based on the number of Ranch Hand volunteers who volunteer for the study. They will be matched by age, job, time in Vietnam, and race.

Action has been initiated to obtain the necessary addresses from the Internal Revenue Service under the provision of Public Law 96–128. We have developed an examiner's handbook to provide guidance and standardization of the physical examinations.

Initial funding has been obtained from the Air Force and additional personnel have been assigned to the project.

The Air Force scientific protocol has been subjected to extensive peer review. To date the protocol has been reviewed by the University of Texas School of Public Health at Houston, the Air Force Scientific Advisory Board, the Armed Forces Epidemiological Board, and the Board of Toxicology of the National Academy of Science.

We are now awaiting the review by the National Academy of Sciences.

We will proceed with the next phase as soon as we can incorporate their recommendations into our protocol. We have attempted to incorporate the expertise of the Air Force and the advice of recognized civilian authorities into this protocol in studying the group of people which we think are the most at risk for Agent Orange.

And, therefore, the results of this study should yield valuable data from which to determine if there are any health problems related to the exposure and to determine whether additional studies are required.

Since the major portion of the Ranch Hand group is comprised of active and retired personnel, we are responsible for diagnosing and treating any health problems which they encounter.

Therefore, we have approached this study with a real appreciation for their concern as well as other active and former military families concerning any health hazard associated with Herbicide Orange.

This study will, of course, not answer all of the questions concerning Herbicide Orange, but we believe that it will be scientifically valid and a manageable starting point for the studies.

We will be happy to try to answer any questions, sir.

Chairman SATTERFIELD. Thank you, very much General Chesney, your written statement will appear at this point in the record.

[Statement follows:]

STATEMENT OF MAJOR GENERAL MURPHY A. CHESNEY, DIRECTOR OF MEDICAL PLANS AND RESOURCES, OFFICE OF THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE, TO COMMITTEE ON VETERANS' AFFAIRS, HOUSE OF REPRESENTATIVES

Mr. Chairman and Members of the Committee: In October of 1978, the Air Force Deputy Surgeon General testified before your committee concerning Herbicide Orange. As a part of that testimony, the Air Force advised that we planned to survey the Ranch Hand personnel to determine the health status of that group. Because of the increasing concerns of Congress, veterans and the public regarding possible health hazards associated with Herbicide Orange, the Air Force decided to expand the questionnaire into a comprehensive epidemiological study of the Ranch Hand group. I would like to review for you our activities to date in the development in implementation of this study.

The study is designed around the question, "Have there been, are there now, or will there be in the reasonable foreseeable future, any adverse health effects among Ranch Hand personnel caused by repeated exposure to Herbicide Orange?"

Accordingly, the investigation is composed of three integrated elements—a mortality study, a morbidity study, and a follow-up study—which address the health issues through a twenty-four (24) year time span, beginning in 1962 through 1986.

The mortality and morbidity study elements will be conducted almost simultaneously by use of study methods that include personnel tracking procedures and medical/personnel record reviews to pinpoint mortality patterns; extensive baseline telephone questionnaires to ascertain current and past symptoms of health events; comprehensive physical examinations to determine exact health status and to provide a baseline data platform with which to correlate the symptoms; and additional questionnaires and physical examinations to be administered periodically during the follow-up phase.

The study will be a six (6) year project; however, substantial data analyses from the most potentially revealing study areas will be available approximately twenty-one (21) months following the date the first questionnaires are administered.

We have taken the following actions as part of the study. Over 2,500 scientific articles related to Herbicide Orange have been reviewed and, where appropriate, conceptually incorporated within the study protocol. Contact has been made with leading Herbicide Orange experts in the country. Several coordinative visits have been made to the principal scientific investigators of at least six active epidemiological investigations on herbicides. Sustained interagency coordination has been accomplished with the Veterans Administration, the U.S. Army, and with several agencies within the Department of Defense, including the Office of the Assistant Secretary of Defense for Health Affairs and the Office of the Deputy Under Secretary of Defense for Research and Engineering (Research and Advanced Technology). Fifteen million Air Force personnel records have been computer processed; 37,000 other historical records have been reviewed by hand. The Ranch Hand group has been identified. The baseline questionnaire has been developed. The mortality study phase is well underway. Basic statistical formats and data repository fundamentals have been established.

In addition to the above actions, a control group has been identified and individual controls will be finally selected based on the number of Ranch Hand personnel who volunteer for the study. They will be matched by age, job, time in Vietnam, and race. Records of other Air Force personnel who have been identified as having possible exposure have been placed in a separate category for selected evaluation. These individuals are not part of the Ranch Hand statistical group. Action has been initiated to obtain necessary addresses from the Internal Revenue Service under the provisions of Public Law 96-128 which you and your committee were so instrumental in enacting. An examiner's handbook has been developed to provide guidance and standardization of the physical examinations. Initial funding has been obtained from the Air Force to begin the study. Additional personnel have been assigned to work on this project.

The Air Force scientific protocol has been subjected to extensive peer review. To date, the protocol has been reviewed by the University of Texas School of Public Health, Houston; the Air Force Scientific Advisory Board; the Armed Forces Epidemiological Board; and the Board of Toxicology of the National Academy of Sciences. We are awaiting the report of the review by the National Academy of Sciences.

Generally, the protocol has been well received from the standpoint of scientific content and thoughtful, unbiased concern. The peer critiques have thus far been exceptionally helpful and their constructive comments and suggested methodologies have been incorporated into the protocol. The peer review process has been very time consuming and of considerable interest because of the substantial discussions of issues within and between peer groups. Various aspects of the three study elements have been alternately viewed as "too little, or too much," depending on the observers' point of view. Their wide span of commentary provides ample testimony to the scientific polemics surrounding Herbicide Orange.

The next phase of our study will begin with contacting Ranch Hand personnel and administering the questionnaire. This will be followed by comprehensive physical examinations of those who volunteer for the study. We will proceed with this phase as soon as we can incorporate the recommendations of the National Academy of Sciences into the protocol.

This study is a very complex undertaking and one which we are doing with full understanding that we will be alternately criticized, condemned, and praised.

Be that as it may, we have used the expertise within the Air Force and the advice of recognized authorities on herbicides in both the civilian and governmental community to develop our study protocol. We believe the Ranch Hand group to be the best documented and most accurately assessable group of individuals who could be considered "at risk." Therefore, the results of the Ranch Hand study should yield valuable data from which to determine if there are health problems related to exposure to Herbicide Orange and whether additional studies are required.

I would be most pleased to answer any questions.

Chairman SATTERFIELD. I recognize Mr. Montgomery for any questions that he may have.

Mr. MONTGOMERY. Thank you, Mr. Chairman. I appreciate the distinguished witnesses that we have this morning.

Since Max Cleland mentioned that he and Dr. Custis had been exposed to Agent Orange, I might say that Congressman Hammerschmidt and myself were in Vietnam and I recalled with him a few minutes ago that we flew in a helicopter into the combat zone and there was—Agent Orange was being spread at that time.

So Congressman Hammerschmidt and myself can be added to the list. I mentioned that to him and he said, "I am not feeling very well." [Laughter.]

It seems to me that the bottom line is that it is going to take some time with the different agencies making these studies to fully determine if there are major ill effects from Agent Orange. We just can't give a complete answer today, positively or negatively.

Is that basically what you were saying? I see the doctor from the Army shaking his head yes.

Dr. CUSTIS. I think that that is very true, Mr. Montgomery, as regards whether or not a chronic state exists. I think that we can speak very specifically about the acute toxicity manifestations.

Mr. MONTGOMERY. How many claims do you have that have actually been traced to nothing but Agent Orange in the Veterans' Administration?

Mr. CLELAND. We know that in 21 cases, disabilities which claimants have contended are due to Agent Orange have been held to be service-connected. Two have been chloracne-like cases, but in none of the 21 cases has it been necessary to determine that Agent Orange is the culprit. The disabilities can be traced to service.

Mr. MONTGOMERY. How many people have been examined and found that they couldn't be traced to Agent Orange?

Mr. CLELAND. We examined almost 10,000 veterans. We have over a thousand claims for disability compensation. We have service connected 21 of those more than 1,000 claims, but have not determined whether these disabilities are necessarily due to Agent Orange.

On attachment I in my testimony, which is the attachment in the back of my testimony, there is a chart that goes into this in some detail.

Mr. MONTGOMERY. But you are—as I understand it, you are encouraging veterans, Vietnam era veterans, to come in and be examined if they feel like they have a problem. Is that correct?

Mr. CLELAND. Yes, sir. If they feel they have any disease or disability resulting from Agent Orange, or if they would just like to have it on the record that they feel they were exposed, or that they might have been exposed, that examination report becomes a part of a permanent record.

The report of examination, particularly, is part of our files that we are currently reviewing to see if there is anything unusual turning up.

Hopefully, we will have some results of that review in a few months, but we are encouraging those who would like to get it on the record to come to our hospitals and our outpatient clinics.

We have an Agent Orange coordinator in each facility to make sure that these exams are properly conducted.

Chairman SATTERFIELD. Would the gentleman yield at that point?

Mr. MONTGOMERY. Yes, sir.

Chairman SATTERFIELD. So that the record will be accurate, will you tell us with regard to the two cases to which you refer, found service-connected, was a particular service-connected problem found and if so, was it connected with exposure to Agent Orange or something else?

Mr. CLELAND. Dr. Jacoby?

Dr. JACOBY. Mr. Chairman, there have been 21 cases that have been allowed as service-connected. In two cases, the veterans had chloracne-like skin condition. One veteran had an acne form of lesion which may have been chloracne. The second had a skin condition that was contact dermatitis.

Mr. MCMICHAEL. Mr. Chairman, I think that the point to emphasize here is that for purposes of service connection determinations, all we have to do is to associate the development of a particular disability with a period of service.

We don't have to determine the causative agent. We don't have to determine that it was caused by Agent Orange just as long as we can determine that it was service related.

Chairman SATTERFIELD. Well, that was going to be my next question. You have determined that these health effects began while these veterans were on active duty?

Mr. MCMICHAEL. Yes, sir.

Mr. CLELAND. Mr. Chairman, the two were service-connected based on the allegation of the veteran that he was exposed.

Chairman SATTERFIELD. But you didn't determine that it was service-connected based solely on that allegation, did you?

Dr. JACOBY. It was based on the fact that they had the condition which existed at the period of time that they were on active duty.

Chairman SATTERFIELD. And it didn't exist previously?

Dr. JACOBY. Yes, sir.

Chairman SATTERFIELD. So the allegation really didn't play any role.

Dr. JACOBY. There is no way that we could establish a direct relationship between exposure to a herbicide and that skin condition.

Chairman SATTERFIELD. I just wanted to ask those questions because I felt that there might be some doubt in the record and I wanted to make this fact very clear. Thank you for yielding.

Mr. MONTGOMERY. Thank you, Mr. Chairman. I have no further questions.

Chairman SATTERFIELD. Mr. Hammerschmidt?

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman. I would like to address some remarks and then a question to the VA and also to the Department of Defense witnesses.

I note an omission in all of the testimony today, and in my opinion it could be a most important distinction in the entire research effort. It is a subject that I got into in the October hearings in 1978. I hope that all of the parties involved will seriously consider taking another

look at their approach to fully examine what I consider to be an oversight.

All through the testimony you mention that the potential ways of being exposed to Agent Orange are threefold: skin absorption, inhalation, and ingestion. While acknowledging the limited probability of exposure by skin absorption and inhalation, every Government witness who comments on this aspect maintains that the possibility of ingestion is almost zero since the only way that this might occur, according to the testimony, is by eating meat from an animal who had in turn eaten vegetation that was sprayed with Agent Orange; in other words, through the food chain.

This totally ignores the way our infantrymen operated in Vietnam, as many of our expert witnesses, I think, would know better than I would. And it was our infantrymen which, according to the recent GAO study, were in the areas where Agent Orange was actually being sprayed.

I doubt that anyone in this room would voluntarily drink a glass of water laced with Agent Orange. I am informed—and you might correct me on this if I am wrong—that a spoonful of dioxin could kill off the entire population of New York City. And yet, we have it on expert authority that our infantry troops, particularly the Marine infantry units who have already been identified by the GAO study as having been in the area of actual spraying at the time of the spraying, frequently were forced to drink from the standing water supplies in those areas. Infantrymen commonly fill their canteens with water from bomb craters and even rice paddies, not to mention ponds and small lakes.

If Agent Orange were sprayed over a foliated area, it would logically fall also into such standing water. Additionally, rains would wash the substance from the foliation so that it gathered in those places, actually intensifying the concentration. As such, it is conceivable that infantrymen could have ingested more dioxin in a single canteen of water than even factorymen could absorb in their skin over a much longer period of time.

It concerns me that your studies do not seem to address this and I wonder if both agencies would speak to my concern. General?

General AUGERSON. First, let me say that we will reappraise since you feel that we have not treated the subject adequately—we will, with your permission, submit something for the record subsequently of a detailed analysis.

Dioxin is not terribly water soluble, as I think you know. Perhaps Major Young, who has thought some on these matters and done some very careful study of the matter, may have something to say.

Major YOUNG. Let me say first, sir, that one of the beautiful things about the Ranch Hands population that we are proposing to study and have already initiated our work on is that their exposure can be very closely documented. And the question of ingestion from the environment isn't such a problem there. We know exposure. That is well documented for us.

The problem with the environmental fate of TCDD, of course, is that it is a very difficult molecule to follow because of its quantity present. The actual amount from a mission in Vietnam over 1 acre of land would have been so finite that it would have been impossible to follow with the instrumentation that was available at that time.

And it has only been within the last few years that we have been able to look for dioxin in the environment. But the studies that have been conducted within the past few years show, one, that when dioxin is applied to vegetation it isn't readily washed off at all.

And we know from studies in tropical areas that herbicides containing dioxins—that when it rains, the herbicide is actually spread very thin upon the leaf and is more readily absorbed.

So after rain one sees much better defoliation than otherwise. The suggestion, of course, is that it is penetrated within the vegetation.

We don't have any studies that show that dioxin washes readily. If it does go off, for example, it misses the leaf and hits the ground, we know that it is very readily absorbed within the ground.

I would point out that the photodegradation studies that have been conducted are quite conclusive. Ninety percent of the dioxin disappears in 6 hours from the time that it hits.

The exception of that has been our own Air Force studies in an area that we see massive quantities of 2,4,5-T containing dioxin. There, because of the massive quantities of herbicide and dioxin applied to a small piece of land, it was able to get into the soil. Those are the only studies where dioxin has been shown to be present in the soil.

Mr. HANSEN. Would the gentleman yield briefly?

Mr. HAMMERSCHMIDT. I yield to the gentleman.

Mr. HANSEN. I would like to ask the witness in this regard having come from a rural community myself and we always have the farmers catching the dickens over the fact that there is a lot of siltation and wash of the soil which has insecticides and other things into the rivers and streams and this type of thing.

And environmentalists get pretty upset about this. Now, you say that the chemical is absorbed by the soil, but is there anything to say that the soil itself with the chemical in it does not wash into the areas that the gentleman from Arkansas suggested, into the low places: the ponds and the places where the water supply was, wherever perhaps the troops were getting the water?

Now, I am just wondering if you are talking about two different things. One is the wash of the chemical and the other is the wash of the soil containing the chemical.

General YOUNG. Right. Exactly. And it is true. In the sites where we have been able to show the dioxin in the soil its movement occurs as a consequence of erosion. But we do show that there are degradation mechanisms working even in those soil systems.

Mr. HAMMERSCHMIDT. In your testimony it was commented that DOD has a computer listing of all spray missions. Have you plotted them on a map with a chronology to match them against areas of operation for U.S. infantrymen in the field?

And, if not, I wonder if you would do so and supply this for the record.

General AUGERSON. There exists—the data about the spray missions has been and can be put on a map. The problem—we would be happy to make our best effort in the second part of your question. It is—given the long duration of the war in Vietnam, the extensive and rapid movement of the units about that country and the way in which records, I have been told particularly in the Army, were kept, I am not certain that we can document all of the unit locations with respect to spray missions.

As you know, sir——

Mr. HAMMERSCHMIDT. I can appreciate the difficulty of furnishing that. If you could give us your best information on it for the record and to the VA as well, I think that it would be vital information, particularly to the professionals who are studying that issue.

General AUGERSON. Yes, sir.

Chairman SATTERFIELD. Without objection, the responses to the question you mention will be admitted to the record where submitted.

Mr. HAMMERSCHMIDT. Now, on page 9 of your statement you state:

> The troops walking through orange-treated forests would have encountered the same amount of dioxin as a person walking through the defoliated ranch lands here in the United States.

It seems to me that it would be important to note that our troops were stopping in many cases to fill canteens from bomb craters and other respositories containing standing water that had run off of defoliated ground and collected there.

I don't want to belabor that point much more except that I just think we may be missing something in the entire study.

Mr. Chairman, I have just one other statement here—one other comment and question.

Mr. HANSEN. While the gentleman is still on this subject, would you yield briefly?

Mr. HAMMERSCHMIDT. I yield to the gentleman from Idaho.

Mr. HANSEN. Where we talked about the bomb craters filled with water, this type of thing, I was curious as to how long Agent Orange's dangerous ingredients can remain lethal if they sat in this water and were later consumed by ground troops.

General AUGERSON. The likelihood with knowledge available to us of any lethal acute toxicity being possible as a consequence with the concentrations of dioxin and Herbicidal Orange, I don't think is too great.

But in terms of having some dangerous amount of dioxin, I think that I would defer to Major Young about what kind of concentrations might have been available. Or if he is not equipped then with his arithmetic, then we might submit that for the record.

Do you have it, Major?

Major YOUNG. One of the interesting things that we have been doing is we have been following a population of rodents and I don't mean to get away from the human aspects of this.

But we have been looking at a population of rodents of 70 generations that live at the test site in Florida where we have tested all of this spray equipment for Vietnam.

There is the one location where we have a significant concentration of dioxin in the soil. We have been able to show that probably 97 to 99 percent of it has degraded over time.

But that 1 percent is still higher than anyplace in the United States that would have received 200 or 400 applications of 2,4,5–T as it is currently used today.

In 70 generations of animals, indeed, they do have dioxin in them. We have not been able—this study has been looked at by an awful lot of people—we have not been able to document adverse health effects in those rodents.

That doesn't say that it can't occur in man. But what it does say is that if we take the data from the laboratory and go to the field with it, in this case our best data in the laboratory is on rodents.

If we go to the field we can't show that those rodents that have been exposed all those years have a significant problem. We see no difference in the number of fetuses. We see no fetal abnormality.

Recognizing, of course, that it is a field study, it isn't the best controlled environment. But it is an environment that we have thoroughly documented and have followed for 10 years. And we can provide the reports on that study.

Mr. HAMMERSCHMIDT. Mr. Chairman, let me address a question to Mrs. Bernstein. Your statement this morning seems to indicate that the various agencies of the executive branch are long on planning and devising protocols for studies, but up to this time are very short on conclusions and results.

Now, I have in my hand just a sampling of recent press clippings from all across this country attesting to unusual cancers both resulting in death, kidney and liver disorders, skin rashes, birth defects in in children and other ailments by veterans who were exposed to Agent Orange in Vietnam.

How much longer must we wait, and how many more studies will be conducted before we reach some positive conclusions about the potential causal relationship between Agent Organge and the strange afflictions experienced by those who were exposed to this chemical?

Mrs. BERNSTEIN. Let me ask Dr. Moore to speak to the limitations of our scientific studies.

Dr. MOORE. Congressman, I think that part of the difficulty is that we are dealing with a pattern of diseases that veterans or families of veterans allege to be associated with Agent Orange that are nonspecific in nature.

Indeed, veterans are identifying health impairments in which there is fairly good background that already exists in our everyday life, forgetting whether Agent Orange is there or not. For example, if one wants to look at the problem of reproductive effects in females, we normally have somewhere around 20 percent of all conceptions that don't result in a live birth.

And, indeed, picking up a small increase in Agent Orange or some other agent above that may not be possible as our epidemiological studies just aren't powerful enough to pick it up. We could also say the same thing for a number of other effects that have been alleged.

A slight increase in liver function decrement is another one that would be very difficult to pick up. Neuro-behavorial problems fall into the same category.

With the single exception of chloracne, there are no clinical findings that are characteristically associated with dioxin exposures.

Mr. HAMMERSCHMIDT. I appreciate your response. I think that it is important that we get that frustration of your study group into the record.

With respect to your interagency working group: how many primary participants in this group are veterans who had operational experience in areas where Agent Orange may have been used?

Mrs. BERNSTEIN. I am sorry. I don't have that information. I would be happy to supply it to you.

[The information follows:]

Major General William S. Augerson, the chief work group participant from the Department of Defense, is a veteran with operational experience in areas where Agent Orange may have been used. Another DOD participant, Dr. Jerome Bricker, is a veteran who was exposed to Agent Orange in his research and development experiences in the United States.

Mr. HAMMERSCHMIDT. Fine. We would appreciate that for the record. And, Mr. Chairman, I have a number of other questions. I have used up my time. I would like to submit those questions for the record. If I may ask the agencies to respond for the record to those questions, I would appreciate it very much.

Chairman SATTERFIELD. Without objection, those questions and answers will be admitted to the record when they are received.

[Material follows:]

MARCH 5, 1980.

Hon. MAX CLELAND,
Administrator of Veterans' Affairs, Veterans Administration,
Washington, D.C.

DEAR MR. ADMINISTRATOR: Pursuant to my closing remarks at the Agent Orange hearing on February 25, 1980, I am submitting for your response additional questions posed by Congressman Hammerschmidt and me. Your answers will be included in the hearing records.

The questions are as follows:

1. Much media attention has been given to a few instances of testicular cancer in Vietnam veterans who were allegedly exposed to Agent Orange. Is it a fact that this type of carcinoma is more generally found in young men rather than in males of the middle or later years?

2. Conservative estimates place roughly 2.4 million young men in United States armed forces in Vietnam during the war years. In order to get some idea of normal mortality among this group, excluding accidents, homicides and suicides, how many of these men with birth years between 1948 and 1952 could have been expected to have died of illness between 1970 and 1980? How many of all forms of cancer? How many of cancer of the liver? How many of testicular cancer? How many of neurological disease?

3. In regard to the offspring of male Vietnam veterans, I believe that it is reasonably accurate to say that the group, as a whole, would have produced an average of two children per veteran. Of this group of 4.8 million live births, how many would have been delivered with congenital anomolies significant enough to pose serious health problems?

4. Information reaching this Subcommittee has indicated that a Veterans Administration physician, Doctor Hirsh of the Wadsworth VA Medical Center, has had considerable success in determining the probability of fetal birth defects in pre-partum women. To your knowledge, has Dr. Hirsh done any studies on males to determine the possibility of producing impaired children?

5. You testified that the Veterans Administration maintains an unusually large data file which is compiled from the diagnosis reported for each hospitalized veteran. This file—called a patient treatment file, or PTF—contains information on veterans who have died in VA hospitals and the cause of death. Taking note of the fact that the average Vietnam veteran is presently 33 years old, has the Veterans Administration seen a significant increase in the mortality of hospitalized veterans over the past ten years of veterans aged 23 to 33?

Enclosed are questions submitted by the Honorable John Paul Hammerschmidt. It would be greatly appreciated if you would respond to our questions at your earliest convenience.

Sincerely yours,

DAVID E. SATTERFIELD III,
Chairman Subcommittee on Medical Facilities and Benefits.

Enclosure.

COMMITTEE ON VETERANS' AFFAIRS,
CANNON HOUSE OFFICE BUILDING,
Washington, D.C., February 25, 1980.

HON. DAVID E. SATTERFIELD,
Chairman, Subcommittee on Medical Facilities and Benefits, Committee on Veterans' Affairs, U.S. House of Representatives, Washington, D.C.

DEAR DAVE: I indicated during today's hearings on Agent Orange that I would submit additional questions for our witnesses to respond to in writing for the record. Enclosed please find a list of these questions. I would appreciate your directing them to the appropriate witnesses in my behalf.

Sincerely,

JOHN PAUL HAMMERSCHMIDT,
Member of Congress.

Questions for the Veterans Administration:

1. I do not understand your testimony to the effect that it would be difficult, if not impossible, to determine precisely whether an individual was exposed to Agent Orange. (VA, p. 6 and p. 23). Vietnam was an extensively monitored war. Every movement of every combat unit was reported continuously. It seems to me that we could take the dates of actual spraying, and the areas sprayed, and plot them on a map that also depicts the movement of troops on various operations, and develop a very close correlation. Then, any veteran reporting exposure could have that exposure verified by the denotation of those operations in his service records, which list the operations he participated on. Can this be done? If so, why have you not done it?

2. Your comment that "spraying missions usually occurred at dawn or dusk, at a time when U.S. field troops were not likely to be active" (p. 4) really avoids a central question. It doesn't matter if the troops were "active" if they were encamped near the area sprayed. Nor does it matter that "efforts were made" to permit a period of time to elapse before the troops entered a sprayed area if they were already in that area, or if those "efforts" were not successful. Why are you using such rhetoric when it avoids the facts?

3. p. 33: As I read your data, 13 of the 20 veterans exposed to Agent Orange did in fact have dioxin in their fat, however small the quantities. How much dioxin does it take to physically harm a person if he swallows it? How much must one absorb before it shows up in his fat?

4. You mention (p. A–3, response to Q. 3) that many people in the United States may have detectable levels of dioxin in their tissues, yet most of them are asymptomatic. Is that really relevant? Millions of Americans smoke, and yet most of them are "asymptomatic" of cancer. Such a fact hardly establishes that smoking doesn't contribute causally to cancer.

5. p. A–12 through A–14: I have difficulty with the five areas which you recommend to provide a framework of analysis as to whether an individual has been exposed to Agent Orange. Area No. 2, for instance, is inaccurate when we consider the GAO study that documented very close and immediate contact with the substance as it was sprayed, particularly among the Marines in I Corps. Nor does it recognize the possibility of the substance being ingested through drinking water. Area No. 3 ignores the frequent use in I Corps. Area No. 4 doesn't really say anything. Area No. 5 ignores the possibility of ingestion through drinking water. Who designed this? What are your plans to redesign it?

6. Re: the Conference held in September, 1979 (p. 20): Who presented the testimony regarding how Agent Orange was employed during the Vietnam War? Was there anyone at the conference who had potentially been exposed, and now has a position of responsibility?

7. p. 30: The way you define the "crux of the problem" eludes me. What are you suggesting?

8. Re: the animal studies (p. 9): 1. the witness from HEW seems to believe that the animal studies have some very important relevance. Why is the VA downplaying any correlation? 2. How much (p. 9) is a "large enough quantity" to kill an animal?

9. Re: the "human studies" (p. 12): We are not talking in these other cases about whether these persons who were studies actually drank any of the dioxin. They were sprayed with it, or continually handled it in the atmosphere of a factory environment. Do you agree that there is a distinction? If so, aren't we talking about potentially a much graver risk on the part of combat veterans who not only lived around the defoliant, but who probably drank it?

10. p. A–8, response to Q. 7: You say that the data being collected on Vietnam veterans participating is considered "adequate at this time." Adequate to what? You maintain that we don't know if they operated in those areas, we don't know if or how exposure took place, or in what intensity, or how it was absorbed, if at all. My reaction at this time is that we don't know anything. How can the data being collected be adequate?

11. With respect to your VA Advisory Committee on Health-Related effects of Herbicides (p. 15): How many of your Advisory Committee Members served in units in Vietnam which may have been exposed to Agent Orange? This, I would submit, is relevant as to factual expertise regarding the physical circumstances of the operating units, which I find lacking in the testimony.

VETERANS ADMINISTRATION,
DEPARTMENT OF MEDICINE AND SURGERY,
Washington, D.C., May 12, 1980.

Hon. DAVID E. SATTERFIELD III,
Chairman, Subcommittee on Medical Facilities and Benefits,
House of Representatives, Washington, D.C.

DEAR MR. SATTERFIELD: I am pleased to reply to your March 5, 1980, letter in which you and Congressman Hammerschmidt request answers to questions for the record of the February 25, 1980, hearing on Agent Orange, The questions and answers are enclosed.

Sincerely,

DONALD L. CUSTIS, M.D.,
Chief Medical Director.

Enclosure.

Mr. SATTERFIELD. Much media attention has been given to a few instances of testicular cancer in Vietnam veterans who were allegedly exposed to Agent Orange. It is a fact that this type of carcinoma is more generally found in young men rather than in males of the middle or later years?

Mr. CLELAND. There are six major types of testicular cancers which are morphologically distinct. The age-related frequency of occurrence of these different types of testicular cancers is as follows:

Morphological types	*Highest frequency of occurrence*
Teratomas, embryonal, carcinomas and choriocarcinomas	Under 30 years.
Seminomas	30–50 years.
Spermatocytic seminomas and adrexal sarcomas	Over 40 years.

Overall, between 20–30 percent of all testicular tumors occur in men under age of 30 years.

Mr. SATTERFIELD. Conservative estimates place roughly 2.4 million young men in United States armed forces in Vietnam during the war years. In order to get some idea of normal mortality among this group, excluding accidents, homicides and suicides, how many of these men with birth years between 1948 and 1952 could have been expected to have died of illness between 1970 and 1980? How many of all forms of cancer? How many of cancer of the liver? How many of testicular cancer? How many of neurological disease?

Mr. CLELAND. In the table below, I have listed statistics on expected mortality rates in 1970 through 1980 for Vietnam era veterans born between 1948 and 1952. The entries in the table were calculated by my staff on the basis of statistics provided by the National Center for Healh Statistics. These calculations indicate that from a population of 2.4 million, about 48,553 individuals would be expected to die from natural causes during the decade ending in 1979. Of these, 2,625 deaths would be from malignancies of all types, with 380 from cancer of the testis and 27 from liver cancer. Deaths from neurological disorders in the group would be expected to total 865.

Cause of death	Expected deaths, 1970–79 as a percent of the population	Expected deaths, 1970–79
All causes	2.02	48,553
External causes[1]	1.50	35,912
All causes excluding external causes	.52	12,641
All malignancies	.11	2,625
Cancer of the testis	.016	380
Liver cancer	.0011	27
Neurological disorders	.036	865

[1] This refers to all diseases due to accidents, homicides, suicides, and other noninternal causes.

Mr. SATTERFIELD. In regard to the offspring of male Vietnam veterans, I believe that it is reasonably accurate to say that the group, as a whole, would have produced an average of two children per veteran. Of this group of 4.8 million live births, how many would have been delivered with congenital anomolies significant enough to pose serious health problems?

Mr. CLELAND. The Center for Disease Control estimates that approximately 2–3 percent of live births have a structural congenital anomaly which is either life-threatening, causes significant morbidity, or poses a significant cosmetic or psychological handicap. Therefore, in a group of 4.8 million live births, it would be predicted that between 96,000 and 144,000 of them would have birth defects in one or more of these categories.

Mr. SATTERFIELD. Information reaching this subcommittee has indicated that a Veterans Administration physician, Dr. Hirsh of the Wadsworth VA Medical Center, has had considerable success in determining the probability of fetal birth defects in pre-partum women. To your knowledge, has Dr. Hirsh done any studies on males to determine the possibility of producing impaired children?

Mr. CLELAND. Gerald P. Hirsh, Ph. D., a biochemist on the staff of the Wadsworth Veterans Administration Medical Center, has participated in the development of a test to detect mutations in human hemoglobin after exposure to radiation. This test does not provide predictions regarding fetal abnormalities. Furthermore, it has not been used in any studies on males to determine the possibility of their producing impaired children nor has it been validated on abnormalities due to chemical toxins.

Mr. SATTERFIELD. You testified that the Veterans Administration maintains an unusually large data file which is compiled from the diagnosis reported for each hospitalized veteran. This file—called a patient treatment file, or PTF—contains information on veterans who have died in VA hospitals and the cause of death. Taking note of the fact that the average Vietnam veteran is presently 33 years old, has the Veterans Administration seen a significant increase in the mortality of hospitalized veterans over the past ten years of veterans aged 23 to 33?

Mr. CLELAND. In the table provided below, I have listed the total number of Vietnam era veterans aged 25–34 each year from 1970 through 1979. The table also indicates the number of these veterans who died in VA hospitals during this period and their death rates. It is interesting that these death rates appear to be declining somewhat at the end of the decade.

Since the VA health care facilities treat only a portion of the nation's Vietnam era veterans, it is impossible to extrapolate these findings on death rates to the entire group. However, they do indicate that the Vietnam veterans who utilize VA facilities did not experience an increasing death rate over the past decade.

TOTAL POPULATION AND NUMBER OF VA HOSPITAL DISCHARGES BY DEATH FOR VIETNAM ERA VETERANS AGED 25 TO 34 FOR THE YEARS 1970–79

	Vietnam era [1] veterans aged 25 to 34 (thousands)	VEV [2] aged 25 to 34 discharged by death from VA hospitals	VA hospital VEV [2] aged 25 to 34 deaths per 100,000 Vietnam era veterans aged 25 to 34
1970	2,193	160	7.30
1971	2,975	223	7.50
1972	3,772	296	7.85
1973	4,617	330	7.15
1974	5,207	362	6.95
1975	5,640	373	6.61
1976	5,894	429	7.28
1977	6,004	406	6.76
1978	5,963	359	6.02
1979	5,764	335	5.81

[1] We do not have specific figures for those veterans who served in Vietnam.
[2] VEV stands for Vietnam era veterans.

Mr. HAMMERSCHMIDT. I do not understand your testimony to the effect that it would be difficult, if not impossible, to determine precisely whether an individual was exposed to Agent Orange. (VA, p. 6 and p. 23). Vietnam was an extensively monitored war. Every movement of every combat unit was reported continuously. It seems to me that we could take the dates of actual spraying, and the areas sprayed, and plot them on a map that also depicts the movement of troops on various operations, and develop a very close correlation. Then, any veteran

reporting exposure could have that exposure verified by the denotation of those operations in his service records, which list the operations he participated on. Can this be done? If so, why have you not done it?

Mr. CLELAND. The Department of Defense has informed us that they have fairly comprehensive records on herbicide spraying missions conducted by fixed-wing aircraft during the Vietnam war. However, these records do not provide any information about what is called the "environmental fate" of these herbicides. By this we mean such parameters as the distances over which the herbicides were disseminated from the point of spray and the rate at which they were degraded.

Of even greater significance is the fact that DOD informs us that they do not possess complete information on the movements of units or of individual military personnel during the Vietnam war. To some extent, this data can be obtained from an analysis of unit histories and individual personnel records. However, this analysis will probably not permit a precise determination of the movements of many individual personnel much less provide a measure of their exposure to herbicide orange. My staff has been working with DOD in an attempt to obtain accurate data on troop exposure to herbicide orange. Progress has been made in this endeavor, but it is clear that the process will be a long one and the data obtained from it may have only limited value.

Mr. HAMMERSCHMIDT. Your comment that "spraying missions usually occurred at dawn or dusk, at a time when U.S. field troops were not likely to be active" (p. 4) really avoids a central question. It doesn't matter if the troops were "active" if they were encamped near the area sprayed. Nor does it matter that "efforts were made" to permit a period of time to elapse before the troops entered a sprayed area if they were already in that area, or if those "efforts" were not successful. Why are you using such rhetoric when it avoids the facts?

Mr. CLELAND. We have been informed by our scientific advisors that the extent of exposure of individual military personnel to herbicide orange in Vietnam may have been affected by a number of factors. Of critical importance in the assessment of the significance of these exposures is data concerning the actual amount of dioxin in the batch of herbicide orange utilized; the degree to which the dioxin has been degraded by environmental factors; the length of time the individual is exposed to dioxin; and the route by which the dioxin enters the body. Unless these factors can be assessed, conclusions regarding the extent of an individual veteran's exposure to herbicide orange remains speculative.

Mr. HAMMERSCHMIDT: p. 33: As I read your data, 13 of the 20 veterans exposed to Agent Orange did in fact have dioxin in their fat, however small the quantities. How much dioxin does it take to physically harm a person if he swallows it? How much must one absorb before it shows up in his fat?

Mr. CLELAND. There is no available information on the lowest quantity of dioxin which will cause harm if ingested by a human being. It is likely that the amount varies with the particular individual involved. We also do not know the minimal quantity of dioxin that must be ingested in order for it to accumulate in measurable quantity in human fat. Such data will be difficult to obtain since there are virtually no opportunities to measure the precise extent of exposure of humans to herbicide orange constituents.

Mr. HAMMERSCHMIDT. You mention (p. A–3, response to Q.3) that many people in the United States may have detectable levels of dioxin in their tissues, yet most of them are asymptomatic. Is that really relevant? Millions of Americans smoke, and yet most of them are "asymptomatic" of cancer. Such a fact hardly establishes that smoking doesn't contribute causally to cancer.

Mr. CLELAND. The relevant point is that many people in the United States may have been exposed to dioxin, and may have it stored in body tissue. However, we cannot make scientifically valid statements about the correlation between detectable dioxin levels in an individual's fat tissue and any adverse effect on his health. Hopefully, future formal studies of this particular issue will provide the basis for a definitive conclusion.

Mr. HAMMERSCHMIDT. p. A–12 through A–14: I have difficulty with the five areas which you recommend to provide a framework of analysis as to whether an individual has been exposed to Agent Orange. Area No. 2, for instance, is inaccurate when we consider the GAO study that documented very close and immediate contact with the substance as it was sprayed, particularly among the Marines in I Corps. Nor does it recognize the possibility of the substance being ingested through drinking water. Area No. 3 ignores the frequent use in I Corps. Area No. 4 doesn't really say anything. Area No. 5 ignores the possibility of ingestion through drinking water. Who designed this? What are your plans to redesign it?

Mr. CLELAND. We believe in the accuracy of the statement made in Area No. 2, that most of the exposure of U.S. military forces in Vietnam to herbicide orange was indirect. The GAO study deals with a relatively small number of marines but does not provide data on exposure of the vast majority of the other military personnel.

We have been made aware of the possibility of ingestion of herbicide orange through food and water. It appears that this possibility is relatively remote since herbicide orange has an offensive odor and it is relatively insoluble.

Area No. 4 points out that most of the herbicide orange utilized in Vietnam was sprayed by fixed wing aircraft which was camouflaged and often accompanied by fighter aircraft. Accordingly, many of the reports by veterans of being in the vicinity of planes spraying herbicides are probably inaccurate. It is far more likely that the planes they sighted were spraying pesticides or some substance other than Agent Orange.

Area No. 5 inadvertently left out the possibility of ingestion of herbicide orange through drinking of contaminated water. As I have indicated, we are aware of this possibility and will include it in our studies.

This set of responses were prepared by members of our Advisory Committee in response to our explicit request. It will be utilized by my staff as input in their planning of programs, and will be revised where appropriate.

Mr. HAMMERSCHMIDT. Re: the Conference held in September, 1979 (p. 20): Who presented the testimony regarding how Agent Orange was employed during the Vietnam War? Was there anyone at the conference who had potentially been exposed, and now has a position of responsibility?

Mr. CLELAND. The presentation dealing with the military use of Agent Orange was made by Major Alvin Young of the U.S. Air Force. Major Young has made a number of major contributions to the scientific literature on the environmental fate of herbicide orange and its associated dioxin. In addition, Major Young and his associates have prepared the major literature review in this area published thus far. He is widely considered one of the world's major authorities on herbicide orange.

There were several people at the conference who had potentially been exposed to herbicide orange and now have positions of responsibility. Among these, I must list myself since I am a Vietnam veteran and I have been exposed to herbicide orange during my tour of duty there.

Mr. HAMMERSCHMIDT. p. 30: The way you define the "crux of the problem" eludes me. What are you suggesting?

Mr. CLELAND. We are aware of the concern of many Vietnam veterans about the possibility that their health was adversely affected by exposure to Agent Orange. However, we are also aware that there is debate within the scientific community as to whether there is any valid scientific evidence currently available that such exposure has any permanent effect on human health. Accordingly, we are vigorously pursuing a series of activities which we anticipate will help resolve the question of herbicide orange effects on humans. In the meantime, we are providing examinations and appropriate health care to Vietnam veterans who come to our hospitals and clinics with illnesses which they attribute to herbicide orange exposure. This helath care will be provided to these veterans to the full extent of their eligibility without regard to the etiology of the illnesses involved.

Mr. HAMMERSCHMIDT. Re: the animal studies (p. 9): 1. the witness from HEW seems to believe that the animal studies have some very inportant relevance. Why is the VA downplaying any correlation? 2. How much (p. 9) is a "large enough quantity" to kill an animal?

Mrs. Joan Z. Bernstein testifying for the Department of Health, Education, and Welfare stated:

Research with animals has indicated the TCDD, a dioxin contaminant in Agent Orange, is one of the most toxic agents known. These animal studies have already established that TCDD can cause cancer, birth defects and fetal toxicity when when pregnant female animals are exposed, and can also cause depressions of the immunological systems and increased susceptibility to infectious agents.

Animal toxicity tests have served us well in reliably predicting toxic effects in man. Thus, the animal studies which show TCDD to be highly toxic are extremely important. Epidemiologic studies will help to define the full nature and expression of the toxicity of TCDD and other dioxin contaminants in man.

In my testimony before the House Veterans' Affairs Committee on February 25, 1980, I have presented a more detailed discussion including the statement:

Animal studies of the effects of 2,4–D, 2,4,5–T and TCDD are helpful in suggesting the potential for toxic actions of these chemicals in human beings. However, the animal studies can only be regarded as suggestive since no clear-cut relationship

has been established between the response of humans to these chemicals and that of other animal species. Accordingly, the only way to reach definite conclusions about the effects of Agent Orange constituents on humans is through studies of exposed human populations.

This statement reflects no intention to denigrate animal investigations. Rather, the variations from animal species to animal species compounded by the differences in the route of administration, doses, and duration of exposure between man and animals are mentioned to indicate how they limit the direct and uncritical extrapolation from laboratory to human conditions. Such limitations are recognized by all toxicologists and are reflected in the DHEW testimony as well.

How much is a "large enough quantity" to kill an animal? The amount of a substance required to kill is commonly expressed as the LD_{50}, the "lethal dose" for 50 percent of the animals receiving it. The amount differs according to the species and the route by which it is given, i.e. by ingestion, inhalation, injection under the skin (subcutaneously), into the body cavity (intraperitoneally), or into the vein (intravenously), by rubbing it on the skin, or by some other route. The amounts of the LD_{50} also depends upon the age and sex of the animal in some instances, whether death is prompt (acute toxicity) or follows repeated administration (subacute and chronic toxicity), and often upon the carrier or vehicle in which the toxic material is administered. In addition to the LD_{50}, toxicity can be expressed as the LD_{100}, the dose that is just large enough to kill all the animals, or as the LD_2, the amount that kills two percent of the animals in an experiment. Each of these variations has its uses in study toxicity.

The attached table 9. Summary of literature data on the no effect, LD_{50} and LD_{100} levels of the acute toxicity of tCDD for animals" and "table 10. Survey of literature data on the subacute and chronic toxicity of TCDD in animals" illustrate how widely the lethal dose varies depending upon the experimental conditions. The tables are taken from Chapter IV of "The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and Its Associated Dioxin" by A. L. Young et al. (Report OEHL TR-78-92).

Since the human differs from animal species, as they do from each other, it is impossible to be certain from animal data what a man's response will be to a given dose. Such variations explains the Veterans Administration's reluctance to accept animal data as directly translatable to the human.

TABLE 9.—SUMMARY OF LITERATURE DATA ON THE NO-EFFECT, LD_{50} AND LD_{100} LEVELS OF THE ACUTE TOXICITY OF TCDD FOR ANIMALS

Animal: Number used	Route of administration	Dose—Toxicity	Single dose, μg/kg	Reference
Mouse:				
CD-1 strain, C57B1/6Sch strain:				
10	Oral	LD_{100}	>50	59
NS[a]	Oral	A few sporadic deaths	1-130	121
C57B1/6 strain: 29M[b]	Oral	LD_{100}	150	50
M NS	Intraperitoneal	LD_{50}	~120	138
Rat:				
Sherman (spartan) strain:				
5 M	Oral	No effect	8	121
5 M	Oral	No effect	16	121
10 M	Oral	LD_{100}	32	121
25 M	Oral	LD_{50}[d]	22	121
NS F	Oral	LD_{50}[d]	45	121
Guinea pig: Hartley strain:	Oral	LD_{50}[e]	.6	121
NS M		LD_{50}[e]	2.1	121
Rabbit: New Zealand albino:				
NS M/F	Oral	LD_{50}[e]	115	121
5 M/F	Topically to skin	LD_{50}[e]	275	121
5 M/F	Intraperitoneal	No effect	32	121
5 M/F	Intraperitoneal	2 of 5 died	>252	121
5 M/F	Intraperitoneal	3 of 5 died	500	121
Dog: Beagles:				
2 M	Oral	No effect	300	121
2 M	Oral	LD_{100}	3,000	121
2 F	Oral	No effect	30	121
2 F	Oral	No effect	100	121
Monkey: Rhesus: 1 F	Oral	LD_{50}[f]	<70	87

[a] NS—Number of animals in study not stated or unavailable from literature source.
[b] M—Male.
[c] H—TCDD.
[d] A calculated LD_{50}.
[e] Responses to individual doses when LD_{50} could not be calculated.
[f] Correlated the acute LD_{50} of TCDD with the clinical and pathological manifestations—not true calculated LD_{50}.

TABLE 10.—SUMMARY OF LITERATURE DATA ON THE SUBACUTE AND CHRONIC TOXICITY OF TCDD IN ANIMALS

Animal: Number used	Route of administration	Effect	Dose	Reference
Mouse:				
C57Bl/6JFh (J67) strain; Specific—Pathogen free: 377 M[a]	Once per week by gastric tube for 4 weeks.	No effect on weight gain	0.5, 1, 5 and 10 μg/kg.	134
		Significant decrease in weight gain.	20 μg/kg	134
		No effect on mice challenged with Herpesvirus suis.	0.5, 1, 5; 10 and 20 μg/kg.	134
		No effect on mice challenged with Salmonella bern.	0.5 μg/kg	134
		Significant increase in mortality of mice challenged with Salmonella bern.	1 μg/kg and greater.	134
C57Bl/6Sch F[b] strain; C57Bl/6 M[a] strain: 5–6 per group.	Oral dose given days 14 and 17 of gestation and postnatally on day 1, 8, and 15.	No effect on weight gain	2 μg/kg	140
		Suppressed cellular immunity.	2 or 5 μg/kg	140
NS[c] F, CD–1	Single oral dose after 8 weeks of age.	Hematological changes at 1 week after does; normal at 3 weeks.	1, 10 or 50 μg/kg	148
C57Bl/6 strain 12 M	Oral dose once per week for 4 weeks.	2,000 fold increasd in carboxyporphyrins in the liver.	25 μg/kg	50
Rat:				
Sprague-Dawley strain:				
NS M/F	Daily oral dose for 90 days.	No signs of toxicity	0.001, 0.01 or 0.1 μg/kg.	93
NS M/F	Daily oral dose, 5 days per week for 13 weeks.	No toxicity, slight increase in relative liver weight at 0.01 μg/kg.	0.001 or 0.01 μg/kg.	77
CD strain: NS F	Daily oral dose for 30 days.	Liver enzyme changes and hematological changes.	10 μg/kg	148
Guinea pig: Hartley strain: NS F.	Weekly oral doses for 8 weeks.	Moribund at 3 to 5 weeks	1.0 μg/kg	148
		Significant decrease in lymphocyte counts.	0.04 μg/kg	148
Rabbit: NS	Applied to inside of ear, 5 days per week for 4 weeks in a 0.1 ml volume.	Acne with increasing severity as dose was increased.	0.04 to 400 μg/kg	121
Monkey:				
Macaca mulatta:				
NS	Fed fat containing 64 percent mass tetrachlorinated compounds in diet for 100 days.	Multiple toxic signs	Unknown	98
8 F	Fed in diet for 9 mo	Hematologic changes, 5 animals died.	500 μg/kg of diet, 2–3 μg/kg total exposure.	2
2	Fed in diet	Death in 12 days	20 μg/kg diet	89
		Death in 76 days	2 μg/kg diet	86

[a] M—Male.
[b] F—Female.
[c] NS—Number of animals in study not stated or unavailable from literature source.

Mr. HAMMERSCHMIDT. Re: the "human studies" (P. 12): We are not talking in these other cases about whether these persons who were studies actually drank any of the dioxin. They were sprayed with it, or continually handled it in the atmosphere of a factory environment. Do you agree that there is a distinction? If so, aren't we talking about potentially a much graver risk on the part of combat veterans who not only lived around the defoliant, but who probably drank it?

Mr. CLELAND. The question is not completely clear but apparently refers to the fact that the route of exposure in Vietnam may have different from that in industrial situations, including accidents. The conditions may not be so discrepant as they appear at first glance. When veterans were actually in contact with herbicide orange spray or liquid they may have absorbed the material through the skin; the same is true if factory workers handled materials containing TCDD or contaminated 2,4,5–T. Some inhalation could occur in both situations. Finally, chemical factories differ as to their industrial hygiene and workers as to their personal habits. One source of contamination in many instances is ingestion from hands soiled with the chemicals or from food dusted with the product, the biological equivalent of drinking it. Among disasters, the Seveso incident stands out as having contaminated food, plants and water in the surrounding areas with subsequent consumption of contaminated materials by the populace.

The amount of the exposure and generally the level of harm done by a toxic substance is related both to the amount received by the person at each "dose" and the number of "doses" or the amount received each day and the number of days of exposure. Industrial workers may or may not have received more of the toxic material daily than military persons in Vietnam but industrial exposure extended over may months or years. The industrial accidents sometimes caused only a brief exposure but the amount received was generally very high. As a consequence the workers in both situations are thought to have had a greater total exposure to TCDD than even the Ranch Hand personnel and certainly than troops in the fields and forests. This belief is strengthened by the high incidence of chloracne as a result of industrial and accidental exposures.

Mr. HAMMERSCHMIDT. P. A–8, response to Q. 7: You say that the data being collected on Vietnam veterans participating is considered "adequate at this time." Adequate to what? You maintain that we don't know if they operated in those areas, we don't know if or how exposure took place, or in what intensity, or how it was absorbed, if at all. My reaction at this time is that we don't know anything. How can the data being collected be adequate?

Mr. CLELAND. Over a period of years we will be collecting data on the health status of the Vietnam veterans participating in our examination program. The primary purpose behind this effort is to detect and, where possible, treat any disease which might develop among these veterans. A secondary goal is the recognition of possible disease syndromes among them which might be related to herbicide orange exposure. Of course, the scientifically valid establishment of such a relationship would require a formal epidemiological study.

For a variety of reasons, it appears that the large majority of Vietnam veterans cannot provide accurate information on the likelihood of their exposure to herbicide orange. Accordingly, we will attempt to determine the probability of such exposure for each Vietnam veteran participating in our program by utilizing Department of Defense records.

In conclusion, I believe that we are currently collecting all of the data related to possible exposure to herbicide orange from these Vietnam veterans that they can reasonably provide.

Mr. HAMMERSCHMIDT. With respect to your VA Advisory Committee on Health-Related effects of Herbidices (p. 15): How many of your Advisory Committee members served in units in Vietnam which may have been exposed to Agent Orange? This, I would submit, is relevant as to factual expertise regarding the physical circumstances of the operating units, which I find lacking in the testimony.

Mr. CLELAND. None of the members of our Advisory Committee actually served in military units in Vietnam. However, I believe that this fact is not relevant to the degree of expertise which that body can develop with regard to the physical circumstances of the U.S. military forces during the Vietnam war. For example, the DOD member has direct access to the available data on this matter. Additional data has been provided to the Committee by outside experts invited to give testimony before it such as Major Alvin Young and Lt. Colonel William Wolfe of the U.S. Air Force. I am confident that this data has given the committee competent understanding of the use of herbicide orange in Vietnam and the likelihood of troops having contact with it. I do not believe that this understanding would have been significantly enhanced by the anectodal remembrances of an individual who had served in Vietnam.

MARCH 10, 1980.

Maj. Gen. WILLIAM S. AUGERSON,
Deputy Assistant Secretary of Defense for Health Resources and Programs, Department of Defense, Washington, D.C.

DEAR GENERAL AUGERSON: Pursuant to my closing remarks at the Agent Orange hearing on February 25th, I am enclosing for your response additional questions posed by the Honorable John Paul Hammerschmidt. You may wish to coordinate your response with General Chesney, Director of Medical Plans and Resources, Office of the Surgeon General, Department of the Air Force.

Please respond to these questions at the earliest possible date, in order that the hearing record may be completed.

Sincerely,

DAVID E. SATTERFIELD III,
Chairman, Subcommittee on Medical Facilities and Benefits.

Enclosure.

Questions for Department of Defense:

1. How much dioxin must one person drink before it kills him?

2. How long could Agent Orange's dangerous ingredients remain lethal if they sat in the water that filled a bomb crater, and was later drunk by ground troops?

3. P. 2: Your comment that the substances were "considered to have no human toxicity" when first used actually militates in favor of their having been used unwisely. If there was no sense of possible harm, the precautions could be justified as being less than urgent. As such, the sort of approvals mentioned on p. 5 could conceivably have been given for reasons that had little to do with the subject of these hearings. Do you agree?

4. I hope you're not trying to whitewash our use of Agent Orange. I find the comments regarding use, particularly on pages 6 and 7, to contradict the nature of our military operations. Does it really matter if Agent Orange was sprayed in "low population density" areas or in "enemy controlled territory" when our troops were also operating in these areas?

5. P. 5: You comment that DOD has a computer listing of all spray missions. Have you plotted them out on a map, with a chronology, and matched them against areas of operations for U.S. infantry troops in the field? If not, will you do so, and supply this material to both the VA and this committee?

6. Why does your testimony contradict itself with respect to whether troops were in the area of spraying? On pages 10 and 11, you maintain that "generally our forces did not operate in these areas until the cover was eliminated." On p. 15, you acknowledge the GAO study which found 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." What are you asking us to believe?

ASSISTANT SECRETARY OF DEFENSE,
HEALTH AFFAIRS,
Washington, D.C., April 4, 1980.

Hon. DAVID E. SATTERFIELD III,
Chairman, Subcommittee on Medical Facilities and Benefits, Committee on Veterans' Affairs, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: As requested by your letter of March 10, 1980, enclosed are specific responses to the six questions for the record posed by the Honorable John Paul Hammerschmidt.

Sincerely,

(For WILLIAM S. AUGERSON, Major General, MC, USA, Deputy Assistant Secretary of Defense, Health Resources and Programs).

Enclosure.

HERBICIDE SPRAYING IN VIETNAM

Mr. HAMMERSCHMIDT. How much dioxin must one person drink before it kills him?

General AUGERSON. The human lethal dose of dioxin is unknown at this time. Extrapolation to man from animals cannot be accomplished with any degree of confidence because in the various species of animals the lethal dose can vary a thousand-fold. Further, the mode of action of dioxin is not fully known from a toxicology standpoint.

Mr. HAMMERSCHMIDT. How long could Agent Orange's dangerous ingredients remain lethal if they sat in the water that filled a bomb crater and was later drunk by ground troops?

General AUGERSON. No definitive answer can be provided, it is not known how much herbicide or dioxin an individual would have to consume to be either dangerous or lethal. Most scientists would probably agree that the amount of 2,4–D or 2,4,5–T that generally penetrated the jungle canopy and intercepted the *soil* (a quantity estimated to be 1.4 pounds of 2,4–D plus 2,4,5–T per acre) would be toxicologically insignificant. The amount of dioxin in this quantity of herbicide would be non-detectable assuming the normal levels of dioxin found in the Orange used. The question does not provide data upon which to calculate actual residues at even the time of application. For example, was the crater assumed to be an old crater full of stagnant water, silt, algae, insects and micro-organisms surrounded by dense vegetation; or was it a new crater recently filled with rain water?

The question does not give a set of environmental factors upon which to base a standard for residue degradation. Although some environmental fate data are available for Herbicide Orange and TCDD, different sets of environmental factors would have had a profound effect upon the persistence and toxicology of the residue. Hence, without very well defined parameters and conditions, no

scientifically reliable answer can be provided about the quantity of dioxin that might be present in the water.

Mr. HAMMERSCHMIDT. Your comment that the substances were "considered to have no human toxicity" when first used actually militates in favor of their having been used unwisely. If there was no sense of possible harm, the precautions could be justified as being less than urgent. As such, the sort of approvals mentioned on p. 5 could conceivably have been given for reasons that had little to do with the subject of these hearings. Do you agree?

General AUGERSON. I believe the term "unwisely" can only be applied in retrospect, since at the time of herbicide application usage was entirely appropriate for the intended purposes of defoliation. The precautions mentioned on page 5 of my testimony were entirely for political, social, or military reasons. We did not intend to imply that the precautions were for health reasons—as you correctly note there was no reason then for such actions. We also intended to convey by those remarks that herbicides were not used indiscriminately or haphazardly.

Mr. HAMMERSCHMIDT. I hope you're not trying to whitewash our use of Agent Orange. I find the comments regarding use, particularly on pages 6 and 7, to contradict the nature of our military operations. Does it really matter if Agent Orange was sprayed in "low population density" areas or in "enemy controlled territory" when our troops were also operating in these areas?

General AUGERSON. I do not believe my remarks are a whitewash of our use of herbicides. We have been quite frank in discussing the area sprayed with them and the large quantity of herbicides applied in Vietnam. Certainly, one of the pressing concerns of these hearings is the likelihood of American troop exposure. The comments about usual locales of herbicide spraying were intended to say that spraying tended to be away from U.S. troop concentrations and that, therefore, there was reduced likelihood of exposure, not that exposure did not occur. Certainly, upon occasion, U.S. troops were in the vicinity of spraying missions and equally certain they later went into sprayed areas since the purpose of spraying was to improve the safety of U.S. troops in the jungle seeking out the enemy. The greater the delay between spraying and troop entry, the less likely was exposure to dioxin.

Mr. HAMMERSCHMIDT. You comment that DOD has a computer listing of all spray missions. Have you plotted them out on a map, with a chronology, and matched them against areas of operations for U.S. infantry troops in the field? If not, will you do so, and supply this material to both the Veterans Administration and this committee?

General AUGERSON. We do have a chronological computer listing of the herbicide spraying missions, and these have been plotted on maps. We do not have matching data on troop locations so that we may compare them with spraying locales. We are now working with Army and Marine Corps historians and document experts to determine how this may be done. The data will have to be expertly extracted by hand from a vast quantity of records completed and handled under combat conditions. The primary documents are unit histories and daily unit diaries. Early estimates indicate a cost that will run into the tens of millions of dollars. The full task is a formidable one, consisting of attempting to accurately place 2.5 million men for each of the 365 or more days that they were in the Republic of Vietnam.

Mr. HAMMERSCHMIDT. Why does your testimony contradict itself with respect to whether troops were in the area of spraying? On pages 10 and 11, you maintain that "generally our forces did not operate in these areas until the cover was eliminated". On page 15, you acknowledge the GAO study which found 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." What are you asking us to believe?

General AUGERSON. I did not intend to be contradictory; at least part of the problem derives from the fact that we are presently working in terms of incomplete and imprecise data. As I mentioned in my reply to question number 4, I am talking about a general probabilities of exposure. More precise definition will await the development of co-ordinate defined troop location and an agreed upon definition of exposure in terms of the geographic and temporal relationship of the troops to the sprayed areas. At the moment, we simply do not know how many people were exposed and to what extent. Realistically, looking at the records, the best we will be able to do is speak in terms of reasonable approximations. I do not expect our data about exposure or lack of it to ever have a high degree of certainty.

MARCH 10, 1980.

MS. JOAN Z. BERNSTEIN,
General Counsel, Department of Health Education, and Welfare,
Washington, D.C.

DEAR MS. BERNSTEIN: Pursuant to my closing remarks at the Subcommittee on Medical Facilities and Benefits hearing on February 25th, I am enclosing for your response additional questions posed by the Honorable John Paul Hammerschmidt.

Please respond to these questions at the earliest possible date, in order that the hearing record may be printed.

Sincerely,

DAVID E. SATTERFIELD III,
Chairman, Subcommittee on
Medical, Facilities and Benefits.

Questions for Health, Education, and Welfare:

1. With respect to your interagency Working Group: how many primary participants in this Group are veterans who had operational experience in areas where Agent Orange may have been used?

2. You point out (p. 7) that research with animals establishes that dioxin is "one of the most toxic agents known." How can the VA and DoD fail to point this out in their testimony? Do you know how much it would take in a cup of water to kill a person if he drank it?

3. You state (p. 13) that it is possible that a disease causally related to Agent Orange might also be found causally related to other agents, and thus not be totally attributable. Isn't this true in almost every case, not only in HEW claims but in VA claims? For instance, what if a coal miner who also is a heavy smoker gets black lung? Or what if any serviceman gets cancer when he is a cigarette smoker? Do we actually make these distinctions in present law?

4. (P. 13): I hope you will refine your information-gathering priorities with respect to "whether Vietnam veterans as a class are as healthy as other relevant population groups." It seems to me that it would be better to limit this class to those who have had the greatest possibility of being exposed to Agent Orange—Army and Marine Corps ground combat troops, for instance. Do you have any tentions in this regard?

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
THE OFFICE OF THE SECRETARY,
Washington, D.C., May 5, 1980.

HON. DAVID E. SATTERFIELD,
Chairman, Subcommittee on Medical Facilities and Benefits, Committee on Veterans' Affairs, House of Representatives, Washington, D.C.

DEAR MR. SATTERFIELD: This is in reply to your recent letter requesting responses to additional questions posed by Rep. John Hammerschmidt following up on the hearings by the Subcommittee on Medical Facilities and Benefits.

Attached are responses to those questions for inclusion in the hearing record.

Sincerely,

JOAN Z. BERNSTEIN.

Enclosure.

Question 1. With respect to your Interagency Working Group: how many primary participants in this Group are veterans who had operational experience in areas where Agent Orange may have been used?

Answer. The response to this question was included with the hearing transcript previously forwarded to the subcommittee.

Question 2. "You point out (p. 7) that research with animals establishes that dioxin is 'one of the most toxic agents known.' How can the VA and DOD fail to point this out in their testimony?"

Answer. We suggest that the first question regarding the failure of DOD and VA to include references to toxicity studies of dioxins using animals may be simply a matter of emphasis rather than one of substance but the question can best be answered by those agencies.

"Do you know how much it would take in a cup of water to kill a person if he drank it?"

This question cannot be answered with any accuracy because, despite human exposures due to occupational accidents and general exposures in Seveso, Italy, there is no quantitative information that relates any toxic effect of dioxin in man to dose or amount of exposure. Traditionally, in such circumstances scientists

turn to animal toxicology data for evidence which can then be extrapolated to humans.

However, dioxins show an extremely large variation in the dose required to produce a toxic effect. For example, the oral LD_{50} (the dose that will kill 50 percent of the animals exposed) for 2,3,7,8-TCDD in guinea pigs is one microgram per kilogram of body weight. A hamster would require a dose 1,000 times greater to produce a similar effect. Humans appear to be more tolerant than the guinea pigs based upon accidental exposures that are presumed to have been heavy but which did not result in severe acute effects such as death.

Question 3. "You state (p. 13) that it is possible that a disease causally related to Agent Orange might also be found causally related to other agents, and thus not be totally attributable. Isn't this true in almost every case, not only in HEW claims but in VA claims? For instance, what if a coal miner who also is a heavy smoker gets black lung? Or what if any serviceman gets cancer when he is a cigarette smoker? Do we actually make these distinctions in present law?"

Answer. As pointed out in the prepared statement, there is no assurance that the best research of which our scientists are capable will produce definitive, incontrovertible scientific evidence of the human health effects of phenoxy herbicides and their contaminants. The research being carried out or planned is important and valuable, but cannot by itself answer the questions that seem to to be ones of broad social policy that both the administration and the Congress must soon confront.

As to the issue of causation as it relates to disability compensation, our understanding is that VA policy is that where a disability occurs coincident with service in the Armed Forces, it is unnecessary to identify a causative agent. It is our understanding, however, where a disability becomes manifest post service, it may be considered "service connected" only if a connection between it and exposure to a causative injurious agent or disease occurring in service can be established. Certain diseases with post service manifestations may be service connected without regard to causation on a statutory presumptive basis pursuant to 38 U.S.C. 312.

Question 4. "(p. 13): I hope you will refine your information-gathering priorities with respect to "whether Vietnam veterans as a class are as healthy as other relevant population groups." It seems to me that it would be better to limit this class to those who have had the greatest possibility of being exposed to Agent Orange—Army and Marine ground combat troops, for instance. Do you have any intentions in this regard?"

Answer. We are concerned that studies focusing solely on Agent Orange will fail to identify whether a real health decrement exists among Vietnam veterans because Agent Orange may not have been the causative factor. The question to be answered is whether the veteran has an illness or disability that is service connected.

By this we do not mean to suggest that Agent Orange is not a plausible candidate for causing illness but rather that our studies need a dual focus: Vietnam veterans and a specific Vietnam circumstance which is likely to be associated with Agent Orange. In the latter case, the degree of success is heavily dependent upon the availability of military records which can identify appropriate field or combat units. The VA epidemiology study is likely to include identifiable subsets such as a group with probable Agent Orange exposure and another with a remote chance of Agent Orange exposure.

A proposed study of human birth records data to determine whether Vietnam veterans are at greater risk of siring malformed children will also attempt to create subsets of the veterans population as a function of likelihood of Agent Orange exposure.

Chairman SATTERFIELD. Before I move to the next member of the panel I would like to follow up on a question answered by Dr. Moore. You stated that the difficulty with respect to epidemiological studies as far as second generations are concerned. Do you feel that we would experience the same problem with epidemiological studies of a control group and veterans who were exposed?

Are we saying that you have to show some clinical effect or will an epidemiological study in this area be broad based enough with respect to the whole population that you really can ascertain anything?

Dr. MOORE. As Mrs. Bernstein's testimony pointed out, it is entirely possible, after one designs what is likely the best epidemiological study, that when it is done one can't detect any cause-effect relationship between Agent Orange and health decrements.

Chairman SATTERFIELD. Thank you, very much. Mr. Danielson?

Mr. DANIELSON. Thank you, Mr. Chairman. I have a couple of questions only. The gentleman from the Air Force, you mentioned that the test with rodents and I wasn't able to distinguish whether you said "seven generations" or "seventy—seven zero—generations."

Would you clarify that?

Major YOUNG. That is 70, sir. It is 70 generations.

Mr. DANIELSON. It is seven zero.

Major YOUNG. That is seven zero.

Mr. DANIELSON. That is one more than 69, OK.

Major YOUNG. That is an approximate figure.

Mr. DANIELSON. Well, it is good enough. That is a lot different from seven. You mentioned also that the test plot that apparently you use as a control would have had some 200 times as much application of the chemical as would be found in an agricultural area and definitely at least that much more than would have been found in the defoliated areas in Vietnam. Is that correct?

Major YOUNG. That 200 would be today.

Mr. DANIELSON. That is 200 of what?

Major YOUNG. The concentrations of dioxin in the soils right now are averaging around 300 parts per trillion.

Mr. DANIELSON. Is that in the test plots?

Major YOUNG. That is in the plots today.

Mr. DANIELSON. Well, which plots. That is what I am interested in.

Major YOUNG. Those are the ones that I am referring to at Eglin, sir. Those are the ones where the rodents have been and we have been following——

Mr. DANIELSON. That is a test plot, then. That is not a forest in Vietnam.

Major YOUNG. No, sir.

Mr. DANIELSON. Well, I think that it is essential that we identify the plots that we are talking about.

Major YOUNG. We have looked at the sites where Orange was actually applied in the United States in 1973 in a test program at Oregon State University.

There it was put on at the rates of between 2 and 4 pounds per acre. We monitored that entire system for TCDD in a forested environment and could not find it there.

Mr. DANIELSON. Would that be a heavier concentration than the application in Vietnam?

Major YOUNG. It was Orange. But Orange in Vietnam would have been used at a much greater concentration: Approximately anywhere from 6 to 12 times greater in Vietnam.

The difference between Oregon, however, and Vietnam was that in Oregon we had a single canopy forest. In Vietnam the vegetation frequently exceeded 100 feet high and what we called a triple canopy forest.

And after all most Orange—better than 90 percent was applied in a triple canopy forest.

Mr. DANIELSON. All right. One other point that you brought up was that when the Orange does on some occasions fall to the ground subsequent to a rain, for example——

Major YOUNG. Yes, sir.

Mr. DANIELSON. It disappears quickly into the ground. By "disappear" what do you mean when you use the word "disappear"?

Major YOUNG. In the case of the active components, the 2,4-D and the 2,4,5-T, once into the soil the major route of degradation is microbial converting it to the basic——

Mr. DANIELSON. You are talking about the degrading rather than just a physical loss of the discrete compounds. Is that it?

Major YOUNG. It is a disappearance due to the microbiological activities. Micro-organisms use it as a good source. Of course, there——

Mr. DANIELSON. Then it is destroyed. It is degraded.

Major YOUNG. Yes.

Mr. DANIELSON. It no longer exists in its original chemical form.

Major YOUNG. That is correct.

Mr. DANIELSON. There was one exception that you made to that, that something like 1 percent remains somewhere. One percent—one part per something or other.

Major YOUNG. At Eglin going back to the plots in Northwest Florida where the spraying equipment was developed for Vietnam, we figured that about 2 percent of the dioxin is currently there in the soil. It was not photodegraded. It was not microbially degraded. It got into the lower portions of the soil due to simply sand covering it up.

Mr. DANIELSON. Or percolation down with water I suppose.

Major YOUNG. We haven't been able to show percolation, but we have been able to show sand movement.

Mr. DANIELSON. And do you——

Major YOUNG. Once in that soil it is very stable. There is no question about its stability once in that soil.

Mr. DANIELSON. Where does the microbiological degradation take place, then?

Major YOUNG. At the surface.

Mr. DANIELSON. Right on top.

Major YOUNG. Right at the surface.

Mr. DANIELSON. In other words, this which is down into the soil having been covered by windblown or other soil on top of it will probably stay for quite a long time. Is that correct?

Major YOUNG. It could well. We have found it to be very persistent.

Mr. DANIELSON. Can that be absorbed into plant life then?

Major YOUNG. No; we haven't seen any basis to show that it is taken up by plants. And we have got a very extensive program in that area.

What we have seen, however, is that animals that come directly in contact with their skin do get contaminated soil on their skin. Now, the way that the rodents get it in Florida is they come back and they lick that skin.

We believe that most of it is due to ingestion by licking the skin.

Mr. DANIELSON. When that is ingested, does it pass through the rodent or does it lodge——

Major YOUNG. It accumulates in the liver.

Mr. DANIELSON. And that results in a detriment to health, I would assume. Or am I wrong?

Major YOUNG. We haven't seen a detriment.

Mr. DANIELSON. You are not sure.

Major YOUNG. At concentrations of 2.9 parts per billion which is as Dr. Moore has testified quite an insignificant concentration.

Mr. DANIELSON. It sounds like my bank account. [Laughter].

Do you have on that long sheet—this is to Mr. Cleland—on that long sheet showing the incidence of complaints and diagnoses and attributions to the Agent Orange. I believe you have the first—I have lost my sheet here, but the first figure that you attribute to Agent Orange has two units. I believe that was chloracne.

I don't know what chloracne is. I guess that it looks like a pimple or something. Is that right? Is it just like acne?

General CHESNEY. It is similar.

Mr. DANIELSON. Is it ——

Dr. CUSTIS. Chloracne is a pustular dermatitis that results in scarring.

Mr. DANIELSON. It is sort of acne roseacea which erupts there.

Dr. CUSTIS. That is the form of eruption, yes.

Mr. DANIELSON. Would it be similar to the acne roseacea that adults have that forms little scars.

Dr. CUSTIS. It has a different distribution and pattern.

Dr. JACOBY. If you will, to look at it you would think that it was the same as acne.

Mr. DANIELSON. All right.

Dr. JACOBY. It is somewhat like acne vulgaris. It has a different distributional tendency so that it can be distinguished. It does not cause as much inflammation as acne vulgaris that you usually see and it does result in scarring.

Mr. DANIELSON. Can it—does it ——

Dr. JACOBY. It is specifically different clinically and when you look at it pathologically.

Mr. DANIELSON. Will it respond to treatment? Can something be done about it?

Dr. JACOBY. It does respond to treatment; however it can become chronic and persist for many years. It can be a self-limited illness. In most acute exposures that we have seen in industrial accidents, it has been of a limited duration.

Mr. DANIELSON. Is it any more difficult or any more harmful to the victim than the acne vulgaris which you described?

Dr. JACOBY. I would say not, other than the scarring and the disfigurement.

Mr. DANIELSON. It is pretty much a trade-off.

Dr. JACOBY. That is right.

Mr. DANIELSON. There were 17 units attributable to the Agent Orange in your second category of skin lesions of some kind or another.

Can you tell me what they are? What categories of problems are in those skin lesions?

Dr. JACOBY. I am sorry. I can't answer that specifically. I don't have a list of the diagnoses. I know that some of the cases have been various other types of dermatitis. Some have a neurodermatitis. Some are secondary to anxiety. And some have been secondary to fungus infections which were common.

Mr. DANIELSON. Would they go, sir, as far as basal cell cancers or are they under the malignancies farther over to the right?

Dr. JACOBY. I would make two comments to the Congressman. No. 1, we would be glad to look at these 17 cases. And, second, the

basal cell, this is a very distinct type of a situation. I think that it would be classified under a malignancy.

Mr. DANIELSON. Well, the reason that I asked the question is over in that column farther to the right where I believe that you have two more units attributable to Agent Orange, you list leukemia, lymphoma, and a third malignancy which I don't now remember. Is that myeloma?

I saw no basal cell cancers there. Therefore, my question is: Would you classify the basal cell over in those malignancies or would you have classified it in the more general group in which you have 17 findings?

Dr. JACOBY. I believe that the basal cell would be classified as a malignancy.

Mr. DANIELSON. Thank you.

Dr. JACOBY. I would say, too, that these were cases that were service connected but were not attributed wholly to herbicides.

Mr. DANIELSON. Oh, well, my sheet came back or maybe someone gave me one. I thought that that said "Of disorders due to Agent Orange, the number deemed service-connected". Oh, it does not necessarily mean that they are Agent Orange connected.

Dr. JACOBY. Yes, sir. That is correct.

Mr. DANIELSON. That is just supposed to show that all of you highly intellectual scientists made it possible for laymen like me to misunderstand your classifications.

You have really got to spell it out. We are pretty innocent up here. So those 21 units you have there are not necessarily attributable to the Agent Orange. They could be but they are not necessarily. Is that correct?

Dr. JACOBY. That is correct.

Mr. DANIELSON. Thank you.

Chairman SATTERFIELD. Mr. Deckard?

Mr. DECKARD. Thank you, Mr. Chairman. Mr. Cleland, this is a controversy that in all likelihood has or will affect every Member of Congress, having constituents who would have served in Vietnam during the period that Agent Orange was in use.

Just recently, my staff and I completed work on a claim involving a young constituent of mine who served as a member of a helicopter crew in Vietnam and served on numerous missions where Agent Orange was sprayed.

He just died recently of pancreatic cancer at the age of 31. Now, it is my understanding that pancreatic cancer is a disease which is very rare in a person of that age and is normally found only in elderly people.

His claim was based solely on having been exposed to Agent Orange and the claim was just recently approved. As a matter of fact, within days of his death, his wife was notified that she would be eligible for survivor's benefits.

I have just had the findings of fact in that case sent down from my office. And as I read this and there are a number of technical medical terms which escape me, but as I read this it does seem to be based on the fact that this person apparently incurred this disease while serving in Vietnam.

And while it doesn't specifically attribute the disease to exposure to Agent Orange, nevertheless, the claim was based on this fact and I almost have the feeling that the Board of Appeals felt that it had a

moral obligation to approve this claim but yet it couldn't officially prove this claim but yet it couldn't officially admit that Agent Orange was the causative agent.

Once the precedent has been officially established, and in my opinion it eventually will, what do you foresee as the implications, the economic implications for one, the social implications involved for those who have been exposed and may incur some type of a disease as a result, and perhaps even military implications?

Mr. CLELAND. Thank you, very much, Mr. Deckard. I think that you have put your finger on a delicate point here. We have not only a moral obligation, we have an obligation under the law that if we can find evidence that shows with some reasonable certainty that the disease or disability was related to military service, we service connect and give the veteran the benefit of the doubt whether or not there was Agent Orange exposure.

In some of the more celebrated Agent Orange cases that have received media attention, service-connection has been granted not on the basis of Agent Orange exposure, but based upon other evidence in the record suggesting that the disability or the disease had its origin in the service.

Under the law, we are obligated to service connect.

The key point, it seems to me, is that we don't currently have any evidence to suggest a higher rate of pancreatic cancer or liver cancer—these kinds of things—among persons claiming exposure to Agent Orange.

That is a matter which we hope the epidemiological study will clarify. Dr. Custis may want to respond a little bit. But we have been in the business for years of keeping a record of cancers in the VA irregardless of the questions surrounding Agent Orange.

Dr. Custis?

Dr. CUSTIS. Well, I am sure that what Mr. Cleland is referring to is our current effort to track the incidence of malignancies in our diagnostic data bank. We are doing it for the period of the last 9 or 10 years.

It is not at a point yet where we can analyze in depth these statistics except to say that regarding the one tumor that has been researched a little more than any of the other malignancies, namely, testicular carcinoma, there does not appear at this time to be any increase or any variation in the incidence in that population of veteran patients being seen in VA hospitals over the past 9 years.

This data can be of some help in connection with the overall epidemiologic effort which we will shortly be undertaking.

Mr. CLELAND. Mr. Deckard, I think that you raise a point that I tried to raise in my testimony and that is that the law in effect allows the Veterans' Administration a little more flexibility, I think, than would exist in a court of law.

In effect, we don't actually need to prove an actual linkage to Agent Orange. What we need to do is to see if there is any evidence that the disease or disability was incurred in service.

The problem that we are having is that allegations of service-connections are being made with no evidence of a disease or disability being present in service; whether latent diseases can be linked to Agent Orange is an issue that the scientific community is still uncertain about.

And that is what leaves us with a problem.

Mr. DECKARD. Thank you, Mr. Chairman.

Chairman SATTERFIELD. Mr. Hall?

Mr. HALL. Mr. Cleland, in going through this testimony that I have read—not only yours but those others that we have here today—I gather that prior to the use of this toxic substance that the U.S. Army and the people connected therewith knew that we were dealing with something that was highly sensitive.

It had for its purpose the object of defoliation. It appears that even the troop commanders were told with plenty of time in advance to get their people out because of what was coming, that we usually did this in the morning early or at dusk, dark.

There is other testimony that it took from 2 to 3 months sometimes, I think, from the gentlemen from the Air Force—it took 2 to 3 months for complete effectiveness to take place once it had been dropped.

During those periods of time we were prone to try to keep military personnel out of those areas, but at times some elements of the Marine Corps and others would get in there.

Now, I notice that one statement that you make on page 8 you are talking—I am talking about Mr. Cleland—that one of the problems that we are facing is that, "Third, the data with respect to the extent of individual exposure to Agent Orange is extremely difficult to obtain."

Yet, I notice on page 5 of General Augerson's testimony it states that:

> We now have in the Department a computer listing of all such spray missions for the period of 1965 to the end of spraying in 1971 which is believed to be complete. This printout shows the date, the time, the agent used, gallons of agent dispensed, the map coordinates and the area covered by the mission.

Now, if we have all of that information according to what the general said, why do we not have sufficient data to determine who was or who was not exposed to this agent and why are we having so much difficulty establishing that fact?

Mr. CLELAND. Well, I think that the problem lies not so much in where the spraying was, but where the troops were in regard to the spraying.

Mr. HALL. Well, certainly, we should know with some degree of certainty where our troops were during the period of time that we were spraying these areas, should we not?

I don't know who is to answer that, but I am sure that someone in the field knew where his folks were or should have been. Who can answer it?

General AUGERSON. I will make an effort, Mr. Hall. It is a double problem that in war and in the field there is always—one of the problems of command, is, indeed, trying to keep track of where everybody is and people do get lost or end up in different places.

The real problem, sir, is not what may have been present at any instant in time, but having a record now available as to where people were with respect to the spray missions.

It might be useful to point out that my understanding, sir, is that the reason that commanders were told about missions when they were—and I don't know that it always took place—was more nearly to see that U.S. forces were not in the vicinity of the spray not so much as

a matter of being concerned about the health effects of the spray as much as being sure that we did not have Americans in a region where the escort aircraft for the spray missions could return fire if it took place.

It is always a concern not to be putting fire down on friendly people.

Mr. HALL. Well, I understand that it was the reason why we were—that the people were notified—that the commanders were notified to vacate those areas was because of the defoliation that may come about.

Was it not because we did not fear any probability of harm to the men who may have been there when this stuff was dropped?

General CHESNEY. Let me answer that, Mr. Hall. The majority of the herbicides in Vietnam were dropped either on enemy-held territory or on territory that was being contested.

To the best of my knowledge we made no major effort to move people out of areas where we were going to spray. The herbicides that we were using at that time were the standard herbicides that were developed and used for commercial uses. There has been more of that dropped in the United States than there ever was in Vietnam.

It was a standard that you could go by and put on your lawn at that time. So it was not something that we really worried about that much at that time.

Mr. HALL. Well, did we drop Agent Orange at any time where we had troops beneath where that substance was being dropped?

General CHESNEY. There was an occasional time that this happened, but it was to help clear out the area around where the troops were being shot at so that they could see to shoot back.

Mr. HALL. I understand that. But I mean that we made no effort to try to get the troops out while we were trying to defoliate the area.

General CHESNEY. In general, we did not. No, sir.

Mr. HALL. Now, I notice a moment ago that you stated that there have been a few service-connected cases in which you have not been able to prove a service-connected disability or causal connection as I put it.

My question is this: How can you establish a service-connected disability if you cannot prove that the veteran did not have prior latent condition from some industrial job that he received before he went into the Armed Forces.

I understand from some page here that I looked at a moment ago that it is merely impossible to determine—indistinguishable. I think Mrs. Bernstein stated a moment ago on page 11, that:

> Research is clearly establishing that other members of the dioxin family of chemicals can produce toxic manifestations that are indistinguishable from those produced by TCDD.

Do I understand that the chemicals that are being used today and have been used since the 1940's can produce the same type of condition that Mr. Cleland stated can be manifested on page 7: "Such common symptoms include restlessness, lethargy, headaches, confusion"—you have read all of that. You know what I am talking about on page 7.

Are we led to believe that the industrial area should be causing a lot of things that we are now hearing from veterans claiming that they got in Vietnam?

Mrs. BERNSTEIN. To the extent that we have that information or don't have it, I should say, Congressman, that is true.

Mr. HALL. How are you going to differentiate between what is legitimate and what isn't?

Mrs. BERNSTEIN. Well, I don't know how we are defining "legitimacy" but that——

Mr. HALL. I am talking about legitimacy——

Mrs. BERNSTEIN. Just in terms of causation?

Mr. HALL. Yes. How are you going to get causation that something occurred in Vietnam and didn't occur in a plant in Peoria?

Mrs. BERNSTEIN. Sir, one of the things I tried to say in my statement is that we may finish all of the studies and still not have a definitive answer on this subject.

You have put your finger right on it, I think. It may not be possible to establish that kind of causation.

Mr. HALL. How will we ever get to the end of the problem?

Mrs. BERNSTEIN. Well, there are solutions other than scientific solutions. There are legislative solutions. There are administrative or policy-type solutions in which one simply makes the judgment that there is enough association even though it may not constitute causation in a legal sense. The Congress could decide, as has been suggested in a couple of legislative proposals, simply to act on that amount of association of those people who were there and decide to compensate them at a certain level.

Mr. HALL. Well, do you feel—maybe this is not your question, but someone. Do you feel that the investigation that is now ongoing without any legislative enactments involved will lead to a definitive conclusion that would separate Vietnam from that plant in Peoria as far as causation is concerned?

Mrs. BERNSTEIN. Let me have a scientist speak to that—again, the limitations on the science—I have my own biases, but you probably don't want to hear them.

Mr. HALL. I will listen to anything.

Dr. MOORE. Mr. Hall, I think that one of the reasons that the Department is focusing on the occupational exposures, or the large-scale accidental exposures, gets to the root, I think, of what you are trying to get at. We feel that if we look at the populations that likely had the most heavily exposed milieu, either during a short period of time or over a long worker experience—and some of these cases have now had a 30-year duration since the exposure—if we can't find anything there, there should be some reassurance in that regard.

However, if you do these studies and get some indications of certain types of health effects, one then would have to come back maybe to an Agent Orange exposure where the exposure was transient, of lower magnitudes of exposure, to see if indeed you could get hints, based on occupational exposure, that the disease patterns that may be produced can be defined in other populations.

Mr. HALL. Well, you are eventually going to have to get back to making either a subjective finding as opposed to an objective finding as to causation.

Dr. MOORE. [Nods, yes.]

Mr. HALL. Are you shaking your head in the affirmative?

Dr. MOORE. I agree.

Mr. HALL. All right. Thank you. I yield back my time.

Mr. CLELAND. Mr. Hall, can I take a stab at some of the things you have been raising?

Mr. HALL. Yes, sir.

Mr. CLELAND. First of all, you mentioned the list of symptoms. I mentioned in my statement that those were symptoms attributed by veterans to Agent Orange and are not necessarily actual negative health effects of exposure. That is what has not been established—the fact that 8 or 9 years after exposure you can first be affected by those kinds of symptoms.

The one long-term effect that it seems that the scientific community has come to a consensus on is chloracne, which we have discussed. Beyond chloracne there is no consensus, it seems to me, on what the long-term negative effects of exposure to dioxin are.

In terms of industrial exposure, one study that was published in January is, I think, interesting. And that is that of the over 200 workers who were exposed in Nitro, W. Va. 31 years ago, 121 developed chloracne and suffered some of the initial acute toxicity symptoms.

A followup study has been done and was published in January 1980, which shows that there was no increased level of cancer or mortality in those 121 who got exposed 31 years ago.

So the long-term negative health effects of Agent Orange are not known at this point.

The other point that you mentioned about service connection, the law does provide that veterans are to be given the benefit of the doubt.

Given the current lack of scientific substantiation of latent adverse health effects of Agent Orange, we currently have no basis for service connecting such illnesses as cancer on the basis of exposure alone.

Mr. HALL. Well, Max, if you don't have to prove actual linkage, if the veteran does not have to prove actual linkage between exposure to Agent Orange and making a recovery, it looks to me like you are letting the gate down, so to speak, for many, many fraudulent claims throughout this country.

Mr. CLELAND. Mr. Hall, regardless of Agent Orange, if a veteran comes down with cancer and it is traceable to his service in the military he gets service-connected.

Mr. HALL. If it is traceable, but you have a linkage then.

Mr. CLELAND. That is right, but we don't go behind the cancer and try to determine why it was caused. It becomes, in effect, a service-connected disability that was incurred in the service.

We don't try to say that it was Agent Orange related or it was related to something else.

Mr. HALL. Would you make——

Mr. CLELAND. If it occurs in the military—if a disease or a disability is incurred in the military, it is service-connected.

Mr. HALL. The burden of proof is less strenuous on a person trying to prove causation dealing with Agent Orange than it would be with some other—is that correct?

Mr. CLELAND. No, sir. Charlie, could you—Charlie Peckarsky, Director of Compensation and Pension, could you help us say a little bit?

Mr. HALL. I really think that we are getting back to subjective rather than objective findings on that.

Mr. PECKARSKY. I believe that Mr. Cleland has really stated the basic principles. The law, as this committee knows better than any other, is so beneficial that there is no need to prove any relationship between any incident of service and disability.

First, the law presumes that the man is in sound condition when he enters. It then says that any disability that appears coincident in point of time with the period of active duty will be service-connected regardless of the cause.

The only thing that can refute that is proof of some intercurrent causation, usually post service, or proof in the form of evidence that he actually had this disability prior to service.

So, therefore, as Mr. Cleland has said, the law beneficially assumes and forces us to apply every reasonable doubt in establishing service connection for the disability.

The case that was cited by Mr. Deckard was a case in which this was illustrated. We were not able to show any relationship between exposure to dioxin and the cancer that the veteran died from.

However, from reviewing all of the service records, we found early evidence of a precancerous condition in the man's service records and were able to trace that through the establishment of service connection for the cause of death.

This is an illustration of the way in which we adjudicate.

Mr. HALL. I am not belaboring that particular case that Mr. Deckard mentioned. My point is, and I am just looking at this from the standpoint of an attorney, if you found a precancerous condition at some point in time, was that at a time prior to his exposure or subsequent to his exposure to Agent Orange?

Mr. PECKARSKY. It would not matter, sir.

Mr. HALL. Why wouldn't it?

Mr. PECKARSKY. The only thing that I am interested in is was it at or prior to the period of active duty.

Mr. HALL. If he had cancer before he was ever exposed to a cancerous agent, how could you make causation tie together? I am not saying that you shouldn't, but I am stating how can you from a legal proposition get causation if something happened before the person ever in any way was subjected to what could cause that cancer or did cause that cancer?

Mr. PECKARSKY. I believe, sir, that you are speaking from the point of court law.

Mr. HALL. I sure am.

Mr. PECKARSKY. I am speaking from the point of veterans law.

Mr. HALL. Of what?

Mr. PECKARSKY. Of veterans law.

Mr. HALL. Is there a difference?

Mr. PECKARSKY. As it has been enacted, as it is on the statute books. And all that that law requires is the showing that from a point of time this disability had its inception or was aggravated coincident in point of time with the period of active duty, sometime between the period of induction and the period of separation from active service.

With most cancers we do not know the etiology anyway. So it is not—the Veterans' Administration does not attempt to differentiate between the etiological facts. We merely want to know if the earliest manifestation of this particular disability is concurrent in point of time with military service. If it is, we service connect. If it is not, we do not.

Chairman SATTERFIELD. Would the gentleman yield?

Mr. HALL. Yes.

Chairman SATTERFIELD. I think that there is an element here that might resolve the questions, and I think that as I understand it everything has been correctly stated.

However the problem that we are confronted with here is different from the one we have been talking about. There we are talking about the possible development of a condition of cancer—that is to say, a situation which shows up after discharge from service. In that circumstance it becomes necessary to establish a cause and effect relationship. Am I correct?

Mr. CLELAND. Yes, sir.

Chairman SATTERFIELD. And we are talking about the latent defects here, defects alleged to have been attributable to exposure to Agent Orange.

Mr. CLELAND. Yes, sir, exactly. Mr. Chairman, it seems to me that that is exactly why the research on the long-term effects of exposure to Agent Orange is the real question, not what can happen within 2 weeks or 1 month.

You can come down with chloracne within 2 weeks to 1 month. You can have various symptoms up front due to acute toxicity to Agent Orange or to dioxin. That is what I have picked up from my discussions.

But the key question is what happens 3, 4, 5, 6, 7, 10 years later or 20 years later? That is where the jury is still out and what the scientific community is still in doubt about.

Chairman SATTERFIELD. I think you will eventually make your decision, as was indicated a moment ago, the basis of objective findings rather than subjective conclusions.

Mr. DANIELSON. Mr. Chairman, may I have a couple more questions?

Chairman SATTERFIELD. I was getting ready to recognize Mr. Daschle. He has been sitting here for a long time.

Mr. DANIELSON. Oh, I am sorry.

Chairman SATTERFIELD. If he wishes to yield he may do so.

Mr. DANIELSON. I wouldn't think of going ahead of Mr. Daschle.

Mr. DASCHLE. If the gentleman from California will forgive me, I think that I will proceed with some questions.

I can't help but sit here and be very frustrated with this discussion, and I can understand the frustration of so many of the Vietnam veterans. This discussion capsulizes the kind of frustration that a veteran must be going through.

I think that we are putting our Vietnam veterans in the role of a plaintiff and the VA in the role of a defendant and a judge.

And I really believe that the odds against him right now are 2 in 10,000, which is what your record has just shown, Mr. Cleland.

Out of 10,000 people who have come to the VA, only 2 of them have been able to prove beyond any shadow of a doubt that they were in some way inflicted with the chemical while they were in Vietnam. Those were the 2 people who had chloracne.

It is frustrating because you don't look at other VA recipients that way with other benefits.

The fact of the matter is that Agent Orange victims have to continue to prove themselves—the ones who were affected—as opposed to the VA having to prove it for them.

I get the feeling as you testify today that as much as these studies are going to prove culpability, you might prefer that they prove nonculpability.

Mr. CLELAND. I have to interject here. Now, I can't—I am trying not to take a side here. I have a personal interest in the outcome, as does Dr. Custis because we were both exposed. We are not trying to prejudge.

But given what we know now about dioxin and the fact that some studies have been done by reputable people—the National Academy of Sciences did a study in 1974. And they concluded in their study that the chances of negative health effects for Vietnam veterans in the long-run are "highly remote".

Mr. DASCHLE. That's just what I mean.

Mr. CLELAND. The Air Force has done a definitive study in the last couple of years. Major Young has talked about some of the data. It is not as if nobody cares. It is that, you know, we are open to suggestions as to what else we can do to try to aid these veterans here other than——

Mr. DASCHLE. But you believe——

Mr. CLELAND [continuing]. Manufacturing scientific data which is not available now.

Mr. DASCHLE. Do you believe that out of 10,000 cases you have more flexibility than a court of law does in determining culpability or determining your legitimate responsibility? I would wager that in a court of law, out of 10,000 cases, that there would be better than two wins.

You can't talk to the people that Mr. Deckard has and not be very, very frustrated with the kind of work that the VA has done or better yet, not done.

You indicate that there have been 50 studies. You know, when all is said and done, there is going to be a lot more said than done.

The Food and Drug Administration has indicated that dioxin is 100,000 to 1 million times more potent than thalidomide in causing birth defects.

So I agree, you may have a force on both sides, but the fact of the matter is that you have 10,000 cases that you know of, and you have 2 cases that you have agreed have some relevancy to the exposure to Agent Orange.

Mr. CLELAND. May I respond, please?

Mr. DASCHLE. Yes.

Mr. CLELAND. The issue does not seem to me to be the toxicity of dioxin which is known. It seems to me that the issues are what level of exposure is harmful and what that means later on in life.

That is really the scientific question which the VA is trying to address, given a host of studies on the question. We are trying to find out all we can about it.

I might say that the 10,000 did not all allege a problem. They did not all allege Agent Orange poisoning.

Many of them came in to do what we are asking them to do and that is to get their service on record in case something turns up, in case they thought they were exposed. Maybe they have a problem.

Maybe they don't know.

That is our position. We welcomed those to come and get that on the record because we will make a permanent record of it. It is not, as you suggested, that there were 10,000 cases and only 2 have been found in their favor.

I think that it is important to note that there is scientific evidence that chloracne can be caused by exposure to dioxin. There is no scientific evidence to support some of the more serious allegations. That is what we are left with at this point.

Chairman SATTERFIELD. Would the gentleman yield at that point?

Mr. DASCHLE. Yes; I would be happy to.

Chairman SATTERFIELD. Out of the 10,000 cases, then, how many of them have claimed chloracne?

Mr. CLELAND. I think that we would have to supply that for the record, Mr. Chairman.

Chairman SATTERFIELD. According to an attachment to your testimony this morning, if I read it correctly, there have been five chloracne cases.

Dr. CUSTIS. Mr. Chairman, what you are reading from is that group of cases that has come up for review for possible compensation.

The 10,000 is a rough estimate of where we stand right now in terms of our register—people who are presenting themselves to our clinics for examination.

Their records are being carefully analyzed. Right now, the analysis has gone through 3,500. I think that it is approaching 5,000. It is estimated that there are as many as 10,000 records to so analyze.

We haven't completed that statistical analysis yet.

Chairman SATTERFIELD. Well, my point is that you have found two cases of service connection that are related to chloracne. It would seem to me that the proper question now would be two out of how many claimed?

Mr. CLELAND. Seven—two out of seven.

Chairman SATTERFIELD. That is two out of seven.

Mr. CLELAND. Yes, sir. It is 1,233 claims have been decided on this question, not 10,000. It is 1,233 claims that have been decided, 21 of which have been service-connected.

Again, we don't have to prove the linkage to Agent Orange in certain instances. In the two, we accepted the allegation that the veteran was exposed as fact. And because they had chloracne-like skin conditions, their cases were allowed.

In the others that were part of the 21, again we didn't have to prove linkage there with Agent Orange. There seemed to be a disability that could be traced to the service and that was service-connected.

So I think that the one thing that I agree with here is the frustration in attempting to deal with this issue. As I said at the outset, this is the most perplexing issue that I have dealt with as Administrator.

I have been all over this country in the last 2 or 3 months, and I have been on the receiving end of the frustration. And I wish more than anyone here that I had an answer.

But the scientific evidence to me is something that we are going to have to wait patiently for before we can go back and service-connect some of the more serious disabilities alleged.

Mr. DASCHLE. Well, Mr. Cleland, I would argue with you very strongly that it isn't scientific evidence, it is legal culpability, that you are concerned about.

Let us look at the questionnaire that the veterans are put through. Maybe you can answer this. You say that you were directly affected by Agent Orange. Maybe you can answer question E on the questionnaire.

Where and when did these exposures occur and what was the length of the exposure?

Mr. CLELAND. Landing Zone Nancy, north of Hue, early 1968 for a period of 2 weeks.

Mr. MCMICHAEL. I might also add, Mr. Daschle, that we are accepting for compensation purposes any veteran's claim that he was exposed to Agent Orange unless we have positive evidence to the contrary.

We will accept the veteran's word that he was in fact exposed to Agent Orange. I would like that on the record.

Mr. DASCHLE. And question J, "How long were you present at the site of the chemical exposure?" Can you tell me that?

Mr. CLELAND. Two weeks, at least.

Mr. DASCHLE. That was right on the site?

Mr. CLELAND. Yes.

Mr. DASCHLE. OK.

Mr. CLELAND. The point of the questionnaire is to get as much detail as we possibly can. If the veteran has it, fine. If he doesn't have it, fine, We will move right on.

Mr. DASCHLE. But you aren't worried about culpability? What if he can't answer these? Is he still being considered as far as the claim is concerned?

Mr. CLELAND. That is correct.

Mr. DASCHLE. You can't——

Mr. CLELAND. Suppose that the epidemiological study, or our own analysis of cancers or diseases in the VA over the last 10 years, were to indicate a high rate of pancreatic cancer, liver cancer or any kind of a disease. That would put a lot of weight on the veterans' side in such cases.

And I think that that is the key of why we need the studies.

Mr. DASCHLE. OK, let me——

Mr. CLELAND. Paul?

Dr. HABER. Mr. Daschle, what this questionnaire is designed to do is to get the veteran's statements about what he thinks his exposure was. Now, that helps us then in the epidemiological survey. But obviously in many instances the veteran himself may not know the answers.

We understand all of that, but this is part of the total record.

I would like to say, too, that I hope that it is understood that the 10,000 that we are talking about were not people who asked for compensation but rather people who presented themselves to a hospital or clinic because they had symptoms or because they were concerned.

Mr. DASCHLE. That is right. And so far, it is 2 out of 10,000 have been given compensation.

Mr. CLELAND. But all of those 10,000 have not filed claims.

Mr. DASCHLE. Well, let me ask you: Do you have a copy of the printout of the DOD listing of the Ranch Hand operation? Does the VA have that?

Mr. CLELAND. We have maps of spray missions in the Air Force going back to 1965.

Mr. DASCHLE. Do you have the entire computer printout of the Ranch Hand operation?

Mr. CLELAND. We do have that, sir.

General CHESNEY. To 1965, but there were some before 1965. There were sprayings before 1965, and we only got it in the computer from 1965 on. We sprayed from 1962 to 1965.

Mr. DASCHLE. Do you use that routinely to determine the exposure to veterans in addition to a questionnaire like this?

Mr. CLELAND. I don't know. I don't know—the problem as I mentioned earlier is not so much the spraying as the location of the troops in relationship to the spraying.

The Marine Corp information, I understand, is available on computer tapes. The Army information is not. So it is not readily retrievable.

Mr. DASCHLE. So you don't use the Ranch Hand information is what you are telling me. Is that correct?

Mr. CLELAND. Well, maybe I am not the one to respond to the question, but it seems to me that the linkage of service with the disability is the important factor.

Mr. DASCHLE. Yes; but how are you going to get it? How are you going to associate the disability if you don't use the Ranch Hand operation data?

Mr. CLELAND. Dr. Jacoby?

Dr. JACOBY. Mr. Daschle, I submit to you that the cause and effect is not there. What we are trying to do is establish whether or not they have a disease process which we can see occurring during the period of time that they were on active duty. Whether they were exposed to Agent Orange is not a factor.

That is the etiology. We are not looking at that as far as awarding claims. There are two areas that we need to look at so that there is no confusion.

The 10,000 that we are reviewing are part of an earlier epidemiological study—not the one mandated under Public Law 96–151. It is an effort to review a group of patients who claim that they were exposed to agent orange and want to be examined.

This has been ongoing for about a year, and it is the 10,000 part. There are 1,200 plus individuals who have submitted claims for disability compensation based upon Agent Orange exposure.

But there is no relationship between etiology and the awarding of compensation in the cases decided to date.

One other point, and that is that Agent Orange is not—or dioxin is not the only compound that can cause chloracne. And there are many other compounds—chlorinated biphenyls—that can cause chloracne and we can't tell whether it is the dioxin or whether or not it is PCB.

Mr. DASCHLE. But the point is that through all of your testimony you are saying that you really don't know what may cause the symptoms that we have in your chart here.

And yet when you try to draw a relationship between these symptoms and their exposure or their problems that may have surfaced as a result of that exposure, you don't even make that connection.

It seems to me that is where you are failing. How can you prove or disprove culpability if you don't even know, if you don't even use routinely the Ranch Hand data sheet as to where that was used.

It seems to me that that was a glaring error, does it not to you?

Mr. CLELAND. Suppose that a veteran came back from Vietnam and said that he was exposed. We accept that. What we don't have is information that would link exposure to long-term negative health

effects—that is a problem right there—or information as to the degree to which he was exposed.

We do know that the Ranch Hand people themselves, the pilots and the crew who flew the missions, were exposed to Agent Orange in concentrated forms, which is why the Air Force study, I think, is going to be so important.

I think that that is a very key study to watch. The point is that we don't know, really, and in many instances the veteran doesn't know the extent to which he was exposed.

Mr. DASCHLE. I would challenge your statement that you take their word for it. It is obvious that even if you use the conservative figure, the 1,233, you don't take their word for it when they tell you that they were exposed and they had——

Mr. CLELAND. Well, we don't know what exposure means. That is the problem, in terms of long-term negative——

Mr. DASCHLE. Let me go on. There are some other questions that I want to ask. Are you going to submit your protocol for the epidemiological study mandated by Public Law 96–151 to the Office of Technology Assessments?

Mr. CLELAND. Yes, sir.

Mr. DASHLE. Will the VA be doing a retrospective epidemiological study as well as a prospective study?

Mr. CLELAND. Yes, sir.

Mr. DASCHLE. When will the results from the retrospective study become available?

Dr. HABER. The first results of our retrospective study will be available within several months. This is the analysis of the 10,000 cases that have been examined by us.

Mr. DASCHLE. What contact and what work have you done with the EPA? They, of course, have mandated the suspension of the use of 2,4,5-T. What EPA interface do you have?

Mr. CLELAND. They are on our advisory committee that we created back in June.

Mr. DASCHLE. Have you reviewed the EPA decision?

Mr. CLELAND. Yes, sir.

Mr. DASCHLE. Can you provide for the record all of the pertinent memos regarding correspondence that you have had with EPA in regard to the use of 2,4,5-T?

Mr. CLELAND. Yes, sir. We should be able to provide that. Yes.

Chairman SATTERFIELD. Without objection, that will be admitted to the record when provided.

[Subsequently the Veterans' Administration furnished the following information:]

The Veterans Administration has not engaged in any formal correspondence with the EPA regarding its conclusions on the possible effects on human health of 2,4,5,-T. However, we have discussed this matter informally with the EPA's representative on our Advisory Committee. It is through these discussions that my staff became aware of the ALSEA studies on which the EPA based its rebuttable presumption against registration on 2,4,5-T. These studies concluded that women residing in the Alsea region of Oregon close to forested areas sprayed with 2,4,5-T had a higher rate of spontaneous abortions.

In contrast to this, we have also learned through our Advisory Committee that some reputable scientific groups have taken exception to the conclusion of the ALSEA study. These groups disagree that this study established a correlation between 2,4,5-T spraying and a higher than normal abortion rate among Alsea residents.

Mr. DASCHLE. Mr. Chairman, I have one last question. Some time ago, a VA physician announced that some of the results of the VA fat biopsy program—have you published a final study or any study of those results?

Dr. HABER. We are submitting the results of the study to the Office of Technology Assessment and the National Academy of Sciences, the Inter-Agency Work Group, and our own advisory work group for their review and comments. As soon as we receive their comments, we will publish the study.

Mr. DASCHLE. Thank you, Mr. Chairman.

Chairman SATTERFIELD. Thank you. I have a question and it follows along the line of those just asked. The epidemiological study which was ordered last session will follow protocols to be established and approved by the Office of Technology. What is the status of that study and the protocols at this moment?

Mr. CLELAND. Dr. Hobson?

Dr. HOBSON. The request for proposals from a nongovernmental epidemiological group to design a study is already in the process for publication in the Commerce and Business Daily. I can't give you the precise date on which it will appear, but it will be within the next week or two.

Chairman SATTERFIELD. At least it is started and you are now awaiting their establishment to actually begin the study.

Dr. HOBSON. That is correct.

Chairman SATTERFIELD. I would like to ask the Air Force the same question. You stated that you had been conducting a study based upon certain general protocols. Have your protocols been completely approved or are they subject to review? What is the status of those?

General CHESNEY. The Air Force protocol has been through three peer reviews and is now awaiting the results of the National Academy of Science. And they promised us those results within the next 2 weeks. When we get their results we will rapidly start on with the next phase of our study.

Chairman SATTERFIELD. So that all of the discussions as of this moment have been with respect to voluntary epidemiological studies created by your own protocols, but that we can anticipate in the future will be more coordinated and will be according to protocols approved at least by some independent agency other than the Air Force.

General CHESNEY. Yes, sir. And we have asked the National Academy of Science to monitor our study.

Chairman SATTERFIELD. I think that is a welcome development which should provide needed credibility to these studies. I certainly support that.

I would like to ask the VA a question. Have certain studies started already? You talked about certain studies already begun when you appeared back in October 1978. You referred to them again today. I assume that notwithstanding the epidemiological study which has been ordered by statute, these basic studies will continue. Is that correct?

Dr. CUSTIS. Yes, sir.

Chairman SATTERFIELD. I mention that because it seems to me that we are dealing with an area in which we don't know answers. I am not at all certain in my own mind that we can obtain answers by a fixed period of time.

It may very well be that latent problems might not appear for years. I don't think there is any other way to ascertain latent, long-term problems except through VA population, Air Force population, and HEW with respect to U.S. citizens over whom it has jurisdiction.

I would certainly hope that an epidemiological study with a report date certain would not end the matter.

Mr. CLELAND. Mr. Chairman, I think that one thing should be said. I think that Mr. Daschle has expressed the frustration of many veterans. I think that he is very accurate in that.

Onething that we can do right now and right up front is treat whatever disease or disability is brought to the Veterans' Administration regardless of whether Agent Orange is related or not, regardless of whether or not the studies have proven Agent Orange linkage with it or not.

The treatment is there. We have an Agent Orange coordinator in our hospitals and outpatient clinics. So that is something that can be done right away. And we understand the sense of immediacy there in terms of allaying fears, because a good deal of fear has been generated by serious allegations.

We hope that we can allay some of those fears by a good, thorough examination and making sure that the veteran understands that this is part of his permanent record.

Were anything to turn up in the future, we would be back in touch with him in that regard.

Chairman SATTERFIELD. The reason that I asked that question is because I know the Air Force apparently has an epidemiological study underway which will terminate in 1986. I wonder will that be the end of that investigation of this matter or will it continue on an ongoing basis?

General CHESNEY. We may continue on with this. The latent period for toxicity to cause cancer, for instance, can be 20, 30, or 40 years as seen in cigarette smoking and asbestos.

So we may continue, but we are right now looking it 1986.

Chairman SATTERFIELD. The reason I am interested in that is my experience on another committee where announced conclusions by Federal agencies were where a cause and effect has not been established have cooled the urge to engage in needed research. We don't want that to happen here.

I firmly believe that this investigation concerning Agent Orange ought to be a long-range study. I was pleased to hear what Mrs. Bernstein had to say about that because I agree with her.

I have one other question. There has been some discussion that perhaps a great deal of information could be obtained from the general public in terms of those people who were born in 1946—especially those who were in the Vietnam war who have passed away. Information could be gleaned from death certificates. Has any thought been directed to that sort of an inquiry?

Mr. MCMICHAEL. We will have to give some thought to that and provide that for the record.

[Subsequently, the Veterans' Administration furnished the following information:]

We concur that comparisons of morbidity and mortality data of veterans who served in Vietnam with that found among other groups of U.S. citizens might reveal some instructive conclusions. The groups compared with the Vietnam

veterans should be matched with them on the dimensions of age and sex, and, if feasible, on the basis of occupation. Among the groups that might be most productive compared with the Vietnam veterans are: Vietnam era veterans (i.e., those who did not serve in Vietnam) and nonveterans.

Particular interest in these comparisons should probably be directed to the incidence and prevalence of diseases claimed by some to be associated with Herbicide Orange exposure. Among these diseases are cancers of the liver, lung and kidney, porphyria cutanea tarda and reproductive system failures. In addition, the offspring of these several groups should be compared in terms of the prevalence of birth defects.

We have initiated such comparative studies of the incidence of selected diseases among Vietnam era veterans and other groups in our patient population. The first area of emphasis in these studies will be on cancers of the liver, lung, reproductive organs and kidneys. Subsequent studies will look at diseases of the skin, particularly acne; porphyria cutanea tarda; inflammatory liver diseases and other conditions allegedly related to Herbicide Orange exposure.

Preliminary efforts have been made to design such studies by VA staff. These efforts have shown that the required statistical data are not readily available in all instances. As a result, it is clear that specific efforts will have to be made to obtain this required data and that it will require establishment of a cooperative relationship between the VA and other relevant federal agencies to assure that the necessary data can be collected.

Chairman SATTERFIELD. All right. I am aware, and I'm sure you are, too, that the Australians have begun an investigation into Agent Orange due to similar questions which have arisen in their veteran population. I wonder whether or not there has been any effort of coordination with the Australians.

Dr. HABER. Mr. Knowles of the State Department with the Australian Desk has been in contact with us. We have shared information with him. Our information is that we will further hear from the New Zealanders in the same vein.

Chairman SATTERFIELD. And there would be coordination in the future, then?

Mrs. BERNSTEIN. We will be meeting with them within the next 2 weeks.

Chairman SATTERFIELD. Fine. Mr. Danielson, I believe has some questions.

Mr. DANIELSON. Thank you, Mr. Chairman. On the death certificates, that is the most recent thing that has come up here, I imagine, that they would mean very little unless an autopsy was performed. Isn't that true? Most people don't have an autopsy unless they die in a hospital. I imagine that there would be a limited resource at least in that area.

Dr. MOORE. [Nods, yes.]

Mr. DANIELSON. The gentleman is nodding his head.

Dr. MOORE. Yes, sure.

Mr. DANIELSON. I want to make one suggestion here which is serious with me, at least. First of all, I will prefix that with stating that I am most gratified with the quality of the information that you have all given us this morning. So I am not being critical along that line.

But I hope you will be as meticulous in the use of language in reporting your various findings as you are in the scientific investigation itself because no matter how well you do your scientific work, if it is out of focus when it is reported to us we are going to get misinterpretations, misperceptions, and the public, which doesn't deal in these subjects, is going to have twice as many.

For example, on this long chart that we have all belabored on this morning, that third category of "Disorders claimed due to Agent Orange, number deemed service-connected."

I will concede. I will stipulate that that doesn't say that they were connected to Agent Orange, but to a casual reader the mind immediately takes the next jump and assumes that these were Agent Orange connected.

I don't want you to do violence to your findings or to your conscience, but I would respectfully suggest that you might change these classifications to be more precise. You are going to have to be as precise as a Philadelphia lawyer.

And you must do that or the wrong impression is going to be conveyed. I notice this morning that I was thrown by it. Mr. Hall was. Mr. Daschle was, not just that one category, but other things.

Mr. Cleland, you must have stated four or five times in my hearing that the VA and you and your associates—that if the VA finds that a health defect had its origins during a period of time in which the person was in the military service, it is service-connected regardless of whether as a biological or pathological fact there is a service connection; simply because he became sick in the service, it is deemed service-connected.

I believe you said that or the equivalent a number of times.

[Mr. Cleland nods, yes.]

Mr. DANIELSON. Yet, some of our members have jumped intellectually to a finding of culpability. That isn't the factor you use in veterans law as I understand it. It is a time coincidence. Did the health defect appear during the time of service or within such a short time thereafter that you are going to presume a connection?

But the inference that the average person will draw from this language isn't that. It is going to jump the other step and find culpability—cause and effect—a causal relationship. And I think you have got to be careful on that because this, as Mr. Cleland said, "The public has great fear here." We all are afraid of things which are dangerous and which we do not understand.

Bad health always generates fear; and it is compounded many times over if we don't understand the cause of it, and you compound it again when you put on a name—I don't think that it is your fault, but somebody put the name "Agent Orange" on there. That is a clever name. It is repeatable, quotable, it makes a dandy headline. It would make a good name for a paperback book. It sounds like a character out of "Star Wars" or "Mission Impossible."

So I am only imploring that we use a little bicarbonate when we start putting together the reports and great precision in drawing up the names of these classifications.

Now, Mr. Daschle, who is as fine a gentleman as I have ever known, assumes that those two chloracne cases are causally related to Agent Orange. So did I until I was told that you have got service connection but you do not necessarily have—I am going to use dioxin connection. It is not so inflammable.

The same is true with the other 17 and the other 2. I think that you must be careful. I take my work on this committee fairly seriously. I think that a veteran should get every break in the world to which he is even remotely entitled, but we shouldn't screw up the findings by inadvertence. And that is what I am pleading for, if I may.

Now, I am going to get specific for a moment. The 10,000 cases—I put the word "cases" in quotes—that language is based upon really something like 1,233. Is that not correct? There have only been some 1,233 claims.

Dr. HABER. The 10,000, sir, are the people who came to the Department of Medicine and Surgery, to our hospitals or clinics, because they had symptoms, because they were worried, because they were concerned. They may or may not have filed claims for compensation. The 1,233 are people who went to the Department of Veterans Benefits and applied for compensation.

Mr. DANIELSON. Well, they are the 1,233 out of the 10,000 then who had at least enough concern about their health condition that they felt it at least appropriate to file a claim which necessarily means that the other 8,700-odd did not have that degree of concern.

Mr. CLELAND. Mr. Danielson?

Mr. DANIELSON. Yes, sir.

Mr. CLELAND. I think that there have been a few more claims other than the 1,233. The 1,233 is the number of claims that has been decided.

Mr. DANIELSON. All right.

Mr. CLELAND. It is along this level and 21 have been service-connected.

Mr. DANIELSON. Let's say—let's double it. Let's say that there are 2,500 because I am only discussing a policy here rather than fact.

Mr. CLELAND. We would like to supply the number of claims for the record.

Mr. DANIELSON. Would you? So then people will quit using this 10,000 figure. Because when you compare the No. 2 with the No. 10,000 that is way out in orbit and I think that if we used the correct figures it might not be so frightening.

Chairman SATTERFIELD. Without objection that information will be admitted to the record.

[Subsequently the Veterans' Administration furnished the following information:]

The Veterans' Administration does not maintain records on the number of claims filed alleging disability resulting from exposure to Agent Orange. Based upon our experience with those claims which have been adjudicated thus far, we estimate that not more than 2,000 claims have been filed.

Mr. DANIELSON. There is another point that has been made, but I want to emphasize it. I am trying to summarize here a little bit. It is my understanding that it is the law and it is the policy of the Veterans' Administration in administering that law to give the veterans every presumption possible in any of his claims or protestations. Is that not correct?

Mr. CLELAND. Sir, I think that the law calls for the resolution of reasonable doubt in the veteran's favor.

Mr. DANIELSON. All right. If a veteran makes a claim that he is exposed to a dioxin you are going to assume that he was, in the absence of proof to the contrary.

Mr. CLELAND. That is correct.

Mr. DANIELSON. If a veteran claims that he began to experience adverse symptoms while he was in the service, you are going to take that for granted unless you have got some evidence to the contrary?

Mr. CLELAND. Charlie?

Mr. PECKARSKY. We will accept his statements at face value. We will look at the records and see if there is any documentation.

Mr. DANIELSON. What you are looking in the records for is to find out if there is any reason not to believe it.

Mr. PECKARSKY. True.

Mr. DANIELSON. He starts off 100 percent and anything after that which erodes away depends upon a subsequent finding of some kind.

Mr. PECKARSKY. Yes.

Mr. DANIELSON. All right. I think that that is good. I am not criticizing it, but I think that the record ought to reflect that the benefit is given every intendment—reasonable intendment—from the facts associated with the case.

Now, on spraying, is it not true—I am talking to the Army colonel, I guess or general—two of them for Heaven's sake—major general.

General AUGERSON. I will be colonel when I get back. [Laughter.]

Mr. DANIELSON. You probably wish that you were only a colonel sometimes. But you are stuck. You have got two stars.

Let me ask you this: as a matter of policy the spraying was generally done where the American troops were not, isn't that true—generally I said.

General AUGERSON. I don't know if it was policy. That is the way that it worked out.

Mr. DANIELSON. All right. You weren't so interested in spraying our side of the lines as you were in spraying the cutting edge, and the other side of the line. So that is going to lead up to something.

Now, I believe this is for you, Mrs. Bernstein. I missed the first part of the testimony, but have efforts been made to examine the effects if any of this chemical on persons who work in the factories which manufactured it?

Mrs. BERNSTEIN. Yes; Jack, do you want to——

Mr. DANIELSON. Don't expand. I just want to know for sure if that has been done.

Mrs. BERNSTEIN. Yes, sir.

Mr. DANIELSON. Second, has a similar effort been made to check those nonmilitary civilian people who sprayed the people who are here in our farms, for example, in America or are in our forests—wherever it may be?

Dr. MOORE. I don't know of any well-designed study, but I do note that the Department of Agriculture is reviewing the feasibility of doing just such a study in its forestry workers.

Mr. DANIELSON. I hope that you can crank that in because, obviously, the people who did the spraying of the chemical here in the United States must have been exposed to it.

Mr. CLELAND. Mr. Danielson, can I call upon Dr. Haber?

Dr. HABER. There is a study done by the Forestry Association on individuals who were sprayed in the course of defoliating.

Mrs. BERNSTEIN. And it will be incorporated because the Department of Agriculture sits on our inter-Agency committee.

Mr. DANIELSON. Right. I just talked about sprayers. I guess that that will necessarily include the sprayees, as well.

Mrs. BERNSTEIN. Yes.

Mr. DANIELSON. Very good. Now, lastly in that regard, has any effort been made to determine whether there have been any intelligently tabulated examinations of the Vietnamese people?

They must have been sprayed with a little more than our own people.

[No response.]

Mr. DANIELSON. I know that you have got problems there, but has any effort been made.

Dr. CUSTIS. The——

Mr. CLELAND. Dr. Jacoby?

Mr. DANIELSON. Whoever.

Dr. JACOBY. The National Academy in their 1974 report referred to anecdotals of the material that they had, Mr. Danielson.

However, they did recommend a followup of this study but that has never been done. According to the newspapers, the North Vietnamese have allowed one American newspaper reporter in order to show him some results from this.

But from a scientific standpoint, no one from any country has been able to evaluate the North Vietnamese.

Mr. DANIELSON. Has—I am going to carry it just one step farther. Has it been possible to obtain any soil samples from the sprayed samples within Vietnam, and would they be useful if they could be obtained at this late date?

General AUGERSON. I believe that Major Young has something to say on that.

Major YOUNG. There were a lot of samples collected in the 1972 to 1974 studies by the National Academy of Science. With the exception of a test site where equipment was recalibrated in Vietnam, no other soils were positive for dioxin.

Mr. DANIELSON. You don't feel that further efforts along this line would produce any useful—I mean new, novel or useful information then?

Major YOUNG. Probably where the herbicides were actually stored, at the three or four bases one could find it, but elsewhere I don't believe so.

Mr. DANIELSON. Thank you. Next to last: Agent Orange is a commonly used name in this subject matter. I see that we use Herbicide Orange now and then which isn't much different. Is dioxin synonymous?

General AUGERSON. No; it is not.

Mr. DANIELSON. It is not.

General CHESNEY. It was a trace contaminant that was not even known to be in it for many years.

Mr. DANIELSON. I see. It is just a trace component and was not the active ingredient.

General CHESNEY. No, sir. It was in parts per trillion.

Mr. DANIELSON. And then I have heard 2,4,5-T is the——

General CHESNEY. That is half of the Agent Orange and there was another substance that it was mixed with.

Mr. DANIELSON. Well then I will almost have to use the term Agent Orange here because it is the greater and the others are the components within it. I wish you had a little better name like flytox or something.

And truly, last, I want to know—I think that I am right, but it has been my impression over the years in listening to and looking at these veterans problems—and this goes to a finding of 2 chloracnes and 17 other skin disorders and 2 malignancies, that in veterans

law, the veteran making the claim is given far more favorable interpretation to his claim than would be the case in an ordinary civil law suit where a plaintant is trying to blame a defendant for something. Isn't that generally true?

Mr. CLELAND. Yes, sir.

Mr. DANIELSON. Unless there is something which may be not quite so outrageous but way off base about a claim you generally will grant it if it is possible.

Mr. CLELAND. Yes, sir. That is right.

Mr. DANIELSON. The benevolence and grace that is involved in the VA honoring and respecting a claim of a veteran who has a health problem and for whom there is at least some kind of a connection with his service.

Mr. CLELAND. We would like to be perceived as the advocate although we are sometimes perceived as the adversary. But we are prepared to continue to act as the veterans' advocate in establishing service connection for disabilities.

Mr. DANIELSON. Well, I don't fight that. I think that there should be a good deal of *ex gratia* in handling veterans claims.

And Mr. Cleland, I want to tell you that I am really pleased at the way you have taken hold of your job.

Mr. CLELAND. It has taken hold of me, sir.

Mr. DANIELSON. I have seen a lot of Administrators and they are all lovely people, but you seem to know what the job is about and I thank you for it.

I am done, Mr. Chairman.

Chairman SATTERFIELD. I am at this moment going to exercise a prerogative of the Chair and make two short statements because I think they may have some bearing on the things that have been said in questions and answers which arose today.

The first one has to do with our discussion about 10,000 claims and notifications or whatever you want to call them. I am going to recite a personal experience to provide a different viewpoint into what may be happening.

Anybody who has been in combat and anybody who has been in the military is naturally going to start planning for any eventuality in order to get out whole. And that carries over into civilian life.

I happened to have received a gunshot wound—a bullet—in World War II. And out of prudence and caution, the minute I was separated from service I wrote a letter to the VA telling them that I had been hurt while in combat and that I wanted to get it on the record in case I experienced trouble in my future years.

That was a notification. It wasn't a claim. And I am confident that many of these 10,000 people are doing the same thing. They are trying to cover all possibilities.

And I don't think we ought to talk about them as cases until a firm claim is filed. In my own case, and I know that it happened to a lot of people in World War II, I was awarded a disability even though I didn't request it. Then I had to go through the trouble of refusing the money and rejecting the award. But that happens, and I'm sure my notification would have been classed as a claim.

I think we ought not to consider these 10,000 as being individuals who have a problem. A vast majority of them may be looking out for their future. They may be doing nothing more than making certain

that the VA has a record of their exposure to a possible service-connected health problem in case something happens in the future.

The second thing that I want to address is an argument that I have heard many times over, that this committee, the VA, the Defense Department and the other agencies of the Government involved aren't really going to try to find out anything about Agent Orange because of the cost if they did.

Now, this committee has stated time and again that this is not a consideration as far as we are concerned. And for those who are still skeptical I would point out that any compensation, disability, and indemnification or other payment of money if Agent Orange is found to produce a health problem would become entitlements which cannot be cut. As such, increases pose no problem and do not affect budget problems with regard to other portions of the budget.

So I think on the face of it, this suggestion really doesn't carry any weight. I cannot conceive that the VA would be concerned about it and I don't think that this committee is because this is not the area where we have our fights over budget items.

This concludes our hearings this morning. The committee will stand adjourned subject to the call of the Chair.

[Whereupon, at 12:40 p.m., the subcommittee was adjourned.]

[Subsequent to the hearing the following statements were submitted for the record.]

PREPARED STATEMENT OF ROBERT O. MULLER, EXECUTIVE DIRECTOR, VIETNAM VETERANS OF AMERICA

Mr. Chairman, I am honored to submit a statement before the Subcommittee on Medical Facilities and Benefits as part of their new round of oversight hearings on Agent Orange. I commend the Chairman, and the members of this Committee, for their leadership in calling these hearings.

The Agent Orange debate is reaching a watershed—the first major point of decision. The time is approaching where positions will be established, or perhaps have already been established, by the Veterans Administration, and maybe even this Committee.

Mr. Chairman, the Vietnam Veterans of America strongly supports the approach toward the Agent Orange compensation problem outlined in the Vietnam Veteran Act, H.R. 6050 and S. 1872, introduced by the Vietnam Veterans in Congress, and separately introduced as H.R. 6483. The Vietnam Veterans of America is deeply concerned about the continuing inability, or unwillingness, of local VA hospitals to respond fully and compassionately to the needs of Vietnam veterans exposed to Agent Orange.

But, I am more concerned that, before we all write our positions in stone, we step back a moment to look at the underpinnings of our positions. It is that which I would like to do today.

Throughout the major years of U.S. ground action in Vietnam, up through 1970, over ten million gallons of a defoliant named "Agent Orange" was used in South Vietnam. Made up of equal parts of two chemicals, 2,4,5–T and 2,4,–D, Agent Orange was contaminated by a third chemical, a highly toxic dioxin, referred to as TCDD. which is a necessary by-product of making 2,4,5–T.

Principally because of its contaminant, TCDD, major questions have arisen about the possible health effects of exposure to Agent Orange. In the last two years two CBS one-hour specials, two stories on ABC's 20/20, and lead stories in most major newspapers, (See, for example, The New York Times, May 27–29, 1979) have heightened national attention.

Many of the nation's leading papers have spoken out editorially. See The New York Times, July 5, 1979; The Philadelphia Inquirer, July 2, 1979; The Washington Post, July 21, 1979; Boston Globe, December 9, 1979 for editorials exclusively on Agent Orange. See also the Detroit Free Press, October 8, 1979; The Detroit News, November 2, 1979, for editorials on Vietnam veteran policy with paragraphs on Agent Orange.

THE PRELIMINARY QUESTIONS

Before exposure to Agent Orange can be declared a policy problem, two questions must be answered:

Are there chronic health consequences from Agent Orange exposure?

If so, were many veterans exposed?

Together, these two questions can be called the components of a risk assessment.[1] Importantly, in the last year, two events have provided guidance on both questions.

There are chronic health consequences

That 2,4,5-T contaminated by dioxin causes short-term or acute health hazards is widely recognized. But, short-term health effects may pass without chronic health impact. The question has become, accordingly, not whether there are health risks, but whether there are chronic health risks.

On March 15, 1979, the Environmental Protection Agency, for the first time, used its most extreme remedy—the emergency suspension order which allows it to remove a pesticide from the market without a prior hearing. (See, 44 F.R. 15874, March 15, 1979). The suspension was used to remove 2,4,5-T from almost all domestic markets.

The emergency suspension followed on an earlier action which established a rebuttable presumption against Regulation (RPAR) and began a comprehensive risk assessment of 2,4,5-T. (See, 43 F.R. 17116, April 21, 1978).

Both notices were based on extensive findings of chronic health risks from exposure to 2,4,5-T. (Summaries of the RPAR and the court opinion on the emergency suspension are attached.) Not all of those health risks, however, are immediately relevant to the Agent Orange question. The action considered health consequences to males and females and, in particular, to fetuses. In contrast, principally males were exposed to Agent Orange.

But, EPA did conclude that 2,4,5-T contaminated by TCDD is carcinogenic, a health risk which will be faced by exposed veterans. Because of the unique emotional sensitivity of the nation to cancer, this finding raised particular concern. But more generally, the finding of diverse toxic effects sparked a more generalized health concern. In each case, a kind of policy threshold was crossed, a prima facia case, as it were, was made. The EPA action gave official sanction to public fears that there are chronic health consequences.

Many veterans were exposed

The DOD has, in the past, maintained that even if there are health consequences from exposure to Agent Orange, there is not a significant policy problem because few veterans were exposed. (See, for example, Testimony of Major General Garth Dettinger, Deputy Surgeon General, United States Air Force, before the House Veterans Affairs Committee, October 11, 1978, pp. 1–2). The DOD's principal analysis has been:

Because of the triple canopy, almost no 2,4,5-T actually reached the ground.

But, even if it did, few veterans were exposed because troops did not enter sprayed area for four to six weeks. By then, the 2,4,5-T and TCDD would have been dissipated or broken up by the environment.

Both steps in the argument raised serious questions about what is called the "environmental persistence" of TCDD—how it acts and how long it stays in the environment. In both cases, the DOD's position is highly controversial and may conflict with their own studies. (See, The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and its Associated Dioxin/USAF, October 1978, Chapter III, especially pages III–7 to III–22).

On a simpler level, however, the argument gained its persuasiveness from its implicit statement that, scientific disputes about environmental persistence aside, few troops were exposed because no ground troops came in contact with Agent Orange.

Recently, the General Accounting Office has conclusively disproved this conclusion for the one group they were able to study in depth—the Marines. The GAO found that 5,900 Marines—3 percent of the total—were within three-tenths mile of a spraying mission on the day of spraying. They were, for all intents and

[1] In any final conclusion that a policy problem exists, the two questions will be closely connected. But, nevertheless, they must be isolated and answered separately. Debate is confused when, in the midst of a determination whether or not there are health consequences of exposure, discussion shifts to the question of whether, after all, anyone was exposed.

purposes, sprayed directly. An additional 10,600 were within nine-tenths mile on the day of the spraying missions—the distance of normal "drift" during aerial spraying. The total equals 8 percent of all Marines in the area during the 3 years covered by the study. (See, U.S. Ground Troops in South Vietnam Were in Areas Sprayed With Herbicide Orange, Report by the Comptroller General, November 16, 1979).

THE TORTUOUS TURNS OF THE HEALTH QUESTION

All significant parties in the Agent Orange dispute are agreed that science will decide. The fundamental question is, "Are there chronic health consequences?" And, the measure of that question is the medical evidence.

In seeming harmony with this, an increasing volume of the advocacy, and legislation, has addressed the need for more studies. This is accompanied by a concern to not jump the gun, to wait until the scientific question is resolved.

This turn toward science has important consequences. For a scientific determination is not a policy question. We cannot determine, as a matter of policy, that TCDD causes cancer in rats. Only science can. Accordingly, waiting on science means we can wait to make policy.

But, there is science and there is science: there are different kinds of scientific evidence. Saying science decides is fine as long as we have determined what we mean by science.

There is scientific evidence on 2,4,5-T. The evidence is clear and horrifying. But, it is principally evidence from animal experiments.

Saying we need more scientific evidence does not mean we do not have the evidence now. It means, rather, we need a different type of scientific evidence: human evidence.[2]

But, two questions are raised:

Can we get human evidence, even if we need it?

Do we need it?

Can we get human evidence?

Human evidence means, principally, epidemiological evidence. But two problems mar the use of epidemiology in policy determinations. First, for a series of technical reasons, epidemiological evidence can take a long time to develop. The Air Force study on Agent Orange, it appears, will take six (6) years. It is not unusual for studies to take a decade.

But, veterans who were exposed—predominantly older Vietnam veterans who served in country before 1971—are now at least average age 35, married with two children. Waiting a decade means waiting till they are 45.

Second, epidemiological evidence is notoriously ambiguous. Because of collection and methodological problems, it tends to produce not only a string of "maybe's," but a string of "Maybe's" that are of a special sort. The "maybe's" often do not mean that the evidence is equivocal so much as the investigators were unable to find much data that was finally usable as evidence at all, one way or another. To use a metaphor, the problem is not a lack of bodies from which to infer murder, but few fingerprints, and those we have are badly smudged. It usually means just that the study's methodology and data base was not adequate to address definitively the problem.

Importantly, the problems that plague epidemiology are not simply the product of bad studies. They are systematic, indemic to the very difficult problem of spotting specific health difference against the confusing background of complicated individual health and life histories. (See, for example, Samuel S. Epstein, The Politics of Cancer, Sierra Club Books: San Francisco, 1978; pp. 38–73).

Do we need human evidence?

Precisely because it is hard to find human evidence, the question of whether or not we actually need human evidence at all becomes more important.

EPA explicitly allows the inference of human health consequences from animal experiments for regulatory purposes. (See, 40 CFR 162.11). Similarly, the occupational Safety and Health Administration (OSHA) in its proposed rule regulating carcinogens in the work place, allowed inference from animal studies. (See FR 54148, especially, 54155 and following). And on July 6, 1979, the Interagency Regulatory Liaison Group (IRLC) published for public comment its "Scientific Bases For Identification of Potential Carcinogens and Estimation of Risks."

[2] Again, debate is confused when it moves arbitrarily from a discussion of the adequacy of the animal evidence in terms of its experimental design or statistical basis to a general criticism that the animal evidence is inadequate simply because it is animal evidence. The two discussions must be separated.

(See, 44 FR 39858). The IRLC followed OSHA in allowing inference from animal studies.

For purposes of regulation, the trend of federal policy is clear—animal evidence does provide an adequate basis to infer human risks. Human evidence is not required.

But compensation policy may create different analtytical problems than regulatory policy. It may be one thing to preempt projected risks, another to compensate for projected risks. In addition, there may be special remedial problems in paying compensation that do not exist in regulatory exposure. In each case, compensation policy may justifiably be separated out from the general trend of regulatory policy.

But, the important point is that the determination of health risk in Agent Orange policy does not wait on scientific evidence alone. Indeed, science is not the leading edge of the health question at all.

Instead, the determination waits on the formal policy standards governing the evaluation of health risks: whether human evidence should be required and the relevance of the regulatory precedents. But, it is precisely this policy determinaton which is not being made. According to the publicly available information, no agency is establishing the framework of standards which will govern the use of existing and the upcoming scientific evidence.

Without such a framework, the dispute cannot be clarified because each party implicitly applies different standards to the existing evidence and moves back and forth between fundamentally different types of critiques of the medical evidence.

All or nothing at all?

Beyond the threshold question of what will be the governing standard of medical proof, lies a second, fortunately, much simpler problem. If we decide what are the standards of medical adequacy, we then have to decide what specific symptoms of exposure we will look at.

While we might disagree over how firm the medical evidence for the various symptoms is, all parties would apparently have to agree that the evidence for certain of the symptoms is stronger than for others. Chloracne, for example, is a widely documented symptom in the existing studies of the manufacturing accidents. In contrast, because of the latency period, cancer is not as widely documented a sympton in human studies.

The question of exactly what will be our standard of medical proof gains its immediate urgency because if we can determine what our standard is, we can then apply it to the different symptoms of exposure individually. And it may very well be the case that when we do, we may be forced to acknowledge that there are a range of compensable injuries that we could act on today—without further delay.

In contrast, compensation could be delayed for any disabilities on the grounds that there are certain other disabilities that we do not yet understand. So, for example, the Veterans Administration could continue to deny claims for liver disfunctions on the grounds that we do not yet understand whether TCDD is indeed a mutagene.

This policy divided is crucial, but unexplored. Is compensation for Agent Orange related health effects a case of "All or nothing at all?" Or, can we decide the question incrementally? One disability at a time.

The problem strikes at the heart of policy implications of medical evidence. If compensation is to be paid under the policy of "All or nothing at all," then waiting on the science does indeed mean we have to wait on policy. If, on the other hand, we can attack the problem incrementally, then we have to turn now, and take our standard of medical proof—whatever we decide it is—and apply it individually to each type of symptom.

THE REMEDIAL PROBLEM

The VA estimates that 2.4 million veterans served in Vietnam during the years of spraying. The GAO found that nearly 10 percent of the Marines in the Northern I Corps faced a high risk of exposure. And the GAO report is conservative—it addressed only spraying missions, for example, bracketing the wide scale exposure from back-packed administered perimeter spraying. The number of veterans at risk may be huge.

But precisely the size of the problem creates special remedial problems. If the various health policy questions are resolved in ways that argue for compensation, then the problem becomes: can compensation be effectively administered?

At the background of the Agent Orange dispute, unspoken but yet present, is the concern that the problem may be beyond remedy.

The size of the problem is compounded by its nature. If the health policy questions are resolved in a way that argues for compensation then, at the threshold, each individual case presents two (2) fundamental evidentiary problems:

(1) How do we determine a veteran was exposed?

(2) Given exposure, how do we determine that a veteran's present disability is causally related to his exposure?

If 250,000 veterans were potentially exposed, then conceivably the VA may have to make a quarter million individual adjudications of exposure and causation. As many as 50,000 could be serious cases.

The Evidentiary Questions

Two questions are raised surrounding proof of exposure: first who has to make the showing, and second, the nature of the showing required.

Considerable problems make it nearly impossible for the veteran to establish even the probability of his exposure in most cases: lack of access to the necessary records; lack of necessary marker diseases; a lack of any reliable residual chemicals left in the body from exposure; and, in most cases, the veteran's own uncertainty of whether or not he was exposed. It may be easier for the DOD to make a determination. But even if the Department makes the determination, the question becomes what standards to apply.

Do we require proof of actual exposure, or only the possibility of exposure?

It may be impossible to show that exposure actually occurred in individual cases. On the one hand, DOD records may not be adequate in many or even a large minority of cases. But more importantly, given the absence of marker diseases and an identifiable residue, even with adequate records, we cannot, in most cases, establish that exposure actually occurred, merely that it might have.

The questions become, accordingly, whether we can draw standards that sift degrees of probability; and, if we can, what degree of probability will be required?

But, the problems raised in establishing exposure are small compared to the problems raised by causality.

It is one thing to establish that a disease may be causally related to a certain toxic chemical like TCDD. It is another thing altogether to show that an individual's specific disease was the result of exposure. TCDD may cause stomach cancers, but any individual's specific stomach cancer may or may not be caused by exposure. In any individual's case, there may have been preexisting conditions, or another cause altogether, to name only two alternatives.

With the exception of a unique marker disease—one that meets the logical condition of "if, and only if" exposure—it is virtually impossible in individual cases to go back a decade and then, unraveling ten years, move forward from exposure to any specific disease, taking account of all other possible causes.

But, the inability to show individual causations does not mean any individual cancer or liver disfunction was not caused by exposure. It very well may have been. The problem is methodological, not substantive.

A remedy

The problems of showing causation and exposure, however, are not unique to Agent Orange policy. They have occurred in a variety of other legal settings. In addition to the existing H.E.W. black lung program, for example, the entire VA compensations system is built on a series of presumptions—over 40—that various disabilities appearing after service are service connected. (See, 38 USC 301; 311–313; 38 CFR 3.1 and following). Within the VA system, for example, a presumption exists that Multiple Sclerosis, appearing within seven years of discharge, is service connected. (See Public Law 87–645, 1962).

In a recent decision that may have broad implications, the VA acted by regulation to presume that ischemic heart disease or other cardiovascular disease developing in a veteran who has certain service-connected amputations is caused by the amputation. (See Notice of Federal Register Document, August 22, 1979, Pension, Compensation and Indemnity Compensation: Proximate Results, Secondary Conditions). The action was based on a National Academy of Sciences study of mortality amongst World War II amputees and a VA literature survey. (See, Causal Relationship Between Service-Connected Amputation and Subsequent Cardiovascular Disorder: A Review of the Literature and A Statistical Analysis of the Relationship, Veterans Administration, February 15, 1979).

A similar presumption framework could be established for Agent Orange. A specific proposal was recently introduced in the Vietnam Veteran Act; S–1872 and H.R. 6050, Section 201.

CONCLUSION

The exposure of Vietnam veterans to Agent Orange may have created the largest environmental crises of the chemical age. Compensating victims will, accordingly, stretch the very fabric of our remedial structures.

But while the problem is new, and its scope huge, Agent Orange is only the first of what may be several major compensation policy questions stemming from exposure to toxic chemicals (Love Canal) or radiation (Three Mile Island).

For environmental law in America has been oriented toward the prevention of disasters, not compensation for past disasters. Its dream has been that the problems of compensation could be preempted by precluding wide-scale environmental catastrophies. That dream has been disproved.

Agent Orange policy is important not just because of the thousands of lives at stake, but because it brings the compensation problem to a head. In the final analysis, as it sets a compensation policy for Vietnam veterans, the government is also establishing the precedent for compensation policy generally.

PREPARED STATEMENT OF U.S. ENVIRONMENTAL PROTECTION AGENCY

We appreciate the interest of your Subcommittee in learning about current activities of Federal agencies as they relate to concerns of veterans or members of the U.S. Armed Forces who may have been exposed to Agent Orange and who believe that they may have been injured by their exposure. As Members of the Subcommittee know, Agent Orange was used during the Viet Nam conflict by the military. Although its two active ingredients, 2,4-D and 2,4,5-T, are also contained in herbicide products approved for certain uses in this country, Agent Orange itself was not required to be evaluated or approved under domestic pesticide regulatory law.

Before discussing the rather complex regulatory history of 2,4,5-T, and EPA's actions early last year to remove major uses from the market, we would like to give those Members who may not be familiar with our pesticide responsibilities some background information so that our actions can be evaluated in the context of our legal mandate.

The Environmental Protection Agency conducts a comprehensive regulatory program for pesticides, including herbicides, under authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. The objective of FIFRA is to ensure that pesticides will not "cause unreasonable adverse effects on the environment," which the Act defines as "any unreasonable effects on man or the environment, taking into account the economic, social and environmental costs and benefits of using any pesticide." To further this objective Congress has placed a number of regulatory tools at EPA's disposal.

First, FIFRA is a licensing law. Pesticides may enter commerce only after they are approved or "registered" following an evaluation against statutory risk/benefit standards. As I will explain in more detail later, the Administrator may take action to terminate any approval whenever it appears to him, on the basis of new information, or a reevaluation of information, that the pesticide no longer meets the statutory standard. These decisions are made on a use-by-use basis, since the risks and benefits of a pesticide vary considerably from one use to another.

FIFRA is also a use control law. Special precautions and instructions may be imposed such as requirements that applicators wear protective clothing, or restriction of use to trained and certified applicators which can mitigate risks and at the same time permit use and the attainment of benefits. These instructions, warnings and prohibitions are incorporated into product labeling, which may not be altered or removed. Comprehensive amendments to FIFRA enacted in 1972 made the use of a pesticide "inconsistent with" its approved labeling a crime, thereby providing some measure of assurance that uses are limited to those which have been evaluated and found not to pose unreasonable risks when all prohibitions, restrictions and precautions are observed. Penalties for pesticide misuse are substantially higher for persons who apply pesticides for hire than for private citizens or farmers.

FIFRA embodies the philosophy that those who would benefit by government approval of a pesticide product should bear the burden of proof that their product will not pose unreasonable risks.

This allocation of burden of proof applies both when initial marketing approval is sought and in any proceeding initiated by the Administrator to interrupt or terminate registration (suspend or cancel). Licensing decisions are usually based on tests furnished by an applicant for registration, which must be performed in

accordance with testing guidelines prescribed by EPA. Current requirements for testing of pesticides for which major uses are proposed can be satisfied only through the expenditure of several millions of dollars and up to four years of laboratory and field testing.

Pesticide registration test standards have not, however, always been as rigorous as they are today. Advances in testing methodology, and heightened awareness of the potential chronic health effects of long-term low-level exposure to chemicals which have come only within the past decade, have brought about major changes. Therefore, many products that are on the market today were subjected to risk evaluations at the time of first approval, which are plainly inadequate by contemporary standards. Congress directed in 1972 that EPA should reevaluate its licensing decisions, and those of its predecessor in pesticide regulation, the U.S. Department of Agriculture, through a process called reregistration. At the same time, FIFRA provides that manufacturers must be given time sufficient to conduct tests to satisfy any new requirements.

We hope this lengthy discussion is useful to the Subcommittee. It is especially important for the Subcommittee to understand that the fact that the govenment has once approved a pesticide for domestic use does not mean that EPA can be confident today that its use can continue without unreasonable adverse effects. Moreover, the basis for pesticide approval has for many years been risk/benefit balancing, and registration therefore should not be confused with a finding by the government that absolute safety is assured.

The toxicity of 2,4,5-T and its TCDD contaminant became a focus of regulatory concern even before EPA assumed responsibility for pesticide regulation in December 1970. Investigations of allegations that the military uses of Agent Orange could have severe deleterious human health effects prompted the U.S. Department of Agriculture to suspend uses of 2,4,5–T in waterbodies, on food crops, and around the home in April and May 1970. Of these suspensions only one, use on rice, was contested by the manufacturers of the herbicide.

All registrants were advised of these actions and two of the 2,4,5-T registrants, Dow Chemical and Hercules, exercised their right under the version of FIFRA then in effect to petition for referral of the cancellation of the rice use to an Advisory Committee. A nine-member Advisory Committee of scientists was then appointed to consider all relevant facts, submit a report and recommendations regarding registration of certain uses of 2,4,5-T and state the reasons or bases for these recommendations. Their report was submitted to the Administrator of EPA on May 7, 1971.

The Committee recommended that use of 2,4,5-T be permitted in forestry, range land, and rights-of-way, providing that a limit of 0.1 ppm of contamination with TCDD be set for all future production of 2,4,5-T; that 2,4,5-T be applied not more than once a year at any one site; and that 2,4,5-T be applied with proper caution so that it will not contaminate other areas where it may come into contact with humans. The Committee also recommended that this action be reviewed again when existing deficiencies in information about possible magnification of TCDD in the food chain were rectified by specific research.

In July 1972 the Dow Chemical Company, a major producer of 2,4,5-T, obtained an injunction against further cancellation hearings, which was later overturned by the U.S. Circuit Court of Appeals for the Eight Circuit. On July 20, 1973, EPA issued a notice of intent to hold a hearing to determine whether to cancel the remaining uses of 2,4,5-T under the 1972 revisions to the FIFRA cancellation proceedings. However, on June 24, 1974 EPA withdrew from the proceedings in order to obtain better TCDD monitoring data.

The state of our knowledge of 2,4,5-T was more limited in the sixties and early seventies than it is today. Indeed, it was more limited than the information available to EPA on other pesticides which were candidates for regulation. The lack of a detection methodology precise enough to find TCDD in environmental samples, human tissues, or market basket surveys at levels we now know to be present raised the question of whether exposure could occur at all. Secondly, the use of animal data to predict effects in humans was not so well accepted as it is today.

Regulatory agencies with responsibility to protect public health rely on carefully controlled animal experiments of varying duration and design to estimate risks of chronic hazards and acute effects. Of course, ethical considerations, as well as the practical impossibility of isolating an experimental population from all potentially harmful substances during an investigation which may require many years, do not permit human experiments for chronic effects. While confirmatory epidemiological data is useful in reaching regulatory decisions the expense and time associated

with gathering epidemiological data limit its usefulness. Further, the many difficulties in investigative design, data collection, and data validity which are commonly encountered in epidemiology create a strong bias in the direction of false negative results. These false negatives, in turn, limit the value of such studies for regulatory decisionmaking. Most health and safety regulatory laws proceed from the philosophy that potential harm which can be averted without unreasonable economic consequences should be averted, even if it is not certain that harm will otherwise occur.

Regulators and academics are not the only scientists who recognize the value of properly designed animal experimentation. Manufacturers routinely conduct long-term animal feeding studies in order to demonstrate that their products do not cause chronic effects. While use of animal testing is born out of practical necessity, such tests have been shown to have reliable predictive value (virtually all known human carcinogens are also carcinogens in test animals.)

One of the principle reasons for EPA's decision to terminate the 2,4,5-T cancellation proceeding in 1974 was our concern about the absence of exposure data to combine with the well established evidence of extreme teratogenic, fetotoxic, and carcinogenic toxicity of 2,4,5-T or TCDD.

In July 1975 EPA promulgated new procedures designed to make easier our work in reaching conclusions on pesticides which had been identified as being "suspect" of causing serious adverse effects. We felt that the new approach, described as "Rebuttable Presumption Against Registration", or RPAR, would complement the statutory mechanisms for pesticide review which, because of their adjudicatory nature, tend to make it difficult for some interested parties to participate. Also, RPAR was expected to offer advantages in collecting additional toxicity or benefits data needed to reach sound public policy decisions, where there were obvious deficiencies in the existing data base in spite of years of official and unofficial concern about possible health effects.

On April 27, 1978 EPA issued a Notice of Rebuttable Presumption for 2,4,5-T and a related dioxin-contaminated herbicide, Silvex. This document summarized the extensive toxicity testing which had been undertaken for these chemicals and TCDD by manufacturers, academic researchers, and the government. We encouraged the public to supplement this information with further scientific evidence concerning risks, and with economic analyses of the impact of cancellation for the various uses of the herbicides. We received thousands of submissions. Among these was a carefully presented account of what appeared to a member of the lay public who contacted us to be an unusual incidence of miscarriage in an area of Oregon where forest use of 2,4,5-T and Silvex is an annual occurrence. After interviews with the women who had experienced the miscarriages, EPA decided that our epidemiologists should investigate records of hospitalization for miscarriage. In the first weeks of 1979 EPA found a statistically significant increase in miscarriage frequency in areas of 2,4,5-T use in forestry which correlated in time with spray operations. It is important to note here that we did not claim that the study proved a cause and effect relationship between miscarriage and the spraying. Rather, we concluded that the correlation which existed was consistent with what one would expect based upon the available animal data and if exposure was occurring; and that the study therefore suggested evidence of the previously undiscovered human exposure link. This evidence became available literally on the eve of the large scale spring herbicide treatments that are conducted annually in commercial forestry.

On February 28, 1979, EPA took emergency action to halt forest spray operations and other major uses of 2,4,5-T and silvex. The emergency action withstood almost immediate challenge in the U.S. District Court for the Eastern District of Michigan. Following the Court's ruling, the Dow Chemical Company and other registrants withdrew from EPA's administrative suspension hearing. This hearing opportunity is accorded to registrants by the statute as an expedited mechanism through which to present evidence as a basis for modifying the suspension order.

Suspension under FIFRA is analagous to a temporary restraining order. It is based on a finding that the risks of continued use during the period required to complete a cancellation hearing outweigh the benefits that would be foregone during that period (historically, 1–3 years). The cancellation hearing is the mechanism by which evidence is adduced and tested concerning the totality of risks and benefits resulting from use of the pesticide over its life. The consolidated hearings on whether all uses of 2,4,5-T and Silvex, a related herbicide, should be finally cancelled are expected to begin next month. The suspension and cancellation notices issued by EPA, as well as the Agency's pretrial brief on the risks of 2,4,5-T and Silvex which was recently filed with the Administrative law judge will be maintained in the Committee file of this hearing.

Before closing we should mention that information on the risks of 2,4-D, the other constituent of Agent Orange, is undergoing an intensive evaluation to determine the significance of studies of its reproductive and inheritable (mutagenic) effects. We recognize that 2,4-D use may increase since 2,4,5-T is unavailable for many of its former uses and for that reason an early decision on whether the risks of 2,4-D warrants issuance of an RPAR notice or some other regulatory action is desirable. Although theoretical chemists believe that one dioxin isomer (2,7dichlorodioxin) could be formed during the manufacture of 2,4-D, no dioxins have been found during years of study.

We hope that this account of EPA's regulatory actions under FIFRA will compliment the extensive testimony you have received from other agencies who are investigating exposure to phenoxy herbicides with a view toward developing appropriate public policy where that exposure may have occured due to military service. EPA is an observer to the interagency work group established last December, and in that capacity will share with the work group information which we develop or which comes to our attention in the conduct of our duties under FIFRA which may be of value in its efforts.

Thank you.

STATEMENT OF PHILIP R. MAYO, SPECIAL ASSISTANT, NATIONAL LEGISLATIVE SERVICE, VETERANS OF FOREIGN WARS OF THE UNITED STATES, TO THE SUBCOMMITTEE ON VETERANS' AFFAIRS, UNITED STATES HOUSE OF REPRESENTATIVES.

Mr. Chairman and members of the subcommittee: Thank you for the privileg[e] of presenting to this distinguished Subcommittee the views of the Veterans of Foreign Wars of the United States with respect to the herbicide commonly known as Agent Orange.

Mr. Chairman, as you are no doubt aware, considerable adverse media space and time has been devoted to the disturbing allegations made with regard to the health hazards experienced by Vietnam veterans as a result of their exposure to the herbicide known as Agent Orange, which contains a highly toxic substance, dioxin. In addition, similar attention has been afforded the cases of various people so exposed in the continental United States as a result of the commercial use thereof for the purpose of weed and forest control.

Further, contradictory positions emanating from the scientific community, some indicating the existence of serious problems and others the opposite, have hindered accomplishment of meaningful scientific investigation into the effect of such herbicides on humans. In addition, after the passage of legislation which became Public Law 96–151, providing therein for a VA study of the effects of herbicides on our veterans, an additional piece of legislation, which provided for a more far-reaching investigative effort through other agencies of the government, was recently vetoed. Unfortunately, these events have served to further incite and confuse veterans as well as the general public, thereby making adverse media coverage of herbicide exposure more newsworthy.

Mr. Chairman, the voting delegates to our most recent V.F.W. National Convention held in New Orleans, Louisiana this past August, recognizing the necessity for expeditious action with regard to scientific investigation into the potential health hazards of dioxin, adopted Resolution No. 618, entitled Herbicide Exposure, which dictates that ". . . .we use every means at our disposal to insure an accurate and timely completion of studies to resolve this question, be the studies either conducted within or independently of the Veterans Administration." It is to this end that the V.F.W. has utilized the resources of its publications, various conferences, V.F.W. Posts and Departments, and our Service Officer Network to encourage every Vietnam veteran who may feel he has suffered as a result of such exposure to seek examination and make his symptomology a matter of record.

And, it is in outreach that the V.F.W. feels that the VA has been most remiss in meeting its responsibilities to our veterans. When one considers the content of radio and television "spots" sponsored by the VA, he hears the Administrator extoll educational and home loan benefits, but not the advantages of seeking examination and advice concerning, and treatment for, health problems, particularly those which may be service related such as herbicide exposure. This apparent reluctance on the part of the VA, whether or not intentional, we believe, coupled with adverse media coverage, may have contributed to the apparent reluctance of Vietnam veterans to seek examination. Outreach programs undertaken thus far, according to the best information available to us, have been on a local basis without VA initiative but with VA cooperation once they were in operation. When the

decrease in the number of "Veteran Representatives" on college campuses over the years is considered, one must ask if they would not be an excellent source, with their demonstrated knowledge and ability, to plan and execute an outreach program for the purpose of aiding Vietnam veterans. Similarly, aggressive VA sponsored outreach programs conducted with the aid of employers, through national business organizations, and through the communication media would also help identify veterans so exposed.

In addition to the foregoing, we are convinced that the utilization of the resources of the "Vet Centers" program in conducting such an outreach effort to be of primary importance in the VA's ability to maintain its credibility and to resolving this question. Should the VA fail to utilize this resource, with its obvious potential, one could conclude therefrom that there exists some degree of reluctance to establish etiology which might generate a large volume of compensatory claims.

Mr. Chairman, the V.F.W. is also mindful of the budgetary limitations that have been and continue to be imposed upon the VA and its hospital and research resources. We solicit your support in our efforts to rectify this situation, as we will unquestionably aid this Subcommittee in similar efforts it will surely undertake in the near future. Obviously, without adequate funding, advances in herbicide research will be slowed or nonexistant.

Mr. Chairman, the V.F.W. commends you for holding this hearing, thereby bringing into the public forum information concerning the advances made on the studies of the herbicide Agent Orange. We believe that periodic and timely oversight of this nature to be an indispensable component in the completion of those studies and to allaying the fears that many bear as a result of the uncertainties surrounding this issue. We believe this issue should be met squarely and forthrightly, inasmuch as our Nation's veterans deserve no less.

Thank you.

RESOLUTION NO. 618

HERBICIDE EXPOSURE

Whereas, defoliants, the most commonly known being "Agent Orange," were utilized extensively in Vietnam; and

Whereas, many of this Nation's Vietnam veterans were exposed, in varying degrees, to these toxic defoliants; and

Whereas, some researchers contend that dioxin found in herbicides cause cancerous tumors in test animals in concentrations of as little as five parts per trillion; and

Whereas, other researchers contend that exposure to herbicides containing dioxin cause health defects, nervous system disorders, liver dysfunctions, genetic changes, spontaneous abortions or miscarriages, nausea, dizziness, and skin disease; and

Whereas, some experts contend that dioxin concerns are considerably overblown and that no medical evidence exists to substantiate compensatory claims; and

Whereas, these factors, as well as several industrial accidents involving dioxin, have brought about one of this Nation's most heated and potentially wide-ranging controversies; now, therefore, be it

Resolved, by the 80th National Convention of the Veterans of Foreign Wars of the United States that we use every means at our disposal to insure an accurate and timely completion of studies to resolve this question, be the studies either conducted within or independently of the Veterans' Administration.

Adopted by the 80th National Convention of the Veterans of Foreign Wars of the United States held in New Orleans, Louisiana, August 17–24, 1979.

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