STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON MEDICAL FACILITIES AND BENEFITS

OF THE

VETERANS AFFAIRS COMMITTEE

HOUSE OF REPRESENTATIVES

FEBRUARY 25, 1980

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. Regretably, 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 3 1/2 million acres of South Vietnam. During this time, Agent Orange constituted 94% 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 that 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 strength, loss of libido, impotence, infertility, abdominal pains, sweating, tremor, pallor, change of personality, irritability, insomnia, and difficulty in concentration.

Two other problems are of significiant 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 congenital 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 physiological 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.

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. Since many types of studies that can be performed with these chemicals in animals 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. Administation 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 occurred 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 Environmental 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 2,4,5-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 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 abortions 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.

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 Central 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 known 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 Advisory 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 not be 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 in 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 directed.

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 a 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 perspective 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 disabiity 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 many 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

servicemembers 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 biospy 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 epidemiologist 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 objective 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.

In its efforts to resolve the Agent Orange issue, the VA is maintaining 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% 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 atep 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 VA. 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 Sciences, 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 workers 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 P.L. 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 P.L. 96-151, will be completed by December 1980.

- The VA's Agent Orange 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 regardless of causation. We owe them no less.