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SUMMARY REPORT OF

THE PUBLIC MEETING OF

THE INTERAGENCY WORK GROUP TO STUDY

THE POSSIBLE LONG-TERM HEALTH EFFECTS

OF PHENOXY HERBICIDES AND CONTAMINANTS

held

September 22, 1980

Washington, D.C.

Panel Members from the Interagency Work Group
to Study the Possible Long-Term Health Effects
of Phenoxy Herbicides and Contaminants

Joan Z. Bernstein, Department of Health and Human Services, Chair
Dr. John A. Moore, Department of Health and Human Services
Leslie A. Platt, Department of Health and Human Services
Maj. General William Augerson, M.D., Department of Defense
Dr. Donald Barnes, Environmental Protection Agency
Dr. Michael Gough, Congressional Office of Technology Assessment
Dr. Patricia Honchar, Department of Health and Human Services
Dr. Phillip Kearney, U.S. Department of Agriculture
Dr. David Logan, Occupational Safety and Health Administration, Department of Labor
Dr. Harold Margulies, Department of Health and Human Services
Guy McMichael, Veterans Administration
Dr. David Rall, Department of Health and Human Services
Kathy Schroeher, Department of Health and Human Services
Dr. Barclay Shepard, Veterans Administration

INTRODUCTION

The Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants was established by the White House in December 1979. It oversees all Federal research efforts regarding the possible health effects of phenoxy herbicides, such as Agent Orange, and is charged with reporting to the public the results and implications of this research.

The Work Group is chaired by Joan Z. Bernstein, General Counsel of the Department of Health and Human Services. It includes representatives of the Departments of Defense and Health and Human Services and the Veterans Administration. Representatives of the Environmental Protection Agency, the Departments of Agriculture and Labor, the White House Office of Science and Technology Policy and Congress' Office of Technology Assessment also participate as observors.

On August 29, 1980, a notice was published in the Federal Register announcing that a public meeting would be held on September 22 in Washington, D.C. The public was invited to appear before the Work Group to summarize written statements and to submit questions for response by the Work Group during the meeting.

SUMMARY OF THE PROCEEDINGS

Following opening statements by Ms. Bernstein and Dr. John A. Moore, Chair of the Work Group's Scientific Panel, eleven persons representing organizations or speaking as individuals presented statements to the Work Group. The Work Group then responded to twenty-one questions which had previously been submitted in writing by eight individuals, as well as to several questions from the floor.

Mr. Stuart Eizenstat, Assistant to the President for Domestic Affairs and Policy, also made a brief statement.

Statements and questions for the record were received from a number of persons who could not attend the meeting. Written responses to such questions have been provided by the Work Group and are included in this report.

Approximately 75 persons attended the meeting.

OPENING STATEMENTS

Joan Z. Bernstein
Chair
Interagency Work Group

I would like to summarize briefly what the Work Group has done since we came into existence.

Our task is extensive. We were directed to oversee, coordinate, and set priorities among relevant Federal Government research activities. We were to design a research agenda and organize the means by which that research agenda would be carried out.

I believe we are making significant strides in carrying out that task. So far, we have identified all research activities being conducted by the Federal Government relating to phenoxy herbicides and Agent Orange; identified those areas where additional research is required; and arranged for necessary funding to be made available on a cooperative basis to meet those research needs.

I am pleased to note that the Work Group's interim research agenda has been endorsed by the National Research Council of the National Academy of Sciences.

In addition, members of our Scientific Panel have been in contact with scientists outside of the Federal Government who are involved in related research activities, including scientists in Europe and elsewhere who are conducting follow-up studies of occupational exposures to phenoxy herbicides.

The Work Group takes seriously our pledge to conduct a thorough, objective and scientifically impeccable examination of the possible health effects of exposure to phenoxy herbicides, including Agent Orange. As I have said in testimony before the Congress, we owe the Vietnam veterans and their families nothing less.

We also take seriously the health concerns of Vietnam veterans. We do not underestimate the veterans' very real worries about their health or the health of their offspring. While we are making our best efforts to fulfill our commitment to the public and especially to the Vietnam veterans and their families, it is becoming increasingly apparent that science is not likely to be able to answer all of our questions. Nevertheless, the Work Group intends to carry out the work that can be done and must be done in a thorough and timely manner.

Given what we know about phenoxy herbicides and recognizing that additional scientific inquiry will take time, the Work Group asked its Scientific Panel to report on current knowledge about Agent Orange and the time that will be required before gaps in our knowledge will be filled. In preparing its report, the Panel reviewed research already under way as well as research still in the planning stage.

The Panel concluded that, with the exception of a few studies whose results will be known in the next few months, it is unlikely that our scientific knowledge about the long-term health effects of Agent Orange will increase significantly in the next six months and that two to three years longer will be required.

A major stumbling block to conducting studies of the effects of Agent Orange on the health of Vietnam veterans continues to be an inability to identify a population of ground troops, the nature and extent of whose exposure to Agent Orange can plausibly be reconstructed or documented with any degree of reliability.

Unfortunately, records which were kept of Agent Orange spray missions and coincident ground troop locations, along with names of individual troop members, may not be adequate to document the nature and degree of exposure of individual ground personnel to Agent Orange.

For that reason, the Work Group examined other ways to obtain data on the health effects of Agent Orange on veterans. The Work Group believes the most promising alternative at this time is the Epidemiologic Study of Ranch Hand Personnel proposed by the Air Force.

Therefore, the Scientific Panel and the full Work Group seriously considered the merits of the Ranch Hand study, which is designed to determine what health effects, if any, have occurred among this heavily exposed population.

The Work Group concluded that the study will be useful, although its results will not be able to be used to establish a quantitative risk for specific health decrements among ground troops. This is because the exposure of Ranch Hand personnel to Agent Orange is estimated to have been much greater.

However, if the Ranch Hand study does detect adverse health effects, those results should be useful in providing a focus as to the type of health effects that may possibly occur in other veterans.

Furthermore, neither the Ranch Hand study nor any future studies of ground troops will tell us whether Agent Orange is the cause of particular health effects among veterans, especially if the studies do not identify any rare or unique diseases associated with Agent Orange exposure.

Moreover, many of the health effects about which concerns have been raised by veterans and others are already known to be found in the general population as the result of other factors.

What the Ranch Hand study and similar studies will be able to do, however, is define an association between exposure to Agent Orange and an increased risk of particular health effects.

Given the limitations on what scientists may be able to tell us in the future about the general long-term health effects of Agent Orange and its health effects on individual veterans, the Scientific Panel recommended and the Work Group agreed that additional studies should be conducted which focus on the health status of Vietnam veterans.

Such studies should determine whether service in Vietnam, rather than solely Agent Orange exposure, may have placed Vietnam veterans at a greater risk of suffering certain adverse health effects.

The Work Group also agrees that the focus of the Veterans Administration's epidemiologic study of Vietnam veterans exposed to Agent Orange or dioxins, which is required by P.L. 96-151, should be broadened to include an examination of the overall health status of Vietnam veterans as a result of their service in Vietnam.

We are pleased that the Senate recently voted to authorize the VA Administrator to expand the scope of the VA study in that manner. We are gratified by the show of confidence in the Work Group's judgment in this regard as indicated by the Senate's support of this modification.

I also believe that the overall approach of the Senate proposal for a framework by which decisions can be made about the veterans' claims for benefits based on adverse health effects suffered as a result of exposure to Agent Orange or other aspects of service in Vietnam is a creative response to a critical aspect of the Agent Orange problem which deserves careful consideration.

The Work Group also recommended to Stuart Eizenstat that the Ranch Hand study be conducted by the Air Force. We conditioned our approval on a commitment by the Executive Branch and the Congress that the evaluation may have to continue for a period of time much longer than five years -- and perhaps up to 20 years -- in order to improve the chances of detecting and validating latent or subtle effects.

The Work Group recommended that the Ranch Hand study be conducted by the Air Force because it is convinced that significant delays in beginning the study -- and thus in obtaining even preliminary results -- would otherwise occur.

However, the Work Group recommended that the conduct of the study be overseen for at least the first five years by an independent monitoring committee, comprised of representatives of the Work Group, scientists from the private sector and academia, and persons with scientific backgrounds nominated by veterans organizations.

Mr. Eizenstat has concurred with the Work Group's recommendations.

In addition to the Ranch Hand study, the Work Group has considered and initiated a number of other scientific activities. VA, DOD, and HHS will be signing an interagency agreement in the next several weeks to fund a birth defects study to be conducted by HHS' Center for Disease Control.

The purpose of the two-year study is to determine whether Vietnam veterans are at an increased risk of siring children with birth defects, a major concern among veterans.

The study is not expected to provide data on infertility among Vietnam veterans or on reproductive problems other than major birth defects. However, it is consistent with the Work Group's view that additional studies should be conducted which focus on service in Vietnam as a possible causal factor.

The birth defects study will also build on the results of an important study released last month on whether exposure of male mice to Agent Orange is associated with birth defects among their offspring or infertility. Dr. John Moore, Chair of our Scientific Panel, is one of the authors of the study. The study found no significant increase in birth defects among their offspring.

The male mouse study, together with ongoing tests of the mutagenicity of the constituents of Agent Orange, should permit our scientists to form a reasoned opinion in the next few months as to whether a scientific basis exists for concerns that Agent Orange exposure may increase the risk of males siring children with birth defects.

Vietnam veterans are also concerned that they may be suffering from a higher incidence of cancers than is expected in a population their age. In connection with that expressed concern, the Scientific Panel reviewed one German and four Swedish scientific papers on the carcinogenicity of the chemical constitutents of Agent Orange.

The Panel concluded that despite the studies' limitations, they do show a correlation between exposure to phenoxy acid herbicides and an increased risk of developing soft tissue tumors or malignant lymphomas. The Panel also noted that independent verification would further validate these studies.

The National Cancer Institute and the National Toxicology Program have completed a cancer bioassay on TCDD, the dioxin contaminant in Agent Orange. The results confirm earlier reports that TCDD is carcinogenic in laboratory animals.

The Work Group is convinced that we need to conduct a large-scale study of the Vietnam veterans population. We need to know whether Vietnam veterans are as healthy as a population of their size, with comparable age and other characteristics, who did not serve in Vietnam.

If not, we need to know what specific health problems are occurring with abnormal frequency. We can then further refine our inquiry to try to determine the likely cause or causes of a particular health effect occurring with higher than normal frequency.

Again, on behalf of the Work Group, I would like to welcome all of you to this meeting. We look forward to a productive exchange on these important issues of public concern.

I will introduce the gentleman who has served a very important function and has already been introduced once, Dr. John Moore, the Chair of our Scientific Panel.

Dr. John A. Moore
Chair
Scientific Panel

For those of you who are scurrying for the written copy of what I was going to say this morning, I will save you some effort. Since you have that, you can read it any time you like. What I am going to say will not necessarily follow that document.

As the title of the Work Group signifies, our responsibilities extend beyond Agent Orange. But in the months we've been in existence, there is no question that a substantial amount of our time has been focused on the Agent Orange issue and, to a lesser extent, on the public health implications of phenoxy acids which might be associated with their use in non-Vietnam circumstances.

What is the issue? At the sake of being a little redundant, I think the basic issue as it relates to Agent Orange is that there are veterans and others who are concerned that Agent Orange use in Vietnam, and obviously presumed exposure to that substance in Vietnam, is having, has had or will have adverse health effects, principally in the long-term.

By long-term, I think what we are talking about is that months, years, or even decades after exposure to those agents, one might come up with a sequelae of health impairments that is a consequence of that earlier exposure.

Let's pursue this a little further. What is the nature of some of these health concerns? I think it is fair to say that the health concerns have no single focus. Indeed, the variety of health concerns alleged or feared ranges from cancer to infertility to birth defects in offspring to nervous disorders and to skin lesions, to mention but a few.

Why Agent Orange? Certainly I think it is reasonable to assume that somebody was exposed any time roughly 100 million pounds of a chemical are used in a country over a period of several years. Events that led to its curtailed use and final suspension in the Vietnam war were a consequence of concerns that exposure to 2,4,5-T, or specifically the TCDD contaminant in 2,4,5-T, might be associated with birth defects.

Certainly a variety of incidents occurred in this country that also build on the concern of some people that health consequences may be associated with it. To mention but a few, there are allegations or concerns of an increased incidence of birth defects or miscarriages among women exposed in places such as Alsea, Oregon. The Long Island Railroad has workers who are concerned that they may be at risk of cancer.

The EPA action of a year and a half ago to suspend the use of 2,4,5-T in a majority of its applications in this country also, I think, raised suspicions that something is going on. 2,4,5-T, or more particularly its TCDD contaminant, has been a subject of scientific fascination for the last decade, simply because of its exquisite toxicity as well as the way in which it asserts its toxic effect. A number of scientists have said that TCDD is the most toxic man-made chemical known to man. To hear a statement of that sort certainly catches the attention of even the casual listener.

Certainly the Vietnam concerns, as well as the domestic issues I have mentioned, have received their play in the media. I think there is a general awareness that there is something that relates to 2,4,5-T or TCDD and, of course, Agent Orange. 2,4,5-T represented 50 percent of what was Agent Orange.

What do we know? 2,4,5-T has been in use in this country and throughout the world for several decades in a variety of applications. A number of industrial accidents occurred associated with its production and manufacture. The first accident occurred in this country in 1949 -- some 31 years ago.

Most accidents involved a relatively small number of workers who were heavily exposed. In a number of instances, a long time has elapsed since their exposure. Therefore, we can learn something from those people as to what has happened to their health.

Some of the first evidence that 2,4,5-T -- more specifically TCDD -- can cause chloracne came out of studies of those people. Those studies have shown that chloracne can persist for decades after exposure.

In other instances, the chloracne disappeared. The evidence out of Seveso, Italy, where three years ago there was an accidental exposure of the general population to TCDD, rather than the worker population, was that chloracne appeared.

In that case, as is typical in most of the known exposures, the chloracne was somewhat mild and transient and disappeared over a period of time. The instances of chloracne which have persisted for a number of years or decades are clearly sequelae of some of the massive exposures in occupational accidents.

There has also been evidence of liver effects, decreases in the ability of the nerves to conduct impulses and alterations in lipid metabolism.

Without exception, I believe all of the occupational exposures have involved males. No females were involved in these occupational accidents. However, as near as I know, there is no information dealing with fertility, birth defects or birth outcome among the offspring of these exposed workers. The data simply has not been collected.

There is no unequivocal data from a follow-up of these people with regard to long-term effects. Some of the known exposed populations have been poorly followed. We also have the problem of small population -- you won't see something in that population.

Indeed, I think one of the major frustrations, which also applies to the Agent Orange issue, is that no specific disease has occurred -- no unique constellation of findings -- with the possible exception of chloracne.

As to the liver effects, the lipid effects or any of the other type of effects, one can find a variety of possible causes. These effects are not unique, like mesothelioma, a rather unique tumor such that when one sees it, you almost have to say it is asbestos-related because it is so rare. Another example is vinyl chloride and angiosarcoma.

This just does not occur as far as we know as a consequence of Agent Orange or phenoxy acid exposure. If it did, it would be much easier.

A number of ongoing activities are following occupational exposures. One is the NIOSH dioxin registry. It is trying to enroll and follow-up on in a systematic fashion all workers exposed to 2,4,5-T or dioxin in a worker setting, with the hope being that if you combine them together, you might have a big enough population to look at from which you can draw some conclusions.

Taking that one step further, we are actively trying to establish an international registry which will allow us to pick up a number of the accidents that have occurred outside of this country, most notably some in Germany, Czechoslovakia and Britain. Again, the intent is that we would have a large population from which to glean some results. Follow-ups are already ongoing of some of these past exposures.

We have maintained contact particularly with the British and Czechoslovakians to find out what is the current health status of their exposed worker populations. Not much has been reported on them in the literature in recent years. We were told in both instances that further reports are due out between now and the end of the year.

Seveso, Italy, while not a long exposure from the standpoint of the time that has elapsed since exposure, does represent a rather significant exposure given the number of people involved. This is also being followed.

There are also a number of studies going on in this country some of which you will hear about today from the witnesses who will appear later. A West Virginia accident which occurred in 1949 is currently in the process of being looked at simultaneously by two studies. One study is being conducted by the Mt. Sinai School of Medicine and the other by the University of Cincinnati. This is certainly information we hope will give us some insight as to the nature of the effects associated with long-term consequences of exposure.

We certainly want to follow all of these studies. The reason we have an interest in following these as far as they are related to Agent Orange is very simple. They involve known exposures, so there is no issue of who was exposed and who was not exposed. They also involve very heavy exposures and one of the basic foundations of toxicology is that there is typically a dose response relationship between exposure and the likelihood of health effects. Indeed, the chances of finding health effects among the most heavily exposed population are much greater than among those who were maybe casually exposed.

Also, as I mentioned, the time lapse that has occurred in some of these exposures will give us some hint as to the long-term sequelae. Any effects associated with these studies will give us, I would say, concrete ideas as to the nature of health effects that should be looked for in all exposed populations.

A number of toxicity studies of TCDD have been done and some are ongoing. TCDD is known to be a teratogen in mice and to be fetotoxic in low dose levels in almost all animal species that have been looked at.

It is known to persist in the body for a long period of time. It is not the type of chemical that, if you get exposed at 10 o'clock this morning, is gone by 12 o'clock today or tomorrow. It is known to persist for up to two months in the tissues of animals exposed.

However, one of the problems with this type of information is that there is marked species variability as to how long it stays in the body. In some species, it is removed rather rapidly and in others, it may persist for up to a couple of months. When you try to extrapolate this data to a human population, you don't know which animal species to use.

TCDD has been found to be a carcinogen in animal studies. It was associated with increased carcinogenic risk in three rat studies and one mouse study.

TCDD is also known to be associated with immunosuppression. However, there is also evidence that low doses of exposure might enhance one's immune capabilities. There are no clear-cut black and white answers yet.

The immuno enhancement is clearly a finding that the Italian scientists reported as a consequence of their follow-up of some of the children exposed in Seveso, Italy. It tends to suggest that the effects on the immune systems -- or one's ability to resist infectious disease -- may be related to dose. Very low doses might stimulate immune capabilities and a higher dose level might result in a more profound type of suppression.

There is certainly species variability as to the nature of the type of toxicities observed. In general, I would say the animal toxicity studies give a good qualitative suggestion as to the nature of effects or the organ systems attacked. What they don't do is give any quantitative estimate as to the likelihood of effects in humans from a given exposure.

The inability to give a quantitative estimate, say with cancer, certainly is not unique to TCDD. That is one of the problems with our current state-of-the-art with regard to all cancer studies. We can say a risk is associated with it with some degree of assurance. But science has difficulty trying

to establish the degree of that risk -- one in a million, one in a billion, one in a hundred.

But again, the animal toxicity studies, as do the occupational studies, suggest the type of health effects to look for in any study in humans.

A number of ongoing studies are trying to determine if TCDD, 2,4-D, 2,4,5-T or those chemicals in combination have the ability to cause a mutagenic insult or to cause genetic damage.

A variety of efforts are under way to develop better analytical methods for detecting TCDD. A lot of studies under way are trying to understand various facets of how TCDD does what it does. I would characterize these studies as more in the nature of basic research thrusts.

To summarize, I think the studies that are available certainly have told us a lot. Unfortunately, however, I don't think they have told us enough. There is still much to learn. Often many of the studies raise more questions that need to be pursued than the number of questions they answer.

But certainly we need to continue these types of studies and someday, hopefully, we will get some definitive answers. However, I don't think we can sit back and wait for this magical data to appear. We don't know if it will appear next week, next month, next year or ten years from now.

Indeed, it probably does not need to be stated to this audience that the veterans' concern is an issue now, not a decade from now or two decades from now. The concern is right now. There are a number of veterans who feel they are suffering health impairments as a consequence of their exposure in Vietnam, and I don't think we can wait for the classic epidemiological studies in occupational or laboratory settings to give us those answers.

Obviously, the simple thing to do is the straightforward approach -- identify veterans who were exposed and design and conduct a study on those veterans. Quite likely, you will have more than one study on veterans because of the wide variety of disease parameters that need to be looked at.

However, as has been pointed out, we seem to have trouble getting to first base on this approach because we are having great difficulty identifying a population to study whom we can say with some degree of certainty was exposed.

Obviously, a classic exception to that is the Ranch Hand population of roughly 1100-odd Air Force personnel involved in the distribution of roughly 100 million pounds of Agent Orange. We will come back to this group a little further along.

One of the frustrations everyone in general as well as the Science Panel has is why can't ground troop personnel be identified. Simply stated, no systematic records were kept for this purpose to enable us to go back and benefit from the existence of those records a number of years later.

Another fact that certainly confounds the issue is that our leaving of Vietnam was not done in the most orderly fashion. Indeed, there is very good evidence that some of the records we do have are not neatly filed away, as a result of the rapid pull-out that occurred. That is especially true of the army records, as I understand it.

Efforts are under way to see if we can identify ground troop personnel. We on the Scientific Panel are not interested in identifying who among all of the better than 2 million veterans in the Vietnam theatre were or were not exposed. We can certainly get on with the types of studies that we feel need to be done with a more modest population of several thousand. So our search is maybe more limited than the records needs of others.

An effort has been under way for several months to identify a battalion of marines and battalion of army personnel in Vietnam to see if we can find any evidence that would correlate their position on any one day or days with the HERBS tapes the Air Force maintained. The tapes identify generally where they sprayed Agent Orange, on what days they sprayed it and on what days they came back and sprayed a second or even a third time.

That effort has recently been completed and it is my understanding that a report was transmitted to the Scientific Panel last Friday for our review. We will review it thoroughly.

We are also aware of the fact that the General Accounting Office was consulted on the design and conduct of this search effort. We have talked to GAO and intend to talk to them some more to get the benefit of their findings as well as what insights they may have from their previous effort which led to the GAO report suggesting that marine records might serve us in identifying gound troop personnel.

I might mention in this regard that early on in the search Dr. Honchar and I did spend a number of hours with Department of Defense personnel during which they outlined to us the nature of their approach and what they hoped to accomplish.

Without prejudicing what we will find when we examine the report in detail, I think I would be less than candid if I did not share with you that, at least from the verbal briefings I have received on the content of this report, one need not be overly optimistic that DOD has succeeded in its efforts to identify with any degree of certainty ground troops who were exposed to Herbicide Orange.

That's not to say that it didn't happen, but only that they cannot verify it. I am sure there will be further attempts after we review the DOD report and talk to GAO and others. I am sure other ideas may pop up that would suggest other avenues of approach.

I think it is quite likely or at least possible that, after all of these efforts, one could end up in a circumstance in which you have only odds that a population was exposed. The odds may be such that we cannot say with any degree of certainty that we have a population of sufficient size who were exposed for scientific studies.

But you might get an odds ratio better than simply putting all the names of Vietnam veterans in a hat and pulling out some to use for an epidemiological study. The certainty of their exposure may be 20 percent, 30 percent or 80 percent, but it will nevertheless be only a probability and not necessarily a fact. One has to be aware that if this is the best that can be done, there will be problems in trying to interpret study results.

Coming back to Ranch Hand, there certainly has been some concern over the design and conduct of the study. I might point out that it has received five reviews, the last of which was by the Scientific Panel and full Interagency Work Group.

As a result of our review of the previous four peer reviews, as well as our own evaluation, we did recommend that the Ranch Hand population be studied, and be studied under the aegis of the U.S. Air Force.

The reasons we came to this conclusion were several-fold. First, there were 1100-odd people who were heavily exposed, in my opinion, and I think they deserve to have the benefit of knowing what is happening or what might happen to their health.

Probably more important for the larger issue of all Vietnam veterans, the study may identify some health effects. To the extent that it identifies some health effects, and as we draw on the studies of occupational exposures, the health effects identified should be incorporated into a larger study, such as a VA epidemiological study.

The Work Group and the Scientific Panel have been asked to perform an oversight function as to the Ranch Hand study while it is performed by the Air Force. In doing this, we intend to augment the Scientific Panel with nongovernment scientists who are experts in the area as well as to freely call upon scientists anywhere on an ad hoc basis when a particular issue comes up that requires a great depth of specific expertise. We certainly hope that veterans and veterans organizations will also identify for us scientists whom they feel are qualified to participate in this effort.

One issue has come up several times -- and I think it still exists in the minds of some -- and that regards credibility. I might say that, in closely reviewing all of the peer reviews that the Air Force Ranch Hand protocol had been subjected to, there was never any concern on the part of the reviewers that the Air Force could not conduct the study in a credible manner.

I think the issue really is concern that the public might perceive the Air Force conducting its study as less than objective. I personally do not hold that view and I don't think the previous peer reviewers held that view. I think the attempt to get an outside group of scientists as part of the oversight group should also go far in allaying the concerns on the part of veterans or the public that the study just won't be done in a proper manner and whatever results come out will not be made public. Indeed, they will be made public.

Time was another factor that was important to our recommending that the Air Force conduct the study. Certainly it was one that was considered, although it was not the prime factor. There is no doubt that the Air Force will be able to mount that study in a shorter time than could most any other group I can think of. They have been involved; they have some of the machinery and some of the early processes in place. I think that's important. To the degree we can have the Ranch Hand study far enough along so that we start to get results emerging from that study before a VA epidemology study begins, we will have the benefit of whatever findings may be emerging to incorporate into the design of the general veterans study.

Finally, the last matter I would like to mention is the issue of widening the scope of the VA study. Our recommendation that any epidemiological study of veterans should go beyond a singular focus on Herbicide Orange does not imply that we feel Agent Orange should be dismissed or relegated to a minor role in such an effort.

In fact, as I understand it, the VA is mandated by law to conduct a study of Vietnam veterans that relates to their Herbicide Orange exposure. I don't think anything has been suggested that would allow them to do otherwise.

What we are suggesting is that, in the design and conduct of such a study, other causal factors be considered. Why other causal factors? One, obviously, because there is some difficulty in identifying an Agent Orange-exposed population.

However, and primarily, we failed to perceive the logic behind Agent Orange being the sole possible agent considered, because there are other causal possibilities involved in some or part of the health effects claimed, if, indeed, they are related to Vietnam experience. For example, the animal bioassays are one of the pieces of information that causes concern that TCDD, and therefore Agent Orange, may be associated with cancer risks. You cannot lose sight of the fact that, using similar type methodologies, other chemicals used in Vietnam also were found to be associated with increased carcinogenic risk. Dapsone, one of the anti-malarials used in Vietnam, was found to be positive in cancer bioassay studies. Picloram, one of the ingredients in another herbicide, has similarly been found to be associated with possible cancer.

Also, I think one intuitively questions whether a single agent, Agent Orange in this case, can be associated with the entire spectrum of health complaints claimed to result from Herbicide Orange exposure. As I just mentioned, other possible agents should also be considered.

I feel it would be a disservice to design and conduct just an Agent Orange study. If the study comes out negative, suggesting there is no association, I think a disservice will have been done if indeed there were other chemical factors or a constellation of factors in Vietnam which could be associated with those health impairments. Indeed, you might have gotten the specific answer on Agent Orange to be "no", but you might have missed the broader issue of whether there was something in Vietnam associated with health effects in veterans.

Stuart Eizenstat
Assistant to the President
for Domestic Affairs and Policy

I appreciate the work the Work Group has been and will be doing. This for me is a very important meeting.

Last December when I asked Secretary Harris to establish the Interagency Work Group, I indicated that one of its main responsibilities would be to assure that all relevant research findings would promptly be made available to the public and to the Congress in a comprehensive and comprehensible manner.

That communication goes both ways. Those of you who have submitted data and testimony today provide a very valuable service to the government's efforts to determine the long-term health effects of exposure to phenoxy herbicides, particularly Agent Orange, and to establish a sound compensation policy.

Let me assure you that all of the testimony presented here today will be analyzed by the Interagency Work Group and the relevant agencies and will be responded to promptly and appropriately. We need to work together on this difficult and important issue.

This kind of interchange provides a forum in which to do so. We painfully recognize that fully conclusive scientific answers will not be avaiable for a long period of time, indeed if ever. But basic information from a wide variety of sources about the possible adverse health effects from exposure to Agent Orange in Vietnam is coming in.

The preliminary results of the Ranch Hand study and the planned VA study should be available in a few years. These, combined with the results of various studies of industrial accidents, the Center for Disease Control's birth defects study and other human and animal studies, should produce the development of an informed government policy on compensation long before the definitive scientific data is available.

While initial decisions may need to be modified or expanded as additional data comes in, it is our firm intention to address policy issues as soon as basic data permits.

In addition to seeking answers to Agent Orange exposure, the Interagency Work Group recommended to me in their August 1 report that it will also be important to determine whether service in Vietnam itself may have placed Vietnam veterans at a higher risk of suffering certain adverse health consequences.

I have endorsed this important recommendation. Veterans in service to their country in Vietnam were exposed to other herbicides, chemicals, drugs, environmental hazards and stressful conditions. We owe it to each and every one of those Vietnam veterans to determine, if possible, whether service in Vietnam has predisposed him or her to particular health problems.

The medical community would be in a far better position to offer useful preventive health suggestions and to provide earlier medical treatment if they know what to look for. This approach is consistent with the VA's current statutory scheme of benefits which is less concerned with the cause of given disability than relating it to a particular period of military service.

Let me assure those of you who are rightfully concerned, as we are, about Agent Orange that we remain committed to finding firm answers to whether Agent Orange exposure produced adverse health effects. Any inquiries we may undertake into the more general area of service in Vietnam will not, under any circumstances, replace the Agent Orange studies that various agencies will be conducting.

They will be additive -- in addition to -- not in place of the investigation concerning Agent Orange. Of that, I can assure you.

In closing, I appreciate how frustrating it is for veterans to be told to wait until data comes in. Many veterans have illnesses or have produced deformed children and believe deeply that exposure to Agent Orange was the causative factor. Many have questions about their future health and future well-being.

We owe them answers so that that cloud of doubt and uncertainty will be removed as swiftly and promptly as possible. Until the evidence is in, we can and we must offer them the compassionate and competent medical care and counselling that each so richly deserves.

The Veterans Administration is committed to providing that care and we at the White House are committed to assuring that they provide it. The VA's outreach efforts are being expanded and its educational programs for health professionals intensified, partly because of the firm and resolute actions taken by many of you on behalf of Vietnam veterans.

All of your suggestions regarding how we can appropriately respond to the concerned or sick Vietnam veteran will be carefully and sensitively reviewed. I greatly appreciate your willingness to be here today to offer criticism and constructive suggestions and make recommendations.

I hope we can continue to keep the channels of communication open because we share the same goals. To that, Jodie, I again want to compliment you on the work you have done. I think you have made

the Interagency Work Group widely respected for its objectivity and I am committed to working with you and the panel to assure that these critically important issues are addressed honestly and objectively. The facts will fall where they may.

SUMMARIES OF STATEMENTS FROM PUBLIC PARTICIPANTS

Dr. Robert Tardiff, Executive Director of the Board on Toxicology and Environmental Health Hazards of the National Academy of Sciences (NAS):

- TCDD is an extremely potent toxicant to the female reproductive system of laboratory animals and has also been found to be carcinogenic.

- NAS will soon complete a brief report on an evaluation of data relating to herbicide spray missions and the development of congenital malformations in South Vietnamese children. The data is equivocal at best; if Agent Orange caused any birth defects in South Vietnam, the absolute number must have been quite small.

- NAS would welcome the opportunity to review the Air Force protocol for the Ranch Hand study as revised by the Air Force in response to the Academy's recommendations.

- NAS has reviewed the German and Swedish studies on occupational exposures to phenoxy herbicides and TCDD. NAS concluded that at best the studies point to an association between occupational exposure and cancer, but that it is unlikely that attribution can be established with respect to exposure to any particular chemical.

- Additional studies should be conducted which focus on evaluation of the health status of individuals accidentally exposed to high levels of TCDD and on intensive and controlled studies of human surrogates, e.g., laboratory animals.

Mr. Lewis Milford, National Veterans Law Center (NVLC):

- The Work Group should independently analyze data provided by DoD on the results of its records search for populations of ground troops exposed to Agent Orange.

- The Air Force will face a conflict of interest in conducting the Ranch Hand study because the Air Force conducted the spraying and Air Force personnel are engaged in the research and promotion of chemical warfare efforts.

- The Work Group's recommendation that the Veterans Administration should expand the focus of its epidemiology study to include service in Vietnam is premature and should not be implemented until the Work Group independently evaluates DoD efforts to identify populations of ground troops.

- NVLC is concerned that the Work Group's recommendation as to the VA epidemiology study represents an abandonment of scientific investigations focused on Agent Orange.

- The presumed high exposure of Ranch Hand personnel to Agent Orange should be documented.

Mr. John Sommer, Assistant Director of the National Veterans Affairs and Rehabilitation Commission of the American Legion:

- The study of the Ranch Hand population should not minimize efforts to identify a population of ground troops exposed to Agent Orange.

- The American Legion supports studies that focus on the health status of Vietnam veterans to determine whether service in Vietnam may have placed veterans at a higher risk of suffering certain health decrements, but only with the assurance that scientific studies on the long range health effects of Agent Orange not consequently be de-emphasized.

- The American Legion believes that it is important that a study be conducted to determine whether or not increased cancer incidence is directly related to Agent Orange exposure.

- The American Legion strongly believes that the scientific study presently being conducted by the Veterans Administration should be completed by an independent agency.

- The American Legion is monitoring Agent Orange screening programs at VA medical facilities for appropriate examinations; its report will be made available to the Work Group.

Mr. Frank McCarthy, President of Agent Orange Victims International:

- A full-blown retrospective and prospective epidemiological study of all 2.4 million veterans is the true answer in terms of a study.

- The Veterans Administration is failing to provide veterans with proper medical examinations, tests, treatment and compensation, despite its own directives.

- Physical examinations conducted by the VA should include basic cancer tests; veterans with skin rashes should be examined by dermatologists knowledgeable about chloracne; veterans and their families should receive genetic counselling.

Dr. James Dwyer, a statistician in the Psychology and Sociology Department of the State University of New York at Stony Brook who is working with Citizen Soldier to analyze data collected from a health questionnaire distributed to Vietnam veterans:

- While the Citizen Soldier survey falls short of a true experiment (e.g., its measures of exposure are indirect, symptomatology evidence is based on retrospective self-reporting), the data may be of considerable importance because they are probably the only source of information on patterns of symtomatology among over 4,000 Vietnam veterans that includes a sufficient number of cases to achieve a reasonable level of statistical power.

- 60 variables -- or pieces of information -- from the survey have been coded. Observed associations will be subject to numerous causal and spurious explanations; thus, analysis must rely on identifying patterns of findings that speak to the merits of various competing explanations.

- Evidence from the data are only moderately suggestive of a causal relationship between Agent Orange and birth defects.

- The evidence is rather highly suggestive of a causal relationship between exposure to dioxin and liver disease.

Mr. Harold Collins, Assistant Executive Director of the National Agricultural Aviation Association:

- NAAA is conducting a health study of its members. NAAA represents about one-third of the agricultural aviation businesses in the U.S.

- The study also includes information on the health of the pilots' siblings and the siblings' families.

- Results of the study will be made available to the public on December 3, 1980.

Mr. George E. Gandenberger administered ground security for a defoliation mission of an area in Vinh Hu Village, Hoa Dong District, Go Cong Province, Republic of Vietnam:

- Informed reading of the HERBS tapes indicates that very few areas in Vietnam were not exposed to combinations of chemicals through spray, drainage and consummables.

- Not all herbicides used during the Vietnam conflict met product standards for use in the United States. Herbicides should be the object of treatment, not study.

- Third country nationals from Australia, New Zealand, the Phillipines and Korea should also be advised that they may have suffered environmental damage.

- The Federal government should develop a data processing program for correlation of data from the various public and private epidemiologic studies now under way.

Mr. Robert Muller, Executive Director of Vietnam Veterans of America:

- The Veterans Administration should begin a national outreach program advising veterans of the availability of the VA medical system.

- The Veterans Administration should grant service connection for chloracne.

- The VA should provide access to its medical system for Agent Orange-related medical examinations on a service-connected priority basis.

- There can be no responsible governmental policy on the Agent Orange issue without a credible scientific review process. Compensation policy must rest on science. Public confidence in Agent Orange policy will depend on public confidence in the process for reviewing and developing scientific evidence.

- The government must face in a manner open to public scrutiny and involvement the policy questions at stake in establishing compensation and a full range of health care for Agent Orange-related disabilities.

Mr. Alfred Baxter, Chairman of the National Forest Products Association Committee on Forest Industry Chemicals and President of the American Forest Institute:

- The forest products industry supports careful use of substances which could be harmful to human health, active concern about the potentially harmful effects of such substances, careful and rigorous scientific inquiry, and necessary governmental controls which properly weigh related social and economic concerns.

- NFPA will provide the Work Group with all studies sponsored by it relating to health effects and phenoxy herbicides.

- The forest products industry is willing to join in cooperative support of independent scientific studies of the relationship between phenoxy herbicides and neural tube birth defects and cancer.

Mr. Jon R. Furst, Chairman of the National Veterans Task on Agent Orange:

- The Work Group should verify data provided by DoD and VA before making recommendations based on that data.

- The Air Force role in the development of a chemical warfare capacity creates a conflict of interest for the Air Force in its conduct of the Ranch Hand study.

- Conclusions as to whether sufficient numbers of exposed ground troops can be identified for study are premature.

- A Vietnam service study in addition to a study of exposed ground troops is much more acceptable than deleting one for the other. The Task Force sees the two studies as addressing different concerns.

- A study of Ranch Hand personnel should be conducted, but it should not be conducted by the Air Force, even if an independent monitoring committee is established. The Work Group should reconsider the merits of having independent researchers conduct the Ranch Hand study.

Dr. Tschirley, Department of Botany and Plant Pathology, Michigan State University:

- A scientific dispute resolution conference held in June 1979 concluded that 2,4,5-T is not the sole

- That conference also concluded that levels of TCDD greater than 100 parts per million have not been detected in any environmental sample associated with normal use of 2,4,5-T; 2,4,5-T itself is of minor ecologic concern.

- The conference concluded that 2,4,5-T is not a carcinogen nor a mutagen; however the Swedish studies published in 1979 and 1980 were not available at the time the conference was held.

Copies of the written statements of each witness are available from the Office of General Counsel, Department of Health and Human Services, Room 716E, Hubert H. Humphrey Building, 200 Independence Ave., S.W., Washington, D.C. 20201.

RESPONSES BY THE WORK GROUP TO QUESTIONS FROM THE PUBLIC

Following the presentations, Work Group members responded to questions submitted in writing by the public. Each question was read to the Work Group by Mr. Leslie Platt. Each question is set out in full below, with the name of the individual and, where appropriate, the organization which submitted the question.

Robert Muller, Vietnam Veterans of America: "If the Veterans Administration epidemiological study conducted pursuant to Public Law 96-151 is broadened to include examination of the overall health status of Vietnam veterans as a result of their service in Vietnam pursuant to the Work Group's recommendation, does that entail that the P.L. 96-151 study will not address the impact of Agent Orange?"

DR. MOORE: As my introductory remarks this morning pointed out, it is certainly not the intent of the Science Panel that the study's focus on Agent Orange should dim at all. I think the statement of Mr. Eizenstat certainly underscored that.

DR. GOUGH: May I add something? I spoke with a member of Senator Cranston's staff today. Senator Cranston does not intend that an expanded study would mean that we would do away with the Agent Orange study. In Senator Cranston's mind, the Agent Orange study was mandated by Congress and will be carried out.

Robert Muller: "If an attempt would be made to study the impact of Agent Orange, does that mean that the Work Group envisions at this time that, subject to change in the protocol development process, two studies should be done under Public Law

96-151, one to look at a cohort which represents a best guess at an exposed population and one to consider service in South Vietnam, or does it mean that one study will be undertaken which will contain a subgroup or cohort which is the best guess at an exposed population?"

DR MOORE: All of the above. I think at this stage in the evolution of the design of that protocol, one clearly can't definitively state that it will be one study with two, three, or four subsets or whether it will be two studies or what the case will be. I don't think it would be prudent to speculate because it would be pure speculation.

Robert Muller: "Will the Work Group submit the report expected from the Department of Defense on their efforts to determine if a ground troop cohort could be found to the General Accounting Office for comment?"

MS. BERNSTEIN: We always have the right to submit something to GAO, and the answer is yes.

GEN. AUGERSON: As I mentioned this morning, we found it best to invite the GAO in to tag along with us, as we cut our teeth on the details of this record search. I have an impression of what they think, but I think it would be better to comment at some future time after we have formally submitted it to GAO.

Dr. Moore will eventually get his copies of the report and I can visualize that he might invite other members of the Scientific Panel to take a look, not just at the report, but at how the records review was conducted.

To reiterate what I said this morning, we have not given up on trying to identify personnel on the ground who were probably exposed. We have just found it extraordinarily difficult to go into the records on the basis of spray flight missions from Ranch Hand and come to grips with who was where on the ground.

We have gotten some useful suggestions to that end today and we will explore those.

Mr. James F. Lee, Jr., Laurel, Maryland: "With all the talk about 2,4,5-T exposure and TCDD exposure, I would like to know whether or not the Food and Drug Administration, U.S. Department of Agriculture, EPA or any other Federal agency is conducting Federal testing programs of any kind to analyze random samples of food for TCDD and for 2,4,5-T residues?

"If it is being done, I would like to know what residues, if any, they have found, how extensive their sampling is, and what the limit of detection is on their analytic method. If

such sampling is not being done, I would like to know if it is being planned or studied by any Federal agency.

"It would appear that all the current concern and evaluation of whether there continues to be exposure of people despite the present ban is important."

DR. KEARNEY: I am aware of six kinds of studies being conducted on various food items that might be of interest. One is mother's milk, one is beef fat, one is beef liver, one is cow's milk, one is fish, and one is wildlife.

As of today, I am aware of four studies on mother's milk. No TCDD has been detected in mother's milk at a level of sensitivity of one part per trillion.

In the beef study, the number of animals involved varies, but I believe that about 85 animals were investigated. One animal had a level of 68 parts per trillion in the fat; two had lower levels and none was detected at a level of 10 parts per trillion. No TCDD was detected in 43 beef liver samples; no TCDD was detected in cow's milk.

No TCDD was detected in fish caught near a pond in a rice growing region in the United Sates where we have used 2,4,5-T extensively for weed control. There is a report from Vietnam, from Messelson and Bachman, of a fish caught there that contained measurable residues of TCDD.

In the area of wildlife, until we supported a study ourselves in the Department of Agriculture, I was unaware of any TCDD residues in wildlife. There is a study now that found nine positive samples in deer in a forest treated with 2,4,5-T. The highest sample was about 5 parts per trillion.

These are the studies I am aware of. There are probably other studies going on that are unknown to us that may not necessarily be in the Federal sector. I think we do have a fairly good overview of what is being done, however, and these are the levels we are seeing.

DR. BARNES: I might be repeating on some of these. The beef fat-beef liver study that was mentioned is in the process of being reanalyzed. The way it is done is to have the samples analyzed by two different laboratories. One laboratory analyzes the samples, and the samples are then reanalyzed at a second laboratory.

There are two different studies nearing completion on deer and elk in different forested areas of the western part of the country. Dating back sometime ago, small roadside animals were analyzed.

The agency is also looking into analyzing materials from the rice growing sectors of this country, which would include catfish and crawfish. Those samples have been collected and extracted and are now undergoing analysis.

The agency plans to continue to look into areas which we think need to be looked into for TCDD contamination. The purpose of this as far as our agency is concerned is not to look at the food supply directly, since that is the purview of the Food and Drug Administration.

For those who are interested, many of these samples have been summarized in the exposure assessment which EPA will introduce into evidence in its hearings in the next ten days. This will become public information at that time.

Maurice Loir, Military Order of the Public Heart: "We have heard a variety of statements concerning persistence of TCDD. We expect that some statement will be made by the Scientific Panel to help clarify this point."

DR. MOORE: As we read this question, we were unclear as to what Mr. Loir meant by "persistence." Two contexts came to mind: one is persistence in the human body or animal body and the other is persistence in the environment. We will try to give the answer to both. I will try to give you the one with regard to persistence in animal tissue or the body and Phil Kearney will try the environmental definition.

First of all, no human data is available that addresses the issue with regard to persistence. There is some human data that might suggest that if indeed the analytics were correct, TCDD can be detected in human tissue. But with regard to persistence, e.g., how long it had been there and how long it would stay there, we have no data. That is one of the major data gaps we have in trying to extrapolate a lot of the laboratory data.

With regard to a number of animal studies done in a variety of species, there is significant variability with respect to the length of time TCDD will stay in the body. But if you will allow me to generalize, one can say that the half-life can vary anywhere from 28 days to possibly 60 days.

What is meant by half-life value is that during the period of 60 days, one half of what was in your body 60 days previously would be gone. In an additional 60 days, one-half of what was left would be gone. In another 60 days, etc., one-half of that, etc.

DR. KEARNEY: Let me talk to the more difficult of the two and state at the beginning that the answer is complex, which means that, scientifically, we are not sure. But looking at the phases of the environment, we know that on plant surfaces and in water the molecule is subject to photodecomposition. The force of sunlight can alter the molecule and alter its toxicity.

On the soil and in the soil, the molecule does appear to be rather persistent. We ran a study, using that term "half-life" again, at Beltsville and we found the half-life was about one year. Other people have studied it and it ran anywhere up to 500 days. It depends on the soil it's in.

A warm, moist soil high in organic matter is different from a sandy soil in a colder climate. We have no absolute numbers but we think the half-life is about one year.

James F. Lee, Jr.: "I would like some information on research being done by the National Institute of Environmental Health Sciences (NIEHS) to examine the effect of TCDD on the immune system of animals. The effect of transplacental and neonatal exposure is also being checked.

"What is the status of these experiments, when will they be completed, and are there any reports available to the public?"

DR. MOORE: Most of those experiments have been completed and printed and have been available from anywhere from six months to two, three or four years in the open scientific literature. Recent testimony by Dr. Michael Luster of NIEHS at the EPA suspension hearings might be a good source because in that testimony he tried to summarize what all of the studies meant. His testimony would also give the references to the majority of the individual studies that are in the open literature.

So the studies are completed and reports are available. Mr. Lee is correct in his assumption that the effects were associated with transplacental and neonatal exposure.

Maurice Loir: "Regarding the teratogenicity of TCDD, it has been noted that little real information exists regarding exposed males and unexposed females.

"A recent study with rodents has been reported. We ask if further studies are planned, particularly with primates rather than rodents? It is our feeling that the use of primates could be regarded as far more definitive than any test with rodents."

DR. MOORE: I know of no further studies being planned. Further, I don't agree a priori that the use of primates might be more definitive with respect to experimental data, particularly if you are talking about birth defects. The reasons for that statement are severalfold.

First, the number of primates one would have to use to end up with a meaningful result I think far exceeds our resources as far as being able to get primates for research in this country. Most of our primates are imported and come from South America, India or Southeast Asia and most of those countries have banned the export of primates to this country and to the world.

Second, quantitative extrapolation of results using the rhesus monkey or some of the other primates is questionable. A number of scientists are of the opinion that the dose effects seen in some of the studies done in primates logically don't suggest they should extrapolate directly to man.

The monkey in this case gives the appearance of being super-sensitive and that's an opinion and not fact. Also, given the fact that the rhesus monky and some of the other primates are so sensitive to certain toxic effects, I think if you studied reproductive effects on exposed males, you would end up with overt toxicity before you could get a chance to study male fertility. Finally, if indeed the thrust of the question is to endocrine effects, maybe the rehesus monkey would be good.

Constance See, Alexandria, Virginia: "The National Center for Toxicological Research is developing pharmacokinetic models for 2,4,5-T and dioxin to assess whether teratogenic responses between laboratory animals differ because of enzyme activity.

"I would like to know what the researchers, Drs. Young and Holson, have discovered so far. I would like to know if they have made a final report of any kind, whether such report is available to the public and, if not completed, when they expect to complete their experiment?"

DR. MOORE: I called the Center for Toxicological Research. They are not doing any work with TCDD and I don't believe they are planning any in the near future. They have done work on pharmacokinetic studies with 2,4,5-T, principally in one species. The results of that study are in internal review.

I believe there is an abstract available from the Society of Toxicology Meeting held last year or this year. The senior author has recently left that organization and I am sure that his leaving will slow down development of the final report, as is typically the case.

I might mention that outside of NCTR but germane to the thrust of the question, there have been a number of studies that have show that there are different effects among strains of species, principally rodents.

Marianne T. Anderson, Alexandria, Virginia: "The first project I am interested in is being done by Dr. Borzelleca at the School of Pharmacy, Virginia Commonwealth University on the effects of TCDD on the male reproductive system and I would like the following information, if possible.

"One, preliminary or final results; two, has a final report been issued; and three, how can I obtain a copy of the final report?"

DR. MOORE: I was afraid when I read this one that they found something we had not found. I called Dr. Borzelleca and he said they never did the studies and don't plan to do the studies for the simple reason that they don't have adequte safety facilities to be able to do such studies.

Marianne T. Anderson: "In the same area, Dr. Lee, with the National Institute of Environmental Health Sciences, is also studying the reproductive toxicity of TCDD and I would like to know the following:

"One, the current status of the research; two, whether potential human health effects of TCDD will be assessed in the study; and three, whether a final report of the research is available at this time?"

DR. MOORE: This is one we did not catch. There are such studies being done by Dr. Lee and they basically concern the effect on male offspring of TCDD administered to pregnant animals. Dr. Lee is interested in testicular function of one sort or another.

I did not have the chance to talk to Dr. Lee before this meeting, but we will get an activity sheet filled out which will give the status and time needed for completion.

Constance See: "The National Institute of Environmental Health Sciences is sponsoring research by a Dr. Peterson at the University of Wisconsin at Madison on effects of TCDD on the lever and pancreas of animals. He was also developing a blood clearance test to detect liver problems caused by TCDD.

"I would like to find out whether such research is actually going on, whether such a blood clearance test has been developed and whether there is any published reference on his research which I could obtain?"

DR. MOORE: We did do a search of published literature and there was no citation of a Dr. Peterson, which suggests it is not published if he has done something.

Marianne T. Anderson: "Dr. W. Piper of the University of Nebraska Medical School is conducting research on toxic effects caused by TCDD through the impairment of endocrine function and interference with the heme biosynthetic pathway in testes. I would like to know the following:

"One, what his research has found to date; two, when it will be completed; and three, whether or not he has written any reports on his research which are available to the public?"

DR. MOORE: Again, on incomplete information, this is a brand new grant, less than one year old, and I would suspect that his research has very few findings to date.

Maurice Loir: "Since other herbicides and pesticides were used in Vietnam, what is being done to discover the extent of synergetic effects?"

DR. MOORE: Nothing.

Maurice Loir: "We are concerned with the type of exposure test animals face. Since the Vietduc Medical Center in Hanoi, Vietnam has reported finding TCDD residue in fish, it would appear that a major form of exposure comes from the use of water. Is this factor being fully considered in planning the various studies?"

DR. MOORE: We are certainly aware of the fact that this is a possibility, based on the Baughman/Meselson data that came out of Vietnam showing levels of TCDD in butterfish and information from this country showing levels of TCDD in some fish downstream from the industrial plants involved in production of these types of products.

I think the more distinct possibility is that there is a likelihood that such residues may be found in the biota rather than the water per se. It is a very water insoluble compound. Perhaps Dr. Barnes would like to add to that.

DR. BARNES: I would like to just mention again that we have a study ongoing of catfish and crawfish in the rice growing areas of the country with that idea in mind. In addition, EPA has a water analysis network in which we look for 2,4,5-T in waterways. This is a continuing activity of the agency.

DR. KEARNEY: I would note TCDD is a very insoluble molecule. One would suspect that it would be liquid filling.

DR. BARNES: Along that line, in natural waters there is suspended sediment and organic material which could act as a carrier and there might be reason to go back and look.

Lewis Milford: "The Scientific Panel concluded that the exposures of the Ranch Hand personnel are known and documented and that attempts to identify the exposures of other non-Ranch Hand subpopulations of Vietnam veterans have proved impossible. Please provide the documentation relied upon to support this conclusion and the method of investigation to arrive at this conclusion. In particular, please explain whether and in what manner any independent evaluation of exposure data was conducted or is contemplated by the Work Group."

DR. MOORE: Part of the association between exposure of personnel is logic. If you are involved with 80 million pounds of material, you must have been exposed to it at some time.

Also, various statements of Ranch Hand personnel describe the lack of precautions they took with regard to trying to reduce their exposure. They often flew in T-shirts and they did not by any stretch of the imagination use routine protection measures.

We also heard a report from the Air Force, which was trying to identify the degree of exposure that may have been a consequence of being Ranch Hand personnel. There was, for example, the function of being the pilot or the console operator in the back, etc. That report is not yet publicly available, principally because the person who did it is using it for a graduate thesis. According to academic rules, it's not available for publication until he defends his thesis. We intend to look at that report in detail once it is available, which I understand is just a matter of a few weeks.

Lewis Milford: "The Work Group recommended the conduct of the Ranch Hand study by the Air Force on the express condition that an independent peer review committee monitor the conduct of the study. With regard to this recommendation, please explain, a) whether and which veterans orgnizations were consulted before this recommendation was prepared; b) how the establishment of such a committee would alleviate problems of credibility where the Air Force is perceived to have a clear conflict of interest in promotion of chemical warfare weaponry; c) whether organizations other than the Air Force were considered as possible candidates for the conduct of the study of the Ranch Hand, and if so, the reasons for rejecting such alternatives; d) the significance of possible delays in the decision to approve an Air Force controlled study and whether the need for credibility that might be restored by the conduct of the study by a group other than the Air Force may offset the negative impact further delays may cause."

MS. BERNSTEIN: I will try to respond to that first.

As to part (a), whether and which organizations were consulted before this recommendation was prepared, no formal consultations were held with any group as we went about preparing these or other recommendations. That was not for reasons of cutting out outside people, but simply because as the Work Group established itself and went about trying to do its work, we found early on that the best way for us to get the best product and best judgment from people was to proceed informally, without formal votes, without formal procedures.

However, as we went about forming our recommendations, we did talk to a lot of people, including congressional committees

and congressional staff and various veterans organizations. I would not say we talked to every single one, but we had informal consultations as we moved along. I would not try to document that in any sense of a listing of groups consulted or not consulted for any purpose. But I felt strongly and I think others as well that we worked together best by achieving consensus on a whole variety of recommendations as we moved along.

If anyone would like to add to that, feel free to interrupt.

Part (b) concerns the review committee. On the issue of credibility, I will express my own personal view on that but will try to characterize the views of the Work Group as well. After working on the Ranch Hand study, thinking about it and reviewing the work of others, I came to believe that the credibility issue was less an issue of a formal conflict of interest than it was an issue of general perception of lack of credibility. In straightforward lay language, people said nobody will believe the study if the Air Force does it.

To me, that means it is a judgment call. That is to say, there are some people who, I suppose, would say we don't ever believe Group A just because we've had experience with Group A over the years and we will never trust them no matter what they tell us. By the same token, others would say we don't see any reason not to, unless they do something wrong or don't have the competence in the first place.

What I was doing was trying to determine how to assess a perception. There is no scientific way or any scientific inquiry that can help you very much in that.

The best you can do is try to get a feel for it by talking to a lot of people and getting many expressions of views. If then a perception problem remains, the best way of reassurance is to have a continuing mechanism to evaluate what it is that that group is doing.

It's as simple as that for me. It's similar to an oversight committee of the Congress continuing to look at an agency as it goes about its work. The agency or department can't be doing too much wrong if there is an external group watching over its shoulder, keeping it open and making sure there are no biases consciously or unconsciously being expressed.

For me it was just one way in which to add some reassurance to those who continued to have a perception of lack of credibility. I did not feel that lack of credibility. But I thought it was a wise judgment to take that last step to insure continuing credibility. That is the way I would explain our judgment on that.

GEN. AUGERSON: May I add a footnote to that?

MS. BERNSTEIN: Absolutely.

GEN. AUGERSON: I must say I was surprised by this idea of linking the way in which medical people in the Air Force might somehow affect the outcome of the Ranch Hand study because of some perception of the interest, or the lack of it, of the Air Force in chemical warfare.

I guess it is a form of left-handed compliment that assumes that somehow we are well enough coordinated in one of our large military departments that medical people thumping chests and examining people would somehow be susceptible to influence from some of the more weapons-oriented people.

I assure you that is not the case. I think whatever happens in terms of national policy about chemical warfare will be driven more by present and future determinations of a threat and the United States' posture vis-a-vis that threat than any regrettable or unintended consequences of what has happened in the past.

DR. GOUGH: One issue we have heard a lot of today, and I guess everyone in this town hears all the time, is the question of government credibility. I don't think any agency of the government or the government as a whole will establish credibility if, every time a delicate and sensitive subject comes along, the government farms it out to an independent agency.

MS. BERNSTEIN: I was hoping you would add that because I know most people in our group and others we talked to were concerned with that aspect. Increasingly there seems to be a sort of almost adjudicatory -- as we lawyers think about it -- movement that suggests that anybody who has had anything to do with anything can never make another statement on it because it will be somehow suspect

I think we were concerned about it. I don't think we overreacted, but I think we did feel that we did not want to get to a state of affairs in which a part of the government could never examine itself and its operations.

DR. LOGAN: It may be important, too, to mention that many of us on the task force were impressed with the Air Force presentation of the Ranch Hand study and the sophistication and obvious level of expertise put into the development and design of the protocol. I think that the scientific expertise that went into that protocol was apparent to members of the committee here and further led to a feeling that the Air Force was going to be very responsible in the conduct of the Ranch Hand study.

MS. BERNSTEIN: In response to the last two parts of the question, the first being that if organizations other than the Air Force were considered and so forth, I think the answer to that is yes, other organizations were considered. Again, in our customary way of working, they were considered by the Scientific Panel and the Work Group generally.

They were not considered in any formalized way. We did not ask people to propose and reject other organizations and so forth. However, we did consider whether it would be sensible to pursue other organizations, particularly those within the government. Again, I could not give you a formal statement of reasons for rejecting each of them because we very soon reached the conclusion -- I don't mean without deliberation but quickly -- that there was a consensus that the Air Force met the standards which we were setting and therefore we did not have to seriously pursue other organizations.

On the question of the significance of delay, we all felt that there had already been considerable delay in conducting this study and other studies. That was one of our primary concerns.

There have been a couple of years of not very productive activity in the sense of simply not getting on with it. I think we were all very sensitive to delay. Surely there would have to be delays if, at this very late stage of the game, after the extensive development of protocols and the extensive reviews by not only our little organization, but the National Academy of Sciences and others as well, we recommended that yet another organization go back and start over again.

I for one -- and I think the rest of the group as well -- was convinced that delays would be automatic and that is what we were concerned about.

Would anyone like to add anything?

Lewis Milford: "With regard to the issue of exposure, the Scientific Panel suggested that 'actual' exposure may be the standard needed to conduct a valid epidemiological study. Please explain the standard of exposure the Scientific Panel believes is necessary for such a study, with particular attention to how such a standard may or may not be met, given the existing quality of exposure data."

DR. MOORE: I think that question gets to the crux of the issue with respect to the quandry caused by the lack of data in some archives somewhere that describe the companies -- "exposed on such-and-such a date." I doubt that we'll get data, if you want to compare it to Ranch Hand, that will say this person was on duty on these dates in Vietnam at this period of time and he flew this many missions, so you can roughly calculate the exposure. I don't think you will find that with regard to ground troops.

I think what one might best come up with is some way down the road being able to get the odds that some particular unit might have been exposed at some particular period in time. It's something like a weather forecast and I think it can be wrong.

I do hope in the efforts we are making we will be able to identify a group and that if it is the best one can get without having unequivocal data saying they were exposed, there would be general agreement saying that it's probably one of the better groups you could look at in terms of ground troops that might have been exposed.

But you will never get the unequivocal data, I don't think, unless something magic appears that I am now unaware of.

Lewis Milford: "The Scientific Panel recommended that a Vietnam service study, rather than an Agent Orange study, be the focus of future scientific investigations. With regard to this recommendation, a) explain whether it would be necessary to identify a subpopulation of veterans exposed to Agent Orange at some time during the conduct of such a study and, if so, the approximate time within the conduct of such a study that this information should be developed, e.g., before proceeding or sometime after possible ill health effects are identified.

b) If the answer to Part (a) is that it is not necessary to identify a population exposed to Agent Orange, please explain why not.

c) Explain whether the difficulty with developing exposure data has played a role in this recommendation.

d) Explain the basis for the expressed belief of Work Group members that veterans are concerned only with whether Vietnam service may have caused them ill health effects, and not whether Agent Orange may be the cause of their ill health problems.

e) Explain whether Vietnam service focus could or is contemplated to produce data on the possible correlation between Agent Orange and ill health effects.

DR. MOORE: With regard to the first question, the study is not yet designed so any answer would be speculative at this time. I think one needs to use some logic in looking at Vietnam veterans and give some consideration to what they did while they were in Vietnam. Certainly, there is a large contrast between a fighter pilot sitting in an air base versus someone who was out on search and destroy missions most of the time he was there. I would expect and hope that when Vietnam veterans who are going to be studied are identified, these factors will be considered in selecting which people should be part of such a study.

Consistent with that logic, assuming we can come up with some units where there is evidence that suggests that if any units on the ground were exposed to Herbicide Orange these stand the likelihood of being the most likely exposed or the more repetitively exposed and more intensely exposed, whether it be engineer units such as postulated this morning or whatever, these units should be a subset.

I would hope in doing this, the timing would be such that we could identify those subsets of populations before the study began. That might be subject to revision if other data becomes available somewhere down the line. But I think the thrust would be to identify populations or subsets of populations before you begin.

I can skip part (b) because the answer was "yes" to part (a).

Part (c) asks whether difficulty with developing exposure data has played a role in this recommendation. Certainly, the people who considered and made the recommendation were aware of the fact that we had difficultities identifying ground troops.

There is no question that it was factored into the decision. I don't think it was the major reason for the decision.

Part (d) asks for the basis for the expressed belief of Work Group members that veterans are concerned only that Vietnam service may have caused ill health effects and not whether Agent Orange is the cause of their ill health problem.

The word that jumped out at me was the word "only". As a general point of clarification, I don't think we have used the word "only. Speaking for myself, the basis for my belief that veterans are concerned about Vietnam service is based, pure and simple, on some of the conversations I've had with veterans.

Part (e) asks whether the Vietnam service focus could or is contemplated to produce data on the possible correlation betweeen Agent Orange and ill health effects. We hope it will but I don't know if it could. We will certainly try to end up with something that will produce data on whether a correlation exists between Herbicide Orange exposure and health.

Terry Jemison, U.S. Medicine: "In testimony prepared for a House hearing on Sepember 16, 1980, Dr. Moore said studies conducted by Dr. Lennart Hardell in Umea, Sweden and others show a correlation between TCDD exposure and an increased risk of cancer, but he said these data do not lend themselves to establishing a quantitative risk for veterans exposed to Agent Orange. He said a study specifically of veterans is needed, suggesting the VA study could detect any excess cancer appearing only ten years after exposure and a positive finding would establish service connection.

"One, would a relative risk in the range of the Hardell studies constitute such a positive finding?

"Two, how large a study population would be needed to place the study beyond criticism for size -- what numbers?"

DR. MOORE: I think my statement was that the VA study might pick up excess cancer and the reason I say might is the fact that a lot of the cancers are not developed ten years post-exposure. That may be a small point.

DR. HONCHAR: With regard to the first question, the relative risk in the studies conducted by the Swedes clustered around six. That is epidemiologically considered to be a positive relative risk, i.e., one worth noting, important and so on.

What would then be done with the relative risk relative to other possible relative risks would be a social policy decision.

The second question is rather difficult because it depends on what kind of study is being done and on what particular cancers may be looked at as end points. In the case of an epidemiological control study, the number of cases of soft tissue sarcomas, for example, that you would need to investigate would be one consideration, into which you would have to factor an estimation of the number of people who might have been exposed -- some estimation from the population your numbers are drawn from.

With regard to a mortality study, which is an entirely different kind of epidemiological study, different considerations have to be taken into account as to the appropriate size of the cohort required to detect cancers down to a certain point so that the study has a degree of power.

It's a broad question to answer specifically.

Lewis Milford: "In order to understand the reasons for the recommendations discussed here, we request access to any documentation, records or other materials of the Work Group that would explain in greater detail the scientific and policy bases for the Work Group and Scientific Panel."

MS. BERNSTEIN: I believe we have already made everything public. We have no intention not to. I would like to ask Les, because my voice is getting tired, to detail the written information we have already made public and will continue to make public.

MR. PLATT: The written material of the Work Group and its Scientific Panel is comprised of the monthly reports of the full panel as well as reports by the Scientific Panel.

In addition, we have been preparing updates of scientific activity timetables and detailed funding charts for each of the activities covered by the timetables to supplement those supplied in the spring in the initial round of reporting by the involved agencies.

Those reports, as well as any writings of members on their activities and the testimony of Work Group members, together with the report of this and similar proceedings in the future, constitute the totality of the Work Group's writings, except for correspondence with individual persons or organizations who write in to us.

We have been making it all public and intend to continue to do so. Anyone who would like a copy of the summary report of today's proceedings, please be sure to complete the form and we will put you on our mailing list for this report and for the write-up of our monthly meetings. In addition, anyone who would like to submit additional questions may do so until the end of this month and we will endeavor to incorporate responses to those questions into the summary report of today's proceedings. If anyone has additional material, please get it in to me before the end of the month.

Roger Runningham, reporter: "Is there any government research going on or anticipated at the Mayo Clinic on Agent Orange."

DR. MOORE: I know of none.

Barbara Saunders: "What is the relationship of the ingredients in Agent Orange to sevin, malathion, diazinon and insecticides in general? Do not these insecticides include derivatives of Orange?"

DR. MOORE: Sevin is a carbamate whereas malathion is an organo-phosphate. Diazinon is not related to phenoxy acids, I know that for a fact. I guess by process of elimination, we would say these insecticides do not include derivatives of Orange. Is that correct?

DR. KEARNEY: That's correct.

QUESTIONS FROM THE FLOOR

MS. BERNSTEIN: We will now open the floor for questions. If you will go to the microphone, state your name and if you are affiliated with an organization, let us know what that is. You may direct your questions to individual members of the panel, if you like.

Mr. Furst?

MR. FURST: Dr. Moore, I am told that the means by which an animal would be exposed to TCDD can greatly change the manner in which it is found to have a toxic effect. For instance, I am told that there is a great difference in the reaction laboratory animals have to small exposures over a long period of time as opposed to a single exposure of the same general dosage. Can you tell me how that works?

Specifically, I am told that in order to cause the same kind of poisoning in laboratory animals who have been exposed over a long period of time, they have to increase the single dose a great deal.

DR. MOORE: TCDD is a lipophilic compound, which means it tends to migrate to the fat. There has been some speculation that there could be some differences depending on the route of exposure, that is, whether you got it on the skin, whether you ingested it, etc. With most lipophilic compounds, there isn't much difference as to whether it will get in. This is known to be true for TCDD. I would not say it's exactly the same, but they are generally the same.

With regard to differences in the type of response one will get -- whether you have one whopping big dose or little doses over a long period of time -- there is a difference and there are a variety of reasons for it.

Let me give one generality. With these types of compounds, what happens is that you have somewhat of an absorption phenomenon. If you get one huge dose all at once, it passes through the body before you fully absorb it, whereas if you get small incremental doses, you will absorb most of it and continue to build body burden.

One of the best examples I can think of is the PBB problem in Michigan where the acute LD-50 was 25,000 mg. But if given in incremental doses in periods of 30 to 45 days, the LD-50 dropped by almost two orders of magnitude.

MR. FURST: Thank you.

MR. GANDENBERGER: My name is George Gandenberger. I'm not affiliated with an organization, but I was directly involved in spraying. I have a study of approximately 150 different studies, really a bibliography, related to TCDD and 2,4,5-T which was published earlier last year. It seems to establish that there is some causation for illness related to both substances.

I also have a copy of my separation physical from Vietnam which explained what I went through in terms of treatment and then had a rubber-stamp entry, "Items 20 to 38 reviewed and answer found to be no medical significance."

Now, I had no medical records, they were in Saigon and I was not. Many people in the service have the same situation. I know a fellow in the 101st Airborne who has four Purple Hearts and zero medical records.

If the VA insists on having direct causation in terms of medical treatment before they will provide service connection, then there is no point to this group's study in the first place. As long as they hold out for that, for many people who were directly exposed there is no way to substantiate that putative exposure.

How can you accommodate that unless you go to area-wide eligibility?

MR. McMICHAEL: While medical records are very valuable in establishing claims for service connection on disabilities, the absence or presence of those medical records are not necessarily conclusive. What we attempt to do in establishing service connection is ascertain whether or not there is a disability of which the veteran is currently complaining and then try to relate it to a period of service.

Obviously, we have medical records that aid, but that's not the only way service connection can be established. Other testimony, your own testimony and the testimony of those you served with can serve to establish service connection in a given case.

MR. GANDENBERGER: Sir, I don't want to dispute you, but I have several responses from the VA office in Newark saying there was no service connection because there are no medical records, I'm sure many other people can come up with the same type of response.

MR. McMICHAEL: If you have filed a claim for compensation and have been turned down, I would urge you to appeal it to the Board of Veterans Appeals and urge you to submit whatever evidence you believe you have that relates directly to that claim.

MR. GANDENBERGER: Thank you.

ADDITIONAL QUESTIONS FROM THE PUBLIC RECEIVED AFTER THE MEETING

The following questions were received from Rayma D. Whited Plummer, the Brotherhood of Vietnam Veterans, Inc., Austin, Texas:

Interagency Work Group

1. "What were your results on the male mice study?"

   Attached is a copy of the report's abstract.

2. "Why wasn't the study of male mice by Dr. Lars Davring in 1977 considered? (Hereditas, 80:255-262 (1975) (Inst. Genestics - University of Lund Sweden))."

   The study by Dr. Lars Daving in Heriditas 80:255-262 (1975) is entitled "Effects of a 2,4,5-T Ester On Early Oogenesis, Fertility and Development in Drosophila Melanogaster." The study utilized the female fruit fly, not male mice. Dr. Moore scanned the article and found it does not talk about or refer to mice.

3. "Why did Dr. Moore tell me that he wasn't aware of any other male mice study?"

   Dr. Moore is not aware of any other male mice studies.

4. "Why was the VA study of the fatty tissues of veterans and controls rejected and what made it unable to comprehend? (as stated by Dr. Moore)"

   Attached is a copy of the Science Panel's report on these studies which provides the information you request.

5. "Have you received a copy of the Dow Chemical Co. reproductive study on exposure to 2,4,5-T (and/or Agent Orange)? If so, what are its findings?"

   Dr. Moore is aware of a study performed by Dow Chemical scientists entitled "Three Generation Reproductive Study of Rats Given 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) in the Diet" which appeared in Toxicology and Applied Pharmacology 50: 241-252 (1979). A copy of the abstract which summarized the study findings is attached.

6. "As per questioned (sic) in my previous letter, what are the effects of contamination when a person receives a wound such as a punji stick with artery involvement?

Since the punji stick and the animal exrement it was dipped in would both be contaminated by dioxin, the dioxin would therefore get directly into the main blood stream thru artery involvement in the wound. Once it is in the blood stream, where does the dioxin go? To the fatty tissues or where? And what happens once in the blood stream?"

Dr. Moore cannot factually respond to your query since there is no data relevant to your question. Is your assumption that a punji stick would be contaminated with dioxin verifiable? One can speculate that dioxin entering the blood stream of a man would rapidly clear and partition into the fat and/or liver.

7. "Have you attempted to produce a duplicate batch of Agent Orange and study it? If so, what were your findings? If not, why haven't you?"

   The male mouse study by Lamb, et al, was performed using a mixture of 2,4-D, 2,4,5-T and TCDD that simulated Agent Orange.

8. "What are your statistics on deaths suspected to be related to Agent Orange or exposure to 2,4,5-T and 2,4-D? What are the statistics on birth defects from exposure to Agent Orange or 2,4,5-T and 2,4-D? What are the statistics on the symptoms of exposure (for example: cancer - how many), etc."

   There are no reliable statistics available for the type of end points you list. It is anticipated that the CDC Birth Defects Study, Air Force Ranch Hand Study and proposed VA study will provide such data.

9. "What are the effects of the antimalarials and Agent Orange when combined?"

   There is no information available to answer this question.

10. "Why was I asked if my husband (and many others asked) was given antimalarials? What is it you suspect about the antimalarials?"

    Dr. Moore does not know why you or your husband were asked if he took antimalarials. There is data that indicated that one of the antimalarial drugs was associated with an increased incidence of cancer in animal studies.