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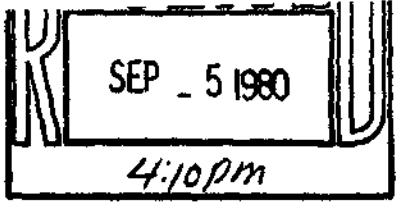

DRAFT/ 8/29/80

STATEMENT

by

Joan Z. Bernstein

General Counsel

Department of Health & Human Services

and

Chair

Interagency Work Group to Study the Possible

Long Term Health Effects of Phenoxy Herbicides

and Contaminants

Senate Committee on Veterans' Affairs

September 10, 1980

(House Committee on Veterans' Affairs)
(September 16, 1980)

Mr. Chairman and Members of the Committee:

I am Joan Z. Bernstein, General Counsel of Health and Human Services and Chair of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. I appreciate this opportunity to appear before the Committee to report on the Federal Government's ongoing efforts to study the possible long-term health effects on humans of exposure to these chemicals.

I will review the status of the Work Group's efforts since my testimony you last February, focusing particularly on the state of scientific knowledge about Agent Orange and its implications for future research.

As you know, the Work Group's task is a substantial one, including:

- o overseeing, coordinating and setting priorities among relevant Federal government research activities;
- o designing a research agenda; and
- o organizing the means by which the research agenda will be carried out and assuring its accomplishment in a timely and competent manner.

I believe that we have made significant strides in carrying out that task. The full Work Group has held monthly meetings

at which ongoing research is reported on and planned research is discussed. The Science Panel also has met on a number of occasions.

Among our significant accomplishments to date are:

- o the identification of all research activities already being conducted by the Federal government which are related to phenoxy herbicides and Agent Orange;
- o the identification of those areas in which additional research is required; and
- o arranging 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 Science 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 occuptional exposures to phenoxy herbicides.

We in HHS and the Work Group have taken 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 before, we owe the Vietnam veterans and their families nothing less.

I have been particularly impressed with the high level of cooperation individual members of the Work Group have brought to the Work Group effort. I have found a genuine commitment among them to carry out the task we have been given.

In that regard, we have taken seriously the health concerns of Vietnam veterans. Individual members of the Work Group have spent considerable time with veterans groups and individual veterans. In addition, the Work Group will hold a public meeting in Washington on September 22 to provide an additional opportunity for dialogue with scientists, veterans and other interested persons. We do not underestimate or dismiss as unimportant the veterans' very real worries about their health or the health of their offspring. Nor do we cavalierly dismiss as statistical aberrations the persistent anecdotal reports we hear suggesting unusually high incidences of particular diseases. In fact, our research agendas in the areas of birth defects and cancers have been prompted in part by just such anecdotal reports.

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.

State of Scientific Knowledge about Agent Orange

Given the base of knowledge about phenoxy herbicides that existed before the Work Group was formed, and recognizing that additional scientific inquiry will take time, the Work Group asked its Scientific Panel to report on the status of 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 all 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.

The basis for that conclusion is as important as the conclusion itself. 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, the fact is that 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 methods by which data can be obtained on the health effects of Agent Orange on veterans. The Work Group believes that the most promising alternative at this time is the Epidemiologic Study of Ranch Hand Personnel proposed by the Air Force. Therefore the Science 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, despite the fact that its results will not be able to be used to establish a quantitative risk for specific health decrements among ground troops 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 are expected to be useful in providing a focus as to the type of health effects that may possibly occur in other veterans.

However, even that potential use of Ranch Hand study results must be tempered with a caveat. The relatively small size of the Ranch Hand population -- and I would like to emphasize that it nevertheless appears to be the only population whose exposure to Agent Orange can at this time be reconstructed with some degree of accuracy -- does limit the level of confidence that we can place on failure to detect an increased incidence of a variety of health effects. The relatively rare health effect may not appear in the study results simply because its rarity, as compared to the size of the study population, is too great. Put simply, the Ranch Hand study will be useful in providing directional signals for health effects we should look for in other veterans, but it will not provide us with a detailed roadmap.

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

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 these 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 Science Panel recommended and the Work Group agreed that additional studies be conducted which focus on the health status of Vietnam veterans. Such studies will permit a determination of 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.

Consistent with that view, the Work Group believes that the focus of the Veterans Administration's epidemiological 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.

In reaching these conclusions, the Work Group considered

at great length the proposed Ranch Hand study designed by the Air Force. In addition to reviewing the the study design, the Science Panel held a several hour discussion on the design with Air Force scientists. It also reviewed the peer review group reports the Air Force had previously received on the protocol.

The Science Panel agreed with the other peer review groups that the size of the cohort (1160 individuals) the Air Force proposes to study does impose limitations on the statistical power of the study, i.e., the study's ability to detect the relatively rare health effect, which is the problem I mentioned earlier. However, the Panel agreed with the Air Force that adding to the cohort ground troops whose exposure to Agent Orange was clearly significantly less than that of Ranch Hand personnel, although not documentable, would dilute the cohort and therefore further diminish the likelihood of detecting adverse health effects.

The Science Panel also considered the recommendation made by the other peer review groups that the number of health indices which the Air Force proposed to study be reduced. The Panel agreed that the wide spectrum of health indices included in the Air Force study design may reduce participation in the study because of the substantial time commitment which will be required of study participants. The Panel noted, however, that the Air Force received no consistent

recommendations from any of the peer review groups as to which health indices should be eliminated, reflecting the lack of knowledge among scientists as to which health indices are of principal importance in evaluating potential herbicide toxicity. The Panel recommended that the Air Force consider reducing the scope of health parameters in the study if it is unable to obtain participation in the study by a substantial number of Ranch Hand personnel.

After receiving the views of the Science Panel, the full Work Group considered the Ranch Hand study. On August 1, 1980, the Work Group forwarded its recommendations on the study to Stuart Eizenstat. The Work Group recommended that the Ranch Hand study be conducted, but conditioned its approval on an explicit recognition 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 twenty years --in order to have a better chance of detecting and validating latent or subtle effects.

The Work Group also considered whether the public would perceive the study's findings as credible if the Air Force conducts the study. This issue of credibility was raised by the National Academy of Sciences and other peer review groups, although none of them questioned the ability of the Air Force scientists to conduct the study.

The Work Group recommended that the Ranch Hand study be conducted by the Air Force because it was -- and 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 peer review committee reporting to the White House Office of Science and Technology Policy or some other high level entity. The Committee should be comprised of representatives of the Work Group, scientists from the private sector and academia, and persons with scientific backgrounds nominated by veterans organizations.

The Work Group has begun working with the Air Force to establish this peer review monitoring mechanism. The Air Force expects to begin the study in November.

In addition to the Ranch Hand study, the Work Group has considered and initiated a number of other scientific activities. VA, DoD and HHS have signed an interagency agreement to fund a birth defects study to be conducted by HHS' Center for Disease Control (CDC). The purpose of the two-year study is to determine whether Vietnam veterans are at an increased risk of siring children with birth defects.

CDC will conduct this retrospective case control study using its Metropolitan Atlanta Congenital Defects Surveillance

Program. Since 1968, this program has maintained a registry of all children born with congenital birth defects at hospitals in the metropolitan Atlanta areea. The registry now has about 10,000 cases on file, from a total population of approximately 250,000 births.

CDC plans to select the families of about 5,000 registry babies for study. This group will comprise those children with serious or major birth defects. Families of an equal number of normal babies will be selected as controls.

Families of each case and each control baby will then be interviewed, with a focus on the father's service in Vietnam. CDC estimates that 25,000 men reside in the Atlanta area who served in Vietnam and that, since their average age is 30, many are likely to have had children in the past five years.

As I pointed out, the study will determine whether Vietnam veterans are at greater risk of having children with birth defects. It will not provide any birth defects data specific to Agent Orange nor any 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 Work Group also believes that the study will provide

important information. As of this date, we have only persistent anecdotal reports suggesting the possibility of a higher than normal rate of birth defects among children of Vietnam veterans, and allegations that this higher rate is due to Agent Orange exposure. This study will be an important step in determining whether there are hard data behind the anecdotal reports, although it will not determine whether Agent Orange is a culprit.

The birth defects study will also build on the base of knowledge which has recently been enlarged by the results of a 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 Science Panel, is one of the co-authors of the study. The study found no significant decrement in fertility among the exposed mice, nor any 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 make 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 Science Panel reviewed one German and four Swedish scientific papers on the carcinogenicity of chemical constituents 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.

Additionally, the National Cancer Institute has 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 Science Panel has recommended that studies be considered to determine whether the risk of cancer suggested by the animal studies and the German and Swedish papers is resulting in the occurance of tumors by examining the veteran population for excess cancer incidence.

The Work Group is convinced that we need to conduct a large-scale case control study of the Vietnam veterans population, similar in concept if not in all of the details to the study being conducted of the Australian veteran population. We need to know whether Vietnam veterans are as healthy as a population of their size, with comparable age and other characteristics, as it should be. If not, we need to know

what specific health problems are occurring with abnormal frequency and then we can further refine our inquiry to try to determine to what cause or causes a particular health decrement occurring with higher than normal frequency may likely be attributed. This is in line with the Work Group's initiation of the CDC birth defects study, as well as its recommendation that studies of tumor occurrence in the Vietnam veteran population be considered.

The research activities I have described above represent what I believe are substantial steps toward finding some of the answers to the many still unanswered questions about the health effects of exposure to Agent Orange and other phenoxy herbicides. Vietnam veterans have expressed concerns that they are also suffering from other adverse health effects as a result of exposure to Agent Orange. These include a tingling sensation in fingers and toes, sleeplessness, loss of sex drive, muscle weakness, liver dysfunction and other medical problems. Expanding the focus of the VA epidemiologic study as the Work Group has suggested to include service in Vietnam will tell us whether Vietnam veterans as a class are as healthy as a similar population their age, and will also tell us whether the anecdotal reports we hear about these other health effects attributed to Agent Orange can be statistically confirmed.

But I would like to repeat the cautionary words of my February testimony before this Committee. While we believe that the research being planned or already underway is important and valuable, we must constantly bear in mind that even the best efforts of which our scientists are capable may not produce definitive, incontrovertible scientific information about the health effects of Agent Orange. The answers may never be found, or may be found many years in the future.

At some point we may have to examine the available evidence and determine whether the scientific information upon which to base policy decisions is sufficient, knowing full well that science has not been and may not be able to provide a complete answer. It will not be the first time that social policy decisions have had to be made on less than total scientific proof. At the very least, the research I have outlined today should be useful in formulating a fair and humane social policy.

In the months ahead, the Work Group will keep this Committee apprised of ongoing and planned research. We will also try to keep you and the public fully informed of our progress.

In that regard, I have attached to this statement and ask that it be considered a part of my testimony, copies of the Work Group's second, third and fourth progress reports

to Stuart Eizenstat as well as its August 1, 1980 letter to Mr. Eizenstat regarding the Ranch Hand study. These documents provide additional details on a number of points I have discussed today, and explore many of the related features of our overall effort.

I will be happy to answer any questions the Committee may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

THE GENERAL COUNSEL

FOR RELEASE UPON DELIVERY

STATEMENT

by

Joan Z. Bernstein

General Counsel

Department of Health & Human Services

and

Chair

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

Committee on Veterans' Affairs

United States Senate

September 10, 1980

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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 Science 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 occuptional exposures to phenoxy herbicides.

We in HHS and the Work Group have taken 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 before, we owe the Vietnam veterans and their families nothing less.

I have been particularly impressed with the high level of cooperation individual members of the Work Group have brought to the Work Group effort. I have found a genuine commitment among them to carry out the task we have been given. They have regularly attended Work Group meetings and have provided staff and other support when needed. As a professional working group, it has been extraordinarily effective. It has also been a personal pleasure for me to work with them.

We have taken seriously the health concerns of Vietnam veterans. Individual members of the Work Group have spent considerable time with veterans groups and individual veterans. In addition, the Work Group will hold a public meeting in Washington on September 22 to provide an additional opportunity for dialogue with scientists, veterans and other interested persons. We do not underestimate or dismiss as unimportant the veterans' very real worries about their health or the health of their offspring. Nor do we dismiss as statistical

aberrations the persistent anecdotal reports we hear suggesting unusually high incidences of particular diseases. In fact, our research agendas in the areas of birth defects and cancers have been prompted in part by just such anecdotal reports.

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.

State of Scientific Knowledge about Agent Orange

Given the base of knowledge about phenoxy herbicides that existed before the Work Group was formed, and recognizing that additional scientific inquiry will take time, the Work Group asked its Scientific Panel to report on the status of 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 all 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.

The basis for that conclusion is as important as the conclusion itself. 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, the fact is that 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 methods by which data can be obtained on the health effects of Agent Orange on veterans. The Work Group believes that the most promising alternative at this time is the Epidemiologic Study of Ranch Hand Personnel proposed by the Air Force. Therefore the Science 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, despite the fact that its results will not be able to be

used to establish a quantitative risk for specific health decrements among ground troops 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 are expected to be useful in providing a focus as to the type of health effects that may possibly occur in other veterans.

However, even that potential use of Ranch Hand study results must be tempered with a caveat. The relatively small size of the Ranch Hand population -- and I would like to emphasize that it nevertheless appears to be the only population whose exposure to Agent Orange can at this time be reconstructed with some degree of accuracy -- does limit the level of confidence that we can place on failure to detect an increased incidence of a variety of health effects. The relatively rare health effect may not appear in the study results simply because its rarity, as compared to the size of the study population, is too great. Put simply, the Ranch Hand study will be useful in providing directional signals for health effects we should look for in other veterans, but it will not provide us with a detailed roadmap.

Furthermore, neither the Ranch Hand study nor any future studies of ground troops will tell us whether Agent Orange is the cause of particular adverse 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 adverse 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 Science Panel recommended and the Work Group agreed that additional studies be conducted which focus on the health status of Vietnam veterans. Such studies will permit a determination of 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.

Consistent with that view, the Work Group agrees that the focus of the Veterans Administration's epidemiological 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, under the leadership of Senator Cranston, voted last Thursday to authorize the 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 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 Administration is currently reviewing the details of this provision and will shortly be prepared to comment more fully on it.

In reaching its conclusions as to the VA study, the Work Group considered at great length the proposed Ranch Hand study designed by the Air Force. In addition to reviewing the study design, the Science Panel held a several hour discussion on the design with Air Force scientists. It also reviewed the peer review group reports the Air Force had previously received on the protocol.

The Science Panel agreed with the other peer review groups that the size of the cohort (1160 individuals) the Air Force proposes to study does impose limitations on the statistical power of the study, i.e., the study's ability to detect the

relatively rare health effect, which is the problem I mentioned earlier. However, the Panel agreed with the Air Force that increasing the size of the cohort by adding ground troops whose exposure to Agent Orange was clearly significantly less than that of Ranch Hand personnel, although not yet documentable, would dilute the effect of exposure of the cohort and therefore further diminish the likelihood of detecting adverse health effects.

The Science Panel also considered the recommendations made by the other peer review groups that the number of health indices which the Air Force proposed to study be reduced. The Panel agreed that the wide spectrum of health indices included in the Air Force study design may reduce participation in the study because of the substantial time commitment which will be required of study participants. The Panel noted, however, that the Air Force received no consistent recommendations from any of the peer review groups as to which health indices should be eliminated, reflecting a lack of unanimity among scientists as to which health indices are of principal importance in evaluating potential herbicide toxicity. The Panel recommended that the Air Force consider reducing the number of health parameters in the study if it becomes evident that this factor poses a deterrent to participation in the study by a substantial number of Ranch Hand personnel or members of the control group.

After receiving the views of the Science Panel, the full Work Group considered the Ranch Hand study. On August 1, 1980, the Work Group forwarded its recommendations on the study to Stuart Eizenstat. The Work Group recommended that the Ranch Hand study be conducted. 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 twenty years -- in order to improve the chances of detecting and validating latent or subtle effects.

The Work Group also considered whether the public would perceive the study's findings as credible if the Air Force conducts the study. This issue of credibility was raised by the National Academy of Sciences and other peer review groups, although none of them questioned the ability of the Air Force scientists to conduct the study.

The Work Group recommended that the Ranch Hand study be conducted by the Air Force because it was -- and 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 peer review committee reporting to the White House Office of

Science and Technology Policy or some other high level entity. The Committee should be comprised of representatives of the Work Group, scientists from the private sector and academia, and persons with scientific backgrounds nominated by veterans organizations.

The Work Group has had discussions with the Air Force on how this mechanism would work. The Air Force believes that, if approved, the Ranch Hand study could begin in the relatively near future.

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 (CDC). 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.

CDC will conduct this retrospective case control study using its Metropolitan Atlanta Congenital Defects Surveillance Program. Since 1968, this program has maintained a registry of all children born with congenital birth defects at hospitals in the metropolitan Atlanta area. The registry now has about 10,000 cases on file, from a total population of approximately 250,000 births.

CDC plans to select the families of about 5,000 registry babies for study. This group will comprise those children with major anatomical birth defects. Families of normal babies will be selected as controls.

Families of each case and each control baby will then be interviewed, with a focus on the father's service in Vietnam. CDC estimates that 25,000 men reside in the Atlanta area who served in Vietnam and that, since their average age is approximately 30, many are likely to have had children in the past five years.

As I pointed out, the study will determine whether Vietnam veterans are at greater risk of having children with birth defects. It is not expected to provide any birth defects data specific to Agent Orange nor any 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 Work Group also believes that the study will provide important information. As of this date, we have only persistent anecdotal reports suggesting the possibility of a higher than normal rate of birth defects among children of Vietnam veterans, and allegations that this higher rate is due to Agent Orange

exposure. This study will be an important step in determining whether there are hard data behind the anecdotal reports, although it is not expected to establish whether Agent Orange is the causative factor.

The birth defects study will also build on the base of knowledge which has recently been enlarged by 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 Science Panel, is one of the authors of the study. The study found no significant decrease in fertility among the exposed mice, nor any 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 Science Panel reviewed one German and four Swedish scientific

papers on the carcinogenicity of chemical constituents 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.

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The Science Panel has recommended that studies be considered to determine whether the risk of cancer suggested by the animal studies and the German and Swedish papers is resulting in the occurrence of tumors by examining the veteran population for excess cancer incidence.

The Work Group is convinced that we need to conduct a large-scale study of the Vietnam veterans population, similar in concept if not in all of the details to the study being conducted of the Australian veteran population. We need to know whether Vietnam veterans are as healthy as a population of their size, with comparable age and other characteristics, should be. If not, we need to know what specific health

problems are occurring with abnormal frequency and then we can further refine our inquiry to try to determine to what cause or causes a particular health decrement occurring with higher than normal frequency may likely be attributed. This is in line with the Work Group's initiation of the CDC birth defects study, as well as its recommendation that studies of tumor occurrence in the Vietnam veterans population be considered.

The research activities I have described above represent what I believe are substantial steps toward finding some of the answers to the many still unanswered questions about the health effects of exposure to Agent Orange and other phenoxy herbicides. Vietnam veterans have expressed concerns that they are also suffering from other adverse health effects as a result of exposure to Agent Orange. These include a tingling sensation in fingers and toes, sleeplessness, loss of sex drive, muscle weakness, liver dysfunction and other medical problems. It is hoped that by expanding the focus of the VA epidemiologic study, as the Work Group has suggested, to include service in Vietnam, the study will tell us whether Vietnam veterans as a class are presently as healthy as a similar population their age who did not serve in Vietnam, and will also tell us whether the anecdotal reports we hear about these other health effects attributed to Agent Orange can be confirmed statistically.

But I would like to repeat the cautionary words of my February testimony before this Committee. While we believe that the research being planned or already underway is important and valuable, we must constantly bear in mind that even the best efforts of which our scientists are capable may not produce definitive, incontrovertible scientific information about the health effects of Agent Orange. Full answers may never be found, or may be found many years in the future.

At some point we may have to examine the available evidence and determine whether the scientific information upon which to base policy decisions is sufficient, knowing full well that science has not been and may not be able to provide a complete answer. It will not be the first time that social policy decisions have had to be made on less than total scientific proof. At the very least, the research I have outlined today should be useful in formulating a fair and humane social policy.

In the months ahead, the Work Group will keep this Committee apprised of ongoing and planned research. We will also try to keep you and the public fully informed of our progress.

In that regard, I would note that we have already supplied to the Committee, and ask that it be made a part of the record, copies of the Work Group's second, third and fourth progress

reports to Stuart Eizenstat, as well as its August 1, 1980 letter to Mr. Eizenstat regarding the Ranch Hand study. These documents provide additional details on a number of points I have discussed today, and explore many of the related features of our overall effort. I hope to be able to forward to the Committee in the near future updated timetables for our research activities and charts which detail the amounts of Federal funds being spent on this research.

I will be happy to answer any questions the Committee may have.

DAVID E. BONIOR
12TH DISTRICT, MICHIGAN

WASHINGTON OFFICE:
1130 LONGWORTH OFFICE BUILDING
WASHINGTON, D.C. 20515
TEL.: (202) 225-2106

Congress of the United States
House of Representatives
Washington, D.C. 20515

HOME OFFICES:
95 NORTH GRATIOT
MT. CLEMENS, MICHIGAN 48043
TEL.: (313) 469-3232

526 WATER STREET
PORT HURON, MICHIGAN 48060
TEL.: (313) 987-8889

TESTIMONY OF THE HON. DAVID E. BONIOR, M.C. BEFORE THE SENATE VETERANS AFFAIRS COMMITTEE. SEPTEMBER 10, 1980

Mr. Chairman, I commend you for holding hearings on the issue of Agent Orange today and for the opportunity to submit testimony for the official record. I also feel the singular aspect under consideration today, the recommendations of the Inter-Agency Work Group on Phenoxy-Herbicides and its Scientific Panel, is a most worthy one to discuss as the Work Group has assumed a major role toward resolving the problem of veteran exposure of Agent Orange. As the recommendations of the Work Group and the Scientific Panel will no doubt have a sizeable impact on the future direction of government policy, it is most appropriate to publicly scrutinize these recommendations.

At the outset, I would like to inform the Committee that I have serious reservations concerning the recent recommendations of the Work Group and Scientific Panel. My first reservation concerns the Work Group recommendation that the Air Force should move forward with their proposed epidemiological study, commonly called the "Ranch Hand" study. My second reservation lies in the Scientific Panel's belief that "...additional studies should be considered...as as to determine whether service in Vietnam, rather than solely Agent Orange exposure..." is the cause of health problems being experienced by Vietnam veterans.

I would like to preface my remarks on these recommendations with a small slice of history. From the time Agent Orange became a source of concern to thousands of Vietnam veterans who feared their health problems might be related to Agent Orange, the obstacles they have faced in attempts to obtain information, understanding and medical treatment have been numerous and overwhelming. While the Veterans Administration should be the veteran's most logical choice to find assistance, this certainly has not been the case. The Veterans Administration performance in helping Vietnam veterans has been less than satisfactory. The horror stories of veterans who have visited or contacted VA facilities in search of answers regarding Agent Orange are legendary and have been experienced by the Administrator himself. The Veterans Administration lack of knowledge regarding Agent Orange is matched only by its lack of desire to attain information which would assist them in helping the veteran. While there has been much speculation that the VA was less than eager to participate with other governmental bodies in turning up information which would shed light upon the human health effects of exposure to Agent Orange, it is the VA again which confirmed everyone's worst suspicions. In information supplied for the record of the House Veterans Affairs Subcommittee on Medical Facilities and Benefits, Agent Orange Hearings, February 25, 1980,

the VA states that "The Veterans Administration has not engaged in any formal correspondence with the EPA regarding its conclusions on the possible effects on human health of 2,4,5-T". While the "conclusions" to which the VA alludes concern the ALSEA I study, I find it incredulous that the VA did not inquire as to the existence of any more contemporary data.

As a Member of Congress, it has not been easy to obtain information on Agent Orange in a cooperative manner. I discovered it is difficult to also make a contribution. When I forwarded a number of epidemiological studies to the VA for examination, I was sent back a letter noting that VA "scientific advisers... do not think the papers make a major contribution to answering the problem that is of concern to all of us". However, nationally known experts, who have studied the papers, have arrived at different conclusions. Dr. Richard Remington, Dean of the School of Public Health at the University of Michigan, stated that "the case control investigations are among the most carefully conducted investigations of their type that I have ever seen. In toto, the Swedish work is credible if not fully conclusive". The opinion I received from the VA has characterized VA policy from the beginning of the Agent Orange controversy; hasty and ill-conceived, resulting in the continued suffering of veterans and a lack of credibility and prestige in the Veterans Administration.

Similarly, the Air Force has decided to embark on an epidemiological study of its own. This study, the "Ranch Hand" study, is proposed to be conducted solely on the personnel who participated in the Air Force Agent Orange spray missions. Such a study, without participation of any exposed ground troops, is almost tantamount to examining the crew of the "Enola Gay" instead of the exposed victims of the atomic bomb.

Many people in the veteran community were extremely skeptical of having the Air Force conduct its own study and their fears were realized when the National Academy of Sciences published its critique of the "Ranch Hand" protocols. The NAS noted that the major conclusion of their report was that the Air Force report "...as designed...probably would not identify adverse health effects due to exposure of the herbicide, primarily because of the relatively small size of the group to be studied and the relatively short time for which it is proposed to follow the health of the group".

The NAS also expressed "grave concern...beyond the scientific review...that given the temper of the times, and the sense of diminishing public trust in the institutions of American society... questions concerning the credibility and impartiality of the report might be raised if the study were to be conducted internally by the Air Force".

As it became more and more apparent that the two major governmental bodies charged with the responsibilities of finding

workable solutions to the Agent Orange dilemma were becoming embroiled in stultifying controversy, the emergence of the Work Group and its Scientific Panel as the new government insurer of credibility and impartiality assumed new importance. It was in this new scientific body that once again the trust of the veteran was transferred in the quest for a successful resolution to this extraordinary problem.

However, after examining the recommendations of the Work Group and the Scientific Panel, I am fearful that the results have been prejudiced as the decisions arrived have come from the same sources which have been continually challenged and contradicted, the Veterans Administration and the Department of Defense.

My strong disappointment aside, I am deeply disturbed that the Work Group refused to acknowledge the discovery made by the General Accounting Office in its report of November 16, 1979, entitled, "U.S. Ground Troops in South Vietnam Were Sprayed With Agent Orange". Even the most casual observer of the Agent Orange saga has been made familiar with the contents of this report so I will not belabor the contents. Suffice it to say, all are not familiar, since in the Work Group letter of transmittal to Mr. Stuart Eizenstat, the Work Group states that a "major stumbling block continues to be an inability to identify a population of ground troops the nature and extent of whose exposure can plausibly be reconstructed or documented with any degree of reliability". The glaring absence of even a reference to the GAO report indicates the Work Group was less than detailed in

their research and such an omission is evident in their recommendations.

It is my sincere hope that this lack of action, the absence of inter-agency cooperation and a less than vigorous pursuit of all available information upon which to base decisions will cease to be the hallmark of the Agent Orange question.

Over ten years ago, the late Senator from Michigan, Phil Hart stated that "absolutely no delay is tolerable in the search for answers to the questions posed" regarding exposure to 2,4,5-T. It is my position that we should not delay either. The veterans of this country have waited for answers long enough. However, we should not tolerate decisions based on incomplete information which would deprive the veterans of this country an accurate assessment and cause for the physical problems they are experiencing.

Thank you.

VIETNAM VETERANS OF AMERICA
329 EIGHTH STREET NE, WASHINGTON, DC 20002 • 202/546-3700

STATEMENT OF

STEVEN M. CHAMPLIN

VIETNAM VETERANS OF AMERICA

before the

SENATE COMMITTEE ON VETERANS' AFFAIRS

September 10, 1980

Mr. Chairman, members of the Committee, I am honored to appear before the Committee to discuss the August 1 report of the Interagency Work Group.

Following the lead suggested by your staff and letter of September 3, I will concentrate on the Work Group's recommendation that future studies focus generally on the health status of Vietnam veterans.

There can be no responsible governmental policy on the Agent Orange issue without a credible scientific review process. Compenation policy must rest on science. If there is no credible review of the science, there will be no credible compensation policy. But equally important is the more amorphous problem of public trust. Public confidence on Agent Orange policy will be dependent on public confidence in the process for reviewing and developing scientific evidence.

The Work Group's official mandate was to coordinate federal studies on the Agent Orange question. But in fulfilling that mandate, they have gone a long way toward establishing a credible review process.

This is an important accomplishment for which the Work Group is to be commended.

But, it remains a tenuous accomplishment. For the Work Group labors not only against the weight of earlier federal policy, it also labors against an almost insurmountable

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SCIENCE AND POLICY

Any expansion of the scientific horizon of the Agent Orange issue is of value, but not all breakthroughs are of equal policy value. In matters as complicated as the impact of TCDD, it is important not only to have answers, but to have answers to the right questions. Which questions are the right questions is essentially determined by the policy perimeters.

So, for example, spending $100,000 to determine whether or not exposure to TCDD causes chloracne would seem foolish, yet the Work Group surely shows that they have their ear to the ground in pouncing on the possibility of a CDC study of birth defects.

This example is simple enough. But, the relations between policy and the conduct of scientific studies become a great deal more complex. It is crucial at the threshold, however, to recognize the obvious.

<u>Science for the sake of science is not what we are after. We need science in the service of policy</u>.

It is a mistake, accordingly, to assume that the Work Group can guide the conduct of scientific studies without regard to the substantive policy questions at states. Almost every decision about the conduct of the studies is implicitly a policy decision.

lifeline on the study, and, perhaps most importantly, an explicit declaration of the statistical power of the study.

This decision may make sense as a matter of science. But, note the implicit problem these steps address but do not control--the possibility that policy makers might misuse false negatives.

The Work Group can only adddress, and not control, this problem because, simply, they are not the policy makers.

I do not fear that the VA will use early negative findings on carcinogenicity to clear TCDD. Surely the public debate has advanced far enough to preclude that. Rather, I fear that false negatives will lead the VA not to proceed on the basis of other studies--some of which are in, and some of which are expected.

<u>It has been the VA's consistent policy, to the degree that they have a policy, that they will pay claims only on the basis of sudies specifically done on Vietnam veterans</u>. Early negatives from the Ranch Hand Study, given this policy perimeter, would require the VA to postpone compensation.

> THE WORK GROUP'S DECISION, ACCORDINGLY, WHATEVER ITS SCIENTIFIC VALUE, MAY HAVE THE POLICY RESULT OF DENYING COMPENSATION TO CANCER PATIENTS, FOR EXAMPLE, FOR AT LEAST A DECADE, DESPITE THE OTHER EVIDENCE AVAILABLE.

The problem rests in the Work Group's mandate. Section 307(c) of P.L. 96-151 mandates that the President coordinate the study of the Agent Orange question, but does not mandate that compensation policy be coordinated. While it is hard to maintain any hard boundaries around anything in Washington, by in large the Work Group has kept to the business of science.

The questions I raise, accordingly, are not meant as a criticism of the Work Group decisions. Instead, it is more an attempt to emphathize with their position. Even the finest decision of the Work Group has a tenuous value. For its impact is in the hands of someone else.

STUDY DECISIONS

If I were to poll the 15,000 or so families who have received Agent Orange information packages from our office, I think they would, at this time, almost unanimously oppose the Work Group's recommendation to broaden projected studies to consider service in South Vietnam, and not merely exposure to Agent Orange. They would feel, first of all, that such a move diffused the issue, deny it the clarity created by the single name "Agent Orange." But, they would also feel that the recommendation really amounts to saying, "Well, you were wrong. Agent Orange really isn't the problem folks."

As many callers have told me, everytime they hear a description of the Work Group recommendation they seem to

Each one of these premises may be accurate. But they raise a series of questions that need public answers to restore confidence in the Work Group's decision.

Turning first to the problem of exposure--after several years of DOD denial that veterans were exposed, the GAO did an independent audit and found a large group of Marines who were in the area of the spraying on the day of spraying itself. As the GAO itself noted, their method might be adequate for construction of a cohort for epidemiologial study.

A variety of different questions have to be isolated. Any ground troop cohort may have so distinct an exposure history from the Ranch Hand crews as not to be usable in expanding the Ranch Hand cohort. But that is distinct from saying they are not an adequate cohort for an independent study.

Of course, the GAO methodology may not be adequate. While the DOD's denial that troops were exposed at all was clearly inaccurate, it may be the case <u>that ground troop exposure from aerial spraying</u> was not as severe as, for example, exposure from perimeter spraying. As such, use of a cohort isolated through the herbs tape may produce a cohort at unacceptably low risk.

In any case, a first question is clear:

1. Why is the GAO methodology not adequate for the definition of a Marine cohort?

3. If we can isolate a subgroup for purposes of protecting against risk dilution, why can't we simply use that subgroup, expanded, as the original cohort?

There are at least two answers to question three. The first says that we ought to do a general study based on service in South Vietnam anyways, as we apparently did after World War II and Korea. This may be true, but if so, it constitutes an independent policy goal. The goal may be commendable, worthy of another piece of legislation. But an Agent Orange study should not be diverted to other purposes unless, and only if, this diversion does not endanger the orginal purpose of the study.

The second answer to question three returns us to the Work Group's other rationale for expanding the study. This answer runs something like this: We need to look at an Agent Orange subgroup in the context of a larger study to look at the impact of other risks.

Vietnam veterans were not exposed to Agent Orange in a vacuum under laboratory conditions. They were exposed in an entire environment. It seems sound environmental sense to study exposure to Agent Orange in a way that allows consideration of the interaction between Agent Orange and other elements in the environment. We strongly endorse such an effort.

Testimony of Steven D. Jellinek
Assistant Administrator for Pesticides and Toxic Substances,
U.S. Environmental Protection Agency
Before the Committee on Veteran's Affairs
U. S. Senate
September 10, 1980

Good morning, Mr. Chairman, I am Steven D. Jellinek, Assistant Administrator for Pesticides and Toxic Sustances, EPA. Accompanying me is Dorothy Patton, trial attorney in our Office of General Counsel, who manages the day-to-day conduct of the Agency's case in the hearings mandated by the pesticide law as a means to come to a final decision on whether 2,4,5-T should be permitted for use in the United States. Donald Barnes, Science Advisor in my immediate office, is also present. Dr. Barnes is EPA's regular representative on the Interagency Work Group.

In your letter of September 2, Mr. Chairman, you stressed the Committee's desire for an "update" on agency activities relevant to the Agent Orange matter. EPA's testimony of February 21, 1980, provided a discussion of the regulatory framework in which pesticides use is controlled and a brief chronology of regulatory activity directed at the herbicide 2,4,5-T, which was a constituent of Agent Orange. For your convenience, that statement is appended to my testimony. In the intervening months, the trial phase of our 2,4,5-T proceeding has begun, EPA has completed an accelerated review of existing data on 2,4-D, the other component herbicide with which Agent Organge was formulated, and the Agency has participated as an observer in the Interagency Work Group. I will provide a brief description of each of these activities and will endeavor to respond to your questions about specific aspects, as best I can.

The 2,4,5-T Cancellation

Like other laws intended to protect health and the environment, the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), embodies the proposition that regulatory action should be taken to avert unreasonable risk of harm although there may not be conclusive evidence that harm will otherwise

result. As regulators, we are concerned with risks - the possibility of future adverse effects from the use of pesticides - against which we balance the benefits which would be lost if that use were not permittted. Science can rarely provide certain measures of the components on either side of this balance. And, equity considerations - such as "who reaps the benefits and who bears the risks?" - are also factored into the decision calculus. For these and other reasons we have been accorded considerable discretion under the law to determine what is and is not an unreasonable risk from a pesticide. In adopting FIFRA, however, Congress has provided important guidance to the Agency on how this discretion is to be excercised. The D.C. Circuit Court expressed that guidance concisely in upholding a major pesticide cancellation action: "Congress made clear that the public was not to bear the risk of uncertainty concerning the safety of a [pesticide]." EDF V. EPA 548 F. 2nd at 1018 (D.C. Cir. 1976)

I have included this brief preamble to my status report on our 2,4,5-T proceedings, because I have found that those who are unfamiliar with the milieu in which EPA operates often have difficulty in fitting the "proofs" on which our decisions are based into other policy frameworks. On reflection, many EPA critics can understand why Congress would not confer a "presumption of innocence" upon chemicals intended to harm a life-form, at least not in a health protection statute. However, I find often that until that fact is made explicit, regulators and others, particularly those we regulate, talk right past each other.

Although FIFRA places the burden of proof that a pesticide does not pose unreasonable risks on the proponents of pesticide use, EPA must of course sustain an affirmative burden of going forward with evidence in

support of a proposal to withdraw the government's earlier approval of a chemical. The Administrator is required to issue findings in support of his belief that a pesticide may cause unreasonable risks. Proponents of registration are entitled to challenge these findings in a trial-like setting. They may cross-examine witnesses called in support of the Agency's case and present their own expert testimony. FIFRA requires the Agency to balance the risk and benefits of a pesticide in order to reach a cancellation decision. The current hearing has two phases, one relating to risk, the other relating to benefits.

The Agency is now completing the presentation of its direct case on the risk issues. We began presenting witnesses in March, and our last direct case witness is scheduled to appear during the first week in October. The U.S. Department of Agriculture has also presented several witnesses, as has the Northwest Coalition for Alternatives to Pesticides, an environmental group. We expect the Dow Chemical Company, the principal registrant actively participating in the risk phase of the case, to begin its case presentation early in October and to complete its presentation early this winter. The benefits presentation is scheduled to begin in January and may be completed early in the summer.

The Agency's risk case is based on data from four different subject matter areas. The first area concerns the toxic effects of 2,4,5-T, Silvex, and TCDD in test animals. Agency witnesses have testified that test animals exposed to these chemicals experience reproductive effects such as birth defects and still births, carcinogenic effects such as tumors; and adverse effects on the immune system, the system which affects the body's ability to resist disease. These effects occur in test animals at very low levels of exposure to TCDD.

The second phase of the Agency's case on risk is based on testimony concerning cancer and abortions in some human populations. In this part of the case, the Agency has presented or will present testimony from several European epidemiologists who have conducted studies showing that some populations who were exposed to 2,4,5-T and/or TCDD also have an increased risk of some forms of cancer. In addition, the EPA study in a 2,4,5-T forest use area in Oregon showed a temporal relationship between the use of 2,4,5-T in that area and the occurrence of spontaneous abortions in women residents of the area.

The remaining parts of the Agency's case relate to potential human exposure to these chemicals. In the third part of the case, Agency witnesses presented testimony on chemical issues relating to exposure potential such as distribution of the chemicals to different environmental compartments, persistence of the chemical in different media such as water and soil, and translocation of these chemicals into growing plants. This information on distribution to and residence time in the environment is relevant to assessing potential human exposure.

The fourth part of the Agency's case is based on case histories of incidents in which 2,4,5-T and Silvex had drifted from their sites of application to non-target property on which people were living and working. Investigation of these incidents led to the development of chemical and biological evidence documenting the occurrence of 2,4,5-T on the non-target property. The case histories are examples of reports, commonly referred to as "anecdotal" incidents, which in this case were well documented because of contemporaneous investigations showing that 2,4,5-T and/or silvex were, in fact, present on sites away from the application sites.

These data, showing toxic effects in test animals exposed to these chemicals, a relationship between 2,4,5-T use and elevated risks of cancer and miscarriage in some human populations, and exposure of non-target sites to 2,4,5-T and Silvex indicate that use of these herbicides may present risks of adverse effects in populations exposed to these chemicals.

We anticipate that testimony will be taken over several more months. At the conclusion of evidence presentation, the parties will brief the case and the Administrative Law Judge will prepare a recommended decision. The Administrator will consider the recommendation, further briefs from the parties, and the certified record, and will either accept or modify the recommendation as he sees fit. The Administrator may cancel some or all uses or decide that cancellation is not warranted. We are probably a year or more away from the Administrator's decision.

EPA's Working Group Involvement

As an observer agency to the Interagency Work Group, EPA has not attempted to play a leading role in the formulation or resolution of policy issues which that body must address in pursuing its mission. This is required by the fundamental differences in EPA's domestic regulatory responsibility from the Working Group's concern with studies which are directed to questions of individual illness causation upon which compensation determinations turn.

However, we have participated fully in discussing issues of a scientific and technical nature, have apprised the Work Group representatives from other agencies about the progress of the 2,4,5-T proceeding, including providing testimony schedules and witness statements. We have also and have furnished technical assistance, such as laboratory sample analysis, when that assistance is needed.

I should add, in this regard, that relatively little evidence concerning toxicity or other characteristics of 2,4,5-T and TCDD which is presented in the cancellation hearing is a product of EPA research. Rather, EPA is organizing and assisting in the presentation of research findings by the principal authors of laboratory and epidemiological investigations from around the world, conducted under the sponsorship of private companies, other governmental entities, and institutions of higher learning.

Results of Our 2,4-D Review

On April 29, 1980, EPA announced that our review of studies on 2,4-D led us to conclude that evidence of adverse effects was not sufficient to justify short-range regulatory action, but that new testing is needed to augment a rather old and sparse data base. EPA has authority under FIFRA to direct manufacturers to perform the needed studies and the Agency intends to do this soon. Attached is a copy of the conclusions we were able to reach concerning major categories of toxicological evaluation based on the studies available to us. While there is a basis for concern about reproductive and mutagenic effects, which will be clarified by future testing, we did not generally see effects as severe as those associated with 2,4,5-T and TCDD nor did 2,4-D evoke these responses at the low dose levels at which 2,4,5-T demonstrates toxicity.

I hope that this description of EPA's current pesticide regulatory activities is helpful to you, Mr. Chairman, as you wrestle with the many complex aspects of the Agent Orange problem. My associates and I will be pleased to respond to your questions.

STATEMENT

OF

DR. RALPH J. MCCRACKEN
ACTING DIRECTOR, SCIENCE AND EDUCATION ADMINISTRATION
U.S. DEPARTMENT OF AGRICULTURE
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

SEPTEMBER 10, 1980

Box 24

1970 WHEN IT WAS DISCOVERED THAT DIOXIN, A HIGHLY TOXIC CHEMICAL, OCCURRED AS A CONTAMINANT IN 2,4,5-T, USDA SCIENTISTS IMMEDIATELY INITIATED RESEARCH ON THE ENVIRONMENTAL BEHAVIOR, FATE, AND EFFECTS OF DIOXINES IN PLANTS, SOILS, WATER, AIR, AND ANIMALS. WE CONDUCTED ONE OF THE FIRST CHEMICAL SURVEYS FOR DIOXINS IN PESTICIDES. THIS RESEARCH HAS BEEN WIDELY USED TO EVALUATE THE POTENTIAL IMPACT OF DIOXINS IN THE ENVIRONMENT. BETWEEN 1967-1976 WE FUNDED RESEARCH TO DEVELOP THE TECHNOLOGY NEEDED TO ASSURE THE SAFE, EFFECTIVE, AND ENVIRONMENTALLY COMPATIBLE DISPOSAL OF PESTICIDES. SAFE METHODS WERE DEVELOPED FOR THE INCINCERATION OF AGENT ORANGE. DR. BOVEY, A SEA SCIENTIST AT COLLEGE STATION, TEXAS, HAS COMPILED ONE OF THE MOST COMPLETE BIBLIOGRAPHIES AND SETS OF PUBLICATIONS ON PHENOXY HERBICIDES. HE RECENTLY PUBLISHED A BOOK ON THESE HERBICIDES.

SINCE AN IMPORTANT MISSION OF THE DEPARTMENT OF AGRICULTURE IS TO DEVELOP THE TECHNOLOGY TO ASSURE PRODUCTION OF HIGH QUALITY FOOD, FEED, FIBER, AND FOREST PRODUCTS AT AN ECONOMICAL PRICE, MUCH OF OUR RESEARCH IS PRODUCTION ORIENTED. WE ARE ONLY INDIRECTLY INVOLVED IN THE AREAS OF PUBLIC HEALTH WHICH ARE MORE ADEQUATELY ADDRESSED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, OR IN THE CASE OF VIETNAM, THE VETERANS ADMINISTRATION. WE HAVE MAINTAINED AN ACTIVE INTEREST, HOWEVER, IN CERTAIN STUDIES THAT ADDRESS THE EXPOSURE AND ENVIRONMENTAL FATE OF PESTICIDE USE IN AGRICULTURAL AND FOREST PRODUCTION.

AGRICULTURAL AVIATION ASSOCIATION. THE NAAA STUDY IS DESIGNED TO EVALUATE THE POSSIBLE EFFECTS OF PESTICIDE EXPOSURE ON REPRODUCTIVE MORTALITY AND MORBIDITY. PART I OF THE NAAA STUDY IS A NATIONWIDE SURVEY COMPARING THE HEALTH EFFECTS ON AGRICULTURAL PILOTS, THEIR SPOUSES AND CHILDREN. IT ALSO INCLUDES A STUDY OF THE PILOTS' SIBLINGS, THEIR SPOUSES AND CHILDREN WHO ARE NOT OCCUPATIONALLY EXPOSED TO PESTICIDES. TO DATE, APPROXIMATELY 500 AGRICULTURAL PILOTS ARE INVOLVED IN THIS STUDY, WITHIN WHICH THERE ARE 200 MATCHED SETS OF PILOTS' SIBLING RESPONSES. THE RESULTS OF THIS STUDY WILL BE RELEASED AT THE ANNUAL CONVENTION OF THE NATIONAL AVIATION ASSOCIATION IN LAS VEGAS ON DECEMBER 3. THE NAAA STUDY, PLUS OUR USDA EXPOSURE RESEARCH, SHOULD GIVE SOME MUCH NEEDED INFORMATION ON THE HEALTH STATUS OF A POPULACE WITH A HIGHER THAN NORMAL EXPOSURE, I.E., AERIAL APPLICATORS AND THEIR FAMILIES.

THE FOREST SERVICE HAS BEEN ACTIVITY CONSIDERING PARTICIPATION IN EPIDEMIOLOGICAL STUDIES CONCERNING HUMAN HEALTH EFFECTS ASSOCIATED WITH EXPOSURE TO PHENOXY HERBICIDES SINCE EARLY 1978. IN LATE 1979, IT WAS CONCLUDED THAT THE FOREST SERVICE WOULD UTILIZE THE EXPERTISE WITHIN THE DEPARTMENT OF AGRICULTURE'S OFFICE OF SAFETY AND HEALTH MANAGEMENT (OSHM) TO DETERMINE IF FOREST SERVICE RECORDS WERE ADEQUATE TO SUPPORT EPIDEMIOLOGICAL STUDIES. SPECIFIC INFORMATION ABOUT FORMULATION, AMOUNTS SPRAYED, DATES OF PROJECTS, AND WORK CREW POSITION (MIXER, LOADER, NOZZLEMAN, ETC.) WERE NEEDED TO DOCUMENT EXPOSURE.

STUDY. THIS WAS THE STUDY THAT MR. NEIL DAVIS WAS TO HAVE DIRECTED. AFTER A PRELIMINARY REVIEW OF AVAILABLE FOREST SERVICE RECORDS, WE DECIDED TO FUND THE SRI PROPOSAL. THE FOREST SERVICE ALSO SUPPORTS THE UNDERTAKING OF THE BIRTH DEFECTS STUDY, BUT AVAILABLE RESOURCES ONLY ALLOWED FUNDING OF THE COOPERATIVE SPONTANEOUS ABORTION STUDY.

THE STUDY IS CURRENTLY BEING CONDUCTED IN OREGON AND WASHINGTON USING A CASE-CONTROL STUDY PROTOCOL. THE STUDY POPULATION INCLUDES FORESTRY WORKERS, WHEAT FARMERS, COMMERCIAL PESTICIDE APPLICATORS, AND SPOUSES IN ORDER TO INVESTIGATE A HIGH PROPORTION OF PERSONS WITH EXPOSURE TO 2,4-D. ONE HUNDRED (100) SPONTANEOUS ABORTIONS (CASES) AND 200 LIVE BIRTHS (CONTROLS) OCCURRING WITHIN THE PAST 18 MONTHS WILL COMPRISE THE STUDY. THE STUDY IS LIMITED TO 2,4-D EXPOSURE BECAUSE THE EPA'S 1979 CANCELLATION SUSPENSION OF ALL MAJOR USES OF 2,4,5-T IN THIS AREA EFFECTIVELY PREVENTED EXPOSURE DURING THE 18-MONTH STUDY PERIOD. THE TARGET COMPLETION DATE IS MID-OCTOBER, 1980.

THE FOREST SERVICE HAS COMPLETED A STUDY WHERE 9 DEER WERE ENCLOSED IN A FORESTED AREA AND TREATED WITH 2,4,5-T. TISSUE SAMPLES HAVE BEEN ANALYZED FOR TCDD RESIDUES, BUT THE QUALITY CONTROL SAMPLES NEED TO BE VALIDATED BEFORE RESULTS CAN BE INTERPRETED.

IN SUMMARY, MR. CHAIRMAN, REGARDING THE PROJECTS SHOWN ON THE AUGUST 1 PROGRESS REPORT OF THE INTERAGENCY WORK GROUP ON THE

STATEMENT OF

GUY H. McMICHAEL, III
GENERAL COUNSEL
VETERANS ADMINISTRATION
BEFORE THE
COMMITTEE ON VETERANS AFFAIRS
UNITED STATES SENATE
SEPTEMBER 10, 1980

Mr. Chairman and Members of the Committee:

Good morning. I am pleased to have this opportunity to appear before you today to update you concerning the progress of the Veterans Administration in dealing with the complex issue of Agent Orange and other phenoxy herbicides utilized as defoliants during the period of conflict in Vietnam.

With me today are Dr. Barclay Shepard, Special Assistant to the Chief Medical Director, Mr. Charles Peckarsky, Director, Compensation and Pension Service and Dr. William Jacoby, the Deputy Chief Medical Director.

Mr. Chairman, since we last appeared before you in February 1980, the Agent Orange issue has continued to generate a great deal of public concern regarding the possible health impact of this defoliant upon our Vietnam veteran population and their families. This concern is genuine and is evidence of the real fears of many of those who believe they may have been exposed to this chemical agent. I wish to assure this Committee that the Veterans Administration

is fully cognizant of these concerns and fears and of the need to find answers as soon as possible. As you know, the problems are many and often their solutions are elusive and extremely complex. There is much we still do not know about the adverse health effects of the components of Agent Orange upon a human population, and it should be recognized that we may never be able to clarify completely the entire matter of the long-range health effects of Agent Orange. We are committed, however, to the rigorous pursuit of a resolution of this complex issue in a forthright and scientific manner.

Today, I would like to describe to the Committee the several Agent Orange related activities in which we have been engaged since our most recent testimony in February. The VA, of course is only one of many bodies that are working to resolve this issue. Our activities have involved us in establishing a closer working relationship with other Federal and non-Federal agencies and scientific institutions, as well as with individual scientists and researchers who are working in this area. We have been in contact with the Governments of Australia and New Zealand, nations which also participated in the Vietnam conflict, whose veterans have also expressed fears and concerns about their exposure to Agent Orange. In my testimony today, I will update you on the activities of the Veterans Administration and explain our role relative to the activities of other Federal agencies.

VA ACTIVITIES RELATED TO AGENT ORANGE

Office of Special Assistant to the Chief Medical Director

When the issue of Agent Orange first surfaced, it was difficult, if not impossible, to foresee the level of activity in which we would ultimately be engaged. At first, the task of coordinating Agent Orange activities was given to our Assistant Chief Medical Director for Professional Services within the Department of Medicine and Surgery (DM&S) as one of his many areas of responsibility. With the increased level of interest and activity, it became apparent that a centralized control point within DM&S, exclusively devoted to handling the heavy demands of the Agent Orange program, was necessary. To provide this essential administrative control, the Office of Special Assistant to the Chief Medical Director for herbicide orange affairs was established in April 1980. Dr. Barclay M. Shepard was selected to serve in that position. It is the responsibility of that office to:

1. Respond to Agent Orange inquiries;
2. Recommend policy to the newly formed Policy Coordinating Committee, about which I will comment in a moment;

3. Direct the activities of the VA's Advisory Committee on Health-Related Effects of Herbicides;
4. Establish liaison with other Federal and non-Federal agencies and institutions;
5. Oversee the Agent Orange functions of the 180 environmental physicians in our 172 VA medical centers and 8 independent outpatient clinics;
6. Coordinate the conduct of special Agent Orange studies; and,
7. Serve as special adviser to the Chief Medical Director on all matters concerned with the Agent Orange issue.

The tasks assigned to the office are many and varied. It is an office which we believe will best serve the needs of this Agency in responding to the Agent Orange problem and ultimately, serve the needs of our Vietnam veteran population and their families.

Policy Coordinating Committee:

The magnitude and complexity of the Agent Orange issues have also dictated the need to establish a high-level policy coordinating body for the entire Agency. Consequently, in June 1980 a special Agent Orange Policy Coordinating Committee (PCC)

was established. This Committee serves as the central coordinating point to review all aspects of Agent Orange activities within the VA and to develop and establish new policy initiatives. The Administrator has appointed me to chair this Committee. Members are selected because of their relationship to, or knowledge of, the Agent Orange program and represent a base of expertise essential to the mission of the committee. This Committee generally oversees the activities of the Special Assistant to the Chief Medical Director and maintains a close liaison with that office and the day-to-day activities for which it is responsible. The relationship is one of mutual support in implementing policy developed by the PCC and carrying out the medical aspects of that policy by the Office of the Special Assistant. We anticipate that this newly formed Committee will prove useful in coordinating the many and diverse Agent Orange activities with which the Veterans Administration is involved.

Advisory Committee on the Health-Related Effects of Herbicides:

The Advisory Committee on the Health-Related Effects of Herbicides has continued its valuable role in providing for the exchange of scientific information concerning herbicides and their possible adverse health effects, advice to the VA on future courses of action, including appropriate research

efforts, and coordination among the various agencies represented. This Committee's function remains that of assembling and analyzing the information which the VA needs in order to formulate policy and implement procedures in the interests of our Vietnam veterans. The Committee, in this regard, has a fact-finding and advisory role and may on occasion recommend policy for consideration by the Agency. We believe that the Committee membership is balanced and reflects a broad range of scientific and medical expertise, as well as representing various veterans groups who are concerned with the Agent Orange issue.

The Advisory Committee holds quarterly meetings which are open to the public. The Committee has held five meetings since June 1979, the most recent being held August 6, 1980. We encourage the submission of questions by representatives of public or private agencies and by concerned individuals who may be in attendance at these meetings. In accordance with the provisions of the Federal Advisory Committee Act, a formal transcript of these meetings is prepared and is made available to various government offices, and interested individuals.

The Committee has acted on several significant Agent Orange related issues including the following:

(1) Considered the various aspects of an epidemiological study of Vietnam veterans exposed to Agent Orange;
(2) Recommended that VA closely monitor epidemiological studies performed on other population groups exposed to the chemical components of Agent Orange in conjunction with agriculture and forest management as well as exposure resulting from industrial accidents.
(3) Discussed the effects of Agent Orange on the male reproductive system;
(4) Discussed the variables involved in attempting to define a threshhold level of exposure to dioxin which might result in toxic effects in humans;
(5) Explored the types of animal studies that might be performed in order to define the effects of human exposure to Agent Orange.

Copies of the recent study of male mice exposed to the components of Agent Orange were provided to members of the Advisory Committee for their review and analysis at the August 6 meeting. We are now in the process of assembling and reviewing the comments on that study which have been submitted by the Committee members. Copies of the Swedish and West German studies on workers exposed to dioxin have also been distributed to Advisory Committee members with a similar request for their analysis and comment regarding the significance of each study.

In this regard, I am aware, Mr. Chairman, of your continuing interest as expressed in a recent letter concerning our current views of these studies. Pending a report from the Advisory Committee, I can state that the Veterans Administration supports the views expressed by the Scientific Panel of the Interagency Work Group, on which the VA is represented, and by the Office of Technology Assessment. We fully agree that these studies provide credible and valuable leads in the scientific pursuit of the health effects of exposure to phenoxy acids. We do not believe, however, that they answer the question as to whether there exists a causal relationship between exposure to phenoxy acid herbicides as used in Vietnam and the appearance of various types of malignancies. We note the use of the term "correlation" by the Scientific Panel in commenting on the Swedish studies. I am informed that when used in the scientific context, the term means "co-existence" of two factors, not a "cause and effect" relationship.

The Advisory Committee on the Health-Related Effects of Herbicides will continue to function as an important focal point of our efforts to find answers to the questions about adverse health effects resulting from the use of phenoxy herbicides in Vietnam or elsewhere and to communicate with the public concerning these matters.

Interagency Work Group:

In addition to seeking advice and recommendations from our own Advisory Committee, we have actively participated in the efforts of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants which was established by the White House in December, 1979 The Interagency Work Group (IWG) is responsible for monitoring and coordinating Federal research efforts and other activities regarding the possible health effects of herbicides such as Agent Orange and is charged with reporting to the White House the results and implications of these efforts as well as recommending policy to the White House. The Work Group is chaired by Joan Z. Bernstein, General Counsel of the Department of Health and Human Services. It includes representatives of the Department of Health and Human Services (DHHS), Department of Defense (DoD), and the Veterans Administration. Representatives of the Environmental Protection Agency, the Departments of Agriculture and Labor, the White House Office of Science and Technology Policy and the Congress' Office of Technology Assessment also participate as observers. The IWG, which meets on a monthly basis, utilizes the services of its Scientific Panel to review, analyze, and comment on research activities already underway or being planned by Federal agencies and non-Federal research organizations.

We believe that the efforts of the IWG and of its Scientific Panel have been extremely helpful to us and we look forward to continued active participation and cooperation.

AGENT ORANGE REGISTRY

The Agent Orange Registry was initiated in 1978 shortly after the VA became aware of the serious nature of the herbicide issue. It was one of the early steps taken by the VA to attempt to evaluate the magnitude of the problem. The purpose of the Registry was to identify those veterans who were concerned about the possible health effects resulting from exposure to herbicides in Vietnam and to document baseline medical information on individual veterans who might later develop illnesses which could be related to earlier herbicide exposure. The information was derived from the answers to a questionnnaire, a physicial examination and a set of baseline laboratory tests. It should be clearly understood that it was never the intent that the Registry would serve in any way as a portion of a research study. It was intended to be and remains simply a catalogue of a self-selected group of Vietnam veterans with some baseline medical information relating to them.

To date, approximately 30,000 veterans have been examined and the data from approximately 12,000 have been entered into the computer. We have, of course, been curious as to what insight an analysis of this information might yield. To assist us in the evaluation of the information contained in the Registry, a Data Analysis Task Force has been established. This group of individuals with special expertise in the areas of biostatistics and automated data processing technology as well as familiarity with existing VA computer files, has been carefully examining various aspects of the Registry in order to evaluate its current and future usefulness. The Task Force is currently reviewing the available information and is developing a data retrieval system which will provide a description of some of the health problems being experienced by those veterans who are enrolled in the Registry. The Registry continues to remain a useful mechanism for identifying concerned Vietnam veterans, for providing some medical information concerning these individuals, and for assisting us in maintaining contact with all participants. We are now developing a follow-up plan to reassure all individuals in the Registry that we will make every effort to maintain contact with them and keep them informed on any new developments relating to the Agent Orange issue.

Chloracne Task Force

As was indicated in our testimony in February, chloracne has been the only long-term finding which has been consistently recognized as resulting from exposure to dioxin, a contaminant of Agent Orange. A diagnosis of chloracne is based upon the distribution and type of lesions and a history of exposure to dioxin. However, it is not always easy to distinguish between chloracne and other, more common forms of acne. In response to concerns expressed before this Committee and in order to take advantage of the best possible expert advice, a special Chloracne Task Force was recently assembled. This group, which consists of four distinguished dermatologists, has been given the responsibility of designing a protocol for chloracne examinations and of preparing special educational materials to be utilized for the training of other dermatologists and our environmental physicians. The Task Force has also been given the responsibility of identifying a larger group of dermatologists who could serve as special consultants for chloracne cases as well as aiding in the adjudication of such cases by the VA. As you know, we are, at your suggestion, in the process of reviewing previous adjudications in this area to assess the validity of our earlier findings. Some educational

materials have already been prepared by the Task Force and are currently being reviewed. It is our goal to make these materials available to our physicians in the near future.

SPECIAL ACTIVITIES

Public Law 96-151 mandates the conduct of two major efforts by the VA relative to Agent Orange: an epidemiological study of Vietnam veterans exposed to phenoxy herbicides and a review and analysis of the world's literature on phenoxy herbicides.

Epidemiological Study:

The Veterans Administration is undertaking to contract with an epidemiologist from outside the Federal Government to design the protocol for the required epidemiological study. We have utilized an open, competitive bidding process. The proposals which we received have been critically reviewed and evaluated by a panel of experts, the majority of whom came from outside of the Veterans Administration. The membership of this panel included: Dr. Robert Hoover, Assistant Chief, Environmental Epidemiological Branch, National Cancer Institute; Dr. Gilbert Beebe, Clinical Epidemiology Branch, National Cancer Institute; Dr. Joyce Lashoff, Assistant Director, Health and Life Sciences

Division, Office of Technology Assessment; and Dr. John Kurtze,. Chief, Neurology Service Washington, VA Medical Center. Also serving on the panel as a non-voting member was Dr. Lawrence Hobson, who at that time was Deputy Assistant Chief Medical Director for Research and Development. A recommendation has been made by the panel and final negotiations with the successful bidder are currently underway.

The process of selecting a contractor has been impeded somewhat by actions taken by the National Veterans Law Center. In May of this year the Center had attempted to obtain a temporary restraining order to preclude the Veterans Administration from opening any proposals for a contract for the design of the epidemiological study. The basic contention of the Center was, and continues to be, that in their view the solicitation would not result in a proper and adequate protocol for the mandated study. Further, it was contended that the Veterans Administration should not carry out the study but rather the responsibility for conducting the study should be given to some unbiased and independent organization. Judge Harold Green of the United States District Court for the District of Columbia denied the Center's motion for a temporary restraining order stating that the complaints made by the Center were premature, since it could not be determined that the ultimate study design

would be deficient or defective until after it was prepared and subjected to careful review and analysis. The court retained jurisdiction of the case and advised the parties that if, after the development of the protocol, the Center still believes it has been harmed in some fashion, it could again seek a preliminary injunction. Subsequent to the denial of the motion, the National Veterans Law Center filed a protest with the General Accounting Office alleging irregularities or violations of procurement laws, rules, and regulations committed by the Veterans Administration in the procedures utilized to select a contractor. We are unable at this time to forecast when a final resolution by the General Accounting Office will be achieved. We are, therefore, somewhat constrained from proceeding with the mandated epidemiological study at this time.

Once a contract has been awarded, a study design will be prepared, and will be submitted to several groups for their review and comments. These reviewers will include the Veterans Administration Advisory Committee on Herbicides, the Interagency Work Group to Study the Possible Long-Term Health-Effects of Phenoxy Herbicides and the Congressional Office of Technology Assessment. Additionally, we are planning to request the National Academy of Sciences to select a panel of epidemiologists to review the proposed

protocol. Once the protocol has been approved, a determination will be made as to what organization will actually carry out the study. I know that this is a decision that is of great concern to you, Mr. Chairman. I want you to know that in arriving at that decision, we will be seeking the advice of many parties, not the least of which will be our oversight and appropriation committees in Congress. Consensus willalso be sought from the Interagency Work Group on this issue.

It is hoped that this study will be under way by late 1981. It should be emphasized that although some early findings and conclusions may be reported, more definitive answers will not be available for at least a decade or more. While this is frustrating to all who want quick answers to this complex issue, the fact remains that any possible long-term adverse effects on human health must of definition wait for a sufficient passage of time. We can reasonably expect some conclusions resulting from a study of this magnitude, but should not expect that this, or any other study, will provide all the answers we might want to obtain. In any event, on both a short- and long-term basis, the VA will vigorously seek answers to this most complex issue. Nevertheless, some basic information about the health status of Vietnam veterans should be available in a few years. That data should enable us to make those informed governmental policy decisions that will need to be made.

Literature Analysis:

The second major effort mandated by Public Law 96-151 is a review and analysis of the world's literature on phenoxy herbicides. The Veterans Admnistration has already undertaken an extensive review of the literature and is aware of much of its content. The goal of the mandated study is the preparation of a bibliography with an annotated review and analysis of the literature on phenoxy herbicides and of the contaminant, dioxin or TCDD.

In view of the large volume of the literature and technical complexity of the subject matter, it was decided that this task would best be accomplished by contract. A number of proposals have been submitted and a panel of experts will soon begin its review of them.

The provisions of Pub. L. No. 96-151 require that a report on the literature review and analysis be submitted by the VA to Congress by December 20, 1980. It is currently anticipated that completion of this review and analysis will require approximately nine months from the date the contract is awarded.

OTHER RESEARCH ACTIVITIES

Many research activities by other agencies concerned with the toxicity of phenoxy herbicides were described in the previous hearings in February. The VA continues to monitor with interest the progress of these studies.

Earlier this year the Center for Disease Control (CDC) proposed a study to determine if Vietnam veterans have a greater than normal risk of fathering children with birth defects. This question has been the source of considerable concern among our Vietnam veterans and their wives. We believe that a carefully designed and conducted study of this type would shed considerable light on this vexing and emotional issue. The CDC has received preliminary approval of the study from the Interagency Work Group and the protocol is currently in the review process. It is anticipated that the study will be jointly funded by HHS, DoD, and VA.

We are also continuing our active cooperation in the Agent Orange Registry at the Armed Forced Institute of Pathology (AFIP) for pathologic materials from veterans with possible exposure to herbicides during the Vietnam War. Currently, there are 79 cases entered in this Registry. An analysis of these cases is being conducted as material is submitted. Although the number

of cases is still very small, to date there is no evidence to suggest any increase in prevalence of a disease or group of diseases above the expected incidence. In order to expand the number of cases submitted, the VA has requested the AFIP to increase its efforts to encourage both civilian and Federal hospitals to submit case material whenever appropriate. The VA has been given every assurance that the AFIP is willing and able to comply with this request.

The VA is likewise monitoring with interest the progress of the Ranch Hand Study. Because of the unique nature of this study cohort with regard to known exposure to Agent Orange, this effort has peculiar and significant importance. The VA strongly endorses this study and has recommended that it be given full support.

VA AGENT ORANGE INFORMATION AND EDUCATION ACTIVITIES

Mr. Chairman, we are cognizant of your concern and of our responsibility to inform concerned invididuals of our activities regarding Agent Orange and of keeping them abreast of the latest developments concerning the Agent Orange issue.

Some of our more significant activities in this area have included an education conference on Agent Orange

which was held in Silver Spring, Maryland, on May 26-28, 1980. This follow-up conference to the one held in Washington, D.C., on September 27-28, 1979, was attended by our 180 environmental physicians and 54 adjudication staff from our Department of Veterans Benefits. Presentations were given by several of the country's leading experts on herbicides and included discussions of current knowledge regarding:

a. The chemistry, toxicology and metabolism of Agent Orange in experimental animals.
b. The manner in which herbicides were used in Vietnam.
c. The environmental fate of Agent Orange constituents.
d. Known and suspected human health effects of Agent Orange constituents.
e. Approaches to the epidemiological study of the effects on humans of Agent Orange.
f. How Vietnam veterans view the Agent Orange issue.
g. Latest VA Agent Orange initiatives and policies.
h. The need for compassionate service to veterans concerned about Agent Orange.

In our continuing effort to keep our Vietnam veterans advised concerning Agent Orange activities, an information pamphlet "Worried About Agent Orange?" has been prepared and distributed to 172 VA medical centers, 8 independent

outpatient clinics, 91 Vet Outreach Centers, 58 VA Regional Offices, members of Congress, State Veterans' Affairs Offices, veterans service organizations, and to other concerned agencies and individuals. The pamphlet, prepared in cooperation with the Interagency Work Group, provides a concise overview of Agent Orange.

Additionally, we are in the process of preparing two educational films on Agent Orange, the first of which will further inform veterans concerning what is known about Agent Orange and advise them of the Agent Orange Registry. The second film will soon be initiated and will serve as a training device for VA physicians and administrative personnel. Both films will be available for general public use upon request.

We will shortly begin publication of a Newsletter which will serve to provide information and guidance to 180 environmental physicians and other VA medical staff concerning Agent Orange related activities. We will continue to review our education and information program on a regular basis and make such modifications as warranted by the situation.

CONCLUSION

In conclusion, the Veterans Administration continues to be concerned about the Agent Orange issue and is striving to resolve it as expeditiously and reasonably as possible. As we have become more involved in the pursuit of answers to this problem, we have come to appreciate more fully the complexity of the many variables which impact on the Agent Orange controversy. The seriousness of the issue and the very real concerns of Vietnam veterans and their families are a constant motivating force for responsible and effective actions and programs. Unfortunately, we cannot provide all the answers to the many questions being raised today nor will we be able to do so in the immediate foreseeable future. As was indicated at the time of our last appearance before this Committee, the scientific inquiry process necessary to produce accurate reliable information does not lend itself to quick answers. We hope that the epidemiological study, the literature analysis, and all other research endeavors concerned with Agent Orange will assist us in providing definitive, scientifically valid answers. It must be stated that this process will take many years with no guarantee that all the answers will be found. We only guarantee that our search for answers will be supported by the full energy and resources at the disposal of the Veterans Administration.

I cannot state in strong enough terms that in the interim, it has been and will be the stated policy of the Veterans Administration that no eligible veteran will be denied medical care and treatment by the VA because the answers are not in. Our goal remains to provide compassionate and understanding service. This is a responsibility that we take very seriously.

PUBLIC HEARING

COMMITTEE ON VETERANS' AFFAIRS
Senator Alan Cranston, Chairman

Agent Orange Update

9:15 a.m., September 10, 1980
Room 412, Russell Senate Office Building

WITNESSES

1. Panel:

Joan Z. Bernstein, Esq., Chairperson, Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (IAG), and General Counsel, Department of Health and Human Services

Accompanied by: Dr. John Moore, Chairman, Science Panel, IAG, and Deputy Director, National Toxicology Program, NIEHS

Guy H. McMichael III, Esq., General Counsel, Veterans' Administration

Accompanied by: Dr. William J. Jacoby, Deputy Chief Medical Director
J. C. Peckarsky, Director, Compensation and Pension Service
Dr. Barclay Shepard, Special Assistant to the Chief Medical Director

2. Panel:

Steven D. Jellinek, Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency

Accompanied by: Dorothy Patton, Esq., Office of General Counsel, EPA

Dr. Ralph J. McCracken, Associate Director, Science and Education Administration, U.S. Department of Agriculture

Accompanied by: Dr. Philip C. Kearney, USDA representative, IAG, and Chief, Pesticide Degradation Laboratory, Agricultural Environmental Quality Institute, Science and Education Administration, USDA
Dr. John Ohman, Associate Deputy Chief, State and Private Forestry, U.S. Forest Service

3. Mylio Kraja, Director, National Legislative Commission, The American Legion, and John Sommer, Assistant Director of National Veterans Affairs and Rehabilitation Commission

4. Steven M. Champlin, Vietnam Veterans of America

5. Lewis M. Milford, Esq., National Veterans' Law Center

OPENING STATEMENT

Senator Alan Cranston
Committee on Veterans' Affairs

Agent Orange Update

September 10, 1980

Good morning and welcome to this morning's hearing of the Committee on Veterans' Affairs. The purpose of this hearing is to receive an update on the status of Agent Orange-related activities currently being conducted by various Federal agencies, particularly activities bearing on the state of scientific knowledge about the long-term health effects in humans of exposure to dioxin as contained in Agent Orange. The Committee is particularly interested in receiving views on the August 1 progress report of the White House Interagency Work Group on the Possible Long-Term Effects of Phenoxy Herbicides -- the so-called IAG -- and specifically on the recommendation of the IAG's Scientific Panel that serious consideration be given to conducting additional studies focusing generally on the health status of Vietnam veterans, so as to determine whether Vietnam service -- rather than Agent Orange exposure alone -- might be the cause for certain health problems.

In this regard, on September 4, the Senate passed S. 1188 with an amendment that I authored to section 307 of Public Law 96-151, the Veterans' Health Programs Extension and Improvement Act of 1979, the provision of law that mandates the VA to "design a protocol for and conduct an epidemiological study of persons exposed to Agent Orange while serving in the Armed Forces of the United States during the Vietnam conflict."

The amendment included in S. 1188 would amend the study provision in two ways: first, it would authorize -- but not mandate -- the Administrator of Veterans' Affairs to expand the scope of the statutory study along lines recommended by the Scientific Panel of the IAG so as to include an evaluation of the possible adverse health effects of factors other than Agent Orange related to service in Vietnam. Second, the amendment would make certain technical amendments to the description of the scope of the Agent Orange study mandate.

With regard to studies of adverse health effects in Vietnam veterans generally -- beyond the Agent Orange question -- the Scientific Panel seems to be suggesting that a combination of chemical, physical, environmental, and emotional factors peculiar to service in the war in Vietnam might be responsible for a host of health problems now being blamed on Agent Orange studies. Further, the Scientific Panel indicated that, because of the difficulties inherent in identifying a population of ground troops who were exposed to Agent Orange in Vietnam and the uncertain scientific data available on the health effects of dioxin exposure, it would be more appropriate to design a study that would recognize other factors as possible bases for any ill-health effects that are shown to exist in the Vietnam veteran population. I hope that our hearing this morning will assist the Administrator of Veterans' Affairs to make an informed decision on the possible expansion of the VA study in addition to determining what other future studies may be necessary for finding solutions to this serious issue.

Also, on September 4, the Senate unanimously adopted an amendment I coauthored with Senator Heinz to provide a neutral process and timetable for the development of guidelines for reviewing compensation claims based on disabilities believed to be related to Agent Orange exposure. We look forward to receiving testimony on this amendment also this morning.

So that the public will have an opportunity to receive an update on its efforts and progress to date, the IAG has scheduled a public meeting on September 22 which will include a review of the state of scientific knowledge about Agent Orange in addition to statements from the public concerning phenoxy herbicides and contaminants (including Agent Orange). This is something I have urged for some time, and I hope the IAG will schedule more such open hearings.

With respect to the VA's activities in this area, its Advisory Committee on Health-Related Effects of Herbicides held its most recent meeting on August 6. At that meeting, it was reported that the VA's Chloracne Task Force -- a group established to develop a methodology for more accurately diagnosing chloracne -- is presently putting together educational materials for dissemination to VA dermatologists to assist them in the proper diagnoses of this condition. In addition, the Task Force is in the process of appointing special dermatologist consultants who will advise VA physicians in difficult-to-diagnose cases. We look forward to an update on that activity.

On July 31, I wrote the VA about my recommendation, publicly announced on June 5, that the management of the Public Law 96-151 study be placed in the hands of an independent organization outside the Federal Government. I had made this recommendation reluctantly after coming to the conclusion that the intensity of emotions surrounding the Agent Orange issue indicated that it is unlikely that the findings of a study managed by the VA would be acceptable to Vietnam veterans and the public. I also requested details from the Administrator on the intensified outreach activities to which he had committed himself. I regret to say that I have not yet received a reply from the VA to this letter. I would hope we will learn today what the VA's position is on this matter.

Earlier this summer, the Committee received reports that some VA facilities have not been informative or responsive in terms of the inquiries of Vietnam veterans with respect to the availability of medical examinations and appropriate follow-up for possible adverse health effects as a result of Agent Orange exposure in Vietnam. Furthermore, some veterans who have undergone Agent Orange examinations have expressed dissatisfaction with the method in which the exam was conducted and the attitude of the staff toward them during that activity. In response to these concerns, the Committee staff, in association with the Veterans of Foreign Wars and the Disabled American Veterans, has developed a questionnaire which has been distributed to the district offices of these organizations. Veterans who have recently visited, or plan to visit, a VA medical facility to undergo the Agent Orange examination are being asked to fill out the questionnaire. I look forward to receiving the responses of these veterans. I believe that this kind of coordinated effort will help to insure a broad, timely, representative, and objective study of how the VA is responding to the needs of veterans who believe they've been exposed to Agent Orange. In addition, I look forward to receiving a report from the American Legion representative today on the feedback that organization has received on their own Agent Orange Examination questionnaire, and I would also welcome comments regarding the Agent Orange examinations from our other witnesses.

Finally, section 307(c) of Public Law 96-151 requires the President to assure that the VA's study is fully coordinated with studies that pertain to the adverse health effects in humans of exposure to dioxin being conducted or being planned by other entities in the Federal Government. Although the creation of the IAG predates the enactment of Public Law 96-151, I believe the IAG is the appropriate body to carry out this coordination on behalf of the President and, in fact, currently operates in this role. However, in order to make clear the IAG's role with respect to section 307(c), I hope the President will delegate formally his responsibility to assure such coordination under section 307(c) to the IAG, and I urge the IAG Chairperson to actively seek such a delegation.

We look forward to hearing the views of the witnesses today with respect to the direction we should be taking for present and future studies and activities related to Agent Orange. The results and findings of these may do much to reassure veterans and their families who are presently experiencing so much anxiety.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

FOR RELEASE UPON DELIVERY

Statement

By

John A. Moore, D.V.M

Deputy Director

National Toxicology Program

Department of Health and Human Services

and

Chair

Scientific Panel

Interagency Work Group to Study the Possible

Long Term Health Effects of

Phenoxy Herbicides and Contaminants

Senate Committee on Veterans' Affairs

September 10, 1980

Box 24

Mr. Chairman and Members of the Committee:

I am John A. Moore, a toxicologist, Deputy Director of the National Toxicology Program and Chair of the Scientific Panel of the Interagency Work Group to Study the Possible Long Term Health Effects of Phenoxy Herbicides and Contaminants. I wish to utilize this opportunity to appear before the Committee by describing several scientific activities that I believe are of relevance to Vietnam veterans. The testimony of Ms. Bernstein, Chair of the full Interagency Work Group, describes the Group's activities in a more comprehensive manner.

The activities of the Scientific Panel can be categorized in four broad areas:

1. identification of research activities being conducted or funded by the Federal Government including current status and targeted completion dates;

2. identification of areas in which additional research is required;

3. reviewing proposed research; and

4. review and interpretation of research results for relevance to the concern of Vietnam veterans that they are or may be at increased risk of suffering a variety of health impairments.

Future activities of the Scientific Panel will also include monitoring the progress of these research activities.

In an issue of this type, the preferred course for gathering scientific knowledge is to identify an exposed population and conduct the appropriate medical studies. Attempts to identify a population from among those ground troops who served in Vietnam have not been successful. This completely frustrates any study whose objective is to define what risk, if any, is associated with Herbicide Orange exposure. Without accurate knowledge as to who was actually exposed, you are likely to misclassify the study population and as a consequence erroneously interpret the study results.

The Air Force Ranch Hand personnel, who applied Herbicide Orange, are the only population whose frequency and duration of exposure are known. The degree of exposure may equal or even exceed that of people involved in the more intensive domestic uses of these types of herbicides. The Interagency Work Group has recommended that studies of the health status of this group be conducted since the detection of adverse health effects would provide an indication as to the type of health effects that may occur in other (ground troop) personnel. I feel obliged to caution the Committee there are definite limitations in the extent to which the results of this will be applicable to the total Vietnam veteran population. Two major limitations are that the small size of the Ranch Hand population restricts the

level of confidence that can be placed on a failure to detect an increased incidence of a variety of health effects; second, the detection of a health effect in this study would not permit the establishment of a quantitative health risk for ground troops since the Ranch Hand exposure is estimated to have been much greater.

It remains the opinion of the Scientific Panel that certain health decrements may be present in the veteran population that are a consequence of Vietnam service and are not directly associated with Herbicide Orange exposure. I suspect that any attempt to specifically and accurately identify who might have been exposed to other chemicals (which may include herbicides, insecticides, or drugs) or agents that may be peculiar to the Vietnam environment (such as fungal toxicants) would prove to be a most formidable, if not impossible, task. In view of these circumstances, coupled with the uncertainty of identifying personnel exposed to Herbicide Orange, the Scientific Panel suggests that a prudent approach to determining if Vietnam veterans are suffering health impairment is to design and conduct studies that would indicate if service in Vietnam is the causal factor.

Two possible health effects which are worrying many Vietnam veterans are birth defects and cancer.

Birth Defects

The principal issue is that veterans allege and fear that they are at an increased risk of siring malformed children years after exposure to Herbicide Orange. It is known that exposure of female rats and mice to 2,4,5-T or 2,3,7,8-TCDD (a constituent and contaminant of Herbicide Orange, respectively) can produce malformed offspring, fetal toxicity or fetal death. One cannot predict male effects from results obtained through studies of female exposure. Logic dictates that the ability to sire malformed offspring years after Herbicide Orange exposure could plausibly occur only if there was permanent gentic damage (mutation) to the spermatogonial cells. Current data on the mutagenicity of the Herbicide Orange components, 2,4-D, 2,4,5-T, and 2,3,7,8-TCDD, are judged to be inadequate. These chemicals are being retested using the best current techniques. The first results are now emerging and more will be forthcoming next year. The Scientific Panel will begin reviewing available data in the next two months.

A direct method of securing relevant toxicology data is through the administration of the constituents of Herbicide Orange to male laboratory animals and examining their sperm, ability to fertilize untreated females, as well as examination of their offspring for viability and malformations. The National Toxicology Program performed such a study in mice and reported its results in August. The study reported that there was no evidence of germ cell toxicity or adverse effects in the

development and survival of offspring as a consequence of paternal exposure to simulated mixtures of Herbicide Orange. This report is now being reviewed by the Scientific Panel.

A third approach is to study and evaluate human birth records data. The Scientific Panel evaluated the potential utility of a birth defects registry that has been maintained since 1968 in the metropolitan Atlanta area. The Panel recommended that a case control epidemiological study be conducted using this registry. The Panel felt that such a study would have a good probability of determining if Vietnam veterans are siring children with an increased incidence of specific malformations. Detailed planning of this study is underway at the Center for Disease Control. A detailed protocol for this study was recently submitted to the Scientific Panel, and will be reviewed September 25. While it will be useful as a means of determining if service in Vietnam resulted in an adverse health consequence, the study is unlikely to be able to indicate that Herbicide Orange was the factor responsible for increased incidence of malformations, should such a phenomenon exist.

Cancer

Veterans are concerned that cancer death, illness, or increased risk is associated with Herbicide Orange exposure.

Previously published studies had reported 2,3,7,8-TCDD (the contaminant in Herbicide Orange) to be a carcinogen in rats. Two additional animal cancer bioassays were recently completed by the National Cancer Institute and National Toxicology Program (NTP). The draft reports were reviewed for the National Toxicology Program by a group of independent scientists in June. This group of scientists concurred in the reports' findings that TCDD was carcinogenic in rats and mice. The recent study in rats confirmed the previously published reports; the mouse study extends the observation that 2,3,7,8-TCDD is a carcinogen to a second animal species.

The Scientific Panel also reviewed several case control epidemiology studies that were conducted by Swedish scientists. The Panel concluded that in spite of the reservations associated with case control epidemiology studies, the studies show a correlation between exposure to phenoxy acid herbicides and an increased risk of some forms of cancer. They also were of the opinion that independent verification would further validate these studies.

While these studies do establish a cancer risk from TCDD and possible phenoxy acid exposure, the data do not lend themselves to the establishment of a quantitive risk for veterans exposed to Herbicide Orange. To determine if "risk" is resulting in tumor occurrence, the veteran population should be studied directly.

A valid scientific criticism of such a study conducted at this time is that the study may be premature and prone to a false negative result given that the time elapsed since exposure in Vietnam is less than the 15-20 years that is typically required for excess cancer incidence to become manifest. However, the perception of cancer risk is a current concern, and in some instances, excess cancer may appear in a population 10 years after exposure. Therefore, such a study should be initiated. The rationale for this recommendation is:

1. A negative finding would allay the current and possibly increasing fear that Herbicide Orange exposure or Vietnam service already is resulting in excess cancer deaths.

2. A positive finding would establish service connection and permit appropriate policy decisions with respect to service connected disability and right to compensation.

3. A positive finding would identify the types of cancer for which there is increased risk and the medical community could focus attention on specific surveillance for early detection of tumors with a possible attendant increase in successful treatment.

4. An appropriate cohort will have been registered that can and must be resurveyed at appropriate time periods to detect changes in major morbidity or cancer incidence.

Such a study could easily be included as part of the Congressionally mandated Veterans Administration epidemiology study. Since results from this study are not expected for several years, other mechanisms will continue to be explored. The proposed Air Force Ranch Hand Study will study cancer incidence; however, the limitation of study size dictates that a larger study also be planned.

In conclusion, I am not optimistic that scientific studies will provide unequivocal data as to the significance of Herbicide Orange exposure to the health of Vietnam veterans. It is plausible that studies can determine if various health effects are associated with Vietnam service. The principal studies needed to provide such data may require several years to complete.

I would be happy to answer any questions the Committee may have.

NATIONAL
VETERANS
LAW
CENTER
4900 MASSACHUSETTS AVENUE NW
WASHINGTON, DC 20016
(202) 686-2741

STATEMENT OF THE
NATIONAL VETERANS LAW CENTER

BEFORE THE

SENATE VETERANS AFFAIRS COMMITTEE

UNITED STATES SENATE

Submitted by:

Lewis Milford
Ronald Simon
Lewis A. Golinker

September 10, 1980

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LAW CENTER
4900 MASSACHUSETTS AVENUE NW
WASHINGTON, DC 20016
(202) 686-2741

STATEMENT OF THE NATIONAL VETERANS LAW CENTER
BEFORE THE SENATE VETERANS AFFAIRS COMMITTEE

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

My name is Lewis Milford. At the witness table with me are Ronald Simon and Lewis Golinker. We are lawyers with the National Veterans Law Center (NVLC) in Washington, D.C. The Law Center is a public interest law firm affiliated with The American University School of Law, specializing in the legal problems of veterans. The Law Center is General Counsel to the National Veterans Task Force on Agent Orange, a national coalition of veterans organizations concerned with the Agent Orange issue; General Counsel to the National Association of Concerned Veterans, a national Vietnam veterans membership organization; and counsel on behalf of thousands of Vietnam-era and other veterans in numerous federal class-action lawsuits and federal administrative hearings. We also have testified before Congress on numerous legislative matters affecting veterans.

are these conclusions supported by facts or are the factual bases for the conclusions presented. Indeed, the only independent review of this data conducted by the General Accounting Office contradicted Defense Department estimates. The Work Group recommendations are short on actual documentation and are replete with conclusory statements about the difficulty of the scientific tasks that face the Panel. We are concerned that these recommendations represent a major shift in the scientific inquiry of Agent Orange, and believe that much more thorough and independent thinking is needed to avoid hasty adoption of the assumptions supporting the Panel's work. An inadequately justified change in scientific perspective at this time could have irreversible consequences for this sensitive issue.

Public discussion of these issues is essential before any action is taken to implement these recommendations, and we commend the Chairman for holding this hearing. The active involvement of veterans and the private scientific community is needed at this time because implementation of these recommendations will affect significantly the nature of scientific inquiry and the development of public policy on Agent Orange. We should emphasize that we do not believe the September 22, 1980 public meeting announced by the Work Group satisfies this need for public discussion of these recommendations and their factual bases. The Federal Register notice of the meeting contains no specific agenda items and provides for only a forty-five minute presentation to the public by the Work Group, and an opportunity for the public's comments on the

study of the health effects of Agent Orange on Air Force Ranch Hand personnel. The recommendation was based on the Scientific Panel's conclusion that the study should be conducted because the Ranch Hand population is the only identifiable population the nature of extent of whose exposure to Agent Orange can plausibly be documented with any degree of reliability. The Work Group recommended that the Air Force itself conduct the study and that an independent peer review committee monitor the conduct of the study. The Work Group concluded that this action "together with the quality of scientific expertise which the Air Force will bring to the study, can and should assure a high quality, unbiased study." One reason the Work Group recommended this course of action was because of the likelihood that delays would result if some other entity were chosen to do the work.

Ranch Hand Exposure

These recommendations were based in part upon a July 30, 1980 status report of the Work Group Scientific Panel. Several of the assumptions contained in that status report evidently were adopted by the Work Group to support the Work Group's Ranch Hand recommendation. These assumptions fall into two categories: those about Ranch Hand exposure data and those about ground troops and other sub-populations of likely exposed veterans. First, the Scientific Panel concluded that the Air Force Ranch Hand personnel constitute a population whose dates of service and frequency and duration of exposure are "documented" and "known," whose exposure is estimated to

of such significance. In addition, the Panel report makes no attempt to define or refer to the government records on exposure that are extant. Without a full inventory of such records, conclusory statements on exposure have less than the credibility that is required to maintain faith in the nature of the Panel's work.

The absence of such references and the lack of documentary support raises another troubling concern. It would appear from the style and tone of the report that the information on exposures was obtained principally, if not solely, from the Department of Defense. Obviously, that agency is the custodian of such information and it can be expected to be a source of such information. However, it appears that the statements about exposure data are based solely on the Defense Department's analysis of such data. We question whether any member of the Scientific Panel conducted an independent evaluation of the exposure data. If that has not been done, we question why it has not been done. If such an independent evaluation has not been done, serious questions should be raised about the independent nature of the Panel's work and credibility of these recommendations. This evaluation is particularly important since the only independent analysis of previous Defense Department estimates of exposure date have been contradicted. */ This GAO report is not even mentioned by the Panel.

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*/ Report by the Comptroller General of the United States, "U.S. Ground Troops in South Vietnam Were in Areas Sprayed With Herbicide Orange," November 16, 197[illegible].

As with the Panel's Ranch Hand conclusion on exposure, the tone of the report suggests that all the efforts to identify other sub-populations of exposed groups are those only of the Defense Department. The report does not refer to and there is no supporting documentation to suggest that any efforts independent of the Defense Department have been made to identify any other exposed sub-populations. Again, the question arises as to whether any member of the Scientific Panel inventoried extant records on possible exposures of non-Ranch Hand personnel, and conducted an independent review of these records to identify any other exposed sub-populations for study. If this was not done, there should be an explanation of the efforts, if any, which were undertaken to verify Defense Department estimates that no sub-population other than Ranch Hand could be identified as having exposures adequate to create a study population. Assuming that no such independent study was conducted, it is not surprising that the Ranch Hand estimates are the principal support for the Panel's recommendations, and the subsequent endorsement of the Air Force study by the Work Group.

We believe that it is the basic moral and scientific responsibility of this government to explore the feasibility of conducting studies on a variety of exposed sub-populations of Vietnam veterans. And that responsibility does not rest, nor should it rest, with the Defense Department. We assumed that the Work Group, in addition to the role of coordination, was established because there were doubts about

same day, as well as another group of 16,000 Marines who were within one-half kilometer of spraying missions within four weeks of the spraying missions. The report concluded that Marine Corps records and files provide a roster of all personnel assigned to a battalion during a given month and that current unit addresses for those still in active duty could be maintained, as well as information on the current names and addresses of those individuals. The report concluded that the chances that ground troops were exposed to Agent Orange were much higher than the Department of Defense had previously acknowledged. The report recommended that Congress direct relevant agencies to determine whether a study is needed on the health effects of Agent Orange based on the ground troops identified.

Remarkably, the GAO study of this group of possibly exposed ground troops was never mentioned in any of the Scientific Panel's reports. And there is no indication that GAO officials responsible for the study were ever asked to brief the Scientific Panel. The only briefing mentioned is that conducted by the Defense Department. This omission is totally inexplicable, particularly in light of the fact that these exposure estimates are the only documentation prepared independent of the Defense Department. Importantly, in this

for the conclusions reached by the Defense Department. Without an independent evaluation of the raw data and underlying facts for the DOD conclusions, the Work Group is not exercising the valuable independent function for which it was established. If the Work Group does not have the capability or the expertise to do this work, it should have at least recognized in its report specifically what should be done and insist that it should be done. Nowhere, for example, are there any references to in-depth investigations that would involve follow-up of individuals to obtain information about exposures that would serve as the basis for identification of other sub-populations. We have consulted experts who assure us that it is standard epidemiological technique to conduct extensive interviews by questionnaires of potentially exposed individuals to develop exposure data for epidemiological studies. The question is whether these techniques have been attempted, or even considered by the Scientific Panel.

Excluding ground troops from study consideration would appear to ignore a population heavily exposed to Agent Orange. Our discussions with Vietnam veterans reveal examples of heavy and persistent exposure. The DOD methods for excluding ground troops from study must be examined. The relevant questions would examine the methods which have been used by the Defense Department to conclude that estimating ground troop exposure is impossible. We understand that one of the major stumbling blocks is troop movement and the resulting inability to pinpoint troop locations during spraying missions. We assume

The reason for this concern is that the study contemplated by P.L. 96-151 probably will include ground troops as well as Ranch Hand personnel. Indeed, there is no indication to date of any limitation on the size or scope of the group to be studied. Nevertheless, the complex issue of level of exposure is one which this study is expected to address in developing a study design. Having made these recommendations, the Scientific Panel appears to have decided the study population question and has precluded any serious effort to conduct a searching analysis of the exposure issue by that study. Despite any misgivings about the way the VA is carrying out the Congressionally mandated study which have been expressed by our clients, the American Legion, the Veterans of Foreign Wars, as well as the Center, it appears that the role of that study, ordered by Congress less than a year ago, has been ignored, without any factual basis.

Another example of the undocumented and conclusory nature of the Panel's work concerns the appropriate standards for exposure for an Agent Orange study. The acceptable standard for exposure to be met for any study is a significant threshold question. The standards for exposure that have been adopted by other federal agencies is an important benchmark to evaluate the Scientific Panel's firm and unsupported conclusion that "accurate knowledge as to <u>actual</u> exposure" is needed before any epidemiological study can be conducted.

The dispute over standards for exposure in fact concerns differences over the level of certainty minimally required to embark on a study. But the standard for exposure expressed in the Panel's recommendation is not defined or explained

nothing more than attempts at modeling the likely contact of "potentially exposed individuals." The Alsea study, for example, contained no data showing actual exposure and noted that scientists have never demonstrated that there is a level of exposure to 2,4,5-T that has no adverse effect on humans. Thus, the agency assumed that the women in the Alsea study were exposed to 2,4,5-T. The level of certainty, or lack thereof, inherent in that study is important here. The agency concluded that the exposures of individuals in areas of spraying was similar to pesticide applicators and persons involved in pesticide application support activity. Thus, the agency equated, for purposes of the study, the exposure patterns of those individuals. The agency concluded that, while it could not determine the actual routes of exposure, there was sufficient information to make assumptions about possible "chances for exposure." Therefore, "exposure potential" was the basis for study conclusions, rather than any proof of actual exposure. The study demonstrates that the standards for exposure used by the Scientific Panel may have been much more conservative than is typically used by other government agencies in health studies.

This is not to suggest that all "potentially exposed" sub-populations be included in a study, because we do recognize the possible diluting effect of including less exposed individuals in any study population. The purpose of this discussion is to suggest other avenues for defining possible sub-populations for study and to emphasize that this

Ranch Hand: Credibility and Participation Rate

The Work Group in its August 1, 1980 recommendation approved on several conditions the conduct of the Ranch Hand study by the Air Force. The Work Group concluded that the establishment of an independent peer review committee to monitor the Air Force study would alleviate the concerns about credibility and conflict of interest raised in the National Academy of Sciences criticisms of the proposed study. The Work Group also recommended that the evaluation period for the study be extended from five to twenty years.

We believe that the lack of credibility inherent in the Air Force study cannot be alleviated by the establishment of any monitoring body. Veterans simply will not believe the results of a study conducted by the same agency that was and is still responsible for developing and implementing policy relating to chemical warfare. */ How can it be expected that veterans will believe that a fair, serious and credible study will be conducted by the agency which, six weeks before its study proposal was announced, stated that

> [W]e do not believe that a study of the health of any Vietnam veterans would add to the knowledge of the long-term health effects of herbicide orange or dioxin. It is extremely doubtful that a retrospective epidemiological study of that population would produce reliable results . . . **/

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*/ See W. Pincus, "Pentagon Speeds Development of Toxic Chemicals," Washington Post, September 5, 1980 at p. 23.

**/ April 4, 1979 letter from Deputy Assistant Secretary of Defense Marienthal to one of our clients.

affect both the participation rate, as well as the veracity of answers submitted to the Air Force, is the current status of many Ranch Hand personnel. We understand that many of the former Ranch Hand personnel are now commercial pilots certified by the Federal Aviation Administration. Such certification requires, among other things, statements that the individuals are in good health. True and accurate reporting to the Air Force about actual adverse ill health effects may jeopardize many of these persons' jobs and FAA certification. Thus, many of the former Ranch Hand people may have a strong disincentive to participate in the study and answer truthfully questions about current ill health effects. This matter evidently was not addressed by the Scientific Panel and is one that may seriously undermine any results of the Air Force study.

In conclusion, the recommendation that the Ranch Hand study be conducted by the Air Force is based on a number of untested assumptions and questionable conclusions. The issues we have addressed deserve a great deal of public scrutiny and independent investigation by the Work Group and the Scientific Panel, and the private scientific community. The purpose of these objections is not to delay further scientific inquiry, but to prevent hasty and ill-informed decisions and judgments that may further erode public credibility on this issue.

action in the two-year history of government activity in the Agent Orange area. It certainly will have the most far reaching consequences of any government decision that has been made. That the recommendation is based on no facts and no presentation of supporting evidence, and apparently without outside consultation, is indefensible.

The Scientific Panel articulated two reasons for the major shift toward future epidemiological investigations of Vietnam experience rather than Agent Orange. The first reason is the impossibility of ascertaining the requisite nature and degree of Agent Orange exposure. This reason was cited in the July 30, 1980 herbicide Orange status report to the Work Group. The second reason for recommending this shift in scientific focus is the purported occurrence of possible chemical and other exposures in Vietnam that may be associated with adverse health effects and which would allegedly make Agent Orange correlations impossible to achieve through epidemiological studies. Other unarticulated assumptions have been suggested as supporting this recommendation. One concerns the shorter time a service study could be completed. Another suggested reason for this recommendation concerns the ostensibly lower level of proof of service connection needed for VA benefit compensation. These assumptions are discussed in turn below.

The basic criticisms of the assumptions supporting the Ranch Hand recommendation are fully applicable here.

The Panel's report contains no documentation whatsoever to identify the substances suggested, the nature or extent of exposures to these substances, the time and places where the substances were used, or the toxicity of these substances; indeed, there is no factual or scientific support presented for the multiple exposure position. The absence of any references or summaries of data to support the position is rather startling. We fear the popular press accounts of multiple exposures has played a significant part in the development of this issue. As with the Ranch Hand recommendation, several questions must be made raised. The first question is whether any member of the Scientific Panel independently has inventoried available government records to determine the nature and use of other substances in Vietnam, or whether the Panel relied principally on the Defense Department for such information. The second question is whether any member of the Scientific Panel conducted an independent investigation to document exposures to these substances, considering the time and place of such exposures, the numbers of troops exposed, as well as the likely confounding nature of such documented exposures on the results of future Agent Orange epidemiological studies. Assuming that the answer to these questions is no, the third question is why not? The Panel at least should have explained the factual bases for the position it took, even assuming that no independent analysis was undertaken.

because of the concern of veterans and the existence of a Congressional mandate to do such a study. Raising the multiple exposure issue obviously complicates problems confronted by epidemiologists and public health agencies conducting studies and making complex regulatory risk assessment decisions. Although we are not scientists, we have discussed the matter with epidemiologists and toxicologists and we offer from a lay perspective our concerns with the Panel's analysis.

Even assuming that there were multiple exposures to harmful substances in Vietnam, the question remains whether these multiple exposures so confound the scientific investigation of Agent Orange that answers to whether Agent Orange is the causative agent cannot be obtained. We offer a somewhat different view on the question of confounding or multiple exposures, a view that appears to be consistent with the nature of epidemiological investigations of worker populations and civilians exposed to toxic chemicals. The issue of multiple causes for long-term health effects is one that has been faced by epidemiologists and public health officials. However, their conclusions appear to be significantly different than those arrived at by the Scientific Panel. That is, the consensus of scientific investigators appears to be that ill health effects such as cancer result from several environmental factors as well as other influences such as genetic and hormonal factors, all of which play varying roles in particular carcinogenic responses. Indeed, the consensus of these experts

has any member of the Panel even requested the basic data from the Defense Department to attempt such an investigation? If no attempts were made, the question again is why not? The government has a basic responsibility to initiate such independent action before major recommendations such as the Vietnam service study are proposed.

What we suggest should have been done is identify a variety of control groups who were and who were not exposed to these other substances for future studies that would attempt to factor out the effects, if any, of exposure to those substances. The purpose of such studies would be to determine the actual effects of exposure to Agent Orange distinct from the effects of the other exposures. We understand from consulting with other experts that such studies could be conducted.

Several factors suggest the feasibility of such an approach. The first is the demonstrated toxicity and potency of dioxin. That it is the most toxic chemical ever created suggests that its effects would be pronounced in comparison to the effects suggested to result from other exposures. In addition, the varied places and times where other substances were used would make possible the creation of several control groups in an Agent Orange focused study. Again, the issue is whether this approach is possible. The Panel's answer that it is not possible simply has no credibility without further evidence. The August materials do not begin to address this matter in a convincing manner.

the inadequate support offered for them. We also would like this Committee and the public to examine the quality of decision making concerning Agent Orange at the highest levels of this government. Questions about the respective roles of the Work Group, the Defense Department, and the Veterans Administration also are raised by these recommendations.

At a fundamental level, the credibility of government Agent Orange efforts cannot be restored while the Defense Department continues to play an increasingly significant role in these public health decisions. Truly independent efforts to evaluate the existing data on Agent Orange and other possible exposures are necessary before these recommendations should even be considered.