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June 11, 1979

TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF :

**Advisory Committee
on Health-Related
Effects of Herbicides**

**Veterans Administration
Washington, D.C. 20420**

1 THE VETERANS ADMINISTRATION

2 * * *

3 ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS
4 OF HERBICIDES
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15 The Veterans Administration
16 Room 119
17 810 Vermont Avenue, N. W.
18 Washington, D. C.

19 10:00 a.m.
20 Monday, June 11, 1979
21
22
23
24
25

1 ADVISORY COMMITTEE MEMBERS PRESENT:

2 PAUL A. L. HABER, M.D., Chairman
3 Assistant Chief Medical Director
4 for Professional Services
5 Veterans Administration
6 Washington, D. C.

7 GERRIT W. H. SCHEPERS, M.D., Vice Chairman
8 Medical Service
9 Veterans Administration
10 Washington, D. C.

11 JAMES R. ALLEN, JR., Ph.D.
12 Professor of Pathology
13 The University of Wisconsin
14 Medical School
15 Department of Pathology
16 Madison, Wisconsin

17 IRVING B. BRICK, M.D.
18 Senior Medical Consultant
19 National Veterans Affairs
20 and Rehabilitation Commission
21 The American Legion
22 Washington, D. C.

23 J. DAVIDSON ERICKSON, D.D.S., Ph.D.
24 Center for Disease Control
25 Birth Defects Branch
Atlanta, Georgia

BILL L. STEPHENSON
Environmental Protection Agency
Washington, D. C.

PHILIP C. KEARNEY, Ph.D.
Chief, Pesticide Degradation Laboratory
Department of Agriculture
Beltsville, Maryland

RICHARD A. LEMEN
Assistant Chief
Industrywide Studies Branch
Robert A. Taft Laboratories
Cincinnati, Ohio

ROBERT H. LENHAM
Special Projects Officer
Disabled American Veterans
Washington, D. C.

1 ADVISORY COMMITTEE MEMBERS PRESENT (Con't):

2 CAROLYN H. LINGEMAN, M.D.
3 Carcinogenesis Testing Program
4 National Cancer Institute
5 National Institutes of Health
6 Bethesda, Maryland

7 JOHN A. MOORE, D.V.M.
8 Associate Director for
9 Research Resources Program
10 National Institute of Environmental
11 Health Sciences
12 Research Triangle Park, North Carolina

13 SHELDON D. MURPHY, Ph.D.
14 Department of Pharmacology
15 University of Texas Medical School
16 Houston, Texas

17 COLONEL J. W. THIESSEN, MC USA
18 U. S. Army Environmental Hygiene Agency
19 Aberdeen Proving Ground, Maryland

20 STEERING COMMITTEE MEMBERS PRESENT:

21 RICHARD A. LEVINSON, M.D., Chairman

22 JOHN J. CASTELLOT, SR., M.D.

23 STRATTON APPLEMAN

24 LYNDON E. LEE, M.D.

25 J. C. PECKARSKY

FRED CONWAY

MARGARET KILDUFF

DONELD HOWELL

ALEX KUTNER

PAUL LEGOLVAN, M.D.

I N D E X

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P R O C E E D I N G S

1
2 DR. HABER: We would like to begin promptly.
3 Without further ado, I would like to introduce to you
4 our Chief Medical Director, Dr. Crutcher, an outstanding
5 internist, a man who is more concerned I think with clinical
6 practice of medicine in the Veterans Administration than
7 any of his illustrious predecessors.

8 Dr. Crutcher has taken time from his very busy
9 schedule to address us this morning, and I therefore
10 introduce him to give you an official welcome.

11 DR. CRUTCHER: Thank you, Paul. The Administrator
12 is receiving his doctorate degree from Emory University in
13 Atlanta, and he is supposed to be making a benedictory
14 appearance this afternoon, but air travel being what it is,
15 he may not make it.

16 I personally wanted to open up this session
17 because I think the problem of long-term effects of herbicides
18 as it may affect our patients in the Department of Medicine
19 and Surgery is one of significant concern.

20 I would like to congratulate Dr. Haber and his
21 committee for having gotten such an expert panel, and I
22 would thank those who are on the panel and advisory
23 committee for taking the time from your busy schedules
24 in order to contribute your experience, your talents,
25 and your thoughts regarding this program.

From my perspective, I think the major area of
difficulty here will be one of communication. Those of us
in the biomedical field often say things and often our

1 patients don't understand what we say, even though we
2 think it is very simple.

3 Those in the bioscientific field say things that
4 those of us in the biomedical field hear but do not
5 understand. Even those who are presenting their scientific
6 treatise are not perfectly clear to those who are in the group.

7 I know from being on a research and development committee
8 for many years that sometimes with some of the more
9 specialized technologies, I couldn't understand the language,
10 although I could read the words.

11 Those patients of ours who are neither biomedical
12 careerists or scientists, but perceive signs and symptoms
13 as they affect them, and its possible relationship to long-
14 term effects of herbicides, have their own language and their
15 own mind set.

16 I think that as a result of this, there is a
17 possibility of having three groups of people, or perhaps
18 four--the advocates of the veterans groups, having four
19 interested groups of people, all well intentioned, all speaking with
20 somewhat inexperience, ending up that there is a veritable
21 Tower of Babble regarding this problem; and I think that
22 the veterans groups and the veterans and the scientists

23 and the biomedical people should probably be overly
24 receptive to try and understand what the people are saying.

25 I have absolute confidence in the experience of
this advisory council, but I am speaking as a physician. I
have confidence in the scientific contributions that many
of the members of this advisory committee have been

1 making in working on dioxin for many, many years.

2 At the same time, I have a tremendous respect for
3 patients, and I feel that they have symptoms. They perceive
4 symptoms that may be related to a specific cause, and
5 then the ability to transmit or to change their attitude,
6 or to change our attitude, becomes then a very difficult
7 problem of who is saying what to whom, and what are we
8 trying to do.

9 I think finally overall, though, that the
10 Department of Medicine as part of the VA, is a very personal
11 agency. We are dealing with people constantly every day.
12 I don't think we are bureaucratic. Of course, it is up to
13 us to prove the fact that we are not an insensitive,
14 bureaucratic agency that is not receptive to what people are
15 saying, but to put forth the picture that we are a group
16 of dedicated individuals whose primary goal is to take
17 care of those veterans that the law says we ought to take
18 care of.

19 I think, Paul, with that as my overview, then
20 I think this committee can work through these difficult
21 communication problems, as well as gathering together
22 some type of logical scientific data and chronology of
23 whatever effects there may be, at what time, of those
24 who served in our armed forces.

25 DR. HABER: Thank you very much, Dr. Crutcher.
We appreciate it.

DR. CRUTCHER: It is good to see you all, and
those that are in the audience.

1 DR. HABER: I would like now to move on with the
2 agenda, and this calls for introductions, and I would
3 like to ask the Committee and the Steering Committee to
4 introduce themselves. We are arranged in alphabetical
5 order.

6 Would you please give us your name, your
7 academic or governmental affiliation, and in a few words,
8 what you do, what is your own particular expertise, whether
9 you are an epidemiologist or a biochemist or a clinician
10 or whatever other appropriate designation you need so we
11 can address you appropriately, and maybe we may begin
12 with you, Dr. Allen, heading the alphabet.

13 DR. ALLEN: My name is James Allen. I am a
14 professor of pathology at the University of Wisconsin
15 Medical School. I have been there for approximately 20
16 years and during this period, have been
17 interested in research on the halogenated hydrocarbons
18 and the dioxins.

19 DR. BRICK: I am Dr. Irving B. Brick. I am a
20 professor of medicine and Chief of the Division of
21 Gastroenterology at Georgetown University School of Medicine,
22 and also a senior medical consultant to the American Legion.

23 My interest is primarily clinical gastroenterology,
24 and in particular liver disease. I am going to be
25 interested myself to learn what these experts are going to
teach me about the effects of these herbicides, particularly
on the liver and other organs in which I am particularly
interested.

1 Also as a representative of the American
2 Legion, in handling many claims of veterans before the
3 Board of Veterans Appeals particularly, the impact of the
4 findings of this Committee will have great future effect
5 I think on veterans' claims.

6 All of us in the American Legion are dedicated
7 to trying to find out the truth over and above the
8 emotional connotations that have been aroused by the
9 particular subject that we are going to study.

10 Thank you.

11 DR. ERICKSON: I am David Erickson. I am Deputy
12 Chief of the Birth Defects Branch at the Center for
13 Disease Control, Atlanta, Georgia, and I am an epidemiologist
14 by training and occupation and avocation, and I am primarily
15 interested in the population dynamics and etiology of birth
16 defects in humans.

17 DR. KEARNEY: My name is Philip Kearney. I am
18 the Chief of the Pesticide Degradation Laboratory, U. S.
19 Department of Agriculture at Beltsville, Maryland.

20 My major interest in this area deals with the
21 chemistry of the dioxins and their environmental aspects.
22 I have followed this for about nine years, and I have
23 visited Italy in '76 and have had a lasting interest in
24 the environmental treatment and chemistry of the dioxins.

25 DR. HABER: I am Paul Haber, Assistant Chief
26 Medical Director for Professional Services whose responsibility
27 it is to help direct patient care programs, and Agent
28 Orange is something very much in our minds.

1 It is my job to try to get to the bottom of this
2 for the VA and to advise the Chief Medical Director and the
3 Administrator, on appropriate steps that need to be taken in order
4 to solve this problem.

5 DR. SCHEPERS: I am Gerrit Schepers. I work for
6 the Medical Service in the Veterans Administration. I am
7 an internist and pathologist by training. I have worked
8 in the field of toxicology, particularly carcinogenesis,
9 for the past 25 years, and for the past year, I have been
10 almost what one might call project officer for our Agent
Orange problem.

11 Recently we have received all this extra help
12 so that I need not call myself project officer any more.
13 Thank you.

14 MR. LEMEN: My name is Richard Lemen, and I am
15 with the National Institute of Occupational Safety and
16 Health, and my background is in occupational epidemiology,
17 and I have done my doctoral training at the University
of Illinois.

18 I am in charge of the Industrywide Studies
19 Branch, which is the primary area where long-term chronic
20 epidemiology is done, and our interest is in the occupational
21 effects of dioxin and what we might be able to help learn
22 as far as the environmental effects by looking at occupational
groups.

23 MR. LENHAM: I am Bob Lenham, the special project
24 officer for the Disabled American Veterans Organization.
25 I do not have a scientific background. I am here representing

1 the veteran as a veteran consumer. I am a Vietnam combat
2 veteran, a hospital corpsman, that was assigned to the
3 Marine Corps over there, and I, too, share with Dr. Brick
4 the concerns and the input that we will have from this
5 Committee and how we shall deal with this input in the
6 claimants that we represent that come before us, before
7 the Disabled American Veterans.

8 DR. LINGEMAN: I am Carolyn Lingeman. I am a
9 pathologist. I work for the National Cancer Institute
10 and have for the past ten years worked in environmental carcino-
11 genesis. We are particularly interested in chemical compounds
12 which cause cancer. I am also at the present time working at
13 the Armed Forces Institute of Pathology on a special project
14 involving attempts to collect pathologic materials from humans
15 exposed to chemical carcinogens, and the problem is to document
16 exposure to a toxic chemical and to determine whether or not a
17 person does indeed have cancer or other disease that could be
18 attributed to that chemical compound.

19 DR. MOORE: I am Jack Moore, Associate Director
20 of the National Institute of Environmental Health Sciences,
21 which is an institute of NIH that is concerned about the
22 effects of environmental chemicals on the health of man.

23 As a toxicologist, I have been involved for the
24 last nine or ten years with research trying to understand
25 what typical benzodioxins as well as other dioxins may do
on biological systems.

DR. MURPHY: I am Sheldon Murphy, professor of
toxicology at the University of Texas Health Science Center

1 for approximately the last two years, and 14 years before
2 that at the Harvard School of Public Health.

3 I have had a long time research interest in
4 pesticide toxicology, and more recently, association with
5 the herbicide dioxin problem largely through committees
6 of the EPA and the National Academy of Sciences.

7 COLONEL THIESSEN: My name is Thiessen. I
8 represent the Department of Defense, and in every-day life
9 I am Director of Occupational and Environmental Health at the
10 Army Environmental Hygiene Agency.

11 My interest in herbicides is relatively recent.
12 I was involved as technical adviser to the Defense Logistics
13 Agency in the disposal of Herbicide Orange.

14 I would like to make the statement that I do
15 represent a large agency. I do not hold that I know all the
16 details of the investigations that are going on and the
17 discussions that are going on in the Department of Defense.

18 Of course, I will be glad to act as a focal point
19 and get you all the answers that you need out of the
20 Department of Defense.

21 DR. HABER: Thank you. As an Advisory Committee,
22 the most important of our efforts is to secure information,
23 but I must also inform you that we have a Steering Committee
24 in the Veterans Administration which gives us direct advice.

25 Its Chairman is Dr. Richard Levinson, --would you
stand when identified--who is Deputy for Clinical Support
Services; Dr. John Castellot on the Committee who is
Director of our Medical Service, a Vietnam veteran and a

1 veteran of Korea as well--just Vietnam; Ms. Margaret Kilduff
2 of the administrative staff at the library to give us advice
3 about the library; Mr. Donald Howell, representing Ms. Dinunzio,
4 Office of Management Services, and Dr. Paul LeGolvan, Pathology Service;
5 Dr. Lyndon Lee of the Veterans Administration who is in
6 charge of one of our research programs; Mr. Tim Conway
7 representing the General Counsel; and Mr. Charles Peckarsky,
8 Director of Compensation and Pension Services, Department
9 of Veterans Benefits.

9 I would like to call to your attention a couple
10 of people who are going to be helping us--Ms. Williams,
11 who labored mightily to produce this volume of paper and
12 who will help us process the material as we go along.

13 I would like to charge the Committee and to give
14 you some information about what I think our job is and
15 some information about the way in which we will proceed.

16 I would like to call your attention to the fact
17 that this Advisory Committee has been duly recognized and
18 registered, complying with all the rules and regulations
19 attendant upon such committees, and has been duly published
20 in "The Federal Register," and future meetings will be
21 advertised in "The Federal Register" to apprise all
22 concerned of the occurrence of such meetings.

23 Let me read briefly from the charter of this
24 Committee. The official designation is Advisory Committee
25 on Health-Related Effects of Herbicides, and I will briefly
read this.

"It has recently been brought to light that

1 enormous quantities of herbicidal chemicals were used
2 during the Vietnam War, and that there is a possibility
3 that large numbers of Americans, many of whom now qualify
4 as veterans, may have encountered these chemicals to an
5 extent that long-range, significant health problems may have
6 been initiated.

7 There is considerable controversy in the published
8 literature and it is probable that much information remains
9 unpublished.

10 The Veterans Administration has not previously
11 been required to resolve toxicological issues of such a
12 complex and highly controversial nature.

13 The Committee will, therefore, assemble and analyze
14 the information which the Veterans Administration needs in
15 order to formulate appropriate medical policy and procedures
16 in the interests of the involved veterans.

17 The Committee will have an entirely fact finding
18 and advisory role and will not be required to develop policy.
19 The Committee will adhere to all the provisions of U. S.
20 Public Law No. 92-463, 5 U.S.C. App. I, Executive Order
21 12024, and Presidential Circular A-63 of March 27, 1974,
22 and subsequent applicable revisions.

23 It is anticipated that the Committee may achieve
24 its objectives within 24 calendar months. However, if an
25 extension is needed, this will be properly negotiated.

The Committee will report to the Chief Medical
Director, Dr. Crutcher, through the Assistant Chief Medical
Director for Professional Services.

1 The Agency responsibility for providing the
2 necessary support is the Veterans Administration, and
3 the duties and functions will be quarterly sessions at
4 the Veterans Administration Central Office in accordance
5 with an appropriate schedule of dates set at the preceding
6 meetings.

7 We will publish a structured agenda. This meeting
8 will be entirely open today. It is likely that subsequent
9 meetings will have both an open and a closed portion.

10 I would like to give you a few bits of information
11 now about procedure. As published in "The Federal Register,"
12 we will adhere to our agenda. If revisions of that agenda
13 are necessary, I will call those to the attention of the
14 group.

15 We will go through presentations this morning,
16 beginning with a presentation by Dr. Levinson on the
17 Steering Committee, a statement of where we are on herbicide
18 research in the Department of Medicine and Surgery, and we
19 will then ask for individual reports beginning at eleven
20 from the members of the Advisory Committee, brief statements
21 of what your agency or office is doing with respect to
22 herbicides, and the determination of their toxicity.

23 This will continue through the afternoon. We
24 will have an hour and a half break for lunch, and then
25 there will be the presentation and discussion of written
questions from the VA Steering Committee to the Advisory
Committee. Our Steering Committee has prepared some
questions to which they want the Advisory Committee to relate,

1 and these will be announced so that everybody can hear.

2 Then we will get written questions from the floor.
3 There will be time for a few statements from people from
4 the floor, and we will begin that at three o'clock. It
5 is expected that our Administrator, Mr. Cleland, will join
6 us sometime later this afternoon, and he may wish to address
7 those questions himself.

8 I would like to tell you that we encourage any
9 questions of this group that you may wish to submit. We
10 would like those questions written, and they should be
11 submitted to Mrs. Grace Meyer in the back of the room,
12 and we will then read these at three o'clock. I will read
13 those, and there may be time, as I say, for a few statements.

14 All of these questions will be answered. All
15 of those that require answers of a general nature will be
16 answered, and they will be answered through a mechanism
17 which I would like to outline, by the members of this
18 Advisory Committee, and that will be done through
19 small task forces. If there is a particular area of
20 expertise in pathology or carcinogenesis we would ask
21 the official member of the Committee to help us prepare a
22 paper in answer to that, a position paper.

23 Obviously that can't be done today. It will
24 take weeks and so on, and my office will endeavor to provide
25 assistance in framing those answers, or we will prepare the
26 paper itself, and then circulate it among the Advisory
27 Committee for its answer.

28 The results of those papers will be available to

1 the public, and we will make it possible so that any
2 question, any legitimate question which is posed to this
3 group can receive a duly considered written answer which
4 will represent the findings of this Advisory Committee.

5 Let me then briefly charge you. You are I hope
6 impressed, as I am, with the fact that this does represent
7 a multi-disciplinary group; many kinds of professional,
8 scientific and technical expertise are represented in
9 the group.

10 It is also a multi-disciplinary group from the
11 standpoint of advocacy. There will be various shades of
12 conviction about the possible connection between herbicides
13 and long-term pathogenesis. Some of the Advisory Committee
14 have already distinguished themselves for having contributed
15 significant works to this body of literature, and I think
16 that we will hope out of this enlightened discussion to
17 arrive at the answer.

18 We in the Veterans Administration consider this
19 a matter of extreme seriousness. The potential link between
20 exposure to herbicides and long-term pathological effects
21 is something that has seized the public interest, we think
22 rightly, and has consumed a prodigious amount of our own
23 time and expertise.

24 We are grateful to the agencies and organizations
25 represented around this table for their willingness and
26 commitment to help us find these very illusive answers,
27 and the answers let me assure you are illusive.

28 We are well aware of the fact that a tremendous

1 amount of literature has been produced. We refer to the
2 classic study of the National Academy of Sciences in 1974
3 accomplished with great input from a variety of disciplines
4 and viewpoints which did not definitely come up with any
5 evidence of long-term pathological effects in humans upon
6 exposure to dioxin and the herbicides.

7 A subsequent study mounted by the United States
8 Air Force, which was completed last October I believe and
9 announced by General Dettinger at a hearing before the
10 House Veterans Affairs Committee looking into this subject
11 similarly failed to come up with hard evidence of the
12 fact that there was a relationship between exposure to
13 dioxin and long-term pathological effects in humans.

14 Nonetheless, the controversy continues in the
15 minds of many. The definitive answers are not yet in,
16 and I think that must, therefore, characterize my charge
17 to the Advisory Committee. Many are not yet convinced
18 that such a link between exposure and pathology does or
19 does not exist, and we have, therefore, to address ourselves
20 mindful of all the research that has been done heretofore,
21 but perfectly willing to take a fresh, a new look at the
22 evidence already in the files or that may yet be adduced
23 by appropriate research or introspect.

24 The Veterans Administration has been concerned
25 with this for the past 15 months, and we continue to be
concerned. Our efforts in this regard can be summarized
under four headings. One is to acquire and exchange
information. This Advisory Committee is the keystone in

1 that process.

2 Secondly, to disseminate such information to
3 all of our field installations, hospitals and regional
4 offices alike.

5 Thirdly, to build and maintain a complete record
6 and registry of all veterans about whom we know or who
7 come to us for treatment, or for adjudication of claims
8 for compensation.

9 Finally, to conduct and offer assistance into
10 further research into this area. All of our efforts, and
11 there have been many, come under one or another of those
12 headings.

13 It has been said that the democratic principles
14 in which one is presumed innocent until proven guilty should
15 not apply to chemicals, that is to say, that dioxin should
16 not be believed to be innocent of pathological effects
17 until proven guilty, and that certainly is true, but I
18 would urge all of us to remember that the Veterans Administration
19 cannot undo what history has done. Try as we will, we
20 cannot reverse the fact that dioxin is a contaminant and was
21 sprayed on the fields of Vietnam, and what we now have to
22 do is not to lament that fact, but to consider whether
23 or not that spraying did carry with it the possibility of
24 long-term pathological effects.

25 We know, of course, that dioxin is extremely toxic
in acute situations. There is no question about that,
and we are well minded on that issue, but whether or not
it does produce long-term effects is something that does

1 concern us, and we have to go on about it.

2 We have got to establish that there is a clear
3 link between pathology and long-term pathologic effects.
4 We must weigh the evidence. We must consider all the
5 information. We must conduct a scientific inquiry, although
6 this is a subject on which emotion swirls about us, and
7 we are all concerned about the plight of Vietnam veterans,
8 and if such a link is established, we want clearly to
9 act on it quickly, prodigiously, and in the appropriate
10 fashion.

11 We must not be projected into establishing such
12 a link until it has been made clearly evident through
13 scientific inquiry.

14 We want to excite new research if that is
15 necessary for the Committee. We want to advise the Chief
16 Medical Director and the Administrator, and indeed the
17 whole country. I need scarcely tell you that this has
18 seized the popular imagination, and the public press has
19 paid a great deal of attention to this issue.

20 We want to provide answers to the questions.
21 I would like to say that one thing which I find reassuring
22 in all this is that at least in the Veterans Administration,
23 the Department of Medicine and Surgery, we are not waiting
24 for the answers in order to treat people. That is to say,
25 if veterans come forward exhibiting pathology or having
symptoms, we would treat them if they are otherwise eligible
immediately. We do not wait for the deliberations of this
Committee in order to diagnose and treat. An individual

1 complaining of carcinoma would be treated in the Veterans
2 Administration whether that was due to prolonged use of
3 tobacco or exposure to other agents, or exposure to Agent
4 Orange, so that that decision we don't have to make.

5 Anybody who is now ill, whatever the cause, if
6 eligible for treatment, would be treated. That does not
7 minimize the importance of our finding the possibility of
8 such links, and in a way, gives us only temporary respite
9 from the tremendous responsibility thrust upon us.

10 That concludes my charge to the Committee. I
11 would urge you all to read again the "Federal Register" to
12 familiarize yourself with the particulars, and I think now
13 we will move ahead with the summary of the VA Steering
14 Committee's activity.

15 Tell us where we are in the Steering Committee's
16 activities.

17 DR. LEVINSON: Thank you. I will stick to the
18 time schedule, but during this period, I would like to
19 introduce, or at least call for brief remarks from members
20 of the Steering Committee who are most expert in the
21 particular aspects that I mention

22 First of all, the Steering Committee was formed
23 last June at the time when the VA became aware that there
24 was a major problem concerning the possibility of herbicide
25 toxicity among Vietnam veterans, and recognized the fact
that our response to this particular situation would have
to be broad based and utilize expertise from throughout
the agency.

1 Accordingly, the Committee was constituted
2 with members from the Department of Medicine and Surgery,
3 which of course is the health care delivery arm of the
4 Agency, but also included representatives from the General
5 Counsel, which is the legal arm, the Department of Veterans
6 Benefits, which handles the compensation claims, as well
7 as other matters, from Management Services, which is our
8 administrative liaison with other agencies, and from our
9 Research and Development Branch, which is also part of
DM&S.

10 The Committee was charged with the task of helping
11 the Chief Medical Director and the Administrator develop
12 appropriate policies regarding the diagnosis of herbicide-
13 related illnesses, the appropriate therapy that is
14 necessary for any of the illnesses that might be discovered,
15 and other related matters which might flow from the
16 demonstration of a distinct connection between herbicides
and permanent human disease.

17 This very broad-based charge was then implemented
18 through a series of separate steps which I will describe
19 to you briefly. Before I do that, I would like to quickly
20 list some of the specific charges that the Committee had
21 and which we hope to be able to fulfill before our tenure
is terminated.

22 I mentioned that we provide advice to the DM&S
23 management, as well as the VA-wide management on policy and
24 actions related to the herbicides.

25 Second of all, we are charged with stimulating

1 and coordinating development to new approaches to the
2 evaluation and treatment of individuals who might suffer
3 from illnesses arising from exposure to herbicides.

4 Related to that, we had a very specific charge
5 and that was to develop a program for examination of
6 veterans who were potentially exposed to herbicides while
7 in Vietnam, and to evaluate any potential illnesses that
8 they may demonstrate. I will describe that more later.

9 We attempted also to act as a liaison not only
10 through our membership, but also through other actions with
11 the rest of the Agency both in the Central Office and in
12 the field, and we are available as a resource to conduct
13 special studies, prepare position papers, and answer
14 questions posed to the Administrator, the Chief Medical
15 Director, and others about this general matter, so we are
16 an interagency clearing, steering and coordinating committee.

17 Just a word about our program for examining
18 veterans. As has been said, the VA has not dealt
19 significantly in the past with environmental exposure, and
20 we have to feel our way slowly, using the best advice that
21 we could obtain. We will, of course, be asking this
22 Advisory Committee to give us additional specific directions
23 in this program, but what we did as a first effort was to
24 set up an official program for the detection and the
25 examination of veterans currently in our patient
population who, A, were in Vietnam during the period when
the herbicides were used, and B, claim exposure to them.

The program consisted of following the

1 identification of these veterans, taking a detailed
2 medical history which also emphasized the matter of exposure
3 to the herbicides, and then a physical examination supported
4 by appropriate special tests which were geared to detect
5 diseases in the organs that various people had suggested
6 might be affected on a long-term basis by herbicides.

7 The number of veterans, as you can imagine, in
8 this category was large. It soon became apparent that we
9 would have to accumulate this data in some central source
10 and continue following these people for a number of years
11 to reach any kind of conclusion about their disease and its
12 connection to herbicides, and so we proceeded to set up a
13 registry which we are now in the process of automating
14 to provide this long-term followup, and to provide a data
15 base for any long-term studies hopefully of a proper
16 epidemiological and scientific nature that might arise from
17 it.

18 We also are attempting with some difficulty to
19 quantitate the exposure of these individuals to herbicides.
20 We are doing this by utilizing the spraying tapes which
21 are available from the Department of Defense that were
22 used by the NAS in their earlier studies, and information
23 about the unit histories of the ground troops who saw action
24 in Vietnam during the period when the herbicides were
25 used.

26 Our hope is to be able to match these various
27 sources of data through the computer and to come to some
28 kind of reasonable conclusion about the presence of a

1 person in Vietnam, and their exposure to herbicides.

2 This has proven to be an incredibly difficult
3 matter, and we will need your help in attempting to
4 interpret the sort of data we have. We have many, many
5 questions about it.

6 We have also been involved in a coordination or
7 stimulation sense with a series of research projects,
8 and Dr. Hobson, a member of our Committee and the Deputy
9 ACMD for Research and Development, will address future
10 research in this area separately.

11 I might just mention that Dr. Lyndon Lee, who was
12 introduced as a member of the Committee, has been coordinating,
13 directing actually, our study on determining dioxin levels
14 in fat. This, of course, was suggested as a potential
15 diagnostic test of great significance.

16 We have done a pilot study. Dr. Lee has been
17 involved in its direction, and I hope we will have a chance
18 to hear from him briefly about this matter.

19 Dr. Lee, would you stand and perhaps just say a
20 few words?

21 DR. LEE: My background is in general surgery
22 and pharmacology.

23 In October, Dr. Haber spoke to the Committee,
24 and Congress, and promised that there would be several and
25 various studies, one of which was the biopsy of fat for
the assay of dioxin in both exposed people and in controls.

In November, he asked me if I could coordinate
this, and I agreed. We developed a protocol which went

1 through the usual human experimentation approvals, as well
2 as the research committee approvals in the hospitals,
3 four of which were in the Chicago area because of several
4 points.

5 First, we had a good many applications from veterans
6 in the Chicago area who felt they had been injured by exposure.

7 Second, it was felt that perhaps these people
8 who came from the more or less urban rather than suburban
9 or rural area might at least have had less exposure as
10 civilians than others from the farm areas.

11 And lastly the men were interested and could
12 be persuaded to follow the program.

13 We also added one further hospital in Lincoln,
14 Nebraska, because that was where the chemist who was to do
15 our assays was centered, at the university, and we needed
16 liaison, so we added one man there.

17 We have approached the National Academy of
18 Sciences National Research Council through their followup
19 agency for statistical participation, and that is being
20 carried out. The protocol has been approved. We now have
21 taken biopsies from 16 individuals; 14 of these have been
22 exposed anywhere from 13 days to 6,600 hours of documented
23 exposure, and these biopsy reports are not yet available.

24 There have been two controls which have had
25 biopsies, and there are four more individuals to be
26 biopsied this week, two additional who have not been
scheduled, and that is the report at the present time.

1 Obviously we have not broken the code. These
2 various materials have been sent to the biochemist coded
3 so that he does not know what types of exposure, if any, the
4 individuals have had, and will be prepared I think to give
5 a more full report on this within probably another month.

6 DR. LEVINSON: Thank you. May I ask Dr. LeGolvan
7 to just say a word to you? He is the Deputy Director of
8 our Pathology Services--to say a word or two about the
9 program with the Armed Forces Institute of Pathology with
10 regard to the storage of biopsy and autopsy tissues from
11 veterans exposed to herbicides who come through our hospital.

12 DR. LeGOLVAN: I am a pathologist in the Pathology
13 Service with Dr. Williams. Our negotiations with the AFIP
14 resulted in the establishment of a registry of tissue
15 pathology for the cases that might appear at the AFIP,
16 and listing possible exposure to herbicides.

17 In this registry, any tissues that are sent to
18 the AFIP will be so coded for future study. These cases
19 all are such that all hospitals have been notified that
20 any cases that appear for routine surgery of any type or
21 for any other studies in which tissues are obtained will
22 be sent to the AFIP for this registry.

23 Thank you.

24 DR. LEVINSON: Thank you. Another function of
25 our Committee is to attempt to increase the understanding
of particularly our professional staffs in our hospitals
and clinics about the matter of herbicides and other
environmental toxins, and to make them more aware of the best

1 ways in which to examine veterans who claim or who should
2 perhaps be claiming possible illnesses related to these
3 agents.

4 We have done this in a fairly formal way through
5 hot lines and circulars and other publications. We are
6 planning some major educational activities in the near
7 future, again hopefully with the help of this Committee,
8 the Committee's expertise to offer more detailed educational
9 information about the appropriate matters.

10 We have also attempted to answer appropriately
11 the many requests for information from the press and radio
12 and television. In that, we have the great help of Mr. Stratton
13 Appleman, the man sitting in the back, who is a member of
14 our Steering Committee, and hopefully, we are increasing
15 the amount of specific and appropriate information of the
16 public at large through most of these news releases.

17 Another matter that we are concerned with is
18 compensation. Compensation for Agent Orange related
19 matters is the province of the Department of Veterans
20 Benefits. One of our members, Mr. Peckarsky, is from the
21 Department of Veterans Benefits, and I will ask him to just
22 say a few words to you about our present status in that
23 matter.

24 MR. PECKARSKY: For me, this type of session is an
25 extreme learning process. We are fortunate in that the
law with regard to veterans benefits does not require the
establishment of a causal relationship between subsequently
experienced disability and any incidence of service.

1 In that regard, any disability that is incurred
2 or aggravated at a coincident point of time with military
3 service receives the status of service connection.

4 Nonetheless, it is important in the lapse of
5 time that has taken place since the exposures in service
6 that we learn as much as we can concerning the effects in
7 the out years of exposures to dioxin. This we expect to
8 get from our participation in this Committee's work.

9 DR. LEVINSON: Thank you. Just in conclusion,
10 I would like to point out that the Steering Committee will
11 continue to carry out its various missions and perhaps
12 add additional ones as they appear appropriate.

13 In doing so, of course, we need all of the expert
14 scientific and medical information that we can obtain on
15 this matter towards that end. Our group compiled a series
16 of questions which you will hear about this afternoon, in
17 areas that we feel answers are very important, and we stand
18 ready to assist you in any way in better carrying out your
19 advisory function.

20 Thank you very much for your time.

21 DR. FABER: Thank you, Dr. Levinson. We really
22 would be quite powerless to implement the advice of the
23 Advisory Committee were it not for the existence of the
24 Steering Committee.

25 We look forward to their continued input and the
26 ability to translate some of this advice into specific
27 rules and regulations so we in the Veterans Administration
28 can implement the advice of this Advisory Committee.

1 On our agenda next is a discussion of herbicide
2 research. I would like to introduce Dr. Lawrence Hobson.
3 Dr. Lyndon Lee described the fat biopsy study. I would
4 indicate to you that the basic idea for the protocol
5 emanated from Dr. Hobson, and he might wish to tell you a
6 little bit about what he had in mind on that, as well as
7 what the Office of the Assistant Chief Medical Director
8 for Research and Development will be doing to help us
9 in the VA to research into this area.

10 DR. HOBSON: In a sense, I am bringing the coals
11 to Newcastle by talking to this group since many of you
12 are much more expert in this particular area than I am.
13 I will just very briefly sketch why the fat biopsy program
14 is undertaken.

15 The claim was made in a television interview that
16 fat would retain dioxin for decades in an inactive form,
17 and that anything that mobilized the fat, for example, a
18 reduction program, during or at the end of those years,
19 would release dioxin in the circulation and produce a
20 problem of dioxin intoxication.

21 This, of course, requires that dioxin be stored in
22 fat, and the most direct way to determine that is by
23 a sensitive assay method to detect the dioxin.

24 We sought the advice of EPA as to what assay
25 technique was best and who was the best one to apply it
and were given the name of a man who had shown the best
results in the sense of consistency, sensitivity, in this
assay, and we, therefore, contracted with him to carry out

1 the determinations in part because he had the best test
2 and because he is not in the VA or in the federal
3 government and therefore would not be biased in his result
4 and we further stipulated that the samples be submitted
5 to him blind so he has no knowledge of what exposure the
6 individual may have.

7 As Dr. Lee has said, there is a variety of
8 exposures here so that when the assays are completed, we
9 will be able to say whether in fact it is possible to
10 detect this material in fat, and if so, to what level,
11 and if it is detectable, whether there is any difference in
12 the amount of dioxin determined in the fat of individuals
13 who had military exposure, and the balance of us who have
14 simply been in the civilian population or were in the military
15 but not in the areas in which it was being used.

16 This is not an attempt to arrive at a definitive
17 epidemiological study at this stage of the game; until we
18 find that this most sensitive method can detect dioxin
19 it would be rather foolish and fruitless to have a large
20 number of people examined.

21 These are biopsy specimens and they require an
22 operation so that we are not anxious to subject individuals
23 to that to no end at all.

24 The other research that has been proposed to us
25 in large part has been accomplished already. Dioxin itself
and the herbicides have been the subject of extensive
research, as all of you know I'm sure. The one area that
has been suggested might be unique for the VA is

1 epidemiological studies of individuals who have been
2 exposed.

3 The difficulties here, as I am sure all of you
4 appreciate, are in the documentation of the precise level
5 of exposure because the mere presence in Vietnam of an
6 individual does not mean he was anywhere near the sprayed
7 area, and presence in a sprayed area does not necessarily
8 mean that he was there at the time when dioxin was present,
9 so that we are really in a very difficult position in
10 attempting to do definitive epidemiological studies of this
11 material under those circumstances.

12 We feel that much better studies can be conducted
13 in the sense of knowing at least the time, approximately
14 the amount of exposure in industrial accidents or industrial
15 exposures such as those that have occurred in the past,
16 but not within the veteran group.

17 The one symptom or sign that seems to be generally
18 accepted as evidence of exposure to dioxin is the appearance
19 of chloracne, which is a skin condition.

20 As you know, the difficulty with using this as a
21 criterion is that the military in most instances under
22 field conditions did not record chloracne as a significant
23 finding. It didn't endanger the individual's health. It
24 was often confused with other skin conditions which were
25 equally benign if treated, and there was not much made of
it so that the record of individuals who may have had
chloracne in Vietnam is really very scanty and probably non-
existent. At least we have been unable to recover them.

1 Lacking that, the level of exposure, the amount
2 of material to which the individual was exposed, let alone
3 absorbed, is a matter of conjecture and we are not going
4 around and exposing people to highly toxic material in
5 an attempt to find out what is going to happen to them, so
6 that we are quite handicapped.

7 I would raise one other point here which I am
8 afraid is a very negative one and rather unpopular with
9 known scientists, and that is that scientists are not all-
10 powerful. We can't do everything. One of the things
11 we can't do is to prove a negative. We can't say that
12 something did not or cannot occur, and yet we are constantly
13 being asked a question which is a very reasonable one in
14 lay terms, namely, prove that nothing did happen or that
15 nothing can happen, that you can't get cancer from this
16 or you won't get sick from that.

17 This is, as I said, scientifically impossible
18 to do. Let me demonstrate that very, very briefly. If
19 you examine 100 people, and none of them had an effect, for
20 whatever reason, you can say well, there was no effect,
21 but somebody can say, but the 101st man may have got it, so
22 you do 1,000, and you still don't find any effect, and
23 they say well, but the 1001 may have got it, and you can
24 continue this kind of endless chain in perpetuity and never
25 be able to say that it cannot happen.

26 The best you can hope to do is to say that there
is less than a certain chance that it would happen, not that
it cannot.

1 The result of whatever kind of scientific studies
2 that are carried out are going to be couched in terms that
3 are going to disappoint some people because it will not
4 say flatly that a certain thing did not or could not
5 appear.

6 I think you have to keep this in mind when you
7 look at research plans and research that has been conducted
8 and not expect that you are going to get a flat answer that
9 it cannot or won't happen.

10 We are at the present time dependent on an
11 epidemiological study on the identification of individuals
12 who were presumably, and with a strong level of presumption,
13 exposed to dioxin, where there are certain groups where we
14 know that was true; people who handled the defoliants and
15 who were not particularly careful about it undoubtedly
16 got exposed to the defoliant, and presumably to dioxin.

17 People who went into areas where the spraying
18 had been done were only presumptively exposed, and it will
19 probably wind up that that is the best epidemiological
20 group we can find, but it is rather unsatisfactory from
21 the scientific point of view, and it certainly will not,
22 as no other study would do, establish the negative if we
23 find that there is no ill effect in whatever group it is
24 that we examine.

25 DR. HABER: Thank you very much. Dr. Hobson
has been the recipient of a memorandum from me asking that
our Research and Development Service consider the likelihood
of other kinds of research, and we will be getting an answer

1 from him and their own advisory committee as to the feasibility,
2 likelihood, and necessity of the Veterans Administration
3 initiating additional studies in certain specific areas
4 that were suggested to him.

5 We look forward to his continued operation and
6 cooperation in this activity.

7 I would like to call attention to the presence
8 of Dr. Stephenson representing Dr. Griffith from the EPA,
9 and we welcome you, Dr. Stephenson.

10 DR. STEPHENSON: Thank you.

11 DR. MOORE: Dr. Haber, may we interrupt for
12 questions?

13 DR. HABER: I think that what I would like to
14 suggest is that if you have procedural questions, any time
15 is appropriate. If they are substantive questions, I
16 would like to delay that until either your presentation,
17 which we are about to ask for now, or until the time for
18 the questions.

19 DR. MOORE: It is a question that is prompted
20 by the presentation. I will pose the question and if you
21 want to hold it, fine.

22 DR. HABER: Yes.

23 DR. MOORE: With regard to the biopsy specimens
24 that have been taken and that have been coded to be analyzed,
25 is it possible to find out what levels of detection they
are going to attempt to look for, PCD or put in positive
controls of that type? Is that type of information available,
or can it be made available?

1 DR. HABER: I would defer that to Dr. Lee.

2 DR. LEE: The level at which they can determine
3 the presence of dioxin is one part in a trillion. They
4 will report in units, giving us an idea, if there are any
5 dioxin units present, how many these may be against controls
6 which obviously may themselves show dioxin levels, but we
7 are not certain about that.

8 DR. HABER: Okay. I think this question needs to
9 be dealt with more fully, and we will this afternoon. I
10 quite agree. I think at this juncture now we would like
11 to go around the table and begin the process of reporting.

12 We will not be able to observe the alphabetical
13 regularity with which we asked you to be seated because some
14 of you have to leave earlier.

15 I would like to ask you to take 10 minutes or
16 15 minutes if that is required for the purpose of giving
17 us a brief on where your particular agency or office is
18 at this point, and I think also what questions you would
19 like to see this group address as well, and in brief
20 to let us know where you come from and to share with us
21 a summary of your experience.

22 As I indicated, since some of you will have to
23 leave earlier, I would ask your forbearance in departing
24 from the otherwise assigned alphabetical listing, and with
25 that, I would like to ask Dr. Brick representing the
American Legion, and himself, to begin.

Dr. Brick, would you tell us what you are doing
and what you would like to see solved in this area?

1 DR. BRICK: I am interested in the general
2 problem of the long-term effects of dioxin as outlined in
3 the charge to the Committee.

4 Representing the American Legion, we are
5 interested in that particularly from the point of view of
6 the compensation angle which is represented here by
7 Mr. Peckarsky, and as he pointed out, he is interested, too,
8 to know whether these problems are real, imagined, what
9 the extent of the problems is, and that type of thing.

10 From a professional point of view, I am
11 particularly interested in the effect of dioxin and its
12 effects on the liver and whether or not any of the liver
13 diseases that we commonly encounter have anything to do
14 with the exposure that may have been obtained in Vietnam.

15 I am not as familiar with the literature as
16 some of the experts here. I don't pretend to be, and have
17 a question about whether or not the National Academy of
18 Science's report, and the Air Force report might be made
19 available to some of us in the Committee who have not seen
20 these reports. I think that might be helpful.

21 Also a question, Dr. Haber--minutes are being
22 taken of this meeting, and will they be available to the
23 members of this Committee?

24 DR. HABER: Absolutely.

25 DR. BRICK: Not all of us are going to be present
at all of the meetings, and/or all of the meetings in toto,
and if such materials are made timely available to us, I
am sure that many of us will, in our own leisure, study these

1 and have questions and possibly some suggestions.

2 That is the end of my presentation.

3 DR. HABER: Okay. Dr. Moore, I understand you
4 may have to leave. Would you, therefore, please address us
5 and tell us what you have been doing and what questions
6 you would like to see answered and so on?

7 DR. MOORE: As I mentioned in introducing myself,
8 we have done work with tetrachlorodibenzodioxin, TCDD,
9 and other dioxins for nine or ten years.

10 Our original work was trying to establish whether
11 or not the benzodioxins can produce teratogenesis or other
12 effects, or birth defects.

13 Since that time, we have tried to look into the
14 types of effects that the benzodioxins may cause. We
15 have not restricted ourselves to TCDD. Indeed, TCDD is but
16 one member of a family of dioxins, others of which can
17 cause toxicity.

18 I would like to point out to the Committee's
19 attention if they are not aware of it, the evidence that
20 is accruing over the last few years is clearly showing
21 that a variety of chemicals that are called halogenated
22 hydrocarbons may have the same target site for whatever
23 effect they do produce, and so therefore, if one is looking
24 for illness as a consequence of dioxin exposure, the
25 expression of that illness may be a total insult, if you
will, from TCDD, other dioxins, chlorinated dibenzofurans,
possibly azoxybenzines, hydrochlorinated biphenyls. In
other words, you can't consider TCDD exposure in a vacuum

1 is basically what I am saying.

2 I would like to point out two publications that
3 have not been mentioned heretofore, and I think the
4 Committee should be aware of their existence and may want
5 to look at them.

6 One is a publication that came out of Sweden
7 which is a culmination of a conference which was hosted
8 by the Royal Swedish Academy of Sciences two years ago
9 on chlorinated acids and their dioxins.

10 Aside from wanting to look at the recommendations
11 that the various groups may have had in there, it is a
12 fairly up-to-date background reference to what is in the
13 literature and what may or may not be of interest.

14 DR. HABER: We are in debt to you for bringing
15 that to our attention. I would hope that others of you, if
16 you know of significant publications would bring them to
17 our attention. We will try to make them available if we
18 can.

19 DR. MOORE: The second one is much briefer in
20 size, and it is a technical report of a meeting that
21 was held in January of 1978 in Lyon, France under the
22 sponsorship of the National Institute of Environmental
23 Health Sciences and the International Agency on Research
24 in Cancer, which is part of the WHO.

25 The one-week meeting was to in essence see if one
could come to grips with the long-term hazards of poly-
chlorinated dibenzodioxins and polychlorinated dibenzofurans.
There are some recommendations in this, but aside from

1 the recommendations, I would again urge the Committee
2 members to look at this as well because it does give a
3 fairly good summary of the previous occupational exposures,
4 the date they occurred, the numbers of populations that
5 were involved in the exposures, and what is the current
6 monitoring aspects of them, and I also tend to feel that
7 if one is going to get insight fairly soon as to the chronic
8 effects of exposure to dioxins or herbicides, it is going
9 to be from some of these worker populations where their
exposures are now approaching 20 to 30 years.

10 Unfortunately, the numbers are very small.

11 DR. HABER: Dr. Moore, is it fair to ask is your
12 office engaged in any of those long-term follow-up studies
13 now underway, the group at Nitro, or have you any input
into that?

14 DR. MOORE: Indirectly. The Nitro, West Virginia
15 group that was followed up, the clinical examination
16 I believe, at least in part was done by the Mount Sinai
17 School of Medicine, which is funded through our grant program.

18 DR. HABER: You will be getting those answers,
19 will you not?

20 DR. MOORE: Yes. I believe NIEHS has a formal
affiliation.

21 DR. HABER: That is one of the things I would
22 like to do, to try to pinpoint who would be likely to
23 find out.

24 Thank you very much, and we are indebted to you
25 for calling those publications to our attention.

1 I think next, Dr. Thiessen, if you would be
2 good enough to address us and we would like particularly
3 if you can help us with that information, I understand
4 your earlier statement about the complexity of the
5 Department of Defense's research assistance on this, but if
6 you can give us any information about the Air Force projected
7 study, that would be most helpful.

8 COL. THIESSEN: Let me again reiterate that I
9 am not familiar with the details of the Air Force study.
10 The Air Force has been so kind as to give me
11 a general statement that I would like to read into the
12 record.

13 Let me make it clear that the Department of Defense
14 intends to and has in some cases involved institutes such
15 as the Armed Forces Institute of Pathology that has been
16 mentioned before. The Armed Forces Epidemiology Board
17 will discuss the study protocol that is being developed by
18 the Air Force.

19 The study protocol will be brought before this
20 Committee for at least advice, if not approval, and all
21 these actions should take place pretty shortly, if they
22 haven't taken place already.

23 Now the Air Force will conduct a study of the
24 health of Ranch Hand personnel involved in the aerial spraying
25 of Herbicide Orange in Vietnam. Operation Ranch Hand was
26 a code name attached to the Air Force air crews between
27 1962 and 1971, when the operation ceased.

28 These personnel would have been the most likely

1 to have had significant exposure.

2 The purpose of the study is to determine if any
3 causal relationship can be established between exposure
4 to these herbicides, and changes in the long-term health
5 status of the individuals involved.

6 The study will involve both veterans and active
7 duty personnel; former Ranch Hand personnel exposed to
8 Herbicide Orange, approximately 1200, will be carefully
9 matched to a control group not exposed. Detailed telephone
10 health surveys will be given all members of the study
11 beginning in early October 1979. Comprehensive physical
12 examinations will be given to a selected number of both
13 exposed and non-exposed individuals. Health surveys
14 and scheduled physical examinations of selected individuals
15 will be conducted for a minimum of six years to see if any
16 long-term health problems emerge.

17 The entire study will be completely reviewed by
18 both government and civilian scientific personnel. This is to
19 preclude any bias, and to ensure the scientific validity
20 of this complex project.

21 The study details, as I said, will be presented
22 to this Committee during this review cycle.

23 That concludes my statement.

24 DR. HABER: I would like to suggest to the
25 Committee that in a prior meeting that I had with General
26 Dettinger on the study, I asked of him permission for this
27 Committee, this Advisory Committee, to get the protocol,
28 which was granted, so when that protocol is delivered to us

1 we will circulate it among the Committee. I think this
2 is really only in the interest of scientific exchange,
3 though some of you may have some suggestions about this
4 and possible suggestions of revision of the protocol which
5 I think would have to be done fairly soon if we were
6 going to do anything about it, but I must tell you the
7 Department of Defense and the Air Force have their own
8 scientific review process, and it strikes me that they are
9 well along in this process.

10 Isn't that right?

11 COL. THIESSEN: Yes.

12 DR. HABER: What are the bodies that would review
13 this?

14 COL. THIESSEN: The Armed Forces Epidemiology
15 Board for the Armed Forces in general, and the Scientific
16 Advisory Board of the United States Air Force for the Air
17 Force.

18 DR. HABER: Then it will have been subjected to at
19 least two prior in-depth reviews, but I asked
20 for the opportunity for our group to see it and review it,
21 and I think we should avail ourselves of that. In
22 some subsequent meeting, you may wish to go on record
23 individually or collectively as, hopefully, approving the
24 study.

25 COL. THIESSEN: Let me also state for the record,
sir, that the Armed Forces Epidemiology Board does not
consist of Army representatives, but of national experts.

DR. HABER: I am well aware of that, and

1* General Dettinger was quite informative on that subject.

2 Okay. I think with those presentations, we
3 ought to now proceed to ask the other members of the
4 group in alphabetical order. Dr. Allen, I guess that
5 puts you up first. Will you please tell us where you are
6 in your research and what your plans are and what you
7 would like for us to help you with if we can?

8 DR. ALLEN: I would like to say that I am an
9 experimentalist. I have done no research at all on human
10 populations that have been exposed to dioxins.

11 I have done no research on Agent Orange per se.
12 My research has been limited primarily to the
13 tetrachlorinated dibenzodioxins and their effects on non-
14 human primates, the Rhesus monkey and on rodent populations,
15 primarily the laboratory rat.

16 We have found that a relatively low level of
17 exposure to the dioxins, namely, TCDD, is extremely toxic.
18 In some of our initial studies, we found that levels, when
19 consumed at 500 parts per trillion in the diet for a period
20 of nine months, produced mortality in over 50 percent of
21 the experimental animals.

22 Within a period of three months, the animals began
23 to lose their hair, had swollen eyelids, dry, scaly skin,
24 and indications of hematological abnormalities.

25 At these levels of exposure
they had consumed in the neighborhood of 1 microgram per
kilogram of body weight.

By the sixth month of exposure, and after having

1 consumed in the neighborhood of 2 micrograms per kilogram
2 of body weight, the animals developed what we would consider
3 a severe pancytopenia, decrease in circulating white cells
4 and red blood cells, and a marked decrease in blood platelets.

5 At this time, we attempted to breed the eight
6 experimental animals; three of the eight became pregnant.
7 Two aborted early in gestation, which is an indication or
8 suggestion of difficulties that we have observed in other
9 studies, in the halogenated hydrocarbons and its effect
upon the reproductive capability.

10 At seven months of exposure, we lost our first
11 experimental animal primarily due to excessive bleeding all
12 over the body. By the ninth month, we had lost our second
13 animal due to widespread hemorrhage, and by the 12th
14 month, we took the animals off the experimental diet.

15 At nine months, they had consumed in the neighborhood
16 of between 2 and a half to 3 micrograms per kilogram of
body weight.

17 During the succeeding three months up to the 12th
18 month, we had lost three additional animals, making a total
19 of five of the eight experimental animals that died from
20 dioxin intoxication.

21 Some of the more pertinent lesions that we
22 found in these experimental animals, in addition to
23 the loss of hair, loss of eyelashes, swollen eyelids, dry,
24 scaly skin, keratinized hair follicles, there was a marked
25 thickening of the gastric mucosa, ulceration. There was
marked dilatation of the gall bladder, and hypertrophy

1 and dysplasia of the epithelium of the gall
2 bladder, as well as the common, cystic and hepatic ducts
3 and the bile ducts within the hepatic tissue.

4 There were hypoplasia and metaplasia and
5 dysplasia in the sebaceous glands, the salivary glands,
6 metaplasia and hyperplasia of the transitional
7 epithelium of the urinary bladder, and also metaplasia
8 and hyperplasia of the lining of the mucosa of the stomach.

9 In subsequent studies, we have reduced the level
10 of dioxin in our experimental diets to 50 parts per
11 trillion. These animals now have been on this diet for
12 over two years. After six months of exposure and after
13 having consumed in the neighborhood of about 3 tenths of a
14 microgram per kilogram of body weight, we attempted to
15 breed the experimental animals.

16 Of the eight experimental animals, six became
17 pregnant. Four aborted early in gestation, and two were
18 able to carry their infants to term, thus further clarifying
19 or substantiating the observation of the effect of dioxin
20 upon the reproductive capability of non-human primates.

21 The animals have been on the diet for approximately
22 two years. They have consumed in the neighborhood
23 of one microgram per kilogram of body weight, and are
24 beginning to show the same signs and lesions that developed
25 in the 500 parts per trillion animal of three months, both
26 groups having consumed in the neighborhood of one microgram
27 per kilogram of body weight.

28 Thus in these studies it would appear that there

1 are very distinct changes that occur. When the
2 levels of exposure to the dioxins are higher some changes occur much
3 more rapidly than when the level of exposure is quite low.

4 It would appear that the same effects develop
5 in the experimental animals, regardless of the time that
6 is required, whether it be three months at 500 parts per
7 trillion, or at 50 parts per trillion over a two year
8 period.

9 This pretty well brings you up to date as to what
10 are the effects that we have observed in our non-human
11 primates. We now have studies that are on going where
12 we are feeding animals 25 parts per trillion of
13 tetrachlorodibenzodioxins. They are being bred at the
14 present time to determine if these levels will have effects
15 upon the reproductive capability, and the general body
16 health of these experimental animals.

17 I would like to mention just briefly our
18 preliminary work with the possible carcinogenic effects
19 of the tetrachlorodibenzodioxin. We did a pilot study
20 approximately three years ago where we had fed rats levels
21 of dioxin ranging between 5 parts per billion and 5 parts
22 per trillion.

23 Those animals that died during the course of the
24 experiment had approximately a 37 percent overall incidence of tumors.
25 Those that were sacrificed after two years on the diet had
approximately a 36 percent incidence, overall incidence of
tumors.

The tumors that were observed were quite variable,

1 involving the liver and the lung. Those two organs were the
2 more severely affected.

3 These observations have been substantiated at a
4 somewhat higher level by the Dow Chemical Company scientists
5 and certainly there are indications from the Illinois
6 Institute of Technology that there are carcinogenic
7 effects of tetrachlorodibenzodioxin.

8 Recent reports at the American Association for Cancer
9 Research meetings in New Orleans strongly indicated
10 the promotional activities
11 of the tetrachlorodibenzodioxins on cancer. Thus it would
12 appear that we are working with an extremely toxic compound
13 that has widespread effect on experimental animals.

14 DR. HABER: Thank you. I am sure there will be
15 questions about it this afternoon. We would like to ask
16 you to elaborate.

17 DR. ALLEN: In our
18 evaluations of populations that have been exposed to
19 dioxin I do not think that we can eliminate those that
20 have been chronically exposed or have low-level exposure.

21 In work done at the National Institute of Environmental
22 Health Sciences, they were able to show that some of the
23 same signs and lesions were produced at levels of 70 micrograms per
24 kilogram of body weight that we observed in the neighborhood at levels
25 of 2 to 3 micrograms per kilogram of body weight over an
26 extended period of time.

27 There may be heavy exposure which produces the
28 effect, but this does not eliminate the possibility of low-

1 level exposure that may occur over an extended period of
2 time that may produce this same effect, and these are what
3 I consider extremely pertinent points, and I have received
4 unofficial reports since, that in some of the peripheral
5 areas that are involved, some of the people are beginning
6 to show ill effects that were not observed in the more
acutely exposed areas.

7 DR. HABER: Thank you, Dr. Allen. We certainly
8 appreciate your statement.

9 I would like to move on. Dr. Erickson, can you
10 please tell us what your laboratory has been doing and
11 can you shed any light on this problem for us?

12 DR. ERICKSON: As I said when we introduced
13 ourselves, I come from a group that is interested in the
14 occurrence of birth defects in humans.

15 We have no experience whatsoever in dealing with
16 this problem from the angle of herbicides. We got into
17 the business that we are in, I think, because of another
18 environmental exposure---that was thalidomide. There was a
19 good deal of interest generated in the early '60's by the
20 disaster which happened in Europe and in the other parts
21 of the world, the epidemic of limb reduction deformities
22 that were a result of maternal ingestion of thalidomide.

23 This epidemic wasn't discovered until a few
24 years after it began, and the people got the idea if there
25 were monitoring programs in place that the epidemic of this
thalidomide syndrome babies would have been discovered
earlier, and so at the Center for Disease Control, we

1 monitor the incidence of birth defects in human populations.

2 This monitoring of the trends is useful for
3 two purposes I would think. One is to detect an epidemic
4 of birth defects which might be due to the introduction
5 into the environment of a new teratogen or due to the
6 change in the prevalence of an old teratogen.

7 The monitoring programs also provide a somewhat
8 unique data source for the mounting of special studies
9 into the etiology of human birth defects.

10 We have two main programs in our branch. One
11 is called the Birth Defects Monitoring Program, and it is
12 a quasi-national program covering about a third of the
13 births in the United States each year.

14 The other program is in metropolitan Atlanta
15 and is a higher quality system, a more intensive type
16 of ascertainment, but monitors only about 25,000 births per
17 year.

18 I would just like to make a couple of comments
19 about the epidemiology of birth defects in humans. People
20 talk about birth defects, but there are really probably
21 several hundred different kinds of birth defects, and each
22 of these is probably a unique disease or a somewhat unique
23 disease; at least from what we know about animals, and
24 their reaction to teratogens, and the few known human
25 teratogens, we have the idea that each teratogen or defect-
causing substance produces a fairly unique type of mal-
formation or syndrome of malformations.

Also each different type of defect is individually

rare. The most common ones occur at a rate of about one per thousand births, and so studies to discover causes of these things are very difficult and very time consuming and very expensive.

The last point I would like to make is that so far as we know, birth defects have been around for a long time, and with a few notable exceptions, the rates have remained fairly stable, and they are relatively stable around different areas of the world as well.

The notable exceptions I would like to point out here in the United States are three. First, we think there is pretty good evidence that the defects of the central nervous system are decreasing.

Over the past decade, we believe they have decreased at an annual rate of about 5 percent per year, and we believe that this decrease is real. We have no explanation for it, however.

Two, heart defects, ventricular septal defect and patent ductus arteriosus, have been on the increase during the last decade. They have been increasing at the rate of about 10 percent per year.

We again have no explanation for this increase. We are unsure whether it is real or not, or whether it is simply a matter of increased awareness on the part of pediatricians who are caring for sick newborn babies who are surviving longer now, and they have immature hearts when they are born.

The last defect which seems to be on the rise is

1 renal agenesiis, and this may be a real increase, or it may
2 be due to increased use of diagnostic technologies which
3 weren't used in previous decades.

4 I think that's all I have to say, Dr. Haber.

5 DR. HABER: We welcome your interest in this field.
6 You have much to contribute.

7 May we go on? Dr. Stephenson, do you want to
8 briefly tell us what it is you do for a living because
9 we went around the table and introduced the group so we
10 get some idea of what special interest you have.

11 DR. STEPHENSON: Thank you, Dr. Haber. My
12 background is industrial hygiene in particular. I am
13 standing in this morning for Dr. Griffith, who is an
14 epidemiologist, and I didn't know that we were going to be
15 asked to give a review, but I will tell you rather briefly
16 what EPA has done and somewhat what they are planning to
17 do.

18 The EPA has done a descriptive epidemiologic
19 study in Oregon where they were looking at spontaneous
20 abortions, and this was not a cause and effect type study,
21 but merely descriptive, and I would like to emphasize that.

22 Through this study, the Agency saw its way clear
23 to issue an emergency suspension of 2, 4, 5-T, which in
24 essence gives the Agency an additional year to weigh
25 scientific evidence to the effects of 2, 4, 5-T, and this
fall, hearings for the cancellation of 2, 4, 5-T registration
will begin, and at that time, more scientific evidence will
be submitted for cause and effect type look by scientists

1 as to the results of 2, 4, 5-T exposure to the general
2 population.

3 I believe, Dr. Haber, since we will be in
4 litigation, that is about all that I have to say now.
5 So far as the design and particulars of the study done in
6 Alsea, Oregon, Dr. Griffith is certainly familiar with
7 those, being the primary epidemiologist in that study,
8 and certainly will be available to this most distinguished
9 group to lend his support in additional meetings, so with
10 that, I would like to close.

11 DR. BRICK: I would just like to ask a question.
12 You said new studies were being done. Are they of the
13 same sort as were done in Alsea.

14 DR. STEPHENSON: Well, what we would like to do
15 are some follow-on studies of those, or I guess the things
16 that were opened up in Alsea, Oregon.

17 Now I don't know exactly what the designs are
18 that Dr. Griffith has in mind right at this time, but he
19 is working also with Dr. Robert C. Duncan at the University
20 of Miami School of Medicine, who is the primary biostatistician,
21 and working together I think they are interested in looking
22 at additional follow-on studies.

23 DR. HABER: Very good. Thank you, Dr. Stephenson.
24 Dr. Kearney, would you care to tell us briefly where you
25 are at in this problem and what you would like to be doing?

DR. KEARNEY: Yes. What might be of interest
to the group is a meeting I attended earlier this month,
June 3rd to the 7th, in Arlington, and it was a dispute

1 resolution conference that looked at the ability of science
2 to interact in the decision-making process.

3 The model selected for that dispute resolution
4 conference was 2, 4, 5-T and TCDD. I will not go into the
5 philosophical aspects of the dispute resolution. Sixty-five
6 scientists attended the meeting, with about 63 observers.
7 There were several Italian scientists there who could
8 comment on the Seveso situation. There were six workshops
9 in the conference.

10 There was a workshop on carcinogenesis and
11 mutagenicity headed by Dr. Jessie Steinfeld, former Surgeon
12 General of the United States, now Dean of Medicine at the
13 University of Virginia.

14 I have the conclusions of that workshop. There
15 was a workshop on teratogenicity headed by Dr. Marshall
16 Johnson at the Philadelphia School of Medicine and I have
17 the conclusions of that workshop.

18 There was a workshop on human exposure headed by
19 Dr. Austin of California. I have no affiliation.

20 There was a workshop on ecological effects. This
21 was headed up by Dr. Ken Kamlett of the National Wildlife
22 Federation, and I have the results of that workshop.

23 I have a report of the chemistry workshop which
24 I was chairman of, and I do not have the results of the
25 benefit workshop headed by Dr. John Staub.

I would feel most comfortable commenting on the
conclusions of the chemistry workshop since they are
pertinent to some of the discussions and some of the trials

1 discussed this morning.

2 We had eleven chemists in the workshop who are
3 actively engaged in TCDD analysis in various forms. The
4 first five questions of the workshop were philosophical
5 and dealt with the role of the chemist and his participation
6 with the decision maker.

7 The second five questions dealt with matters of
8 chemistry and substance, and I think some of these might
9 be of interest to you.

10 First of all, we dealt with what is known about
11 the levels of detection of TCDD in the environment. It
12 was generally agreed there is no level of TCDD in the parts
13 per million or parts per billion range in any sample we
14 have examined thus far, except as it relates to chemical
15 disposal or spills.

16 It was further agreed that levels at 100 parts
17 per trillion or above have not been detected in any
18 environmental sample associated with 2, 4, 5-T. Here we
19 are talking about fish, beef and mother's milk. Below
20 these levels, that is, below 100 parts per trillion, you
21 have to consider each of the studies individually.

22 First of all, dealing with mother's milk; based
23 on three separate studies conducted up to January, 1979,
24 no validated TCDD residues above 1 part per trillion had
25 been detected based on the analysis of 44 mother's milk
26 samples.

27 They concluded that there are no confirmed
28 detected levels of TCDD in mother's milk.

1 In beef fat, out of 85 samples that have been
2 surveyed thus far, one sample of beef fat confirmed at
3 60 parts per trillion of TCDD, and two apparent, but
4 unconfirmed samples at 20 parts per trillion. The
5 remainder of the samples were below the level of detection,
6 which is 10 parts per trillion.

7 We also looked at beef liver, bovine milk, fish
8 and wildlife. These were available for your perusal and I
9 will make copies of these conclusions available to the
10 Veterans Administration if you would like those.

11 DR. HABER: Yes, we would indeed.

12 DR. KEARNEY: There are several other things which
13 I think impinge on what is said here, and I will share
14 those with you.

15 Concerning the manufacture of 2, 4, 5-T, the
16 question was, is it not of interest to this
17 group whether you can measure dioxin contents in commercially
18 available samples of TCDD and make it commercially feasible,
19 and the answer to the question is that yes, we can.

20 Are there problems in the disposal of the waste
21 of this material? There would be problems, but we feel
22 that we can overcome these, but I think germane to this
23 discussion is, can TCDD be produced from 2, 4, 5-T? We
24 concluded that a yield of 1 part per million of TCDD can
25 be the result of combustion of 2, 4, 5-T, particularly when
it is mixed with organic matter.

Another question which I think is very pertinent
to the biopsy study is, is 2, 4, 5-T the sole source of

1 the 2, 3, 7, 8 tetrachlorodibenzodioxin in the environment?
2 This is important, and the answer is that it is not, that
3 there are other sources such as combustion of certain
4 chlorinated organic compounds, whether in commercial or
5 industrial wastes.

6 That brings up another question which I think
7 complicates the situation, but you must be aware of the
8 fact that the chlorodioxins are a family of compounds of
9 which there are 75 members. Tetrachlorodioxin, for example,
10 is represented by 22 positional isomers. The 2, 3, 7, 8
11 tetrachlorodioxin is believed to be the most toxic of that
12 family.

13 It was assumed that the 2, 3, 7, 8 was the product
14 of trichlorophenol. It appears there are other sources
15 of the 2, 3, 7, 8 in the environment.

16 The question which the group also must consider
17 is, can you detect the 2, 3, 7, 8 in the environment
18 as opposed to the other positional isomers? The answer
19 to that question is, yes, we can. It is very new
20 technology. It requires very elaborate facilities, and
21 it is a very highly sophisticated technology, and the
22 cost of analysis is going to be about \$1,000 or more per
23 sample.

24 The question is do we need more sensitive methods?
25 What are the methods of measuring it in commercial samples
and environmental samples?

The methodology which is available to us depends
on the substrata at which we are looking. Now the current

1 levels of sensitivity having the appropriate specificity
2 range from as low as .3 parts per trillion easily analyzable
3 samples such as some of the fruits, to as high as 20 parts
4 per trillion in certain animal and fat samples, and this
5 is based upon certain appropriate chemical technology,
6 what we call a signal to noise ratio of 2.5 to one.

7 The group also dealt with the environmental fate
8 of TCDD, and I don't think that is of interest to this
9 group. However, that information is available, so
10 Mr. Chairman, these reports and these conclusions are
11 available. They are unpublished at this time. There will
12 be great speed to publish those, but the chairman of the
13 conference has agreed to make these conclusions available
14 to you.

15 Some of them are rather detailed in the field of
16 medicine for which I have no expertise, but I think the
17 group might benefit by having these.

18 DR. HABER: Dr. Kearney, thank you for a very
19 illuminating presentation. First of all, let me express
20 my gratitude for your making those available to us. The
21 dispute resolution conference is precisely what we are all
22 about, and I would like to have that made available to all
23 of us, but I would also point out that I think that
24 your dismissal of the fate of TCDD in the environment is
25 something that does concern us, and I think we would want
to look with great interest upon the finding in that
regard because that is really one of the questions-of
people who went into Vietnam, where they came in contact

1 with the herbicides, and the fate of the TCDD contaminants
2 would be of extreme importance to us, so we would be most
3 grateful for any information about that.

4 Thank you again. We will appreciate getting
5 those from you. We will make them available to the group.

6 Mr. Lemen, if you would be able to give us the
7 same kind of summary, we would find it most helpful.

8 MR. LEMEN: NIOSH has had an active interest in dioxin
9 since early this year when Secretary Califano received a letter from
10 Mr. Cleland of the Veterans Administration requesting
11 assistance in looking at industrial exposures to provide
12 some light about what might happen as a result of environmental exposure.

13 As you all may be aware, industrial exposures
14 oftentimes are very ideal for looking for epidemiological
15 findings of a chronic nature simply due to the fact that
16 occupational exposures tend to be oftentimes more intense
17 and the ability to gather together a cohort or a group of
18 people to study is oftentimes much easier in an occupational
19 setting than what it is in the general environmental setting.

20 In attempting to do this, we have found that there are two
21 groups studying the accident Mr. Cleland referred to in his letter
22 to Secretary Califano that had occurred in 1949 in Nitro, West Virginia.

23 This was a Monsanto facility that had manufactured
24 2, 4, 5-T. Dr. Raymond Suskind of Kettering Laboratories
25 at the University of Cincinnati has been

following the people from this accident
since the early 1950's at the request of the company,
Monsanto. At the same time, Dr. Selikoff of the Mount Sinai

1 School of Medicine was also looking at this same set of
2 workers at the request of the local unions.

3 We have contacted both Dr. Selikoff and
4 Dr. Suskind. Two and one-half weeks ago, Dr. Selikoff's
5 group had just been on a field investigation utilizing some of our
6 testing equipment to do a cross-sectional medical study of these
7 workers. I have talked to him in the last several days,
8 and he informs me that they will be ready to start putting
9 together the analysis of the findings of this particular
10 cross-sectional study shortly. They are currently waiting on some
11 laboratory results and when they are received, we
12 will be in touch with him to discuss the results of
13 on the analysis.

14 Dr. Suskind has also been asked by the company
15 to do a similar type of study, and he is planning to go into
16 the field sometime in the near future and do essentially
17 the same thing that Dr. Selikoff has done.

18 In addition, Dr. Suskind is planning to do
19 mortality study looking at the mortality of the
20 workers that were in this particular plant to determine
21 if there is any excess of cancer or any other chronic long-
22 term health effects as a result of their exposure to dioxin.

23 As you may know, carcinogenic effects generally
24 take 20 to 30 years to manifest themselves after first
25 exposure, and this population is just at reaching
26 this period of time where one might be able to detect such
27 chronic effects.

28 We at NIOSH are following the progress of these two
29 studies at the Nitro,

1 West Virginia facility but we are not actively working in Nitro
2 because we feel that there are two competent researchers in the
3 situation now, and we will simply follow their progress
4 and give them any assistance that we can.

5 We have decided to expand our investigation and are
6 at the present time looking for other industrial accidents or
7 exposures that have occurred over the years throughout
8 the United States.

9 We have so far found several, the most recent
10 being last week in Jacksonville, Arkansas. Dr. Selikoff and
11 the State Health Officer, Dr. Young, contacted us
12 about a particular plant which had manufactured 2, 4, 5-T
13 for the past 20 years. The plant had stored the waste material
14 in barrels which they had buried under the ground as well as
15 some above the ground. The barrels now have begun to rust and the
16 material inside (dioxin) has begun to leak and to begin contaminating the
17 surrounding area.

18 There is a lot of concern not only for environmental
19 exposure, but for protecting the workers that will have to clean
20 this up and how do they clean it up?

21 We are in the process now of working with the
22 state health department in trying to remedy this situation.

23 Basically, these describe the extent of the plans at the
24 Institute at present. We are still in our
25 developmental stages of developing and proposing studies to
determine what adverse effects result from exposure to dioxin, and
we will keep the Committee informed as we take further steps.

DR. HABER: Thank you very much. That is very

1 helpful.

2 I would like to ask Mr. Robert H. Lenham, the
3 special project officer of DAV, to give us his views and
4 what the DAV's interest is and what they have been doing.

5 MR. LENHAM: Thank you, Dr. Haber. Some 58
6 years ago, the DAV was chartered a disabled American
7 veterans organization to set up to provide assistance to
8 disabled veterans, and their families.

9 We are very concerned and have received
10 correspondence in the mail from veterans throughout the
11 country expressing their concerns over the possible
12 exposure to the herbicide.

13 Immediately we set up a centralized system for
14 handling these disability claims for dioxin poisoning
15 and trying to collect evidence to substantiate these claims.

16 This is a problem because the medical records in
17 most cases do not specifically reflect that a given veteran
18 was exposed on such and such a date to any herbicidal spray
19 that might have occurred in Vietnam, and we are aware of
20 this, so when a claim comes in from a veteran, we refer
21 this back out to our local national service officer who
22 contacts a veteran, will assist him, sets up a special
23 file, and then alerts us to any and all action taken on the
24 local level by the VA Adjudication Service.

25 We have publicized in our monthly magazine the
various effects that have been referred to us that could
occur as a result of exposure to dioxin. We will naturally
be interested in the reports that will be coming out of this

1 Committee and the other type of reports that will direct
2 themselves to the problem that we are now confronted with.

3 This is a problem, alluded to earlier,
4 that has gotten the attention of the nation, so in this
5 respect, I am glad to be serving on this Committee to act
6 as a veteran consumer and to be able to pass what information
7 I might be able to have gained from our organization to
8 the Committee members of maybe what the direct problems
9 with which we are confronted by the veterans who are contacting
10 us are, and hopefully maybe this will be of some assistance
11 to the Committee members.

12 Thank you.

13 DR. HABER: Thank you very much. Dr. Lingeman,
14 can you please let us know where you are at and where you
15 are coming from?

16 DR. LINGEMAN: I would like to ask a question.
17 Is this Committee interested only in the dioxins
18 and the Agent Orange, or are we interested in other herbicides,
19 which were used in Vietnam? How many others were used?

20 DR. HABER: I would say that our overwhelming
21 interest is in solving the problem of exposure of American
22 Armed Forces personnel in South Vietnam.

23 Now to the extent that we can help shed light on
24 a world-wide problem, and to the extent that the Veterans
25 Administration is increasingly aware of the fact of
26 environmental hazards as a potential carcinogen or damaging
27 agent, we, of course, are interested.

28 We have had intimations that

1 exposure of people during their Armed Forces career to
2 asbestos might cause difficulties, and we are at the present
3 time approached by veterans who have concerns about that,
4 but I would say that is by far the less important objective.

5 Almost entirely we ought to concern ourselves
6 with the potential damage done to American servicemen and
7 women as a result of exposure to the herbicides that were
8 used in Agent Orange in Vietnam.

9 DR. LINGEMAN: In other words, were significant amounts
10 of other herbicides used in Vietnam during that period?

11 DR. HABER: There were other herbicides used I
12 believe. There was an Agent Purple and an Agent White which
13 were composed of cacodylic acid and picloram, but they were
14 so trivial that it would be almost impossible to try to
15 determine--their use was so trivial and infinitesimally
16 less than the millions of gallons of Agent Orange that was
17 sprayed that we can ignore them for the purposes of this
18 discussion.

19 We are interested in shedding light on the whole
20 subject of environmental toxicity, in particular for
21 herbicides, but our main focus is on Agent Orange and what
22 it did to the American servicemen.

23 DR. LINGEMAN: Thank you. This makes my
24 description a little more simple.

25 The National Cancer Institute has for many years
26 been interested in chemical carcinogenesis and devising
27 methods to test for carcinogenicity. This is not a simple
28 matter. There are problems with species specificity and

1 numbers of animals that must be used to provide a statistically
2 significant result. The present Carcinogenesis Testing Program
3 has the responsibility of determining which of 45,000 chemical com-
4 pounds should be tested for carcinogenicity by the National Cancer
5 Institute. The financial resources are very limited, and at the
6 present time, it costs \$250,000 to test one chemical. The standard
7 test in mice and rats involves a chronic study, usually oral feeding
8 or installation by gastric tube of the chemical compound, sometimes
9 other methods, depending upon the compound. At least two species
10 of animals are required. At the present time, we use mice and rats,
11 100 of each. We keep them alive, if possible, for their lifespan,
12 which in the case of the mice and rats is between two and three
13 years, and this has to be done under standardized conditions.
14 There have to be adequate controls. Before each assay is begun,
15 it is necessary to determine for each chemical the maximum tolerated
16 dose so that the dose will not kill the animals but will permit them
17 to survive long enough to develop cancers. The Cancer Institute's
18 primary mission is cancer. The emphasis has been there. However,
19 when possible, we look for other toxic effects.

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Recently, the National Cancer Institute's Carcinogenesis Testing Program has come under the National Toxicology Program, which

1 involves seven other government agencies, both regulatory and
2 scientific, and is under the direction of Dr. David Rall of
3 the National Institute of Environmental Health Sciences.

4 From now on, our program will not be completely independent, and
5 all chemicals nominated by us for testing will also be the
6 concern of the National Toxicology Program.

7 I wish to tell you exactly where we stand with the
8 dioxins and with 2, 4-D and 2, 4, 5-T since these are the
9 materials of interest here.

10 The National Cancer Institute has a system whereby
11 chemicals are nominated for test by means of a Chemical Selection
12 Working Group composed of NCI staff and representatives of other
13 government agencies. We hope to have a member of the Veterans
14 Administration on this Committee soon. This is the nomination
15 form which I will pass around. Anyone can nominate a chemical.
16 We ask people to provide as much information as possible when they
17 nominate a chemical. I think probably most of the chemicals of
18 interest to this Committee have already been tested or are under
19 test at the present time. When a chemical compound is nominated
20 for test, the Chemical Selection Working Group meets with
21 representatives from other government agencies who have an interest
22 in this, including EPA, FDA and others. Members of these other
23 agencies also serve on the Chemical Selection Working Group.

24 The Committee members vote on each chemical
25 according to materials supplied by a contracting firm
known as Stanford Research Institute, which provides information
about each compound including amounts produced and imported,
whether they have been tested previously, and other information.

1 There has been a class study on pesticides in general and
2 several pesticides other than 2, 4-D and 2, 4, 5-T have been
3 tested or are under test.

4 We have to set priorities. Out of 45,000 chemicals,
5 which are most likely to be carcinogenic, we take into account
6 the chemical structure and similarity to known carcinogens, and
7 the amount of human exposure. This is difficult to obtain.

8 I have a sample data sheet on benefin, another herbicide
9 that has been nominated for test by the NCI. After the Working
10 Group assigns a priority for those compounds selected for
11 testing, each one is presented to a subgroup of the Clearinghouse
12 on Environmental Carcinogens, composed of a group of
13 advisers outside the NCI. They are the best experts we can
14 find in the field. They meet approximately four times a year,
15 and each of the nominated chemicals is submitted to this group
16 for their opinions. These are open meetings. The subgroup
17 reviews the evidence for each chemical, perhaps asking for more
18 information, and then ranks them on the basis of 1-10, ten being
19 the highest priority. We then have a list of chemicals ranked in
20 order of priority to enter into the testing program.

21 This is a copy of the monthly report of the status of
22 each of the chemicals which have been nominated for testing,
23 those which are under test, and those for which tests are
24 complete but the reports have not been published. We can
25 make these reports available to the

1 members of this Committee.

2 The dioxins, TCDD and HCDD, are in final stages
3 of the testing procedure. They are under pathology review.
4 The protocols describing the results to be presented to the
5 Clearinghouse subgroup on Risk Assessment/Data Evaluation are,
6 being printed at the present time, and so I can't say
7 anything about them yet because they have not been presented
8 to the Clearinghouse. However, we expect that both of these
9 compounds will be presented to the Clearinghouse in July
10 or September, so that within the time frame of the work
11 described for this Advisory Committee, these results will be
12 available as technical reports. Here is an example of a
13 technical report on another dioxin, DCDD, which was published
14 this year. This and other reports are available either through
15 the National Cancer Institute or through other government sources.

14 DR. HABER: That is excellent. Please continue.

15 DR. LINGEMAN: The International Agency for Cancer
16 Research, under the auspices of the World Health Organization,
17 meets periodically to discuss chemical compounds known or
18 suspected of being carcinogenic. This is Volume 15, which was
19 published in 1977 on the subject of some herbicides, which
20 includes 2, 4-D, 2, 4, 5-T, and the dioxins, the compounds of
21 concern to this group. This is a publication that Committee
22 members should have access to, for it is an excellent summary
23 of known health effects of these compounds in man and animals.

23 The other activities of the National Cancer
24 Institute which have to do with this area involve the
25 Epidemiology Branch, and I have not had an opportunity yet

1 to find out the precise details of all that might be going
2 on there. As mentioned before, epidemiologic information
3 documented with good pathology material is very difficult
4 to obtain. By the time of our next meeting, I hope
5 possibly to have some information about activities of the NCI
6 epidemiologists in this area.

7 DR. HABER: Thank you very much. We are making
8 very good progress. We are at the break time, but I think
9 we have but one more presentation, and I would ask your
10 forebearance for Dr. Murphy to make his presentation,
11 and then we will break for lunch.

12 DR. MURPHY: I can probably be relatively brief
13 since I have not been directly involved in research on this
14 problem, and I do not really represent an agency. Although
15 my name tag says consultant to the National Academy of
16 Sciences, I really am not here representing the NAS.

17 I am merely speaking from the standpoint of a
18 scientist who has been concerned with the toxicology of
19 pesticides for some 20 years, with focus on primarily the
20 insecticides, and have published several papers in this area.

21 For a number of years, I have from time to time
22 served on certain expert committees of the World Health
23 Organization dealing with pesticide residues in foods, and
24 in the process of those deliberations, have gained some
25 experience in going through the process of evaluating
laboratory animal and epidemiological data with respect
to ultimately coming to the conclusions concerning
recommendations regarding the hazard or relative safety of

1 pesticide residues.

2 I am a member of the EPA Science Advisory
3 Board's Environmental Health Advisory Committee, and as a
4 function of that Committee membership, I chaired a study
5 group on the contaminant: pentachlorophenol, the contaminant
6 in a particular pesticide which I think does have some use
7 as a herbicide, but was not to my knowledge used in
8 Vietnam, but the contaminants in that material of greatest
9 concern are the halogenated or chlorinated dibenzofurans.

10 Dr. Moore was a member of that group, and we
11 reviewed the knowledge base concerning the contaminant of
12 pentachlorophenol. Tetrachlorodibenzodioxin does not appear
13 to be a contaminant of pentachlorophenol, but the other
14 dioxins that are, as Dr. Moore has indicated, produce very
15 similar actions as that produced by TCDD, and there is
16 a wide range of toxicities involved among the number of
17 different isomers that are contaminants.

18 Some two years ago, I was a member of an ad hoc
19 panel chosen by the National Academy of Sciences to meet
20 with Italian health officials to evaluate and recommend
21 possible collaborations in research on health effects
22 associated with contamination of the environment around
23 Seveso, which we have heard mentioned several times today.

24 The contamination resulted from an explosion of a
25 reactor producing trichlorophenol near the town of Seveso.
This Academy-sponsored panel met several months after
the occurrence of the accident with the counterpart committee,
and then subsequently this past March met again to review

1 the status of the studies that were largely being conducted by
2 the Italian scientists in the area around Seceso,
3 both laboratory and epidemiological studies.

4 In a very brief summary of the discussions of this
5 meeting last March, from the studies conducted

6 so far, there were three health effects that were
7 observed that the epidemiologists' reported suggested
8 association with this exposure to TCDD from the industrial
9 accident.

10 These included chloracne clearly associated with
11 the exposure, some suggestion of what was described
12 earlier as hepatomegaly, and apparently some specific
13 tests conducted showed some deficiency or slowing of nerve
14 conduction.

15 The epidemiologists were developing plans for
16 following a fairly large group of people over a long period
17 of time in connection with the concerns for carcinogenic
18 potential of TCDD, and one of the interesting observations
19 was that the concentration of dioxins in the wild animals
20 that roamed in the area did not appear to correlate very
21 well with the incidence of chloracne that was reported,
22 and I was very interested in Dr. Allen's comment concerning
23 evidence of some effects reported in the peripheral areas
24 of exposure, and I wonder what these relationships mean.

25 An interesting point that has come to my attention
during these two committee activities, one in the EPA
and this activity of the Academy, is, what is the relationship
between the dosage for effects in laboratory animals and

1 in humans, and this seems to be a rather illusive
2 relationship.

3 In some respects, one would have almost
4 anticipated that the Seveso incident would have been even
5 more severe effects than apparently had been noted.

6 There was an attempt to evaluate the potential
7 contribution to teratogenic actions in the human population,
8 and so far, it appears that statistically nothing sorts out
9 as a positive finding in that regard.

10 You asked for what kind of things we would like
11 to see. Well, I would like to see the earlier NAS report
12 after the Air Force report. I would like to see more about
13 what is the nature of the designs of the studies that are
14 now underway, and I wonder how much alternate designs
15 have been considered, looking for clustering of possible
16 effects and so forth.

17 What are the plans for long-term studies?
18 You do have a group of human population that can be followed,
19 but what are the plans for these, and to the extent possible,
20 although as I said I don't represent NAS, I would hope
21 to coordinate some of the information with the Committee
22 on the National Academy of Sciences which has now been
23 renamed to something like Committee on Response Strategies
24 to Unusual Chemical Hazards, so they can respond to other
25 things than Seveso.

26 DR. HABER: Thank you very much. That then
27 concludes our morning. I must say that I am more optimistic
28 at this moment than I have been for some months, that we

1 will find an answer, although that answer is not clear.

2 I would like to thank everybody for the morning's
3 proceeding. Would the members of the Advisory Committee
4 and the Steering Committee remain behind just a moment,
5 please?

6 We will reconvene at 1:30 as per the agenda.

7 (Whereupon, at 12:15 p.m., the hearing was
8 recessed, to reconvene at 1:30 p.m. the same day.)
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A F T E R N O O N S E S S I O N

1:30 p.m.

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3 DR. HABER: Let me reiterate if you will,
4 please. For those of you on the floor who have questions, give
5 them to Mrs. Meyer, dutifully sitting back there.

6 She will give them to me and I will attempt to read
7 them. If they are relatively simple and are procedural,,
8 I will endeavor to answer them this afternoon.

9 Those that are more substantive, we will have
10 some discussion from the Committee if the time allows,
11 but I will tell you that we will get a position paper on
12 it because I don't believe that the Committee yet is pre-
13 pared definitively to answer. There may be differences
14 of opinions which obviously is our job to resolve. So,
15 while you might have some discussion about the question,
16 that should be regarded as a tentative answer only in
17 that the Committee will obviously want to deliberate
18 further on some of the complicated questions, and we will
19 adopt a position on it at some point, which will be made
20 public either through the use of subcommittees or circulat-
21 ing documents through the committees all together.

22 I would like now to move along with our agenda

23 I think that because we did so well this morning in
24 covering each of the participants on the Committee and
25 their agency's specific orientation toward the problem,

1 think what I would like to do now is to engender some
2 dialogue among the members of the Committee. Undoubtedly
3 each of your comments excited some concerns, some questions,
4 some suggestions on the part of the rest of the group.

5 I would like now to encourage us to go at that business
6 to try to get some indications of what the substance of
7 these deliberations are.

8 Dr. Allen, may I begin by posing a question to
9 you? In your work with primates, you have reason to
10 believe that there were birth defects, but were these
11 confined to females who were pregnant at the time of
12 exposure, or did you have any evidence suggesting that
13 males could transmit damage that they sustained to the
14 offspring of non-exposed females?

15 DR. ALLEN: Dr. Haber, I would like to answer
16 this by first clarifying a point. We have observed no
17 birth defects in the offspring of monkeys that have been
18 born to mothers that have been exposed to the TCDD's.

19 There have been abortions, and most of these
20 abortions occurred early in gestation. Those animals
21 that were born to the mothers that were exposed prior to
22 and during gestation, had normal infants, with the
23 exception of being small. Otherwise, they were, generally
24 speaking, small.

25 We have observed alterations in the menstrual

1 cycles, increase in cycle length and duration of the menstrual
2 cycle, and alterations in progesterone levels in the females that
3 have been exposed to the dioxins. We have not done thorough
4 studies on the male Rhesus monkeys.

5 In our early report published in 1967, we did
6 observe a marked decrease in spermatogenesis in monkeys
7 that were exposed to high levels of dioxins, including
8 the tetras, the hexas, the heptas, and the octachlorodibenzodioxins.
9 Those of you that are older might remember the toxic fiasco
10 that we had in the '50's, so we would expect, and we
11 certainly would feel, that it does affect spermatogenesis.

12 We have observed no indications of a mutagenic
13 nor teratogenic change in the animals so far.

14 DR. HABER: I am indebted to you for clarification,
15 and I'm sorry I interrupted. I will tell you that Dr.
16 Ton That Tung, the North Vietnamese physician who had had
17 some experience with this several weeks ago came and briefed
18 us, and when we put that question to him, although he
19 had talked about birth defects in offspring of exposed
20 females, he did not extend that to the males. He said
21 he had no evidence of that, so it is a question of some
22 concern to us.

23 DR. ALLEN: I also had the opportunity to visit
24 with Dr. Tung while he was visiting the United States,
25 and I think that I would like to say that in most instances,

1 the data that were presented by Dr. Tung were those of a
2 practicing physician, and they were meager as to the
3 information that they were able to relay to us.

4 DR. HABER: I can only agree to your observation,
5 and I think Dr. Tung himself disclaimed any epidemiologic
6 certainty from his findings and stated to us that they
7 were suggestive only, that he was not an epidemiologist
8 and portrayed himself as a practicing clinician in these
9 observations, but of course, they were useful to us as
10 observers.

11 I wonder, Mr. Lemen, if you could tell us a
12 little bit more about the work of Dr. Suskind and Dr.
13 Selikoff, if that is possible? I guess it was you who first
14 suggested that?

15 MR. LEMEN: Fine. First of all, as far as
16 results are concerned, I can't give you anything because
17 Dr. Selikoff is just analyzing this, and I might suggest
18 that you invite Dr. Selikoff or
19 Dr. Marian Moses, who is the physician that was doing a
20 majority of testing, to come to the Committee and present
21 the results to you.

22 I can tell you the design of the study was that
23 of a cross-sectional medical study, looking at workers
24 who had been in the 1949 episode. Some had developed
25 chloracne, and they were looking for any medical findings

1 in that group of workers.

2 At the present time, Dr. Selikoff has discussed
3 the possibility of doing mortality analysis on the total
4 work force. However, he has not started that.

5 Dr. Suskind has been following these people,
6 according to my talks with him, since about the early '50's,
7 and he has been looking primarily at dermatological
8 conditions in the workers that were exposed to the 1949
9 episode.

10 Dr. Suskind says that he is in the process of
11 doing mortality studies. However, he does not have
12 results on the mortality study to date. We will continue,
13 as I said, to monitor both of these to try and get results
14 as soon as they become available, but neither one of the
15 two studies has any results that we can speak of today.

16 I think at the next meeting,

17 Dr. Selikoff's group would
18 probably be able to talk to you about their findings.

19 DR. HABER: I think we might invite him to make
20 a presentation to us. Does the group have any objection
21 to that sort of thing if we were to invite people that
22 you might suggest to make presentations to us?

23 DR. KEARNEY: I think it would be very helpful.

24 DR. MURPHY: I wonder, Mr. Lemen, in Dr. Suskind's
25 studies, has there been any attempt to assess morbidity

1 from whatever cause other than dermatological? How
2 about infectious diseases?

3 MR. LEMEN: Quite frankly, the information that
4 we have received from Dr. Suskind has been a little bit,
5 I don't want to use the word sketchy, but it is
6 inconclusive, and I can't really answer that question.

7 He says that he is looking at the health effects
8 in total among the workers, but in talking to him, it
9 appears that it has been more of a dermatological evaluation.
10 That is about the best I can do.

11 DR. MURPHY: Are Dr. Selikoff's studies designed
12 to assess immunofunction?

13 MR. LEMEN: Yes, to my knowledge, they are. As
14 you well know, though, in the cross-sectional type of
15 study, it would be very difficult to detect any chronic
16 long-term health effects such as cancer because those
17 people tend to cluster in one population at the same time,
18 so the type of studies without the aid of the mortality
19 study would probably not answer the carcinogenicity
20 question that you have posed, and also the question of
21 teratogenic effect would have to be addressed in talking
22 to family members and doing a fairly detailed questionnaire
23 of the wives and offspring of those workers.

24 DR. HABER: I would like to comment, though, on
25 this problem of chloracne, and invite any comments from the

1 Committee or questions about it.

2 The chloracne for us has a particular significance
3 because it really constitutes a marker. If a serviceman
4 comes to the Veterans Administration for treatment or for
5 adjudication of a claim, if there are problems with
6 substantiating the possible exposure, Dr. Levinson described
7 this morning how we are trying to match the tapes on
8 movements of various units in the Armed Forces with areas
9 of known exposure to sprays, so that we can get some
10 concurrence of data. One thing we do feel pretty
11 confident about, is that if a veteran should have,
12 any evidence of chloracne attendant upon his service in
13 Vietnam, that probably would give us pretty clear evidence
14 that he has indeed been exposed, so it would constitute
15 a kind of a marker. We know that chloracne should
16 occur within a matter of days or weeks or at least a few
17 months after exposure; that it is not likely to occur
18 years later.

19 Its first occurrence having taken place during
20 the period in which he was in Vietnam or very shortly
21 thereafter then gives us some feeling that there may be
22 long-term other effects. Chloracne has been associated
23 with systemic symptomatology and general pathology, so
24 we feel a little bit more confident about that.

25 Is there any comment about this?

1 MR. LEMEN: I have one question, and maybe the
2 Committee can answer it.

3 Are there any levels below which you come in
4 contact with the Dioxin or 2, 4, 5-T that you do not get
5 the chloracne?

6 DR. ALLEN:

7 This was the question that I was looking at. From an
8 experimental standpoint, there can be reproductive
9 abnormalities in the females without showing obvious signs
10 of dermatological alterations.

11 I have a question for Dr. Moore.

12 DR. MOORE: Can I finish? I can add something
13 to his comment. There was a report in the British literature
14 several years ago in which there was accidental exposure
15 of several chemists trying to synthesize or work with
16 TCDD, and in those cases where they did come down with
17 clinical symptomatology consistent with dioxin exposure,
18 it occurred in the absence of chloracne.

19 DR. HABER: What we are saying is that chloracne
20 is not a sine qua non for evidence of exposure. That
21 has been our suspicion, that people could have dioxin
22 poisoning, if that is possible, exposure, and not come
23 down with chloracne, but if they do come down with
24 chloracne, the burden of proof is upon him who says that
25 it was not due to exposure, and I think it has to be thought

1 of in that way. Where we find chloracne, we have got to
2 really be very, very concerned. Where we don't find it,
3 it still may be. Could you tell us a little bit
4 more, Dr. Allen, about the dermatological abnormalities
5 you saw in these monkeys and how long after exposure did
6 they occurred? What would you say?

7 DR. ALLEN: One of the first indications that
8 we had was in the let's say, for instance, the 500 parts
9 per trillion. After they consumed 1 microgram per kilogram
10 of body weight, we began to see the development of
11 alopecia, loss of hair and dry, scaly skin, and if you
12 look closely, you could see the accentuated
13 hair follicles within a period of three months after we
14 began to see indications.

15 In the 50 parts per trillion group, after they
16 consumed in the neighborhood of 3 tenths of a microgram
17 per kilogram of body weight, there were no obvious changes.
18 However, we began to have indications of reproductive
19 abnormalities that were obvious in these females.

20 DR. HABER: From ingested toxin?

21 DR. ALLEN: Ingested, not from dermatological
22 or inhalation exposure.

23 DR. HABER: We have to keep in mind both
24 possibilities. The troops or an exposed person may have
25 wandered through areas infested with the

1 dioxin and become contaminated.

2 The other concern we have, of course, is that, and
3 I look to Colonel Thiessen about this, there weren't
4 too many dermatologists in the front lines so that the
5 condition of chloracne might not have been precisely
6 identified, but rather some other dermatological abnormality,
7 trenchfoot or something like that. So we would be inclined
8 to say that any dermatologic abnormality, unless it is
9 pretty clear that it could not have been caused by dioxin,
10 would have to be suspect.

11 Do you have any comment?

12 COL. THIESSEN: Individual cases maybe; I am
13 not so sure whether an epidemic quote, unquote, of
14 chloracne or acne or any dermatosis would have gone unnoticed.

15 DR. HABER: I didn't mean that. I just mentioned
16 in individual cases that somebody might have ascribed
17 that. It is conceivable at least that someone would say
18 chloracne is a pretty tough diagnosis, and you have got
19 to be a dermatologist to do it, and they were just corpsmen,
20 so how would you have made that diagnosis at that time?

21 COL. THIESSEN: If the soldier had complained
22 about a disfiguring acne, I'm sure that would enter into
23 the record. I am certain of that.

24 DR. ALLEN: Dr. Haber, I have a question of
25 Dr. Moore. One of the charges of the World Health

1 Organization, the group was to study the various industrial
2 accidents.

3 Is there any feedback on this? What is
4 happening with that charge? Are they pursuing this?

5 DR. MOORE: A number of those groups are being
6 followed. The hope of the exercise was that the various
7 groups that were studying their exposure here and their
8 exposure there would come up with an agreed-upon questionnaire,
9 a case history, so that there would be some consistency
10 in what was looked for and the way it was they went about
11 looking for it so that one could have the benefit subsequently
12 of trying to amalgamate these various groups to get a
13 bigger statistical cohort to try to look at.

14 At the time we met, which was a year ago January,
15 nobody had been looking to the Nitro, West Virginia group
16 subsequent to the actual accident which occurred in the
17 early '50's, and the recent flurry of activity that we
18 have found in the Nitro, West Virginia group is that it is
19 a recent flurry of activity.

20 MR. LEMEN: Can you tell us some industrial
21 sites that you are looking at?

22 DR. MOORE: They are in here. We are not looking
23 at any sites. The sites that were identified by various
24 people include some in Germany, some in this
25 country, one in Holland, one in Germany Obviously

1 the Seveso circumstance from a time standpoint was in its
2 infancy.

3 DR. ALLEN: Are there epidemiological studies
4 that are being financed by WHO?

5 DR. MOORE: No, not epidemiologic studies as
6 such; basically morbidity, seeing what the cause of death
7 is, et cetera, on some of these older groups, to see if
8 anything will show up.

9 MR. LEMEN: We have been looking just to answer
10 a little bit more, and we have not found, except for the
11 Nitro situation, any epidemiological studies that are
12 going on in the United States looking at dioxin exposures.

13 DR. HABER: At this juncture, it might be useful
14 to have Dr. Schepers tell us something about this problem.
15 He has looked into this, and has identified a number.
16 Every time we consider it, it turns out there are more
17 industrial exposures than anybody knew, and Dr. Schepers
18 has what I believe is one of the more complete anthologies.

19 Would you please let us know about this, and
20 maybe we ought to enter that into the record, the complete
21 thing, and tell us about the exposures we know about.

22 DR. SCHEPERS: It is not terribly complete. I
23 just happened to accidentally have it in one of my folders,
24 but the first exposure of human beings to 2, 4, 5-TCL--
25 it wasn't 2, 4, 5-T--was at the Nitro site, and that was in

1 1949. About 188 people were exposed there in the
2 factory, and probably the children and wives, too, because
3 there is recorded illness of those children and wives, so
4 that the number of human beings could be quite sizable.

5 Now one of the problems with our group is to
6 identify these individuals because after 30 years, they
7 have been disbanded. I traced the actual Director of
8 Personnel for the Monsanto factory to Mr. Baum through
9 some friends of mine, and I am going to ask Mr. Baum if
10 he has a record of all these people, and I think he has,
11 so that we may be able to trace the human beings through him.

12 The next series of accidents occurred as four
13 events in West Germany, from '49 to '74, and they
14 can be found in the literature, and I would be glad to
15 supply the Committee with details.

16 Then there was a group of two accidents in
17 France from '56 to '66; 38 people were exposed to dioxin-
18 containing materials there. They all developed chloracne,
19 incidentally.

20 Then the next exposures were in the United States
21 from the period '56 to '74, and these were the four separate
22 events that most of you will know, that totaled to 81
23 people. This is in Arizona, the group out there in Missouri,
24 the horse farm, and so forth, and of course the employees
25 of different chemical factories.

1 Then in '62, there was a small accident in a
2 factory with five people exposed in Italy. In Holland,
3 there was a group exposed in '63 with 50 workers, and
4 they are being followed,; hyperlipema and asthenia being
5 the main features so far identified.

6 There have been two industrial accidents in
7 Russia between 1964 and '72. All the people recovered.
8 These two events were at intervals of eight years, all
9 symptomatic. The follow-up study is not known, but we
10 are trying to find out what happened to those people.

11 Then in England in 1968 there was a single big
12 reactor leakage event, and most of the descriptions are
13 related to chloracne, but there are obviously
14 possibilities there.

15 In 1970, there was a single accident in Japan. We
16 are trying to follow that.

17 In Czechoslovakia in '72--there were very severe
18 industrial exposures, gross poisoning--six of the 55
19 workers actually died, showing the severity of the exposure.
20 Now that should be an extremely interesting group to
21 follow.

22 Then in 1976 in Switzerland and Italy, that is,
23 of course, the Seveso incident, and that is the largest
24 single group. I understand there are about 70,000 children
25 under surveillance by the Italian government.

1 I totaled up the numbers of people in these
2 incidents, and they come to almost 1,000 people, so that
3 we have a fairly large group of human beings that can
4 be researched collectively.

5 DR. HABER: I think one of the things that this
6 Committee should be expected to do is to try to compile
7 as complete a dossier as we can on the numbers of and kinds
8 of such accidents therewith to stimulate the appropriate
9 research by the appropriate agency, and hopefully to share
10 in the results of such research.

11 DR. MOORE: Dr. Haber, one of the best groups
12 is that Czechoslovakian group that Dr. Schepers mentioned
13 in that it has at least appeared in the literature. All
14 of it has appeared in the literature. We have had those
15 articles transmitted, and we will give you a copy of the
16 translation.

17 DR. HABER: I have asked our staff to do two
18 things for us. One is to draw up a general chart of
19 organization of the federal government and the private
20 and academic sectors as well to see whether or not we can
21 develop a kind of chart so that all of us can have a ready-
22 made indication of who is doing what. This would be
23 keyed with the number of studies, and I think each of us
24 could use that so we could find out where the responsibility
25 lies or who accepts responsibility for doing certain things.

1 The other thing that I think might be very
2 useful is,if we could begin to see, try to indicate some
3 time lines so that we would have some indications as to
4 when these studies would be complete, and we get some
5 idea,at least in gross,about when we might expect some
6 definitive answers.

7 I know that some of it would take years to
8 complete, but hopefully we would be able to get some clear
9 indication that we can give to the public about the
10 latest date the information would have been in. Maybe
11 that can be improved upon.

12 I wonder, Dr. Kearney, if you could tell us a
13 little bit more about that conference on the dispute
14 resolution because really that is what we are about. and
15 it is the kind of a process in which I think this Committee
16 would be very interested. If you could, give us any
17 general guidelines as to how we use the scientific method
18 to resolve a problem that is plaguing all of us.

19 DR. KEARNEY: Well, I can provide you with the
20 background paper. I think in a dispute of this nature, it is a
21 question of how it could be resolved and what would be the outcome.

22
23 I suppose in some respects the first conference
24 we had was largely discipline oriented, i.e., the field of
25 medicine and chemistry dealing with specific subjects of



1 teratology and mutagenecity, carcinogenecity, human
2 exposure.

3 The more philosophical question of how one
4 deals with dispute resolution will probably be the next
5 conference in which we would have local people, sociologists,
6 political leaders, and others involved, but it does bring
7 to mind something which I think is germane to these
8 deliberations. It would be helpful to us
9 the advisory panel to perhaps at some point clearly define
10 what the Administration wants from us with regard to
11 resolution of this dispute.

12 In other words, is teratology a legitimate
13 subject for deliberation here? I don't know the answer
14 to that question because were there females in
15 the Vietnam area that ~~ae~~ involved here inclaims for compensation?
16 Are we talking about males primarily, the number of males,
17 and perhaps what you want us to focus on, because some
18 of the issues are peripheral as far as we are concerned.

19 I don't know that we can answer that question
20 today. As we get into this thing, these things will
21 begin to surface.

22 DR. HABER: Well, I think that is part of the
23 question I was asking Dr. Allen really because our concern
24 is not exclusively directed towards males in Vietnam, as
25 there were obviously women in the Armed Forces, and some

1 of them may have been pregnant at the time. Although
2 such cases have not yet come to my attention, if the
3 clear link is established that a pregnant female does
4 produce a mutagen or a teratoma, and she can have
5 claimed to have had exposure that would be something that
6 would be useful for us to know.

7 On the other hand, a thousand, perhaps a hundred
8 thousand times more likely just on the basis of the
9 prevalence of people, would be the possibility that males
10 thus exposed might transmit genetic damage to offspring
11 by females not so exposed.

12 As I say, it seems to me that no clear evidence
13 has been adduced to that effect, and I think that is
14 something that, therefore, should concern us, but I would
15 not turn my back on the other.

16 I think that we have an obligation first to
17 look at our own problem, but I would say that we must not
18 pass up the opportunity to contribute to the general knowledge
19 if in so doing we don't obstruct our major objective.

20 I think it is appropriate
21 for us to discuss teratology in pregnant exposed females,
22 but it certainly should not loom very large in our
23 discussions.

24 DR. SCHEPERS: May I comment on that?

25 DR. HADER: Please.

1 DR. SCHEPERS: You have answered many telephone
2 calls, Dr. Castellot, and I perhaps more. This is
3 probably the most distressing thing to the veteran. Many
4 of the calls that I get is Doctor, I have just had a
5 child, and the child is deformed. Is this de to Agent
6 Orange?

7 They want an answer to that. Now Dr. Erickson
8 told us today that he has perceived a decrease in neurological
9 teratology an increase in heart and renal agenesis.

10 They mention club feet, cleft palate, the
11 obvious things. Those are the things that distressed
12 them.

13 We need to give them an answer on that. If
14 there is an answer here, let's hope we find it, but it is
15 a distressing thing, and I think this Committee should
16 stay with that.

17 DR. HABER: Absolutely. I agree with Dr. Schepers,
18 and I hope I didn't mislead anybody. I think that is a
19 cogent subject for discussion, and one that we really
20 should zero in on, and I think we have to focus on this
21 to be able to reassure the veterans, if we can, which
22 would be extremely useful.

23 On the other hand, if there is a reasonable
24 doubt, I think we have to place that.

25 DR. MURPHY: I would like to ask a question of

1 Dr. Erickson and Dr. Allen in relation to this. With
2 the kind of surveillance program that you have, Dr. Erickson,
3 would the number of malformations that might be
4 found in a group of, approximately 10,000 people, show up
5 in this? Would there be a big enough blip in the ordinary
6 incidence of things to show up?

7 I don't mean 10,000 malformations, but a whole
8 population of 10,000 people.

9 DR. ERICKSON: It is possible. It is also
10 possible that it would not.

11 DR. MURPHY: In general surveillance
12 you don't focus on a select
13 population, and I would worry about drawing conclusions
14 from the kind of general trends you reported this
15 morning.

16 The other question, Dr. Allen, you mentioned you
17 didn't have any evidence of mutagenic or teratogenic
18 actions. Is that correct?

19 DR. ALLEN: I think that, and I will refer this
20 question after I have attempted to answer, to Dr. Lingeman
21 here, if a compound generally speaking is carcinogenic,
22 more than likely we will find it to be mutagenic. I
23 think there is very little doubt that in animals, that
24 TCDD is a carcinogenic agent. Thus, with the proper tools,
25 I think we will likely find it to be mutagenic.

1 Are you in agreement with that? I mean,
2 generally speaking, we think of a carcinogen as also more
3 than likely being a mutagen.

4 DR. MURPHY: This is precisely what I was
5 wondering about, and I think it has been reported mutagenic.

6 DR. ALLEN: It is a very difficult compound
7 with which to work, particularly in your system or
8 whatever it might be .

9 DR. MURPHY: Do you have tests on this?

10 DR. MOORE: Carney in Canada did contaminant
11 studies and reported this negative.

12 DR. HABER: Repeat that.

13 DR. MOORE: Carney in Canada has reported on
14 a dominant lethal study which would be in effect for genetic
15 damage in the male transmitted to the offspring which
16 would be picked up by fetal absorption . His study was
17 negative.

18 DR. HABER: Could you give us that citation at
19 some point?

20 DR. MOORE: Yes.

21 DR. HABER: Thank you very much.

22 DR. KEARNEY: In that regard, the carcinogenesis
23 work, we did address this. It did say that TCDD is a
24 mutagen in two bacterial reverse mutation systems, and
25 they cite the reference, but no correlates of mutagenicity

1 have been found

2 Citing the reference, they also say TCDD is
3 a carcinogen for rats, and cite four references, and mice,
4 and cite two references.

5 DR. HABER: Is there any further discussion
6 among the members of the Committee? One of the things I
7 would like to ask the group to consider is,
8 one of the problems we have is to translate
9 the kind of data that Dr. Allen has presented
10 into possible field exposures.

11 It is very useful to have his other detailed
12 observations upon ingestion or exposure of a chronic
13 nature to these toxic agents over a long period of time,
14 and then to be able to make post-mortem pathologic
15 diagnostic studies of exposed animals. That is clearly
16 the first step, and it appears that in non-human primates
17 and certain other species, that is pretty well along.

18 One of the things that I would like to ask the
19 group to speculate and ruminare about, and maybe suggest how
20 one could go about it, is, how does one begin to translate
21 that kind of quantitative data into how could we begin
22 to get a grip on the likelihood of intensity of the exposure
23 of human beings in the field?

24 In other words, how much exposure would somebody
25 have to have to sprayed foliage and vegetation in order

1 to come up with dosages that might be comparable even in
2 an order of magnitude to what Dr. Allen has been feeding
3 his experimental animals?

4 What I am trying to get at is some feeling
5 among the group as to how we could begin that process
6 because I think that is an important element . Are we talking
7 about the same order of magnitude or are we talking about--
8 Dr. Moore?

9 DR. MOORE: I would like to make one request, if
10 somebody doesn't have any information, and I will get on
11 the bandwagon; in response to the question, it is my
12 understanding that the use of Agent Orange in Vietnam, or
13 herbicides in general, markedly decreased in the early
14 '70's, and the bulk of herbicide exposure occurred in the
15 late '60's

16 Keeping that fact in mind, it was only
17 around 1970, '69, '70 that the concern about the level of
18 dioxins in herbicides became an issue, and there was
19 an overt attempt to reduce the level of dioxins which
20 would suggest that the actual material that was sprayed
21 would be higher than that which would be found on Johnson
22 Island, which has been subsequently disposed of and was
23 -analyzed At least it was analyzed.

24 It is my understanding that samples of some of
25 the pre-'69 or pre-'70 Agent Orange materials that were
used do exist, and I would urge you to find if indeed

1 that is the case, and if it is the case, to see what the
2 level of dioxins are that were in that material

3 DR. SCHEPERS: We have tried very hard to get
4 a lead on where these samples could exist, and we can't
5 trace them. If you know, let us know.

6 DR. KEARNEY: As you know, in '70 we did do some
7 sample studies for manufacturers. We got back to '68 I
8 guess, and then we asked for other samples, and we were
9 unable to obtain them .

10 The problem also on Johnson Island, I think
11 perhaps the Air Force has, is one could not identify lots
12 to manufacturers in the rebarreling process. I think
13 records became lost.

14 DR. ALLEN: Can you give us an idea? I know
15 the Air Force reported as high as 47 parts per million
16 I have heard unofficial reports that there were levels
17 higher than this. Can you give us any insight as to what
18 the levels of dioxin TCDD, was in the material that was
19 being sprayed?

20 DR. KEARNEY: Dr. Allen, I wish I could. I am
21 not sandbagging you. I simply don't know. I heard this
22 figure of 50 also. We did not analyze the sample, but

23 apparently industry became aware of the problem and
24 one manufacturer quickly tried to rectify it.
25

1 Others became aware of it later, and were unable
2 to rectify it until the very end, toward the end of the
3 situation.

4 I only wish we had those samples to analyze, but
5 we can't get hold of them either. We haven't tried legal
6 means, but we simply have not been able to get hold of
7 them.

8 DR. HABER: I think this is a very important
9 question, Dr. Moore. I think you are right on target. I
10 think there are two parts of it. One is we need to--
11 Colonel Thiessen, maybe you can be of assistance to us--

12 Dr. Schepers has been unable
13 to run down where such samples might exist, but if
14 we could begin to isolate such samples, and then,
15 allowing for decomposition and so on over this length of
16 time, decide whether or not there was any TCDD at the
17 time of the spraying. The second part of

18 that would be to translate spraying information into the
19 possibility of exposure.

20 That seems to me to be a mathematical possibility
21 at least, but probably a very difficult epidemiologic task
22 to perform.

23 COL. THIESSEN: As far as TCDD is concerned of
24 course, all the information that is available is either
25 in the Air Force report. I don't know if there are any of
the samples still available that were used to determine the
TCDD level.

On the other hand, though, I wouldn't be surprised

1 if a chemist, a manufacturing chemist could simply, looking
2 at a production process, say something about a maximum
3 level of TCDD possible. I thought you had a representative
4 of Dow Chemical; he is not here any more, but I am
5 sure that Dow could give that kind of information
6 Certainly I have never heard a level that high, but 50, 50
7 PPM is, as I understand it, the level that was present in
8 some samples; in most of the samples, the contamination was
9 below 10.

9 DR. HABER: Can you tell us what steps we went
10 through to try to get that information?

11 DR. SCHEPERS: Well, we went to the Army records;
12 to the Air Force records. We went to the Dow Chemical
13 Corporation, the Hercules Corporation, 18 different chemical
14 corporations to see what records they have.

15 My genuine impression is that one, they did not
16 know of this problem until around about the late '69, '68
17 era, so that they genuinely did not know what the dioxin
18 content was of the earlier samples.

19 My other impression is that the manufacturing
20 process was fairly standardized so that the way the
21 ingredients of Agent Orange were made in the '70's is
22 probably the same way that this same material was made
23 five years or six years earlier. There was no real change
24 in the manufacturing method. Therefore, the probability
25 is that the incidence of TCDD in 1970 was probably the same
26 range as it might have been in 1963.

27 Now a lot of emphasis is often made on the

1 occurrence of large quantities, relatively large quantities
2 compared to the experiments Dr. Allen has made, and when
3 we talk of 50 parts per million, this is about 50 million
4 times as much as you are using in your experiments, but
5 often, not enough is said about the fact that quite a
6 number of the samples that were tested had zero TCDD in
7 them, and we don't know what the distribution was of the
8 barrel with 50 in them, and the barrels with nothing in
9 them, whether the analytical methods were sharp enough to
10 be able to measure the presence of TCDD below one part per
11 million.

11 We, of course don't know. I should rather suspect
12 that the analytical methods were not available, but it
13 almost becomes a moot issue when you, Dr. Allen, produce
14 results at 10 parts per trillion, whether there was exposure
15 to 40 parts per billion or 30 parts per million.

16 I don't understand the dimension. I see no
17 relationship. It is just that there was a heck of a lot
18 of TCDD in Agent Orange compared to your experiments.

19 What I would like to get from you is whether you
20 have ever tried to calculate quantitatively how much dioxin
21 is needed to produce an effect in an animal, what is the
22 least quantity that will produce it, and then for us to
23 relate that to the least quantity that we can identify
24 in the herbicides used in Vietnam. That would be an
25 interesting mathematical calculation.

26 DR. ALLEN: The only thing that I can say is
27 that in my more recent studies, we have found that 50

1 parts per trillion in the diet when consumed over a period
2 of approximately six months, and it is about 3 tenths
3 of a microgram per kilogram of body weight, will produce
4 reproductive abnormalities, and over a period of two years,
5 a consumption of 1 microgram per kilogram of body weight
6 will produce obvious signs, gross signs, of intoxication.

7 DR. SCHEPERS: Have you found a no effect level?

8 DR. ALLEN: Not in non-human primates, no. We
9 are going down to lower levels at the present time, but we
10 have not found a no effect level when the exposure has
11 been extended over a period of time.

12 At six months when they have consumed 3 tenths
13 of a microgram, we did not see any obvious signs of intoxication
14 grossly with the exception of reproductive abnormalities.

15 If we waited two years, we did see signs.

16 DR. SCHEPERS: What about the experimental model
17 to compare to the experience of a soldier who might have
18 been in Vietnam say six months in an area, combat zone,
19 where he might have been contaminated in one shape or
20 another, either sprayed on his head or in his clothes or
21 in his water or whatever, and then he leaves? Have you got
22 anything in your experiments, animal experiments to match
23 that? In other words, a short period of exposure in the
24 life cycle of the animal and then wait and see; that is
25 the one we are interested in.

DR. ALLEN: The only one, and certainly it is
far removed from your particular example, is in the 500
parts per trillion studies we had three that survived. We

1 have followed these animals now for approximately three
2 years after they have been removed from the experimental
3 diets. They have shown a dramatic improvement in their
4 physical status. However, there are still abnormalities
5 that we are encountering after three years of the exposure
6 being discontinued.

7 DR. SCHEPERS: That would be the closest?

8 DR. ALLEN: That would be the closest that we
9 have in our laboratory.

10 MR. LEMEN: You indicated this morning, though,
11 that you did have tumors after two years on the ones that
12 were sacrificed.

13 DR. ALLEN: We are talking about rats versus
14 monkeys.

15 MR. LEMEN: Okay, but in the rat, you are talking
16 about in the rats you saw the tumors?

17 DR. ALLEN: In rats, in the rats we saw the tumors.
18 Monkeys are somewhat like the higher primates in that they
19 do not develop tumors rapidly, so it requires a long period.

20 MR. LEMEN: I understand that, but in talking
21 about the dose effect, if we are going to find anything,
22 carcinogenic effects in Vietnam veterans, it is not going
23 to occur for another 15, 20 years?

24 DR. ALLEN: That is more than likely correct,
25 unless we have promotion of existing tumors.

MR. LEMEN: Right.

DR. HABER: I wonder, Dr. Allen, I understand you
brought some slides with you. Would it be possible for us

1 to see those now?

2 DR. ALLEN: It's up to you.

3 DR. HABER: How long would that take?

4 DR. ALLEN: Five or ten minutes.

5 (A discussion was held off the record.)

6 DR. ALLEN: (Showing slides) We will go through
7 these rapidly. If we could focus that just a little bit,
8 this is just one of the non-human primates, the Rhesus
9 monkeys that we employed, and I want you to pay particular
10 attention to the hair coat.

11 If we could have the next slide--this is an animal
12 of six months of exposure, and you will note the near
13 complete loss of hair, particularly about the head, and
14 the abdomen, shoulders, and if you look closely, the animal
15 has practically no eyelashes, and the next slide will show
16 you really what the animal looks like.

17 Here is another animal at six months. You will
18 note the marked edema about the eyelids, the absence of
19 eyelashes. You can't see the dry, scaly skin, but you can
20 see the development probably on the side there, little
21 acneform lesions, and I think the particularly obvious
22 edema at the upper lips and generally all over the face.

23 This is just an example of some of the hematological
24 changes we saw. At the top, it gives you the normal values
25 of the monkeys and you will note in the white blood cell
count we had a very decided decrease from about 9,000 down
to in some of the animals about 2,000; of course, with the
platelets, average of 327,000 down to 234450. You will note

1 the very decided decrease in platelets, and this is why
2 we got what we feel is extensive hemorrhage.

3 The hemoglobin dropped from 13 down to 4, 6 and 8, as
4 you see here, and of course associated with this is a
5 decrease in hematocrits.

6 One of the more striking things that we saw was
7 a marked thickening and proliferation of the finger-
8 nails and toenails, and note the clubbing of the peripheral
9 digit there. This we feel could have been associated with
10 the very decided decrease in circulating red cells.

11 We also got dry gangrene. The peripheral digits
12 would very frequently sluff off, associated with the dioxin
13 intoxication.

14 Another thing we saw, rather striking, was the
15 decided increase in the size of the gall bladder, maybe
16 five or six times the average size, and here we have a
17 probe introduced through the ampulla into the common duct,
18 and you will note the tip of it, you can get an idea as to
19 the size of this gall bladder and the ducts.

20 When we examined these, there was a marked
21 thickening of the walls of the various ducts and the gall
22 bladder associated with hypertrophy and hyperplasia of the
23 epithelium.

24 This is just an example of the hemorrhage that we
25 saw in the lungs of these experimental animals, and a
rounding off of the heart, which was associated with the
very decided anemia that these animals were experiencing.

This is just hemorrhage in the uterus. That was

1 very common in the animals that died.

2 The bone marrow, of course, there is the near
3 complete absence of bone marrow, and the hemorrhage in the
4 marrow.

5 The next slide shows hematopoësis and a predominance
6 of lymphoid appearing cells. Both the myeloid and erythroid
7 elements were affected.

8 One of the more striking lesions was a marked
9 thickening of the gastric mucosa, and to a lesser extent,
10 the small intestine and large intestine. You note the
11 hemorrhage on the surface of the stomach.

12 The next slide will show us the reason for this
13 thickening. About three fourths of the way up is the muscularis
14 mucosa, and toward the top is the lumen of the stomach
15 and the increase in glandular elements in the submucosa.

16 Could we have the lights on, please, and the
17 slides off.

18 DR. HABER: Thank you very much, Dr. Allen. We
19 are enlightened by your presentation.

20 I would like to call attention to the fact that
21 Mr. Max Cleland, the Administrator of the Veterans Affairs,
22 has taken time from his very busy schedule, and has flown
23 in from Atlanta so that he could address this group.

24 ADMINISTRATOR CLELAND: I would like to thank
25 you all for helping us in the Veterans Administration make
some sense out of what has become possibly a very serious
public health problem to Vietnam Veterans, and myself
included.

1 I want you to know that I have a personal
2 interest in the resolution of the questions surrounding
3 Agent Orange. The Veterans Administration is quite
4 concerned about the aftermath of exposure to Agent Orange,
5 and we have picked you all to help us and lead us and guide
6 us in the resolution of the questions surrounding Agent
7 Orange.

8 One of the most difficult things I have had to do
9 in the last few months is to try and answer questions about
10 Agent Orange in a vacuum of ignorance, and in an area
11 where even the scientists who are most knowledgeable about
12 herbicides disagree.

13 That puts us in a very ambiguous and difficult
14 position. We hope that this Committee will move with the
15 greatest speed to resolution of these problems, which we
16 face daily.

17 There are many interested citizens in this country
18 who are concerned about the effects of herbicides on people
19 and we are especially interested in the effects of herbicides
20 on veterans, and whatever the data shows to be the case,
21 so you all have a great challenge because we are greatly
22 challenged as an agency that deals with veterans, and
23 purports to deal especially with the health problems arising
24 therefrom.

25 You are challenged to help us meet this quite
serious question of Agent Orange, so I just want you to know
that I am personally interested in your deliberations. I
look forward to reading the minutes that you all have

1 accumulated today. There are others who will follow every
2 word, and each point raised with much interest.

3 You have a great responsibility. I know you will
4 tackle your job very well.

5 I thank Paul Haber for leading this Committee
6 in its deliberations. I know that there will be a great
7 deal of give and take and a great flow of information, and
8 ideas and sharing of opinions and views.

9 I urge you to do that because we look upon you
10 as the mechanism by which we can air all the complaints
11 or ideas or fears, and especially the scientific data
12 surrounding the questions of Agent Orange and herbicides
13 used in Vietnam, so I just speak as the head of the
14 Veterans Administration, and also as a Vietnam veteran,
15 urging you to tackle your job seriously, and especially as
16 Administrator thanking you for your willingness to take
17 time from your busy schedules to help us with this most
18 serious question.

19 Paul, thank you very much for the opportunity to
20 visit. I know you have some other items on your agenda
21 and I won't interfere. I will now resume my duties, but I
22 did want to visit with you personally and tell you where I
23 was coming from and how much we needed you to guide us in
24 the future.

25 Thank you very much.

DR. HABER: Thank you, Mr. Administrator. I am
very encouraged by this morning's discussion. It looks
like we are beginning to make real progress.

1 ADMINISTRATOR CLELAND: Thank you very much.

2 DR. HABER: Thank you, sir. Dr. Allen, would
3 you care to resume your presentation?

4 DR. ALLEN: (Showing slides) This is just a
5 typical example of the marked thickening that occurs, and
6 the gastritis that develops in animals exposed to the
7 dioxins. Very frequently there are ulcerations that are
8 also associated with this hypoplastic gastritis, and in
9 my instances, we feel that these severe changes in the gastro-
10 intestinal tract are associated with the demise of the
11 experimental animals.

12 Dr. Moore and his associates have done a
13 considerable amount of work with the effects of the dioxins
14 on the immune capabilities of the animals, and certainly
15 in our experimental animals we got a marked decrease in the
16 lymph nodes throughout the body. This is just a typical
17 example of hypocellularity that occurred in the lymph node,
18 and with the decrease in cellular population, of course,
19 there was necessarily a decrease in the immunologic response
20 of the experimental animals.

21 This is hair follicles. You note the swelling
22 of the eyes that occurred in the experimental animals. This
23 is what they looked like microscopically, and the hair
24 shafts are filled with keratinized material.

25 This also occurs to a lesser extent in hair
26 follicles over the surface of the body.
27 One of the more striking things that we saw was the marked
28 changes that occurred in the epithelium throughout the body;

1 changes in cell types suggestive of, quote, possibly
2 transformation of one cell type to another.

3 This happens to be pancreas, and generally
4 speaking, there are very few, if any, mucous secreting
5 cells in the epithelium.

6 Here we have a marked increase in the cells.
7 They would normally be in the epithelium. They would be
8 stratified in the epithelium.

9 Here we have a change in cell type. The same
10 thing occurred in the salivary glands, and also in the bile
11 ducts, indicating a change from one cell type to another
12 as a result of exposure more than likely to the dioxins in
13 one way or another.

14 We also saw marked changes in the transitional
15 epithelium of the urinary bladder, not only changes in cell
16 types, but also a piling up of the epithelium.

17 I just wanted to show you the reproductive
18 abnormalities that occurred. It would appear that this
19 is one of the more extensive. If you look only on the left
20 side here, there is the 50 parts per trillion study animals,
21 you then note the 500 ppt; compare the two. Total impregnated,
22 3 of 8 on 500 ppt. and we got 100 percent in our control
23 animals on both experiments.

24 Total impregnated with 50 ppt, six of eight
25 abortions, with four of eight in the 50 ppt and two of
26 eight were normal births on
27 50 parts per trillion, two of eight, and one of eight on 500 ppt.

Also one of the more critical things that we are

1 concerned about in our study is the effect upon fetal
2 development, and as quickly as we are able to have sufficient
3 numbers of infants survive, we will also be doing learning and
4 behavioral studies in an attempt to see if there are any
5 deficiencies.

6 We have found with other halogenated hydrocarbons
7 alterations in the learning capability, and the animals
8 show behavioral deficits, so we will be pursuing these
9 particular questions.

10 That's it.

11 DR. HABER: Thank you very much, Dr. Allen.
12 Those slides speak eloquently of your work. We are
13 indebted to you.

14 DR. MOORE: Dr. Haber, could I just make a
15 comment about dose which is where we were going earlier?

16 I think one of the things that I feel very strongly
17 about is that despite all of the work that is available
18 experimentally or anything else with respect to the
19 benzodioxins, we do have some understanding as to the
20 kinetics of TCDD in the rat. We have a bit of data of TCDD
21 in the primates, but we don't have good comparative
22 pharmacology, and until we get that type of data, we are
23 going to be hard pressed or whistling in the wind in trying
24 to extrapolate from primate or rat or guinea pig into dose
25 the same as man because we don't have good dose response
26 ratios.

27 DR. KEARNEY: That brings up another point. I
28 notice in our schedule that the last five minutes will be

1 devoted to future meetings. I am wondering if it is in
2 order in light of the fact that you have represented
3 on this panel various sources of expertise and what
4 they can get from their agencies. However, due to a number
5 of things which are evolving, there are people who now
6 have summary information on such things as human exposure,
and I don't think the group is aware of it.

7 I only became recently aware of this myself. I
8 am wondering if at some time we could spend more than five
9 minutes talking about the future meetings, as to what sort
10 of things we need to hear, for us to make some sort of an
11 intelligent decision?

12 In other words, I think this thing of human
13 exposure is very important. I think the Environmental
14 Protection Agency has taken the point of view that if the
15 risk is high, that is suspect as a carcinogen, and if the
16 exposure is low, then the hazard is low. If the exposure
17 is high and the risk is high, then the hazard is very high,
18 and these kinds of deliberations go into making some sort
of an option on the pesticide.

19 We may have to take that same thinking process
20 to deal with this situation. What I suppose worries me
21 a little bit I guess I don't understand what the levels
22 of exposure in Vietnam were, and maybe we won't get to that,
23 but I would like maybe the Air Force to give us their
thoughts on this, if someone can do this.

24 I am aware of some exposure research underway
25 right now on 2, 4, 5-T, which I think might be usable to us.

1 I am aware of someone who is beginning to summarize the
2 teratology data. I think it might be helpful if we could
3 bring these people before the group and gain what we can
4 from them. I think this is rather important as to where
5 we go from here.

6 DR. HABER: Let me explain the item that is
7 labeled 3:25-3:30, future meetings. That was to decide
8 only the date of the next meeting. It was not to attempt
9 to address any substantive issues, but only to take five
10 minutes to agree upon a date, but I think that the composition
11 of the Committee is mandated by the charge we have in "The
12 Federal Register."

13 That does not, however, prevent, and I would
14 certainly suggest that we should bring before the Committee
15 experts of whatever stripe or disciplinary background or
16 persuasion that we can get in order to enlighten us.

17 In other words, this group is not yet complete.
18 We have had a recent resignation for reasons that I won't
19 go into here, and a replacement will be sought for that
20 individual, but except for that, I think the group is pretty
21 well set. It was chosen very carefully, and I think that
22 I would only echo Mr. Cleland's confidence in the group.

23 Again, if we need outside expertise, that is not
24 of the group, from whatever source, we can obtain it and
25 should, and I would say that people who can provide us with
it ought to be available.

I think this Committee will continue to meet
periodically as we see fit, but again, we should be able to

1 make available to us all kinds of expertise, and I would
2 be completely subject to the wishes of the Committee. I
3 think that if any of you wishes to suggest a presentation
4 by somebody, we can certainly arrange for that as soon as
5 appropriate.

6 I would like at this point to distribute--there
7 are a number of copies for the group here, and there may
8 be enough for members of the audience as well--and these
9 are some questions which we will refer to the Committee to
10 be answered.

11 We will prepare position papers on all of these
12 questions unless we feel a question is encompassed in another,
13 along with questions from the audience.

14 If any of you have any written questions, would
15 you please submit them to Mrs. Myer so that we can--because
16 what I would like to be able to do is to address--let me
17 go over this list of questions briefly, and I will endeavor
18 to secure answers to these in the form of position papers.
19 I will quickly read these questions, and if anybody has
20 any comment or further question, please feel free to mention
21 them.

22 These are questions framed by our Steering Committee
23 through the Advisory Committee. Remember the Steering
24 Committee, with Dr. Levinson as the chairman, are the action
25 group, and we are the advisory group here. If they need
information or advice about particular aspects of the Agent
Orange problem, each work group is
to find the answers itself or to get the answers from others.

1 I will quickly read these. One, do the available
2 data on exposure of Vietnam veterans to herbicides permit
3 the performance of scientifically valid epidemiological
4 studies on the long-term health effects of herbicides
5 in this group?

6 I think that clearly is a substantive question
7 for which we will endeavor to get an answer. As I say,
8 we will have position papers in answer to each of these
9 questions which would be made available to the public and
10 will form part of the record.

11 Two, what are the best human population groups in
12 which to study the long-term effects of herbicides on health,
13 and how may these studies best be conducted?

14 That relates to the question you just mentioned.

15 Three, of what diagnostic value are the following
16 procedures in assessing possible herbicide toxicity: levels
17 of dioxin in fat pad biopsies; study of immune factors;
18 study of chromosomal patterns; and study of liver microsomal
19 enzymes?

20 What additional diagnostic procedures should be
21 considered?

22 The first of those will be answered by Dr. Lee's
23 study, and he will be communicating that to us as soon as
24 those studies are completed, and it may be that Dr. Lee
25 and Dr. Hobson will have to advise us where
26 those studies will lead and whether indeed they would
27 generate other studies of a similar nature.

28 We have, as I have indicated, a number of suggested

1 items for research that Dr. Hobson and we will be
2 responding to presently.

3 Question 4, is it possible for herbicides to have
4 long-term adverse effects on the male reproductive system?

5 That question certainly surfaced. We recognize
6 it, and we will continue to pursue that.

7 Five, what topics should be included in the educational
8 curricula being developed to upgrade knowledge of potential
9 herbicide toxicity among VA staff members?

10 One of the things we have tried to do before is
11 to make the staff of our field hospitals responsive to the needs
12 of veterans who come in complaining of dioxin poisoning
13 or toxic effects of dioxin.

14 This is a continuing process. We get out
15 information to our field as quickly as possible. Dr. Lee's
16 study will have some effect on this. Physicians had
17 to be brought on board with respect to the possible toxic
18 effects, and he has gotten cooperation from a number of
19 hospitals in doing these biopsies, so this itself contributes
20 to the general knowledge on the part of our professionals
21 throughout the hospitals.

22 Six, what sorts of animal studies would make the
23 most important contributions to understanding the
24 potentially toxic effects of herbicides in humans?

25 Clearly it is an important question.

Seven, what additional data should be included
in the VA's herbicide registry over that being currently
produced?

1 Dr. Castellot, can you tell us about the herbicide
2 registry and where it is now? Is that a fair question?

3 DR. CASTELLOT: I can't give you any specific
4 data in terms of how many names have been entered into the
5 registry, but at the present time, on a quarterly basis,
6 each of the field facilities, and there are 172, are required
7 to submit data on the individuals who have presented
8 themselves or were sought out in their particular geographic
9 area with regard to herbicide exposure, and as you heard
10 this morning, the history and physicals and other laboratory
11 data which are accumulated at that time are submitted to
12 the Central Office for review. That review is an ongoing
13 process.

14 Dr. Levinson has the specifics in terms of the
15 numbers involved, but it is an ongoing process and will
16 be accumulated and will eventually I'm sure be subject to
17 rather specific analysis in terms of determining any trends
18 that may be developed, but that is an ongoing process
19 here in the Central Office and the multi-disciplinary
20 board which is reviewing all of these, so it is not done
21 by any single individual.

22 Many of the people on the Steering Committee
23 are involved with that as well.

24 DR. HABER: Eight. What are the known facts on
25 the persistence of dioxin and the herbicides used during
the Vietnam War in water, soil and the atmosphere?

Can these media serve as a source of human
exposure to dioxin and herbicides?

1 We have touched on that, and clearly we need more
2 data on the chemical formulations and how they persist.

3 Nine, what medical tests should be utilized
4 to help establish a diagnosis of chronic herbicide-induced
5 toxicity among Vietnam veterans?

6 One of the most vexing problems we have when
7 veterans come to us is when a veteran says I don't know.
8 I think I have been exposed, and I don't know whether I am
9 sick or not. Can you please study me and tell me whether
10 indeed I am harboring long-term ill effects of dioxins
11 unbeknownst to myself, and what test would one do?

12 Well, faced with a situation like that, all we
13 can do is the general physical, complete blood count,
14 X-rays, general EKG, electroencephalogram, and so on.

15 There is no laboratory test at this point which
16 would say yes, you have been exposed or no, you haven't.
17 Liver profile, sperm count, all of those things are
18 done when people come in with symptoms referable to that
19 particular organ system, but unless the biopsy or the fact
20 proves out, and if it does, we may have albeit a difficult
21 and not trivial biopsy procedure that will be of help, if
22 our current pilot studies prove out.

23 Ten, can criteria be established for determining
24 the level of exposure of military personnel to dioxin during
25 the Vietnam War based on spraying tapes and unit histories?

 We will undertake to try to answer that.

 Finally, will it be possible to develop standards
and criteria which define the precise relationship between

1 herbicides and dioxin with chronic adverse effects in
2 humans?

3 Can these criteria also specify the reasonable
4 limits between the time of exposure to herbicides and the
5 development of disease?

6 These questions have been submitted by our
7 Steering Committee, and as I indicated to you, we will get
8 answers for them and position papers on each of them.

9 I have here several questions submitted by the
10 floor, and I will undertake to read these. If the answer
11 is quickly forthcoming, we will attempt to give it to you.
12 If not, we will treat these questions in the same way
13 that we would those submitted from our Steering Committee
14 and provide position papers in answer to them.

15 One, what is the U. N. doing concerning Agent
16 Orange which may have an effect on U. N. troops that served
17 with us in Vietnam?

18 Does anybody around the table have any answer
19 to that?

20 Okay. We will undertake to get an answer and
21 give it to you. Who submitted this? Does anybody want
22 to be identified with that? Do you have any further
23 amplification?

24 MR. GERKEY: No.

25 DR. HABER: We will try to get an answer.

MR. DE YOUNG: There has been some rumors around
that we have heard that Australia and the Republic of Korea
have taken a claim to World Court; something having to do

1 with troops being poisoned. It is total rumor, to my
2 knowledge. I think it is totally false.

3 DR. HABER: We will undertake to find out that
4 at the same time.

5 Next question, when is it likely that significant
6 results from the Ranch Hand study will begin to become
7 available?

8 Colonel Thiessen, can you give us any answers
9 on that?

10 COL. THIESSEN: The results of the retrospective
11 study, which is basically the questionnaire type study of
12 all 1200 people, should be available by the end of 1980.

13 The cross-sectional study is the physical study
14 on selected individuals and should go on at more or less
15 the same time. It should also result in data at the end
16 of 1980.

17 Of course, the prospective study will take years,
18 but there will be interim results at the end of '80, '81
19 and so on and so forth, until 1985 when the study is con-
20 sidered to be finished.

21 DR. HABER: That is something I would like very
22 much for our Committee to be able to do. As I indicated
23 to you, I have done that, so we would like to try to get
24 some answers as to when the definitive study will be
25 completed.

Obviously everybody needs to know that from a
policy standpoint. It is extremely important.

DR. ALLEN: You are going to get us the

1 experimental protocol on this?

2 DR. HABER: Yes, sir. I have made that agreement
3 with them, and General Dettinger was very forthcoming and
4 said he would.

5 MR. LEMEN: I have one question. You said that
6 the prospective study was going to be cut off in 1985?

7 COL. THIESSEN: That is as the plans are now.
8 Our protocol will be before the Committee for approval.

9 MR. LEMEN: My comment is that if you
10 are looking for carcinogenic effects, you probably
11 would miss them if you cut them off the study in 1985.

12 DR. HABER: We are very mindful of that in the
13 VA, and we intend to follow identified people.

14 MR. LEMEN: Have you got a group already
15 identified.

16 DR. HABER: I think that when we get the protocol
17 we can make that comment. I am sure they will have to
18 match men with capability and money and so on, but on
19 the other hand, I think that while we want quick answers,
20 I think it is incumbent upon those of us who are following
21 these people to be prepared to follow them for a long
22 period of time.

23 Dr. Hobson has talked to me about that several
24 times, so we are well aware of that: 4.2 million veterans
25 reportedly may have been exposed to Agent Orange. I
26 think that is probably not true.

27 I don't think 2.4 million people
28 were in Vietnam. However, the question is, is gross

1 information on subsequent health of many of these
2 individuals available, and might it be useful?

3 There is no question that it would be useful. I
4 would say the information--who asked that question?

5 MR. STONE: I was just wondering with the protocol
6 that has been made, of perhaps trying to contact very large
7 numbers of the individuals who may have been exposed.

8 The 4.2 million figure I believe comes from VA
9 testimony last October.

10 DR. HABER: I hope not.

11 MR. STONE: Before the Subcommittee on Health.

12 DR. HABER: I gave that testimony, and if it is
13 in there, it is a misprint.

14 MR. STONE: Perhaps they had the figures reversed.

15 DR. HABER: I think so.

16 MR. STONE: The proposal has been made that
17 perhaps a general notification process of veterans who may
18 have been exposed would be justified, and that useful
19 information might be forthcoming.

20 DR. HABER: That is certainly something that is
21 very much in our minds. That would be an extremely tedious
22 expensive and difficult action to take, but on the other
23 hand, if the facts warrant that, and if that is the advice
24 of our Advisory Committee, if that is what they think,
25 then we would undertake to do that.

I think that is something that is very good.
Dr. Schepers gave me a note.

DR. SCHEPERS: The question is whether we have
health records on Vietnam War veterans. They are mostly

1 young people, and they are still employed mostly, and
2 so they don't come to the veterans hospitals, but we are
3 already currently seeing about 150,000 of these Vietnam
4 War veterans in our hospitals annually, so we are developing
5 an enormous amount of medical information of a general
6 kind about them, and this information is available to
7 the Committee through Ms. Kilduff.

8 DR. HABER: The VA expressed extreme scepticism
9 about the possibility that dioxin would be traceable in human
10 tissue of even heavily exposed veterans. What will be
11 the significance of a finding from the present tests of no
12 detectable dioxin cases?

13 Well, it is difficult for me to anticipate
14 the answer, but I think, and I
15 will ask Dr. Hobson to comment on this, what our present
16 study is designed to do is to tell us whether or not a fat
17 biopsy would be useful in distinguishing between people
18 who have been exposed to dioxin in Vietnam, and controlled
19 subjects.

20 If that turns out to be the case, then we have
21 a potentially, maybe not definitive, but useful
22 way of determining whether others who claim they were
23 similarly exposed do indeed store
24 dioxin in their fat tissues.

25 It does not specifically say no, you could not
26 have been exposed, and we don't pretend it is. Larry,
27 do you have anything you want to say?

28 DR. HOBSON: No, except that we would not, under

1 any circumstances be going beyond the data if with the
2 detection methods we had available to us, we could not
3 find any in the fat. If it is there, we would give the
4 amount that we were able to detect,

5 DR. LEE: Quite evidently if you find dioxin
6 in the fat, it means there has been exposure, but it does
7 not say when or where. Neither does it say that there
8 will be disease as a result of it, either currently or
9 in the future.

10 If you do not find dioxin it does not say you
11 were not exposed, and it does not say that you won't have
12 future difficulty from the exposure if dioxin was there.

13 As Dr. Haber pointed out, the only thing this
14 will do, if there is dioxin present in those exposed and
15 not in controls, is to tell you that these are individuals
16 who can and should be followed, and that they do have known
17 exposure proven, simply by the fact that the dioxin is in
18 their tissue.

19 I might also say that those people who are exposed
20 agriculturally or in the manufacture, probably have the
21 same problem. It may be that we should put in a third
22 group that would be a control group from neither industry
23 nor from the agricultural people to see if they have the
24 same sort of thing.

25 At the moment, all we know is that we have 16
people who had had a biopsy, and if there is dioxin in any
of them, we will find out if it is in the controls or the
others, and it does not indicate that they are or will be

1 sick, or that they won't be.

2 DR. HABER: Thank you. We have here a number
3 of questions addressed to specific members of the panel.

4 Incidentally, the gentleman who said the 4.2
5 million quotes correctly. That is what the testimony said.
6 That was an error, and I want to retract that. It was 2.4
7 million. It was a typographical error.

8 MR. DE YOUNG: There is good reason from where
9 we sit in Chicago to say that 4.2 million is probably an
10 accurate figure, the reason being that many stateside bases
11 under the Freedom of Information Act have admitted to using
12 2, 4, 5-T during that same period of time, and so it
13 is very reasonable to assume that anyone who was in uniform
14 at that time came into contact with it, possibly in lower
15 dosage at stateside, but into contact with it.

16 DR. HABER: That opens up a whole new range of
17 possibilities.

18 MR. DE YOUNG: We have reports from men in Panama
19 who said the jungle was defoliated. In Louisiana, it was
20 made to resemble Vietnam by defoliation and so forth.

21 DR. HABER: That is a very interesting piece of
22 information that we will have to deal with, so we will
23 take that under consideration, too.

24 A number of questions have been addressed to
25 various members of the panel. To Dr. Erickson--what is
the usual percentage of wasted pregnancies in the population?

DR. ERICKSON: It depends how hard you look.
The best studies that I know of come from the Hawaiian Island

1 of Kauai where something on the order of between 25 and
2 30 percent of pregnancies were wasted. A typical figure I
3 think is something on the order of about 15 percent. It
4 depends how early into pregnancy one is able to ascertain
5 the fact of pregnancy.

6 MR. LARSON: Please define wasted.

7 DR. ERICKSON: I presume that meant lost at
8 term, live birth.

9 MR. DE YOUNG: I can define it. The toxicologist
10 in Chicago used the term to mean any pregnancy that was
11 not delivered of a healthy child, a pregnancy that was in
12 some way abnormal, possibly a still birth, possibly
13 spontaneous abortion, or a birth gross deformity.

14 The figure he gave was 10 to 15 percent, and I
15 wanted to see what CDC's figures were on that, if you
16 had any.

17 DR. ERICKSON: CDC doesn't have any figures of
18 their own, but this Hawaiian study was of a population on
19 a small Hawaiian Island where all the women of reproductive
20 age were registered and followed on a monthly basis so
21 that very early pregnancy losses could be determined and
22 studies where you will find the figure of 10 to 15 percent,
23 usually the ascertainment of pregnancy is later into
24 pregnancy, and there is a quick falloff from a fairly high
25 in early pregnancy to a lower level later in pregnancy.

MR. DE YOUNG: Thank you.

DR. HABER: The next question is addressed to
Dr. Kearney, and it is, what are the other ways, quote, unquote,

1 of production of 2, 3, 7, 8, TCDD, other than TCP?

2 DR. KEARNEY: What are the other sources of the
3 2, 3, 7, 8 other than in the production of the 2, 4, 5?

4 DR. HABER: Right.

5 DR. KEARNEY: Well, there appeared, and I don't
6 have the dates on this exactly, in '75, '76, reports from
7 Europe that industrial incineration was giving rise to
8 dioxin materials, and these are reports from Rappe, and
9 Dr. Otto Hussinger from Amsterdam, and Dr. Boozer at
10 Boshart in Switzerland.

11 It appeared that any situation where you had
12 chlorine and industrial wastes that were incinerated at
13 high temperatures, could be a
14 source of dioxins.

15 The Dow study went further than this. They
16 repeated the European studies. They looked at mufflers.
17 They looked at wood burning fires. They looked at
18 industrial incinerators, and they looked at municipal
19 incinerators, and there were dioxins associated with each
20 of these, so this raises the question -- are there other
21 sources of dioxins other than the production of trichlorophenol
22 and it raises a question as to the biopsy study--do you
23 have proper controls so that you would see Vietnamese veterans
24 not in Vietnam who were not exposed, although this
25 question of the Vietnam veterans not in Vietnam being
26 exposed raises another complication.

27 DR. MURPHY: Dr. Kearney covered it, but the
28 question asks 2, 4, 5-T at least as you traced it, and I

1 think he pointed out trichlorophenol, which I think is
2 important to recognize, 2, 4, 5-T is not the only product
3 through which trichlorophenol, in the production of
4 trichlorophenol that you get the TCDD, and wherever you are
5 producing that--many processes.

6 DR. HABER: My understanding was that it was
7 a degradation product as well as a deformation product.
8 Is that true?

9 DR. KEARNEY: Now you raise a very interesting
10 question. For example, I understood the question to say
11 phenol, but maybe it said 2, 4, 5-T.

12 For example, in Italy what was being produced
13 there was trichlorophenol for the production of
14 hexachlorophine and most of the explosions in Westphalia
15 were trichlorophenol-producing plants rather than 2, 4, 5-T
16 producing operations, so that is a question.

17 You can get pyrolysis of certain phenols and
18 2, 4, 5-T, and you can produce TCDD. It is also possible
19 that is a source, so that there appear to be a number of
20 sources, and this does further confound the issue.

21 That's all I am prepared to say.

22 DR. HABER: Thank you. Dr. Lingeman, you have
23 been asked to answer two questions. You asked about other
24 herbicides used in Vietnam, and if the Committee was to
25 address the story with Agent Orange; do you have any
information on their health effects which leads you to ask,
and are you recommending this study?

DR. LINGEMAN: Other herbicides are known to

1 be carcinogenic, including several
2 arsenal compounds; some of the inorganic compounds are known
3 and accepted as human carcinogens.

4 One of the others in Vietnam was picloram. It
5 has been tested by the National Cancer Institute and there
6 was a possible increase in hepatic nodules which are
7 considered by some to be pre-cancerous conditions in rats,
8 so yes, the answer to the question is other herbicides are
9 known to be carcinogenic, and possibly toxic in various
ways.

10 DR. HABER: I think the question would be are
11 you recommending such a study?

12 DR. LINGEMAN: If other herbicides were used
13 concomitantly with Agent Orange, I believe that they
definitely would be relevant.

14 DR. HABER: Our information is the amount they
15 used was almost trivial. Is that not true?

16 MR. LEMEN: Just to add on to what you have said
17 one of the things that concerns me is the massive use of
18 the related compounds, particularly the pesticides used in
19 Vietnam that have thus far not been addressed.

20 I would like to agree with you to
21 say that I think the pesticide issue is one that may well be
22 just as big as the herbicide issue, and we should certainly
look into it at the same time.

23 DR. HABER: I think that is important, and
24 we should obviously address the official charter of this
25 Committee, the VA Advisory Committee on Health-Related

1 Effects of Herbicides, but I am sure that narrow
2 construction was because of our main concern about Agent
3 Orange, but it would not stand in the way of our getting
4 other information made available.

5 One final question from the group. This one was
6 signed by Mr. Donald A. Larson. To what extent is information
7 potentially available on the effects of Agent Orange on the
8 indigenous Vietnam population?

9 I would like to answer that and that is to say
10 that there is information available in the original National
11 Academy of Sciences report, and then we have the report of
12 Dr. Tung, and other people, which we have to look at
13 more carefully and continue to see whether or not we can
14 get updated information.

15 I think Dr. Tung is anxious to cooperate with us.
16 Wasn't that your impression, John? You may have been here
17 when he briefed us and expressed the desire that he could
18 continue to work with us, and I think we will certainly
19 try to make available from him any information which is
20 of value.

21 I think Dr. Allen has already characterized it
22 as lacking the quantitative sophistication that we are
23 accustomed to, at least in this country, and one has to
24 understand he was in a war-time condition and maybe some
25 of the niceties couldn't be observed.

MR. LARSON: I meant general. That was an isolated
instance. I meant general.

DR. HABER: As I said, we will endeavor to review

1 the minutes. If we feel the questions have been
2 definitively answered, we won't deal with it any further.

3 If it was a more substantive question which could
4 not have been answered precisely and must therefore only
5 represent a tentative view, we will develop a position
6 paper on this.

7 There are two people who I would like to specifically
8 call on if they are present. Mr. Frank McCarthy, is he
9 present, or is Mr. Michael Gerkey present?

10 MR. GERKEY: Did you have a question you wanted
11 to ask me?

12 DR. HABER: I was informed by the Administrator
13 that you might wish to make a statement, and if you do,
14 this is the time and the place.

15 MR. GERKEY: Okay. Then I guess I will have to
16 do it.

17 What I am basically concerned about is the effect
18 of Agent Orange on the world, as there were people from
19 different parts of the world who served with us in Vietnam
20 who most likely, if we were affected, would have been affected.

21 They were part of the United Nations. I feel
22 that if any research is to be done to help us, there should
23 be research done to help them also, and they should be made
24 aware of the effects of Agent Orange on the populations in
25 their countries. There should be some sort of a world
organization set up to work with scientists and work
with people in the Veterans Administration and work with
people at the local level, at the state level, at the

1 government level, along with the military level, and
2 I believe one should look into this matter and pursue it.

3 DR. HABER: That's good. We are indebted to you.
4 I think that is an excellent suggestion. There have been
5 a couple of indications around the floor that the people
6 in the U. N. may have been involved. I think it is only
7 fair that we make some representation through the
8 Administrator's office to the World Health Organization, or
9 some other international body, and offer to share with them
10 the possibility of our getting data on that, so we will
11 do that.

12 In the future, we will have opportunities for
13 those of you in the general public who wish to make prepared
14 statements to the group, and we will, in our "Federal
15 Register" notification, indicate that if anybody does wish
16 to make such a prepared statement, if he submits it to us
17 before, he would then be asked to read it before the
18 general group, and we will make provision for that.

19 This being our first meeting, that has not been
20 deemed possible, but I would suggest that if others
21 in the audience wish to make brief statements not
22 exceeding five minutes in length, we would be anxious to
23 accommodate you, so if anyone wishes to make such a
24 statement, will you please come to the microphone and
25 identify yourself and please confine yourself to no
more than five minutes.

MR. DE YOUNG: Frank McCarthy is not here today.
I saw Frank in Kansas City last week and Frank said

1 essentially that he didn't feel it was worthwhile coming
2 because he thought the purpose of this Committee was to
3 whitewash the subject.

4 I no longer think that. I no longer think that.
5 I came here specifically to watchdog this Committee from
6 my point of view.

7 Let me get into my prepared statement, and maybe
8 it will make some sense.

9 I am the Veterans Services Coordinator at Columbia
10 College in Chicago. It is under the VISA program funded
11 by HEW.

12 Eighteen months ago, an extremely agitated woman
13 appeared in my office in Columbia College in Chicago. Her
14 name was Maude DeVictor, and she was at that time a VA
15 Benefits Counselor at the Chicago Regional Office.

16 She told me of 27 cases of cancer among Vietnam
17 veterans she had seen there in the Chicago Region. They
18 all had one thing in common besides cancer. All served
19 in areas of Vietnam defoliated by the now almost mythical
20 Agent Orange.

21 She went on to show me the research she had compiled
22 articles from scientific journals showing evidence of
23 the herbicide 2, 4, 5-T's ability to cause skin problems,
24 cancer, miscarriages, mutations, and birth defects; letters
25 and notes of phone conversations with scientists and researchers
who provided further statements documenting the contamination
of herbicide with dioxin, that most toxic of all man-made
chemicals,

1 She further told me that she had written the VA
2 Central Office repeatedly about this and received no response.
3 The claims for service connection for these men had not
4 been granted.

5 We decided that the veterans of the Vietnam
6 War had the right to know if Agent Orange had caused
7 these problems 5, 10 and 15 years after their exposure, so
8 we asked Mr. Bill Kurtis with WBBM-TV, CBS in Chicago to
9 have his investigative team research Agent Orange and its
10 dioxin contaminant.

11 For six weeks they traveled the country pulling
12 in all the loose ends, and trying to weave together the
13 pattern of dioxin poisoning that had emerged in so very many
14 widely scattered episodes--dead horses in Missouri, and the
15 sick owners who had sprayed dioxin-contaminated oil on
16 their horse barn; dead Rhesus monkeys in an experiment done
17 by Dr. Allen in Wisconsin; deformed goats and ducks and
18 sick people in Globe, Arizona; sick residents of the national
19 forests where Agent Orange like herbicides were still in
20 use; and of course, veterans of Vietnam from Chicago.

21 In all those episodes, some common symptoms
22 emerged--skin problems, hair loss, joint problems, headaches,
23 nausea, fatigue, psychological changes, blood disorders,
24 cancer, and birth defects.

25 The documentary that grew out of this, called
"Agent Orange: Vietnam's Deadly Fog," was aired on March 23,
1978 in Chicago. WBBM referred calls to my office, and the
ensuing weeks found me with an epidemic of calls from

1 Vietnam vets saying they, too, showed these problems--
2 hundreds of phone calls from all over the midwest from
3 vets talking about skin rashes persistent since Vietnam;
4 severe headaches; joint pains and swelling, often mistakenly
5 diagnosed as arthritis, and resistant to treatment;
6 nausea and continued fevers, some for seven years; extreme
7 debilitating fatigue; an endless progression of sick days,
8 days they had not been able to work; and an unending series
9 of colds, flu and other common ailments; mysterious stomach
10 disorders, intestinal disorders, urinary disorders, kidney
11 disorders, liver disorders, auto-immune responses; allergies
12 and blood disorders; and nervous system problems, typically,
13 numbness of the hands, arms, feet and legs; a collection
14 of psychological changes--tempers, violent behavior,
15 depression, anxiety, brooding, memory loss, confusion, an
16 inability to cope with the pressures of life, a loss of
17 resiliency, and cancers and tumors in men 25 to 35 years old.

18 Some doctors have described those as almost
19 unheard of in men that age.

20 They also reported difficulty in conceiving children
21 after their return from Vietnam. Many of them reported a
22 loss of interest in sex or physical impotence as well.

23 Some reported multiple miscarriages by their
24 wives, often followed by the birth of a child with severe
25 physical deformities, typically of the fingers and feet,
heart murmurs, and cleft palate, as well as hyperactivity
and learning disabilities of various sorts.

What was the VA response? "No firm evidence

1 exists to incriminate these herbicides." Men who were
2 legitimately worried about their health and their
3 children's health were brutally turned away with the statement
4 that their problems couldn't be from Agent Orange, that it
5 was all in their heads, and were sent to the shrink.

6 The news media in various cities picked up that
7 story. The Chicago pattern was repeated first in St. Louis,
8 then New York, Los Angeles, San Francisco, Denver and
9 Detroit. Each time the media carried the reported symptoms,
10 calls from Vietnam vets poured in.

11 Hundreds of claims were filed and denied. "No
12 firm evidence exists." Months later, a tissue biopsy was
13 instituted by the VA as a first step in determining whether
14 these vets had been poisoned by dioxin. In Chicago, the
15 tests were so badly handled that three vets in Chicago are
16 suing the VA for malpractice.

17 The first VA advisory committee on toxic herbicides
18 was established by the VA Central Office last year. It
19 was so flagrantly in violation of the Federal Advisory
20 Committee Act that it was abolished and this Committee
21 formed, an action that took a year, and which we applaud.

22 VA Central Office promised to issue instructions
23 to all medical facilities on how to test Agent Orange
24 victims. As late as three weeks ago, VA doctors were still
25 asking vets what is Agent Orange.

A document came to us which authorized the
destruction of certain tumor and cancer registry records, and

1 at the same time spokesmen from the Central Office were
2 assuring me that all medical records would be preserved and
3 sent to the National Cancer Institute.

4 Mr. Cleland denied any knowledge of the destruction
5 of those records. Veterans all over the country have
6 called in to tell us of the run-around, ignorance, the futility,
7 the red tape, the insolence, and the outright malpractice
8 of the VA health care system. The VA seems to have lost
9 all credibility with this country's Vietnam veterans. It
10 has broken faith with us by not telling us the whole truth
11 at first. We got PR statements carefully worded to avoid
any conclusions or responsibility.

12 Is it any wonder vets have not been beating down
13 the VA's doors in haste to get medical care? Until the
14 VA gives vets their legally mandated benefit of reasonable
15 doubt and aggressively researches the Agent Orange, vets
16 will stay away. Until the VA gives vets their rightful
17 first-class medical care, courteously, sympathetically, and
18 with dignity befitting their status as the warriors of our
society, vets will stay away.

19 The VA must take the lead in Agent Orange research.
20 In the past, VA doctors have won international awards for
21 contributions to medicine. I hope that is not over. The
22 VA must act immediately not in its own interest or in the
government's interest, but in the interest of the vet.

23 Information must be gathered, and the start has
24 been made, not only from the manufacturers of the
25 chemicals, but from scientists and doctors and researchers

1 without the vested interest of the petrochemical industry.
2 The fox cannot watch the chickens.

3 Information must be sought from vets themselves,
4 from service and fraternal veterans organizations, from
5 environmental groups and individual citizens. The word
6 must be put out to all Vietnam veterans--you may have
7 been poisoned. Come in and get checked, but before we do
8 that, we must have programs in place to do the testing,
9 extremely subtle testing, checking more than just blood,
10 chest and urine, and then we must provide treatment, and none
11 of us knows where to begin on that.

12 Then there are children. Current claims by
13 veterans that Agent Orange has deformed their children get
14 administratively disallowed in that cold exactness of
15 language so favored here in Washington.

16 These men want to know if their own government
17 has crippled their children, and if they can safely have
18 more children, and they need answers soon.

19 Because vets need these answers now, and because
20 the VA has lost credibility, many of us of whom the
21 Agent Orange questions were first asked a year and a half
22 ago, veterans groups and citizens groups from all over
23 the country have joined together to look for these answers,
24 answers that can be believed.

25 We have organized an Agent Orange Task Force to
26 seek out those answers and help those vets. This group is
27 composed of representatives from ten veterans organizations
28 nationwide, including the National Association of Concerned

1 Veterans, the Vietnam Veterans of America, the Vietnam
2 Veterans for Self-Reliance, Vetline/Hotline, Agent Orange
3 Victims International, Concerned American Veterans Against
4 Toxins, and others.

5 We extend an invitation to other veterans groups
6 to join us in this effort. We are gathering information
7 on Agent Orange from veterans and researchers all over
8 the country, and respond with the best answers we can as
9 we go. These answers will not protect the chemical industry.
10 They won't protect the government or protect the military
11 or the VA. They will protect the vet.

12 Secretary Califano of the Department of Health,
13 Education and Welfare has assigned the Assistant Surgeon
14 General, Dr. James Dickson, to analyze our caseload data,
15 looking for the patterns of illness emerging. Dr. Dickson
16 will also listen to scientists, researchers, and doctors
17 who have information on dioxin poisoning.

18 Secretary Califano has played his department's
19 aggressive action to find answers to the questions of Agent
20 Orange. We take him at his word, and hope this second
21 herbicide committee will be as aggressive in the interests
22 of Vietnam veterans.

23 The eyes of the nation are on this Committee.
24 Twice as much of these herbicides were sprayed here in the
25 U. S. as was sprayed on Vietnam. Whether they know it or
not, the outcome of this Committee is important to every
citizen of this country.

On top of the spectre of Three Mile Island, we

1 now have the spectre of Agent Orange, and I may add of
2 Agent White and Purple and Blue and Green and Pink.

3 I am here today with John First of Southern
4 Illinois University. I mentioned in my prepared statement
5 that St. Louis was the next city after Chicago to report
6 a large case. In about five weeks, John had 607 phone
7 calls for more information about Agent Orange.

8 I would like him to take five minutes, if you
9 wouldn't mind, and let him go through the data that he has
10 collected on that.

11 DR. HABER: All right.

12 MR. FIRST: I would like you to know that we do
13 not consider this scientific information. What we wanted to
14 do more than anything was find out what the people were
15 complaining about.

16 We asked them to tell us what they had experienced
17 since Vietnam. In an effort to avoid pre-disposing their
18 answers, we chose not to ask specific questions until they
19 had nothing further to add to their spontaneous remarks.

20 We have two tallies here. I would prefer to
21 call them accountings. Of the 607 reports that we got,
22 89 reported nothing but their name and address so that
23 they might receive further information. We received no
24 information from them.

25 Of that 607, 301 reported numbness and tingling.
That is 49 percent; 305 reported various rashes. A
significant number of those rashes were reported to have
acne-like eruptions. They come and go with time. They

1 are often reported to increase in severity with heat.

2 This tally includes a list of birth defects that
3 are reported. I am not a doctor. I do not know the
4 significance of these. I make them available to you in
5 the hope that you will know whether or not they are significant
6 in the general population figures.

7 We totaled 55 veterans with full intake, at which
8 time we now have 89 percent reporting a rash. This is not
9 a scientific sampling. They called on their own response
10 to published symptoms which they recognize, for which they had
11 failed to receive adequate treatment.

12 I do have copies of this available for the Board.

13 DR. HABER: We would appreciate that very much.
14 Incidentally, let me now say that we would appreciate any
15 representations from any interested parties--scientific,
16 lay, of whatever description, and would undertake to make
17 this information available to the concerned members of the
18 Committee.

19 Additionally, anybody who wishes to make a
20 presentation to us at times other than the meeting, can do
21 so by writing or calling my office and arranging for such
22 an opportunity. We would grant him a hearing, in addition
23 to which we will have opportunities at future meetings for
24 public statements of the kind we just had, to be read into
25 the record, and the questions to be exercised.

I see by the clock that we are right on schedule,
and I wish to thank both the Committee and the audience
for helping us meet that precise time limitation.

1 I would like now to take a few moments to simply
2 set the date of the next meeting, which ought to give us
3 time to prepare our papers and to circulate documents
4 among us.

5 Notwithstanding the fact that we are in the midst
6 of the summer and people's schedules are disrupted, I
7 would like to set this meeting for early in August, and my
8 first cut will be August 9th.

9 Can you all determine if that is not possible
10 for you? Dr. Murphy? When would be?

11 DR. MURPHY: Late in August.

12 DR. HABER: Supposing we make it early September,
13 September 7th. Is that a possibility? Can everybody make
14 it?

15 DR. KEARNEY: I will be in Europe.

16 DR. HABER: I think this is going to be difficult
17 to do this way. I therefore think that it would be
18 best to circulate several dates to all of you by
19 some written communication, and then we will ask you to
20 circle the most propitious date, and when we get the
21 greatest number of attendees, we will convene.

22 Is that satisfactory to the members of the
23 Committee?

24 MR. LEMEN: Yes.

25 DR. HABER: Dr. Schepers reminds me if you cannot
attend, your alternate who has been named could attend,
but we would like to keep the group as much as possible to
this representation. We will give you ample opportunity to

1 indicate any problems.

2 MR. LEMEN: I have a question. You said that
3 we would develop position papers. Are you going to be
4 writing to us then to ask us to comment on these?

5 DR. HABER: Yes. We will handle these position
6 papers in one of two ways. We will endeavor to make a
7 preliminary statement which we will circulate to the group
8 for corrections, or if we feel incapable of doing that, we
9 will ask a small group of you, or one or two of you to help
10 us frame the original paper, and then circulate it. You
will not be tasked until I specifically contact you.

11 Is there any further business of the members of
12 the Committee? If not, please accept my heartfelt thanks
13 for what is a challenging and difficult task. I think it
14 is well begun. I think I have gotten several new ideas.
15 I am indebted to all of you for the dispatch and scientific
16 way in which you have approached this very, very difficult
17 subject, and I have no question but that we will produce
18 the answers sooner because of the existence of this
Committee than would otherwise have been the case.

19 Thank you all very much, and we stand adjourned.

20 (Whereupon, at 3:30 p.m., the hearing was
21 adjourned, to reconvene at an undetermined date.)
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3 REPORTER'S CERTIFICATE

4 DOCKET NUMBER:

5 CASE TITLE: ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS
6 OF HERBICIDES

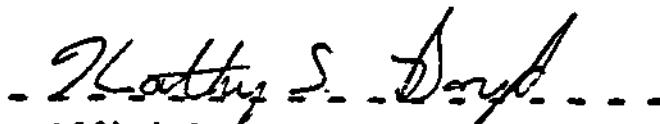
7 HEARING DATE: June 11, 1979

8 LOCATION Washington, D.C.

9 I hereby certify that the proceedings and evidence herein
10 are contained fully and accurately in the notes taken by me
11 at the hearing in the above case before the
12 VETERANS ADMINISTRATION

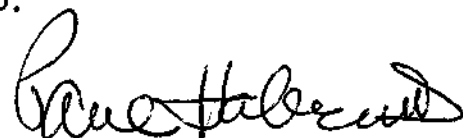
13 and that this is a true and correct transcript of the same.

14 Date: June 18, 1979

15
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17 Official Reporter

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19 1411 K Street N.W.
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20 I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE HEREIN ARE CONTAINED
21 FULLY AND ACCURATELY, AS CORRECTED.

22 
23 PAUL A. L. HABER, M. D.
24 Chairman
Advisory Committee on Health-
25 Related Effects of Herbicides

August 7, 1979

595846

143



SEPTEMBER 24, 1979 (SECOND MEETING)

TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF :

Advisory Committee on Health-Related Effects of Herbicides

Veterans Administration
Washington, D.C. 20420

314

1 THE VETERANS ADMINISTRATION

2 * * *

3 ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS
4 OF HERBICIDES
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15 The Veterans Administration
16 Room 119
17 810 Vermont Avenue, N.W.
18 Washington, D.C.

19 10:00 a.m.
20 Monday, September 24, 1979
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25

1 ADVISORY COMMITTEE MEMBERS PRESENT:

2 PAUL A. L. HABER, M.D., Chairman
3 Assistant Chief Medical Director
4 for Professional Services
Veterans Administration
Washington, D.C.

5 GERRIT W. H. SCHEPERS, M.D., Vice Chairman
6 Medical Service
Veterans Administration
Washington, D.C.

7 IRVING B. BRICK, M.D.
8 Senior Medical Consultant
9 National Veterans Affairs
and Rehabilitation Commission
10 The American Legion
Washington, D.C.

11 J. DAVID ERICKSON, D.D.S., Ph.D.
12 Center for Disease Control
Birth Defects Branch
Atlanta, Georgia

13 PHILIP C. KEARNEY, Ph.D.
14 Chief, Pesticide Degradation Laboratory
15 Department of Agriculture
Beltsville, Maryland

16 ROBERT H. LENHAM
17 Special Projects Officer
Disabled American Veterans
Washington, D.C.

18 CAROLYN H. LINGEMAN, M.D.
19 Carcinogenesis Testing Program
20 National Cancer Institute
National Institutes of Health
Bethesda, Maryland

21 JOHN A. MOORE, D.V.M.
22 Associate Director for
23 Research Resources Program
National Institute of Environmental
24 Health Sciences
Research Triangle Park, North Carolina

25

1 ADVISORY COMMITTEE MEMBERS PRESENT (Con't):

2 SHELDON D. MURPHY, Ph.D.
3 Department of Pharmacology
4 University of Texas Medical School
5 Houston, Texas

6 WILLIAM HALPERIN, M.D.
7 Medical Officer
8 Robert A. Taft Laboratories
9 4676 Columbia Parkway
10 Cincinnati, Ohio

11 ADRIAN GROSS, Ph.D.
12 Chief, Toxicology Branch
13 Hazard Evaluation Division
14 U.S. Environmental Protection Agency
15 499 S. Capitol Street, S.W.
16 Washington, D.C.

17 MAJOR PHILLIP G. BROWN
18 Office of the Air Force Surgeon General
19 Bolling Air Force Base
20 Washington, D.C.

21 STEERING COMMITTEE MEMBERS PRESENT:

22 RICHARD A. LEVINSON, M.D., Chairman

23 JOHN J. CASTELLOT, SR., M.D.

24 STRATTON APPLEMAN

25 LYNDON E. LEE, M.D.

J.C. PECKARSKY

FRED CONWAY

MARGARET KILDUFF

DONELD HOWELL

PAUL LEGOLVAN, M.D.

LAWRENCE HOBSON, M.D.

MARJORIE J. WILLIAMS, M.D.

ROBERT W. LOVE, M.D.

I N D E X

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P R O C E E D I N G S

1
2 DR. HABER: Good morning. I would like to
3 convene the second meeting of the Veterans Administration
4 Advisory Committee on Health-Related Effects of Herbicides
5 on time at 10:00 o'clock, September 24, 1979 in conformance
6 with the duly published notice of such meeting in the
7 Federal Register. I would like to call the meeting to
8 order and to give you the benefit of some observations
9 that we have made since our last meeting.

10 I want to thank those of you who have made it
11 your business to attend, and to assure you that we are
12 looking forward to the deliberations today in
13 an endeavor to get further clarification and much needed
14 information about the problem of health-related effects
15 of herbicides.

16 I would like to first point up a couple of
17 business items. Dr. Allen just called us at 9:15 this
18 morning, Mrs. Williams tells me his flight was delayed
19 from Madison and he could not get another until this
20 afternoon, which, of course, would put him here too late
21 to participate in the meeting. Therefore, he will not
22 be in attendance today, and his absence will be noted and
23 his presence missed. We will, of course,
24 send him complete information on today's
25 deliberations and/or decision making.

1 I would like to call your attention to the
2 fact that some specific progress has been made. The
3 minutes of the last meeting have been finalized and
4 action papers have been developed. We can send copies of
5 the minutes of the last meeting and of
6 subsequent meetings to individuals. Our facilities do not
7 permit us at this time to prepare tapes of the entire
8 minutes of the meeting, although we will have a verbatim
9 tape available in VACO for anyone who wishes to listen to it.
10 We cannot, unfortunately, reproduce the tapes for distribution; that
11 would be a prodigious job. If the minutes do not satisfy anyone's needs
12 then they should communicate with my office and arrangements will be
13 made for you to listen to the tape here in central office.

14 I would like to talk to you about where we are with regard
15 to Agent Orange. Our resolve to solve this problem has only been
16 intensified. There have been some additional activities that have
17 been undertaken which I will endeavor to call to your attention
18 momentarily. The evidence mounts up on both sides of the issues.

19
20
21
22
23 I would like again to reiterate our conviction
24 that veterans who are suffering the long-term effects
25 of herbicide exposure are being examined and if treatment

1 is needed they will be treated at VA hospitals without the
2 necessity for establishing causation or indeed any
3 linkage with Agent Orange exposure.

4 This is a reflection of our general policy to
5 treat ailing veterans regardless of the cost whether
6 it be service connected or not and should they require
7 hospitalization, they will be so hospitalized and treated.

8 The adjudication process for compensation to
9 people who believe themselves to be the victims of
10 untoward effects because of exposure, is a process which
11 does require either the establishment of a causal link
12 between exposure and subsequent ill effects, or a common
13 time frame. If the origin of symptoms or disabilities a veteran
14 now suffers can be established to have occurred during a period in
15 which the veteran was in active service, the causation is deemed to
16 be established.

17
18
19 In other words, if it happened to him while he
20 was in service, if there were abnormal pathophysiological
21 signs or symptoms which can be established to have begun
22 during his service period, the causation is assumed to
23 be present, and we would then proceed to grant this
24 individual service connection.

25 With that information, let me just say that we

1 have had continued recourse to the Press in various ways,
2 A number of articles have appeared; an interview I had on the
3 Health Related Effects of Exposure of Herbicides appeared in a recent
4 issued of Science Magazine, the official journal of the American
5 Association for the Advancement of Science; an interview with the
6 New York Times, and there have been several TV and radio interviews
7 with me and others.

8
9
10 Our Administrator is absolutely delighted with
11 the idea that the Veterans Administration will help to
12 solve this issue; and indeed other branches of government,
13 as you will hear today, have redoubled their
14 efforts to help solve this vexing problem of the
15 health-related effects of herbicides.

16 I would like to call to your attention a number
17 of activities which have taken place. We
18 continue to refer to the Armed Forces Institute of
19 Pathology, specimens which are obtained during the course
20 of normal diagnostic procedures performed on Vietnam veterans exposed
21 to Agent Orange. The Armed Forces Institute of Pathology is codifying
22 and retaining these specimens.

23 In other words, if we get a sample of tissue
24 from an individual who was exposed to Agent Orange we
25 are sending these to the Armed Forces Institute of

1 Pathology for their further study and classification.
2 The obvious intent here is to be able to form a tissue
3 bank so that if we subsequently discover any tissue
4 abnormalities specific to Agent Orange toxicity then we can go back and
5 re-examine all those tissues that we have acquired and
6 sent to the Armed Forces Institute of Pathology to see
7 whether they show these changes.

8 I have in hand a letter
9 from the Armed Forces Institute of Pathology to the
10 Director of our Pathology Service, dated August 15, 1979,
11 in which Captain Coward, Director of the Armed Forces
12 Institute of Pathology acknowledges receipt of these
13 tissues and details their examinations. These
14 tissues are from the VA, and from other federal
15 hospitals, e.g., Willford Hall Hospital in Texas,
16 and the Great Lakes Naval Medical Center in Illinois.

17 We expect to have further
18 dialogue with the Armed Forces Institute of Pathology
19 about this.

20 We have issued a Circular to our VA hospitals, requiring
21 them to collect certain information from veterans who apply to them
22 for treatment and diagnosis of disabilities believed to have been
23 incurred in connection with exposure to Agent Orange. These hospitals
24 are required to send us quarterly detailed reports on those examined,
25 including the medical history, the physical examination, and the
laboratory examinations performed. We are now in the process of

1 of coding that collection of information, which is a very laborious
2 time-consuming procedure. we have had special people detailed into
3 Central Office from our field hospitals to help us do this.

4
5
6
7
8 Dr. Levinson will undoubtedly have more to
9 say about that when he gives you the report of the Steering
10 Committee.

11 Later this week we will have a meeting of the
12 responsible physicians representing all VA hospitals, who
13 have been assigned the task of coordinating the field
14 activities entailed in investigating the alleged harmful
15 effects of herbicides. At every VA
16 hospital a physician has been designated and in some
17 instances there is more than one, to be the center point
18 of information about this problem. As I
19 have indicated to you in the past, we have made it a point to
20 keep these individuals informed on the advances relevant to Agent Orange
toxicity. Circulars have been issued
21 to our field hospitals and hotline conversations have been conducted
22 advising them of the information we have.

1 Later this week we plan to have the first conference, this will be
2 the first time all of the physicians have been brought together.

3
4 The purpose of this conference is two-fold:

5 First of all, to instruct them in the latest
6 developments of what we have undertaken with regard to Agent
7 Orange and what types of efforts are underway elsewhere.

8 And second to have them share with us
9 their experiences and their suggestions, ideas, about
10 solutions to the problems they face in trying to deal with Agent
11 Orange. There will be recourse to the
12 knowledge of the Advisory Committee Members during the conference since

13 some of them will be addressing the group. Other
14 experts and representatives of some of the
15 Veterans organizations have also been invited to speak.

16 We hope that much good will come out
17 of this conference, the first of its kind ever held, in
18 which we can share information with those individuals who are
19 bearing the burden of the responsibility at the field level.

20
21 Many things have happened and we
22 are pursuing a number of other investigations. We have
23 engaged the services of an outstanding epidemiologist
24 who
25 is not in the Veterans Administration, but whose services

1 the VA has engaged -- namely, Dr. Lillianfeld of Johns
2 Hopkins University,
3 to consult with and give us advice, which we
4 hope will guide us in our efforts to initiate an epidemiological
5 study. Other efforts have been made, and you will
6 hear more from our group today.

7 At about 11:00 o'clock we will begin the
8 discussion of the position papers which were prepared in
9 response to questions posed by the VA Steering Committee,

10 I must
11 emphasize that these position papers are not yet in the
12 final stage of preparation. We are going to have to do
13 more work on them and hopefully the discussions we
14 have here today will help us complete that
15 process.

16 I think that launches us, and without
17 further ado then, I will turn
18 to the report of the VA Steering Committee's activities,
19 and I would ask Dr. Levinson to come up and talk with us
20 about this.

21 DR. LEVINSON: Thank you very much. I am glad
22 once again to be able to address this group concerning
23 the activities of the VA Central Office Steering Committee.
24 You remember from my last discussion with you that the
25 Steering Committee is intended to coordinate the

1 activities of the entire VA with regard to
2 Agent Orange and its attendant problems. And within the
3 time allotted to us today I will try to introduce most
4 of the people involved in the committee so that you can
5 see the range and scope of activities in which we are engaged

6 Just to review, in slightly more detail some
7 of the things that Dr. Haber has already mentioned, I wish
8 to reiterate that

9 we have received reports on 3100 veterans who have
10 been examined in our hospitals under our Agent Orange
11 program. The next set of reports is due within a week
12 and we expect substantially more will have been included
13 in this group.

14 Remember that these are veterans in the VA patient
15 population who served during the Vietnam War from the
16 period between 1962 and 1970, and who agreed to parti-
17 cipate in our expansion and followup program. We have not yet gone
18 to outreach, although that may follow at some later point.

19 The information that we have received from this
20 program, is in my opinion quite good. We are endeavoring to
21 improve the format in which it is collected and we will
22 be completing that process in the near future.

23 In the meantime, we have devised a coding
24 sheet which will allow us to make the next big step in
25 this process to computerize the information so that it
can be readily studied and so we can follow the

1 veterans who have been entered into the study.

2 As Dr. Haber mentioned, we are using this as
3 the basis for a potential expansion into a full fledged
4 epidemiological study of these veterans; and I think that
5 we have laid the groundwork for a successful study.

6 The Agent Orange Educational Conference for VA physicians also
was mentioned by Dr. Haber.

7 A number of members of the Advisory Committee will
8 participate as speakers, and I thank them for that in
9 advance. We will also have a number of other experts from
10 the outside who will be addressing the group on various
11 aspects of the effort to draw connections between Agent
12 Orange exposure and subsequent illness.

13 We are in the process of setting
14 up a formal process liaison with all the other federal
15 agencies that are concerned with the study of Agent Orange.
16 Thus far, we have been attempting to follow most closely
17 the activities of the Air Force and their proposed study
18 on the ranch-hand group, but over the next several weeks
19 and months we will hopefully establish an equally firm
20 liaison with each of the other appropriate federal
21 agencies, and if indicated, will expand our attempts at
22 liaison to other groups outside the government.

23 We have made further progress in our pilot
24 study of levels of dioxin in humans for biopsies,
and we will have Dr. Lee report on that in a minute.

25 Mr. Pecharsky is a member of our committee

1 from the Department of Veterans Benefits and is not here
2 today; but speaking for him, I report to you that
3 there have been 650 claims filed thus far for compensation
4 for Agent Orange-related illnesses. One claim has thus far been
5 allowed.

6 It was a patient
7 with chloracne. Nineteen others have received compen-
8 sation but the Agent Orange exposure was considered
9 incidental to the process for which they were compensated.
10 So the number of new people applying for Agent Orange-related
11 compensation has not increased very much since the time of our last
12 meeting.

13 We continue to work with the Department of Defense
14 on attempting to correlate data on spraying in Vietnam
15 with troop movements. This has been a very cumber-
16 some and difficult process, but an essential one, if we
17 are to complete an epidemiological study. We will hear
18 more about these efforts. They are proceeding slowly,
19 not because of lack of
20 cooperation but because of the complexities of the
21 process.

22 I will ^{now} introduce some of the other members/^{of the Steering Committee} so
23 that they can briefly bring you up to date on some of
24 the specific areas ^{which} in / they are involved. I might
25 mention before I do this that the minutes of the
Steering Committee are always typed and duplicated.

1 They are sent out to a large number of people who follow the
2 VA's activities in the Agent Orange area. I want to let
3 you know that these minutes are available if you should want to
4 see them, both the current minutes as well as the older ones from
5 the last 8 or 9 meetings.

6
7
8 Let me call first on Dr. Lyndon Lee to bring us
9 up to date on the fat biopsy study.

10 DR. LEE: It is well known this is a segment of
11 a series of commitments that the VA has made to the
12 Congress and to the public in order to see if we can't
13 delineate some of the problems in this Agent Orange
14 exposure.

15 At the present time, we have fat biopsies on
16 34 total volunteers. Twenty of those are study cases,
17 11 are controls, and 3 are volunteers from the active
18 Air Force who have had 1,000 or more documented hours of
19 exposure to Agent Orange. Of that 34 biopsies taken,
20 21 have been reported by the chemist and 13 are presently
21 in process by the chemist in order to give us an assay
22 by his mass spectrometry techniques. It has been our
23 thought that perhaps because we are working in the levels
24 of one part per trillion it might be well to have some
25 kind of parallel assessments and this is being worked out

1 with the EPA. We have sent them a randomized sample of
2 those 34 people-- in fact, 8 of those who have been
3 exposed. That randomized sample is broken into
4 exposed people, those who have had no exposure are
5 the controls, and we have included a
6 known sample which is with known zero exposure to dioxin,
7 and one we have purposely contaminated in order to check
8 on EPA's use of different techniques from the mass
9 spectrometry.

10 At the same time we have asked our DVB people
11 to go back in their records and in the ^{relevant} military records
12 and see if they can verify for us what exposures may have
13 been experienced by the people who are the study
14 cases. All we have ^{now} is the word of these people that they
15 were exposed and when and how much. We
16 would like to double check that with DVB if we can. That
17 is not a simple process.

18 We are also attempting to augment the information
19 from the records, both in the hospitals and from the
20 materials which are coming in here to Central Office
21 to give us as much as we can get on both laboratory and
22 on individual histories, physical findings and so forth.

23 *FF* A paper has been drafted in order to report all of this work.
24 It has been circulated to the investigators. It needs
25 now the chemist's statement of his techniques, his

1 processing, his means of reporting and that sort of
2 thing. And it needs in addition, the analysis by the
3 National Research Council's biostatistical participant
4 before we can finish it.

5 We plan a meeting of all of these investigators
6 including the chemist and the statistician in Chicago,
7 sometime in October, probably at the time of the College
8 of Surgeons Conference

9
10 And sometime in the week of our
11 21-26 October meeting, we will discuss the various
12 reports. We will break the code from the chemist and see
13 what it looks like from the standpoint of each of the
14 investigators and see if we can't bring that report to
15 final form. And we will make that available for publi-
16 cation for this group as soon as we can.

17 DR. LEVINSON: Dr. Lawrence Hobson spoke to you
18 last time about the VA's research considerations in this
19 area. Dr. Hobson, do you have anything further to add?

20 DR. HOBSON: There is very little more to add.
21 Protocols are attempting to be developed using the
22 veterans who are exposed to Agent Orange in order to study
23 the immunological effects. Principally the difficulties
24 are ones that were reported before and are reviewed each
25 time this is mentioned: namely documentation of actual

1 exposure is extremely difficult. And secondly, there has
2 been a long time lapse in exposure to other substances
3 in the interval so that it is difficult to say

4 who had a significant exposure and
5 who did not get exposed to other agents that might have
6 had a similar or somewhat complicating effect.

7 DR. LEVINSON: Margaret Kilduff, from
8 our Medical Administration Section, would like to show
9 you some of the progress that we have made on the
10 coding of our charts.

11 MS. KILDUFF: As Dr. Haber and Dr. Levinson have
12 said the data collection at our field facilities started
13 in our medical records in May of '78. We started the
14 quarterly reporting into Central Office in September of
15 '78. We have about 3,000 of those reports in, and we
16 have had about 7 people from our field hospitals abstracting the
information.

17 On the data items that were designed, we have
18 devised a code sheet which I would like to distribute
19 to the members of the Advisory Committee. And this is
20 based on the information that we gave to our field
21 facilities and we are slowly abstracting this information.
22 It is, as Dr. Levinson says, a laborious process. We hope
23 to be finished within another month if possible.

24 The data elements may be changed. They are
25 under subject to review at the present time.

1 DR. LEVINSON: Thank you very much.

2 MS. KILDUFF: That is our present status on
3 the registry at this time.

4 DR. LEVINSON: Additional copies can be made
5 available if anyone feels the need for them. I wonder if
6 Dr. John Castellot could say a few words about some
7 special considerations he wants to present to the
8 committee.

9 DR. CASTELLOT: My comments will be directed
10 toward a more personal vein, if you will. Medical service
11 in the Central Office has something to do with this
12 people problem and one of our responsibilities is pre-
13 paring replies to a great deal of the correspondence
14 that comes in concerning Agent Orange. Fortunately, we
15 don't handle all of it but a significant share of it.

16 Two of the replies from the Central Office
17 contain comments to the effect that the individual problems
18 cited in the letters would be brought to this committee's
19 attention. In one case, this was made as a result of
20 a specific request from the Congressman sending in the
21 letter. In a second case, the Central Office respondent
22 felt this was appropriate. So I would like very briefly
23 to recount these cases with privacy being protected.

24 In the letter from the Congressman, the person
25 involved, of course, was a veteran and he and his wife

1 are having significant marital difficulties, and the
2 individual himself is having problems of a physical
3 nature with skin rash and other things. I won't go into
4 specific details because I don't think it is appropriate,
5 but the Congressman did indicate specifically that this
6 matters should be brought to this committee's attention.

7 I should point out this is representative
8 of many letters that we get along a similar vein. And
9 these, letters, of course, will be included and many data abstracted
10 from them have already been included in the registry. This veteran,
11 of course, is included in our registry.

12 The second letter is from another veteran who is
13 also in the registry whose child was born with a series
14 of congenital deformities involving the upper extremities.
15 This particular case is also called to your attention
16 for the reason I mentioned. It is representative of
17 several of a similar nature that have reached our
18 office.

19 As I said, these two and others will have been
20 recorded in the registry for appropriate analysis later.

21 Thank you.

22 DR. LEVINSON: I neglected to mention Dr.
23 Castellot --

24 DR. MOORE: Could I interrupt?

25 DR. LEVINSON: Sure.

1 DR. MOORE: I am puzzled by the last presentation.
2 I thank you for the knowledge. To state that in
3 compliance with the congressman I am bringing this to
4 your attention and give us a 15 second dissertation as
5 to what that was all about suggests
6 to me that you are trying to meet the letter of the
7 request, and I am not sure what the spirit of the request
8 was. I am just puzzled.

9 DR. LEVINSON: This was presented and will be
10 passed out for your review and discussion later. They
11 will be given to you. We are not trying to short circuit
12 the discussion.

13 Dr. Castellot is Director of Medical Service
14 in the VA Central Office.

15 Let's call on Mr. Doneld Howell of
16 Management Support Services to tell us about his liaison
17 with the Department of Defense regarding the spore
18 spraying tapes and military unit history.

19 MR. HOWELL: Dr. Levinson indicated I am from
20 the Office of Management Services. We have overall
21 responsibility for records management policies and
22 procedures in VA. We also have responsibility for
23 liaison with the Department of Defense and other interested
24 government agencies for the exchange of records and
25 information necessary to ensure that the VA Department

1 and staff offices have all the information they need to
2 provide full service and benefits to our veterans.

3 Better than a year ago, we became involved with
4 obtaining information from military service records of
5 veterans claiming exposure to herbicides. It became
6 quickly apparent to us that we were going to need specific
7 information from the Department of Defense and military
8 services, their official personnel records, if veterans
9 claiming exposure to herbicides were to receive proper
10 consideration of their claims.

11 We will need particular information as to
12 location of areas that were sprayed in Vietnam, dates
13 spraying missions occurred, dimensions of the areas
14 sprayed, and military units if any that were in those
15 sprayed areas.

16 We contacted the Deputy Undersecretary of Defense
17 for Research and Engineering to ask them for the specific
18 information. In response to this request they provided
19 us computer printouts and tapes that had been prepared
20 by the National Academy of Sciences. These tapes
21 identified the locations of and the dates of herbicide
22 missions flown in Vietnam. They also identified the type
23 of agent sprayed, the area covered, and the amount of
24 material sprayed.

25 After we received these tapes and computer

1 printouts we then went to the various history centers
2 for history within the military services and asked them
3 for information on histories of units in Vietnam. These
4 we have obtained.

5 We are also continuing to assist the Steering
6 Committee members in obtaining information from specific
7 military records, personnel records, for instance in
8 Dr. Lee's case, he had 11 people that we researched at
9 the National Personnel Records Center for him.

10 DR. LEVINSON: One of the problems, of course,
11 is that records gathered for one purpose, in this case
12 military troop movements and spraying, are not necessarily
13 readily adaptable to different purposes, such as the
14 epidemiological study. And this is one of the great
15 problems that we face in our future efforts.

16 Let me call upon Mr. Fred Conway to describe
17 briefly some of the areas in which the General Counsel,
18 whom he represents, is involved in this process.

19 MR. CONWAY: Thank you. Primarily, we are
20 involved with two cases, two litigation cases,
21 one is in New York and the other is in Washington, D.C., They
22 are in the process of the preliminary stages of development
23 right now, one of which is a class action suit brought
24 about by ^{the estate of} Paul Reutersham and others, who are claiming
25 disabilities without exposure to herbicides. In that

1 case the Veterans Administration is not a named party
2 as a defendant, but rather would be a beneficiary of any
3 action that is successful, in that the chemical companies
4 who are the named defendants would be responsible for
5 paying the VA, if successful, for the compensation and
6 treatment that we will be providing these individuals.

7 The other action is an action brought against
8 the Veterans Administration alleging that we have not
9 complied with certain kinds of procedures in development
10 of our policies and our procedures in handling the claims.
11 Both cases, as I say, are still in the preliminary
12 stages. We are nowhere near resolution of them, and no
13 one knows what the outcome will be on those.

14 Another matter, we have had frequent contact
15 with Congress and we are trying to work with the Department
16 of Justice on other matters relating to development of a
17 compensation scheme if necessary, that would handle this
18 kind of a problem in the future if it should arise in
19 other areas. But we are mainly concerned with the
20 Agent Orange problem, and identifying individuals who
21 may have been exposed and devising a system that will
22 adequately and fairly compensate them if the results of
23 this meeting suggest that a cause and effect relationship
24 exists.

25 DR. LEVINSON: Thank you.

1 Let me call on Dr. LeGOLVAN, who is Deputy
2 Director of Pathology Service to give us any update on
3 the AFIP registry.

4 DR. LeGOLVAN: Dr. Haber has already alluded
5 Institute of
6 to the activity of the Armed Forces/Pathology, AFIP. This
7 registry was established in September 28, 1978, and
8 that
9 provides/all pathological material, that is, surgical,
10 autoosy, or other similar tissue from veterans with
11 possible exposure to herbicides, will be examined and
12 reported in a customary manner at each medical facility.

13 In addition, a duplicate set of slides, blocks
14 and representative tissue will be forwarded promptly to
15 the AFIP for inclusion in the special registry.

16 At the AFIP each case is evaluated, diagnosed
17 and report of findings sent to the contributor. Cumulative
18 reports are sent to the VA Central Office each month,
19 listing the cases by name, the material submitted, the
20 diagnoses and copies of the report which were sent to
21 each of the contributors.

22 This demographic pathological data on each
23 case is coded into two systems. The registry is the
24 TERMATRIX system and AFIP computer. When an adequate
25 number of cases have been gathered from this pathological
information, it will be integrated with other studies
-- clinical laboratories, statistical and

1 epidemiologic.

2 Of particular interest are the following unusual
3 or unique tumors occurring in any organ or organ system;
4 unusually high incidence of a tumor for a particular site,
5 a tumor occurring at an unusually young age, a cluster of
6 similar cases in a particular military unit.

7 As of July '79, 13 cases had been registered
8 and reported. Of these 7 were surgical, 5 were autopsies
9 and one seminal fluid.

10 We have other details on this but this is a
11 general summary of the information. Thank you.

12 DR. LEVINSON: I would like to introduce
13 Dr. Robert Love from our Operations Branch. Dr. Love,
14 thank you.

15 And then last but by no means least, Mr. Alex
16 Kutner. Alex has been very helpful in arranging for
17 our conference which is a large and complex undertaking.
18 He and Dr. Castellot have joined me in planning it and
19 I certainly owe him a debt of thanks for whatever success
20 is achieved.

21 I think this gives you an indication of the scope
22 of activities of the Steering Committee, and our goal
23 is to make coherent the policy alternatives for the
24 Veterans Administration in facing the various challenges
25 of Agent Orange and to undertake certain activities as
assigned which are within our scope of expertise.

1 Another thing that we have done, as you will see
2 this afternoon is we have prepared four additional questions
3 in addition to the 13 you have, to
4 which we feel the agency requires an answer in order to
5 better understand the Agent Orange situation.

6 I would like to clarify before finishing one
7 thing. I do have available in my office past and present
8 minutes of the Steering Committee and will make them
9 available in case anyone wants them.

10 DR. HABER: O.K. Thank you very much, Dr.
11 Levinson. I think at this juncture I would like to throw
12 the floor open to questions and comments about the reports
13 of the various Steering Committee members to engage your
14 attention to them. I think I will begin with the
15 question you raised, Dr. Moore, and we will make available
16 to the members of the Advisory Committee the details of
17 those two particular cases. It is a question of privacy
18 here that we have to consider; but I think Dr. Castellot
19 understood our obligation to let the Advisory Committee
20 know about this. These cases may be illustrative, and
21 I think the Advisory Committee needs to consider them
22 divorced from identification of the individuals; but there
23 are principles involved which we would like to get your
24 guidance from. And I think your questioning was right
25 on target; and since my packet held those, I assumed

1 everybody had them. It turns out I was given information
2 which was not generally true. It will be included.

3 Are there any comments from members of the
4 Advisory Committee or from the attending group about the
5 reports of the Steering Committee?

6 DR. MOORE: Could I request copies of future
7 minutes of the Steering Committee as well as any past
8 minutes. I think it would help me and maybe the rest of
9 the group tremendously to have something in front of us
10 to give us a better sense as to what the VA is about.

11 DR. HABER: Dr. Levinson, would you please
12 see to it that minutes of the Steering Committee are
13 henceforth included in the packets for the Advisory
14 Committee.

15 DR. MOORE: On your veterans' examinations that
16 you described these 3100 people that you have
17 received into the Central Office, is it possible to
18 receive a copy of the format that is being used on these
19 people?

20 DR. LEVINSON: Yes. The current
21 format, which does badly need revision, was submitted
22 by us last time as part of a circular. What is the number--
23 we will have it in a minute. I haven't committed it to
24 memory yet. It is 19-79-83, which was dated April 16, 1979.
25 You all received this last time. If you want additional

1 copies, we have it available.

2 In the back of that circular -- there are three
3 attachments which are the format of the examination.
4 The first part is the initial data base which goes into
5 the history of exposure and we try through various means
6 to get both quantitative and qualitative data about
7 where, how long and so on. This is an extremely difficult
8 matter.

9 The second part, Part B, is
10 a review of systems basically from a historical point of
11 view of areas in which it has been said by inference or
12 by direct information toxic effects of Agent Orange
13 might manifest itself.

14 The third part is a physical examination form
15 which again urges emphasis on certain particular areas.
16 In addition, we encourage appropriate laboratory testing
17 to the extent that the findings on either history or
18 physical examination indicate. We don't have a set
19 format but we do have certain suggested guidelines.

20 Now this will be revised to more adequately
21 answer the questions regarding epidemiology that we need
22 to have answered. It will be put in a more appropriate
23 form, and will contain coding information so that the
24 hospitals can code it directly and there won't be a
25 lag between the performance of the examination and the

1 entry of this data into our computer system. We are being
2 advised in this revision process by the epidemiological
3 forces of Johns Hopkins and others, and also hopefully
4 from the members of this committee, so that we can have
5 a truly excellent form.

6 There are additional copies available if
7 anyone wants them.

8 DR. MOORE: Could I have a copy of that too,
9 please.

10 MS. KILDUFF: This form follows the data elements
11 that he just explained.

12 DR. LEVINSON: I will bring copies this afternoon
13 for everyone.

14 DR. MOORE: Of the 650 claims, it was
15 stated that one has been allowed, I think it would be
16 very beneficial to me if I could get some information as
17 to what were the symptomologies or the pattern of
18 exposure associated with the person that apparently led the
19 VA to conclude that it likely was an Agent Orange exposure.

20 DR. LEVINSON: The gentleman
21 who represents DVB is not here today. The basis of it
22 was chloracne. It was on that basis that the claim was
23 granted.

24 DR. MOORE: Did he have any other symptoms --
25 liver pathology or neurologic problems?

1 DR. LEVINSON: I don't know.

2 DR. MURPHY: What about exposure? Does he fit
3 the pattern of heavy exposure or was that taken into
4 consideration at all?

5 DR. LEVINSON: I am sorry, I just don't know.
6 We will have to find out.

7 DR. HABER: The information is that he does not
8 fit the pattern of heavy exposure and what we will do
9 is to get a trace of that case insofar as we can
10 without violating the Privacy Act, which gives you the
11 background. I think it would be illustrative and I
12 think the whole committee would benefit from that.

13 Do all the members of the Advisory Committee
14 have a copy of the coding elements? This will enable
15 us to get the information in the protocol for the examin-
16 ation coded and developed so that it is suitable for
17 automation. The numbers of examinations is mounting.
18 We would like to be able to reduce it to a format which
19 we can deal with in large numbers.

20 DR. MURPHY: Related to Dr. Moore's question,
21 of those 3100 veterans for whom we have received reports,
22 it wasn't clear to me just how this 3100 happened to have
23 been selected other than they agreed to participate.
24 And specifically, does it include reports from the 650
25 claims that have been filed.

1 DR. LEVINSON: The 3100, these are not selected
2 except to the extent they agreed to participate, self
3 selection. These are people who are receiving service in
4 our hospitals, and who were Vietnam veterans, serving
5 during the period of time when Agent Orange was utilized.
6 These people are identified by Medical Administration
7 Service and they are invited to participate in the study.

8 I do not know the number invited who declined,
9 but these are people who have agreed to participate. So
10 to that extent there is a self selection process.

11 This does not reflect at this moment outreach,
12 advertising, come in and so on, nothing like that.

13 DR. MURPHY: My other question was how many of
14 those 650 people are involved?

15 DR. LEVINSON: I don't know. But we have
16 inferences that not all of the people who have filed
17 claims for compensation have been examined under this
18 program. As you may know in our system they are two
19 separate processes. One files claims with one part of
20 the agency, Department of Veterans Benefits, for com-
21 pensation. One receives health care from another part
22 of the agency, the Department of Medicine and Surgery.
23 The two do interact on parts of the processing of
24 claims, but having filed with DVB is not tantamount to
25 being examined in a VA health care facility.

1 DR. HABER: Anybody who files with DVB, if he
2 manifests and he must invariably do so -- some current
3 physical or mental problems associated with this, he
4 would be referred to the Veterans Hospital, Department of
5 Medicine and Surgery, for treatment, diagnosis and
6 treatment.

7 DR. MURPHY: The invitations, you said they were
8 invited to participate. What is the basis of the
9 invitations, was it exposure?

10 DR. LEVINSON: No.

11 DR. MURPHY: Symptoms?

12 DR. LEVINSON: The basis is that they were
13 Vietnam veterans during that era, and that they believe
14 they were exposed. On that basis alone we invited them
15 to participate.

16 DR. MURPHY: O.K.

17 DR. HABER: The invitation is really a self-
18 generated one.

19 DR. MURPHY: That is right. If they believe they
20 were exposed, then that is kind of a self selection
21 process.

22 DR. LEVINSON: Yes.

23 DR. HABER: I hope there was no inference drawn
24 to the contrary.

25 DR. ERICKSON: What is the comparison going to

1 be made to? What is the control group for this group of
2 3100 people?

3 DR. LEVINSON: We don't have a study yet. We are
4 in the process of using this data to develop a study and
5 we felt that the best way to start was to begin collecting
6 data.

7 Our goal is to place the names of all appli-
8 cants in our computer so when they call for
9 additional studies, the full dimensions of the
10 epidemiological study will be available. At the time
11 when we do undertake it, there will certainly have to be
12 an appropriate control group and several are available.
13 The most logical one would be Vietnam era veterans who
14 did not go to Vietnam, presumably they were not so
15 exposed. But there are a number of control groups that
16 we can use, the general population, for example, would
17 be available to us.

18 DR. HABER: Could you identify yourself from
19 the floor?

20 MR. DeYOUNG: My name is Ron DeYoung. I
21 appear here today as a representative of the National
22 Veterans Task Force on Agent Orange. I had a question
23 for the gentleman from the Office of Management
24 Services but I would like to hold that just for a second.
25 The information that the task force has developed is

1 directly counter to your last statement, Dr. Levinson,
2 in terms of that control group. And I would caution you
3 that we have reports from veterans that indicate that the
4 Panama Canal Zone, Fort Lewis, Washington, Aschaffenburg,
5 along with possibly Subic Bay in the Philippines were
6 defoliated. These are eye witness agents. We don't know
7 the exact chemical. It was either 2,4,5-T, or a mixture
8 thereof. It was stated by them it was a very common
9 construction technique for the engineer battalions at
10 that time.

11 DR. HABER: Mr. DeYoung, we are aware of that
12 and we know of herbicide exposure even in

13 the civilian population, so it will be difficult to
14 find a matched group. We will do so, however.

15 MR. DEYOUNG: I wanted to make that a matter of
16 record because of Dr. Levinson's last statement. The
17 question that I really rose for was a question to the
18 gentleman from the Office of Management Services.
19 You are talking about computer tapes and locations of
20 units and so forth. Have you yet had a successful track
21 on any veterans? Has DOD or one of the departments come
22 back and said, yes, this man was exposed, here are the
23 particulars.

24 MR. HOWELL: No, I can't really answer that.
25 We just get the information for the Department of

1 Veterans Benefits. We obtained it for them.

2 DR. LEVINSON: We have not asked them to track
3 individual veterans as yet. We are trying to get the
4 whole process done as it were, automatically, if it is
5 possible. We want to get the data together so that we
6 can do it by the use of a computer.

7 The agencies, of course, do track individual
8 veterans when required. They do this apparently as we
9 understand, as a matter of routine, and may very well
10 have done so for the claims filed before the Department
11 of Veterans Benefits.

12 I can't answer that but for the purposes of
13 our activities, we have not yet tracked individual
14 people. We are storing the data and we hope we can
15 avoid having them laboriously follow some. We hope the
16 use of the information when automated will obviate this.
17 This is what we are aiming for.

18 DR. HABER: Actually, there are several tracks
19 that we are pursuing to try to run down that very
20 important question.

21 MR. DEYOUNG: What bothers me is the implication,

22 I would suggest that you relook at what the
23 adjudicators are sending out to veterans in terms of
24 requesting the veterans to develop his own documentation
25 for exposure to the herbicide. The evidence I will give

1 you as close to a quote as I can--the evidence of record
2 does not contain information which shows you were associated
3 with herbicides; therefore we must deny your claim at this
4 point.

5 That is not word for word, but the theme is
6 very much what the adjudicators at local levels are
7 putting out to veterans who are writing.

8 DR. HABER: Yes. I think your point is well
9 taken. We will be communicating with DVB.

10 MR. DEYOUNG: I think it might be better for
11 the veterans to know that something is going on here in
12 terms of documenting that exposure than just thrusting
13 it back upon their shoulders, which they have no resources
14 to do.

15 DR. HABER: The point is well taken.

16 MR. ENSIGN: I am with Citizens Soldiers
17 Veterans, New York City. I want to try to pin down
18 something. I am a little confused. It is the question of
19 the April 16th memo, and the relationship to the veterans
20 coming into the facility. And I am trying to understand.
21 We, of course, hear from a lot of veterans. We routinely
22 ask them and we generally read right from the memo and
23 ask them about these questions -- were you asked this,
24 asked that.--and I must say that without being hype --
25 most veterans say no, I was not asked that. I was not

1 asked those questions either in specific or in the general.

2 Now I realize that often a guy might not
3 remember. There may be people whose memories are faulty,
4 but it seems as though facilities in many cases are not
5 asking that set of questions. Now what I am trying to
6 understand is, is it because when the person comes in, and
7 he makes the claim, he goes into the regional office
8 and makes the claim, is there some process whereby that
9 person must satisfy himself that he, in fact, shows
10 something which then entitles him to be questioned or
11 is it, in fact, routine that anyone who comes in and says,
12 I believe I was exposed, they will be. Is it your statement
13 of policy that the VA will ask them that set of questions.
14 And if that is a statement, I have to say that from
15 hundreds of guys we talked to it does not seem to be
16 filtering down to the regional level.

17 DR. HABER: Let me answer that question.

18 We have heard that statement made by several individuals
19 such as yourself. One of the purposes in having our
20 conference later this week is precisely to deal with
21 that issue.

22 Dr. Levinson stated it appropriately. The two
23 processes applying for compensation, adjudication for
24 service connection, and or the process of applying for
25 medical care, medical benefits, are independent in the

1 sense that one does not have to wait on the other. And
2 that a veteran who comes to a hospital or a clinic of
3 the Department of Medicine and Surgery alleging ill
4 effects will be treated in accordance with the circular
5 that Dr. Levinson cited. Those questions will be asked.

6 The appropriate physical and laboratory exam-
7 inations will be done. Where that does not occur, it is
8 important to find out why it has not occurred, and we
9 will endeavor to get remedial action. Sometimes, as you
10 say, it may have occurred without the veterans being
11 specifically aware that it has occurred.

12 MR. UHL: My name is Michael Uhl. I have a
13 question for Dr. Levinson. With reference to your
14 epidemiological study that you mentioned a few minutes
15 ago, I have two questions actually. Who will design the
16 study and will you have the benefit of the advice of
17 this committee or some other outside committee of experts
18 on this?

19 DR. LEVINSON: Yes. Since we do not do epidemiology
20 in our agency, the design would surely come from the outside. And
21 very definitely it would take into account the advice and guidance
22 of the Steering Committee.

23
24
25 MR. UHL: Who will do that study?

1 DR. LEVINSON: I can't answer that now.
2 Currently we are talking to people from the Department of
3 epidemiology at Johns Hopkins. Whether they are the
4 ones that are chosen will depend on their availability
5 and on the circumstances. It will be, though, a highly
6 reputable outside group that is not otherwise involved
7 in this.

8 MR. UHL: What will be the mechanism for involving
9 the Advisory Committee in the construction, design,
10 evaluation?

11 DR. LEVINSON: Several. First of all, already
12 in the questions that they have received and for which
13 they are developing position papers we have many aspects,
14 facets of this epidemiological study under their review.

15 Now that hasn't been pulled together but there
16 are specific aspects that they are already commenting on.
17 Presumably,

18 they would be asked to comment on the design
19 after it is completed and to approve every aspect of it
20 before we finalize it. So I think they would have an
21 oversight and a significant role in the final approval
22 of the design.

23 MR. UHL: Thank you.

24 DR. HABER: Let me say something about the
25 epidemiology. One of the things we want to do and one of

1 the reasons this committee was so constituted is that it
2 is not possible for the Veterans Administration to do
3 the total epidemiology. It is not appropriate. It is
4 not possible.

5 The part of the epidemiology that
6 we will be doing will be the result of a number of kinds
7 of advice, some from a group such as this, but also from
8 the members around this table, because, obviously, some
9 of the other federal agencies are already engaged in
10 epidemiological studies. As a matter of fact, all of
11 them around here are engaged in studies of one kind or
12 another. And it will be our function to see to it that
13 those which the VA undertakes are those which are
14 appropriate for us.

15 We won't be trying to duplicate what the CDC
16 is doing or what EPA is doing or the Department of
17 Agriculture is doing. So that is the reason for the
18 structure of this Advisory Committee, to be able to
19 be an interchange clearing house for all kinds of
20 studies which need to be done. Some would be appropriate
21 for us to do, some for the Department of Defense, some
22 for NIEHS. The function of this committee will be to
23 advise us on what kind of epidemiology we ought to be
24 involved in.

24 Were there questions?

25 MR. LENHAM: Mine was asked.

1 DR. HALPERIN: I am Bill Halperin, a physician
2 epidemiologist at the National Institute for Occupational
3 Safety and Health, and I am filling in for Dr. Lemen
4 who couldn't be here today. So you will have to excuse
5 me if I missed some of the points.

6 We have heard that there are going to be
7 epidemiology consultants to design this study, but yet
8 we have been told that there are already 3100 people
9 somehow enrolled in a data system that looks very elaborately
10 developed. And quite honestly my palms start to sweat.

11 It seems to me that if there is going to be an
12 epidemiologic study done by the VA, it ought to be clearly
13 defined by whoever does it with their protocol reviewed
14 before data systems that are developed may in a sense not
15 be appropriate for the kinds of study that they want to
16 develop.

17 I think it would be reasonable to refrain
18 from discussing the 3100 in
19 this data system as a study, and make the plea that as
20 soon as possible that we have a chance to review the
21 actual study design that the consultants will come up with.

22 DR. HABER: Let me be quite clear. This may
23 have been confused. We have a clinical problem right now
24 that does not await the appropriate design of the
25 definitive study. We have veterans out there who have

1 may have clinical problems. We have
2 to react to that now. We cannot afford the luxury of
3 discouraging those veterans until our study protocol is
4 developed.

5 What we are attempting to do now is simply to
6 collect that data which seems to us to be inherent in the
7 problem, and which having been retrieved will give us
8 at least a starting point. And we are going to codify
9 that data.

10 That is not to superimpose upon the design of
11 the study any restraints at all. We are just trying to
12 capture the data as ^{it becomes} available. It may well be that we
13 will have to go back and ask those veterans to return
14 and to subject themselves to additional studies once the
15 protocol for the epidemiology has been decided upon. And
16 we are prepared to do that, and we expect that most
17 veterans would be willing to do that. But I think what
18 we are doing now is reacting to a clinical problem with
19 the sure knowledge that some of that will be useful in
20 an epidemiological study, some of it will not.

21 Some essential elements of an epidemiologic study
22 will not have been gathered in this and this will await
23 the definitive protocol, but you know as we do, that
24 elaboration of that protocol is going to be a very
25 tedious, exacting process. And we simply cannot afford to

1 wait until that time has happened when veterans are
2 literally at our doors asking for help. So we are mindful
3 of your concerns and I assure you that the epidemiologic
4 study will attend to the considerations you have
5 elaborated.

6 Are there any other questions or comments?

7 MR. HIGHT: Henry Hight, I am with the Board
8 of Veterans Appeals. I might make one comment here to
9 this gentleman over here that even if the regional office
10 adjudicators do not question the veteran properly on where
11 he has been, when and so forth, we are remanding those
12 cases for full development. And they won't get by without
13 having all of the development that the veteran can give
14 us, and that we can make as far as determining whether
15 he was there and what kind of situation he was in, whether
16 he was sprayed or not and so forth.

17 There is one other point I would like to bring
18 up here, and it seems to me that some discussion has gone
19 along on the basis of chloracne. And as I understand it,
20 the existence of chloracne in service is not a manifestation
21 of other than that acute manifestation of having been --
22 we will admit that he has been sprayed. This is not a
23 pathological symptom which we will say is related to
24 something later on. Is that correct, Dr. Haber?

25 DR. HABER: What our attitude has been about the

1 existence of chloracne, either at the time of service or
2 very shortly thereafter, if the individual was shortly
3 discharged, would be that that is evidence of the fact
4 that he had been sprayed.

5 MR. HIGHT: He had been sprayed but not that he
6 has something now years later that is related to service?

7 DR. HABER: If there are problems, current
8 problems, that the individual has and he has well documented
9 evidence of chloracne that would be indicative of the
10 fact there might be a connection.

11 MR. HIGHT: Certainly gives them the evidence of
12 having been sprayed.

13 DR. HABER: Right.

14 MR. HIGHT: Thank you.

15 MR. JAMISON: Terry Jamison, a reporter for U.S.
16 Medicine. The VA has announced previously that a study
17 of human fat tissues would be concluded this summer. If
18 that is the study on which Dr. Lee was reporting, it is
19 apparently behind if we are talking about late October.
20 But what can be said about the two-thirds of the samples
21 that have been completed by the chemist? Is there any
22 indication?

23 DR. HABER: No. The code has not been broken
24 until the samples are completed. We cannot give you any
25 information.

1 MR. JAMISON: That is the same study?

2 DR. HABER: Yes.

3 DR. LEE: I would like to add there was no
4 commitment as to when that study would be completed and
5 there has not yet been any commitment.

6 DR. HABER: We have time for two more questions
7 and then we must proceed. But if there are other questions
8 if you would please submit them in writing we will see
9 that you get answers.

10 MR. DEYOUNG: I would submit first of all, with reference
11 to the last statement that there have been commitments made,
12 possibly not by the Central Office, but to individual
13 veterans. In Chicago they were submitted to a three month
14 response time. The time has passed and they are wanting
15 their results. They also want to know why they can't get
16 theirs because the whole program is not done. They don't
17 understand the code hasn't been broken yet.

18 I will try to explain that to them, but I don't
19 think it will sit well. My major concern is the Air
20 Force Study. The HEW Study, the Ranch Hand Study. There
21 was a major announcement last time that there was a major
22 epidemiological study on a thousand to two thousand
23 veterans of the Air Force ranch hand program.

24 The most recent news we got through the news
25 media, the study has been postponed a few months. The

1 protocol is still not yet available. What is going on?

2 I asked some specific questions. Has the
3 Department of Defense developed a protocol for that study
4 and if not, why not?

5 The second one, has the Department of Defense
6 sent it to the White House, and if not, why not? When
7 will it be sent?

8 In both cases, when will it be done? What is
9 the time table for this project? When can we expect some
10 start and some finish?

11 DR. MOORE: Dr. Haber, could I ask for a
12 clarification? Do you infer the Ranch Hand was an HEW-
13 Air Force study?

14 MR. DeYOUNG: That was my understanding, Dr.
15 Moore. I had understood the actual development of the
16 epidemiology would be done by HEW.

17 DR. MOORE: I am not aware of that. Are you
18 aware of that?

19 DR. HALPERIN: No.

20 MR. DeYOUNG: Totally Air Force?

21 DR. HABER: It is an Air Force study. With the
22 exception of the fact that another agency, NAS, I believe, was in-
23 vited to review the protocol, but I will let Major Brown speak to
24 this.

25 MAJOR BROWN: Would you go back and restate your

1 questions! The first one, we will answer that and
2 proceed from there.

3 MR. DeYOUNG: Has the protocol been developed
4 by DOD?

5 MAJOR BROWN: The Air Force has developed a
6 protocol and it is under review.

7 MR. DeYOUNG: By who?

8 MAJOR BROWN: We have had three groups now
9 review the protocol and we are now in the process of having
10 the fourth group review the protocol.

11 MR. DeYOUNG: Could I have the names of those
12 groups please?

13 MAJOR BROWN: Surely. I brought a copy of it.
14 There is a Memo for Correspondents. I brought it today to
15 give to the committee, dated September 17th. Would you
16 like me to read it?

17 DR. HABER: Please.

18 MAJOR BROWN: "The United States Air Force
19 announced today the revised schedule for the initial
20 implementation of its study of the health of 'Ranch Hand'
21 personnel who sprayed herbicide orange in Vietnam.

22 Operation Ranch Hand was a name attached to the
23 AF spraying program in Vietnam between 1962-1971. 'Ranch
24 Hand' personnel would have been the most likely Vietnam
25 veterans to have had significant exposure to the herbicide.

1 The purpose of the study is to determine if any
2 causal relationship can be established between exposure to
3 the herbicide and changes in the long-term health status
4 of the individuals involved.

5 The initial phase of the study was scheduled to
6 begin in early October 1979, following completion of an
7 extensive scientific peer review of the medical protocol
8 by several scientific groups. This peer review, which
9 began in June 1979, is not being completed as quickly as
10 originally estimated. It now appears that the initial
11 phase of the study may not begin until January 1980. The
12 medical protocol constitutes the scientific approach by
13 which the Air Force plans to conduct the study.

14 Three scientific groups have reviewed the
15 protocol -- the University of Texas Medical School at
16 Houston, The Air Force Scientific Advisory Board and the
17 Armed Forces Epidemiological Board. A fourth scientific
18 group, the National Academy of Sciences, currently has
19 the protocol under consideration.

20 Upon completion of the reviews, the Air Force
21 will meet with the Veterans Administration Advisory
22 Committee on Health-Related effects of Herbicides to
23 discuss the entire study."

24 If you would like a copy of that, you can obtain
25 it from the Air Force Office of Information in the Pentagon,

1 Major Doug Kenneth.

2 MR. D'YOUNG: Thank you.

3 MAJOR BROWN: You are welcome.

4 DR. HABER: Can I interrupt the questions.

5 Mr. Wisniewski, would it be appropriate either
6 now or sometime this afternoon to give us some of the
7 information about that case that was adjudicated as being
8 due to service in Vietnam at the time the Agent Orange
9 was being sprayed? Do you remember the one case that has
10 been service connected? Either now or later, if you need some time.

11 MR. WISNIEWSKI: It depends on how much data you
12 need. The one case that we did allow as probably due to
13 Agent Orange was a chloracne case and it had a diagnosis of,
14 I think, possible chloracne and we resolved that by
15 holding that it was due to Agent Orange. Although the
16 file itself had no direct proof of exposure to Agent Orange.
17 We did it solely on the basis of this statement of the
18 veteran himself that he was in Vietnam, and that he was
19 exposed to the defoliants.

20 DR. HABER: We have promised the Advisory Committee
21 a blurb on that. Could you undertake to develop one with
22 some of the particulars about this so that we can put it
23 in their folder?

24 MR. WISNIEWSKI: I certainly can and will do so,
25 but when do you have to have it?

1 DR. HABER: Sometime in the next week or so.

2 MR. WISNIOWSKI: Certainly. You will probably
3 have it by the end of today or tomorrow.

4 DR. HABER: I think Dr. Murphy had one question
5 and can we close it with you?

6 DR. MURPHY: This had to do with an earlier
7 question and an earlier comment, and I don't recall whose
8 comment, stating that the position, I believe, for
9 compensation had related evidence to support compensation,
10 was one of cause and effect or concurrence in time, and
11 that symptoms and signs developed within the
12 time that exposure might have occurred.

13 And I wondered if this then rules out any delayed
14 chronic effects in terms of this?

15 DR. HABER: No. What we are saying is if an
16 individual receives a disability as a result of enemy
17 action, he has a gunshot wound, that is established. Then,
18 of course, that becomes service connected. Or if an
19 individual develops an illness / ^{during} the time that he is in
20 service, suppose he begins to show the first signs of
21 leukemia, we cannot ascribe the causation of leukemia to
22 service yet.

23 If his leukemia began while in service and the
24 first abnormality occurred at that time, he would be
25 granted service connection.

1 DR. MURPHY: In other words, you are saying if,
2 for example, an individual were washing machine gun parts
3 with benzene in 1970 and were discharged in 1971 and in
4 1978 got leukemia this could not be associated?

5 DR. HABER: No. I am not saying that.

6 DR. MURPHY: That is what you just said.

7 DR. HABER: I said the clear indication
8 would have to be established, but if he developed signs
9 and symptoms of any disease while he was in service, that
10 would be service connected or if the clear result of it,
11 the approximate result of that was a disability, for
12 whatever, if he fell off a motorcycle, while he was
13 carrying dispatches or as a result of enemy action he
14 was injured, he would be granted service connection.

15 It does not rule out the possibility that there
16 are long term latent effects. Those have to be established
17 but it doesn't rule them out. What it does is rules in
18 the other two kinds of things. O.K.

19 DR. BRICK: Not a question, just a comment and
20 an observation. With reference to the report that
21 appeared in the June, July issue of this year of the
22 Federal of American Science Public Interest report, in
23 which they reported that a Vietnamese scientist spoke on
24 dioxin at their meeting that they held on May 9th at
25 the FAS, which is up the street, on the possible

1 relationship between dioxin and liver cancer. Is your
2 committee aware of this?

3 DR. LEVINSON: Dr. Tung.

4 DR. HABER: We had him here too.

5 DR. BRICK: I wasn't aware of that.

6 DR. HABER: As a matter of fact, we have some
7 observations made as a result of his visit and we can make
8 that available to the committee.

9 DR. BRICK: I think that might be helpful because
10 he concluded apparently by stating that the relationship
11 was not established between cancer and dioxin, but thought
12 his research suggested it.

13 DR. LEVINSON: I think we may even have a tape
14 of his presentation.

15 DR. HABER: We will make that available to the
16 committee. I think the group should know Dr. Brick was
17 forthcoming enough, I believe that is the word, to write
18 to the editor of the Post regarding an editorial that the
19 Post published about responsibility for the research in
20 agent orange. And I thought it was very useful that you
21 did bring them at least in our viewpoint. We are indebted
22 to you for so doing, and I thank you for calling attention to
23 the existence of this committee which we have found very
24 useful.

25 I think we ought to make that letter available

1 to the committee too.

2 DR. BRICK: That is all right with me.
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1 DR. GROSS: I am Dr. Gross. I am replacing
2 Dr. Griffith here who I understand will no longer be
3 attending meetings of the Committee. He is leaving the
4 Service, going to Florida for a couple of years.

5 My question has to do with the Agent Orange.
6 Does the Department of Defense have information from the
7 manufacturer or samples of whatever was sprayed in Vietnam
8 at the time?

9 I understand the levels of dioxin vary a great
10 deal. How is that going to be handled, the matter of
11 exposure?

12 DR. HABER: MAJ. Brown, can I ask you to
13 comment?

14 MAJOR BROWN: I think this afternoon Major Young
15 will address the various levels that the Air Force is aware
16 of in terms of the concentrations of dioxin contaminant.
17 As to how that will exactly be handled in the future, that will
18 perhaps be a VA decision.

19 DR. HABER: Okay. We are 15 minutes overtime
20 on this issue, and I would like to thank the Committee for
21 their comments and so on. I would like now to go into
22 a discussion of the position papers.

23 Hopefully without seeming to impose on the committee, we
24 have the position papers developed. I would say this is
25 not the definitive form in which they will appear. These

1 position papers were the first cut, and I think they need
2 to be refined further. I want to take these up for
3 discussion with the group and this will be my policy: what
4 we will do is ask the discussant, the coordinator, to discuss
5 it, and to then throw it open for discussion.

6 Based then upon these comments and questions
7 from the audience and the other members of the Advisory
8 Council, we will undertake to go further in the process
9 of refining these papers, and then hopefully to get them
10 in a more definitive shape. So Dr. Halperin, would it
11 be fair to ask you to lead off a discussion for the first
12 paper; if you could give a quick summary and your own
13 comments on it, we will throw it open to discussion.

14 I hope we are not catching you unaware.

15 DR. HALPERIN: No. Dr. Lemen asked me if you
16 could clarify the difference between coordinators and
17 contributors? Have contributors partaken in the draft
18 paper so far?

19 DR. HABER: To my knowledge, well, I can't answer
20 that question. Do you know?

21 MRS. WILLIAMS: I don't know, Doctor. These were
22 expressed desires, to have input and participate in the
23 preparation and the coordination. I don't know.

24 DR. CASTELLOT: We don't have any specific
25 information. The individual people were instructed to,

1 as I understand it, as I recall, contact the other people
2 or the other people could contact the coordinator, either
3 way, but to my knowledge, I can't tell whether this was
4 done in any specific case.

5 DR. HABER: The coordinator was charged
6 with the responsibility of filing the paper. At the time
7 we made these assignments, I instructed the other members
8 of the Committee to contribute if they had the desire,
9 and these names represent that group.

10 DR. HALPERIN: Mr. Leman wanted me to say he hadn't
11 discussed his paper with any of the contributors nor had
12 he contributed to any of the other papers where he was
13 listed as a contributor.

14 DR. HABER: All right.

15 DR. HALPERIN: The question that was asked was
16 could one do a valuable epidemiologic study of the
17 Vietnam veterans to try to answer the very pressing question
18 concerning illnesses that were coming up in that group
19 and their association with possible exposures in Vietnam.

20 Basically the way Mr. Leman addressed this
21 question was by saying that it was certainly a valuable
22 and important thing to try to do that. It would require a
23 great deal of information that we do not know at this point
24 whether it exists or not, and we personally have no access
25 to knowing whether it exists or not.

1 You can see he says whether any or all of this
2 information is available lies in the knowledge of the
3 Department of Defense and the Veterans Administration, but
4 if the information did exist, that it may be possible to
5 do a meaningful study. So really he has answered your
6 question with a question, which is, before we say whether
7 there can be an epidemiologic study, one that would be
8 valid and meaningful, we have to know specifically what kind
9 of pertinent information is available to do that kind of study.
10 What he addressed in his paper was the general kind of
11 information that may be necessary.

12 DR. HABER: The only thing we can say is
13 that we need to get back to our own members of the Advisory
14 Committee to be able to take this up with the others who
15 were respondents for this in the hopes that they could
16 produce a more significant answer to this question than
17 appears to be the case.

18 DR. HALPERIN: I don't think that kind of further
19 discussion is really what is needed, in my opinion. If
20 Dr. Lemen's draft position paper could perhaps be given to
21 a staff person to answer specifically whether this
22 information exists and what the character of the information
23 is, then as an epidemiologist he could evaluate that
24 information what could be made
25 of it.

1 DR. HALPERIN: We would then endeavor to
2 make that available. I am going to be called away for a
3 moment. Dr. Schepers, will you hold up for me? Excuse me.
4 There is an urgent summons I have.

5 DR. MURPHY: Doctor, may I ask Dr. Halperin a
6 question?

7 DR. SCHEPERS: Yes.

8 DR. MURPHY: I don't know if this is what was
9 intended or if it is the typing, but it says before
10 drawing meaningful--the third paragraph, "Before drawing
11 meaningful conclusions about the mortality experience..."
12 is only mortality intended, or is it morbidity and mortality?

13 DR. HALPERIN: His first emphasis was on mortality.
14 Morbidity and reproductive effects are even more difficult to
15 answer, as he addressed in his draft position paper, because
16 the data is all the more difficult to get hold of, that
17 is, there is only one definitive piece of paper that is
18 needed to define mortality experience, and that is a death
19 certificate.

20 Morbidity and reproductive effects, he had no information
21 available to him as far as the kinds of information that is
22 available concerning veterans in the United States, and it
23 really is a much more difficult question.

24 DR. MURPHY: I understand--just because it is the
25 first thing that is addressed without these introductory

1 comments--

2 DR. HALPERIN: I think he goes on, "Additionally,
3 studies of morbidity and reproductive effects among the
4 exposed population of veterans can be conducted, if medical
5 records for the exposed and non-exposed populations of
6 veterans and their families can be reviewed for the years
7 subsequent to service in Vietnam"

8 He goes on in more detail. I think the real
9 question is to answer this one needs to know what data one
10 can work with.

11 DR. SCHEPERS: Could I clarify a little? There
12 are two types of veterans--those who come to the Veterans
13 Administration and those who don't. The majority do not
14 come to see us. Generally the veterans who come to see us
15 are older men, and there are specific reasons for that
16 which I don't need to go into, so it is very likely that
17 the majority of the Vietnam veterans do not yet come to see
18 us.

19 Any epidemiological studies should take cognizance
20 of that difference because the health problem which may
21 be related to Agent Orange exposure could be residing
22 amongst those we never see rather than the ones that we do
23 see.

24 Secondly, to start with mortality for this
25 particular group would be unusual because they are young

1 people, and we do have very accurate mortality records
2 pertaining to veterans who do come to see us, but we don't
3 know anything about veterans who die outside of VA
4 hospitals.

5 DR. HOBSON: We have very good records of those
6 who die because of the benefits that are paid at the time
7 of death to veterans.

8 They have not been calculated for the Vietnam
9 veterans, but the Follow-up Agency of the National Research
10 Council feels that we know of 95 to 98 percent of the
11 deaths that occur among World War II and Korean War veterans,
12 probably as high a number among the Vietnam veterans.

13 DR. SCHEPERS: Would that apply to the Vietnam
14 veterans, too?

15 DR. HOBSON: So far as anyone knows, because
16 the death benefit is paid. Usually they say the second
17 question that is asked by the undertaker is, is he a veteran.

18 DR. SCHEPERS. That is very useful.

19 DR. HOBSON: So we do have very good mortality
20 records, and that probably was the reason Mr. Lemen
21 included that.

22 While I have the floor for a moment, I would like
23 to point out that in the position paper question that was
24 sent out, the first sheet that is here, the quotation that
25 2.4 million veterans reportedly may have been exposed, I

1 think this is the inversion of those figures that occurred
2 sometime back. It should be 2.4, and I think the correction
3 should be made.

4 It is also, I am afraid, in Dr. Brick's letter
5 a little farther on, too. This error was made early on, I
6 understand, but it is an error.

7 DR. SCHEPERS: It is purely a typographical
8 error, and it has survived through this document, so we will
9 correct it at this point.

10 Thank you, Doctor. Any further discussion of
11 this proposed position paper? Is it agreed then that the
12 word "morbidity" should be included?

13 DR. MURPHY: Well, I don't know. I understood
14 Dr. Halperin's clarification. I personally feel that for
15 someone who isn't privy to this discussion, reading this
16 might give the impression that the only concern was with
17 mortality or the big major concern, because this leads into,
18 it says mortality.

19 It does not introduce, as you did, Dr. Halperin,
20 the fact that there are two ways of looking, or there are
21 at least two aspects of it. It is just a matter of, I think,
22 a little introductory sentence, but I would accept mortality
23 as being a valid and measurable end point.

24 DR. HALPERIN: It is certainly valid, and Mr.
25 Lemen has said that studies of this may be able to be done.

1 but you have got to understand he is a very pragmatic fellow
2 and what he is really saying here is not to quibble with
3 emphasis. It is all important, as you are saying. The
4 only way to answer whether it can be done is to know what
5 kind of information exists, and he is not privy to that
6 knowledge and, therefore, really can't answer the question.

7 DR. MURPHY: I understand that, too.

8 DR. HALPERIN: If anything functional is to come
9 out of this position paper, No. 1, it is that we have to
10 come up with a mechanism to get from the staff to the
11 Advisory Committee some description of specifically what
12 kind of information does exist.

13 DR. SCHEPERS: May I ask Ms. Kilduff whether she
14 knows how many Vietnam War veterans have died? Do you
15 have that figure?

16 MS. KILDUFF: I imagine we could get it for you,
17 but I don't have it right now.

18 DR. SCHEPERS: Would it be obtainable today?

19 MS. KILDUFF: I will try.

20 DR. SCHEPERS: Then we would know how many we
21 are talking about for the mortality figure. If it is only
22 200, it is a very small study. If it is 50,000, it is a
23 very large study.

24 DR. MURPHY: But the record could be talking
25 about prospective as well in this implication of this paper.

1 I don't seem to be able to make my point to either of you,
2 so maybe it isn't important.

3 My only question is when I read this and when
4 I would assume that others who might read this hadn't
5 heard this discussion, they would have the same reaction I
6 did when I got to the third paragraph, and when it first
7 starts talking about drawing conclusions, it refers to
8 mortality, and they would have the reaction, my God, is
9 that all they are concerned about is mortality?

10 Now, what I am saying is that, the introductory
11 statement that Dr. Halperin has outlined today, would
12 that be inserted before that? That would take care of my
13 concern because he points out mortality studies, current
14 and prospective, have value, but you need a certain kind
15 of information for them to be valid, and then goes on to
16 cover other, something less than mortality, i.e., various
17 morbidity studies, and that is what I am appealing for.

18 DR. HOBSON: No. I think if it starts off with
19 a sentence at the start of that paragraph it would be all
20 right.

21 DR. MOORE: I think the answer to a question
22 might have relevance to this. The question is that earlier
23 today we heard that, well, first of all, we are aware of
24 one thing -- that is the prospective study within DOD which
25 is the Air Force's study on Operation Ranch Hand which we will

1 hear more about this afternoon.

2 Secondly, with regard to exposure information,
3 it was stated earlier that in response to a request to
4 DOD, they gave tapes that essentially were similar tapes
5 that had been prepared for the National Academy of Sciences
6 Committee on the Effects of Herbicides in Vietnam.

7 What I lack is that my sense is that the majority of
8 veterans who are making claims are not Air Force but indeed
9 are Marines and Army, and if that is the case, the
10 information that DOD has provided gives no indication at
11 all with regard to troop movements or troop concentrations
12 in relation to the Air Force information which has been
13 provided as to where they sprayed and when they sprayed,
14 and that is the type of information. I do think, that
15 Dr. Lemen was really saying unless we can have that, you
16 can't really design a study. Until you have the data, you
17 can't decide whether you can or you can't.

18 DR. SCHEPERS: Is all this clear to everybody?
19 It is not yet clear to me.

20 MR. LENHAM: Your point is well taken. Just
21 for information purposes, I know in our legislative
22 headquarters alone, Operation Ranch Hand, I believe, is going
23 to be doing a study on 1200--

24 MAJOR BROWN: Approximately 1200 individuals
25 that were part of that operation.

1 MR. LENHAM: Just in inquiries alone in how to
2 go about filing claims and what have you, in our
3 legislative headquarters we have received over 1300, just
4 here in our Washington headquarters, 1300 responses from
5 veterans indicating some sort of a problem that they feel
6 is related to exposure to the herbicide, not saying that
7 all of these are valid, but this is what we are looking
8 at, so you know this is vast over the country. This is
9 going to be multiplied quite a bit, so your point is well
10 taken as far as looking into the troops in the field.

11 DR. SCHEPERS: Just for clarification, in case
12 it needs clarification, Operation Ranch Hand is the
13 prerogative of the Department of Defense because these are
14 employees of the Department of Defense. They are not yet
15 veterans. We can't study them until they become veterans,
16 so this is their baby, not our problem.

17 MR. LENHAM: Right. I understand that.

18 DR. SCHEPERS: The 1300 you are referring to are
19 Ranch Handers?

20 MR. LENHAM: No. I am referring to the 1300
21 Marine, Army personnel, what have you, veterans. I am
22 referring specifically to veterans that have inquired into
23 our legislative headquarters expressing concern that they
24 have either medical problems that they now have and they
25 feel are related to their exposure to the herbicide, or

1 medical problems that their children now have which they
2 feel might have a co-relationship with any herbicide
3 exposure.

4 MR. ENSIGN: Could I make a point and share a
5 bit of information? I talked with Jack Spay, who is
6 President of the Ranch Hand Association, and his estimate
7 was that no more than 10 percent, possibly 15 percent of
8 the 1200 population are today presently on active duty, so
9 we are not talking about people that are active duty Air
10 Force personnel today.

11 We are talking about people, 85 percent, probably
12 90 percent, who are veterans, so just logically it does follow -- you
13 must conduct that within VA, not the branch in which they were on
14 active duty. You are talking about a veteran.

15 DR. SCHEPERS: We have no problem with that. We
16 have come across one or two individuals who have claimed to
17 us that they were Ranch Handers and are now ill. We have
18 also received letters from other Ranch Handers who
19 emphatically deny that they are ill and claim that those
20 who complain are not experiencing the same thing as they
21 are experiencing.

22 We can study those Ranch Handers once they
23 have left the service of the Department of Defense, and
24 they are very welcome. We are looking for them, so if you
25 know of them, if you have their names and addresses, let us

1 know. We will track them down because we are quite
2 interested in that group.

3 Any further questions?

4 DR. LEVINSON: Let's go back to the information.

5 I forgot who asked the questions about the tapes. The
6 material we are obtaining from the Department of Defense
7 is not the material that NAS had. It had data on spraying.
8 We have that information. The information that we are
9 attempting to gather from the Department of Defense also
10 includes troop movements which NAS did not have, so if it
11 is available, that is a very difficult quest, we will have
12 that information.

13 We will, however, also use the tapes, the spraying
14 tapes, which NAS used in its earlier report, and attempt to
15 correlate the two separate bodies of information.

16 We are aware, we have estimates from all of the
17 services, of the gross numbers of people who might be
18 exposed, and this is as close as you can come, gross
19 numbers, because exposure is very difficult to define.
20 We are aware of the number of people in the Army, the Navy,
21 Marines and Air Force who might have this exposure.

22 The Ranch Hand group is of particular interest
23 as far as we understand because of the fact that we can
24 in many of these cases quantitate or come close to
25 quantitating exposure, so this is why it is a particularly

1 valuable group for study.

2 As far as the Air Force versus the VA, the Air
3 Force wanted to do the study. They felt they were prepared
4 to do it, and I think since they have gone quite far in
5 developing the protocol, it is very appropriate they continue
6 and I know from the Surgeon General that they are very
7 eager to continue at this point.

8 MR. GOLINKER: You stated that you had received
9 from the service the estimate of the gross number of people
10 who were exposed.

11 Could you tell us what that number is, please?

12 DR. LEVINSON: No. It changes every day.

13 MR. GOLINKER: Are we in the hundreds of
14 thousands?

15 DR. LEVINSON: Yes. It is certainly less than
16 the 2.4 million. The current rough estimate that we have
17 is somewhere around 500,000, but this is a very rough
18 approximate estimate. It depends strictly on how you
19 define exposure.

20 MR. GOLINKER: Do you know when the military
21 services will be able to, have you asked for a deadline as
22 to when their search of their records on troop movements
23 would be provided?

24 DR. LEVINSON: No, we haven't asked for a deadline
25 because it appears to be a very complex and cumbersome

1 process. The unit histories, because of war-time
2 conditions, as we understand it, are only partially complete
3 and the process of searching out this data up to this
4 point is a matter of manual rather than a machine type of
5 operation, so we remain in negotiation with them about how
6 this data and if the data can be gathered, and we do not
7 as yet have a deadline as to when they will be available.

8 MR. GOLINKER: Thank you.

9 MR. De YOUNG: The study of Ranch Handers
10 looking for effects of herbicides strikes me as analgous
11 to a study of bombardiers looking for the effects of high
12 explosives. You don't look at the people who drop the
13 weapon. You look at the people upon whom the weapon was
14 used, and I really have trouble with that study for that
15 very reason.

16 I would second Mr. Lenham's comments earlier that
17 we are getting calls from the grunts and from the dogfaces
18 who were down in the mud, who were drinking contaminated
19 water, eating contaminated food, who were sleeping in
20 contaminated jungles and so on and so forth, and had
21 literally a 24-hour existence with these chemicals at some
22 point.

23 I will grant you it is harder to document in
24 terms of dosage levels, but I end this with a question.
25 By what logic and what facts do you include the Ranch Handers

1 as a good target population? Are you certain of how they
2 were exposed and for the hours they were exposed?

3 DR. SCHEPERS. It is really Major Brown's
4 preogative to comment on that, but we first discovered
5 about the Ranch Hand group about a year ago, and seized
6 upon this group as being a group of military staff whose
7 exposure to the material Agent Orange could be very clearly
8 defined.

9 There is no argument about it that these people
10 lived in their planes, ate off their planes, drank water
11 in their planes, sloshed the stuff all over themselves
12 when they were dedrumming, which is one of the new words
13 we discovered, pouring it into their planes, and they were
14 spraying, and some of them were spraying, were following
15 other planes that had just been spraying and riding right
16 into the mist, so there is no argument in my mind that
17 these people were exposed, and therefore if they have
18 symptoms, their symptoms might elucidate this problem.

19 By focusing on the Ranch Hand, we did not at all
20 try not to focus on the man on whom the material was sprayed,
21 but earlier today there was some discussion as to whether
22 we know precisely where the men were, when the spray planes
23 went over. You have just given the answer in that you
24 said they slept in the stuff. They ate the stuff. They
25 drank the water, so if the spraying took place on the top

1 of a hill and the men were down in a valley which was not
2 sprayed, they could still have been exposed through the
3 water they drank. So we essentially are going from the
4 base that anybody who was in Vietnam at the time when spraying
5 took place could have encountered Agent Orange or dioxin
6 in some form.

7 MR. UHL: I would like to address a question to
8 Major Brown. How many pilots were there in Ranch Hand
9 and how many flight engineers or ground personnel in this
10 1200 population?

11 MAJOR BROWN: Well, I can't answer that question
12 for you exactly. We do know that the aircraft that was
13 primarily used, in fact only used, which was the C-123,
14 had three crew members in it. Two of them sat in the cockpit
15 and one in the aft section.

16 MR. UHL: Are you including the ground personnel
17 in this study?

18 MAJOR BROWN: They will be considered.

19 MR. UHL: But they are not the Ranch Hands?

20 MAJOR BROWN: If they were actually assigned to
21 the Ranch Hand organization; in the early years there were
22 some people that were taken in or asked or ordered, whatever
23 you want to call it, to come dedrum material and load the
24 aircraft. Those people were not assigned.

25 They may have been cooks. They may have been

1 aircraft mechanics. Those people were not assigned to
2 the organization itself, even when they were TDY.

3 MR. UHL: Do you have a breakdown now somewhere
4 back in your office, if not with you, or some other place
5 of the number of pilots versus the number of flight engineers
6 versus the number of people who were assigned to Ranch Hand
7 who may have been handling personnel or other personnel
8 within this 1200 population? Does that exist as far as you
9 know?

10 MAJOR BROWN: I don't know.

11 MR. UHL: It seems like we are dealing with a
12 relatively small population.

13 LT. COL. WOLFE: We are developing that list
14 right now. At the St. Louis records repository we are
15 looking for anyone, using multiple data sources to identify
16 100 percent, ascertain every last possible person that was
17 ever permanently assigned to our Ranch Hand unit.

18 MR. UHL: You cannot begin your study until you
19 have that population fully identified by name, address,
20 et cetera, and occupation?

21 MAJOR BROWN: That is correct.

22 MR. UHL: Which will be done by January, 1980?

23 MAJOR BROWN: That's right. We now have
24 approximately 1150 names of individuals. We are now in the
25 process of validating those names, and that is what Colonel

1 Wolfe was referring to.

2 MR. UHL: I just have one comment concerning the
3 study which I would like to make, which is I think that
4 we have to look at the quality of exposure very definitely.
5 I think it is a very valid study because we have talked to
6 many handlers and many flight personnel who obviously
7 worked the machinery who were in fact exposed all the time.
8 Pilots, many pilots we talked to were exposed, but less
9 so than the other people, the people who actually handled
10 the herbicides or actually did the spraying, working the
11 machinery.

12 On the other hand, there is another division I
13 think that has to be made between the quality of exposure
14 among this population and the quality of exposure which
15 I think Dr. Schepers has already referred to, in the other
16 populations, the ground personnel, or people in Saigon
17 who may have eaten the kind of shell fish that Dr. Nesselson
18 brought back and found dioxin present in.

19 DR. SCHEPERS: Is there any further discussion?

20 DR. GROSS: Just a question, sir--this
21 epidemiologic study that is discussed in Mr. Lemen's thing,
22 what do we have in mind? Do we have in mind a prospective
23 study or a retrospective study because the two are vastly
24 different. It would require vastly different numbers of
25 subjects, controlled and exposed I think, or perhaps both

1 kinds of studies are contemplated?

2 DR. SCHEPERS: It was my impression that we
3 wished to do the retrospective study first and then on
4 the basis of what we learned from that proceed to a
5 prospective.

6 Is there any difference?

7 DR. LEVINSON: No.

8 DR. SCHEPERS: First the retrospective and then
9 the prospective.

10 DR. HALPERIN: Until one has adequate information
11 about exposure of individuals and adequate information
12 about outcome, that is their mortality, morbidity and
13 reproductive effects, it is hard to pre-determine what
14 kind of study one is able to do.

15 DR. GROSS: You need the exposure information.

16 DR. HALPERIN: For both of them; the question is
17 what is there? What can be gotten out of it?

18 DR. SCHEPERS: Shall we go through the debate
19 on question one and proceed to question 2? This is for
20 Dr. Brick. You were the coordinator of question 2, which
21 was what are the best human population groups in which to
22 study the long-term effects of herbicides on health and how
23 may these studies best be conducted?

24 DR. BRICK: It is very difficult to me as a non-
25 epidemiologist to pick out the best populations to study,

1 and of course the discussion we have just had indicates
2 among the experts here that it is difficult, without
3 knowing the exact amounts of exposure, et cetera.

4 The information about 2.4 rather than 4.2 million,
5 we are talking about this group of veterans who were
6 allegedly exposed to Agent Orange, and I don't have any
7 idea as to what would be the best groups to study.

8 Now in Mr. Lemen's proposal he says the one final
9 end point that can be studied is mortality. Obviously
10 most of us have other interests than mortality. Most of
11 us have interest in morbidity, and apparently that is the
12 sticking point, which groups can be studied for morbidity?
13 How are you going to pick out these groups is going to
14 be difficult to decide, too.

15 Now in the preliminary remarks by Dr. Haber he
16 pointed out that there are 3100, there was 3100 veterans
17 who were examined under the Agent Orange program by the
18 Veterans Administration. That is correct, isn't it?

19 DR. LEVINSON: Yes.

20 DR. BRICK: These 3100, I don't know what the
21 details of the information relative to exposure is among
22 the 3100. We weren't given that information I believe,
23 but I think to make a start,

24 the Veterans Administration is going to have to
25 examine veterans who were in Vietnam during this period

1 of time and try to determine whether there are any specific
2 morbidity problems in this group as related,
3 to another group of Vietnam veterans
4 who were not in Vietnam, that is,
5 veterans who served in the services, but did not go to Vietnam,
6 to see whether there are any differences in the two groups
7 with reference to morbidity as well as mortality.

8 I don't think we are
9 going to get exact information from the Defense Department
10 with reference to a massive exposure, so it is a difficult
11 problem with reference to which groups are best to examine.

12 I think by making a start and trying to examine veterans
13 who were in Vietnam versus veterans in the same period of
14 service who were not in Vietnam, possibly some information
15 can be obtained.

16 DR. GROSS: Sir, I am experiencing an acute
17 sense of discomfort at the thought that since exposure
18 cannot be well documented, we ought to make the exposed
19 population sort of more inclusive as to include the whole
20 range of people who were in Vietnam.

21 I will tell you why this bothers me. I would
22 be surprised if all the military forces that were in Vietnam,
23 were really exposed to the same extent.
24 There must have been vast proportions who probably were
25 never exposed at all. It is difficult to identify people,

1 but consider the consequence if in fact there is an
2 association between Agent Orange, dioxins, what have you,
3 and certain health problems by having the category of
4 exposed people be considered so widely as to include
5 unexposed people.

6 That will tend to dilute or mask the association,
7 and I think there is a clear danger in that. If anything,
8 I would suggest that if we really want to discover this
9 association, we ought to restrict ourselves to the only
10 cases that were well documented to

11 have been exposed or exposed to fairly high
12 levels. That will make it much more likely for the
13 association to emerge
14 in a more amorphous group, in which a large proportion of
15 it would not have been exposed.

16 DR. BRICK: I would agree with that if we can get
17 exposure data. Now this is the point that Dr. Halperin
18 brought up, Dr. Lemen brought up with reference to whether
19 we can get meaningful exposure data, and the comments of
20 Dr. Moore with reference to troop movements, et cetera, et
21 cetera, and the possible exposure of certain troops at
22 certain times.

23 If that data were forthcoming, then meaningful
24 groups could be studied. From the conversation that I have
25 heard around the table here, I am not sure that that data is

1 going to be forthcoming.

2 Am I hearing correctly or not?

3 DR. SCHEPERS: It is very difficult. We have
4 a great problem getting that information. Ranch Hand is
5 the closest to getting a group with decisive exposure.

6 DR. HABER: we have proceeded to question No. 2
7 and we are on the topic of what are the best groups to
8 study.

9 DR. BRICK: I also brought up in that letter
10 that I wrote the possibility that the Department of
11 Agriculture might have some information. I don't know
12 whether they actually do, Dr. Haber, with reference to
13 exposed rural groups because these herbicides have been
14 used in spraying in this country and many others for
15 peaceful purposes rather than for purposes during war time,
16 and I don't know whether the Department of Agriculture
17 has that information on the possible dangers of exposure
18 of herbicides in that type of group.

19 DR. KEARNEY: I'm afraid we don't have the kind
20 of information that would be helpful in this kind of
21 determination. Largely our surveys are anecdotal with out
22 any survey or scientific approach to the subject.

23 However, we have under contemplation a
24 epidemiology study on exposure to 2, 4-D and 2, 4, 5-T. We
25 have met with CDC, NIOSH, NCI and other organizations and

1 they owe us a report as to the feasibility of doing this.
2 There are problems in this kind of a study. Knowing nothing
3 about it, I can speak with some authority! There are
4 statistical problems that have given us some major concerns,
5 just purely statistics, and until we can resolve for ourselves
6 that we would have a valid study, we are awfully reluctant
7 to press the button to initiate that study.

8 I understand, however, that the National
9 Association of Agricultural Applicators--it is the NAAA,
10 who are the people who provide, it is the National
11 Agricultural Aviation Association, who are the sprayers in
12 this country, have an epidemiology study underway in which
13 they are going to look at their own pilots and their own
14 health records and the health records of brothers and
15 sisters and progeny.

16 Are you aware of this?

17 DR. BRICK: No, I wasn't aware of that.

18 DR. KEARNEY: I am told this. That may be a
19 very difficult group because it is an extremely hazardous
20 population and whether one can make any valid conclusion
21 for them, their mortality rate is extremely high because
22 of the nature of the occupation.

23 DR. HABER: Dr. Lingeman?

24 DR. LINGEMAN: I talked to Dr. Erin Blair who
25 is an epidemiologist at the National Cancer Institute. He

1 told me there are two studies, one of which I think is
2 the one you were talking about, in which 1800 pilots,
3 apparently this same group, and the National Cancer
4 Institute may participate in this study.

5 The other study that he told me about
6 might also be applicable here as another population group
7 to study. Dr. Blair is in the process of doing
8 a cohort study of 4,400 structural pest control operators.
9 These are all Florida licensed, and the reason for using
10 the Florida group was that these people have all been
11 licensed since 1965 and have a Social Security Number
12 available for absolute identification. They are licensed
13 annually, and we know how many years their exposure has been.
14 This could be readily documented.

15 There are seven different groups of these
16 structural pest control operators. For the purposes of
17 our interest, Dr. Blair suggests that perhaps two groups
18 might be of interest, the lawn and garden spraying operators,
19 and those spraying for general household pests.

20 The problem here is that
21 the pest control operators are exposed to
22 multiple compounds; there will be a problem in separating them,
23 but it is possible be possible at least
24 of these people to find out exactly which ones
25 were exposed and maybe making some kind of association will

1 be possible.

2 This study will probably be completed later
3 in this year.

4 Dr. HABER: Which study?

5 DR. LINGEMAN: On the structural pest control
6 operators.

7 Dr. HABER: What is a structural pest control
8 operator?

9 DR. LINGEMAN: An exterminator, Orkin--I don't know.

10 Dr. HABER: Like a combustion engineer
11 turns out to be a garbage collector?

12 DR. LINGEMAN: I believe so, yes.

13 DR. GROSS: It is one that has to do with
14 structures rather than fields I would suggest.

15 HABER: Dr. Moore?

16 DR. MOORE: I would think that in responding to
17 this question, the first group to start with

18 as the best human population in which to study
19 the long-term effects, would be the group that has had the
20 longest exposure. Those whose occupation started

21 back in 1949.

22 Dr. Halperin and NIOSH are in the process of trying to
23 establish a registry on those people.

24
25 Some of these people had massive exposure, and

1 you have got 30 years post-exposure. That doesn't say
2 that is all one should do, but I think it's a start.

3 Dr. HABER: I think that clearly has to
4 be part of our response. The group that has had the
5 longest exposure would be certainly one of the best to
6 study. I can find no fault with that overpowering logic.

7 DR. MOORE: What that probably won't do, if
8 it is a retrospective type or a mortality
9 oriented study, is to bring
10 information to bear on the allegations of some veterans
11 that indeed they have got children that have problems.

12
13
14 DR. HALPERIN: Only if there is a prospective
15 part of it attached on.

16 DR. MURPHY: A related comment, I think
17 that the occupationally exposed group that can be specifically
18 identified with at least herbicides, and maybe more
19 specifically with those herbicides that are constituents
20 of Agent Orange, ought to be the population or group to focus
21 on.

22 I would be a little concerned with taking in
23 1800 or whatever sort of broad spectrum pest control
24 operators, and particularly structural pest control operators,
25 because I don't think they have exposures usually to the

1 chemicals that we are concerned about, and secondly, this
2 question of dilution that was mentioned earlier where we
3 start taking in groups of veterans who are not specifically
4 identified with exposure.

5 We might complicate that dilution problem by
6 taking in a group of people who are indeed exposed to
7 chemicals, who indeed might have a set of health injury
8 parameters that are quite apart from those with the group
9 concerned.

10 I think you have to be careful of just accumulating
11 chemical workers, sort of, as a group.

12 DR. LINGEMAN: I am not sure, Dr. Murphy, what
13 you mean by taking in. I am only reporting on a study.

14 DR. MURPHY: I am not implying that anyone is
15 taking it in, but we are talking about identifying other
16 groups. I am really sort of disagreeing with you with
17 respect to the value of the group that Dr. Blair suggested
18 for this particular purpose.

19 MR. LARSON: My name is Don Larson, and I am
20 here as an interested individual.

21 I would like to mention here in regard to long-
22 term programs with the herbicides that have been used
23 elsewhere, it might be particularly useful to go to the
24 records of the Australians and the New Zealanders because
25 they have had aerial spraying, aerial seeding for many,

1 many years, and with many weeds that would compete with
2 the growing seedlings that would have to be eliminated
3 through whatever means available. So they have used
4 herbicides for many years for those reasons, and their
5 records might be very useful.

6 DR. HABER: That's a good suggestion. I
7 have a note here from Dr. Erickson who is going to have to
8 be leaving this afternoon, and he had the responsibility
9 of discussing question No. 4. I would like to get your
10 comments on the record, Dr. Erickson. Can we interrupt
11 our normal course of events and move to topic No. 4 so
12 that you can get your statement on the record, and then
13 come back and wrap up?

14 DR. ERICKSON: Thank you.

15 DR. HABER: I don't know but what that will do
16 you the disservice of not getting it in context, but at
17 least we will get your statement.

18 DR. ERICKSON: Thank you, Dr. Haber. The question
19 which I had responsibility for answering was, is it possible
20 for herbicides to have long-term adverse effects on the
21 male reproductive system, and, in summary, what I said to
22 that question was yes. That possibility seems to me
23 the reason we are here, and it seems to me that a more
24 useful question would be, do they have an effect, or how
25 strong an effect is it, and so far as I am aware, we are in

1 a state of ignorance with regard to answers to those
2 questions.

3 Further, in my response to the question, I
4 pointed out that we are learning now that males may
5 contribute to reproductive problems, and that they may do
6 so through exposure to chemicals.

7 I wound up by saying that there is, of course,
8 a possibility that there is an effect which is of such a
9 small magnitude that we will never be able to detect it,
10 and finished by noting that there are a lot of veterans
11 out there to complain.

12 Just to make a concrete example, let's say that
13 as a rule of thumb roughly 10 percent of couples are
14 infertile. If all veterans who were in Vietnam are married,
15 that means there are nearly a quarter of a million infertile
16 couples.

17 Therefore, the complaints of a relative few, a
18 few thousand, really can't tell us much, and it seems to
19 me that the urgent need is to know whether these men
20 have a problem/^{which is}excessive in comparison to some appropriate
21 control group. That leads me back to lend emphasis to
22 what Dr. Halperin said earlier about the VA study.

23 It seems to me that the cart is before the horse
24 to a certain extent. There will be a need to decide what
25 it is you are going to use in the way of the control group

1 before you start gathering information.

2 DR. SCHEPERS. I wonder if I could ask whether
3 we have information, Ms. Kilduff, on the marriage status
4 of all veterans?

5 MS. KILDUFF: Yes, we do in our patient treatment
6 file, and I believe in the DVB file, too.

7 DR. SCHEPERS. But only the ones that report to
8 us, but not all veterans?

9 MS. KILDUFF: Only those in contact with the VA
10 through the DVB or the hospital.

11 DR. HABER: Okay. Is there any comment
12 upon question No. 4, or upon Dr. Erickson's
13 statement? We will come back after lunch and discuss it
14 in more detail, but I wanted to now ask whether there is
15 any comment about what Dr. Erickson has said.

16 DR. MOORE: I totally support what Dr. Erickson
17 has put down in writing, and I think it points out the
18 quandry that one faces, and that is this: if indeed
19 there are consequences of Agent Orange exposure and indeed
20 those consequences, reproductive or malformation effects
21 are very modest, the sad state of science today is that
22 you just won't be able to pick them up to such a degree
23 to be able to state there is a cause/effect relationship.

24 DR. HABER: I think I would readily acquiesce.
25 One of the things that makes it so difficult is ^{that} the quantitative

1 effects may be so slight that they may be lost in a sea of
2 other effects, and that just makes our job that much
3 harder. But clearly we have to find ways of dealing with
4 that, so as not to penalize those veterans who may be
5 bothered by this. I think we are going to have to find a
6 statistical way of handling that and translate that into
7 some kind of an action document.

8 DR. MURPHY: My question is more one of, I guess,
9 a technical nature for Dr. Erickson, who mentioned that we
10 are learning that males can contribute to reproductive
11 problems. Indeed I don't think I ever had any question about
12 that, but specifically I am wondering if there is evidence that
13 an injury to the male reproductive system can result in
14 malformations in offspring, when this injury has occurred
15 sometime in the past?

16 I know it is possible during the period of
17 spermatogenesis, for example. I don't know how many days
18 or months that would be, but it seems to me that this is
19 a critical kind of a technical question, and certainly
20 the decreased fertility could be permanent and long lasting.

21 DR. ERICKSON: I don't think I can really answer
22 that question with any authority, but it seems to me there
23 are a few bits of evidence which suggest that, yes, it is
24 possible.

25 For example, one of the suspect paternal effects

1 which have been suspect for a long time have been an
2 increase in dominant mutations for such things, disorders
3 such as the Apert syndrome which occur with increased
4 frequency to older fathers. That would sort of lead you to
5 think that it was an accumulation of insults over time
6 which had resulted ultimately in a defective child, so I
7 would guess it is possible. But I don't think there are
8 really any hard data to suggest that it does indeed occur,
9 but I don't think we looked very hard, either.

10 Downs Syndrome is a really very good example of
11 that. For years we have concentrated on the mother because
12 Downs Syndrome frequency increases remarkably the older
13 the mother gets. But in the last four or five years, we
14 have learned that probably 30 percent of babies with Downs
15 Syndrome have their extra chromosome from the father, that
16 something went wrong in meiosis in the father, yet we have
17 paid no attention to the father for years, so maybe our
18 state of ignorance is because we haven't been looking.

19 DR. HABER: Are there any other comments
20 about this? If not, why don't we adjourn to resume at
21 1:30, and we will continue then to go through these papers.
22 We will go back to^a discussion^{of} question No. 3, and then
23 further discussion on No. 4.

24 (Whereupon, at 12:15 p.m., the hearing recessed,
25 to reconvene at 1:30 p.m. the same day.)

AFTERNOON SESSION1:30 p.m.

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2
3 Dr. HABER: We would like to reconvene
4 the session from this morning, and there will be a change
5 in the order. I would like to ask the Air Force, which
6 has prepared two presentations for us, to go on first.
7 They will be finished, I hope, by 2:15, at which point we
8 will then begin to resume the discussion of the papers.
9

10 MAJOR YOUNG: It will take just a few minutes
11 to get the slides ready.

12 Dr. HABER: The presentations will be made
13 by Dr. Wolfe and Dr. Young, is that correct? Do you want
14 to introduce them?

15 MAJOR BROWN: Well, you are going to have
16 Major Young go first?

17 LT. COL. WOLFE: Yes.

18 MAJOR BROWN: Al Young is a chemist by training.
19 He has been associated with the Herbicide Orange issue for
20 many years. The paper that many of you have, he was the
21 principal author. He has been involved with the problem
22 since his early days in England, when he did some of the
23 spray trial work. He is now involved with the Air Force
24 epidemiology study.

25 Dr. Wolfe is involved with the epidemiological

1. study and is doing a great deal in learning about the
2. possible clinical side of the issue in terms of what should
3. be done, when it will be done, and how will it be done.
4. Unless someone has questions, I think that is adequate.

5. Dr. HABER: Okay. Well then, Dr. Young
6. will go first.

7. MAJOR BROWN: Yes, sir.

8. D R. HABER: As soon as you are ready.

9. LT. COL. WOLFE: Why don't I go ahead with mine
10. while Dr. Young is getting all his slides and things
11. together.

12. I am not sure quite the best way to handle all
13. of this, but I would like to begin to talk briefly about
14. some of the suggested approaches to the evaluation and
15. diagnosis of phenoxy herbicide toxicity in man.

16. My bias is, if I can call it a bias, really in
17. two directions. Number one, as a physician, I feel a real
18. need to respond to the medical care needs of the patient,
19. and as an epidemiologist, I feel that any information that
20. we do gather should have applications to answer the basic
21. scientific questions involved in this whole issue.

22. There are many factors that must be included,
23. must be considered before a diagnostic program can be
24. formulated to assess the adverse health effects that arise
25. from exposures to really any chemical or physical agents.

1 Several of these factors are presented in this
2 slide.

3 (Showing slides) The time between the exposure
4 and the development of effect, of course, allows us to
5 classify these resultant effects as either acute, subacute,
6 or chronic. There is also the duration of the exposure,
7 which can be classified as being acute or chronic. It
8 can also be classified as single exposure and intermittent
9 or continuous, sustained exposure.

10 Part of the problem here is while we have
11 talked about classical dose response mechanisms a bit this
12 morning, whereas the disease either increases in duration or
13 in frequency or amount, the effect is also increased in
14 severity, or occurs earlier in the process. There

15 has been some suggestion of a hypothetical dose-
16 response paradox with the dioxin kind of chemicals in that
17 with a high dose, the toxin would cause cell death, but
18 a low dose would possibly cause abnormalities of one sort or
19 another, in the cell but the cell would
20 still survive, and after a prolonged latent period or lag
21 time, subsequent disease would develop.

22 While this is purely hypothetical at this point,
23 it is interesting sometimes to consider what impact this
24 would have on some of our traditional medical ideas.

25 This concept of lag time or incubation period is

1 also quite important in assessing occupational illnesses.
2 This concept is the traditional one when we are talking
3 about the development of cancer and other malignant
4 problems at 15, 20, 25 years later. There is some
5 delay, some confusion and debate in the dioxin issue as
6 to whether these later effects are due to storage of the
7 chemical and then subsequent release with stress or
8 weight loss or other illness at a later period of time, or
9 whether the insult did occur at the time of the exposure
10 and this lag period then was required before the disease
11 manifested itself.

12 Confounding exposures to other chemicals in the
13 work place or in fact in background levels, exposure to
14 herbicides in lawn fertilizers, lawn herbicides to kill
15 the undesirable weeds in the garden, also make it very
16 difficult to attribute adverse health effects to any real
17 specific agent.

18 Many of the chemicals suspected of being hazardous
19 to health are used in combinations; 2, 4, 5-T was used
20 in combination with 2, 4-D and it also had the industrial
21 contaminant of dioxin. Many of these compounds by themselves
22 are used with dispersants or other contaminants of their
23 own.

24 The phenoxy herbicides as they were used in
25 Vietnam created additional problems for us. Again, the

1 Herbicide Orange and its predecessor orange and some of
2 the other herbicides were mixtures of several chemical
3 compounds.

4 The extremely wide range of effects that are
5 recorded in literature has been a problem. This slide is
6 just a brief summary of some of the multiple effects
7 caused by these chemicals. Many of these symptoms have
8 been attributed to all three -- 2, 4-D and 2, 4, 5-T
9 and dioxin--a lot of overlap. Many of these symptoms and
10 signs are quite subjective in nature. It would be very
11 difficult and they are very difficult to evaluate from a
12 medical standpoint.

13 The next slide goes into some of the components
14 of this, the asthenic syndrome, which has been reported
15 fairly frequently--anxiety, depression, apathy, sleeplessness,
16 emotional instability are very, very difficult to get a
17 real handle on in a physical examination.

18 There is a real severe lack of clinical, defined
19 clinical end points. The next slide will show a few more
20 of the disorders that have been attributed to phenoxy
21 herbicide toxicity. Again, several of these, cardiac
22 disturbance and some of the renal kidney problems, can be
23 detected with ancillary medical procedures, but all in all
24 we are still stuck and faced with a vast range of
25 symptomatology.

1. This slide is a brief review and folks here at
2 the VA were kind enough to give us some data on some of the
3 initial claims. There were 361 claims. Of course, they
4 were all male. Mean age was 34, and, interestingly enough,
5 there were at least on the average of two symptoms or
6 slightly more per claim.

7 Sixty-six percent of these were Army veterans;
8 17 percent as you can see were former Marines; 11 percent
9 had been in the Air Force, and 5 percent were Navy personnel.

10 DR. GROSS: How does that correlate with the
11 actual distribution by corps in Vietnam?

12 LT. COL. WOLFE: I am not sure of that. This
13 slide, again based on those claims, has broken the signs
14 and symptoms into these basic categories. As you can see,
15 the dermatologic and neuropsychiatric categories make up
16 substantial, are the two primary areas of difficulty that
17 these people have had.

18 We can now go back to that slide number 3 if I
19 may for just another brief minute or two. The identification,
20 as was also brought up this morning, of populations at
21 rest was is quite difficult and verification of their
22 exposure histories is even worse.

23 Now when it comes to reconstructing the exposure
24 history or trying to quantitate this exposure, we are in
25 a very difficult area, and Major Young will be discussing

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that to some extent a little later this afternoon.

This factor of identification and verification is probably the major obstacle to any epidemiologic study. In order to reach a valid conclusion, we really need to identify the entire population at risk.

We could do a study on those folks of the 3100 that have identified themselves to the VA as thinking they have problems, but in fact that probably represents a biased group. Those are again a group of veterans that we are aware of and they are also the veterans that, as has been mentioned, have presented themselves to the VA medical system.

After consideration of all these factors, there are really three basic approaches that can be used in formulating a plan of attack for the physical examination of individuals who are suspected, or who claimed results of herbicide toxicity.

These approaches essentially fall on a continuum from an examination, very limited in scope, limited just to the patient on one end, all the way up to an extremely comprehensive study of the patient, his family, his past history, and generally a social-cultural-medical survey.

The first approach generally would limit

1 itself to an examination of those conditions which are
2 proven or widely recognized to be the result of phenoxy
3 herbicide toxicity. This strategy would essentially limit
4 itself to dermatologic examination only. This approach
5 basically would assume that chloracne is the herald sign
6 of herbicide toxicity and that other signs of more severe
7 toxicity would not really occur in the absence of chloracne.

8 This fact may not be true, and there is some
9 very presumptive, very early evidence in some studies that
10 in fact there may be signs of toxicity without chloracne.
11 A lot of this information is being debated and has not been
12 verified at this point, but it is a potential problem.

13 The second approach is somewhat more comprehensive
14 in nature and would include evaluations of those conditions
15 which while not proven to be associated with herbicide
16 exposures are nevertheless suspected. These include
17 peripheral neuropathy, minor or even more major psychological
18 disturbances, and, of course, disturbances in liver function.

19 Recent reports from Seveso, Italy are beginning
20 to enlighten some of these areas and there have been some
21 reports out of Seveso concerning the neuropsychiatric
22 problems. It seems as though there is an increase in some
23 neurological kinds of problems--delays in nerve conduction
24 times and a few other sorts of conditions. A more
25 comprehensive approach is indicated not only by the spectrum

1 of illness that has been shown in the veterans' complaints,
2 but also from extrapolation from animal studies. While,
3 again, extrapolation from animal studies has been described
4 by some people as a wasteland of uncertainty, there is
5 still valuable evidence to be gained from those data that
6 will support the broad range of signs and symptoms that
7 had been recorded.

8 The third and most comprehensive approach to
9 the evaluation of herbicide toxicity would be an attempt
10 to evaluate the full range of effects that have been
11 attributed to herbicide exposure--assessment of reproductive,
12 immunologic, endocrine systems would probably need to be
13 included in this examination process.

14 Fertility histories, pregnancy outcomes, and
15 evaluation of family members would be an integral part
16 of this kind of an effort.

17 The major factors now that would affect the
18 choice of which diagnostic approach that should be used
19 are basically time and manpower. An approach as in No. 3,
20 comprehensive approach, would take a good bit of time to
21 plan and implement. As the comprehensiveness of the program
22 increases, the makeup of the medical specialists involved
23 to conduct that examination would also be a real constraint.
24 There just aren't that many neurologists. I know in the Air
25 Force we don't have an overabundance, and I don't imagine

1. the VA has an oversupply of neurologists either.

2. After all these factors have been explored, the
3. basic scientific question still remains--in fact, does
4. exposure to phenoxy herbicides result in adverse health
5. effects?

6. This decision as to which of these approaches
7. should be used is obviously not an easy one, and an
8. argument can be presented to support either of the three.
9. Perhaps the best solution lies midway along that spectrum
10. between the limited approach and that broad diagnostic
11. net cast by this third approach.

12. Whatever the choice, again my epidemiologic
13. background is coming through, I think standardized procedures
14. and examination techniques are absolute musts in this kind
15. of an effort, both to assure that every veteran gets the
16. same treatment that he deserves, and other veterans with
17. similar problems also, but also to again gather a data base
18. that can be used to answer this scientific question because
19. we in this room are not the only ones interested in this
20. basic problem.

21. Standardization of procedures will ensure a
22. maximum degree of comparability between examination
23. facilities. Obviously the best approach would be to use
24. a single center to bring everyone to one specific facility
25. and have the examinations performed by the same group of

1 physicians and paraprofessional personnel. This obviously
2 would be very difficult to do. I don't think anyone would
3 be able to handle the patient load that is expected with
4 this kind of a study.

5 The only other alternative would be to use
6 multiple centers, but with a very clearcut, very well
7 outlined protocol of procedures on how the questions are
8 supposed to be asked, how the procedures should be done.

9 A thorough general physical examination should
10 be an integral part of evaluation, regardless of the level
11 of complexity that is finally selected--urinalysis, complete
12 blood counts, sedimentation rates, platelet counts,
13 cardiograms, BUN's and creatinines, and lipid studies,
14 cholesterols and triglyceride studies, should probably be
15 considered as part of this general examination, and chest
16 X-ray or abdominal X-ray may . . . also be helpful.

17 The hepatic dysfunction that has been claimed
18 with herbicide exposures can be investigated with any of
19 the usual enzyme procedures, and a battery of several would
20 probably be quite desirable. SGOT's, transpeptides, LDH's
21 any number of these enzymes are commonly used and would
22 be quite helpful in evaluations.

23 Endocrine dysfunctions have also been suggested
24 as being caused by these herbicides, and an evaluation of
25 glucose metabolism and thyroid function would also be

1 important to consider. The dermatologic examination
2 itself should be performed in all three. Obviously all
3 three of these three approaches I have outlined include
4 a dermatologic examination and a detailed search for
5 chloracne and possibly the inclusion of evaluation of
6 porphyrin metabolism would also be very useful.

7 A complete, detailed neurologic exam is almost
8 a necessity. Some of the recent studies, the studies
9 underway at Nitro, West Virginia, the Seveso studies, and some
10 others have relied heavily on nerve conduction velocity
11 as measures of neurological function to detect early
12 clinical and even subclinical neurological disease, and
13 this may also be a very valuable tool.

14 The psychological function of these individuals
15 will also be assessed. This esthetic syndrome discussed
16 briefly earlier is very difficult to evaluate. Many of
17 these same symptoms are very closely age related. We all
18 age, unfortunately, and many of these things--the fatigue,
19 the boredom with the job, the loss of sex drive--many of
20 these things are obviously age related, and this is a major
21 confounding factor. Only through careful psychological
22 evaluation will these effects be able to be teased out and
23 hopefully be able to be separated from one another.

24 The reproductive effects which have been claimed,
25 impotence and some of the others, may well be able to be

1 evaluated with a determination of the reproductive hormones.
2 Semen analysis is also a very reasonable procedure, so
3 that can be included to investigate these phenomena of
4 fetotoxic effects--the abnormal birth, the miscarriages,
5 the birth defects.

6 In the past, most of the literature, most of the
7 scientific work has been based on the effects through the
8 female, but again the studies have just not been performed.
9 In fact, the male may well be able to transmit these
10 conditions, either through a chromosomal variation or it has
11 been suggested by some that dioxin may be excreted in the
12 seminal fluid and in turn exert an effect.

13 These again are hypotheticals that have not been
14 evaluated, even in some of the animal studies, and there is
15 a real need for some of this research.

16 Again, because of this lack of data, it may well
17 be important that in those individuals, who have a history
18 of fertility problems or a history of birth defects, and in
19 their families that the chromosomal studies may well
20 contribute to this kind of an evaluation effort.

21 Immunology studies can be useful. In
22 the aftermath of the Sevaso, Italy accident, immunological
23 studies were conducted and so far they have been unable
24 to detect any major effect on the immune system.

25 However, there are only three or four years now

1 after their accident, and in a few more years maybe some
2 of these immune problems may well surface.

3 Fat biopsies have also been suggested and this
4 is a difficult area. The procedures are very difficult
5 to do. They are very time consuming. There is a lot of
6 interference with the dioxin determinations by DDT residues,
7 PCW's that are ubiquitous in the environment and likely
8 very ubiquitous in everybody's fat. Everybody sitting in
9 the room probably has some of these contaminants floating
10 around. These contaminants show up in the lab procedures
11 that are now used. The ability to detect the differences
12 between dioxin and these other chemicals is a very
13 tedious procedure to perform.

14 For these reasons, it may be reasonable to
15 include fat biopsies only in those individuals who have
16 exhibited chloracne or other disease conditions that are
17 felt to be more likely due to the herbicide exposure, to
18 use the fat biopsy as a more selective kind of procedure
19 in specific individual cases.

20 The optimum approach to the clinical evaluation
21 of this herbicide toxicity again lies somewhere down that
22 continuum, and regardless of how comprehensive the examination
23 is to be, I feel it is still a real necessity to develop
24 a standardized program, and above all, to motivate the
25 examining physicians and the other paraprofessionals that

1 are involved to keep them aware of the problems, and aware
2 of their role in this whole effort.

3 However, it should be kept in mind that the
4 determination of cause and effect between abnormal health
5 and exposure to phenoxy herbicides cannot be based solely
6 on a clinical evaluation. Cause and effect really needs
7 to await more definitive epidemiology studies based on
8 large numbers of individuals.

9 The ability to make a cause and effect
10 determination again is based on numbers of people as well
11 as the prevalence of the disease condition you are looking
12 at.

13 If it is a very rare disease that is hardly
14 ever seen in the normal population, two or three cases in a
15 group of a thousand folks or so would be very meaningful.
16 However, if it is like many of these other conditions that
17 are age related, and they are very common, it may well
18 take studies of 20,000, 30,000 people to detect significant
19 differences in the incidence of heart disease, say, in a
20 group of Vietnam veterans.

21 In conclusion, we need to keep in mind that the
22 purpose of a diagnostic evaluation program is not to condemn
23 or defend the use of defoliants in the Vietnam War, but
24 rather to identify adverse health effects in the veteran
25 population and to refer these people to the appropriate

1. medical care and followup that they will need.

2 The question then becomes have there been, are
3 there currently, and will there be in the reasonably
4 foreseeable future any adverse health effects that can be
5 traced and linked to herbicide exposures?

6 Thank you very much. Major Young?

7 MAJOR YOUNG: (Showing slides) My first slide
8 is not mine. What I would like to do is to give you an
9 overview of, first, Ranch Hand in Vietnam. There are a lot
10 of misconceptions going on, and I think this overview will
11 give most of you a good feel for the Ranch Hand program.

12 It will also give you a good feel for perhaps
13 how many people may have been involved. I have a very
14 short film clip I will show in a few minutes after I give
15 some earlier shots or slides of the Vietnam area.

16 I would like to talk a little bit then about
17 exposure and give you some parameters that I think are very
18 important for our consideration of an exposure index.

19 Pacer Ho was the operation that the Air Force
20 was involved in in the destruction of the herbicide.
21 This was 1977, a timeframe when industrial hygiene techniques
22 were available to monitor the herbicide in the air, and
23 all during the dedrum operation and destruction of that
24 herbicide, those industrial hygiene data could be very
25 valuable in exposure in Vietnam, and I am going to bring

1 them up. Then last I am going to talk about the
2 environmental fate of the herbicide and dioxin as we know
3 it today. Someone earlier alluded to the fact that here
4 are these ground troops living in the area that had been
5 sprayed. They touched the plants. They eat the plants.
6 They touch the soil. They live on the soil.

7 Well, let us talk about how that in fact may
8 relate to exposure from our history of the environmental
9 fate.

10 I have to preface the use of herbicides in
11 Vietnam with two pictures. Those pictures deal with how
12 phenoxy herbicides have been used in the United States
13 and worldwide and continue to be used throughout most
14 of the world, that is, in this kind of a situation, this
15 is what prompted their use in Vietnam, and it is important
16 we understand that.

17 This is a right of way, heavily infested with
18 brush. This is the same right of way after two pounds per
19 acre one year later--an excellent technique for removing
20 dense brush, ecologically one that appears to be very sound,
21 and it was that concept then that prompted Maxwell Taylor,
22 General Taylor, in 1961 to go to President Kennedy and inquire
23 about the use of defoliants in Vietnam.

24 With this kind of a perspective, it became very
25 obvious that defoliants could be used in Vietnam to reduce

1 air attacks, and that was the salient reason why
2 they went to Vietnam, to save American lives.

3 To that end, in January of 1962 Operation Ranch
4 Hand began. After tests had been conducted to show that
5 effective defoliation could be carried out with aircraft,

6 Ranch Hand began.

7 Initially it consisted of three C-123's. By 1964,
8 the program was considered such a success that

9 six C-123's were committed.

10 By 1965, 12; by 1966, 18; and later in that
11 year, 24 aircraft; by 1967, 36 aircraft were flying Ranch
12 Hand missions.

13 Initially the crews were assigned TDY, temporary
14 duty to Vietnam. This was the '62 through '64 timeframe.
15 They were gone over for about a four-month period and
16 would come back to the United States. Many of them rotated
17 back and fourth for two or three years.

18 Beginning in 1965, the program began to have what
19 we call permanently stationed personnel. That is when the
20 large number of Ranch Hand people began to be assigned
21 to Vietnam.

22 Ranch Hand was the name of the squadron, the
23 aerial spray squadron, as well as the operation, and it
24 involved about 1200 personnel. Now some of
25 these may have been dedrummers and some may have been mechanics.

1 Many of them were pilots or navigators. They were all
2 members of the Ranch Hand program.

3 Herbicide was transported to Vietnam in 55 gallon
4 drums. Once in Vietnam, it was transferred by pumps from
5 the 55 gallon drums to F-6 tankers which
6 were transported to the aircraft.

7 I would point out many people believe that
8 Herbicide Orange went to Vietnam in 1962, but this is not true.
9 Herbicide Orange did not go to Vietnam until 1965. The
10 first use of the phenoxy herbicides in '62 were with
11 materials we call purple, pink and green. That is very
12 important to note because the dioxin concentration of
13 purple, pink and green was far in excess of that in orange,
14 and I will show you some data in a few minutes to elaborate
15 on that.

16 Likewise, the quantity involved was tremendously
17 different, but so were the number of people that would
18 have been exposed. Recognize that there were very few
19 ground troops in Vietnam in the '62 through '64 era, but
20 after that, the ground troops increased tremendously.

21
22 The primary dissemination vehicle was the C-123
23 aircraft. It was outfitted with what we call the internal
24 modular spray system, the AA45Y1, and it is important
25 because we have a tremendous amount of dissemination data

1 for this piece of equipment which may help in the calculation
2 of an exposure indices.

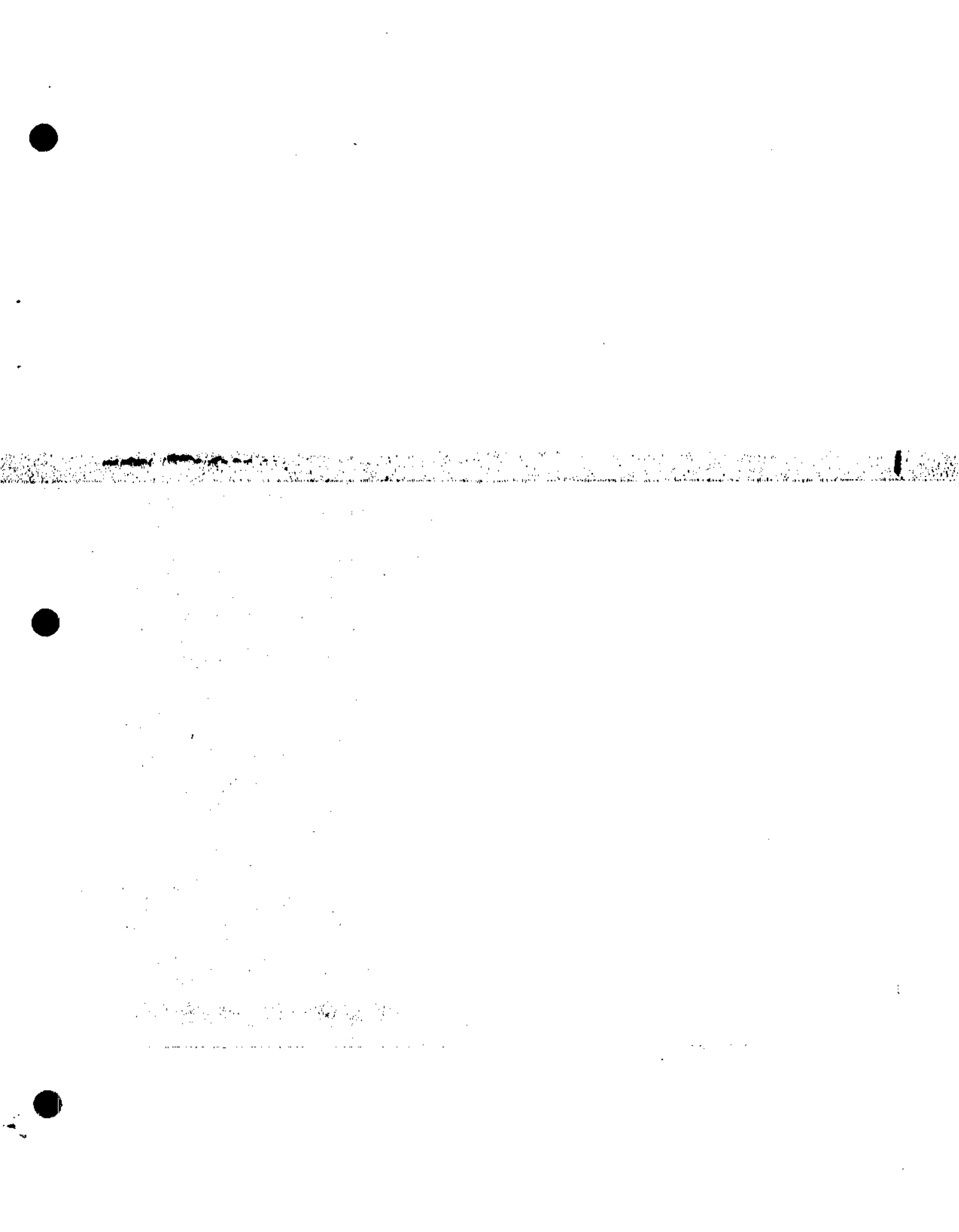
3 The C-123 is a cargo aircraft, and this is a
4 picture of a new one, very recent--this one from Vietnam,
5 but it is a recent picture. Inside the aircraft there is
6 lots of room, and that AA45Y1 dispenser would just roll
7 right into this area as shown in the slide.

8 In addition, spray booms were outfitted under
9 each wing. There was a 22 foot boom, 16 nozzles per boom,
10 one under each wing, and also one right behind the cargo
11 door.

12 Now that was the configuration for missions.
13 Let's go on a mission. Here we are in the C-123 in
14 formation. Now because of the few number of aircraft in
15 Vietnam in the '62 through '64 time period, a mission
16 usually consisted of only one or two aircraft, but by 1965
17 a mission could have as many as 12 aircraft.

18 In 1966, because the enemy began to focus
19 on the Ranch Hand aircraft, fighter support was provided
20 The orange band on the aircraft did not say it was carrying Orange
21 Herbicide but rather it was a Ranch Hand aircraft. It may
22 well have had Orange Herbicide inside of it.

23 Typically orange was disseminated twice a day in
24 the morning and in the evening. A couple of reasons were involved:
25 one, it was nice from a physiological point of view



1 was undertaken in order to remove the vegetation so we could
2 uncover enemy cache sites.

3 For example, in the Mekong Delta after a
4 defoliation mission, about two weeks later as the leaves
5 began to disappear and to fall, a whole boat city was
6 located, over 140 craft all tied together. Then it could
7 be attacked, but we didn't even know it was there before
8 defoliation. That is the point I am trying to make.

9 Here is shown an aircraft spraying different areas.

10 Here is a picture of the Ash Valley, three
11 aircraft involved here. Here is a canal that had been
12 sprayed about three months earlier, regrowth in some
13 places beginning to show. Here is a cache site, tunnel
14 network, a whole city built underground uncovered.

15 Here is a road uncovered. Here is another road,
16 conifer forest, a different application of a different
17 herbicide. This was white, containing 2, 4-D and picloram. We
18 mentioned the phenoxy herbicides 2, 4-D and 2, 4, 5-T. It
19 appeared in green, in purple and in orange, but we haven't
20 talked about the others.

21 You see, white was used also, picloram and 2, 4-D;
22 likewise cacodylic acid. To say one was sprayed by aircraft
23 does not necessarily say he was sprayed by Orange. There
24 could have been others. We haven't even talked about
25 insectide missions, and I will show you some of those.

1. These other sprayings continue to complicate that idea of an exposure
2 indices.

3 Here is a forested area that was sprayed in
4 1968. This is about half a dozen to eight aircraft wide,
5 well over 8 to 9 miles in length. The effectiveness of the missions
6 is one of the reasons why the critics began to charge ecological damage.
7 The truth of the matter is we sprayed 10 percent of Vietnam. That also
8 says that the likelihood of a troop moving into defoliated
9 areas would have been quite small -another point to consider.

10 Here is an area that was sprayed for crop
11 destruction. This particular area had been sprayed by
12 blue, i.e., cacodylic acid.

13 The
14 Army, the Navy, the Marines, and the Air Force all had
15 Hughey Aircraft, helicopters that were involved in the
16 spraying of herbicides around base perimeters.

17 About 120 different spray rigs existed to go
18 into helicopter units. The crews assigned to those
19 helicopter units were not assigned with a specific job of
20 spraying herbicide. It was an incidental job. Therefore,
21 there may be many helicopter crews that were involved in
22 just a few missions. Some may have been involved in many
23 missions.

24 Interestingly enough, very little Orange was
25 disseminated from helicopters. Most of the helicopter

1. disseminations involved cacodylic acid.

2
3 This is the hydraul system that fit into the
4 aircraft, and look at the rags wrapped around this. Could
5 exposure to the herbicide have been possible? You bet!

6 Here is shown the big application
7 of herbicides by helicopters. This was for what we call
8 control of elephant grass, a grass that would grow a foot
9 a day and get to be 30, 35 feet tall, and the enemy could
10 come in through that grass right up to the edge of the
11 base, lope over their mortars, and leave. We never saw
12 them coming or going, and hence the use of Agent Blue which
13 would brown that within 24 hours. Then it could be burned,
14 but because Blue was a contact herbicide, regrowth would
15 occur in just a few weeks and the problem would have to be
16 treated again--a recurring problem.

17 Here is an example, of Orange being
18 disseminated from a chopper. This is chopper swaths up
19 near the demilitarized zones that were sprayed. This is
20 a swath from a helicopter, B-52 craters on either side.

21 All Ranch Hand aircraft that sprayed herbicides, i.e.,
22 all C-123's were camouflaged, but there were also C-123's
23 spraying material that were not camouflaged. These were
24 "the bug birds." These were aircraft that disseminated
25 malathion, and there were hundreds of thousands of gallons

1 of malathion sprayed around wastes, around the edges of
2 the cities prior to battles. It would have been a common
3 thing for troops to say we saw a spray bird come over and
4 spray, but it was spraying pesticide not herbicides.

5 Of course, if that spray bird had been spraying
6 malathion for control of mosquitos, it would have been a
7 common sight throughout much of the combat regions of
8 Vietnam, and as a matter of fact it was a common sight.

9 The distinction, however, was that it was not a
10 camouflaged aircraft, and even the enemy knew that that
11 aircraft was spraying for the control of vectors, mosquitos,
12 and these aircraft took very few shots as compared to
13 Ranch Hand aircraft.

14 Another one of the differences, not only in the camouflage,
15 but in the nozzles under that wing--60 nozzels on each
16 boom, resulting in tremendous difference in terms of the particle size
17 that was sprayed.

18 I alluded to purple, pink and green. That amount
19 of that material used in Vietnam through out procurement
20 records is about 218,000 gallons. It was procured in late
21 1961. It was delivered to Vietnam in 1962, and no other
22 purchase, green or pink, was ever procured and sent to
23 Vietnam. This was it, a one-time shipment, so the first
24 few years, '62, '63 and '64, had only that material to
25 spray, just that quantity, and most of that was used along

1 roadways, and very small amount of crop destruction involved
2 with that material.

3 We are going to talk a little bit about the
4 TCDD contents in a couple of minutes. Now beginning in
5 1965 Orange arrived and Orange was the major herbicide
6 used in Vietnam-- in excess of 10,600,000
7 gallons, a tremendous quantity, no doubt about it, but how
8 was it used? Another question we have to ask.

9
10
11
12 Now
13 it doesn't say it is an exact figure, but we believe that Agent
14 Orange was probably disseminated
15 on about 3.2 million acres of land in Vietnam.

16 The inland forest received almost exclusively
17 orange. The mangrove forest received almost exclusively
18 orange. The cultivated crops received almost exclusively
19 blue.

20 I would like to stop for just a moment and show
21 you a very short film clip of Ranch Hand in Vietnam. We
22 are going to be able to see a lot of indications of why
23 the Ranch Hand population may be our very best population
24 to study because of exposure to herbicides. May I have
25 the film, please?

1 (Showing film) These are your F-6 tankers that
2 were used. Herbicide was transported to the aircraft.
3 Look at the ground. It is covered with herbicide.

4 These are the nozzels in the tail boom. There
5 were really no nozzel shutoff valves. Personnel do not
6 have gloves on. They are taking the herbicide into the
7 aircraft. Here is one of the valves. Here is a picture
8 of the C-123 at DaNang.

9 Here is a formation leaving DaNang, one of about
10 three major bases for the Ranch Hand aircraft, on their way
11 to a mission, at least six aircraft probably involved in
12 this one.

13 A pilot and a co-pilot, two officers in
14 the front; an enlisted man, the console operator in the
15 back; he is now turning on the AA45Y1. The leader aircraft
16 starts to disseminate. He is flying right into that spray.

17 I want to show you this terrain picture
18 on the next shot. You can see the aircraft in line. Here
19 is a good shot of a pilot. Watch as we go over the terrain
20 here. This is a side door that is open, which talks about
21 the effects of the herbicide perhaps coming in that side
22 door. We are going to go beneath that spray. We are
23 passing over a mangrove swamp, by the way. This is a side
24 door that is open--as Bill Curtis called it, the deadly
25 white fog. That is where the connotation comes from, this

1 white cloud.

2 End of film; that is a very, very quick
3 shot of disseminating the herbicide in Vietnam.

4 Let me talk now about exposure. I have given
5 you some factors for your consideration. We believe that
6 there were three groups of personnel exposed to herbicide
7 in Vietnam. The first group we call the Ranch Hand
8 personnel. I have already told you they number around 1200.
9 That epidemiological is the group that the Air Force proposes to focus on
in its study.

10 The second group we call the secondary support
11 personnel, the Army pilots that may have been involved in
12 helicopter spraying, the Navy pilots, even the Marine
13 pilots. There were also people that transported the
14 herbicide say from Saigon out to Beinhoy out to DaNang.
15 Those people transported the herbicide in 55 gallon
16 containers, but we know that in general, there was about
17 .1 percent of those containers that were defective so it
18 probably would not have been uncommon to have a drum leaking
19 and personnel picking that drum up and moving it around.

20 There were also specialized mechanics, electricians,
21 for example, that were assigned to work on various aircraft
22 that may have been in fact not assigned to Ranch Hand but
23 had to work in contaminated aircraft.

24 There were also during the Tet Offensive situations
25 where every single C-123 available was reconfigured for

1. transport and brought into the operation, so here is a
2 contaminated aircraft that non-Ranch Hand pilots might have
3 flown, and these are all people that may have been exposed,
4 a second group then--how big, we have no idea.

5 The last group that we could talk about would be
6 those individuals on the ground and there are some scenarios
7 that we could create, individuals that might directly be
8 exposed, sprayed directly by the aircraft, individuals
9 that might have gone into an area that had just been freshly
10 sprayed, or individuals that might have gone into an area
11 weeks or even a month or two months after defoliation
12 operation, so those are the three groups that one might
13 talk about.

14 How large are those populations? We have talked
15 about the size of the Ranch Hand. This morning we heard
16 the figure 500,000 for the ground troops, but if you
17 suggested about half all the ground troops in Vietnam were
18 involved in combat operations, about a million troops may have been
19 involved in areas that might have been defoliated. Recognize, however,
20 that 10 percent of Vietnam was defoliated.

21
22
23 There were many bases that did not receive any
24 herbicides of any kind, so that has to be considered.

25 We believe that for a troop to have fully received

1 herbicide directly, no canopy involved, just actual
2 herbicide application on top of them, was probably a unique
3 event; that they saw aircraft disseminating herbicide may
4 not have been unique. That they perhaps were involved in
5 being sprayed by a bug bird may not have been unique, but
6 we believe it to have been unique for a Ranch Hand aircraft
7 to have sprayed troops with Orange-- although it might have been
8 some other situations with even blue or white. It was probably also rare
9 for ground troops to move into an area that had just been
10 defoliated, probably a rare event, but much more frequent
11 would have been troops entering into an area
12 where defoliation took anywhere from two weeks to
13 a month to a month and a half, (so if we say a month average,)
14 and that probably was a frequent event.

15 Now how does one go about preparing calculations
16 on exposure? Well, once you start in this area, you have
17 to begin to speculate. What kind of scenario are we going
18 to set this man up in? Are we going to put him out there
19 with a short-sleeve jacket on, with a helmet on? How do
20 we actually create an actual event?

21 We don't know all the different ways these people
22 went into the areas, so just speculating what an actual
23 event might have been is very difficult. If we do come
24 up with a value, then how do we take and put it to a meaning?
25 What does it mean? We have no data on no-effect levels. We

1 have some data, but we don't know what they mean in terms
2 of man. There are no effect levels for animals perhaps, but for man
3 we just frankly don't know. To say that he received 10
4 manograms of TCDD per kilogram body weight may have
5 absolutely no meaning. That is the point I am trying to
6 make. I think we could calculate various exposure levels
7 for scenarios, but would that really be an honest evaluation?

8 You must remember that all of these things change--
9 the size of the individual, the body surface exposed, the
10 route of exposure, inhalation versus ingestion of large drops.
11 The mean diameter of a drop of herbicide is 350 microns.
12 That is not a particle that one would inhale but what
13 if it begins to volatize? Therefore, the temperature during the
14 time it was disseminated may be a big factor.

15 The frequency is also important, i.e., how many times did
16 an individual /go into that area that had been sprayed? How long was the
17 individual in the area? Was it Orange? Was it white?
18 Was it purple? Was it Blue? Was it malathion, and was
19 that herbicide produced back in the 1950's or early 1960's?
20 Did it contain a large amount of dioxin or was it in fact
21 Orange that had perhaps a low dioxin concentration?

22 Let me elaborate now on the nature of some of
23 these things. Many people do not understand about the
24 herbicide itself. Let's talk a little bit about that.
25 Then we can talk a little bit more about handling and quantity

1 sprayed which we have already alluded to a little.

2 For example, Orange contains about 8.6 pounds
3 of active ingredient per gallon. It is water insoluble.
4 Had it been sprayed into a pond, most of it would have
5 gone straight to the bottom and been in the silt. Even
6 more important is the insolubility of the dioxin, the
7 vapor pressures. Do you realize that so many other materials,
8 including water, are much more volatile than were the
9 herbicides. Furthermore, the vapor pressure of TCDD, which is somewhere
10 around one times ten to the minus 7, suggests that its
11 volatility would have been remote.

12 Viscosity of Orange is

13 about the same as light machine oil. It is non-
14 corrosive to metal, but it was deleterious to boots,
15 particularly neoprene, and that was one of the problems
16 that the Ranch Hand crews had. As they worked around
17 those aircraft, the bottom of their boots got eaten off
18 and that was a constant problem, to renew their boots.

19
20 The material was very stable in terms of a shelf
21 life, and that, too, should be considered.

22 Now in terms of some of the biological aspects,
23 I will very briefly talk about those. We know that in
24 the case of herbicides, when they are applied to a plant,
25 they are very rapidly absorbed and generally speaking,

1 they are rapidly metabolized.

2 In the case of animals, they are readily ingested.
3 Likewise, they are also excreted quite readily, and that
4 should be kept in mind.

5 Human skin absorption studies that have been
6 conducted suggest that about 6 percent of the applied
7 dose on the skin, and these were forearm studies, was
8 absorbed within the body. This was detected over a five
9 day period using urine excretion data. Toxicity was in
10 terms of LD-50 for rats, both by inhalation and by oral.

11 MR. GOLINKER: What on?

12 MAJOR YOUNG: This is on Orange. These are the
13 data I want you to see on dioxin concentration. We have
14 looked at some 488 samples of Orange. These were Orange
15 samples that had been produced probably some of them even
16 in the early dates, the 1965 timeframes, although we don't
17 absolutely know that.

18 These were samples collected over a long time
19 period literally. The mean concentration went from .02
20 parts per million less than .02 to 15 parts per million.

21 The weighted mean concentration of Orange we
22 believe to be about 1.98 parts per million, but compare
23 that to purple, material that had been produced much, much
24 earlier, and when you hear people speak of those large
25 values of 47 parts per million, they are really referring

1 to Purple. It has been confused by the press as being
2 part of the Orange inventory. It was separate and it was
3 different. That herbicide went to Vietnam, as I indicated,
4 in January of 1962. No more ever came into Vietnam--in
5 the range from 17 to 47 parts per million in the five
6 archive samples that we have, 32.8 parts per million mean,
7 so the pre-1965 versus the post-1965 periods may be important
8 in terms of dioxin concentration.

9 I mentioned to you about how Orange was used
10 specifically, about 90 percent in forest defoliation,
11 8 percent in crop destruction, and about 2 percent around
12 the base. We will talk a little bit more about the base
13 in a moment.

14 Here is some application parameters that may be
15 of interest. The speed of the aircraft was about 130 knots;
16 altitude, 150; the tank volume, 1,000 gallons; the spray
17 time, 3.5 to 4 minutes. The mean particle size was about
18 350 microns, which says it has a volume of about .61
19 microliters. One could say that if a man had 25 percent
20 of his body exposed, you could take a rough calculation
21 and get a volume that could have hit someone on direct
22 application. It can be done.

23 A spray swath normally applied at 3 gallons per
24 acre; a single tank would treat about 340 acres at a time.
25

1
2 Here are the chromacoat plates showing you how
3 that particle is disseminated, its uniformity.
4

5
6 All the drums were marked with a color band
7 around the drum. In the early 1962 timeframe,
8 those drums were marked with a 12 inch band, so it was
9 easier to distinguish '62 from '65 products even if the
10 color of the band had faded; about 50 days in shipping
11 time from the U. S. to Vietnam; about .1 percent of the
12 drums were defective, as I mentioned to you; 85 percent
13 went to Saigon; 35 percent went to DaNang, the two ports
14 that received it in Vietnam, the drums transported in Ranch
15 Hand squadrons by non-Ranch Hand personnel; transferred
16 then to the F-6 trailers, and the Orange that was used
17 around the base perimeters was Orange obtained from the
18 drippings of the drums.

19 All the drums after they were initially sucked
20 out by the pump were set up and drained into containers.
21 That was the Orange that was sprayed around the base
22 perimeters.

23 The drums went primarily to runway and bunker
24 construction, although we are aware that many of the
25 Vietnamese did in fact manage to take drums away from the

1. area where they had been stored, empty drums, and we do
2. know that many of those empty drums might have, probably
3. were used in the storage of gasoline.

4. Someone mentioned that C-120 aircraft, or C-123
5. aircraft probably defoliated Saigon. Not true. What
6. apparently happened was that discarded orange drums were
7. picked up by the Vietnamese, gasoline was put into them,
8. the gasoline was put into the mopeds, and the mopeds
9. fogged Saigon--could well have happened. It is a tale to
10. tell!

11.
12.
13. In terms of environmental fate, we have to talk
14. about the air, the vegetation, and the soil. The particle
15. size for the herbicide, is an important aspect for
16. exposure. About 1.9 percent of the particles that were
17. disseminated from our AA45Y1 spray system were less than
18. 100 microns. Now only those very small particles might
19. have been inhaled. You have to talk about very, very
20. small particles for inhalation exposure.

21. Now the bulk of them were in the 100 to 500 micron
22. range, and 20 or so percent in the greater than 500 micron
23. range. Because of the size of the particles, we have
24. studies that show that 87 percent of that material impacted
25. within one minute from the time it was applied. However,

1 about 13 percent of it may well have drifted or volatized
2 and one now can talk about downwind areas being contaminated.

3 Photodegradation of the herbicide has been well
4 documented in terms of effect on vegetation from canopy
5 studies of vegetation like that in Vietnam, studies from
6 Thailand, from Puerto Rico, they all indicate that in
7 the case of Orange, most of the material disseminated
8 by the C-123 aircraft, about 94 percent, was intercepted
9 by that vegetation, which says that only about 6 percent
10 might have penetrated to the ground had there been ground
11 troops beneath that multi-canopy forest.

12 Six percent would suggest about 1.4 pounds
13 active ingredient per acre, which would be very comparable
14 to a Ranch Hand application in the United States. Isn't
15 that an interesting comparison?

16 Cuticular penetration of the herbicide has been
17 shown to occur within some 30 minutes. This was the
18 ester formulation, a non-water soluble formulation, which
19 rapidly moves within the plant.

20 These are data taken on actual studies of soils
21 with herbicide Orange, tropical soils. They were the
22 Philippine studies. The half-life is only 7 days for 2, 4-D,
23 14 days for 2, 4, 5-T. In some sites where there were 3 gallons
24 / per acre applications of Orange growth of very sensitive
25 plant species resumed within a four month period, which says that the

1 persistence is very minimal of the herbicides.

2
3 The studies by Crosby and Nash are significant.
4 Crosby's study was done with herbicide Orange, while that of
5 Nash utilized sllivex. They concluded that 98 percent of the
6
7 dioxin was degraded in less than six hours, in
8 the presence of sunlight. They also concluded that when
9 dioxin is on a surface, a molecular layer, if it is down beneath
10 many layers, these degeneration rates may not hold true.

11 Thus, Nash found about 86 percent was degraded in about
12 32 hours.

13 In the case of TCDD, there is minimal transport
14 within the plant. A number of studies have shown this.
15 Also there is negligible plant uptake of TCDD. Our own
16 Air Force study by Dr. Kerry at Beltsville have all shown
17 there is essentially no uptake of TCDD by plants. It is
18 not likely that new plants growing in contaminated soil
19 would have had enough dioxin in them for someone who ate one
20 of them to become intoxicated with dioxin.

21 Studies by Crosby on soil showed about
22 20 percent that actually fell on the soil was degraded in
23 about six hours. Our own Air Force studies of sites where
24 heavy concentrations of purple had been applied in Florida,
25 and I will show those in just a couple of minutes, showed that

1 The half life of dioxin in that soil could well be one year.

2
3 However even after the herbicide the herbicide
4 disappeared, we have found continued persistence of the
5 TCDD. Those are facts, folks. Those are facts. In the
6 soil, once in the soil, the dioxin is very persistent, but
7 it doesn't leach. It doesn't go up in the plants. In
8 order for animals to have been exposed, they would actually
9 have to dig into that soil, to go back to one of the comments
10 made earlier this morning.

11 If the dioxin got into the soil, presumably one
12 could come in contact by handling soil. However, the
13 concentration would be very, very minute as compared to
14 what originally was applied.

15 There are data from our Eglin Air Force studies
16 that show that it does bioaccumulate in animals, and I will
17 elaborate on those.

18 Pacer Ho, is the operation on which the herbicide was
19 destroyed. Gulf Port, Mississippi, shown on the slide is
20 where the Air Force stored some 15,000 55 gallon drums of herbicide
21 Orange for about seven years prior to the time that it
22 was destroyed in September of 1977.

23 In the destruction of that material, the
24 dedrumming operations, we had an excellent industrial
25 hygiene program in operation. Not only did we monitor the

1 air within the dedrum facility itself, but also within
2 the inventory.

3 Here in the dedrum facility is shown that tops were
4 cut off the drums, the herbicide was sucked out and the
5 rest of the drum was dumped. As you see here, for many of these
6 workers in the facility, we had breathing zone units in operation during
7 that entire operation.

8 How much herbicide would they have taken in
9 during their actual operation? We have industrial
10 hygiene data, that can answer that question.

11 In the dedrum operations we know from
12 actual breathing zone studies that these kind of values
13 were found: for 2,4-D, 23.2 in micrograms per cubic
14 meter; for 2, 4, 5-T, 13.7.

15 Now you have a considerable order of magnitude
16 here for the dioxin determination. We did not detect
17 dioxin breathing zones, at a detection limit of 8 parts
18 per trillion in the air, 8 anograms per cubic meter. The
19 TLV, the time limit value of these materials is 10,000
20 micrograms per cubic meter.

21 In the air downwind from the dedrum facility,
22 you can see the values we obtained. Certainly the concentration
23 inside of the dedram facility in breathing zones was much
24 greater than downwind from the dedrum facility, as one
25 might expect.

1 Likewise, we sampled the water that was all around those
2 facilities, and these are data from the Johnston Island samples.
3 We did the same sampling out on Johnston Island where we had
4 an inventory out there of about 25,000 drums. There was
5 a chance for water contamination. We were able to monitor
6 the water. You can see there was no TCDD detected there;
7 but we did find 2, 4-T and 2, 4, 5-D. Downwind, we observed the
8 same sort of values as one saw at the Gulf Port.

9
10 I have very quickly gone through Vietnam.

11 I very quickly have
12 gone through exposure. I have some slides of Eglin, but
13 I know my allotted speaking time is up. I will just say that
14 our study at Eglin Air Force Base has taught us a number of things.

15
16 One, that the dioxin, the bulk of dioxin does
17 disappear very rapidly; about 97 percent of all the dioxin
18 applied down at the Eglin test site in northwest Florida
19 where 162,000 pounds of 2, 4, 5-T were applied on an area
20 of less than one mile, 97 percent of the dioxin disappeared.

21 Three percent which persisted is that which
22 is beneath the soil surface, and it has continued to persist
23 for almost 15 years. Half life is very slow in that kind
24 of a situation. However, we have found that animals that feed on
25 the plants are not contaminated. Only those animals that

1 interact directly with the surface are contaminated.
 2 The beach mice that go in and out of that soil have
 3 concentrations of as high as 2.6 parts per billion in
 4 their liver, yet after 70 generations of study in this
 5 animal, we looked at them for 70 generations, we have not
 6 detected changes in the frequency of the number of fetuses
 7 per pregnancy. We have found no evidence of tertogenesis,
 8 no evidence of mutogenesis; because the life of the animal
 9 is too short, we have no data on carcinogenesis, but it
 10 doesn't say it doesn't occur.

11
 12 We have found the toxicity
 13 symptom, however, at those concentrations. We find an
 14 enlarged liver weight in the pregnant female--highly
 15 significant--although we find no histological abnormalities
 16 in any of the organ systems, including the liver, that we
 17 have examined.

18 We have found no evidence of uptake by glands.
 19 We have found no movement to the aquatic community, except
 20 in areas where there is erosion. It does not leach
 21 by itself.

22 That is my summation. There are technical reports
 23 available with open distribution on the Eglin studies. The
 24 Vietnam data that I have presented is
 25 available in the technical report that has been presented

1 to all of you on the Committee.

2 DR. SCHEPERS: Thank you very much, Dr. Young.
3 Are there any questions for either of these two doctors?

4 DR. MOORE: With regard to looking for populations
5 to follow up the possible long-term health effects, I am
6 inclined to want to look at the population that most likely
7 got the heaviest exposure. According to Major Young's
8 presentation, that population would be that which is
9 associated with the '62 to '64 timeframe, even though they
10 aren't part of the Operation Ranch Hand.

11 MAJOR YOUNG: They were.

12 LT. COL. WOLFE: But there were very few of them,
13 somewhat less than 100 people involved.

14 DR. MOORE: You have got a 20-fold increase in
15 dioxin.

16 MAJOR YOUNG: We are well aware of that, Doctor.

17 DR. SCHEPERS: We have time for a few short
18 questions.

19 MR. LARSON: I would like to ask about the
20 time frame of the green cloud area of Seveso, Italy. I
21 understand some of the area is now beginning to be habitable
22 after what was it, two or three years since it was exposed.

23 Now how does this jive with what Dr. Young just
24 said?

25 MAJOR YOUNG: First, the dioxin was a totally

1 different source when it was put out as a herbicide.

2 It was put out with hydrogen right there. When it is
3 put out in caustic soda, there isn't a hydrogen donor
4 available right there, although there may be one when it
5 lands, so the way they were applied was totally different.

6 Dioxin is dioxin, but when it is applied in a
7 herbicide, its fate may well be different than when applied
8 in a caustic cloud. That is all I would point out.

9 MR. SMITH: Richard Smith--Major Young, was the
10 Air Force's Operation Ranch Hand so coordinated that it
11 was aware of the troop movements of the other branches of
12 the service?

13 MAJOR YOUNG: When an area was selected for
14 defoliation, that area had to be approved by the commander
15 of that area. You are talking about the Army commanders
16 would have been coordinated with, as well as the local
17 Vietnamese commanders. Documentation of a herbicide
18 mission was generally carefully done. There could have
19 been times, uniquely in my opinion,
20 where this might have not been true, but most times the
21 coordination was done.

22 As a matter of fact, in the '67 timeframe, it
23 had to go all the way up to Saigon and the upper echelons
24 for approval, and then leaflets were even put out in some
25 areas that were going to be defoliated.

1 MR. LINDLEY: Rusty Lindley--a lot of the Ranch
2 Hand was done along the borders to demarcate the borderline
3 between Vietnam, Cambodia and Laos, wasn't it, and also
4 what would be the effect--we used to see Monsoons pretty
5 heavily about four o'clock in the afternoon coming in from
6 Cambodia and Laos when we were operating on the border
7 areas--would that have any effect of picking up some of
8 the residual herbicides on the plants and exposing it to
9 troops that way?

10 MAJOR YOUNG: Demarcation was primarily done
11 with blue. Could there have been a mission of
12 orange with an immediate rainfall afterwards? The answer
13 is certainly there could have been and probably was many.

14 However, because it was a water insoluble
15 formulation and because it penetrates so very quickly, there
16 was probably very little runoff that could have occurred.

17 That doesn't say it didn't. There may have been
18 situations where most of it might have, but I don't think
19 that would have been a normal situation.

20 MS. BEVERDORF: Cheryl Beverdorf--I wanted to
21 ask a question in terms of diagnostic procedures. You
22 mentioned quite a few that are used in terms of tracing
23 herbicides.

24 Has there been any test done on hair?

25 LT. COL. WOLFE: Not that I am aware of. Hair

1 has been analyzed for lead and a lot of other metallic elements,

2 but I am not aware of anyone having checked it
3 for dioxin because it is basically fat soluble, and hair
4 is not likely a good spot.

5 MR. UHL: Dr. Young, two brief questions--one
6 maybe you touched on when I was out of the room. Do you
7 have a theory or perhaps even an explanation for data
8 that seems to show that dioxin is present in mothers' milk,
9 beef fat, and perhaps even meat of the shell fish from
10 Vietnam, number one, and number two, should we be concerned
11 with other toxic, if that is the right
12 adjective here, isomers of dioxin that may have been
13 produced in the manufacture of 2, 4, 5-T?

14 MAJOR YOUNG. I am speaking for myself. In
15 terms of the mother's milk samples of Dr. Messelson, the
16 fish samples of Dr. Messelson and Dr. Brockman, two things
17 should be kept in mind. One is where were the samples
18 collected? Art Westing has indicated those samples
19 were collected near Naval docks which is very interesting, because
20 Pentachlorophenol could account for dioxin contamination
21 in those kinds of samples, Accordingly, we don't know for sure if the
22 substance found actually is dioxin. We don't know for
23 sure the source of that "dioxin".

24 Dr. Messelson was the only one that did those
25 analyses. They were never confirmed by another laboratory.

1 I am not suggesting that his laboratory isn't the best, but
2 I am suggesting to you that the dioxin issue is so
3 complex that no two laboratories often come up with the
4 same data, and you must remember his analyses were done
5 when the instrumentation technique was new, and so I don't
6 know how much faith to put in on his data.

7 The Eglin data suggest that indeed dioxin can
8 get into the aquatic community, but it doesn't move very
9 far, only in erosion areas. We have never seen it move,
10 for example, in areas even where there is heavy dioxin.
11 In the silt we have never seen it move more than just a
12 short distance, hundreds of feet. To move 27 miles downstream,
13 and then to be present at that kind of concentration, 800
14 parts per trillion, would suggest that a massive quantity
15 of herbicide Orange would have been added directly to the water
16 a very short distance upstream. There is no other way to account
17 for those large concentrations.

18 MR. UHL: That takes care of the mother's milk
19 and the shellfish. What about the beef fat?

20 MAJOR YOUNG: The beef fat studies in the United
21 States would suggest there is only one positive, 60 parts
22 per trillion--Dr. Moore could be much more apropos to speak
23 on this than myself. That is an EPA study. I will back
24 off on it if I might.

25 MR. UHL: The other question was the other dioxin

1 isomers?

2 MAJOR YOUNG: There are many isomers available
3 in Pentachlorophenol, probably in 2, 4, 5-T dioxin, that
4 might be present there. You would have no more than 3 or
5 so isomers of the Tetrachlorodibenzoparadioxin, the
6 2, 3, 7, 8 being the most toxic, and the most numerous
7 of the three tetra isomers.

8 We recognize that it is possible for the 2, 7
9 dibenzoparadioxin to be present for 2, 4-D, but its toxicity
10 is totally different than the 2, 3, 7, 8.

11 DR. MURPHY: Are there analyses of Agent Orange
12 and blue or whatever for hexa?

13 MAJOR YOUNG: Yes. We have analyzed it, the hexa,
14 oxa-, penta-, and tri-isomers. We only find three tetras that
15 are present in Orange, and at very low concentrations; only
16 the 2, 3, 7, 8 being the most prevalent. We also find a tri-,
17 and a di-isomer.

18 DR. MURPHY: You don't find any hexes?

19 MAJOR YOUNG: No, we don't. Dr. Kearney, you are
20 aware of 2, 4, 5-T analysis. I am not aware of any.

21 DR. KEARNEY: Well, there is an early analysis
22 done by Wolfson, Enzer and Thomas that said that there
23 was hexa in 2, 4-D, but we have been unable to confirm it.

24 MAJOR YOUNG. Right. I was aware of that.

25 DR. SCHEPERS: I think we have exhausted all our

1 questions, so we thank you gentlemen both again for your
2 contributions, and we will proceed with the position papers
3 and we will deal with No. 3, coordinators Dr. Walter Melvin
4 and Dr. James Allen, who couldn't be present, so I believe,
5 Dr. Lingeman, you should discuss it if you wish to do so.

6 I will re-read the question, which says, "Of what
7 diagnostic value are the following procedures in assessing
8 possible herbicide toxicity, levels of dioxin in fat pad
9 biopsies, study of immune factors, study of chromosomal
10 patterns, study of liver microsomal enzymes? What additional
11 diagnostic procedures should be considered?"

12 May I ask volunteers from the Committee to
13 comment on level of dioxin in fat pad biopsies?

14 DR. MURPHY: Well, I gather that the answer to
15 this question was prepared largely by Dr. Allen just
16 because it has his name at the top of the page, and I think
17 his conclusion was the presence of dioxins in the tissue
18 indicates exposure. However, its absence does not rule
19 out previous contact is the answer to that part of the
20 question.

21 DR. SCHEPERS: Can we get anything further from
22 that position? Any contrary statements?

23 DR. MURPHY: I would also add with regard to the
24 area of hydrocarbon hydroxylase or the microsomal enzyme,
25 it is again, as he points out, rather non-specific. It

1 could indeed be a result of exposure to dioxin, but there
2 are so many other things that would also induce that
3 enzyme, or that group of enzymes that it would be rather
4 difficult to say it was cause and effect.

5 DR. SCHEPERS: Would it be worthwhile, therefore,
6 in the opinion of the Committee to pursue that further
7 if it is so diffuse?

8 DR. MURPHY: If you are dealing with current
9 exposures, I think it might be something that
10 you would design into a clinical study.

11 If it is past exposure, long past exposure, I
12 doubt very much whether it would have value just because
13 I think probably the effects would disappear. It is a
14 reversible effect.

15 DR. LINGEMAN: It is too non-specific.

16 DR. MURPHY: It is non-specific. The chromosomal
17 aberrations may not be. Somebody else should comment
18 on that.

19 DR. SCHEPERS: I believe that Dr. Moore told us
20 at lunchtime that there is some work that is being resumed
21 by his department on the Aims test, so we will wait for
22 the next meeting to hear from him since he is no longer here.

23 What about any additional diagnostic tests? Are
24 there any that can be suggested by the Committee at the
25 present time? I might mention that we are constantly

1 beseiged by the veterans asking us to do something to
2 diagnose their condition, and we don't know what to do.
3 We just have no specific diagnostic tests for Agent Orange.
4 Unfortunately, many veterans have been told that there are specific tests
5 and time leads to discouragement on the part of some of the veterans
6 involved.

7 DR. MURPHY: Just to comment, as we discussed
8 earlier today, demonstrating the presence of the dioxin within
9 a certain level would be, of course, a test of
10 dioxin exposure. Chances are, in my view, and I gather
11 this is shared by a number of other people, that you would
12 not find measurable dioxin level at a prolonged period after exposure
13 ceased. Furthermore, dioxin levels will not confirm or deny
14 previous exposure, nor confirm or deny that any condition
15 or complaint was associated with previous exposure.

16 Would you agree with that? Sad as it may seem,
17 there are very few chemical exposures to which any particular
18 measurement of any particular clinical condition is solely
19 diagnostic of that chemical exposure. We just don't know
20 enough about I guess how they cause their effects to isolate
21 them out, so I don't know that there is any specific
22 diagnostic procedures.

23 DR. SCHEPERS: May I ask that if any of
24 the members of the Committee or indeed anybody present
25 in this room were to hear or to read of a test that might

1 be applicable to our area of inquiry, that you would report
2 it to us at the next meeting so that we can consider it?

3 DR. MURPHY: Rather than ending my comment on
4 such a negative point, it would seem to me that again
5 there is a set of syndromes in which I suppose if a
6 certain number were common, this would lead to a presumption
7 of possible association.

8 DR. HALPERIN: Could I make a comment? The
9 question reads of what diagnostic value are these things.
10 We don't know what their prevalence is in a known exposure
11 situation, for instance, in one of the occupational
12 exposures.

13 If we don't know what the probability of exposures
14 is, to do diagnostic studies on potentially exposed individuals, doesn't
15 make much clinical decision theory kind of sense.

16
17 DR. SCHEPERS: Possibly after you have studied
18 the Arkansas data, you might be able to tell us more about
19 them. We have to wait for a solution.

20 Dr. Lee, did you want to make any further comment
21 on the diagnostic value of the fat biopsy for the record?

22 DR. LEE: None whatever, thank you.

23 DR. SCHEPERS: Let's proceed to question five
24 then, which was what topics should be included in educational
25 curricula being developed to upgrade knowledge of potential

1 herbicide toxicity among VA staff members? This was
2 assigned to Jack Griffith. Dr. Gross, did you get a chance
3 to go over, review with Dr. Griffith what he said?

4 DR. GROSS: The answer is no, sir. That is the
5 first time I have seen his response, right here. You all
6 can read this as well as I can.

7 Jack was thoughtful enough to have brought along
8 a training course, a package that we used in training
9 health professionals. As you can see, it is that big. It
10 contains some literature, a bunch of slides and tapes, and
11 you would be welcome to have that to see whatever use
12 this could fulfill.

13 DR. SCHEPERS: Could you leave it with Mrs.
14 Williams so that we can study it and see what practical
15 use can be made of it?

16 You know, Dr. Gross, that we are going to have
17 an educational exercise on Thursday and Friday for about
18 172 doctors, and we will see if any of that is even applicable
19 for that.

20 Certainly the presentation such as Dr. Wolfe
21 and Dr. Young made will be extremely useful to our staff.

22 Are there any other comments from the Committee
23 on this topic? We have drawn a blank sort of so far. Any
24 from the Steering Committee? None.

25 MR. HIGHT: Henry Hight, Board of Appeals-- from

1 what you have said, and I don't have a report on that, is
2 the VA continuing with the fat biopsy study?

3 DR. SCHEPERS: Dr. Lee will answer you.

4 DR. LEE: We have closed the accession of case
5 material at 34. We are now busy processing the data, also
6 waiting for the chemist to do his thing.

7 DR. SCHEPERS: Once we know what the answer is
8 from that study, we will know what to do next.

9 DR. LEE: I hope!

10 MR. HIGHT: Thank you.

11 DR. SCHEPERS: Let's proceed to question No. 6.
12 I am trying to beat a time limit because we have another
13 20 minutes for our meeting and six more questions to
14 consider.

15 This was a position paper on what sorts of animal
16 studies would make the most important contributions to
17 understanding the potentially toxic effects of herbicides
18 in humans?

19 The coordinator was Dr. Allen. The paper was
20 written by Dr. Allen. Has anybody had an opportunity to
21 study it? Would any of you like to comment on it? Dr.
22 Murphy, you are an experienced animal experimentalist.
23 Would you like to comment?

24 DR. MURPHY: I have a few lines emphasized in
25 yellow color here, but I didn't really have too much in the

1 way of comment. He does comment that he would select an
2 animal model which responded to herbicides in a manner
3 similar to man and was as closely related phylogenetically
4 as possible. "In our work, we have found the rhesus monkey
5 to be a suitable model."

6 I believe he is referring to the rhesus monkey in
7 PCB work, or maybe it is dioxin. I don't know how
8 Dr. Allen judged it was a suitable model because I don't
9 know that there is enough data in man to say that man
10 responds similarly, and certainly in this I think there are,
11 in the Seveso circumstance, one of the surprising things
12 I guess is that it wasn't any more severe, acute, apparently
13 systemic toxicity experienced by man than there was in
14 view of the rather severe effects on a number of laboratory
15 animals.

16 Of course, they were eating grain and forage and
17 so forth, and so I agree with the principle, but I don't
18 know what animal to select.

19 DR. GROSS: You mean domestic animal?

20 DR. MURPHY: I don't know what other--I mean non-
21 human animal. I don't know what non-human animal model
22 best represents humans. Do you?

23 DR. GROSS: No.

24 DR. MURPHY: For this particular study?

25 DR. GROSS: No.

1 DR. MURPHY: The principle is well taken,
2 but I don't know how to answer that.

3 DR. SCHEPERS: The statement was made a little
4 earlier by Dr. Young that--what was the little animal
5 called that burrows?

6 MAJOR YOUNG: The beach mouse.

7 DR. SCHEPERS: The life is too short for you to
8 be able to do a carcinogenesis study. Is that really true?

9 MAJOR YOUNG: The life is short only because of
10 high predation. At the Eglin test site we find that many,
11 many other animals feed on the beach mouse and in data
12 that I did not show you, we put animals into that site,
13 beach mice, and then came back at 90 day intervals and
14 we found that for the dioxin levels to reach the same level
15 as the animals in the environment, indigenous, it was
16 about 90 days, but we also found from that study that the
17 life of the animal was very short because other animals
18 preyed on it so rapidly.

19 DR. SCHEPERS: Could that animal be placed in a
20 laboratory where it would be protected?

21 MAJOR YOUNG: We have raised it in the laboratory
22 for as long as two and a half years.

23 DR. SCHEPERS: Could you produce any health
24 effect?

25 MAJOR YOUNG: We did not at the exposure rates

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that we gave the animal, which was comparable to those on the sites, but our population for a carcinogenesis study was very small and we felt it to be so preliminary as to be unpublishable.

DR. SCHEPERS: You said you went through 70 generations?

MAJOR YOUNG: In the field over the years of following those animals we began in 1970 and our last sampling of that population occurred in April of this year.

DR. SCHEPERS: Life wasn't too short if there were 70 generations for the animal to reproduce obviously, so were there any teratogenesis effects or would that also be destroyed by predators?

MAJOR YOUNG: Conceivably if you are going to examine for teratogenesis, you have to know when fertilization occurred, and because these are field populations, you don't know exactly when fertilization would occur and since how we examine the burrow is to dig up the nest and examine the female with the offspring, we have done this many, many times. We have never seen cases of teratogenesis of the 180 or so animals that we have examined.

DR. SCHEPERS: Did I hear somebody say today that somebody mentioned that dioxin is excreted in the spermatic fluid?

LT. COL. WOLFE: That has been hypothesized, but

1 no one has ever gathered enough material to have it
2 analyzed I guess.

3 I am not aware of any studies. That has been
4 hypothesized purely from a theoretical chemistry standpoint,
5 but no one has done that work yet.

6 MR. LINDLEY: I don't know what its significance
7 is, but there was some work accidentally done with dioxin
8 at the Jackson Laboratory in Bar Harbor, Maine, in an
9 experiment with pin worms that had considerable adverse
10 effects on their mice there that somebody might look into.

11 DR. SCHEPERS. Yes. We have seen most of those.
12 We are still trying to look for that ideal animal. Mr.
13 DeYoung?

14 MR. DE YOUNG: I am sure I don't have the ideal
15 animal, but I do have an animal, and I submit that we have
16 some pretty good documentation.

17 I would like to read a statement that you will
18 be seeing in print later this week.

19 "During July and August, 1972, I was assigned
20 to the K-9 Corps at Phu Cat Air Force Base. During this
21 period, many of our dogs came down with a mysterious illness."
22 This is written by an Air Force MP guard dog handler.

23 "The symptoms were that at first the dogs became
24 very lethargic and vomiting a lot. Then some of the dogs
25 who weighed 100 pounds or so suddenly lost weight drastically.

-1 I mean some of them lost over 50 pounds in less than two
2 weeks. The dogs had also developed a change of personality.
3 They became more aggressive during this period. The ones
4 still well enough to go out on patrol turned on their
5 handlers, were very hyper, and seemed very confused. Later
6 when we took these dogs to Cam Rahn Bay, they developed
7 severe rashes and blotches of hair fell out. Nobody really
8 knew what caused this.

9 "At the same time, almost all of the K-9 personnel
10 got a sudden, severe case of diarrhea and abdominal cramping.
11 There were lines of people so long that other facilities
12 had to be made available to us.

13 "Many of the dogs died after getting what seemed
14 like a sudden and last symptom--a bloody nose. Once the
15 dogs got the bloody nose, they died.

16 "I was quite aware of these symptoms because my
17 dog contracted them also and could not work, so I was
18 assigned duties which included caring for these dogs. My
19 dog eventually got better, but was never quite the same. He
20 remained very slow and seemed confused all the time. I
21 was so attached to him I would never have turned him in
22 for another dog," signed by a veteran who was there in
23 1970, '71.

24 I would submit that the Air Force has probably
25 kept excellent records on these guard dogs. They are a major

1 investment. I have spoken to a number of the handlers
2 who were over in Nam. They have very similar stories to
3 report of sudden mysterious illnesses with their dogs,
4 hair falling out and rare blood disease, quote, unquote.

5 I submit there is enough verbal similarity there
6 that it should be researched intensively. I think Lakeland
7 Air Force Base would be the place to start.

8 DR. SCHEPERS: We will ask the Department of
9 Defense officials to check this. Thank you.

10 DR. LINGEMAN: They are all sentry dogs that
11 died during that period that you are talking about. Tissues
12 were sectioned at the Armed Forces Institute of Pathology,
13 and I will check today or tomorrow and find out if one of
14 your questions can be answered because the dogs were des-
15 troyed it is my understanding when they finished their term
16 of duty there. They were not brought back to the United
17 States.

18 However, those that died, some tissues I know came
19 from Vietnam into that registry and I will check that out.

20 DR. GROSS: In veterinary pathology they call
21 them military working dogs.

22 MR. DE YOUNG: It strikes me as strange that
23 none of those dogs, almost without exception, were brought
24 back from Vietnam. Most of them were destroyed over there
25 because they were unusable for any practical purposes.

1 DR. LINGEMAN: They were destroyed, but the ones
2 who died, there are at least 600 I think, something like
3 that, on file, not just from Vietnam but all the sentry
4 dogs wherever they were.

5 DR. SCHEPERS: It sounds very valuable to me.

6 DR. HOBSON: Is there any evidence that those
7 dogs were exposed to any of the herbicides, specifically
8 those contained in dioxin?

9 MR. DE YOUNG: Logical evidence from the veterans'
10 statements, if you assume they would have worked the
11 perimeters around the wire and were in that general area,
12 that is the area that would have been defoliated by the
13 hand-operated units.

14 DR. HOBSON: Not with Orange, as I understand it.

15 MR. DE YOUNG: I have no opinions on that at all.
16 Captain Young would be the person to talk to about that
17 I'm sure. It is unquestionable herbicide was used. We
18 have many photographs from the vets who brought those
19 photographs back that showed dead brush by the wire.

20 DR. SCHEPERS: Thank you very much, Mr. De Young.
21 We will look into that.

22 Now the 7th question, if I may go on, is
23 what additional data should be included in the VA's
24 herbicide registry over that currently collected, and
25 Robert Lenham was the coordinator and he thought that our

1 registry was perfect, which was very flattering.

2 MR. LENHAM: I don't want to burst your bubble,
3 but just in the discussions today, what we did, we went
4 out to our field personnel and asked them for their
5 comments also as representatives, and at the time they
6 felt that the VA was making the right approach upon
7 arranging to get as much data as possible.

8 Now this morning it was learned that apparently
9 an epidemiologist from John Hopkins, Dr. Lilienfeld, being
10 an expert in his field, has questions that possibly we
11 should be asking. Maybe we should include in this registry
12 as far as information that we should gather, and I would
13 suggest then and recommend that if this be the case, that
14 we go ahead and include those questions in the registry.

15 DR. SCHEPERS: That we shall do. Ms. Kilduff
16 has returned. We have been discussing your registry. You
17 heard what he said?

18 MS. KILDUFF: What are some of the items?

19 MR. LENHAM: Dr. Levinson didn't really give us
20 that information. I would assume he would have it, and I
21 just want to point out that if we are getting information
22 and the Doctor has said it, I would suggest that you do that,
23 that we follow suit and put that in with the registry.

24 DR. SCHEPERS: If there are any brainwaves which
25 come from any of you as to what we ought to really put into

1 our inquiry, documents, please send them into us and we
2 will give them all the consideration that is due to them.

3 Let's proceed to question 8, which was what are
4 the known facts on the persistence of dioxin and the
5 herbicides used during the Vietnam War in water, soil and
6 the atmosphere? Can these media serve as a source of
7 human exposure to dioxin and herbicides?

8 Dr. Kearney was the coordinator. Dr. Kearney,
9 would you like to comment?

10 DR. KEARNEY: First of all, we discussed the
11 amounts used there. We have talked about the persistence
12 of these four materials in soil, 2, 4 being the least
13 persistent, and TCDD being one of the more persistent
14 materials.

15 We talked about concentrations in air. We talked
16 about the persistence and concentration of these materials
17 in water, and then we tried to talk about routes of human
18 exposure.

19 I don't know from any data we have from the
20 domestic United States that we can get any clear idea of
21 what the human exposure might be. I want to talk to the
22 Air Force a little more closely to see if they might have
23 some impression as to what the inhalation exposure might
24 be, but I don't think we can calculate it.

25 We tried a number of calculations, and they

1 weren't very successful. I guess that's all I have to
2 say.

3 DR. SCHEPERS: A question for Dr. Young--in
4 your slide presentation, you said that the penetration
5 through the skin was 30 minutes?

6 MAJOR YOUNG: That is cuticular on leaf surfaces;
7 In six individuals
8 in the case of humans, the study we have of 2, 4-D, the
9 penetration was about 5.8 percent of the applied dose and
10 that was a calculation based upon following the 2, 4-D
11 acid in the urine, and it was a five day collection period
12 showing that only 5.8 percent was absorbed.

13 Now how good a study was done on six people is unclear.

14 DR. SCHEPERS: What about the persistence of
15 dioxin in clothing and utensils? What can you inform us
16 with respect to that?

17 DR. KEARNEY: In the lab we have to get rid of
18 the glassware. It can become contaminated after a while.
19 We melt it, bury it. We don't want to keep it in the room.

20 MAJOR YOUNG: I would suggest indeed that
21 contaminated clothing was a big problem in Vietnam with
22 the Ranch Hand personnel.

23 DR. SCHEPERS: You mentioned the shoes.

24 MAJOR YOUNG: The shoes, the pants--a continual
25 problem.

MR. LENHAM: Wouldn't this also be a problem with

1 the troop personnel?

2 MAJOR YOUNG: Had they received a direct application,
3 then perhaps you would be correct. We haven't done studies,
4 for example, of putting dioxin on leaf surfaces and walking
5 through it to see what amount might go off, but its
6 immobility in water would suggest that if it is on the
7 surface of the clothing, the likelihood of it getting in
8 probably would be fairly small. That doesn't say it can't
9 happen, and if they reversed their underwear perhaps maybe so.
10 I don't know. We do know that changing clothes all the
11 time was not a frequent occasion for the battle troops
12 or the troops in the field. They might wear the same clothes
13 for more than one day certainly.

14 MR. DE YOUNG: There was an episode of a plant
15 accident in England where the workers in a phenol plant
16 of some sort were contaminated with dioxin and by going
17 home after the work at the plant was done, and cleaning
18 up for that day, their family got contaminated as well.
19 Some of the women had an outbreak of chloracne after washing
20 the clothing which leads to the next logical question, if
21 indeed the Ranch Hand clothing may have been contaminated,
22 does this possibly explain the women that we have seen
23 who are wives of the Vietnam veterans and yet manifest
24 symptoms themselves?

25 MAJOR YOUNG: Let me clarify the accident. This

1 was in Derbyshire, England, in 1968. This is the incident
2 where there had been an explosion in the factory and these
3 individuals went in and were cleaning an area where there
4 was gross contamination of caustic soda and TCDD, and then
5 they took their clothes home for their wives to wash them.

6 That is a totally different picture than if one
7 talks about having herbicide and TCDD together. They are
8 not comparable at all. Not only that, but you are talking
9 gross exposure. The Derbyshire situation probably had
10 well over 2 kilograms of TCDD involved in a small
11 confined area. Most of the men developed chloracne during
12 the time they were working with it.

13 Not surprisingly, the women who handled the
14 clothing came down with it because apparently there was
15 a heavy concentration of TCDD.

16 MR. DE YOUNG: Are you saying no then?

17 MAJOR YOUNG: I am saying the likelihood of
18 having orange on you and doing that is a different story.

19 MR. DE YOUNG: How about purple?

20 MAJOR YOUNG: In the 1962 through '64 time period,
21 it is much more likely, surely--again, all the more reason
22 to perhaps focus in on that early group.

23 MR. DE YOUNG: I wouldn't say it is widespread,
24 but we have a number of women, interestingly enough, four
25 or five of them wives of helicopter pilots, all of whom were

1 shot down on herbicide missions, and many of them grounded,
2 of course, in freshly sprayed patches. Those are some of
3 the more seriously sick of the cases as far as the men
4 themselves are concerned.

5 Three or four of their wives also have skin
6 eruptions and have had the female problems that come with
7 a woman being exposed.

8 MAJOR YOUNG: Was the woman in Vietnam?

9 MR. DE YOUNG: Not at all. The woman never
10 left stateside, and it has got us going up a tree, needless
11 to say.

12 LT. COL. WOLFE: It seems like he would have to
13 bring a lot of dirty clothes home.

14 MR. DE YOUNG: We are casting around for an
15 explanation of how this, whether this is psychosomatically
16 induced by the husband's illness or what.

17 DR. SCHEPERS: This problem of contamination of
18 clothing, utensils, is receiving growing attention in the
19 present era, and it cannot be minimized, and it certainly
20 is a factor possibly in the military situation in Vietnam
21 so we will study it some more and see what can be had.

22 I hear no other great enthusiasm about this topic,
23 so we will go on to question No. 9. Dr. Lingeman responded
24 to the question what medical tests should be utilized to
25 help establish a diagnosis of chronic herbicide-induced

(Note: Page retyped per Dr. Lingeman's changes)

1 toxicity among Vietnam veterans? She wrote an M.D.
2 thesis here I believe.

3 DR. LINGEMAN: I apologize for the length.

4 DR. SCHEPERS: It was beautiful, but I hope you
5 won't read all of it this evening. Could you comment some
6 more on that?

7 DR. LINGEMAN: Dr. Wolfe very nicely provided
8 a background for my comments. My recommendations encompass both the
9 left and right sides of Dr. Wolf's diagram. Many of the suggested
10 studies should be considered research studies.

11 We are dealing with a large number of unknowns,
12 and I would suggest certain of these veterans should volunteer to be
13 studied extensively according to special protocols. To develop such
14 protocols we might enlist the assistance of research institutions,
15 such as the National Institutes of Health. For example, the National
16 Institutes of Mental Health might be interested in developing a set
17 of standardized tests suitable for testing for psychiatric symptoms
18 caused by toxic materials. Perhaps the National Institute of
19 Neurologic Diseases and Blindness would be interested in developing
20 an appropriate protocol for evaluating the neurologic problems.
21 Universities affiliated with VA hospitals may also cooperate in
22 developing appropriate protocols.

23 I have prepared an addendum to question 9. My neurologist
24 consultants advised nerve conduction velocity studies, and nerve and
25 muscle biopsies in the cases in which signs suggesting abnormalities of the
peripheral nervous systems.

I think we should emphasize that veterans who served in
Vietnam

1 were, before, during and after the Vietnam war exposed to
2 a great number of chemicals other than herbicides what may
3 cause some of the same types of syndromes that might be
4 attributed to dioxins. To determine which of these constitutes a
5 medical syndrome that specifically applies to dioxin will be extremely
6 difficult. It might be possible to do some very exhaustive studies,
7 perhaps pilot studies, on a few veterans to answer some questions or
8 develop some hypotheses that would be applied to the larger population
9 of veterans. We should of course emphasize those systems which we
10 believe are most likely to have been damaged by dioxins.

11
12 DR. SCHEPERS: Dr. Wolfe commented on the scarcity
13 of neurologists in the Air Force. The Veterans Administration
14 has a large supply of neurologists, not all that we
15 need, but perhaps enough, but tests like electromyograms
16 and nerve conduction velocities can be done at any Veterans
17 Administration hospital because they are done in our
18 rehabilitation medical services, and they all have the
19 instruments for that, so that would be a practical thing,
20 not difficult to do on a Vietnam veteran, so we will
21 consider including that in our protocol.

22 Any other comments pertaining to question No. 97

23 DR. HALPERIN: Yes. The addendum that you just
24 made should clearly be stated because in reading this, it
25 was not clear to me that we were recommending

1 special thing be done, on all veterans claiming exposure
2 to herbicides from Vietnam, including nerve biopsies and
3 testing, before we even do neurology consulting and so
4 forth.

5 I think I understand your point, the difference
6 between clinical practice and experimental research, but
7 that is not clearly stated in the position paper.

8 DR. LINGEMAN: Perhaps I should follow Dr. Wolfe's
9 line of thinking because to separate out what is practical
10 from what is research and maybe somewhere in the middle
11 between these two extremes would be good.

12 DR. SCHEPERS: Just to reassure you, Dr. Halperin,
13 I have seen nerve and muscle biopsies done on some of
14 these Vietnam veterans who are under study.

15 DR. HALPERIN: Under study, comma, under study,
16 is this someone coming into the VA for some unrelated
17 disease who says that he may have been exposed, and all of
18 a sudden he is down the buzz saw of some tremendously
19 invasive procedures?

20 DR. SCHEPERS: This would be done only on people
21 who are obviously very seriously ill who are hospitalized
22 who have been studied for all other possible explanations
23 and none found, and then the doctors resort to these rather
24 unpleasant and very expensive procedures.

25 I know they do them. Thus far we have had no

1 clues from any of this information, but it certainly is
2 an experiment.

3 DR. LINGEMAN: It is too strong a statement perhaps.
4 Maybe the statement should read, "selected" veterans.

5 DR. SCHEPERS: Just for clarification, the
6 staff of the central office will edit all these position
7 papers, consolidate the comments that we received today,
8 with the position papers, and possibly add a few sentences
9 where we think it is relevant, and then re-present them to
10 the members of the Committee for further consideration.
11 Is that the game plan?

12 DR. CASTELLOT: Yes. In view of the time, you
13 probably ought to consider the possibility that those
14 papers which were not covered by the Committee members, if
15 they have any pertinent comments which are felt to be
16 important, they should submit them to the central office
17 to Mrs. Williams. We will then put all these things
18 together into a revised packet of position papers sent to
19 the Committee for their review before any further adoption
20 is carried out.

21 MR. HIGHT: Since the Administrator has indicated
22 that any veteran who thinks he was sprayed or exposed
23 shall be given an examination, as they put it,
24 should not then these examinations be put into two or three
25 different classes--those who have symptoms and those who

1 merely say I think I was exposed, and I want to know
2 whether anything is wrong with me, so you are going to
3 have to put two different classes of examinations on those
4 people.

5 You are not going obviously, as the Doctor
6 pointed out here, that you wouldn't go into the deep
7 examinations that might hurt someone if he has no symptoms
8 at all.

9 DR. SCHEPERS: I agree with you absolutely, and
10 I think we will write recommendations along those lines,
11 Dr. Castellot, to have sort of a circular spelling out the
12 details.

13 DR. CASTELLOT: This whole thing needs to be
14 reviewed. I think that is a good point.

15 MR. LINDLEY: If you don't have any valid
16 diagnostic tests at this point, what is the purpose of
17 telling the veterans to come in and be tested?

18 DR. SCHEPERS: Because medical diagnoses,
19 practically all medical diagnoses are made by reviewing
20 the total spectrum of the patient's condition and deducing
21 from that collected information a diagnosis.

22 It is sometimes 100 percent accurate, sometimes
23 95 percent accurate. We are hoping that by doing it in
24 like manner for the present problem that we will get those
25 two diagnoses.

1 There is no specific test, as for instance in
2 pernicious anemia where you can do a blood count and make your
3 diagnosis. There is no blood count to tell you about
4 dioxin poisoning.

5 MR. LINDLEY: I think it is very important that
6 that point be made clear to the veterans, that they will
7 try and assess what problems they might have, but that the
8 VA cannot definitively detect dioxin.

9 DR. SCHEPERS: That is a good point.

10 MR. LENHAM: If the veterans that are being
11 tested now are given the tests that you recommend and
12 this information is put in the herbicide registry and then
13 if later on down the road we find certain specific
14 examinations which would be a pretty good clear indication,
15 give us a pretty good clear indication to us whether or
16 not a given individual, was exposed to dioxin,
17 would the VA maybe attempt to re-contact the early veterans
18 that had been examined to maybe let them go through this
19 examination also?

20 DR. SCHEPERS: That is our standard procedure, yes.

21 MR. LINDLEY: This is sort of an irrelevant
22 point, but a lot of veterans are using Agent Orange as a
23 lead into possible personal adjustment or psychological
24 problems they might be having as a result of their military
25 service, and there probably should be some coordination

1 with the readjustment counselling program for veterans
2 that might need assistance in that area, and it is also a
3 good way to avoid some of the stigma that is associated
4 with psychological problems in Vietnam veterans.

5 DR. SCHEPERS: We agree with you absolutely.
6 It is just a little bit difficult to get them all
7 together in hospitals and this is the reason for our
8 conference here with our doctors.

9 If I might clarify it again, we have asked one
10 doctor for each one of 172 hospitals to come in this week
11 and some of the members of the Committee who are able to
12 be with us on Thursday and Friday will discuss with our
13 doctors how best to handle the veteran, and this point
14 will again surface during that discussion.

15 MR. LARSON: I thought of three possible modes
16 of entry of dioxin in the husband and wife cases--one, a
17 possible exhaling of the husband's breath, could the wife
18 foreseeably inhale the husband's breath, and secondly,
19 saliva; thirdly, are there any organisms such as viral
20 organisms or bacteria that could ingest, perhaps selectively
21 ingest the dioxin and be transferred to the spouse?

22 DR. SCHEPERS: Those are all three new ones to
23 me. Any comments from the Committee? Certainly it is on
24 the record. We will think about it. Thank you, Mr. Larson.

25 Let's go on to question No. 11. We are crowding

1 the time, and I notice that question 10 has no position
2 statement, so we can pass it. Eleven is by Moore and
3 Thiessen. Neither of them are here now. Would you prefer
4 that we discuss this at the next meeting? We will do it
5 by mail.

6 DR. CASTELLOT: Dr. Haber's view is that those
7 papers which are not discussed at this time by the
8 Committee should be reviewed by individual Committee members.
9 If they have any changes or comments, they should submit
10 them to Mrs. Williams as soon as possible. We will get out
11 a timetable in that regard as soon as we can.

12 DR. SCHEPERS: We have Dr. Murphy here, so let's
13 do the last one on question 12. To what extent is information
14 potentially available on the effects of Agent Orange on
15 the indigenous Vietnam population?

16 Dr. Murphy, any more you want to add?

17 DR. MURPHY: I have nothing more to add, just
18 re-emphasize the question is one that can only be speculated
19 on. It is not really a position paper, but it would seem
20 to me that another group of potentially
21 high exposure people are natives of Vietnam,
22 and the problem of identifying, following them, et cetera,
23 is probably much greater than that for the involved

24 U. S. military personnel, but nevertheless, I don't
25 think they should be excluded.

1. The rest of it is international politics. I can't
2 speculate on that.

3 DR. SCHEPERS: Is it not true that some of the
4 Vietnamese personnel participated with the United States forces
5 in Ranch Hand and other similar operations?

6 MAJOR YOUNG: In the early years of the Ranch
7 Hand program, '62 through '64, there were a few Vietnamese
8 that worked with Air Force personnel in loading the aircraft
9 and this would have had to have been almost done exclusively
10 by hand. We didn't have any big pumps or automated systems
11 for transporting the herbicide by hose networks, so it was
12 all done by hand--a very slow, tedious process.

13 There were Vietnamese involved. However, in
14 '64, late '64 through '66 time period, there were a lot of
15 Vietnamese, the National Academy of Science talked about
16 a group of at least 50 individuals that worked on the drum
17 handling operations.

18 After 1967, late '67, '68, and especially the '69
19 timeframe, we got away from using Vietnamese primarily
20 because of the security problem, but there was a period
21 in there where there were Vietnamese that were involved
22 in handling, and I would also point out there were many
23 women. As a matter of fact, most of the Vietnamese that
24 handled them in those years were women.

25 DR. MURPHY: You also have children involved as

1 a community exposure, too.

2 MAJOR YOUNG: Very definitely.

3 DR. SCHEPERS: We discussed this topic briefly
4 with the Vietnamese doctor who came to visit us, Dr. Tung,
5 and he wasn't very knowledgeable of this aspect because
6 he is a North Vietnamese and he didn't know what we did in
7 the south, but hopefully when their country is reunited,
8 they will study their own people and discuss it further.

9 DR. MURPHY: Did I understand earlier today
10 there was a report or you had a report from this doctor
11 that you mentioned?

12 DR. SCHEPERS: He came to see us on Dr. Haber's
13 invitation and gave a presentation to our staff, discussed
14 what he knew about the subject. There is no formal report.

15 DR. CASTELLOT: No. Dr. Haber indicated this
16 morning, Dr. Murphy, that he would try to get what data
17 is available in terms of that visit and submit it to the
18 Committee for their review.

19 DR. MURPHY: I noted that in my mind and I thought
20 why didn't I have this if I am asked to write a position
21 paper on it.

22 MR. DE YOUNG: While we are on the subject of
23 populations, Dr. Schepers, has it been considered that we
24 are currently every day now taking in quite a few Vietnamese
25 who are being taken in through immigration in the boat

1. people campaigns, and I would suggest that we have here a
2. very good population for study as well.

3. I would suspect that the documentation of these
4. people coming in is being fairly well done by the Immigration
5. Service.

6. DR. CASTELLOT: I would think the difficulty we
7. are experiencing with our military population as has been
8. expressed earlier, if it is as difficult with those people,
9. I think it would be more difficult with the Vietnamese
10. coming in.

11. DR. SCHEPERS: I feel a little despondent about
12. that subject myself. My impression is that these boat
13. people are chiefly from downtown Saigon anyway. Many of
14. them are Chinese. I doubt whether they were involved with
15. war to the extent the issue that we are trying to
16. address would require, but we will of course take cognizance
17. of any information that comes to us.

18. The last question was one I had to take care of.
19. We did take care of it by asking Mr. Cleland to write to
20. the Secretary General of the United Nations. We do know
21. that letter was sent off. We have had no reply, so we have
22. no comment for you on that subject, but we will forward it to
23. you if we do get a reply.

24. That brings us to the end of our meeting, unless
25. there are other questions and answers that you wish to be

1 involved with. Mr. De Young?

2 MR. DE YOUNG: Just a short statement--in the
3 interest of maintaining credibility for the entire
4 scientific community, I would like to make it a matter of
5 record that the National Veterans Task Force at this
6 point would support an outside study of the Ranch Hand
7 personnel, as I say, in the interest of making sure that
8 everyone to whom the facts are put when the study is over
9 will accept the facts, and that it not be a partisan study
10 or an in-house study either by VA or the Air Force.

11 I would suggest in the interim until a better
12 name is suggested that NAS be asked to do that study, the
13 National Academy of Sciences.

14 DR. SCHEPERS: We thank you for your suggestion.
15 Any further comments? If not, we will declare this meeting
16 adjourned. Thank you very much for your participating. The
17 next meeting will be announced in the mail.

18 (Whereupon, at 3:50 p.m., the meeting was
19 adjourned, to be resumed at an undetermined date.)
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REPORTER'S CERTIFICATE

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2
3
4 DOCKET NUMBER:

5 CASE TITLE: Advisory Committee on Health-Related Effects of
6 Herbicides

7 HEARING DATE: September 24, 1979

8 LOCATION: Washington, D.C.


9 I hereby certify that the proceedings and evidence
10 herein are contained fully and accurately in the notes
11 taken by me at the hearing in the above case before the
12 VETERAN'S ADMINISTRATION

13 and that this is a true and correct transcript of the
14 same.

15
16
17 Date: September 24, 1979

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19
20 Official Reporter
21 Acme Reporting Company, Inc.
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Washington, D.C. 20005

22 I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE HEREIN ARE CONTAINED
23 FULLY AND ACCURATELY, AS CORRECTED.

24 *Paul Haber* 
25 PAUL A. L. HABER, M. D.
Chairman
Advisory Committee on Health-
Related Effects of Herbicides

December 4, 1979

Acme Reporting Company



Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

**(Third Meeting
December 12, 1979)**

THE VETERANS ADMINISTRATION

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ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS
OF HERBICIDES

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The Veterans Administration
Room 119
810 Vermont Avenue, N. W.
Washington, D. C.

8:30 a.m.
Wednesday, December 12, 1979

ADVISORY COMMITTEE MEMBERS PRESENT:

2

1
2 PAUL A. L. HABER, M.D., Chairman
Assistant Chief Medical Director
3 for Professional Services
Veterans Administration
4 Washington, D. C.

5 GERRIT W. H. SCHEPERS, M.D., Vice Chairman
Medical Service
6 Veterans Administration
Washington, D. C.

7
8 IRVING B. BRICK, M.D.
Senior Medical Consultant
National Veterans Affairs
9 and Rehabilitation Commission
The American Legion
10 Washington, D. C.

11 J. DAVID ERICKSON, D.D.S., Ph.D.
Center for Disease Control
12 Birth Defects Branch
Atlanta, Georgia

13
14 PHILIP C. KEARNEY, Ph.D.
Chief, Pesticide Degradation Laboratory
Department of Agriculture
15 Beltsville, Maryland

16 RICHARD A. LEMEN
Assistant Chief
17 Industrywide Studies Branch
Robert A. Taft Laboratories
18 Cincinnati, Ohio

19 ROBERT H. LENHAM
Special Projects Officer
Disabled American Veterans
20 Washington, D.C.

21 CAROLYN H. LINGEMAN, M.D.
Carcinogenesis Testing Program
22 National Cancer Institute
National Institutes of Health
23 Bethesda, Maryland

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ADVISORY COMMITTEE MEMBERS PRESENT (Con't):

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JOHN A. MOORE, D.V.M.
Associate Director for
Research Resources Program
National Institute of Environmental
Health Sciences
Research Triangle Park, North Carolina

SHELDON D. MURPHY, Ph.D.
Department of Pharmacology
University of Texas Medical School
Houston, Texas

HENRY SPENCER, M.D.
Appearing for ADRIAN GROSS, Ph.D.
Acting Section Chief
Toxicology Branch
Hazard Evaluation Division
U. S. EPA
Washington, D.C.

DIANE NORBACK, M.D.
Appearing for Dr. ALLEN
Department of Pathology
University of Wisconsin
Madison, Wisconsin

COL. J.W. THIESSEN, M.D.
Department of Defense

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P R O C E E D I N G S

1
2 DR. HABER: Good morning, ladies and gentlemen.
3 I think we will begin and I would like to welcome you to the
4 third meeting of the Advisory Committee on Health-Related Effects
5 of Herbicides, and I would just like to make a couple of
6 general announcements and then ask Dr. Crutcher to welcome
7 us.

8 As I said, this is the third meeting of this
9 group. There have been some new appointments made to the
10 Committee. Dr. Suskind and Dr. Lillienfeld have been
11 appointed. There will be additional appointments as soon
12 as we can clear the paperwork for making the position for a
13 representative of another veteran's group, and we will then be
14 able to continue our work.

15 I would like to mention that today there are two
16 EPA representatives appearing for Dr. Gross, Dr. Henry
17 Spencer and Mrs. Chris Chasan from the Toxicology Branch of
18 the Hazard Evaluation Division.

19 I would like to also mention that the main purpose
20 of today's meeting is to discuss the position papers which
21 will be made fully public and in printed form so that
22 comments can be invited and questions can be answered.

23 Because this is our major concern today, I would
24 like to get to that as soon as we can. There will be an
25 opportunity for written questions and statements from the

1 audience at about 11:00 o'clock, at which time discussions
2 of these papers will be entertained in the form of written
3 questions and statements.

4 There will be three written statements that we
5 know about, one from the Department of Defense; Colonel Wolf
6 will be presenting that; another one from Dr. Allen's
7 laboratory. Dr. Norback will be presenting that statement, and
8 a third from the Operation Ranch Hand and Mr. Charles Hubbs
9 will be relating that.

10 At that time we will consider questions and
11 statements and comments, as well as written comments from other
12 interested members.

13 At this point I would like to turn the meeting
14 over to Dr. James Crutcher, Chief Medical Director of
15 the Veterans Administration.

16 DR. CRUTCHER: Thank you, Paul. I have no words
17 of wisdom for this group around the table. I would
18 congratulate you on the way that you have attempted to take
19 an issue that is highly emotionally charged, an issue that
20 basically puts into somewhat of an adversary role the
21 science and concepts by constituents in an atmosphere where
22 generally there is distrust of bureaucracy in government.

23 I think that the work that this panel has done
24 to date has been exemplary and I would congratulate you for it.

25 I think the information basis that you are

1 gathering will be evermore important as we enlarge our
2 epidemiological approach to the, perhaps, long-range
3 consequences of exposure of our population groups.

4 I also would congratulate the group. You have
5 deemed it wise to have open meetings on this and in your
6 discussions, as I read the minutes of the meeting, there has
7 been professionalism on both sides.

8 The Chief Medical Director ultimately has
9 responsibility for care of veterans and your contributions
10 in this regard are highly appreciated. Thank you. I will
11 say no more at this time. You have a heavy schedule. I
12 welcome you to this meeting and we expect to have excellent results
13 issuing from it. Thank you, Paul.

14 DR. HABER: Thank you, Dr. Crutcher.

15 I would like, at this point, before we launch into
16 the discussion of the papers, which is again our major
17 preoccupation today, to give you an update on what
18 has happened since our last meeting.

19 I think you are all aware of the fact that the
20 minutes of these meetings are made public. They are
21 available for perusal for interested parties. A number of
22 important events have occurred since our last meeting. The
23 first of these was a meeting that we had on September 27th
24 and 28th, in which we brought together
25 representatives of all the Veterans Administration Hospitals

1 in our system, physicians mostly, but there were others
2 present as well, who were charged with the task of examining
3 veteran patients who come to us alleging deleterious
4 effects of exposure to the herbicides. The purpose of
5 this meeting was twofold: one, to inform those physicians
6 about what was current in the field, and, second to get
7 some feedback from them as to what they were seeing.

8 That meeting was held at a hotel here in Washington.
9 We had about 200 representatives. It was addressed by a
10 number of people, including members of the Armed Forces,
11 Doctors Young and Wolf.

12 There were presentations made by Mr. Ron DeYoung,
13 representing the Vietnam Veterans. There were presentations
14 made by people from Dr. Lillienfeld's laboratory and by
15 Dr. Suskind, and I think the meeting certainly helped to
16 form our positions about what is going on in the field.

17 After that meeting, we have also had additional feedback in
18 how the problem of toxicity allegations is being met in
19 the Veterans Administration.

20 We have just recently received a General Accounting
21 Office report that was issued, a report by the Comptroller
22 General. I call it to your attention. The report is titled
23 "Report by the Comptroller General of the United States,
24 United States Ground Troops in South Vietnam that were in
25 areas sprayed with Herbicide Orange."

1 The date is September 16, 1979, and it purports
2 to indicate that some troops, likely some Marine troops,
3 were found to have been in the path of spraying missions.
4 The Department of Defense has issued a commentary on this.
5 They aren't necessarily in agreement with some of the
6 findings of GAO, and I will commend this report to you.
7 I think it is an important report.

8 In addition, several other things have occurred.
9 There have been representations made by members of Congress,
10 particularly senators who are interested in this, Senator
11 Cranston, Chairman of the Veterans Committee, Mr. Satterfield,
12 and Senator Percy have all written letters to various
13 government agencies urging that we proceed with renewed
14 vigor on the problem of Agent Orange.

15 You will be hearing a little bit later today from
16 the Department of Defense about what they propose to do
17 with respect to Operation Ranch Hand.

18 My understanding, from speaking with people from
19 the Air Force, is that the final review of the project is
20 to take place on December 18. Is that right, Colonel Thiessen?

21 COLONEL THIESSEN: Yes.

22 DR. HABER: The Academy of Science will give final
23 review for the project Ranch Hand.

24 I want to say that we continue to receive
25 information about Agent Orange in the scientific and lay

1 press. I would like to call your attention to a couple of
2 articles. This is not intended to be exclusive, but only
3 illustrative. This is a letter to the editor in the JAMA,
4 November 30, 1979, issue, Volume 242, Number 22, signed by
5 Dr. Gilbert Bogen.

6 Dr. Bogen comments on the study that he has been
7 conducting, a 10-month study of 78 Vietnam veterans in which
8 he finds various complaints and comments on this. I would
9 commend this article to those of you who are interested.

10 Another article on the other side of the fence in
11 the Wall Street Journal on Tuesday, October 23, talks about
12 a study done for the Monsanto Company of 121 workers in an
13 industrial accident. 30 years ago. They say that an
14 article to be written by Judith Sachs and Dr. Raymond
15 Suskind, to be published in the Journal of Occupational
16 Medicine in the next few months found no excess mortality
17 in the study of dioxin exposure. So the problems attendant to getting to
18 the bottom of this very vexing concern continued to mount.
19 Evidence on both sides of the fence continue to pile up. The truth
20 has yet to be revealed to us.

21 One very important occurrence I must call to your
22 attention has been the introduction of a bill in the House,
23 HR3892, and a compromise bill, Senate Bill 17987, the
24 House bill being introduced by Mr. Satterfield, the Senate
25 bill by Senator Cranston, with other colleagues.

1 I won't go into detail on this. You can find it
2 in the Congressional Record. I will give you the precise
3 date: Congressional Record of December 6th, 1979. It would
4 mandate a study to be done by the Veterans Administration,
5 an epidemiological study of Agent Orange, this study to have
6 validity attested to by the Office of Technology Assessment
7 under the Congress, and within, I believe, 180 days after
8 the passage of this law would mandate the Veterans
9 Administration to conduct those epidemiological studies.

10 The reason this is so important to us is the
11 papers we are now about to discuss will form part of the
12 basis of that epidemiological study so what this
13 committee has been doing really has been, in a sense,
14 preparing the groundwork for this very important study.

15 I would also call to your attention a very
16 comprehensive listing by Dr. Kearney of other efforts in
17 getting to the bottom of Agent Orange, in which he points
18 out the various agencies involved: Department of Defense, National
19 Cancer Institute, CDC, HEW, The Environmental Protection
20 Agency, NIOSH, and NIEHS, as well as the Veterans
21 Administration.

22 All of those studies will have to continue and
23 we hope that the epidemiological study undertaken by the
24 Veterans Administration will form the basis for an
25 informative decision about how to proceed on this very

1 important issue.

2 This Senate bill, the compromise bill I
3 understand, was passed by both houses of Congress and is
4 now on the President's desk for signature, and should it
5 become law, we will, of course, spring into action. I think
6 it is the role of this Advisory Committee in relation to
7 the epidemiologic study. I think it will be obvious and
8 it will be a critical role.

9 I have already exceeded my own time limit by
10 five minutes and I think now, that with further ado, I
11 would like to come to a consideration of the papers which
12 we have asked the Advisory Committee to prepare.

13 I went over these papers again last night.
14 Doctors Levinson and Castellot have been working very
15 assiduously on this. This is not the final form. They are,
16 therefore, subject to comment and criticism. When they
17 are finalized, we will present them to the public in written
18 form, inviting comments, questions, rebuttal, as well as
19 additional information.

20 The way we will proceed this morning, I will
21 ask the originator of each paper to make a brief summary
22 statement on his paper. Then one of our staff will
23 make a very brief comment, and we will then open up for
24 discussion by the members of the Advisory Committee, comments,
25 questions, objections, and so forth.

1 I would urge the general public to make notes,
2 which they can then forward to me at the time provided for,
3 11:00 o'clock, and we will deal with those questions and
4 comments at that time.

5 We will begin with the first question. The first
6 question was from Mr. Lemen. Is there anybody here
7 representing NIOSH?

8 DR. LEVINSON: Question Number One. Do the
9 available data on exposure of Vietnam veterans to herbicides
10 permit the performance of scientifically valid epidemiological
11 studies on the long-term health effects of herbicides in
12 this group?

13 Since Mr. Lemen isn't here,
14 I will just summarize briefly what the contents of the
15 response seem to be. The response indicates that
16 epidemiological studies on the health effects of herbicides
17 used in Vietnam might be possible if accurate data on the
18 exposure of those veterans to the herbicides is available.

19 The paper makes a very strong point of this
20 matter. Several components of the data required to document
21 exposure were listed in the paper. I'll condense them.
22 One, quantity of herbicide applied to each specific
23 geographic area on a given date. Two, the precise
24 identity of military personnel located in the sprayed area, and
25 three, information on the length of time that these personnel

1 were in the area.

2 The paper suggests that when valid exposure data
3 is available, a proper study would compare the mortality
4 experience of the herbicide exposed Vietnam veteran with
5 appropriate control groups and the appropriate control
6 groups were specified as other Vietnam era veterans who
7 did not actually serve in Vietnam and the general United
8 States population.

9 It was suggested that the study and control groups
10 be matched according to demographic and other parameters
11 such as age, race, sex, education, job in the service, and
12 there was a suggestion that data on exposure to other herbicides
13 and pesticides be obtained and, as I understand it, finally
14 the paper suggests most of this data could probably be
15 obtained from existing medical records.

16 As we see it, and the staff sees it, this paper
17 reconfirms the information which the Veterans Administration
18 has obtained from others about essential components of an
19 epidemiological study, specifically the crucial necessity
20 of defining exposure, and this is, to us, the most essential
21 ingredient in an adequate epidemiological study, and the one
22 thing with which we have had the most difficulty.

23 We think that if we had gone a little bit further in
24 our own work, we would have discovered still other factors
25 which had to be defined if the study was to be successful.

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1 We have been in discussion with a number of
2 groups, including the Air Force, about how to specify such
3 a model. I think Colonel Thiessen is going to talk about
4 that today, but developing a model of exposure is a very
5 complex task.

6 Now, we also took some issue with the proposal in
7 the paper that this study could be entirely, or largely
8 retrospective, and that data could be drawn from existing
9 medical records.

10 Our experience in looking at some of the available
11 records indicate that they are very limited; they were, for
12 the most part, not sensitive to all
13 of the issues involved in environmental toxin exposure, and
14 we feel very strongly, and I think the other groups agree
15 with us, that the study would have to be largely prospective;
16 that there would have to be careful control on how the
17 medical information, both of an historical and physical and
18 laboratory nature is obtained and gathered and tabulated,
19 and that, therefore, the study would probably have to be
20 done under the Veterans Administration or other similar
21 auspices where we could control the gathering and analysis
22 of information.

23 Our recommendation is that we agree with the paper.
24 Agent Orange epidemiological studies should be done. We
25 agree with them that defining exposure is absolutely critical.

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1 We disagree, however, in that
2 we think the factors involved in the exposure were more
3 complex than listed, and a retrospective study would simply
4 not be adequate to define the nature of the epidemiological
5 problem.

6 DR. HABER: Okay. Are there any questions or
7 comments from members of the Committee with respect to this?

8 Dr. Moore?

9 DR. MOORE: A general question. The thrust of
10 the question deals with the fact, can one do a medical
11 epidemiological study to see if there is association between
12 Agent Orange exposure in Vietnam and health effects
13 consequent to that. Is it of interest to the Veterans
14 Administration to find out in any type of a study what may
15 be pursued and to be able to have identified that there
16 seems to be some untoward health effects that are detected
17 in such a study? indeed, one cannot make with
18 full assurance a direct cause effect relationship between
19 those abnormalities, whatever they may be, and the Agent
20 Orange per se.

21 There is a tacit assumption that people are
22 making that this is due to Agent Orange. I think it is a
23 very likely assumption, but I don't think you should be blind
24 that that could be the only factor that could be associated
25 with these alleged effects.

1 DR. LEVINSON: I think the paper states that other
2 factors should be considered, such as other herbicides,
3 pesticides, other industrial types of exposure.

4 Among the items of information, we would have
5 to gather some data about the person's work in the military
6 and civilian sector, about their hobbies, if they happened
7 to have been associated with certain potential obnoxious
8 pesticides, and it would have to be much more complex than
9 merely looking at the old medical records or sending people
10 a questionnaire asking how they feel, or if there is anything
11 wrong with them.

12 The paper recognized this. I think we all recognize
13 this. We agree that the cause and effect relationship may
14 be extremely difficult to establish, even with the best
15 defined epidemiological study.

16 DR. HABER: I think, Dr. Moore, the concern that
17 we have is that other herbicides that might have been used
18 there, or elsewhere, could be held responsible for the
19 pathological effects, and I think we are going to have to
20 be very careful to open that possibility up.

21 I think people have called to our attention the
22 fact that there were other areas that were sprayed.
23 Incidentally, with respect to that, Dr. Levinson has
24 initiated an inquiry from the Department of Defense about
25 the possible effects of herbicides that might have been

1 sprayed in Korea. We got a negative answer on this.

2 DR. LEVINSON: No, the answer has not been
3 prepared yet.

4 COLONEL THIESSEN: It is still being investigated.

5 DR. HABER: Unless there are further comments,
6 I would like to pursue the next position paper then, please.

7 Question Number Two: What are the best human
8 population groups in which to study the long-term effects
9 of herbicides on health, and how may the studies best be
10 conducted? Dr. Brick, you are the individual who was
11 responsible for this. Do you want to briefly summarize the
12 response?

13 DR. BRICK: This is another difficult question.
14 The answer, probably, is not too satisfactory to some
15 members sitting around the table, but it seems to me that
16 since this group is primarily interested in the veteran
17 group, again, identifying groups of veterans that were
18 exposed to Agent Orange in Vietnam specifically and
19 studying them in such ways as epidemiologists would suggest
20 is one method of trying to get some data, and it has been
21 mentioned by Dr. Haber that to do this, you would have
22 control groups.

23 I think this, too, can be defined very
24 efficiently from the Veterans Administration records and
25 Veterans Administration personnel with reference to veterans

1 who served during the Vietnam era, but weren't in Vietnam. A long-
2 term study of the morbidity and mortality experience of
3 those groups might turn up some interesting findings.

4 Whether or not they are going to be causal, as was
5 pointed out, or just findings that you would have to argue,
6 is another problem.

7 Another thing I wondered about: after all, Agent
8 Orange and dioxin have been used in agricultural work
9 throughout this country for a good many years, and I am
10 sure the Department of Agriculture has some knowledge about
11 which areas and what exposure has occurred. A study of
12 these groups of individuals also might be of great interest.

13 I am not up on the literature of this type of
14 thing. Possibly, some of the members around here can
15 educate us as to whether studies along this line have already
16 been done.

17 DR. KEARNEY: Dr. Haber, could I comment?

18 DR. HABER: Please.

19 DR. KEARNEY: This is Kearney, Department of
20 Agriculture.

21 There is some confusion and it causes concern to
22 us. Dioxin is not a herbicide. Dioxin is an impurity in
23 a herbicide, and to our current thinking, it is largely
24 confined to the phenoxy compounds and more specifically,
25 those which have three chlorides in the molecule.

1 Now, in regard to agricultural experience, I think
2 there is an important new study that we have just become
3 aware of that might be of assistance to us, Doctor.

4 Dr. Lavy has been involved in a study on forest
5 workers exposed to 2,4,5-T. This is a study in which dermal
6 and inhalation exposures were measured. They took
7 analyses of 2,4,5-T in urine and on gauze patches, which
8 were placed on the body and also in the breathing zone
9 of various people involved in the application of this
10 material.

11 They examined pilots, mixers, supervisors, and
12 flagmen. We need to look at the job descriptions of these
13 various people to make any sense of this, but the mixers
14 or leaders are the people that are involved in taking the
15 concentrated material and putting it into the spray apparatus.

16 The flagmen are persons who are on the ground who
17 may be directly in the flight pattern of the application,
18 who signal the pilot as to where to apply the material.

19 These results were rather comprehensive and they
20 show that the mixer, the person who mixes the material and
21 puts it in the tank, has the highest residues in his urine,
22 in his breathing zone, and in his total exposure.

23 The person with the lowest exposure is the flagman,
24 or the person on the ground. Why this is important to us
25 here goes back to the Ranch Hand study. I am convinced,

1 then, that the loaders and mixers, the batch people, have
2 the potential highest level of exposure, and the flagman or
3 the person on the ground, probably has the potentially lowest
4 level of exposure.

5 There are some very good numbers here which I
6 think would be useful to us. This is sponsored by the
7 National Forest Products Association. It is continuing, but
8 I think it gives us a good clue for the first time as to
9 what the actual exposure levels are of various occupations.

10 I think these could be translated to various
11 people involved in Vietnam.

12 DR. MOORE: Dr. Kearney, do you have a reference
13 to that?

14 DR. KEARNEY: It is not published yet. We have
15 the pre-prints of it. We can make this available.

16 DR. HABER: We will get to this in question four,
17 but Dr. Erickson's comments on the male reproductive system
18 and his calculation of the number of population, individuals
19 that have to be surveyed in order to come up with a
20 difference, I think is germane to this subject.

21 DR. BRINK, you may wish to comment on this later.

22 DR. BRICK: Okay.

23 DR. MOORE: I think for the sake of completeness
24 of such a response, there are a number of other studies
25 that have either been done or are ongoing that should be

1 considered in addressing the
2 question that was posed. What comes to mind, though I
3 don't remember the exact citation or authors, are
4 several Swedish publications that have come up and are
5 still being performed which deal with the chronic sequelae
6 of people who they felt were high exposures, spraying railroad
7 right-of-ways, things like that.

8 I am aware of an allegation on the part of a Long
9 Island population -- again, I believe the railroad right-of-
10 way workers that they may have had adverse health effects due
11 to their chronic exposure to herbicides.

12 I think there are a number of populations outside
13 of the Vietnam veterans that might shed information.

14 DR. HABER: You are right. I am sure that all of
15 you are aware of the fact of those other studies that are
16 going on in industrial accidents, in West Virginia, in Italy,
17 railroad workers in the Netherlands, industrial exposures in
18 South America and so forth. We will try to get all of those
19 in, at least referenced.

20 The Air Force study of 1978 calls attention to
21 those. There is, in addition, under the World Health
22 Organization a rather comprehensive look at the international
23 experience with exposures to various herbicides.

24 Are there any other comments on question two?

25 (No response.)

1 DR. HABER: Question three, then deals with --
2 yes?

3 Mr. Lemen, who represents the organization of the National
4 Institute for Occupational Safety and Health
5 has joined us. I wanted to ask him if he had any response
6 to the paper he prepared for question number four. Is there
7 anything you want to say by way of comment on that,
8 Mr. Lemen?

9 MR. Lemen: I think that we have a very brief
10 comment. We had addressed that question we thought in our
11 first position paper pretty adequately.

12 I can read you a response that we have made to the
13 first question. With regard to the relative value of the
14 studies listed in question one for the finding and effects
15 of Agent Orange on human health, it is important to note
16 that human epidemiological data will more definitively answer
17 questions about human health effects.

18 Animal toxicologic studies should be conducted in
19 order to guide and suggest more avenues in humans, and as a
20 source for quick analysis of chronic effects, such study
21 would require a shorter observation period than do human
22 studies.

23 In choosing a population for human epidemiologic
24 study, consideration must be given to the completeness of
25 the exposure and cohort data. Specifically, the question of

1 the appropriateness of the Vietnam veterans for such a
2 study has already been addressed in an earlier position
3 paper, which I think you all have a copy of. We supplied it
4 to you two meetings ago.

5 Studies of the victims of industrial accidents
6 are underway or near completion by a number of investigators.
7 I might add that the Long Island railway situation, which
8 Dr. Moore was referring to, is being looked into by our
9 institute and we have people going into the field to
10 investigate this situation. Also, NIOSH will be including
11 all of the individuals from the various studies in the
12 United States in its dioxin registry and

13 a mortality study on these individuals will be done.

14 With regard to the question of the Veterans
15 Administration's role in such studies, we feel it is
16 imperative that the Veterans Administration encourage
17 defensible investigations by competent scientists and make
18 certain that all such studies supported or conducted by
19 the Veterans Administration undergo a thorough peer review.

20 We feel, to facilitate design of appropriate
21 epidemiological studies for the Veterans Administration,
22 NIOSH strongly urges the Veterans Administration to either
23 hire or contract with an epidemiologist with sufficient time
24 and resources to assist in these endeavors.

25 I think we addressed that in a letter from our

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1 Director to you.

2 DR. HABER: Yes. Mr. Lemen , I was just commenting
3 earlier that legislation which has been passed by both
4 houses of Congress is on the President's desk for signature and
5 directs the Veterans Administration to conduct such studies
6 and this will be the basis on which these studies will be
7 made.

8 I would suggest to you that we will invite your
9 comments on the study as it is being designed.

10 All right. Shall we proceed to the position paper
11 number three? The question is, of what diagnostic value
12 are the following procedures in assessing possible herbicide
13 toxicity: levels of dioxin in fat pad biopsies; study of
14 immune factors; study of chromosomal patterns; and study of
15 liver microsomal enzymes? What additional diagnostic
16 procedures should be considered?

17 The answer is prepared by Dr. Allen. Dr. Norback,
18 would you be able to comment on this for us, please? Then
19 you will have an opportunity to read the paper that Dr. Allen
20 prepared, maybe not in its entirety, but some of it.

21 DR. NORBACK: First, I would like to express
22 Dr. Allen's regret for not being able to be here today. I
23 was pleased to be able to substitute for him. Dr. Allen
24 does agree that there should be a thorough prospective
25 epidemiological study of veterans exposed to dioxin.

1 He commented that there clearly should be
2 identification of risk groups of the veterans that have
3 been exposed to the Dioxin and, indeed, there should be
4 appropriate controls matched to age, race, sex, and other
5 factors, including occupation of the individuals.

6 He would suggest a prospective follow-up of
7 the population of each group that is identified and some of
8 the tests that are listed here would be quite appropriate
9 in gathering the information.

10 It seems appropriate to try to determine the level
11 of Dioxin at the present through fat biopsies in the groups
12 that are identified.

13 In addition to identifying levels of Dioxin, an
14 appropriate study would be the analysis of the microsomal
15 enzymes, specifically aryl hydrocarbon hydroxylase, since this enzyme
16 is so sensitive to Dioxin. It seems this would be another
17 method of analyzing exposure to Dioxin.

18 Studies of immune factors would be appropriate in
19 that much of the animal research has indicated that there
20 is alteration of the immune systems in experimental animals,
21 so it certainly seems appropriate to study immune factors
22 in the groups that will be analyzed.

23 There is evidence, of course, of reproductive
24 dysfunctions in experimental animals exposed to Dioxin.
25 Therefore, it seems reasonable that a study of chromosomal

1 patterns would also be appropriate in this prospective
2 epidemiological study.

3 For example, there is evidence that indicates that
4 there are changes in the sperm, that is, spermatogenesis in
5 experimental animals exposed to Dioxin so perhaps it would
6 be most appropriate to do chromosomal studies as part of
7 a sperm analysis in these individuals.

8 Other diagnostic procedures that could be
9 suggested in the epidemiological study would be directed to
10 evaluating some of the systems that have been associated
11 with Dioxin toxicity in other populations, or else in the
12 experimental animals.

13 Perhaps there should be hematological screening.
14 There should be dermatological studies of these groups.
15 There could be neurological studies, for example, motor
16 conduction velocity studies could be performed. In addition,
17 in the epidemiological study, there should be a long-term
18 registry of neoplastic lesions that may develop in the
19 exposed groups and, of course, in the appropriate control
20 groups.

21 In addition, there should be a long-term morbidity
22 study. Once these groups are identified, there should be
23 attempts to evaluate lesions that might occur over a long
24 period of time.

25 DR. HABER: Thank you. Are there any comments?

1 Dr. Lingeman?

2 DR. LINGEMAN: There is a registry at the Institute
3 of Pathology where pathologic material, from veterans exposed to
4 Agent Orange is collected. This is being collected by Dr. Nelson Irie,
5 and he will analyze the pathological material according to defined
6 protocols. I understand that the VA is participating in this activity
7 through contributions of appropriate pathological specimens.

8
9
10
11
12 DR. HABER: That is right, Dr. Lingeman.

13 May I ask Dr. Legolvan, Deputy Director of our
14 pathology section, to comment on this?

15 DR. LEGOLVAN: This registry has been set up with
16 the Armed Forces Institute of Pathology. At the present
17 time, there are 15 VA cases that have been registered and
18 reported. There are nine surgicals, five autopsies, and
19 one seminal fluid examination has been sent in.

20 As the momentum gains in the collection of this
21 material, I am sure more and more materials will be registered with
22 this registry.

23 DR. HABER: I am in the almost comfortable position,
24 Dr. Norback, of saying that most of these suggestions you
25 have made have already been implemented in our gathering of

1 data. I neglected to mention in our progress report that
2 we are in receipt of some 5,000 records from veterans who
3 have presented themselves to various Veterans Administration
4 medical centers, alleging either exposure or deleterious
5 effects to such exposure, and we are in the process of
6 reviewing those records, coding and analyzing them.

7 Doctors Levinson and Castellot and Miss Kilduff,
8 from our Medical Administration Service, Mr. Kutner and Ms. Meyer,
9 have all been going through those records and most of what
10 you talked about is part of our standard operating procedure.

11 We have not done AAH microscopical enzyme studies yet.
12 We are aware of it. We will comment about the study at the
13 appropriate time.

14
15 DR. MURPHY: I would like to point out that we have
16 discussed a number these tests at the last meeting and our comments
17 are in the minutes. These comments are generally consistent with the
18 remarks that Dr. Norback has made, but I think there are some precautions
19 made in the interpretations raised in the original minutes regarding
20 the specificity of some of these tests. I am really saying, let's
21 don't forget what has been said before.
22
23
24
25

1 DR. HABER: A very cogent remark.

2 DR. MOORE: I would like to make sure that in
3 the response that will be publicly available,
4 three things be mentioned that aren't

5 in the written record. One is I want to reinforce

6 what Dr. Murphy alluded to, that none of the symptomatol-
7 ogies that we are talking about are pathognomonic. The second
8 point: I think that greater emphasis should be put on the
9 possible evaluation of neurotoxicity as a result of this
10 exposure. I have recently received

11
12 an article from Italy dealing with the Seveso population
13 which was in the form of kind of a long abstract, as is
14 typical of the articles from Seveso, Italy.

15
16
17
18 I neglected to bring it. I will send it to you.

19 DR. HABER: Thank you.

20 DR. MOORE: The last point I would like to make
21 deals with immunology studies. Aside
22 from immunologic parameters that may be determined, one should focus
23 sequelae that may appear clinically as a consequence of depressed
24 function such as higher prevalence of a variety of infectious diseases.

1
2 I am aware of a verbal briefing of a bunch of
3 studies that a physician made, which was a 10-year follow-up,
4 of a Dioxin exposed population which
5 suggested that there were some immune alterations in this
6 population. Looking at the
7 records, there was a clear suggestion in his opinion that
8 the increase of "sickness" in that population was quite
9 dramatic.

10 I cannot share that information with you. He
11 cannot release it.

12 DR. HABER: What types of "sickness" are
13 you were talking about? Malignancies? Infectious Diseases?

14 DR. MOORE: No, just absences from work for a
15 variety of reasons -- colds, flu, didn't feel good, what-
16 ever, the total spectrum of reasons an individual might have
17 over a period of years, that he is not at work because he
18 is feeling ill or whatever. Again, that is rather
19 subjective type information, but it is provocative.

20 DR. HABER: Incidentally, I would like to call
21 attention to yet another monograph which I have received. Dr. Lindeman
22 supplied me with a copy of this. It is one of the IARC
23 monographs from the World Health Organization, International
24 Agency for Research on Cancer, and this one is on fumigants,
25 herbicides, 2,4-D and 2,4,5-T, chlorinated dibenzene dioxins,

1 and miscellaneous industrial chemicals. It contains some
2 very useful information.

3 DR. LINGEMAN: I would like to comment just
4 briefly in light of what has been said here. It is very
5 difficult to establish a causative effect relationship
6 between neoprene exposure and disease.

7 It is hoped that if unusual types of neoplasms
8 occur, we might be able to draw some specific etiological
9 conclusions. For example, the studies of vinylchloride have shown an
10 unusual type of neoplasm relating to the liver.

11
12 This type of information is what is attempted to
13 be gathered with this registry.

14 DR. HABER: Yes, that is very useful information,
15 Dr. Lingeman, because I think that just as chloracne is kind
16 of a marker of dioxin exposure,
17 then we have got to assume that an individual with chloracne
18 was exposed, whatever else is the case.

19 He gets the benefit of the doubt without question,
20 so I think the occurrence of unusual carcinomas at an unusual
21 age or unusual incident of carcinomas, would serve as a
22 similar marker.

23 DR. MURPHY: But the animal studies wouldn't
24 suggest that you were going to find such a marker.

25 Is that correct?

1
2 DR. MURPHY: It is a rather nonspecific thing. It
3 is not going to be like vinylchloride.

4 DR. BRICK: Dr. Haber, you mentioned something that
5 I was going to ask about previously. How many veterans are
6 service-connected for chloracne secondary to Agent Orange
7 exposure? Do we have any data on that? The reason I ask that
8 is that here is a group that I think all of us can accept, or
9 most of us non-experienced in this field can accept: if a
10 veteran had chloracne and was exposed to Agent Orange,
11 there is some relationship.

12 If there were a fair number of
13 veterans with chloracne after these many years, then these
14 veterans ought to be studied most intensely with reference
15 to whether or not, after these 20 years or so, there are still
16 evidences of dioxin or, whatever
17 residuals health-wise might be present, other than the
18 chloracne that he had originally.

19 Here is a group that there would be no dispute
20 about, and my question is do you have any data on how many
21 veterans, for instance, service-connected, for chloracne
22 secondary to Agent Orange?

23 DR. HABER: There are only two cases of veterans
24 with chloracne that have been given compensation by DVA.
25

1 analysis of those 5,000 veterans that have come to us. When this
2 analysis is completed, we will assess the incidence of chloracne
3 among them.

4 Again, the significance of chloracne is that it is
5 the marker and the life history of those veterans with it is of
6 paramount importance because they are clearly the ones who
7 are under the greatest risk of dioxin-related disease.

8 DR. MURPHY: In connection with that, will the
9 records of chloracne back at the time they were exposed be
10 examined and be available?

11
12
13 DR. HABER: Yes.

14 DR. MURPHY: I would think that is the way you
15 identify the group, perhaps.

16 DR. BRICK: Right.

17 DR. HABER: We will pursue that.

18 I would like to move on to question four: is it
19 possible for herbicides to have long-term adverse effects on
20 the male reproductive system.

21 Dr. Erickson wrote the paper on this topic. We
22 are going through this paper in order to
23 update this information, and what we are trying to do is
24 get the most current feeling on all of this from each of
25 you, so that we can proceed with it.

1 Dr. Erickson, do you want to make a comment?

2 DR. ERICKSON: Well, I will be very brief since
3 we have discussed this before. I began my response to the
4 question by rephrasing it slightly, suggesting that a more
5 appropriate question would be: Is it possible for herbicides
6 to have an effect, is it probable, or do they have an effect?

7 I went on in my position paper here to say that
8 so far as I am aware we were pretty ignorant, insofar as
9 knowing anything definite about human effects of Agent Orange,
10 particularly with regard to the male reproductive system.

11 I further stated in the paper that we do know of
12 a few environmental agents which are capable of causing
13 reproductive problems through the male and a number more
14 are suspected.

15 I wound up the position paper by pointing out some
16 methodological statistical problems which are going to be
17 faced in any study of this problem.

18 DR. HABER: I am very concerned about that issue,
19 re-reading your paper last night. Part of our problem
20 becomes even more manifest. I think we are indebted to
21 Dr. Erickson for pointing out to us the number of people we
22 will have to examine in order to demonstrate an increase of
23 occurrence. This, statistically, is going to be much
24 larger than we had maybe originally thought.

1
2 I would say this issue is one on which we must rely
3 on our epidemiologists to resolve.

4
5 DR. ERICKSON: Those calculations shouldn't be
6 taken as being anything carved in marble or something like
7 that. They were made merely to illustrate the point.

8 DR. HABER: But I think the point is well made,
9 that it is going to take large numbers in order to get at
10 the increase in incidence.

11 Are there any other comments?

12 DR. LINGEMAN: Maybe again we might be fortunate
13 or unfortunate in that a unique syndrome might occur among
14 people exposed to Agent Orange. Maybe we
15 don't need such large numbers. If we collect data on a
16 few of those, in thoroughly documented fashion, including photographs,
17 clinical records, and X-rays. However, if we uncover just the usual
18 types of congenital anomalies, for example congenital heart disease,
19 it will be much more difficult to document etiological corrections
20 and accordingly require larger numbers.

21 DR. HABER: Dr. Moore?

22 DR. MOORE: I brought some information with me.
23 I think it is the appropriate time to share it with the
24 Committee.

25 DR. HABER: Yes.

DR. MOORE: Being cognizant of the comment that

1 Dr. Erickson made, that
2 there is nothing with regard to male association of
3 effects on progeny in the literature.

4 There has been a study that has just started
5 within the last couple of weeks which is attempting to
6 assess this in a toxicology experiment. We are using
7 formulations of Agent Orange which we have made up since you
8 wanted variations with respect to dose and the amount of
9 dioxin.

10 It will attempt to assess the fertility of these
11 mice as well as malformations that may be associated within
12 the offspring. It will attempt to do chromosomal aberrations
13 on the mice.

14 I won't go into detail. I will make
15 a copy of the protocol available to you.

16 DR. HABER: That will be excellent.

17 DR. MOORE: Secondly, I received, indirectly, an
18 article from Dr. Ton-That-Tung

19 which was in French, which we had translated by
20 non-professional translators, so there may be some errors
21 in it.

22 The title of the article is "The Problem of the
23 Mutagen Effects of the Second Generation after Exposure to
24 Herbicides." In essence, the article, in its introduction
25 says that during a visit to the United States, following a

1 private interview with the Veterans Administration, it was
2 suggested to us that a study of the long-term effects of
3 herbicides on the second generation of Vietnamese soldiers
4 might be of interest.

5 The paper relates that they did attempt to conduct
6 such a study and without commenting on the quality of the
7 study or its inadequacies. if you would take the
8 study at face value, the study is alleged to have reported
9 that, indeed, they find a greater incidence of birth
10 defects in offspring sired by Vietnamese veterans who were
11 in the South, or in the area that was sprayed by Agent
12 Orange, as compared to Vietnam veterans who were not in
13 those locales, or as compared to the "normal Vietnamese
14 population."

15 A further point that deals, I think, with this,
16 they also allege -- I don't remember if they allege -- but
17 it is apparent, as you look at it, the greatest increase in
18 birth defects tends to orient towards neural tube defects.

19 One will recall, indeed, that there was an
20 Australian or New Zealand article that came out a number of
21 years ago alleging there was an increase in neural tube
22 defects, and people that were using phenoxy acid had
23 problems with that as well.

24 Lastly, I believe there was a group of physicians
25 in Lincoln City, Oregon, who signed a statement or issued a

1 paper that said that in their opinion, based
2 on their review of the animal data that there is a direct
3 correlation between the use of herbicides and possible malformations
4 in offspring- of exposed individuals.

5 This could be female-oriented as well. In talking
6 to one of those physicians, she claims that in her practice
7 she sees a higher incidence of birth defects, and I believe CDC
8 is following that up.

9 I also understand CDC is looking at that county
10 as well as adjacent counties to see if, indeed, there is an
11 increase in neural tube defects or any other defects.

12
13 DR. ERICKSON: Yes.

14 DR. HABER: Well, your comments are very germane,
15 Dr. Moore.

16 I think we have had an opportunity -- I think I
17 mentioned at a previous meeting -- that we had an opportunity
18 to be briefed by Dr. Jung on his experience. He presented
19 his slides to us. We put the question to him as to whether
20 there was any etiological clues, although there were malformations
21 clearly demonstrable, in his slides, and he eschewed any
22 skill as an epidemiologist, saying simply that these were
23 observations that he had made and was not commenting on
24 their statistical validity and frequency.

25 We asked him specifically about the possibility of

1 male inheritance, and he said that he had not had any
2 information on that and felt that that was not a
3 possibility. It is conceivable in the translation something
4 got mixed up.

5 In any event, we must continue to be alert to the
6 possibility of transmissible diseases.

7 Are there any other comments? Incidentally, I
8 think it would be useful if, as you comment, you give us,
9 as several of the speakers have done,

10 an indication of where your agency is, if you feel you
11 can do so, in pursuing this. We will continue.

12
13 The next question is number five. This was
14 presented by the representative from EPA, Dr. Griffith:

15 What topics should be included in the educational curricula
16 being developed to upgrade knowledge of potential herbicide
17 toxicity among VA staff members.

18 Dr. Spencer.

19 DR. SPENCER: Yes. I am Henry Spencer. I am
20 representing Dr. Griffith at this time. Unfortunately, I
21 was not aware that this paper had been produced, and I
22 believe it was turned over before Dr. Griffith left and
23 was unavoidable detained elsewhere.

24 I am not prepared to cover any aspect of this,
25 as I was not aware of it.

1 DR. HABER: The topics, if I could just address
2 this briefly, the topics Dr. Giffith suggested were those that we
3 would use in educating our people, and Dr. Levinson has designed
4 a follow-up to our conference that we had with our physicians.

5 The topics that Dr. Griffith suggested, systemic
6 poisoning syndrome, chronic poisoning syndrome, and topical
7 effects. He said that in emphasizing herbicide toxicity,
8 special attention should be given to animal and industrial
9 studies, documented and suspected known effects from
10 contaminants, specialized forms and procedures developed
11 for use in training, and methods used to collect patients
12 needed to identify poisoning and appropriate treatment
13 procedures. Descriptions of these topics would also have to be
14 prepared in written form for use in the training session.

15 Dr. Levinson, do you have any comment to make
16 about the continued training of veterans affairs physicians?

17 DR. LEVINSON: We started out at the point of
18 relatively minimal information of this area among our staff,
19 which is not surprising, since occupational and
20 environmental medicine, are not things that are usually
21 covered in medical schools or during residencies.

22 Looking at the comments that participants have submitted
23 it appears that the educational program did some definite good.

24 It is our intention, to continuously update the expertise of
25 our professional staff in the area of detecting herbicide toxicity.

1
2 I think Dr. Griffiths paper was very helpful. We
3 have already implemented its principal suggestions. For example, we did
4 define a data-gathering form and our instruction was constructed around a
5 data-gathering instrument. That instrument will be improved
6 as time goes on.

7 DR. HABER: Dr. Castellot, do you have any comment
8 you want to add?

9 DR. CASTELLOT: No, not at this time.

10 DR. HABER: Any other comments from the floor?

11 DR. MURPHY: Dr. Gross did mention at the last
12 meeting something about a training course. Did your people
13 have this? I don't know the specifics.

14 DR. LEVINSON: We had a course in which a number
15 of the members of this group spoke, and others. We
16 presented scientific information about TCDD, and we did talk about
17 epidemiological approaches to the study of its effects on humans.

18 It didn't
19 have many practical aspects. We didn't give them any
20 exercises because of the size of the group. We hope to do
21 that later.

22 DR. HABER: Any suggestions from the Advisory
23 Committee would be useful in this area. What is at stake is
24 the fact we have a group of physicians out there who are
25 not necessarily epidemiologists or toxicologists. We have

1 addressed it to all of our medical centers, suggesting that they
2 designate an individual who can, therefore, become most
3 familiar, and I was reasonably assured that we made some
4 pretty good choices out in the field, that we will have to
5 continue to make available to this group our latest
6 information and to give them refreshers.

7 The biggest problem is that there was a fair
8 amount of innocence, I will say, with regard to the
9 potential toxicological effects of
10 herbicides that we had to overcome, and any suggestions
11 any of the group has to make would be useful.

12 DR. MURPHY: I will suggest something in the last
13 minutes that may or may not be useful. Jack was thoughtful
14 enough to have brought along a package that we use in the
15 training. It contains literature, slides, and tapes.

16 You would be welcome to have that. You suggested
17 it would be of value.

18 DR. HABER: It was.

19 DR. MURPHY: Is it something that can be
20 distributed or is it of a nature that could be distributed
21 to various hospitals?

22 DR. HABER: Not at this point. We would have to
23 modify it. We will do that. There is an additional
24 activity that I didn't tell you about. We have a readjustment
25 counseling program for Vietnam veterans, of which you may

1 have heard. This is a psychological readjustment counseling
2 program under recent legislation.

3 The Administrator of Veterans Affairs is
4 authorized to solicit intervention on behalf of the Vietnam
5 veterans who have problems through these psychological
6 readjustment programs. The veterans participating in this program
7 are made aware of the prospect of the VA's Agent Orange activities,
8 and referred to a VA medical center for health care, if required.

9
10
11 I will move to Position Paper Number 6: What sorts
12 of animal studies would make the most important
13 contributions to understanding the potentially toxic effects
14 of herbicides in humans.

15 Again, Dr. Allen was to lead on this. Dr. Norback,
16 are you in a position to comment?

17 DR. NORBACK: Yes. Dr. Allen suggested animal
18 studies to again define toxic effects of dioxin.
19 In addition, he suggested animal studies might provide some
20 mechanism to determine if there would be any way to treat or
21 to modify the problems of dioxins.

22 He emphasizes that the rhesus monkey is a very
23 suitable animal model for determining toxicity of dioxins
24 in that the rhesus monkey, of course, has some similarity
25 to man. He suggests that during exposure studies

1 psychological irregularities also be looked at, and he has
2 data indicating that there are behavioral abnormalities
3 related to certain chlorinated hydrocarbon toxicities.

4 Neurological studies could be done on these
5 experimental groups. He points out that the experimental
6 compounds could be quite similar to those that the veterans
7 were actually exposed to in Vietnam. In other words, their
8 dioxin content should be similar.

9 If Agent Orange would be used as an experimental
10 compound, the dioxin content, of course, should be very
11 similar to that which was present in the Agent Orange.

12 In evaluating the carcinogenic potential of the
13 compound, he would suggest using rats or mice, as the
14 animal of study, rather than the rhesus monkey in that one
15 would expect tumors to develop in a shorter period of time
16 than one would expect in the rhesus monkey.

17 In order to discuss treatment of symptoms caused
18 by dioxins, it would be helpful to clarify the mechanism of
19 action of the dioxin. That has, of course, remained very
20 elusive, but a number of investigators have tried to
21 investigate the mechanism of action. Emphasis should be
22 put on this very important experiment even though it is a
23 difficult experiment to conduct.

24 Some of the problems of doing studies on the
25 mechanism of action are reviewed in Dr. Allen's paper, including

1 the fact that the material is extremely insoluble so it is
2 difficult to work in cell-culture systems with the dioxins.

3 It is difficult to evaluate ^{and quantitate} the material in that it is
4 so toxic that once a high enough level has been administered
5 to the animal to detect the compound and thus be able to study its
6 location and action, the animal often succumbs to the toxicity of the
7 material.

8 He also points out that the persistence of the
9 material could be studied by using experimental animals.
10 He has several studies of long-term exposure to the dioxins
11 in the monkey population, and the animals succumb to the
12 toxicity once a dosage of about 1 microgram per kilogram
13 has been reached.

14 He suggests that the persistence of this material
15 in this population of rhesus monkeys could be determined
16 and this might shed some light then on the persistence of
17 the compound in the veterans groups that have been exposed
18 to dioxin.

19 To elaborate on that somewhat would be to answer
20 the question, "If a person has been exposed to a dioxin 3, 4,
21 5 years ago, would the materials still be present in the
22 fat?" One could use these exposed monkeys which have
23 already achieved a rather high level of dioxin, and study the
24 experimental animals over a period of time. Fat biopsies could
25 be done and analyzed ^{for dioxin} in order to determine the persistence

1 of the material or how quickly it disappears.

2 That would answer the question, "Would it be
3 meaningful to do biopsies on the veterans at the present
4 time?" The
5 correlation between toxic effects and the level of
6 dioxin present would also be established.

7 DR. HABER: Do you know of any work on tissue
8 culture?

9 DR. NORBACK: I am aware of some work that is in
10 progress at the University of Wisconsin, actually, in
11 another laboratory, using dioxin. It is being done at
12 McArdle.

13 DR. HABER: Does this go towards elucidating the
14 mechanism of action?

15 DR. NORBACK: To some extent, yes. I can't really
16 comment on how far along this work has gotten. I know
17 there has been a lot of problems in just getting a system so
18 that the dioxin could be dissolved in appropriate solvent
19 and applied to the tissues. There have been difficulties
20 in getting this system set up.

21 DR. HABER: As one would expect, it is hydrophilic
22 and hydrophobic and problems occurⁱⁿ working with a water insoluble
23 compound.

24 I would like to ask the
25 Committee members to give us some indication, if possible,
about when one might expect the studies would be complete.

1 I think that will be very useful. One of our efforts will
2 be to try to make some time sequences so that we can begin
3 to develop an overall strategy with respect to how these
4 studies will fit in the time sequence.

5 I am going to be pressing for that kind of
6 information.

7 DR. MOORE: Without taking issue at all with the
8 response that Dr. Allen prepared, I would think it would be
9 of benefit if the committee could focus the response a little
10 bit more on the purpose for which you are trying
11 to get this information.

12 What I would like to propose for the Committee's
13 consideration is several things that should be stressed in
14 providing more focus. One, I think there should be
15 some focus in the area of neurobehavior.

16 This certainly is an area that TCDD exposure in
17 humans is suggesting untoward effects. There is
18 also some animal data that also corroborates this feeling.

19 In addition, there is evidence in the literature
20 that suggests that 2,4-D itself may be involved with neuro-
21 behavioral and neurotoxicity sequelae. So I think, indeed,
22 animal studies here may shed more light as to how these
23 occur. Are they reversible? Irreversible? What
24 specific types of effects might one expect to see?

25 Secondly, I think it leads back to the previous

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1 question. One of the main things that is facing the
2 Veterans Administration is the association of
3 possible effects on male fertility and, therefore, on their
4 offspring.

5 Thirdly, since most of us would consider that if
6 there are male effects that are associated with offspring
7 abnormalities, it has to be associated with a
8 mutagenic event; therefore, this is an area that
9 one might possibly stress.

10 With regard to the tissue position,
11 I am a bit skeptical as to whether animal data is going to
12 answer that question today with regard to direct application
13 to man and my reason for saying that is this: If one looks
14 at the species in which this has been done, rodents^{and} primates,
15 there is species variability with regard to tissue
16 distribution, and
17 with regard to clearances and half-life. As far
18 as trying to extrapolate to man, which species is the
19 proper one? Until we get information with regard
20 to distribution in man,
21 we don't know what animal species
22 to focus on as far as trying to get more information.

23 DR. HABER: I think your comments are valid. I
24 appreciate Dr. Allen's specifications for the animal models.
25 These are the areas we should look at.

1 I think clearly the problem is a complicated one.
2 Any other comments on number six?

3 DR. MURPHY: I would like to ask a question of
4 Dr. Norback regarding this. Dr. Allen has a population of
5 rhesus monkeys I presume that have been exposed, some of
6 which have succumbed to the exposure, some of which
7 survived. Does he have any existing colony that was exposed
8 five years ago and are still surviving and hasn't been
9 exposed since?

10 DR. NORBACK: I don't know -- (SEE INSERT - PAGE 50a)

11 DR. MURPHY: Has there been a biopsy?

12 DR. NORBACK:

13
14
15
16 He has not followed
17 the storage of the material in the fat because the material
18 is so difficult to assay. Presently he has established
19 a dosage of about 1 microgram per kilogram of body weight,
20 which is really very toxic to the animals. And so, if we could
21 assume for simplicity that the material would be
22 equally distributed in the body, which it isn't,
23 this would indicate that there are 10 to the minus ninth
24 grams in the material of a gram of fat.

25 This is a very toxic dose. Certainly, analytical
methods with a sensitivity to detect dioxin at levels
several orders of magnitude lower than
ten to the minus ninth grams, for example, ten to the minus twelve, would

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2 There are four distinct groups of animals that have received dioxins
3 in experimental diets. One group of three animals received a diet
4 containing 500 parts per trillion for nine months and ingested a
5 total of approximately 2.5 to 3 microns per kilogram of body weight.
6 This group has received a diet free of dioxins for the past three
7 years. A second group of eight animals received fifty parts per
8 trillion of dioxin in the experimental diet for thirty-three months
9 and ingested a total of 1.3 microns of dioxin per kilogram of body
10 weight. These animals have been recently removed from the experi-
11 mental diet. Two additional groups, each containing eight animals,
12 are presently receiving diets containing dioxin at levels of twenty-
13 five parts per trillion or five parts per trillion.
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1 be necessary before the persistence of this material could be evaluated.

2 DR. MURPHY: Lower than available methods?

3 DR. NORBACK: I believe methods of detection are
4 available. Review of the present state of the art for
5 measuring dioxin has come out of the Environmental Chemistry Branch
6 of NIEHS in a paper by Hass and Friesen,
7 / and I believe the technology would be available to
8 perform these studies and to determine the persistence of
9 the material in the fat of the rhesus monkey population,
10 but it hasn't been done yet.

11 DR. MURPHY: It seems it might be fortuitous to
12 try and use that population of controlled exposed animals.

13 DR. NORBACK: I agree.

14 DR. MURPHY: I don't know if there still is.
15 There was at the last meeting a lot of discussion about the
16 value of this biopsy program and sampling analysis of fat
17 biopsy in terms of what it meant.

18 DR. HABER: I think it is an excellent idea.

19 DR. NORBACK:

20
21
22
23
24 We would assume the rhesus monkey would probably
25 store and excrete these compounds more

1 similar to humans than many other experimental animals.

2 DR. MOORE: I can't accept that.

3 DR. HABER: Okay. In any event, it would be
4 useful if we could get that kind of data on monkeys that had
5 been exposed and no longer were. We will be in touch.

6 DR. NORBACK: Dr. Allen, I think, would be very
7 happy to make the animals available.

8 DR. HABER: Question number seven, Mr. Lenham.
9 The question was, what additional data should be included in
10 the Veterans Administration's herbicide registry over that
11 currently collected.

12 Do you want to make any comments?

13 MR. LENHAM: The comments I made at the last
14 meeting, we are finding more and more information coming
15 into the Committee, where it is very obvious that if an
16 epidemiologist recommends that specific testing be performed
17 on the veteran population to determine whether or not he has
18 been exposed to dioxin, then those testing procedures should
19 naturally be included in the process that the Veterans
20 Administration has included in the herbicide
21 registry.

22 DR. HABER: Has your membership
23 given you any indication of areas that they feel
24 have not been addressed in our collection of data through
25 the laboratories?

1 MR. LENHAM: No, because I don't think they have
2 seen that much of it.

3 DR. HABER: Are there any other comments about
4 that? This, obviously, is an area that we want the
5 epidemiologists to address. Do you have any comments,
6 Dr. Levinson?

7 DR. LEVINSON: As we look at the records as they
8 come in, we encounter a series of problems. We are attempting
9 to force, as it were, the veterans to remember whether or
10 not they were exposed, and it turns out most of them really
11 don't know. However, they attempt to help us by speculating.

12 I believe that it is difficult, if not impossible, to gather accurate
13 spraying information from the veterans. Similarly, with regard to
14 symptoms, the more you press them, the more symptoms they will report
15 because they believe you want them to come up with something.

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20
21 It is very difficult to develop a totally neutral
22 stance that would get veterans to answer in a completely
23 objective sense, so we are eliciting a lot of data in our
24 collection which is basically invalid, but we continue to
25 gather it, at least to see what it yields, and we are

1 attempting to follow up any leads vigorously.

2 It is clear that our existing data collecting instruments
3 need to be significantly improved. We intend to undertake the necessary
4 revisions in the near future.

5
6
7
8 DR. HABER: Let's proceed on then to question
9 number eight, "what are the known facts on the persistence
10 of dioxin and the herbicides used during the Vietnam War
11 in water, soil, and the atmosphere? Can these media serve
12 as a source of human exposure to dioxin and herbicides?"

13 We have Dr. Kearney's response. I would ask
14 Dr. Kearney to comment on his paper and then I will ask
15 the Air Force representative if he has any comments he wants to add.

16 DR. KEARNEY: I think we may have discussed parts
17 of this the last time. The only areas that I would like to
18 perhaps update are in the very last section.

19 We have information, I think, now that gives us
20 some idea of levels of exposure, quantitatively, and with
21 that I would like to look at this last section again on
22 Page 4 and perhaps update it.

23 DR. HABER: Very good. Colonel Thiessen, have
24 you got any comments that you want to make based on the
25 Eglin Air Force Base studies?

1 COLONEL THIESSEN: No. The data in Dr. Kearney's
 2 report are basically taken from the Eglin report.

3 DR. HABER: I think this is really an extremely
 4 important area and I do commend Dr. Kearney for a very
 5 learned discussion of it. One of our problems is
 6 to be able
 7 to translate the kind of data that Dr. Allen and Dr. Moore
 8 were talking about derived from animals with known exposure,
 9 where one could quantify the amounts of toxic agents into
 10 animals, and to try to get that data transmuted into something
 11 that approximates the kind of field exposure that human
 12 beings would have in walking through exposed areas where
 13 spray was common. That is a very difficult thing for us
 14 to be able to do, and that kind of model is what we are
 15 going to have to continue to pursue.

16 We need all the help we can get on that because
 17 to have a laboratory animal ingesting pellets of a fixed
 18 known composition for a certain number of days or weeks or
 19 months is one thing. To be able to infer from what might
 20 have happened to ground troops or to airborne people who
 21 could have gotten exposed either from the atmosphere or
 22 from the soil, by ingestion, by contact, or by inhalation
 23 is a very tricky business, and the
 24 models for these processes are going to have to be developed with
 25 great care.

1 DR. KEARNEY: Dr. Haber, just one comment. I
2 think now we can get some fairly quantitative ideas of
3 what levels of exposure might be by certain routes. What
4 we don't know, and it is very difficult for us to get at,
5 is what is the daily life pattern of a soldier in Vietnam;
6 what is his food source; what is his water source.

7 If we knew some of these kinds of things, maybe
8 we could get a better picture, but this is a different kind
9 of environment than an agricultural or forestry situation.
10 We have no clue as to these other sources, possible sources
11 of exposure. If we could get some idea of a lifestyle, what
12 a person experienced there, maybe we could sharpen our focus
13 on that.

14 DR. HABER: We will undoubtedly pursue that. We
15 will need all the help we can get from the Department of
16 Defense. The Department of Defense has been very cooperative
17 in giving us data and suggestions, including Major Brown and
18 Dr. Wolf. They have been very helpful to us. We will have
19 further comments from them at the appropriate time.

20 Moving on, what medical tests should be utilized,
21 to help establish a diagnosis of chronic herbicide-induced
22 toxicity among Vietnam veterans?

23 Dr. Lingeman of the National Cancer Institute
24 will comment on her paper.

25 DR. LINGEMAN: This is a very, very complicated

1 problem. The main difficulty is to rule out all other causes of any
2 of the abnormalities observed.

3 First, a complete medical history and standard physical
4 examination should be done with attention to the target organs
5 that are most likely to have been damaged by TCDD.

6 The immunologic system is one of these. Dr. Costan Berard
7 of the National Cancer Institute has offered help on this problem.
8 He stated that effects on the immune system might be quite subtle
9 and that these should be evaluated by someone with special experience
10 in examining the immune system. Certain veterans could be selected
11 for very intensive studies of the immune system.

12 Studies of possible effects on the reproductive system
13 also might be considered a research project. In other words, limited
14 numbers of people could be studied intensively, with attempts made
15 to document all the findings.

16 With regard to the liver, the usual method for measuring
17 porphyrins in the urine may not be satisfactory. The porphyrin
18 fractions should be measured and this will require specialized
19 facilities. Again, this type of procedure should be considered
20 research rather than routine.

1 At least one Veterans Administration hospital may have this capability.
2 Affiliated universities or perhaps some of the NIH people might be
3 interested in working on this problem.

4
5 With regard to the central nervous system, I
6 think this is the most difficult of all. Neurological
7 evaluation of toxic neuropathies has only begun to be
8 explored. I have a list of at least 40 chemical compounds
9 that are known to cause toxic neuropathy, so it is going to
10 be a very complex issue to decide which symptoms
11 or signs might be caused by dioxin.

12
13 The psychiatric evaluation, I think, will be
14 extremely difficult. Toxic psychiatric
15 symptoms are extremely difficult to differentiate from
16 those in which we can not identify a toxic chemical. Studies
17 are being done on early psychiatric changes
18 that occur following heavy exposure to alcohol.

19 An alcoholic brain syndrome can now be
20 defined by some standard psychological test. This
21 information has only recently become available to me, and
22 I will refer it to the members of the Steering Committee.

23
24 DR. HABER: Have you any information as to what
25 kinds of tests would be of use in neurologic testing? Are

1 you talking about nerve velocity?

2 DR. LINGEMAN: Yes, nerve velocity. On Page 8
3 of the position statement it is recommended that electromyogram and
4 and nerve conduction velocity studies which are available in many
5 Veterans Administration hospitals be performed on any veteran com-
6 plaining of neurologic problems. The nerve biopsies when done should
7 be sent to the AFIP, where neuropathologists can examine them and render
8 consistent diagnoses. Some of the reports have indicated visual
9 abnormalities or defects in taste or hearing. These should be
10 objectively evaluated by ophthalmologists, audiologists and other
11 specialists in addition to neurologists.

12
13 DR. HABER: Again, we are
14 indebted to you for outlining the approach and I appreciate
15 your flow chart.

16 Dr. Castellot, do you have any other comments on
17 this issue?

18 DR. CASTELLOT: Just to state it was very
19 comprehensive as a review and I think the staff position is,
20 at the moment, that we should take portions of this
21 protocol for the Veterans Administration's epidemiological
22 studies.

23
24 DR. HABER: It seems to me we will have to have
25 sub-groups looking at the specific organ systems,

1 for example, the immunological area, the liver, the reproductive organs,
2 the central nerve system, special sense organs, the skin, respiratory
3 system and the hematopoietic systems.

4
5
6 This brings us to question number 10, "Can criteria
7 be established for determining the level of exposure of military
8 personnel to dioxin during the Vietnam War based on spraying
9 tapes and unit histories."

10 Colonel Thiessen, I know we are springing this on
11 you. You have not had a chance. Do you want to comment on
12 this now?

13 COLONEL THIESSEN: I brought it in myself. so
14 I have no problem with it right now. I can summarize it
15 for you.

16 DR. HABER: Why don't we distribute it to members
17 of the Committee and maybe you can comment on it briefly.
18 This is a very critical issue, one that we have talked to
19 the Department of Defense about and particularly the
20 Air Force, and we will be pursuing this because one needs
21 to know what the level of exposure was, and if you have
22 any comments to make, Colonel Thiessen, this would be the
23 appropriate time.

24 COLONEL THIESSEN: Let me make clear first, sir,
25 that although my name is on the paper, the report was

1 prepared by Major Young and Colonel Wolf. The first draft, let
2 me say, was prepared by Major Young and Colonel Wolf, who
3 were here last time. We have tried to address the question
4 of exposure criteria, namely, what determines exposure and the
5 conditions that were extant in Vietnam. The authors addressed
6 basically three groups of questions that they felt were
7 important to be answered in this respect.

8 One, was the individual in Vietnam; what job did he
9 he perform, and what was the situation at the time of
10 exposure? ^{Then,} what were the exposure conditions; were aircraft,
11 vehicles involved? ^{then,} And/how actually did the exposure occur?

12 Each of those question areas are addressed in
13 the document. In tabular form, we have tried to provide
14 you all the information that determines or that would be
15 input factors into any estimate at all of what the potential
16 exposure could have been.

17 It is a rather large document, as you see. I
18 think you deserve some time to study it. We have tried
19 by different means to give the best estimates possible ^{as to} the
20 amounts of herbicides that were being disbursed in Vietnam,
21 ^{and} the different means of distribution.

22 In two tables, 2 and 5, I believe they are, you
23 will find two separate estimates that agree very well, one
24 based on the actual amounts that were shipped to Vietnam
25 and the other based on spray data.

1 Again, the totals read very well.

2 We have discussed the type of military aircraft and
3 other
4 /vehicles that were involved in the exposure because there
5 are differences here. The bulk of the Agent Orange,
6 Herbicide Orange, was disseminated by C123 fixed-wing
7 aircraft, so it is important to know what the individual
8 says that source of exposure was. Was it a spraying aircraft,
9 fixed-wing, or a helicopter, or was it by some other means?
10 All of those different means of delivery are explained in
11 the document.

12 Then, how did the exposure occur? Clearly, it
13 is important to analyze whether or not we are talking about
14 inhalation or ^{vaporized} aerosols, or whether we talk about late
15 exposure to material that had been deposited much earlier, or
16 whether we talk about ingestion of foods contaminated with
17 the Herbicide Orange.

18 Tables 7 and 8 gives you that and some of the
19 physical and chemical characteristics of the different
20 compounds involved.

21 I must stress the limitations of the information,
22 maybe not so much the information as the use of the
23 information. We are pretty well convinced that it will be
24 extremely complex, if not impossible, in individual cases
25 to determine exposure with any degree of accuracy at all.

DR. HABER: Thank you very much, Colonel Thiessen.

1 We will want an opportunity to digest it. This is a
2 crucial and vexing matter.

3 We have accomplished the first step I mentioned, namely,
4 translation of animal data into something like exposure
5 data that is likely to have been experienced by troops and
6 by the people in Vietnam, and secondly, to get some idea
7 of the degree of exposure.

8 The GAO report that I called attention to earlier
9 is illuminating, and certainly there are a lot of unanswered
10 questions.

11 I would like to say that my own approach toward
12 this would be that we would try to learn
13 as much as possible about the likelihood of exposure so as
14 to look for particular populations to study further. However,
15 with regard to specific individuals,
/because of the fluid nature of the hostilities and because
16 of the fact that under wartime conditions, particularly in
17 the kind of war that was being fought in South Vietnam, it
18 might be almost impossible
19 to deny the possibility of exposure to any given individual.
20 Accordingly, it will be ^{necessary} to make it possible for any individual
21 who believed he was exposed to have the obvious right of a
22 thorough examination, regardless of whether that fits in
23 with ^{other} data that we obtain about his views of his exposure.

24 MR. LEMEN 1: I have one comment. I addressed it
25 in the first meeting we had. We still have concern,

1 and I think it is very pertinent to your epidemiology study
2 as to what the exposures to Orange were outside of Vietnam.
3 I don't think that has been addressed. It is our under-
4 standing American soldiers were exposed to the dioxins in other areas
5 of the world. Having this data is very important in the selection of
6 any control group.

7
8 DR. HABER: I think it was addressed.

9 Major Young pointed this out to us some time ago. In
10 and in
Aschaffenburg, Germany, certain areas of the continental
11 United States, herbicides were used and troops may have been
12 exposed. So I think that just complicates our problem,
13 Mr. Lemen. You are quite right. We are so anxious to
14 get on to the bottom of the Vietnam experience that I think
15 rightfully that preoccupies our thoughts, but it should not
16 necessarily eliminate the possibility that other exposures
17 were made. This factor makes it more difficult to find a control
18 population.

19
20 MR. LEMEN: What I would like to suggest is the
21 preparation of a position paper dealing with Vietnam, and I also think
22 a position paper of at least related answers should be
23 prepared dealing with the rest of exposures to soldiers throughout the
24 world.

25 DR. HABER: I don't know whether you were here at

1 the time or not, but earlier in the meeting I asked
2 Dr. Levinson to comment. We had some indications that
3 there might have been herbicides used in Korea, and we
4 have addressed that question to the Department of Defense
5 and we expect an answer.

6 Thank you, Colonel Thiessen. Let's move on to
7 number 11. The question, "Will it be possible to develop
8 standards and criteria which define the precise relationship
9 between herbicides and dioxin with chronic adverse effects
10 in humans?
11 Can these criteria also specify the reasonable
12 limits between the time of exposure to herbicides and the
13 development of disease?"

14 DR. MOORE: Well, basically, my response is in
15 the package you have. It is relatively brief. I think you
16 can read it almost as fast as I can describe it.

17 The main point that I think I make in the first
18 sentence is that since the question said, define the precise
19 relationship, the answer is no. We then go on to what can
20 we do and what can't we do.

21 DR. HABER: Okay. I think your previous discussion
22 has covered some of this. Is there any other comment from
23 members of the Committee?

24 DR. KEARNEY: I have been trying to find an
25 appropriate place to introduce this. I don't know if it

1 fits well here or not, but it addresses the subject of
2 epidemiology studies already conducted on 2,4,5-T and
3 dioxin as you know, there is a study that has triggered
4 the regulatory action on 2,4,5-T, which is called ALSEA-2;
5 it is conducted by EPA.

6 I didn't want to go into the whole background of
7 that. However, there has been a follow-up study conducted
8 by Oregon State University, the Environmental Health Sciences
9 Center, conducted by an^{M.D.} epidemiologist and two
10 statisticians. I think it is informative in that there
11 are pitfalls in conducting epidemiology studies, and I
12 think it is well to review this and find out what these
13 pitfalls are. There is one sentence in here

14 that is perhaps a key to it: "Retrospective studies such
15 as the ALSEA-2 study are exceedingly difficult to conduct."

16 The net effect of attempting to do a comparison
17 among several perfectly definite population groups is to
18 obscure the potential data by a mass of other information.
19 When poorly done, these studies tend to confuse rather than
20 clarify the issue.

21 If you look at the statistical approach, it is
22 voluminous and one finds major problems with the ALSEA
23 study, per se, which I believe may invalidate it. But I
24 think it is perhaps even better for what you are involved
25 with. If you are going to go about this particular thing,

1 you would best go about it in the most scientific manner
2 you can because it will certainly be subject to much
3 challenge. As much front-end information as you can gather
4 and the kinds of statistical validity that you can bring to
5 bear on the subject, I think will help you.

6 That is all I want to comment. I will give this
7 to you, though, for your edification.

8 DR. HABER: Thank you very much.

9 COLONEL THIESSEN: In that respect, Mr. Chairman,
10 it may be helpful to announce a recent publication by EPA,
11 I believe, a draft inter-agency guideline for documentation
12 of a epidemiological study. I think that will be extremely
13 important to follow. I think that contains some of the
14 general comments that Dr. Kearney made.

15 MR. LEMEN: You are talking about IRLG?

16 DR. KEARNEY: Yes.

17 MR. LEMEN: That should be made available to the
18 Committee.

19 DR. HABER: Could we get that?

20 MR. LEMEN: I can send you a copy.

21 DR. HABER: That would be very useful. Thank you
22 very much.

23 Are there any other comments about that issue?

24 (No response.)

25 DR. HABER: If not, we will go to 12. We are

1 within our time limit. That is good. I want to have more
2 time for comments from the floor when we finish.

3 Dr. Murphy, this question was addressed by you.

4 DR. MURPHY: As I commented at the last meeting, I
5 really have no particular expertise to address that
6 question. It seems that is one that has to be
7 arranged with the State Department, perhaps, but I think
8 Dr. Moore has attached to the handout an article that
9 somehow or other got through the United States Committee for
10 Scientific Cooperation on Vietnam. I don't know what that
11 committee is.

12 Maybe that is a source of obtaining such
13 information and I commented on some of the reports, some
14 of the data of the earlier NAS studies regarding exposures
15 of the Vietnamese population.

16 Much of that was rather anecdotal data obtained
17 from a not too objective kind of description but it might,
18 as I have suggested, identify some groups to be followed,
19 just as this paper that Dr. Moore distributed suggests some.

20 I might go on. I might extend this to the new
21 set of questions. My comments to the new set of questions,
22 which I didn't respond to, I think the question was, what
23 are the sources of information and how might the Veterans
24 Administration best remain informed of the literature
25 relevant to the toxicology of Agent Orange and its related

1 compound. I didn't prepare a position paper on that,
2 but I will comment.

3 I think that Dr. Kearney actually, in his response,
4 has provided a list of agencies and groups that are involved
5 in the studies, and I would think establishing liaison
6 there would be an important part. I would say that the one
7 that he did identify, the National Academy's Committee on
8 Response Strategies to Hazardous Materials, whatever the
9 title of that committee is, through their Board on Toxicology
10 and Environmental Health has, in fact, been attempting to
11 accumulate the world's literature on subjects relating to
12 dioxin, not 2,4,5-T necessarily, but dioxin contaminants,
13 and I would assume if you would contact Dr. Hardy you could
14 be placed on a mailing list for distribution.

15 Dr. Moore may have other sources that you would
16 recommend in addition to those that Dr. Kearney has indicated.

17 One thing I didn't think was covered, and I don't
18 know whether you could tap it, but the major manufacturer of
19 2,4,5-T, Dow Chemical Company, has a very good information
20 resource recovery group, and I think, I would imagine that
21 they have tried to get, to collect the reference material
22 on the world's literature there, and you might be able to
23 use their data bank, literature bank.

24 DR. HABER: Very good. Are there any comments on
25 that question?

1 DR. MOORE: Dr. Haber, just an additional
2 thought as an additional source of information that may
3 already be assembled. There is litigation pending between
4 EPA and a variety of manufacturers dealing with the
5 suspension of 2,4,5-T and its use, and I am sure the
6 attorneys for EPA, in the preparation of this case, probably
7 will have a fairly complete file on published literature
8 of 2,4,5-T and dioxin. That is part of the suit.

9 Again, it is available. It is already assembled.
10 That, coupled with the Dow or the National Academy ^{should} do it.

11 DR. HABER: That was EPA?

12 DR. MOORE: EPA.

13 DR. MURPHY: EPA is in a number of different
14 activities. I don't know if you could focus on one. I
15 expect the Office of Pesticide Programs should be the one
16 to trace this information.

17 DR. HABER: Give us that name again, please?

18 DR. MURPHY: Office of Pesticide Programs.

19 DR. KEARNEY: Dr. Ed Johnson.

20 DR. MURPHY: We have some EPA people here.

21 DR. HABER: Dr. Spencer, could you comment on
22 that for us, please?

23 DR. SPENCER: I am sure they would give you
24 anything they have in the files and the literature. It
25 would not be covered under the confidential publications.

1 DR. HABER: Are you aware of the existence of this?

2 DR. SPENCER: I am very aware of the existence of
3 that, yes.

4 DR. HABER: Could you endeavor, is it possible for
5 us to make contact with them in some fashion through your
6 office?

7 DR. SPENCER: I would expect it to go through the
8 Office of Pesticide Programs, Mr. Johnson, in that regard.
9 I am sure he will give you first class, first rate service
10 on that.

11 DR. HABER: Thank you.

12 Okay. There are now four additional questions
13 which were posed, which have not been read into the record
14 and I would propose to read these now verbatim. The answers
15 have not been completely prepared and we are at this point --
16 I just want to read these so that we get them into the
17 record, and then invite comments from the group about them.

18 These are the four additional questions, in
19 addition to the thirteen we had proposed. I am guilty of
20 skipping one particular item. Question 13 was posed by a
21 letter to/ the United Nations. The letter was addressed to the Honorable Kurt
22 Waldheim and the question was: "What is the United Nations
23 doing concerning Agent Orange which may have an effect on
24 UN troops that served with the United States in Vietnam?"

25 We have addressed a letter to the Secretary General,

1 which can be made available to you, signed by the
2 Administrator of Veterans Affairs. This answer, to the
3 best of my knowledge, has not yet been received. We will
4 be pursuing it because, obviously, the experience abroad
5 is germane and we don't want to overlook that possibility.

6 Let me then return to a recitation of four
7 additional questions, position papers, which we will be
8 seeking answers to.

9 The first of these is: "What is the relative value
10 of the following types of studies for the definitive
11 establishment of any toxic effects of Agent Orange on human
12 health: epidemiological studies of exposed Vietnam
13 veterans; epidemiological studies of the victims of
14 industrial accidents; primate toxicological studies;
15 toxicological studies on non-primate mammalian species;
16 and statistical studies on the incidence of "target organ"
17 diseases among different groups of veterans? What should
18 the VA's role be in the direct performance of each type of
19 study?"

20 That is addressed to all members.

21 The second question: "what is the scope of an
22 adequate epidemiological study of Vietnam veterans exposed
23 to Agent Orange in terms of the following parameters:
24 numbers of veterans involved; length of follow-up required;
25 and the types of medical studies that should be performed

1 on the participants?"

2 That has been assigned to Dr. Suskind, one of the
3 new members of the Committee who could not be here today.

4 The third question: "How can the VA best remain
5 informed on the literature relevant to the toxicology of
6 Agent Orange and related compounds? How can this information
7 be most effectively disseminated to the staffs of the VA
8 health care facilities?"

9 That has been assigned to Dr. Murphy. He has
10 already addressed it partially. We will look forward to
11 his submission on that.

12 Four: "How can the VA most effectively coordinate
13 its research and clinical activities relevant to Agent
14 Orange toxicity with those of other federal and non-federal
15 agencies engaged in similar efforts?"

16 That is assigned to Dr. Kearney. Dr. Murphy
17 and Dr. Moore have already commented on this, as has
18 Dr. Spencer.

19 What we will be doing then is we will be driving --
20 I hope I use the word advisedly -- toward the completion of
21 these position papers with approval by the coordinators of
22 these papers.

23 There has been some concern about whether the
24 coordinator and the contributors had equal access. We will
25 expect the coordinator to finalize his version and we will

1 be getting those from him within the next several weeks.
2 We are driving toward completion of these papers for several
3 reasons. One, our Administrator is going to be testifying
4 before one or both of the houses of Congress early next
5 year. We want to have these statements in completed form
6 then.

7 Secondly, a White House Committee has been formed --
8 I note that Dr. Margusti is here from HEW. Good to see you,
9 Dr. Margusti, and the other people. They are pressing for
10 decisions about this.

11 Third, and as important as any of the others, is
12 the fact that this will form the substrata for the
13 epidemiological studies which the new law will direct us to
14 do. I think in a fairly real sense we can take some
15 satisfaction from the fact that we have laid a very
16 effective groundwork for an epidemiologic study.

17
18 I think that I would direct that any effort of an
19 epidemiologic nature be thoroughly conversant with these
20 information papers. We have been striving to get these
21 papers completed and signed off. They will be released.
22 We will invite comments, rebuttal from all concerned.

23 I would like now to move to a status report from
24 the Steering Committee, and I would like to ask Dr. Levinson
25 if he would please bring us up-to-date on several important

1 issues that you need to be made aware of. Following that,
2 we will hear the presentation of the three papers that I
3 mentioned and we will open this up for written comment.

4 DR. MOORE: I may be daydreaming. We are going
5 to try to answer these four questions? Are they add-on
6 questions?

7 DR. HABER: Yes.

8 DR. MOORE: Today? Subsequent?

9 DR. HABER: Subsequently. We will await the
10 presentation of written answers as to this which will then
11 form the basis for comment. I don't know that they will
12 have the opportunity for this kind of discussion.

13 I think at this point, unless you have something
14 you want to say now, I don't think it is fair to these
15 folks to expect them to comment. Do you have any further
16 comments you want to make about any of these issues?

17 DR. MOORE: No.

18 DR. HABER: Thank you.

19 Dr. Levinson, will you bring us up-to-date on
20 the Steering Committee's efforts?

21 DR. LEVINSON: I will stay within the 15-minute
22 time period. We may not be able to list all-activities,
23 but we can give you the highlights of some important ones.
24 We continued to collect data through our program for
25 examining Vietnam-era veterans who claim Agent Orange

1 exposure and wish to be examined at one of our facilities
2 for the possible health effects of such exposure.

3 As of September 30, 1979, we have gathered some
4 5,000 records of some 5,000 examinations. The next
5 quarterly status report will be in on December 31, and the
6 number will surely go up further.

7 We are continuing to code this material, to key-
8 punch it, to place it in the computer, and we are writing a
9 program, computer program, for analysis of the data.

10 We hope that by the middle of January we will at
11 least have the first 5,000 records in the computer and as
12 many more as we can possibly code by that time.

13 The analysis that will be available in the month
14 of January will merely consist of a series of frequency
15 tabulations of the responses. We are not going to attempt
16 to project or come to any types of scientific conclusions,
17 which we certainly could not do, on the basis of the
18 data or the amount of time that we have available, but we
19 will at least have some frequency and trend data, some
20 frequency data as to what is being reported as a result of
21 the examination of the 5,000 veterans.

22 We think that that material may be of some
23 usefulness. We have heard about the AFIP collection of
24 the materials. We won't repeat that. I would like to call
25 on Dr. Lyndon Lee to bring us up-to-date on the progress of

1 the fat biopsy study.

2 DR. LEE: Let me remind you that the last time I
3 told you that we had 33 cases who have had biopsies, three
4 of those were Air Force volunteers with a tremendous amount
5 of exposure, a thousand hours and more. Twenty of these cases
6 were in the study group and ten of them were controls.

7 Of those 33, we have had 22 reported by the
8 chemist and validated so that we know that these are
9 accurate, and six of the 16 study cases in that group have
10 shown a range of anywhere from three parts per trillion to
11 19 parts per trillion over the control on the mass
12 spectrometer.

13 In other words, they may or may not be significant.
14 The 19 could be an aberration or it could be the only one
15 significant in those tested, and that is under study at the
16 present time by the statistician. Other than that one case,
17 which had 19 above the standard, and the range was from three
18 to six parts per trillion above the standard, the question
19 being whether that is significant in any way.

20 Of the non-validated, so far, study groups, four out
21 of the eight who were study cases have shown a range
22 anywhere from three to 57 parts per trillion above the
23 standard for the mass spectrometer. That 57, like the 19,
24 may be an aberration, and it may also be the only one that
25 is significant, but first those findings have got to be

1 validated, and after that the statistician has got to do
2 his thing about determining what the significances may be.

3 So, what I have told you is that ten of the 20 cases,
4 show anywhere from three to 57 parts per trillion in
5 our first run on the chemistry, and we will try to figure
6 out whether that means something or not.

7 DR. KEARNEY: Dr. Lee, what you have said here is
8 rather important. As you know, these have been followed
9 with much interest by chemists and other people. I had
10 great difficulty in amassing the numbers you gave me because
11 of the rapidity with which you were giving them, but I want
12 to caution you that this is a very sensitive area that you
13 are in, and I hope the numbers you are giving us here are
14 numbers that you can live with and then sleep with, because
15 these are kind of bed-bug numbers. They may keep you up at night.
16 I am hoping that when you are prepared to release these at a final stage,
17 that these numbers are correct and have some meaning. I don't mean to
18 preach to you. That is not my intention, but I am concerned about the
19 sensitivity of what you have just said.

20 DR. LEE: Nobody is more sensitive than I to the fact that this
21 is a very delicate area, and one reason I have gone through it very rapidly is
22 in order to avoid having you attempt to attach or ask me to attach, some

1 significance to these.

2 The caveat I presented to you was that the first
3 series of 22 had been analyzed and validated by the chemist
4 and those are solid numbers so far as we are concerned.

5 I will take you a step further, which I reported
6 the last time. There has been a series of that group
7 sent over to EPA for them to see if they can't, in addition,
8 validate what may have been, so that we would have two
9 different techniques by two different groups of chemists
10 going over these materials.

11 We will do the same thing in sampling that second
12 group, so that I think at least we will have these things
13 solid. The meaning of these is going to be the open question
14 because the fact that there may or may not be dioxin in
15 the tissue of these people is not evidence of the fact
16 that they have disease, that they have threat of disease, or
17 lacking the dioxin, it certainly does not mean that they
18 are then free of any threat for the future.

19 DR. KEARNEY: Dr. Lee, I don't share your optimism.
20 As soon as you release these numbers, everyone will attach
21 significance to them. My concern as a chemist is that you
22 are absolutely certain as to the magnitude and reproducibility
23 of these numbers.

24 I warn you that, once they are released, they
25 will have great significance.

1 DR. LEE: Nobody is more aware of that than we.
2 That is why I am giving you what I have here and, I might
3 say, I am attaching no interpretation to it. Now, having
4 gone that far, we met in October with the various
5 investigators, statisticians, chemists, and so forth, and
6 thought at that time that several things would occur
7 in the next few steps in this program. That is in the
8 minutes, and, I think I have those. If not, they are available.

9
10
11 Let me update you on those steps which we thought
12 were necessary. We thought that copies of the clinical
13 laboratory data sheets from each of those patients should
14 be supplied from each of the hospitals on both study and
15 control people. That has been done. That material is
16 now in the hands of both the statistician and our pathology
17 people, and thanks to Dr. LeGolvan there is an effort now
18 to see if we can't, along with the Air Force, develop a
19 formality of presentation of these various clinical data,
20 and laboratory data, so that it will be uniform and will
21 touch each of the systems involved, nervous system, hepatic
22 system, neurologic system, and so forth. That is
23 under study and beginning to be put together for
24 presentation.

25 The chemical analysis of fat biopsies is to be

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1 completed, with reports provided by our chemists and
2 the parallel separate study by the EPA. We anticipated this
3 would be finished very quickly after that October meeting.
4 At that point, the chemist's spectrometer went out. He
5 is busy getting it back into function, and is going to have
6 to recalibrate that thing before we can use the last small
7 bits of specimen for validation and those that need study.

8 The chemist also said he would include in his
9 report to us a finished document on the chemical methodology
10 reporting and interpretations. That is in hand. I would be
11 happy to make it available if you wish.

12
13 The DVB would be approached in order to determine
14 what additional specific information can be provided on
15 exposure. That has been done. The Department of Veterans
16 Benefits has given me copies of the pertinent data from
17 the various military records. We have correlated that against
18 the reported problems and exposures which were provided by the patients
19 themselves, so that is done.

20
21 The fifth item was that statistical analysis
22 would go forward as soon as usable data is available and
23 that still holds.

24 The sixth, a draft report will be developed,
25 including chemical and statistical methodologies and

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1 conclusions. That is done and waiting the addition of the
2 various chemical items and the laboratory material when it
3 is set up in the format we wish, And, finally, we thought
4 that the report which we would tender to the Veterans
5 Administration's Central Office should be paralleled by a
6 publication in some reputable general medical journal, and
7 that is still an open question as to whether it should be
8 done and, if so, in what detail.

9 That is the end of the report. I am open for
10 questions.

11 DR. HABER: Dr. Moore?

12 DR. MOORE: You started out by saying you had 33 samples, of
13 which three were Air Force volunteers with heavy exposure, 20 were in your
14 case study, and 10 in controls. Then you said that you
15 had 22 samples that had been reported and validated. And
16 you said, as I got it, that six out of 16 had values that related
17 between three and nineteen.

18 DR. LEE: The others were control.

19 DR. MOORE: And what were their values?

20 DR. LEE: I don't have that right here. I do have it here
21 but I haven't tried to break it down. What you are asking is did any of
22 the controls show an elevation?

23 DR. MOORE: You got it.

24 DR. LEE: I don't know.

25 DR. MOORE: And then the others, the four, the unvalidated

1 would have been in the case studies, not controls.

2 DR. LEE: Exactly, we can look at that here if you want to.

3
4 DR. MOORE: Maybe this is a bit of a follow-up to
5 what Dr. Kearney was alluding to. I think a two-fold
6 question: I think you broke it two-fold. If you send the
7 sample to another laboratory and they come up with the same
8 number, all that that is saying is by following the same
9 cookbook procedure, they are doing the same things and
10 perpetuating the same errors, if indeed they are faithfully
11 producing the same flaws in the technique.

12 DR. LEE: On the contrary. They are doing it by
13 a different technique.

14 DR. MOORE: That would be even more better. It
15 is my understanding, based on a group of chemists that got
16 together, I believe last month, as part of the HEW effort to
17 keep itself informed as to what is going on, and without
18 getting down to how low can you go and think it is
19 significant, which is issue number one. To my knowledge, and
20 I am not a chemist, there is no method today that can
21 unequivocally say that what you are measuring is TCDD by
22 GC mass spectrometry methods.

23 Dr. Kearney might wish to comment on that. There
24 is, for example, a hydroxy metabolite of PCB that gives the
25 exact same mass spectrum and this comes out on the same GC

1 reading. There is no definitive answer.

2 DR. LEE: This is an area which the chemists are
3 going to have to argue, in which I would not enter, and which I know
4 nothing about.

5 DR. KEARNEY: My caution here is that remarks you
6 have just made will probably end up in the Washington Post
7 by the end of the week, ^{and} / I expect they will be in Science
8 next month.

9 Without really understanding the magnitude and
10 significance of these numbers, I am afraid that they have
11 not helped us in some respects, sir, but I think you thought
12 this over, and if it is your choice to release these at
13 this time, then that is your choice.

14 DR. SPENCER: I have to voice my concerns with
15 Dr. Kearney and Dr. Moore both. I think that unless or
16 until, since we are an advisory committee, it would seem as though we
17 are a little bit premature until these samples have been
18 re-evaluated by that second independent method, and then
19 delivering them to the public if you so wish.

20 DR. LEE: I share your concern and I am sure the
21 rest of us do. Our problem has become one of the press
22 which is now on the Veterans Administration to indicate
23 that it is doing something. / ^{I am} giving you and anybody who
24 needs to know it a current status report, which is that we
25 have now completed what I have told you, and that it is up

1 now for interpretation and evaluation, and that is as far
2 as we can go.

3 DR. SPENCER: I think we have to go back. EPA
4 found itself in the same boat and it was premature in some
5 of its pronouncements on evaluations of dioxin levels. When
6 they were rerun again by different methods, they turned out
7 to be nil or zero.

8 DR. LEE: That may well occur, too.

9 DR. SPENCER: As a consequence, I caution these
10 values going out to the public until they have been validated.

11 DR. MOORE: I must say I laud the attempt that is
12 being made to see if, indeed, one can find dioxin in tissues
13 of Vietnam veterans. I don't question that, and indeed, if the answer
14 comes out to be yes, or no, if it is acceptable, you have got a very
15 important thing.

16 DR. SPENCER: On top of that, I think you already
17 indicated that you have done something. The veterans
18 Administration has at least gotten the first step out of a
19 long, tedious process of analysis. This is laudable in
20 itself, but it costs \$1,000 to operate one sample, and as
21 a consequence, you are talking about funds, where do
22 they come from, and the time involved is immense. I
23 think it is laudable that this has been accomplished to
24 this point in this short a period of time.

25 DR. LEE: Dr. Haber promised the House Veterans

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1 Affairs Committee in October a year ago that we would do
2 this. The answer is we have done this up to this point, and
3 we are still in the process of refining the report.

4 DR. LEVINSON: I will call on Lawrence Hobson to
5 comment any further on this.

6 DR. HOBSON: First of all, I want to second very
7 strongly what has been said about the use of the figures.
8 I spent considerable time with the assay chemist, though I
9 am not one myself.

10 This is a technique that has pushed the detection,
11 let alone the measurement of those substances to the
12 absolute limit of present assay techniques. As always,
13 when you are on the forefront, there are questions as to
14 the validity of what you do and none has more question about
15 it than the assay chemist himself who did this work.

16 For example, in the 22 cases, what is meant by
17 validation is a technique that he has introduced to
18 determine that the peak he is measuring on his output is,
19 in fact, the substance TCDD that he set out to assay.

20 I believe that he has "validated" to that degree.
21 Whether there are any possible interfering substances is
22 another question, but he thinks it unlikely.

23 He doesn't know that it is impossible.

24 Secondly, the amount of material that has been
25 found to date is far exceeded by the concentration of a

1 number of other substances suspected at least of being equally
2 or more toxic than this material. It is literally impossible
3 to isolate this and say it is the only dioxin substance in
4 any of these samples, regardless of anything else you say
5 about it. In fact some of the known contaminants in our environment
6 are in many-fold greater concentration than the amount that he has found
7 measured in parts per trillion. If I am not mistaken, that is 10 to
8 the minus 9.

9
10
11 The second thing that I would like to say is that
12 the samples of the first 22 were sent to EPA. This is no
13 criticism of EPA. They have the same problems as our own
14 assay chemist does.

15 He sent along some spiked specimens containing
16 known amounts and some unspiked specimens by his assay, not
17 containing any known amounts of this material.

18 EPA found this TCDD, he tells me, in every sample
19 that he sent, whether it had been found before or not. In
20 other words, there is a discrepancy between the two different
21 systems of assay at this time, and that must be resolved.

22 I am grateful for one thing. We took a considerable
23 amount of fat on each biopsy from the veterans so that we
24 could have more than one test. We are just about at the end
25 of the material, however, and so we can't keep on testing

1 each sample indefinitely.

2 This is an area where we are perfectly willing to
3 report it out when we have some reasonable basis for saying,
4 "this is probably true," but at present I doubt seriously
5 that we can say unequivocally that any of these samples
6 contain it or that none of these samples contain it, or that
7 some do and some don't.

8 I am hoping that by the time the equipment is
9 repaired there and by the time EPA has had a chance to rerun
10 the specimens that have been sent to it, we can come up
11 with definitive information.

12 At present, I have considerable doubts and I
13 would not like to have those announced as anything approaching
14 a factual statement.

15 DR. MOORE: Has your lab also run blind salted
16 samples?

17 DR. HOBSON: Yes, and he is finding it in salted
18 samples and not finding it in unsalted samples. I would say none
19 of these have been broken down as to which were exposed
20 subjects and which were the controls. That has not been
21 contracted for the latter group, so we are not really in a
22 position to make an informative statement, so far as I know,
23 that none of the controls has any material in it.

24 DR. LEVINSON: In the interest of time, let me
25 condense the rest of the activities we have been engaged in.

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1 I would like to point out that veterans continue, although
2 in ever decreasing numbers, to file claims with the Department
3 of Veterans Benefits for compensation.

4 Mr. Feckarsky is not here. His October report
5 shows that since the beginning of concern with Agent Orange,
6 which would be over a year now, some 750 veterans have filed
7 claims with the Department of Veterans Benefits for
8 compensation of Orange-related illnesses. Only two cases
9 have been allowed for connection, and the connections did
10 not attempt to conclude that that was epidemiological
11 relationship, but merely there was a temporal, and, therefore,
12 a possible relationship.

13 Though we have not started the epidemiological
14 study, we are still working with the Department of Defense
15 in attempting to correlate troop movements with spraying
16 missions and perhaps Dr. Haber will say something further
17 about our experience thus far. We have not yet completed
18 this exercise. We are still in discussion with the
19 Department of Defense as to how this might best be done and
20 by whom. Mrs. Pildor or Mrs. Landry, do you have anything
21 to say about this matter or any other comments about
22 gathering the record?

23 (No response.)

24 DR. LEVINSON: The Veterans Administration, like
25 other agencies involved in this, has had a certain amount of

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1 legal entanglement. They are few and are being resolved,
2 these legal entanglements.

3 Dr. Castellot, do you have anything further?

4 DR. CASTELLOT: No.

5 DR. LEVINSON: I might close by pointing out that
6 through our interaction with you and with your colleagues,
7 we are very well aware of the large and growing amount of
8 activity, both scientific, clinical, and otherwise regarding
9 Agent Orange, and its contaminants.

10 We have recently been privileged to have on loan
11 Dr. John Walsh who is seated here on the side, who will be
12 visiting your agencies and others in an attempt to discover
13 what projects you are undertaking and when these projects
14 will likely be completed.

15 The purpose of this effort is to present to our
16 agency and to others who may be interested a kind of overall
17 synopsis of the activity regarding Agent Orange and when
18 the various phases of these activities are likely to reach
19 the stage of completion.

20 Hopefully, at least, some of the preliminary data
21 in this regard will be ready by the end of January. I think
22 that is all I have.

23 DR. HABER: Thank you very much for a comprehensive
24 report, Dr. Levinson. I would like to reiterate the fact
25 that one of the functions of our committee will be to endeavor

1 to stitch together information from various other agencies,
2 groups, interested parties. The basic underlying thesis
3 behind establishment of this committee last summer was to
4 be able to provide a common forum for all people interested
5 in the problems, and we, along with others, will attempt to
6 make that possible.

7 I would like to underline again Dr. Levinson's
8 statement, a reiteration of what I said earlier, and that is that

9 we are endeavoring to find a time sequence, because
10 one of the commonest questions posed to us is if you don't
11 know now, when can I expect to get some definitive answer.

12 The difficulty in our problem is, as Dr. Hobson
13 has pointed out in previous meetings, we have to prove the
14 null hypothesis. We have to prove it has happened, is likely,
15 or cannot possibly happen, a very difficult procedure in
16 scientific parlance. Therefore, it is important for us to
17 get some idea as to when we can begin to see a reasonable
18 answer to these questions.

19 I would like now to move on.

20 MR. LEMEN : Could I ask Dr. Levinson a question,
21 just a very quick question? We have heard about the law
22 and what the Veterans Administration will be doing on
23 epidemiologic studies. Where do you stand on your protocol?

24 DR. LEVINSON: We have been in conversation with
25 Dr. Lilienfeld, a new member of this Committee, regarding

1 approaches and he is currently -- he has not received a
2 contract or permission or anything else -- he is currently
3 attempting to summarize for us the various possible
4 approaches that might be used.

5 We would like to marry his work with the work of
6 this Committee in coming up with a tentative design, and then
7 proceed, as mandated by law, to let appropriate contracts
8 or find appropriate groups to study it. But we at least
9 have been gathering preliminary information.

10 MR. Lemen: Thank you.

11 DR. HABER: I would say that much of what we have
12 discussed, the assay, the establishment of the AFIP records,
13 5,000 people who have come to us alleging health effects
14 or exposure, the 750 who filed disability claims, all of those are the
15 substrata for the epidemiologic study, and indeed, the basis
16 for future physiologic studies.

17 DR. MOORE: One other point, Dr. Haber, one other
18 point in relation to what we have already discussed. I
19 would suggest that Dr. Walsh be directed to contact
20 Dr. Raymond Shapiro, whose address I can give you later.

21 There has been, for a number of months, within
22 HEW an effort by a group to keep track of what is going on
23 in its department, and he is the focal point of dissemination
24 and receipt of information.

25 DR. HABER: I shall also call attention to the fact

1 that Dr. Rall of HEW has been named as the coordinator for
2 Agent Orange, herbicide toxicity in the Department of HEW,
3 and that there is a new group. I have before me a release from
4 the Office of the White House Press Secretary which says that
5 "The White House today established an interagency work group
6 to study the possible long-term health effects of the type of
7 herbicides that includes Agent Orange, the herbicide which
8 was used extensively in Vietnam.

9 "In a memorandum to the Secretaries of Defense and
10 HEW and to the Administrator of Veterans Affairs, Stuart
11 Eizenstat, Domestic Advisor to the President, called upon
12 the interagency group to 'oversee, coordinate and set
13 priorities among Federal Government research activities
14 designed to relate exposure to phenoxy herbicides to long-
15 term health effects.'

16 "The Interagency Work Group will have the major
17 Governmental responsibility for reporting to the public the
18 results and implications of all research on the long-term
19 health effects of phenoxy herbicides and their contaminants.
20 The Work Group, which will be chaired by HEW, must assure that
21 the protocols and methodology of ongoing and proposed
22 Federally funded research studies are scientifically sound.

23 "The Work Group will establish a working
24 relationship with the Veterans Administration's Advisory
25 Committee on Health-Related Effects of Herbicides, which is

1 advising the VA on compensation policy for veterans claiming
2 health problems because of exposure to Agent Orange in
3 Vietnam. There is currently an inadequate scientific basis
4 for determining whether exposure to the herbicides could
5 have caused long-term health effects.

6 "The Interagency Work Group will oversee a number
7 of ongoing agency activities related to the phenoxy
8 herbicides and contaminants.

9 "The Air Force has initiated a major study to
10 determine the current health status of the Operation Ranch
11 Hand participants, who were responsible for spraying Agent
12 Orange in Vietnam. The protocol for that study has been
13 revised based on reviews by the Air Force Scientific Advisory
14 Board, the Armed Forces Epidemiological Board, and the
15 University of Texas at Houston School of Public Health. The
16 protocol is currently being reviewed by a Committee of the
17 Assembly of Life Sciences of the National Academy of
18 Sciences.

19 "The Department of Health, Education, and Welfare
20 research grant programs support major research in two broad
21 areas: epidemiological and laboratory studies. A major
22 focus of the epidemiological efforts is on studies of
23 industrial workers exposed to the phenoxy herbicides or their
24 contaminants, which include the class of compounds called
25 dioxins. Studies of workers exposed in Nitro, West Virginia,

1 Jacksonville, Arkansas, and Sauget, Illinois, should yield
2 information on the possible health effects of chronic dioxin
3 exposure. HEW is in the process of establishing a registry
4 of workers involved in the formulation or synthesis of phenoxy
5 herbicides. In addition, HEW research grant programs
6 support 21 grants dealing with the chemistry, biochemistry,
7 pharmacology, and toxicology of dioxins and related
8 compounds.

9 "The Veterans Administration has established a
10 central registry which contains data obtained from
11 comprehensive medical examinations of Vietnam era veterans
12 claiming exposure to herbicides. This registry will be
13 utilized in a formal epidemiological study of ground troops
14 who served in Vietnam, which the VA soon will initiate.
15 In addition, the VA is currently performing a pilot study
16 of the feasibility and diagnostic usefulness of determining
17 dioxin levels in the fat of veterans exposed to phenoxy
18 herbicides."

19 I won't go on to read this in detail but it talks
20 about the Air Force and the Ranch Hand study, Colonel Thiessen.
21 It mentions the Department of HEW, gentlemen and ladies, and
22 what they are doing and calls attention to the studies at
23 Nitro, West Virginia, Jacksonville, Arkansas, and Sauget,
24 Illinois, and talks about the registry that HEW is developing
25 in the formulation and synthesis of phenoxy herbicides, and

1 about the Veterans Administration registry, the formal
2 epidemiologic study which will be underway, and the pilot
3 study on the feasibility of measuring dioxin levels.

4 In addition, NIOSH has been named as the point of
5 contact under recent Federal legislation, to approach the IRS,
6 in order to get needed names and addresses.

7
8 That would be a vital link in our effort
9 because when we begin to get names and addresses, all
10 addresses of veterans who may have been exposed, we may
11 be coming to NIOSH for you to help us update the location
12 of these people in an effort to reach out, as that becomes
13 feasible or necessary.

14 There are two prepared statements which I would
15 like to give an opportunity now for airing. One of them, a
16 recent study by Dr. Allen. Dr. Norback, could you briefly
17 summarize this for us? We would appreciate hearing from
18 you.

19 DR. NORBACK: Dr. Allen has given me data of an
20 ongoing study which he is conducting in his laboratory at
21 the University of Wisconsin on chronic exposure of female
22 rhesus monkeys to dioxin at a level of 50* parts per
23 trillion in the diet.

24 This study has revealed that there is toxicity
25 after consumption of approximately 1 microgram per

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*Stated as "500" but corrected
by Dr. Norback to be "50" - See Page 99, Lines 23, 24 and 25.

1 kilogram of body weight. In other words, once the animals
2 have received 1 microgram per kilogram of body weight on
3 this chronic study, they exhibit severe toxicity.

4 At three months, there were reproductive
5 abnormalities in the eight female animals that were studied.
6 The animals were bred, but somewhat unsuccessfully. Two
7 animals were successfully bred and carried their infants to
8 term. Two have not conceived at all on repeated attempts,
9 and the remaining animals conceived, but aborted.

10 At 20 months of the study, the animals had
11 received approximately 1 microgram per kilogram of body
12 weight of the material. At this time, the animals showed
13 clinical signs of toxicity, including swollen limbs, loss of
14 eye lashes, dry scaly skin, and alopecia about the face.

15 These symptoms are approximately the same symptoms
16 exhibited in / a group of animals, of another study, which had received
17 500 parts per trillion. These are the same symptoms that
18 the animals at the higher dosage showed at three months of
19 exposure.

20 The/ accumulated ingestion of dioxin by both groups was approximately
21 the same. The dosage was approximately 1 microgram per
22 kilogram of body weight when the extreme toxic clinical
23 signs were shown.

24 The study is approximately 33 months in duration
25 currently, and the animals have received approximately

1 1.3 micrograms per kilogram of dioxin. It was necessary to
2 remove them from the diet at this time. They were showing
3 extreme weight loss, anemia, and leukopenia.

4 At 30 months it was attempted to breed the eight
5 females in the study. They became pregnant, but all aborted.
6 None of them carried their fetus to term.

7 DR. HABER: All right. Thank you, Dr. Norback.

8 I would like at this time to call on Mr. Charles
9 Hubbs, former President of Ranch Hand, who has a prepared
10 statement he would like to read.

11 MR. HUBBS: Thank you, Dr. Haber. I am a former
12 Air Force pilot. I was a former detachment commander for
13 the Ranch Hands in Vietnam. I am the original President of
14 the Ranch Hands. I am no longer President.

15 I am reading this for Jack Spey, who is the
16 current President, and ^{who} could not be here. We would like to
17 insert this in your record, sir, if you wouldn't mind. I
18 will make it available to you. It is a statement from the
19 President of the Ranch Hand Vietnam Association.

20 "There is no doubt that during the Vietnam conflict
21 USAF aircrew and ground maintenance personnel of Operation
22 Ranch Hand experienced the most frequent and direct contact
23 with the defoliant 2,4,5-T.

24 "To our knowledge, during the entire Vietnam
25 involvement (from 1962 until 1971) there were never any

1 symptoms that manifested themselves following exposure to
2 highly fluorinated hydrocarbons such as dioxin. There were
3 no unusual unexplained physical problems. Annually, USAF
4 aircrews received thorough flight physicals. The men
5 lived and worked closely together and any unusual problems
6 such as chloracne (the hallmark symptom of exposure to
7 dioxin) would not have gone unnoticed or unreported had
8 they been present.

9 "Today, the Ranch Hand Vietnam Association knows
10 of no individuals having physical problems that can be
11 linked to contact with ^{2,4,5-T.} We are aware that the pre-
12 ponderance of valid scientific data shows no cause and
13 effect relationship between exposure to dioxin in the minute
14 quantities found in ^{2,4,5-T} and any present medical difficulties.

15 "It is the Association's position, and mine, that
16 2,4,5-T, as used in Vietnam, was a safe and proven defoliant,
17 and posed no risk to personnel involved with handling or
18 disbursal of the material.

19 "Jack Spey, Major USAF (Retired), President,
20 Ranch Hand Vietnam Association; Date: November 26, 1979."

21 DR. HABER: Thank you very much.

22 Dr. Norback?

23 DR. NORBACK: I would like to possibly make a
24 correction. The report of the study was meant to be on the
25 group of monkeys that had received 50 parts per trillion

1 in their diet. I compared the study with a group of animals
2 that had received 500 parts per trillion, but the data that
3 I gave you is on the study that received 50 parts per
4 trillion.

5 DR. BRICK: Dr. Haber, with reference to the last
6 statement, is it all right to ask a question?

7 DR. HABER: Yes, of course.

8 DR. BRICK: How many Ranch Hands were there and
9 what is the numbers we are talking about?

10 MR. HUBBS: I had in hand 900, and approximately
11 68 addresses with which I communicated. There were more
12 than that. There were approximately 1200 people that I can
13 just about be sure of.

14 After this information came out, I started looking
15 for addresses. I was not able to get them. Twelve hundred
16 is a good figure.

17 DR. HABER: Any other comments or questions of
18 Dr. Norback or Mr. Hubbs?

19 DR. MOORE: One further question, Mr. Hubbs. What
20 constitutes flight crew besides the pilot and the co-pilot?

21 MR. HUBBS: The engineer, except on the lead
22 aircraft, where we have a navigator. The maximum in the
23 first would be four.

24 DR. MOORE: That constitutes Ranch Hand, so the
25 fellow who was in the back who was the one that was

1 releasing this spray, is he part of Ranch Hand?

2 MR. HUBBS: Yes, sir. He ran the pumps. He was
3 our flight engineer.

4 DR. MOORE: Ground personnel who would have loaded?

5 MR. HUBBS: Same man, possibly.

6 DR. MOORE: They would not be in your Ranch Hand
7 group?

8 MR. HUBBS: No.

9 DR. MOORE: What is the make-up of your organization?

10 MR. HUBBS: Well, it depends. There were Ranch
11 Hands on duty who did not fly in most cases.

12 DR. SPENCER: Are these indigenous Vietnamese
13 included in the 1200 personnel?

14 MR. HUBBS: No.

15 DR. SPENCER: You were talking about much more
16 than 1200 people.

17 MR. HUBBS: We are talking^{about} a handful, maybe half
18 a dozen loaders, at the maximum.

19 MR. LEMEN : Were there other Air Force personnel
20 besides the crew of the plane that formulated and loaded
21 the material?

22 MR. HUBBS: The South Vietnamese.

23 MR. LEMEN : No Air Force personnel?

24 MR. HUBBS: Our personnel.

25 MR. LEMEN : Other than the ones that were in the

1 crew?

2 MR. HUBBS: No. Let me qualify that. Are you
3 talking about people in Ranch Hand? There were certain
4 people that had ground jobs.

5 MR. LEMEN .: Right.

6 MR. HUBBS: Yes.

7 MR. LEMEN .: But they are included in the 1200?

8 MR. HUBBS: Yes.

9 DR. HABER: We commend your statement, Mr. Hubbs.
10 Thank you very much. Are there any other questions?

11 DR. LINGEMAN: Dr. Haber, I would like to respond
12 to a question which was raised at the September meeting by
13 a member of the audience, regarding the illness of dogs
14 which occurred in Vietnam.

15 I wish to respond to this after consulting with
16 some veterinary pathologists, one of whom served in
17 Vietnam.

18 DR. HABER: That would have to be a Viet vet vet.

19 DR. LINGEMAN: Right, very good. There was an
20 epidemic disease in dogs in Southeast Asia,
21 including Vietnam, between 1968 and 1969. It was an infectious
22 disease known as tropical canine pancytopenia, caused by a
23 micro organism which has been isolated.

24 This disease has been the subject of several reports by
25 Dr. Paul Hildebrandt of the Walter Reed Army Institute of Research.

1 I have given copies of reprints of this paper to Dr. Schepers or Dr. Haber.
2 The main symptom was hemorrhage. Many dogs died. This disease could be
3 confused with toxic effects of a chemical such as dioxin.

4 DR. HABER: It was an infectious process?

5 DR. LINGEMAN: It was an infectious process.

6 DR. HABER: All right.

7 Mrs. Williams, we have no written questions, have
8 we?

9 MRS. WILLIAMS: I have received none, unless some
10 were picked up.

11 DR. HABER: Okay. We will entertain oral
12 questions at this point. I wanted to give priority to
13 written questions. There are some.

14
15 There is a question to Dr. Spencer. There are
16 several questions here. Let me get to them. Then we will
17 go to the oral ones. The question to Dr. Spencer, EPA, and
18 to the whole Committee.

19 Groups interested in human health effects of phenoxy
20 herbicides, including user groups, are looking for
21 situations where adequate data may exist on use and
22 exposure and health effects, miscarriage or birth defects.

23 I believe EPA is sponsoring such search for
24 suitable data, with at least one team from Columbia. Can
25 you tell us the percent of this search effort, what has

1 been found so far and what will be done if suitable data
2 sources are found?

3 DR. SPENCER: First of all, I think I can answer
4 this in one fell swoop, and the later questions really won't
5 apply.

6 The Toxicology Branch is not per se the
7 epidemiological group that would be involved in this search.
8 As a consequence, I didn't know that a search was being done
9 on the epidemiology of the problems. That may be in the
10 field.

11 I am sorry. That is the best I can do for that.

12 DR. HABER: The second question: Are there other
13 agencies making such a data search that are not generally
14 known about?

15 These questions were submitted by Mr. William
16 McCredie of the National Forest Product Association. This
17 is addressed to the whole Committee: Are there any other
18 agencies making such a data search that are not generally
19 known about?

20 DR. SPENCER: There might be other agency searches
21 by Dr. Kearney's group. I would imagine they have some. I
22 would not be at all surprised if HEW does not also have a
23 search going on in this area.

24 DR. KEARNEY: We are doing a proportion mortality
25 study on all USDA employees, and then we are going to bracket

1 those in the Forest Service that have been concerned with
2 the application of phenoxy herbicides.

3 DR. SPENCER: I am one of those. E

4 MR. LEMEN : I think we have listed all of our
5 studies that we are doing.

6 DR. HABER: I have here several written questions
7 submitted by Mr. DeYoung. Some of these have been
8 answered. One question: Has official response been
9 received from the Air Force on the guard dog problem? That
10 has been answered. That is the guard dogs you were talking
11 about. That has been answered.

12 Next question from Mr. DeYoung: How would you
13 characterize the Department of Defense response to your
14 request for data in sprayed areas in unit movements?

15 Colonel Thiessen, do you want to respond to that?

16 COLONEL THIESSEN: The question is how would you
17 characterize it?

18 DR. HABER: I would say that's the reason I wanted
19 you to have your licks in. I would say it is a very
20 difficult problem because in response to our queries the
21 Department of Defense has had to indicate that certain
22 news had very good information and that information was
23 difficult to come by for others.

24 I would also indicate that because of the fluid
25 nature of the war, it was difficult for them to be able to

1 track down the individuals. I would say that ^{obtaining} the information
2 about what individuals are likely to have been exposed, except
3 for the Marines and the Air Force ground detachments,

4 and possibly the Navy, will be a difficult,
5 cumbersome procedure.

6 Is there anything you wanted to add to that,
7 Colonel Thiessen?

8 COLONEL THIESSEN: No, sir.

9 DR. HABER: Major Brown, is there anything you
10 want to add?

11 MAJOR BROWN: No, sir.

12 DR. HABER: We intend to continue to try to find
13 the names of the individuals as best we can. The General
14 Accounting Office report on identifying Marine units is
15 helpful, but it is not the complete answer because, again,
16 all that that tells us is where the headquarters of those
17 Marine battalions were and not necessarily where the
18 individuals were.

19 They may have been in areas more highly sprayed.
20 It is useful, but certainly not definitive. Again, our
21 approach would be that we are trying to find these groups,
22 which are most likely to have been exposed, and then we
23 will make it possible for any other veteran who believes he
24 was exposed to be examined and to get the full benefit of
25 the examination procedure.

1 There is one for you, Colonel Thiessen, after
2 all, specifically addressed to you. Does the Department of
3 Defense, represented by Colonel Thiessen, discuss
4 construction or pre-construction use of herbicides to clear
5 the grounds?

6 COLONEL THIESSEN: Do we evaluate the data that
7 exists in that field? Is he talking about perimeter
8 spraying, right-of-way spraying?

9 DR. HABER: Do you want to clarify the question?

10 MR. DE YOUNG: I talked to a number of Navy
11 CB types, Army engineers and so forth. They indicated --
12 as a matter of fact, one of them, a quote from one of them
13 Friday evening was, I never saw a live tree in front of my
14 bulldozer.

15 That statement put together, I think, is a
16 fairly good generic of what has been said. In other words,
17 when they moved into an area to do the heavy equipment work
18 preceding construction of bases and perimeters, and so
19 forth, the trees had very obviously, from their statements,
20 already been killed by something, an unknown herbicidal
21 agent.

22 To my knowledge, no one has yet documented out
23 that specific use from the Department of Defense. We have
24 talked about fixed-wing, rotary wing, crops, defoliation,
25 and so forth, but no one has yet come down with figures on

1 how this construction technique was used, where and when.

2 I am wondering if this report you mentioned
3 earlier has it.

4 COLONEL THIESSEN: In the paper I submitted, we
5 have data on that. We have a good idea about what herbicides
6 were provided to the troops in Vietnam,
7 how they were dispersed.

8 If you ask for specific information on specific
9 areas, I don't know, but we certainly have the information.
10 That is about it. Do you have a copy of our paper?

11 MR. DE YOUNG: No. I would like one very much.

12 COLONEL THIESSEN: I think it will be in the
13 record.

14 DR. HABER: It is a working document, but it
15 will be made available.

16 MR. DE YOUNG: Can I get a copy, sir?

17 COLONEL THIESSEN: I don't have a copy here. Are
18 we going to get copies? Are you going to make them
19 available? You have distributed some.

20 DR. HABER: To the committee. These are working
21 documents with the committee.

22 COLONEL THIESSEN: We have no problem providing
23 you with one. I can make a wholesale distribution.

24 DR. HABER: Okay. The next question from
25 Mr. DeYoung: Have individual veterans been informed of their

1 biopsy results? No. Has any correlation between dioxin
2 content and disease been done on these cases? No. The
3 codes have not yet been broken. They will, obviously, be pursued.

4 MR. DE YOUNG: If the answer to that is no, then
5 I have another question.

6 DR. HABER: I have another written question, if
7 you will permit, Mr. DeYoung. This is a question by
8 Mr. Todd Ensign of the Citizens Soldiers: The Army made
9 extensive use of chemical corps personnel in helicopters to
10 spray around United States defense installations and fire
11 bases in Vietnam.

12 We have located at least 15 such instances. This
13 obviously doesn't encompass such men, in light of the GAO
14 report concerning the 16,000 Marines. What is the
15 Department of Defense doing about this? Can you respond?
16 Shall I read that again?

17 COLONEL THIESSEN: Please. Reread it.

18 DR. HABER: Let me pass it to you and you can see
19 it and then respond.

20 COLONEL THIESSEN: We haven't approached this
21 from the point of the user. We know how the herbicides
22 were distributed from the source point of view. We don't
23 know which personnel were actively involved in things like
24 perimeter spraying and that sort of thing.

25 Are we gathering data? I wonder whether we have

1 them. If we have them, we would, no doubt, have gotten
2 them, but I am pretty sure we don't have them.

3 DR. HABER: All right. Those are ~~all~~ the written
4 questions. We will open it up ^{now} to oral questions. I believe
5 you had another question, Mr. DeYoung?

6 MR. DE YOUNG: Yes. I have some problems with
7 this tissue biopsy study. I would like to make an observation first
8 of all. If my / ears went off at the right point, then Dr. Allen's rhesus
9 monkeys are showing toxic manifestations at lower amounts
10 than was found in the fatty tissue of one Vietnam veteran,
11 5 parts per trillion.

12 Have I misinterpreted the data?

13 DR. NORBACK: Yes.

14 MR. DE YOUNG: Thank you for setting me straight.
15 I don't want to go ^{broadcasting} something that is not correct. Possibly,
16 after the meeting, one of you experts can explain to me why,
17 although the numbers are the same, the results are not.

18 What is troubling me about the tissue biopsy
19 result is that I got a call from an upset veteran Saturday
20 morning, who ^{that a Dr. Lee from Central Office and} said he had spoken, Dr. Lyndon Lee, so it must
21 be the same one ^{that is would} here, I assume, and that, the results of his
22 biopsy were back and that the results were positive, that
23 there was more dioxin in his tissue than was called for ^{I think} was
24 the way he phrased it to me, and that subsequently, after
25 that conversation, at that time he was asked if they could

1 follow him up for the rest of his life because he was an
2 important piece of medical information, and he agreed.

3 And a few days to a week
4 later, he received a call from Dr. Levinson, at which time
5 he was told that the information was coded and that he
6 should disregard the previous phone call.

7 Can someone please take this out of the realm of
8 rumor and into the realm of Veterans Administration official
9 fact and please recount for us the statements surrounding
10 the phone call to Mr. Belcher around a month ago, according
11 to his word?

12 DR. LEE: I would be glad to follow that up. I
13 have had two phone calls from that particular
14 gentleman, who comes from out/^{near} Gary, Indiana.

15 His initial call was, Was the biopsy back? The
16 answer was, yes, we didn't know/^{really} what the validation report
17 might be, and therefore had nothing that we could tell
18 him.

19 The second time he called back, we did have
20 validation. We did give him a number which had to do
21 with his particular circumstance, with the same caveat/^{that} we
22 have had here.
23we are unaware of what the significance of
24 these numbers are, and would he be good enough to stay in
25 touch with his hospital of origin so that they could follow

1 him in any way that it seemed appropriate from that
2 standpoint.

3 One further point. I then suggested to him that
4 it might be desirable, as he had already had a biopsy, if
5 these epidemiological studies developed, that he and others
6 who had had the biopsies might be included in that group
7 who were to be studied and he might hear from us further.

8 MR. DE YOUNG: The basic facts of that are
9 correct, then?

10 DR. MURPHY: Did you give him his number or just a
11 number for the group as a whole?

12 DR. LEE: I gave him a number for the group as a
13 whole.

14 MR. DeYOUNG: Is he the only veteran with whom
15 these statements have been discussed?

16 DR. LEE: I have had one call from another
17 veteran who attempted to get his numbers, but he is in that
18 second group so he was given no information except the
19 promise that we would be back to him through his hospital,
20 if he would stay in touch.

21 DR. HABER: Any other comment?

22 DR. HOBSON: It is very easy to create the
23 impression of being very secretive about this business.
24 We are not secretive. It is the same reason a doctor
25 doesn't tell his patient he has pernicious anemia until he

1 has a chance to check it out. He may have nothing at all
2 wrong with him. We are not trying, nor don't intend to
3 conceal it from these people one minute longer than we need
4 to be sure what we are talking about.

5 On the other hand, they have to realize that the
6 mere presence of a substance in fat or in any other part
7 of the body does not in and of itself constitute a disease.
8 The consequences, as Dr. Lee pointed out, of having some of
9 this in the fat is not obvious from the biopsy figure, that
10 is for sure. It will be yes, you do, or no, you don't. There
11 are detectable amounts of material in there, well under
12 what has been proved to be toxic and we don't know whether
13 they have significance in terms of yourself. That is the
14 only answer we can give in all honesty.

15 DR. LEE: The corollary is if he doesn't have
16 this material in his fat and if he, in fact, was exposed,
17 we have no way of knowing that he is or is not either ill
18 at the moment or will be ill in the future.

19 DR. HABER: There was a question over there, please.

20 MR. ENSIGN: I just want to follow up. My name is
21 Todd Ensign, with the Citizens Soldier. I am concerned about
22 the impression by Charlie Hubbs about the Ranch Hand.
23 The question I tried to pose is that we are talking about
24 a number of categories of high risk exposure here, guys
25 who were out in the plains, who loaded choppers, talking

1 about the Army personnel, which I believe constitutes
2 several thousand men.

3 The Ranch Hand group -- I don't know on what
4 Charlie is basing his conclusions about ^{there} being no health
5 effects, but I do ^{not} think it is more than word of mouth or
6 informal reports, you know, Christmas cards -- I am fine,
7 family is fine -- that kind of thing.

8 I don't want to have the impression conveyed that
9 this represents the sum of those who were at high risk. It
10 doesn't. Many used backpacks to spray the stuff around
11 installations. That was pretty standard from what we can
12 get, a pretty standard means of application -- choppers,
13 packs, trucks using 55-gallon drums.

14 We are talking about a high risk population which,
15 from what I can gather from Colonel Thiessen's response, has
16 not yet been identified by unit or even, certainly, by
17 unit personnel.

18 We have got a large job ahead of us. I am
19 concerned. It doesn't seem, so far, we have really made much
20 progress in identifying these people.

21 The high risk is much less than those who have
22 a long term. That is one concern I would like to put in
23 front of the whole panel.

24 DR. HABER: I think our information is to the
25 effect that 95 percent of the spraying was done by Ranch

1 Hand, isn't that about it?

2 MR. HUBBS: Yes. I have to agree. I can speak
3 only for Ranch Hand. I don't know what the Army did. I
4 agree with you 100 percent.

5 DR. HABER: Obviously, we want to pursue all
6 possibilities. Are there any other questions?

7 MR. MILFORD: I am with the Veterans Law Center,
8 the National Veterans Law Center. I have a question about
9 the claims processing system that has been going on so far.
10 Has the Veterans Administration considered suspending the
11 processing of claims, pending some better understanding of
12 the scientific information?

13 As you know, all the claims so far have been
14 denied. That means in many cases --

15 DR. HABER: No. Two have not been.

16 MR. MILFORD: I have a follow-up question on that,
17 as well, but the 700 or so claims have been denied on the
18 basis of any causation between Agent Orange exposure and
19 long term health effects.

20 It would seem to me that it might be more equitable
21 to have those claims filed, but then not deny them until
22 you have some better information about the causative
23 issues. You have a real discrepancy between the number of
24 people who would file claims and the number of people who
25 would receive treatment.

1 I suggest many people who are going to be in
2 hospitals have been deterred from filing claims because of
3 the negative information they get from the Veterans
4 Administration officials about the causative relationship.

5 DR. HABER: No. Permit me to correct you on that.
6 Our early assay, at least, of the people who came to the
7 Veterans Administration seeking medical care, wanted not
8 care for symptoms, but some reassurance. 80 percent on
9 random samples of the first 500 cases we had looked at had
10 no complaints.

11 They were just concerned that they might have
12 had some. I don't think it is necessary to assume that
13 these people were, indeed, ill.

14 My own feeling is that there has to be some --
15 there ought to be some equity between the two groups. I
16 think that there will be. I can assure that.

17 People who are found to have medical disabilities
18 in the normal course of events will be advised about their
19 compensable rights and people who are awarded compensation
20 or come to the Veterans Administration seeking benefits
21 will be referred to the hospital for evaluation of their
22 health.

23 Mr. Conway, from General Counsel's Office, might
24 wish to address your concern.

25 MR. CONWAY: Consideration was given to the

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1 idea of suspending action on claims now pending and future
2 claims, so as to permit the Advisory Committee and the
3 Veterans Administration's Steering Committee to come up with
4 a policy recommendation as to how we should, what kind of
5 evidence we should be looking for. It was decided that we
6 shouldn't do that.

7 We shouldn't disrupt the normal claims process
8 because we thought it would be unfair to the veterans who
9 may have a legitimate connectable disability in their
10 claim.

11 If, at some point in the future, evidence is
12 presented that shows a cause and effect relationship
13 between a disability and exposure, those claims can be
14 recalled and reopened on the basis of new evidence, so that
15 by giving a final action now, they are not really being
16 hurt. Rather, they can be hurt if they are put into a
17 suspension action/ ^{rather than} reviewing claims and finding actual
18 disabilities now.

19 MR. DE YOUNG: Isn't there a way to see they are
20 not hurt, in a sense, to have that suspended and the
21 Veterans Administration to contact them if something else
22 happened?

23 I think statistics show you have a significant
24 fall-off when you have initial claims filed, denied. Many
25 people don't appeal. They don't know their rights. They

1 don't appeal. They don't contact the Veterans
2 Administration and are forgotten. I think you will have
3 a significant drop of people denied the claims, and if
4 something comes up in the future, they will not be contacted
5 again, unless the Veterans Administration considers it an
6 affirmative obligation, so that these people are taken care
7 of now, not hurt now, when the Veterans Administration
8 has the obligation.

9 I think the argument that certain people may be
10 harmed by the suspension doesn't seem to be very strong
11 when you have, at most, two people out of 800 who fit into
12 that category so far.

13 MR. MILFORD: But those were the concerns that were
14 taken into consideration, and that is the reason the
15 decision was taken to go, not suspending at the present
16 time.

17 MR. DE YOUNG: Thank you.

18 DR. HABER: Any other questions?

19 MR. DE YOUNG: In this question of claims
20 processing, I take it ^{that it} is standard procedure at this point,
21 if a man files a claim, to refer him to a medical center
22 for possible examination and treatment. Is that correct?
23 If a man files an exposure to Agent Orange Form 526,
24 Compensation Disability, he automatically is referred to a
25 medical center for some sort of examination?

1 DR. HABER: I would have to turn to the Department
2 of Veterans Benefits.

3 MR. CONWAY: No. He is not automatically referred
4 to there. It makes contact in the Veterans Assistance
5 Office. He is given the information that that is available
6 to him, that he may appear at the closest Veterans
7 Administration hospital and request the examination.

8 DR. HABER: The information is given to him.

9 MR. CONWAY: He is made aware at that point that
10 he may go to a medical facility for testing and treatment.

11 MR. DE YOUNG: It is another point of concern
12 that veterans are being given a letter back, you have failed
13 to furnish proof of your exposure to herbicides. Therefore,
14 your claim must be denied.

15 I am paraphrasing, but not very much. I find
16 that, personally, from what I have seen, extremely
17 inadequate because the burden of proof is thrown back on
18 the veteran, when he doesn't have access to the data, and
19 the Veterans Administration has, at least, better access to
20 the data than the individual would have.

21 If he can provide you with pictures of numbers
22 and Ranch Hand aircraft, that is one thing; if he can
23 provide you with pictures of himself with a back-spray
24 sprayer, with an unidentified substance coming out of the
25 backpack, that is another thing; a dead tree, that is

1 another thing - the kind of evidence the veteran will have.
2 I submit that that is ineffectual and^a totally ineffectual
3 response to the veteran.

4 DR. HABER: I think we need to pursue that because
5 it might be extremely difficult for the veteran to give
6 uncontrovertible proof that he was in an exposed area.

7 MR. DE YOUNG: I would suggest the implication of
8 this is the Department of Defense had better throw open its
9 files on herbicide spraying and troop movement mighty soon.

10 The reason I am concerned about claims, though,
11 is that there are some strange things happening in Chicago
12 at the regional office. There was a fire in the Chief
13 Adjudicator's office approximately six to nine months ago,
14 earlier this year, and the grapevine told us that the only
15 thing that was destroyed were Agent Orange 526 forms which
16 were segregated in a special record holder on the Chief
17 Adjudicator's desk, and that this fire of undetermined
18 origin destroyed these documents and nothing else. That
19 struck me as unusual, to say the least, and so we asked the
20 Chief Adjudicator, in a public meeting, whether or not
21 this was the case, and he said it was not the case; there
22 was a fire of electrical origin, and that it destroyed tips
23 of a few pieces of paper, but nothing serious, and, no,
24 all the Agent Orange papers weren't destroyed.

25 Two days later in an interview with CBS, he said

1 the opposite. I would like this particular fire in
2 Chicago checked into, made a matter of record for this
3 Advisory Committee because^{of} the implications of a few
4 526 forms getting away completely from us, in light of
5 Mr. Conway's statement about going back to the veteran and re-
6 calling the case. Now it is my understanding that these do
7 not exist any more in Chicago.

8 The master files were put back into the stack.
9 The only thing kept out was the special processed form, and
10 with their destruction, there went the veterans' claim to
11 this particular matter. So we need some facts on this.

12 What happened in Chicago with this fire in the
13 Adjudicator's office? What was destroyed?

14 DR. HABER: I think this is a real concern of
15 yours, but I think, Mr. DeYoung, it might be more
16 appropriately pursued if you were to contact some responsible
17 administrator in the Administrator of Veterans Affairs
18 Office. I think it requires investigation. It may not be
19 appropriate to discuss at this point.

20 Are there any other questions?

21 (No response.)

22 DR. HABER: If not, we stand adjourned. I want
23 to thank the Committee and the group for really having gotten
24 to these papers. It was an extremely useful session.
25

1 (Whereupon, at 11:35 o'clock a.m., the meeting
2 in the above-entitled matter was concluded.)
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REPORTER'S CERTIFICATE

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4 DOCKET NUMBER:

5 CASE TITLE: Advisory Committee on Health-Related Effects
6 of Herbicides

7 HEARING DATE: December 12, 1979

8 LOCATION: Washington, D.C.

9 I hereby certify that the proceedings and evidence
10 herein are contained fully and accurately in the notes
11 taken by me at the hearing in the above case before the
12 Veterans Administration
13 and that this is a true and correct transcript of the
14 same.

15
16
17 Date: December 31, 1979

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19
20 Official Reporter
21 Acme Reporting Company, Inc.
1411 K Street, N.W. Suite 600
Washington, D.C. 20005

22 I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE HEREIN ARE CONTAINED
23 FULLY AND ACCURATELY, AS CORRECTED.

24 PAUL A. L. HABER, M. D.
25 Chairman
Advisory Committee on Health-
Related Effects of Herbicides

March 13, 1980

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603981 P



Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

**(Fourth Meeting
April 23, 1980)**

1 VETERANS ADMINISTRATION

2 - - -

3 ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

4 - - -

5 Room 119
6 Veterans Administration
7 810 Vermont Avenue, N.W.
8 Washington, D.C. 204209 Wednesday,
10 April 23, 198011 The meeting was convened, pursuant to notice, at
12 8:30 a.m., DR. PAUL A. L. HABER, Chairman, presiding.13 APPEARANCES:14 ADVISORY COMMITTEE MEMBERS:15 DR. PAUL A. L. HABER, Chairman
16 Assistant Chief Medical Director
17 for Professional Services
18 Veterans Administration Central
19 Office
20 810 Vermont Avenue, N.W.
21 Washington, D.C. 2042022 DR. GERRIT W.H. SCHEPERS, Vice Chairman
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DR. SHELDON D. MURPHY
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University of Texas Medical School
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COLONEL J. W. THIESSEN, MC, U.S. Army
U.S. Army Environmental Hygiene Agency
Aberdeen Proving Ground, Maryland 21010

(Accompanied by:)

MAJOR PHILLIP G. BROWN, U.S. Army
Office of the Air Force Surgeon General
Bolling Air Force Base
Washington, D.C. 20332

DR. CAROLYN H. LINGEMAN
National Cancer Institute and
Department of Environmental and
Drug-Induced Pathology
Room 2051
Armed Forces Institute of Pathology
Washington, D.C. 20306

ALSO PRESENT:

MR. MAX CLELAND
Administrator, VA

DR. BARCLAY M. SHEPARD
Special Assistant to
the Chief Medical Director

DR. PAUL LE GOLVAN
Director of Pathology Service

DR. MATTHEW A. KINNARD
Office of ACMD
for Research and Development

DR. DONALD L. CUSTIS
Chief Medical Director
Veterans Administration

DR. RICHARD A. LEVINSON
Chairman
Steering Committee Activities

1 FRED CONWAY, Esquire
2 Office of The General Counsel

3 MS. MARGARET KILDUFF
4 Chief, Medical Record Program

5 Mr. LAYNE DRASH
6 Staff Assistant to the
7 Special Assistant to the CMD

8 Ms. Marjorie Leandri
9 Office of Management Services

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P R O C E E D I N G S

(8:34 a.m.)

1
2 CHAIRMAN HABER: May we begin this morning's delibera-
3 tions, please. I am happy to welcome you all here and I think
4 before I begin my opening remarks I would like to ask the
5 panel members to introduce themselves, starting over at our
6 extreme left. And if you would please identify yourself and
7 the institution you represent.

8 MR. THOMPSON: Charlie Thompson, with the DAV.

9 COLONEL THIESSEN: I am Colonel Thiessen and I repre-
10 sent the Department of Defense.

11 DR. MURPHY: I am Sheldon Murphy, Professor of
12 Toxicology at the University of Texas Health Science Center in
13 Houston.

14 DR. MOORE: I am Jack Moore, Department of Health,
15 Education and Welfare, and specifically the National Toxicology
16 Program.

17 DR. SCHEPERS: I am Gerrit Schepers with the
18 Central Office of the Veterans Administration.

19 DR. SHEPARD: Barclay Shepard, Central Office of the
20 Veterans Administration.

21 DR. PLIMMER: Jack Plimmer, Science and Education
22 Administration of the U.S. Department of Agriculture.

23 DR. ERICKSON: Dave Erickson, DHEW Center for
24 Disease Control.

25 MR. DE YOUNG: Ron DeYoung, National Veterans Task

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1 Force.

2 (Whereupon, the staff were introduced.)

3 CHAIRMAN HABER: All right. Thank you all very much.
4 We have an agenda. This meeting is entirely open, it will be
5 recorded, and the minutes will be circulated in May as a matter
6 of public property.

7 We will kindly ask the audience to confine its remarks,
8 quotations, questions, and discussions to the period reserved
9 for that at 11:00, at which time we will be happy to entertain
10 questions and to take statements from the general interested
11 public.

12 I have a number of announcements I would like to make.
13 First of all, I would like to welcome one new member of the
14 Advisory Committee on Health-Related Effects of Herbicides,
15 Mr. Ron DeYoung, who has been an active participant in these
16 meetings and who will contribute a very needed viewpoint to our
17 discussions.

18 Mr. DeYoung represents the Agent Orange Victims
19 International.

20 MR. DE YOUNG: No, sir.

21 CHAIRMAN HABER: I am sorry.

22 MR. DE YOUNG: Yes, sir. But indirect.

23 CHAIRMAN HABER: All right.

24 MR. DE YOUNG: I am directly affiliated with the
25 group called "CAVAT" -- Concerned American Veterans Against

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1 Toxics -- in Chicago. And, through that organization, the
2 National Veterans Task Force on Agent Orange. And I consider
3 myself to represent -- as does Mr. Thompson and Dr. Brick --
4 organizations of Vietnam veterans, in this case specifically,
5 who are concerned about the answers to the softer questions,
6 the less scientific approaches.

7 I view my role as that of the veteran observer.

8 CHAIRMAN HABER: Very good. Thank you.

9 I would like to call attention to Dr. Carolyn
10 Lingeman. Dr. Lingeman, would you introduce yourself and the
11 organization you represent?

12 DR. LINGEMAN: Carolyn Lingeman. I represent the
13 National Cancer Institute.

14 CHAIRMAN HABER: Did everybody hear that? Dr. Carolyn
15 Lingeman represents the National Cancer Institute.

16 One of the earlier participants in the task force,
17 Dr. James Allen of the University of Wisconsin, has submitted
18 his resignation and we note that with gratitude for his help
19 in getting this launched. His departure will be noted and we
20 are grateful to him for his contribution.

21 I will be yielding my seat as Chairman to Dr. Barclay
22 Shepard, seated on my right. A word or two about Dr. Shepard.
23 Dr. Shepard has been appointed Special Assistant to the Chief
24 Medical Director for herbicide orange affairs.

25 It has been felt for some time that the Veterans

4.

1 Administration needed to have an individual devoting all of his
2 time, and a small hard working, dedicated staff to the problems
3 of Agent Orange. Dr. Shepard has accepted that post, and
4 will be chairing this committee at its next meeting.

5 Dr. Shepard has been immersing himself in the
6 complex situation of Agent Orange. He has shown an amazing
7 aptitude in terms of the complex situation. He is a
8 distinguished clinician and surgeon. He served his resi-
9 dency in general surgery at the National Naval Medical Center
10 in Bethesda and did a specialty in thoracic surgery at the
11 Naval Hospital in St. Alban's.

12
13 Dr. Shepard took his medical training at
14 Tufts University, and Boston University prior to that. He
15 served as the Chief of Outpatient Service in addition to his
16 surgical chores at the National Naval Medical Center in
17 Bethesda, and has been Chief of Thoracic Surgery in a number of
18 Naval Hospitals -- principally, as I said, at St. Alban's and
19 Bethesda.

20 He is a member of the American College of Surgeons,
21 the Society of Thoracic Surgeons, the American Medical Associa-
22 tion, and the Association of Military Surgeons of the United
23 States.

24 We welcome you, Dr. Shepard, and look forward to a
25 vigorous stewardship on your part. We pledge all of our

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1 assistance to you. I would like to request that all of the
2 members of the audience and the Advisory Committee work with
3 Dr. Shepard to bring this very complex, vexing question to a
4 successful termination so that we can answer the questions that
5 the veterans of the United States Armed Forces have been raising
6 with respect to the problems of Agent Orange.

7 I would like now to give you a brief update on what
8 has transpired. The herbicide orange situation is a very com-
9 plex one and it changes almost daily. And I cannot, in the
10 brief space of time that I have at my disposal, hope to cover
11 this completely.

12 I will try to run over some of the highlights,
13 and if any of the members of the panel feel that I have omitted
14 or glossed over some significant enterprise, I would appreciate
15 it if you would call it to my attention for edification to the
16 group and for inclusion in the minutes.

17 I think it goes without saying that the news media
18 has continued to exhibit, unabated, their interest in this
19 problem. The stories that appear in the newspapers, on tele-
20 vision programs, on radio programs have been enormous. I would
21 like to pay tribute to the VA's Information Service -- Mr. Strat
22 Appleman, back there -- who has done a yeoman job in trying to
23 ride herd on this very complex issue of keeping us all informed
24 and in representing a complete coverage so that as developments
25 occur we are apprised of them.

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1 We have accumulated a file in our Medical Service,
2 under Mrs. Rennie Williams and Dr. John Castellot, which is a
3 prodigious compilation of clippings and reports, articles,
4 scientific articles, and so on.

5 While I don't want to exaggerate its importance,
6 I think one of the things that we endeavor to do within the
7 Veterans Administration is to keep a current file of material
8 and I think we are pretty much up-to-date on that.

9 I think it will be improving our own scientific
10 literature coverage. I keep reading compilations of research
11 projects and, as might be expected, no two such compilations
12 completely jive. There are always different perspectives and
13 this problem involves epidemiology; toxicology; molecular
14 biochemistry; genetics; medicine; counseling; pharmacology;
15 agriculture; agronomy; chemistry, of course; physical chemistry;
16 statistical methodology; and sociology, psychology, psychiatry
17 and all the specialties of medicine.

18 It is pretty hard to be sure that you are
19 keeping up with all the developments, but we attempt to do that.

20 Since I introduced the folks around the table,
21 Dr. Irving Brick-- representing the American Legion -- has joined
22 us. Dr. Brick has done yeoman service on the committee and we
23 welcome him to our deliberations this morning.

24 In addition to the developments in the news media and,
25 as I say, hardly a day goes by that there is not some mention

1 made in the press or on the television or the radio which, I
2 think, has certainly -- one must acknowledge -- has certainly
3 alerted the general American public to the possibilities of
4 long-term toxicity from these agents.

5 Another significant occurrence was the appearance on
6 February 25th of Mr. Max Cleland, the Administrator of Veterans
7 Affairs, who will be joining us later this morning -- in about
8 an hour or so. He feels that it is important to address the
9 Advisory Committee, and he will be doing that.

10 We have available for you copies of the statement that
11 Mr. Max Cleland made before the Subcommittee of Medical Facili-
12 ties and Benefits of the Veterans Affairs Committee in the
13 House of Representatives on February 25th, and then again a
14 comparable statement before the Senate Veterans Affairs Commit-
15 tee several days earlier.

16 I would like to read just a couple of paragraphs from
17 this testimony because I think it is most significant.
18 This is in a section headed, "Overview of the Agent Orange
19 Problem."

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

25 "One of the most vexing issues in the Agent Orange

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1 area is the problem of how much exposure individual troops
2 received. The war was a fluid combat experience with many small
3 units involved and no fixed battle lines. We are informed by
4 DOD that they do not possess accurate information on the dispo-
5 sition of many of the 2.6 million troops who served in Vietnam.

6 "This circumstance makes it very difficult to deter-
7 mine precisely whether any individual might have been exposed.
8 The General Accounting Office has reported that we do have
9 some information about the movements of Marine troops, particu-
10 larly in the I Corps Area, although it is unclear to what
11 extent the amount of exposure to Agent Orange can be determined
12 even with this group."

13 I have more information to report to you which is
14 of a slightly more hopeful nature that I will be sharing with
15 you a little bit later on this morning.

16 "Still another difficulty relates to the fact that
17 even if an individual veteran does have toxic symptoms at this
18 time, it is frequently impossible to determine whether these
19 symptoms are related to exposure to chemicals experienced in
20 civilian life after returning from Vietnam or whether they were
21 indeed due to exposure to Agent Orange in Vietnam.

22 "For example, there are many known examples of toxic
23 exposures of human population following industrial accidents.
24 In addition, there is the possibility of damage from a range of
25 universal environment contaminants such as PCB and PCP.

1 "The symptoms alleged by veterans as a result of
2 exposure to Agent Orange are multitudinous and many of them
3 occur so frequently among all segments of the population that
4 it is impossible at this time to attribute these symptoms speci-
5 fically to Agent Orange.

6 "Such common symptoms include restlessness, lethargy,
7 headaches, confusion, dizziness, loss of strength, loss of
8 libido, impotence, infertility, abdominal pains, sweating,
9 tremor, pallor, change of personality, irritability, insomnia,
10 and difficulty in concentration.

11 "The other problems are of significant concern to us,
12 but their relationship to exposure to Agent Orange has not been
13 proven. I refer to the occurrence of malignancies of various
14 sorts and to the production of abnormal children with birth or
15 congenital defects.

16 "Although there have been allegations of both occur-
17 rences by many Vietnam veterans, there is an absence of vali-
18 dated scientific information to relate these occurrences to
19 human exposure to Agent Orange." We will have several of
20 the panel members who will have more to say about that later on.

21 "There are a number of reasons why it is difficult to
22 get to the root of the problem. First, there are a large
23 number of unknown factors, some of which have already been dis-
24 cussed. Second, the current scientific conclusions are largely
25 based on animal experiments.

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1 "Whereas there are a number of reports of human ex-
2 posure to Agent Orange constituents from industrial settings
3 and accidents which I will share with you, the only clearcut
4 health related finding is that such exposures may be followed
5 by the development of a skin condition known as chloracne.

6 "However, there are no scientifically validated data
7 yet available to show frequency among Vietnam veterans of this
8 or other diseases or of any deaths attributable to long-term
9 toxicity of Agent Orange constituents.

10 "Third, the data with respect to the extent of
11 individual exposures to Agent Orange is extremely difficult to
12 obtain. Fourth, there is no single test yet
13 available for determining exposure to Agent Orange."

14 Current literature seems to indicate -- as I say, the
15 evidence that there is toxicity on the part of animals after
16 laboratory experiments begins to mount, and some definite
17 conclusions can be derived from that. The evidence with respect
18 to human beings, however, continues to be a source of scientific
19 debate.

20 The experiments in humans -- they should not be
21 called experiments -- the experience of humans with respect to
22 herbicide orange and its constituents' toxicity relates either
23 to industrial accidents or to industrial exposures where
24 people have been exposed over long periods of time. And, again,
25 the evidence here is conflicting.

1 Recently, studies released by the Environmental
2 Protection Agency and given to two congressmen who were interest-
3 ed and distributed by them, copies of which are in your meeting
4 package, indicated that there are some reasonable forms of
5 exposures in Sweden and that long-term toxic effects are ex-
6 perience in humans.

7 On the other hand, there are some studies -- particu-
8 larly the one done by Dr. Raymond Suskind of Cincinnati -- to
9 the effect that the experienced mortality in a long-term follow-
10 up of patients exposed -- or people exposed -- to an industrial
11 accident in Nitro, West Virginia -- the expected mortality --
12 the observed mortality -- did not exceed that which was normal
13 for a comparable population.

14 So there is still a good deal of unresolved debate
15 about the pertinence of these findings. And, of course, the
16 Veterans Administration and others are deeply engaged in trying
17 to get to the bottom of this.

18 One of the significant events that I must call to
19 your attention has been the appointment of a White House Task
20 Force and I would like, at the conclusion of my remarks, to go
21 around the table and I think at that point it would be appro-
22 priate to ask Dr. Moore to bring us up-to-date on the Task
23 Force.

24 The White House Task Force has been appointed by the
25 Order of the President and is composed of the Department of

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12.

1 Defense, the Department of Health, Education and Welfare -- the
2 former HEW -- and the Veterans Administration. It is
3 directed by the Honorable Patricia Harris, the Secretary of HEW,
4 Ms. Jody Bernstein is the Chairman, and Dr. Moore will be
5 talking to us. He is the head of the scientific panel and her
6 deputy on this committee, and he will be talking to us present-
7 ly about what that committee has done. I think that is a very
8 useful device and we will certainly hear much more from the
9 White House Task Force presently.

10 You know, of course, that Congress has passed the
11 Public Law 96-151 which has, among other things, mandated two
12 activities on the part of the Veterans Administration.

13 Dr. Levinson and Dr. Kinnard will be talking about that.

14 One is the conduct of an epidemiological study which
15 we are going to be doing, and we have had the first conference
16 with prospective bidders. Dr. Levinson and Dr. Kinnard can
17 tell you about that.

18 We are also going to be conducting our literature
19 search and analysis. Actually, literature searches have been
20 done before. Two very effective searches have been done. One
21 by the National Academy of Sciences in 1974 and one by the Air
22 Force which was completed, I believe, in 1978. But events have
23 moved so rapidly that another study is certainly indicated.

24 We will talk a little bit later about the fat biopsy
25 study. You will remember that the Veterans Administration

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1 undertook to do some biopsies of a group of people who were
2 definitely exposed to herbicide orange and of a group of
3 people we think probably were not, hoping to find some clue as
4 to the persistence of herbicide orange in fat tissue. The
5 results, at least at this point, need further clarification.

6 The data is being submitted to a number of
7 analytic bodies and will be submitted to this group as well --
8 I think it may have been already circulated -- for further
9 analysis and interpretation.

10 One of the things we have done has been to have an
11 increased focus on the problems of chloracne. It has been
12 brought to our attention that the diagnosis of chloracne may
13 have posed difficulties under war confrontations, and we have
14 decided, therefore, to focus on this problem by a two-pronged
15 effort.

16 One was to update skills of our clinical people with
17 respect to chloracne. It is not conceivably within the realm
18 of many physicians of ordinary experience -- except for derma-
19 tologists, probably, or people involved in industrial medicine.

20 On April 14th we had a meeting with a group of
21 our dermatologists who represent our ^{Central Office} Advisory Committee in
22 Dermatology, together with an
23 industrial physician, Dr. Raymond Suskind, who has enormous
24 familiarity with that. Dr. Levinson will tell us more
25 about what came out of that meeting.

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We are trying to find ways of developing our skills, and the point here is that we will be looking at several groups of veterans where it is conceivable that we might find residual or, indeed, active cases of chloracne.

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There will be three groups: one, a group brought to our attention by Mr. Victor Yannacone, an attorney representing the group of veterans; another, a group of people from records of the Department of Veterans Benefits -- Mr. Peckarsky and we have had discussions about that --;

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12

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16

and a third will be a group of people discharged from VA hospitals with skin conditions. The idea is that we will go over these records and some of these people may well be called back for re-examination in an endeavor to determine whether or not chloracne could have been conceivably underdiagnosed.

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When we get around the table I will ask Colonel Thiessen to discuss the problem of Ranch Hand. Ranch Hand, you will remember, is the study proposed by the Air Force which would look, in some detail, at a group of people who were heavily exposed to orange by virtue of the fact that they loaded the planes and flew the mission, and so on.

23

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These would be compared with an age, sex, and otherwise match group of servicemen who were not exposed. There are problems with that. I will let Colonel Thiessen, when we get

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1 around the table, discuss that.

2 The White House Task Force had a scientific committee,
3 and at a recent meeting on April 18th the scientific panel
4 dealt with the problem of congenital anomalies. Subsequently,
5 I will ask Dr. Erickson and Dr. Moore to talk about what came
6 out of that meeting because there will be efforts in their
7 proposals to study the possibility of congenital anomalies --
8 something that looms very high in importance and one which we
9 need to be able to work on very assiduously.

10 At the series of meetings held with Captain Peter
11 Flynn of the Department of Defense and people from the
12 Veterans Administration -- Dr. Shepard, Dr. Levinson, myself,
13 and others -- we came into possession of some information that
14 is difficult to evaluate at this point.

15 It may be that there are ways of tracking down
16 where the disposition of troops may have occurred. As I said
17 earlier and pointing to the Administrator's statement, one of
18 the very important difficult items that we have had to deal
19 with is the fact that we haven't known where the troops were.

20 Early on in this business it seemed to us that the
21 easiest thing in the world was to match the two sets of tapes
22 that we had -- one from the Air Force which indicated where
23 the spraying occurred, and the other from the Department of
24 Defense which indicated where the troops were.

25 The logic was overpowering -- to find out where the

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1 Air Force sprayed, to find out where the Army had its troops.
2 You put those together and, presto, suddenly you have a group
3 of people that you can say were definitely exposed. Or, of
4 equal importance, you can point to a group of people that you
5 can say were definitely not exposed.

6 Well, it turns out that that is very, very difficult.
7 We spent several months trying to get from the Department of
8 Defense more precise information. It was very difficult to
9 come by.

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10 A General Accounting/report seemed to indicate that
11 at least some groups of Marines in the I Corps were heavily
12 exposed, but the Department of Defense has problems with that
13 report, which maybe Colonel Thiessen can address later.

14 Anyhow, it was a very difficult matter to try to
15 make the correlations between where the troops were and where
16 the spraying was.

17 Now I am not going into the difficulties of trying to
18 make analyses based upon persistence of the materials. They
19 undergo -- the herbicide orange undergoes rapid degradation in
20 bright sunlight, but once it gets into the soil it may persist
21 for months or years.

22 Does it enter the food chain? Well, there is some
23 speculation about that. Does it enter the water supply? Well,
24 presumably it is highly insoluble in water and, yet, it is
25 not impossible that it may have entered the water supply.

1 But we do feel that if we could get precise informa-
2 tion about where the troops were with respect to spraying we
3 have a much easier job in forging ahead with this. It now
4 appears that there may be some signs of hope, and Captain Peter
5 Flynn and we have engaged in some discussions which seem to say
6 that there are ways of trying to track down where these Army
7 troops are.

8 How successful that will be we can, as yet, only
9 speculate. But it would enormously simplify our very compli-
10 cated task.

11 There are, as I say, a number of other developments
12 but I think that I will, at this point, stop so that we can
13 begin to hear from the panel members who will bring us up-to-
14 date and elaborate on some of the issues I have mentioned.

15 I would like to ask Dr. Shepard if he has any other
16 significant occurrences.

17 DR. SHEPARD: Well let me just say that, as Dr. Haber
18 indicated in his very kind remarks, I am very new at this job
19 and I am attempting to get up-to-speed, so to speak.

20 Some impressions have formed early in my mind, and
21 one of them indicates the complexity of the problem, but as a
22 corollary to that I am tremendously impressed by the amount of
23 talent that has gone into trying to solve these problems.

24 The inter-agency group meeting which I attended last
25 week is composed of some very highly talented people and we

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1 will be hearing from some of them this morning. And I am
2 tremendously impressed with the overall government action and
3 initiative that has been thrown into the fray, so to speak.

4 I look forward to working with this committee and
5 the other committees, and hopefully we can come to some sub-
6 stantial resolution. I think that the spin-off will be
7 significant in that it will go beyond the Veterans Administra-
8 tion.

9 Obviously there are many other groups interested.
10 You have had a meeting already with some members from the
11 National Forest Products Association. The whole question
12 of herbicides has a much wider application, and I am sure that
13 we will be getting into those issues as time goes on.

14 But, again, let me say that I am glad to be a member
15 of this group and will look forward to working with you all.

16 CHAIRMAN HABER: Thank you.

17 All right, I would like now to ask the committee
18 members to bring us up-to-date and I will call upon each of you
19 in turn. But I think maybe, because of the importance of the
20 White House Task Force, it might be appropriate for us to begin
21 with a review of what has happened with the Task Force and the
22 scientific panel, Dr. Moore, and I think following your dis-
23 cussion maybe you could lead right into Dr. Erickson's dis-
24 cussion about the proposal for the congenital anomalies study.

25 DR. MOORE: Briefly, as Dr. Haber mentioned, just

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1 before Christmas there was established at the White House's
2 request an inter-agency work force to look at the long-term
3 health effects of phenoxy acids and their contaminants, such as
4 TCDD or other dioxins.

5 The lead responsibility for getting that task force
6 going was assigned to the Department of Health, Education and
7 Welfare and, as Dr. Haber previously mentioned, the other
8 formal members of the inter-agency work group are the Department
9 of Defense as well as the Veterans Administration.

10 The U.S. Department of Agriculture, the Environmental
11 Protection Agency, as well as the Occupational Safety and
12 Health Administration, part of the Department of Labor, and the
13 OSTP serve in observer status on that group.

14 The charge to the group was to
15 look at what was known or what wasn't known with
16 regard to the long-term health effects associated with phenoxy
17 acids. The group was also specifically asked to focus its
18 initial attention on the veteran's concern as it relates to
19 Agent Orange.

20 As I think everybody in this room probably knows,
21 Agent Orange was composed of two phenoxy acid herbicides --
22 2,4-D and 2,4,5-T. Both of those phenoxy acids have been used
23 extensively worldwide as well as in this country, and 2,4-D is
24 still in very wide use in this country today.

25 2,4,5-T's major uses were suspended a little over a year or

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1 a year and a half ago by EPA who was responsible for its registration.

2 Indeed, formal administrative legal hearings are underway right now to
3 determine whether that suspension should be made permanent or not.

4 I guess that some of the members of the group have developed
5 a bias as it relates to their focus on Agent Orange. This deals with
6 the fact that they are unwilling to foreclose the possibility that if
7 there are health problems in Vietnam veterans, they are not willing
8 to totally concede that studies which attempt to identify cause should
9 focus solely on Agent Orange. There were a variety of chemicals used
10 in Vietnam. Agent Orange is a plausible candidate to be investigated
11 in trying to come up with some facts of a cause-effect relationship.
12 But, given the difficulties of knowing precisely who was exposed,
13 the quantities to which they were exposed or the duration of such
14 exposures, it becomes a very formidable and difficult task to design
15 a scientific study involving Vietnam veterans exposed to Agent Orange.

16 Perhaps a better approach is to design a study that attempts
17 to relate Vietnam service as the causative factor associated with
18 that health effect. In any study of veterans one would hope to
19 determine if an effect was associated with a particular group, such
20 as combat troops, a Ranch Hand Unit, or with a rather specific task.

21 The group has initially attempted to get a listing of what
22 is going on within the federal government as it relates to phenoxy
23 acids or dioxins. Subsequent to getting that listing, we have gone
24 back and fleshed out or expanded the descriptions of these activities.
25 For each activity we have asked each person to identify where they are
in their study: are they planning it, are they half-way through, and,
very importantly from our perspective, when do they think it will be
completed -- so that one can end up with some sense as to when appropriate
assessments might be able to be made based on on-going activities.

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1 Several areas have been looked at by the scientific panel.

2 One area has been the efforts that are trying to establish the potential
3 for these compounds, singly or in combination, to cause genetic alterations.
4 There are a number of studies on-going in that regard, some of which will
5 start to emerge next month, I believe.

6 Also, we have looked at the issue of birth defects as a concern
7 of Vietnam veterans. Obviously, the genetic studies that are on-going
8 will yield data relevant to that concern.

9 The scientific panel is also cognizant of the fact that there
10 is a male reproductive study that is well underway and is due to be
11 reported out on July 1st, in which male mice were exposed to the maximum
12 tolerated dose of Agent Orange with a variable being the amount of dioxin
13 contaminant. After they had been exposed, there was a sequence of serial
14 matings of these animals to see if their fertility has been impaired and
15 if there is an increased incidence of malformed offspring.

16 Thirdly, as it relates to birth defects, there was a meeting
17 held a couple of weeks ago to investigate the possibilities of using
18 human birth records data. It has been proposed that, using some birth
19 records data that has been collected by the Center for Disease Control
20 in Atlanta, there might be a possibility of conducting a case-control
21 type of an epidemiology study to find out if veterans of the Vietnam
22 era are at increased risk of fathering children with major malformations.
23 This is the study that Dr. Erickson has given some thought to.

24 There are two other areas that I will just briefly mention.
25 One deals with the issue of the methods of chemical analysis by which
one can determine the presence of dioxin in human tissue. More precisely,
how well can one do that and end up with an unequivocal answer? Just
what is the state of the art of these analytical procedures which are
very cumbersome and tedious?

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1 The second is in the area of carcinogenicity. The group is in
2 the process of evaluating four Swedish papers that have come out in the
3 last year or year and a half and a West German paper.

4 I think I will stop there. I will mention to anybody who is
5 interested that the group periodically reports on about a six-week basis
6 to Mr. Eisenstat at the White House as to what activities there have been.
7 There have been two such reports thus far -- one issued, I believe, in
8 early March or late February, and the second one issued or submitted
9 early in April. Those reports are available to anybody who is interested
10 in them. The report, aside from a descriptive narrative as to what is
11 going on or what it is planning on doing, does include the detailed
12 listing of the activities that are on-going within the federal government,
13 so one could get a sense as to what is being done, when it is supposed
14 to be finished, et cetera.

15 CHAIRMAN HABER: Thank you, Dr. Moore.

16 I think I would like to ask, if it is not an imposition, for
17 Dr. Erickson to discuss in a little detail the proposal, and I wish to
18 emphasize that it is only a proposal at this point.

19 He made this to Dr. Moore's committee on April 18th, and
20 although it is only a proposal -- and I certainly don't want to judge
21 or to prejudge the deliberations of Dr. Moore's panel -- nonetheless,
22 it seems to me one of the more useful ideas that has been aired for the
23 purpose of monitoring the possible untoward occurrence of excessive numbers
24 of birth defects.

25 Dr. Erickson, could you just briefly describe what you are
proposing and make it a matter of our deliberations?

1 DR. ERICKSON: All right. What we have proposed at
2 the Center for Disease Control is to do a case-control study
3 of congenital malformations. For those of you who are not
4 familiar with the term "case control" perhaps I should digress
5 for a moment to explain that.

6 The usual kind of scientific study that most people
7 are aware of is a prospective study or what epidemiologists
8 call a "cohort study." And in that type of study people who
9 are exposed to a particular agent are followed over time and
10 the occurrence of some disease in them is ascertained.

11 And that occurrence of disease is contrasted with
12 the frequency in a control group of people who were not exposed.
13 And a case-control study is sort of backwards from that.

14 What we do is start out with cases of disease and
15 look retrospectively for a difference of frequency in exposure
16 to a putative causal factor. In the case in hand what we would
17 do in Atlanta would be to start out with cases of malformations
18 in babies and a control group of normal babies and retrospective-
19 ly determine the frequency of service in Vietnam among the
20 parents of these babies.

21 Since 1968, CDC has been collecting data on all mal-
22 formed babies who were born in a five-county area surrounding
23 Metropolitan Atlanta. There have been since that time somewhere
24 on the order of a quarter million births in the metropolitan
25 area, and from among those quarter million births there are

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1 roughly 5,000 babies who have been born with what we would
2 consider serious malformations.

3 What we had proposed doing then was to do a large
4 case control study targeting at least perhaps 5,000 cases and
5 an equal number or perhaps fewer numbers of controls and to
6 interview the parents of these babies, trying to find out what
7 their record of service in Vietnam was.

8 The end result then would be a comparison of the
9 frequency of Vietnam service among parents of abnormal babies
10 with parents of normal babies.

11 In addition to getting information about service in
12 Vietnam we would be asking questions about a wide variety of
13 other factors. The cause of most birth defects is unknown but
14 it is suspected that a large number of both natural and manmade
15 environmental factors may influence the occurrence of defects.

16 So we would be questioning parents about a variety
17 of things such as drugs taken in pregnancy, occupational
18 exposures, exposures in general-- a wide variety of things
19 for two purposes.

20 One, would be to be sure that there weren't other
21 things that might separate Vietnam veterans from other people,
22 and, secondly, because of the spin-off value of this sort of
23 study in terms of understanding the causation of birth defects
24 in general.

25 I would be happy to entertain any questions, but I

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1 think perhaps that is enough of a description.

2 DR. MURPHY: What was the number of years -- the
3 births during how many years -- the past how many years?

4 DR. ERICKSON: I don't have an accurate count, but
5 since 1968 we have been collecting data and I think as of the
6 end of 1979 there were about a quarter of a million births
7 which took place to women who were resident in this five-county
8 area that we targeted as our population.

9 DR. MURPHY: What do you -- some idea of what your
10 cut-offs for serious malformations are. Is cleft palate a
11 serious malformation?

12 DR. ERICKSON: Yes, we would call that a serious
13 malformation. That is a tough thing to deal with. There are
14 some things that everybody would agree was a serious malforma-
15 tion and some things there might be some argument about.

16 Our rule of thumb has always been that roughly half
17 the babies we collect have a serious malformation and we define
18 serious in that a malformation that is life threatening either
19 during fetal life or after birth, a malformation which requires major
20 surgery for correction, results in a serious handicap, or results in a
21 serious handicap in either a physical or a psychological sense. So a
22 cleft lip might fit the latter category, for example. It is easily repaired,
23 but --

24 DR. MURPHY: Is there any attempt to go beyond the morphologic --
25

1

2 DR. ERICKSON: No, there is not. There are a number
3 of limitations to this study that we would do. First, it would
4 be targeted only at what were structural malformations --
5 malformations which result in some abnormality of structure.

6 Some of those abnormalities of structure lead to
7 abnormalities of function. For example, babies with chromo-
8 somal abnormalities are virtually always mentally retarded.
9 But in terms of focusing on problems which might be manifested
10 only by, say, mental retardation discovered at entry to school,
11 this study would do nothing for that.

12 It would also tell us nothing about other problems
13 of fertility, problems of sterility, or relative infertility.
14 It wouldn't tell us anything about frequency of spontaneous
15 abortion, because we don't get babies until after they have
16 passed that stage of fetal development.

17 Other problems are that we think we would stand a
18 good chance of demonstrating any significant increased risk to
19 Vietnam veterans in general, but in terms of fractionating them
20 down into documenting exposure to Agent Orange is another
21 question altogether.

22 DR. MURPHY: In your apparent follow-up you could --
23 probably are going to attempt to get some, at least, subjective
24 -- probably more than subjective -- especially as spontaneous
25 abortion goes in a particular population that you select.

1 DR. ERICKSON: Oh, yes. For those people we would be
2 getting a complete history of the reproductive performance of a
3 couple, but it is not quite the same as targeting a group and
4 looking at spontaneous abortion.

5 CHAIRMAN HABER: Thank you very much, Dr. Erickson.

6 I would like to ask Colonel Thiessen and Major Brown
7 if they could bring us up-to-date on where we can expect our
8 Operation Ranch Hand study to go.

9 Major Brown?

10 MAJOR BROWN: Well we are still -- the National
11 Academy of Sciences is still deliberating the protocol pre-
12 sented to them on December 18th. We have, in the interim, done
13 some additional work.

14 One of the things that we tried to do was go back and
15 look at the aerosol dynamics that occurred within the C-123
16 aircraft during the spray missions. There has been some
17 simulation work carried on and the data is still preliminary,
18 but that work continues at this time.

19 And that is basically the status update.

20 CHAIRMAN HABER: Thank you very much. Colonel
21 Thiessen, is there anything else you want to add to that?

22 COLONEL THIESSEN: No, that is about it. I would
23 like to say a few things about the study that Major Brown
24 mentioned.-- the matter of exposure in the airplane. The
25 Air Force has been doing some runs with the C-123 under the

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1 simulation of the sort of conditions that existed in Vietnam.
2 At the moment we are discussing how we could get some sort of
3 at least semiquantitative estimate of the levels of exposure
4 that are actually in the airplane -- in the cockpit vis-a-vis the
5 rear of the plane, and so on. That should result in data within
6 a couple of months, I would say.

7 CHAIRMAN HABER: Thank you.

8 I would like now to go around the table and ask the other
9 members of the committee to bring us up-to-date on activities that
10 they either know about or their agency has been specifically engaged in.

11 Maybe we can begin with you, Dr. Lingeman. What is new with
12 herbicide orange at NCI?

13 DR. LINGEMAN: Well, I don't know that there is anything
14 new. The testing of dioxin TCDD in rodents is still incomplete.
15 We already know and have accepted the fact that TCDD is a carcinogen
16 in rodents. Rodents are different than humans and they have different
17 metabolic systems. The dosage given to the rats may or may not
18 relate to amounts to which Vietnam veterans were exposed.

19 This report will be out within the year. Perhaps it will
20 reveal new information.

21 Epidemiologic studies of pesticide operators are still incomplete.
22
23
24
25

1
2 Perhaps in the future the NCI might be interested in studies
3 of mechanisms of carcinogenic activity of TCDD.

4 There are at least two possibilities. One idea is that because
5 TCDD affects the immune system, its carcinogenicity might be explained
6 on that basis. Or it might be caused by damage to DNA. We don't know.
7 This is something to investigate.

8 Regarding the possible carcinogenicity of TCDD in man, I am
9 sure that you know that Dr. Nelson Irey of AFIP is collecting histo-
10 pathologic material from veterans who were exposed to Agent Orange in
11 a Pathology Registry. Some of these lesions are neoplasms.

12 Biopsy and autopsy material from Vietnam veterans who are ill
13 or have died should be submitted to the AFIP. The process of collecting
14 pathology material is very slow and it may be months or years before
15 answers to questions about the human carcinogenic effects of TCDD are
16 known.

17 At the AFIP there is a wealth of 100 years' experience in
18 pathology diagnosis and specialists in all sorts of -- in every organ
19 of the body. For example, liver specialists, skin specialists -- any
20 organ that you name.

21 Any biopsy that is submitted can be examined by specialists.
22 For example, if a biopsy from a person with Hodgkins' Disease is sent in,
23 it is referred to the Hematologic Pathology Department for diagnosis and
24 classification.

25 I think that the total number of materials submitted so far
under this program is around 40. Material is still coming in and
the rate of referral is gradually increasing. We frequently see skin
lesions. These have caused diagnostic problems. Dermato-pathologists

1 at the AFIP really have not had very much experience with this lesion.
2 The absolute criteria are very difficult to establish, even with a biopsy.

3 We have examples in our registry of Japanese people who were
4 exposed to a different compound (PCBs) which was ingested in contaminated
5 cooking oil. The chloracne is the same, whether caused by PCBs or TCDD.
6 The Japanese people exposed to PCBs had very severe skin lesions. One
7 skin biopsy from a Vietnam veteran that we examined recently did not
8 look like the Japanese chloracne lesions. If it is or was chloracne, it
9 is not so advanced. Whether there is an intermediate stage of severity
10 of chloracne that can be accurately diagnosed has yet to be determined.

11 We hope that we can increase the interest not only of the
12 Veterans hospitals, but also civilian hospitals, and also people involved
13 in investigating industrial accidents throughout the world to send
14 pathologic materials to the AFIP from skin lesions of people who are
15 known to have been or suspected of being exposed to TCDD or other
16 halogenated hydrocarbons to increase our experience in this area and
17 permit accurate diagnoses.

18 Dr. Taylor at the Cleveland Clinic is an industrial dermatologist.
19 He told me that he has a great deal of difficulty -- he said this in a
20 letter to us -- a great deal of difficulty in distinguishing chloracne
21 from other forms of acne in individual case situations. I think we
22 could contribute a great deal to this if we had a little more material
23 to work with. So if any of you have access to biopsy material from
24 individuals suspected of having chloracne, we would like to see it.

25 CHAIRMAN HABER: Incidentally, I would like to invite you
and Dr. Shepard will take pains, Dr. Levinson will take pains also to
see that you are invited -- to future meetings and involved in this
chloracne exercise that we are working on, because you should know what

1 they are doing and they obviously need to know where you are coming from.

2 COLONEL THIESSEN: Mr. Chairman, may I make a remark? Colonel
3 Allen has written a monograph on skin disease in Vietnam. He is still
4 on active duty and I am sure he is available to assist you in this.

5 I have discussed chloracne with him. To him -- at least at
6 the time that he was in Vietnam, it definitely wasn't a problem that was
7 identified as such.

8 DR. LINGEMAN: I have some other points I wish to make.
9 Speaking again of cancer, neoplasms that result from industrial carcinogens
10 generally have very long incubation periods. It can be as short as
11 one or two years but usually five, 10, 20 and even 30 years. So we are
12 going to wait a long time before we find out whether or not the Vietnam
13 veterans have environmentally induced cancers. However, we are collecting
14 examples of these cancers and we have a huge backlog of cancers from
15 other populations to compare. We have a lot of epidemiological data
16 about age distribution and other demographic information about specific
17 types of cancers.

18 It will be possible, I think, to decide within -- we are now
19 approaching, what, 10 or 15 years since the earliest of these veterans
20 served in Vietnam. We are approaching a time when we might be able to
21 see some of these neoplasms if they do occur with any excessive frequency.

22 I would also like to suggest to Dr. Erickson and anyone else
23 who is involved in collecting data about infants with congenital anomalies,
24 the AFIP also has a pediatric registry which concerns itself primarily
25 with the perinatal diseases. I wish to suggest that any pathologic
material, autopsy material, or biopsy material, be sent to the AFIP
for evaluation. The Atlanta 5-county area involves a relatively small
number of hospitals. Perhaps the AFIP would be a good choice to serve as

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1 a repository for pathological materials.

2 CHAIRMAN HABER: Thank you very much. Dr. Murphy?

3 DR. MURPHY: I really have nothing to report other than the
4 fact that I have been contacted by physicians in the local veterans
5 hospital in Houston, who initially were quite concerned that they
6 didn't seem to have all the appropriate information.

7 I referred them to your office and the last I talked with
8 Dr. Cromwell he seemed much more satisfied with their program for
9 handling veterans' complaints. He related to me a couple of rather
10 specific examples that reflected the frustration of some of the veterans
11 that they are seeing where, in one case at least, one veteran's wife was
12 convinced that she would give birth to a malformed infant and had an abortion
13 on that basis. And there are other such incidents, but he said that they
14 now are better informed and seem better organized.

15 One thing Dr. Cromwell did a couple of days ago -- he called
16 me on the phone and asked me if I had seen an article, very anecdotal,
17 I presume, in some VA or veterans news media -- I can't recall whether
18 it was a disabled veterans newsletter or what -- alleging an association
19 or cluster of leukemia occurrences. Do you know about that or has
20 anyone seen that? As I said, I think it was very much an anecdotal case.

21 CHAIRMAN HABER: Can you give us the name of someone that we
22 can contact?

23 DR. MURPHY: I am sorry I can't, except for Dr. Cromwell who
24 said he would call me back.
25

1 CHAIRMAN HABER: Get in touch with Dr. Cromwell and
2 see if we can't chase that down.

3 DR. MURPHY: The nature of this was that someone in
4 a unit tried to get in touch with a number of crew members or
5 other people that had been in the unit and found that a large
6 number of them had died -- all from the same disease. But that
7 could be known. There is nothing scientific about that.

8 The other point, I, as well as several other people
9 here, attended an NAS workshop jointly with an Italian
10 group entitled, "Clinical and Epidemiological Follow-Up of
11 Unusual Areawide Chemical Contamination," which dealt in
12 several cases with dioxin and various aspects of dioxin.

13 I think that nothing particularly new came out of
14 that except to reaffirm what we have been saying here that
15 such things as enzyme induction and various kinds of assays
16 are not sufficiently specific to be diagnostic.

17 That is about all that I thought really related to
18 our activity here. There is nothing new, wouldn't you agree?

19 CHAIRMAN HABER: Thank you. Mr. Thompson, is there
20 anything that you wanted to add to the record?

21 MR. THOMPSON: Not at the present time, Dr. Haber.
22 Thank you.

23 CHAIRMAN HABER: Dr. Brick?

24 DR. BRICK: Just this morning I had a letter from a
25 veteran -- it so happens, coincidentally, that I read it this

1 morning -- who alleges that his skin condition was related to
2 Agent Orange and that whatever the skin condition was, he hadn't
3 received very good care -- and probably no compensation, I
4 might add -- from the VA'.

5 I referred him to our Department Service Office
6 to get him in contact with people at the hospital in question
7 to see that he has the appropriate examinations. We keep
8 getting letters from service officers and veterans with
9 reference to various conditions.

10 Leukemia has been mentioned in a couple of instances,
11 lymphomas, et cetera. And, way out, the last one was colon
12 cancer. From my point of view, most of these are anec-
13 dotal, as was pointed out by Dr. Murphy.

14 In the media one finds, unfortunately I think, a
15 lack of credibility of the Veterans Administration. I think
16 that Dr. Haber knows this better than I can express it.

17 I am a bit concerned about this proliferation
18 of committees examining this problem. Is this committee now
19 superfluous? We have a White House committee. What is going
20 to be the relationship?

21 I don't know. I am just voicing my own thoughts
22 on this. Is there going to be a direct relationship between
23 this committee and the White House committee? Are we going to
24 be doing studies that are being proposed superfluously?

25 Are some of these studies really not pertinent to the

1 matter that concerns the veterans organizations, one of whom
2 I represent here? And that is the problem of veterans coming
3 in the hospitals -- thinking they have a legitimate case -- that
4 their disease -- whatever it is -- all the way from athlete's
5 foot, as it sometimes turns out to be, to^{scabies} -- is related to their ex-
6 posure.

7 The anecdotal story of this wife of a veteran who
8 has an abortion based on the fact that she might have a
9 defective child is somewhat typical of the literature that one
10 reads in the media.

11 And the bottom line to me is this. Would it not be
12 better to have a blue ribbon panel appointed directly by the
13 President. One panel -- not a proliferation of government
14 panels -- appointed by the President outside of the Veterans
15 Administration.

16 The problem comes that the Veterans Administration,
17 as I know it, is trying to do a very reasonable, good job --
18 scientifically based -- as this committee attests to.

19 But is the public, the media, Congress -- and there
20 are certain congressmen who are criticizing the VA, as the
21 people in the VA know better than me -- are they going to
22 accept the findings of this committee as bona fide when this
23 committee comes out and says, as the Administrator said before
24 Congress, that at the present time there is no scientific
25 evidence aside from the chloracne problem that any of these

1 alleged diseases and deformities can be related to dioxin?

2 Somehow or other it strikes me that maybe a
3 blue ribbon panel, appointed through the President's office by
4 the National Academy of Sciences and the National Institute of
5 Medicine, might be a device once and for all to get this thing
6 settled. Those are my personal comments.

7 CHAIRMAN HABER: Thank you, Dr. Brick.

8 I think I can say that your concerns are shared by
9 many of us. There seems to be a proliferation of committees.
10 On the other hand, this committee was one of the first, and
11 its predecessor organization. Dr. Schepers and I attempted
12 to set up a body of exchanging information among all those
13 who seemed to know something about this problem.

14 This dates back to the summer of '78 when the
15 problem first really began to manifest itself. I think there
16 are some aspects of this which are peculiar to the veterans'
17 problems and to the Veterans Administration.

18 On the other hand, I well recognize that it will take
19 a great deal of scientific effort on the part of a lot of
20 people. The relationship between this committee and the White
21 House committee is that we tend to share everything with them.

22 We are represented on that committee. The Veterans
23 Administration has people on it. The White House committee has
24 access to many sources of information more directly than we do.

25 The National Institute of Environmental Health Sciences is

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1 represented, the VA, the Department of Defense, and so on. I
2 think that the question as to whether this committee is super-
3 fluous or not can only be answered in the light of time,
4 Dr. Brick, and I think for the time being we have our work cut out
5 for us.

6 We have embarked on some things, and I think that
7 since the membership of these committees tends to be overlapp-
8 ing to a large degree, most of the people sitting around this
9 table have access to the White House Task Force and other task
10 forces.

11 I think there is likely to be no duplication of
12 effort but rather a sharing. At least that is my thought.

13 Dr. Donald Custis is expected to arrive momentarily
14 to introduce the Administrator, but until he is here I think
15 we ought to continue going around the table.

16 I would like to ask Mr. DeYoung -- I would like to
17 say that Mr. DeYoung has been involved in an enterprise, which
18 he himself suggested, making some films of instruction for both
19 veterans and Veterans Administration physicians. I think
20 he brought some films along.

21 Are those the films, Ron?

22 MR. DE YOUNG: No.

23 CHAIRMAN HABER: I don't know if they could be shown
24 today, but I would like to show those films at some point to
25 this committee. But now, if you would, tell us what you are

1 involved in and how you did it, and also, what is new in CAVAT?

2 MR. DE YOUNG: All right. Let me make clear dis-
3 tinction, verbally then, between the two halves of what I will
4 discuss.

5 First, my private professional endeavor is to assist
6 the VA in developing an information package designed to answer
7 some of these questions and hopefully, at least at this point
8 the situation warrants it, trying to quell some of this panic
9 which is evidenced in veterans' wives having abortions and so
10 forth, because that fear is very real.

11 Let me come back to that. The project, I believe,
12 is targeted to finish around Memorial Day now and so at that
13 point in time it will be ready for some sort of viewing.
14 Certainly at the next meeting, if that deadline holds.

15 The tapes which we have today were something brand
16 new which I myself have not seen yet. And we will try -- let
17 me make this request to the VA to set us up with a video player
18 sometime after this meeting. And those of you who are interested
19 can stay and watch.

20 I haven't seen it myself so I can't say too much
21 about it. It is a half-hour documentary that Mr. Bill Curtis
22 from WBBM-TV in Chicago did. Once again, this is his Part III
23 on his continuing series on Agent Orange.

24 He was in Vietnam with a camera crew and has a lot of
25 evidence of some sort or another -- as I say, I haven't seen

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1 it -- about what the current status of Vietnam and its people
2 are. It focuses, of course, on the defoliated areas. It is
3 going to be interesting to me and I certainly invite any of
4 you who will be interested to see that soon. We will try to
5 show it here today if we can. I am going to deal with that
6 during a break.

7 My representation here is for the National Veterans
8 Task Force on Agent Orange and it is another half of that same
9 point of information to the veteran.

10 What I hope you ladies and gentlemen understand --
11 and I think many of you do, certainly, from the remarks I have
12 heard over the course of the last year here -- is that your
13 professional concerns are scientific.

14 And there you have to be hard and cold and calculat-
15 ing, and we understand that. But the veteran's concern is much
16 softer. It resists quantification more so than your professional
17 answers to these questions can.

18 And I think the VA has been slow in addressing that
19 area of concern -- of the softer questions, the human concerns,
20 and the worries and the problems. I am certainly going to
21 continue to work with the VA in that area and try to solve
22 some of those problems.

23 I am real pleased, and I will certainly share this
24 with all the veterans that we are in contact with, to hear of
25 the new studies that are being proposed.

1 I very much like the idea of CDC's gross screen on
2 birth defects. We need that kind of gross screen at this point.
3 It is fine to try to determine the exposure levels in Vietnam
4 of a given unit, at a given time, given date, given place.
5 And those things are real and valid and they need to be done.

6 But the veteran needs more general answers at this
7 point and I will certainly help in any way I can in supporting
8 things such as skin biopsy studies. We will be glad to co-
9 ordinate our data files with you.

10 Through the Veterans Administration the Cancer
11 Institute would like to do a study of skin biopsies and so
12 forth, and you need some people that would be interested in
13 participating. We can help arrange that.

14 And I think this is a legitimate function that we
15 can assist in this search for knowledge. Because, working off
16 Dr. Brick's remark, I think we have a little more credibility
17 with the individual veteran.

18 Many of our member organizations have already done
19 projects like this. The Veteran Hotline, for example, in
20 Chicago, acted as an intermediary with Dr. Doherty in Florida
21 to get the seminal fluid of 75 Vietnam veterans examined. And
22 that project is underway.

23 So there are many things going on that the government
24 is not involved in. You see one of the basic tenets of our
25 existence is the Golden Rule -- he who has the gold makes the

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1 rules. And in order for us to believe the studies, we are going
2 to have to have some of them come out of a place where the
3 gold is not owned by the government who therefore makes the
4 rules. And so we are cooperating with other institutions to
5 get independent research done.

6 The task force itself is a very loosely knit coalition
7 of veterans groups around the country, numbering more than 35
8 at this point. And I throw that resource pool open to
9 scientists -- through our scientific advisory board, who would
10 like to conduct studies of one sort or another on the exposed
11 populations because we got them -- plenty of exposed people.

12 The items I personally will try to provide some
13 detail to the committee on are in documenting the anecdotal
14 stories that we are all hearing, as Dr. Murphy mentioned
15 before.

16 I have got that down and we will try to document
17 that out for you and see if we can get in touch with that
18 veteran. It probably was a newspaper interview or something
19 of that nature. Lord knows, we have seen thousands of them.

20 We would like to cut the wheat from the chaff, as well.
21 But from the veteran's point of view there is good and sound
22 reason in the rat studies and the monkey studies, in the
23 Swedish studies, for example, to make the presumption -- to
24 presume that his disease and his illness was caused by his
25 service in Vietnam and by dioxin.

1 I think at this point the burden of proof is on
2 the VA to show that it is not in the mind of the veteran.

3 CHAIRMAN HABER: Thank you very much. I am glad to
4 have you with us and the viewpoints you express. And it
5 certainly will have an important effect upon the course of the
6 deliberations.

7 I would like now to follow our schedule. We will
8 complete going around the table after Dr. Custis's remarks.

9 I would like to introduce to you our Chief Medical Director,
10 Dr. Donald Custis, who has been very concerned with the posture
11 of the department and the agency with respect to this very
12 perplexing and vexing question.

13 We expect the Administrator, Mr. Max Cleland, to
14 join us at 10:00, at which time, Dr. Custis will have the
15 pleasure of introducing him. But prior to that I think I
16 would like to ask Dr. Custis to address us.

17 I will say one parenthetical remark.

18 On May 28th through the 30th we will be having a meeting of all
19 the VA environmental physicians, one or more representing each
20 VA facility, and a comparable group of people from the Department
21 of Veterans Benefits, one from each regional office, right, Charlie?

22 MR. PECKARSKY: Yes.

23 CHAIRMAN HABER: Many of these people on the
24 council will be addressing them. The purpose of this meeting
25 is to heighten awareness of and proficiency in the diagnosis

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1 of conditions related to possible exposure to Agent Orange and
2 to familiarize our people in the field with the entire range
3 of activities which we under the government and private
4 agencies have been engaged in. So we look forward to that.

5 Dr. Custis?

6 DR. CUSTIS: I welcome the opportunity to
7 express my appreciation for what you are giving to us in terms
8 of your time and so on. I know how busy you all are.

9 I also am sorry I can't stay with you in your meeting
10 today and my inability to do so is no index of how important
11 I think this work is that you are addressing.

12 I don't have to tell you -- I think we have a general
13 concensus -- that there is no issue current right now
14 that is wrought with more difficulty and is more elusive than
15 the problem of Agent Orange and such herbicides, and the
16 problems engendered.

17 I think the heart of the discouragement is the fact
18 that we are not, in my opinion -- and I think I represent,
19 again, the concensus -- we are not going to be able to come
20 up with the hard, fast answers that everyone would like to
21 see in the time frame in which they would like to see it.

22 I think this problem is going to be with us a long
23 time, and I think it is more important, therefore, that we
24 do stay on top of it. The fact that there are so many agencies
25 involved now, and so many programs being sponsored by these

1 agencies, that it has become very necessary to have a very close
2 inter-agency liaison.

3 It was that need, more than anything else, that brought
4 us to the decision that this has become pretty much a full-
5 time job for some one person to stay on top of and orchestrate
6 the VA's involvement with the several agencies and with our
7 own programming.

8 I would presume that the announcement of Dr. Barclay Shepard's
9 acceptance of this role has already been made. We are grateful to him.

10

11 I would suggest, Paul, that you go on around the
12 table and when Max arrives I will do the honors of introducing
13 him -- not that he needs an introduction to any of you.

14 CHAIRMAN HABER: Thank you. Dr. Halperin's repre-
15 sentative?

16 DR. HONCHAR: Yes. I am Dr. Honchar and I am
17 representing Dr. Halperin from NIOSH. I guess the primary
18 activity at NIOSH at this time, which is relevant to the
19 concerns of this group, is the formation of a registry of
20 workers who have been actively involved in the synthesis of
21 2,4,5-T, which is one of the components of Agent Orange.

22 The registry is currently in formation and will
23 include cohorts from a number of industries across the United
24 States. The actual process of assembling the registry is
25 relatively time-consuming.

1 We project within the next few years, once the
2 registry is assembled, first to utilize it for a retrospective
3 cohort mortality study of these workers --- that is, to re-
4 view the mortality experience of this group of people and to
5 compare it to the rates which would be expected from a non-
6 exposed population.

7 In the future we will also be able to evaluate the
8 registry to determine whether it can be utilized for other
9 types of epidemiological studies. So, with regard to the status
10 quo, the data collection is in progress at this time.

11 CHAIRMAN HABER: Thank you, Dr. Honchar.

12 DR. HONCHAR: Thank you.

13 CHAIRMAN HABER: Dr. Plimmer, you will complete the
14 circle then.

15 DR. PLIMMER: Yes. I have no new information from
16 the Department of Agriculture for the record.

17 CHAIRMAN HABER: All right. Pending the
18 arrival of Mr. Cleland, I would like to ask Mr. Fred Conway,
19 representing The General Counsel, if he could bring us up-to-
20 date on the current political ramifications or legal
21 ramifications -- I misquoted myself -- and then when Mr.
22 Cleland arrives we may choose to interrupt, if you don't
23 object.

24 MR. CONWAY: There are times when I begin to think
25 that the legal process moves slower than the scientific one.

1 Not too much has happened, really. We haven't
2 received too many more legal actions against the VA. The
3 action that was brought by the veterans against the chemical
4 manufacturers has been consolidated in New York for pretrial
5 motions and discovery procedures.

6 Tomorrow the Department of Justice is going to make
7 an argument for a motion for dismissal against the United
8 States. The chemical manufacturers sued the United States
9 alleging, very simply, negligence on the part of the United
10 States in its handling of the Agent Orange material, in
11 monitoring and training the personnel in the use of Agent
12 Orange, and in failing to provide appropriate medical care and
13 treatment following their return home from Vietnam.

14 The Department of Justice is going to make an argu-
15 ment on the basis that the United States cannot be held liable
16 for negligence for injuries resulting from service in Vietnam
17 on the basis of Sovereign Immunity-- that the United States had
18 not waived Sovereign Immunity with respect to those kinds of
19
20 injuries, and also on the basis that there is an administrative
21 remedy available to individuals who have sustained an injury,
22 namely, the Veterans Administration's compensation system.
23 That argument is going to be heard tomorrow in New York.

24 Also, you have an affidavit which is incorporated in
25 the materials you were provided with. That affidavit was

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1 reviewed in support of a motion for a preliminary injunction
2 that was brought on behalf of the Environmental Protection
3 Agency.

4 The Department of Justice and the Pollution Control
5 Division brought an action against the Hercules Chemical
6 Company in Arkansas for the improper storage of hazardous
7 substances, among which was 2,4,5-T and the contaminant dioxin.

8 The reason I put that in there is so you get an
9 idea of where EPA is coming from and how they are viewing the
10 situation. EPA has also -- you ought to know -- commenced
11 a cancellation proceeding and are now in the process of
12 obtaining testimony from various witnesses.

13 The Veterans Administration is trying to cooperate
14 with EPA in its endeavor to take down testimony, particularly
15 with reference to the biopsy studies that the Veterans Admini-
16 stration has undertaken.

17 Does anybody have any questions? I would be glad
18 to answer them.

19 CHAIRMAN HABER: Thank you very much. We will look
20 forward eagerly to further developments on the legal thing.

21 DR. MURPHY: Dr. Haber?

22 CHAIRMAN HABER: Yes.

23 DR. MURPHY: Did I understand that the chemical
24 companies are suing the government?

25 CHAIRMAN HABER: Yes.

1 MR. CONWAY: The chemical companies are suing the
2 United States on the basis that--they argue-- that they are not
3 liable for injuries sustained by the veterans. The veterans
4 are suing on account of product liability, that the manufacturers
5 made a known hazardous substance and distributed it without
6 taking the proper precautions, and so forth.

7 The manufacturers are arguing that we are liable.
8 The manufacturers say, "We have an action against the United
9 States because it was the United States that ordered the
10 materials to be made and the United States should have the
11 direct control over the use of the materials."

12 That is how the United States got into the
13 action.

14 CHAIRMAN HABER: I don't want to comment on it
15 because the legalities, of course, escape me, but there is a
16 certain irony in the possibility that one pleads nonculpability
17 on the basis of certain scientific facts; but that if culpa-
18 bility should be established, there is only a proximate
19 responsibility for it.

20 That suit, as I understand it, is for the tidy sum
21 of \$4 billion. Is that right?

22 MR. CONWAY: It is ever increasing because there are
23 more people coming into it.

24 DR. CUSTIS: That would unbalance the budget, I would
25 say.

1 CHAIRMAN HABER: Very good. Well, our job is not to
2 worry about balancing the budget today but to try to balance
3 the Agent Orange --

4 MR. CONWAY: There is one quite unusual anomaly about
5 the situation. The veterans are suing the manufacturers and
6 have said the manufacturers would have to establish a fund to
7 reimburse the United States.

8 So, if the veterans are successful against the
9 chemical manufacturers and the chemical manufacturers are
10 successful against the United States, that would mean the
11 United States would be reimbursing itself.

12 CHAIRMAN HABER: Well, obviously these are just some
13 manifestations of the tremendous amount of concern that the
14 veterans feel and, indeed, all of us are caught up in this.

15 Then, without a break, I would like to ask Dr. Richard
16 Levinson -- again with the caveat that if Mr. Cleland should
17 arrive we will momentarily interrupt -- if he will give
18 us a report on the Steering Committee activities and call
19 upon the members of the Steering Committee to address appro-
20 priate sections of it. We would be obliged to you.

21 DR. LEVINSON: Thank you. I wish to announce that
22 Dr. Shepard will now take over as Chairman of the Advisory
23 Committee and will also be the new Chairman of the Steering
24 Committee, commencing immediately.

25 Let me bring you up-to-date on where we are and what

1 we have been doing. A few words about the fat biopsy study.

2 As you know, or you may remember from Dr. Hobson's
3 last report, the contract chemist, Dr. Gross, has completed all
4 of his duplicate analyses of the 33 specimens.

5 At this time I believe EPA has not completed its full
6 set of analysis of the same specimens, but is rapidly approaching
7 that point. At any rate, two papers are currently being pre-
8 pared:

9 One describes the chemical methodology which will
10 be published in the Chemical Journal by Dr. Gross, and a
11 second paper describes the potential clinical importance of
12 this study which is being prepared by Dr. Hobson and Dr. Lee
13 and the members of the study group.

14 Both proposals will be submitted to the journals
15 after they have been reviewed by a series of groups including
16 one from the National Academy of Sciences and this group, and
17 released by the Administrator to Congress in accordance with
18 his promise.

19 It is hoped that there will not be a public release
20 of this material until the Administrator has met his obligation
21 to Congress.

22 The epidemiological study -- we have Dr. Matthew
23 Kinnard here who can give us some additional input on the
24 status of that study. It suffices to say that on April 11th
25 we held our prebriefing conference for potential contractors

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1 and a number of people did attend, and that on May 8th -- I
2 think I am correct on that -- the bids are to be received from
3 those who wish to submit such a bid.

4 Let me call on Dr. Kinnard to make further remarks
5 about this study.

6 DR. KINNARD: Thank you, Dr. Levinson.

7 Let me preface my statement by saying that I am
8 representing Dr. Larry Hobson. I have been recently assigned
9 to serve as Special Assistant to Dr. Hobson for Agent Orange
10 and related activities.

11 At the risk of being a little repetitious, I would
12 just summarize the proceedings with respect to epidemiological
13 contracts and project as far as I can.

14 In early March the RFP was approved and on the 19th
15 of March the RFP was issued. Now between the time that the
16 prebidders conference was held, which Dr. Levinson referred to,
17 four representatives from the VA met with some representatives
18 from the Department of Defense and the other various branches
19 of the service.

20 At that time it was revealed that there were possibly
21 some records we had not known of earlier that ultimately might assist
22 the VA and the contractor who will ultimately be
23 awarded the epidemiological contract.

24 I won't say anything more about that. But, neverthe-
25 less, on the 11th of April the prebidders conference was held

1 right here in this room. For the benefit of those who may
2 not know what the intent of that conference was, I will summarize
3 it briefly.

4 The purpose of this prebidders conference, which is
5 not always held on a contract that is anticipated to be awarded,

6 was to minimize the extent to which the
7 design would necessarily have to be altered after its initial
8 submission,

9 to eliminate the possible marginal prospective
10 bidders, and finally, to standardize the input that the prospective
11 bidders would receive from VACO.

12 One other date I would like to call to your attention
13 is that May the 8th is the deadline for the sub-
14 mission of the proposals; subsequent to that, the week of
15 May 12th, it is expected that the evaluation panel will be
16 convening to evaluate the submitted proposals.

17 The week of May 19th the contract is expected to be
18 awarded, assuming that there are no further problems. July
19 21st is the target date for the receipt of the design study
20 from the epidemiologist, and July 31st is the projected date
21 for the submission of the design study for the review,
22 evaluation and suggestions.

23 Now I won't project beyond that date because there
24 are four separate groups that must review this contract and
25 must approve it and must make recommendations for alterations.

1 Because there is little control that the VA, or
2 I suppose anyone else, has over how soon these groups will make
3 their input, any date subsequent to July 31st is presumptive.

4 I think at this point I will stop and ask if there
5 are any further questions.

6 VOICE: Has the review panel been formed?

7 DR. KINNARD: As far as I know, I don't think that
8 panel has been formed.

9 VOICE: Do you think you could identify the four
10 groups that would review the design?

11 DR. KINNARD: I can tell you. The four groups that
12 will review the design would be the Office of Technology
13 Assessment, the National Academy of Sciences' National
14 Research Council Committee on Epidemiology, the Interagency
15 Work Group, and the VA Advisory Committee on Health-Related Effects of
16 Herbicides. Those are the four groups.

17
18 Dr. Moore?

19 DR. MOORE: Were there minutes of the prebidders
20 conference or summaries of the discussions?

21 DR. KINNARD: There were no recorded minutes.
22 I failed to make a statement that I wanted to make. Thank you
23 for reminding me.

24 There were approximately 12 to 14 organizations
25 represented and there was a very cordial exchange between

1 those groups represented and the VA personnel -- both in a
2 formal and informal setting.

3 I view the meeting as being very beneficial because
4 there was a lively exchange and there seemed to be universal
5 agreement on what is to be expected on the part of the VA.
6 But there were no formal minutes.

7 DR. LEVINSON: Let me record another activity. This
8 is a meeting of a dermatology panel designed to attempt to come
9 up with a series of diagnostic standards for recognizing
10 chloracne and for broadly educating the physicians in our
11 system who are seeing Vietnam veterans to be very aware of the
12 possibility that one or more of them may have chloracne.

13 The meeting group consisted of Dr. Raymond Suskind,
14 who is a new member of this committee, and four dermatologists
15 from the VA system. I will summarize the discussion very
16 briefly. Dr. Lingeman anticipated some of my statements this
17 morning.

18 First of all, chloracne is not a unique lesion but
19 has morphological and microscopic properties which are virtually
20 indistinguishable from other forms of acne which are more
21 common.

22 The hope is that it might be possible through histo-
23 chemical means to identify dioxin or other substances in
24 tissue removed from an area of chloracne, but this has
25 certainly not been developed at the present time.

1 Dr. Suskind shared with the group his very vast
2 experience in studying this disease and in particular his
3 experience with the people who developed it as a result of the
4 accident at Nitro, West Virginia.

5 He also shared with the group the various morpho-
6 logical studies that he has done. In general, this chloracne
7 is highly persistent and people who were exposed 30 years ago
8 continue to manifest the lesions.

9 The group will now continuously work toward defining
10 standards and towards preparing an educational package for our
11 VA physicians. Public Law 96-151 which mandated the
12 epidemiological study also mandated that the VA perform a
13 comprehensive review and analysis of the literature concerning
14 phenoxy herbicides and their contaminants, and we have made
15 progress on that. I will discuss that in a minute.

16 We have also been involved, and it was mentioned, in
17 developing our second educational program for VA environmental
18 health physicians on Agent Orange and related matters. And,
19 as was also mentioned at this particular meeting, there will
20 be representatives for the first time from the Department of
21 Veterans Benefits.

22 Now let me call upon Mr. Layne Drash, who will be
23 working with Dr. Shepard in the future, to discuss the progress
24 of the literature review and on the educational conference.

25 MR. DRASH: Thank you, Dr. Levinson.

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1 First of all I would like to address the second
2 educational conference which we are going to have in Silver
3 Spring, Maryland on May 28th through the 30th. Dr. Haber has
4 already addressed some of the things that we are going to be
5 doing.

6 Primarily, as he stated earlier, the purpose of
7 this conference is to update our 180 environmental health
8 care physicians and, for the first time attending the meeting,
9 the 54 adjudication officers from the Department of Veterans
10 Benefits on the latest scientific data and information and
11 VA policy relative to the subject of phenoxy herbicides and
12 dioxin and their effect on veterans who may have been exposed
13 to these defoliants.

14 This conference is going to be hosted at the Sheraton
15 Inn. We are being assisted in our efforts to establish the
16 content by the Continuing Education and Development Service who
17 are based here at Central Office.

18 We feel that the participation by DVB is very
19 relevant. They did not participate in the first conference
20 in September, but we feel they should participate at this time
21 because of the role they have in adjudicating compensations
22 and pension claims.

23 We hope to provide them some of the personal approach
24 that we wish to take towards dealing with our veterans on this
25 issue in adjudicating the claims. As the scientific

1 information becomes available this will impact on their
2 adjudication.

3 The second thing I wish to address, as Dr. Levinson
4 has already stated, is the worldwide literature
5 research study in which we are about to engage.

6 As you know, or as has already been mentioned, Public
7 Law 96-151, among other things, has mandated the VA to conduct
8 such a study. The purpose of this study is to research
9 the available scientific information published in manuals,
10 journals, books, what have you, that have been published since
11 1946. We are speaking in terms of scholarly publications.

12 We are, right now, routing through Central Office,
13 a request for projects similar to the avenue that was under-
14 taken for the epidemiological study. We are about 60 to 70
15 percent of the way through on our process on getting this
16 Request for Project through. This Request for
17 Project outlines our requirements for the contractor who will
18 be selected for a competitive bid in undertaking this study.

19 We have some target dates similar to that of
20 the epidemiological study. We originally had a target date of
21 April the 30th for the selection of an outside group to perform
22 the research and analysis of the literature.

23 This target date has now been established as May the
24 15th. Ultimately we will have to submit to Congress, by
25 December 20th, a completed review and analysis of that study.

1 Essentially, what we are asking for in the study
2 is preparation of a systematic bibliography of all the
3 literature that has been identified. We are also asking that
4 the contractor conduct a review and systematic analysis of the
5 conclusions reached in that literature.

6 Finally, we are going to ask that they analyze
7 that data to ascertain its applicability to our research or our
8 activities in assisting Vietnam era veterans who may have been
9 exposed to this herbicide and other herbicides, or dioxins or
10 phenoxy herbicides.

11 Essentially this is it. We are looking for a
12 contractor or contractors who have extensive background in
13 their dealings with phenoxy herbicide that can submit to us
14 a protocol which outlines the methodology by which they will
15 accomplish this study.

16 We will be evaluating them on a point system
17 based on 100 points: twenty points will be assigned to the relevancy
18 of the method, forty points will be assigned to the con-
19 tractor's qualifications, and we are talking in terms of what
20 experience they have had in their backgrounds in dealing with
21 the particular subject,

22 and, finally, the remaining 40 points will be for
23 the contractor's affiliations with outside agencies and
24 scientific bodies which can assist them in the conduct of this
25 study.

1 As I stated previously, we are going to have a
2 target date of December 20th. The Steering Committee will be
3 reviewing the study. We are asking for two progress reports
4 from the contractors and that they should complete the study
5 within six months from the date of the award of the contract.

6 I will be willing to answer any questions you might
7 have on either the education conference or the literature
8 research study.

9 CHAIRMAN HABER: Good morning, Mr. Cleland. We
10 would like to welcome you to the fourth meeting -- I believe
11 your second opportunity to meet with this group -- of the
12 VA Advisory Committee on Health-Related Effects of Herbicides.

13 Ladies and gentlemen, I would like to introduce to
14 you the Administrator of Veterans Affairs, Mr. Max Cleland.
15 Mr. Cleland has impressed upon all of us the seriousness and
16 the importance of this issue.

17 I think on his shoulders rests the great bulk of the
18 concern that veterans have about Agent Orange. He has stopped
19 at nothing to encourage all of us -- friends and employees of
20 the Veterans Administration -- to double and redouble our
21 efforts to get to the bottom of this vexing and perplexing
22 question.

23 Certainly the issues involved in herbicide toxicity
24 do not relate only to veterans, but certainly they are the most
25 important and the most crucial fulcrum of all of our concerns

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1 about this very important matter.

2 Mr. Cleland?

3 MR. CLELAND: Thank you very much, Paul.

4 Let me just say I wanted to particularly meet with
5 you today and ask you some of the questions that veterans have
6 been asking me -- particularly for the past 90 days.

7 The problem seems to be what the scientific community
8 really feels about Agent Orange now, and I wanted to get it
9 straight from the horse's mouth. I want to go around the
10 room with, really, two questions.

11 The first is your estimate of the linkage to cancer.
12 For instance, when I go around the country -- because of radio,
13 television and news reports, the various human interest
14 stories about veterans -- the question is posed almost as if
15 the answer was the foregoing conclusion. "You know, doesn't
16 Agent Orange cause cancer?"

17 What I would like to ask you, each individual at
18 the table, for a veteran who has been to Vietnam,

19 what would you tell him if he came in and said, "I
20 was in Vietnam," and he didn't give you any more specifics
21 than that.

22 He didn't tell you that he was an Air Force MP at
23 Natran, which had an airport nicer than most any in this country,
24 and it was a beautiful resort, but he didn't tell you that.

25 He just said, "I was in Vietnam." He didn't say, "I

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1 was out in the jungle with the Army or the Marine Corps or I
2 was in the Air Force." He just said, "I was in Vietnam. I
3 was one of the 2.4 million. What are my chances of coming
4 down with cancer due to this Agent Orange?" What would you
5 say?

6 Then, secondly, "Because I was a Vietnam veteran --
7 I was one of the 2.4 million there -- what are my chances in
8 terms of birth defects?" Is there anything that you would tell
9 him? What would your answer be?

10 So, based on your scientific understanding of the
11 problem, why don't we go around the table and start off
12 with Dr. Brick of the American Legion, and tell me how
13 you would answer a Vietnam veteran on those two counts.

14 CHAIRMAN HABER: May I just interrupt for a moment,
15 please? As you answer, would you please identify yourself and
16 your organization to Mr. Cleland so he knows from what per-
17 spective you are speaking.

18 DR. BRICK: I am Dr. Brick from the American Legion.
19 Max, I have answered that question many, many times.
20 I think our organization gets a good many letters. I related,
21 before you came in, one that I received just this morning from
22 a veteran, directed directly to me, telling me that the VA isn't
23 treating him very well because he is not getting compensation
24 for his problem that he alleges came from Agent Orange.

25 As a physician, as a Professor of Medicine for many

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1 years, I don't think there is any evidence scientifically that
2 you can really answer that in one word -- yes or no.

3 He said was he going to be exposed to cancer at a
4 greater risk than the veteran who was in World War II, let's
5 say, or the non-veteran. My answer to that would be that
6 there is no scientific evidence to indicate that he is at
7 greater risk to get cancer.

8 I am not a specialist on birth defects but from what
9 I have read about this problem -- and I think there are people
10 on this panel who are much more experienced in this particular
11 line -- from what I have read there is still no solid evidence
12 that birth defects occur from the types of exposure that our
13 veterans were exposed to in Vietnam to dioxin and Agent Orange.

14 So, unfortunately, from the emotional point of view
15 of some of these veterans and groups of veterans who indicate
16 that all their problems are related to Agent Orange, I don't
17 think I can give them an honest answer that encourages them.

18 MR. CLELAND: Well you may not be able to give them
19 an answer that is encouraging. You wouldn't say that your
20 answer wasn't honest, though, would you?

21 DR. BRICK: No, of course it is honest to the point
22 of what I know.

23 MR. CLELAND: Yes.

24 Ron, do you want to take a stab at this?

25 MR. DE YOUNG: Well, I have been doing it for about

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1 two years, Max, in pretty much the same way you have -- directly
2 from vets.

3 I have had that phone call. I spent a year sitting
4 in an 8 by 12 office in Chicago answering telephone calls
5 that had just that to say. Every day. From 20 to 50 of them
6 a day, once the news hit.

7 The best thing we have been able to say -- and the
8 thing that we have developed as a response to that question at
9 this point -- is this. There is no scientific evidence to
10 indicate that your chances of getting cancer are greater merely
11 because the scientific studies have not been completed. That
12 is not an answer; that is a delay.

13 The reason there is no scientific information is
14 because it hasn't moved fast enough. But we have got to look
15 at the laboratory studies which generically say the stuff is
16 troublesome. It is toxic, it causes cancer in rats, we don't
17 know for sure if it causes cancer in people -- merely because
18 the studies are not done.

19 I think the same holds true for birth defects.
20 The necessary corollary of that is let's get moving on the
21 studies. And that is now underway with the creation of this
22 committee and a few of the studies in recent months here.

23 But it is damn cold comfort, and we all know it.
24 What will be comforting are the statements that the answers are
25 in and in a particular study of people at Atlanta and the births

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1 and so forth, which was discussed this morning, and in these 5,000
2 malformations an ordinary percentage of these people were
3 Vietnam veterans, no greater than the average of Vietnam
4 veterans in the country.

5 Those are the answers we need because by our figures
6 right now things are inflated. But our figures are not
7 scientific and we know that; they are very anecdotal. We have
8 been getting all the veterans with problems.

9 We do not get calls from veterans who are healthy.
10 All right, and we realize the built-in bias that makes, but
11 there is still an add-in there. There is a very troublesome
12 and a very, very disturbing repetition to the skin rashes, the
13 numbness, the weakness, the psychological changes, and too
14 often, the birth defects and the cancer.

15 We have seen reports from guys who -- I talked to a
16 doctor at Vanderbilt University in Memphis -- excuse me,
17 Nashville -- who was the attending physician for a Vietnam
18 veteran who had died of a certain very rare form of cancer.

19 And he, on the phone to me, expressed the concern that
20 this was very unusual in a man of this age. It was an old
21 man's cancer, as he phrased it. He said he just shouldn't be
22 seeing this in a 28 year old man.

23 And it is statements like that that are off the
24 record and only a little bit scientific that give us this
25 concern. I am personally -- we don't feel you can answer those

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1 questions and stop there. The people that work with the task
2 force and that are working with veterans are trying to go on in
3 more intensive detail.

4 If the man has psychological problems, for example,
5 we will send him to your vet center. We have started to
6 deal with the question of the problems of the Vietnam veteran,
7 regardless of their causation, and I am very pleased to see
8 that you are doing that, too.

9 MR. CLELAND: Yes. Thank you very much.

10 CHAIRMAN HABER: We were just discussing this morning
11 a study that CDC is proposing to do on birth defects, which
12 they talked about at the White House Task Force meeting. It
13 is a very interesting study.

14 Maybe, Dave, you could express that to Mr. Cleland
15 in your answer, too.

16 DR. ERICKSON: Well, Mr. Cleland, I will just tell
17 you what we do at CDC in the Birth Defects Program where I work,
18 in terms of fielding these sorts of calls. I will bypass the
19 cancer issue because I have never fielded one of those.

20 But I have fielded quite a few inquiries, both from
21 veterans and from genetic counselors and private physicians,
22 regarding the risks for siring children with birth defects of
23 Vietnam veterans.

24 I guess our answer is very equivocal. We say
25 that there are no data to our mind which suggests that there

1 is an increased risk. On the other hand, there are no data
2 available at the moment that suggests there is not.

3 In terms of an extra risk engendered by exposure
4 to Agent Orange or some other factor during Vietnam service we
5 have no idea. We go on to tell people, though, that in terms
6 of birth defects, there is a background risk of somewhere
7 between 2 and 3 percent of a serious malformation.

8 MR. CLELAND: By background do you mean that it
9 occurs in the population as a norm?

10 DR. ERICKSON: Yes, that occurs in the population as
11 a norm. Now that risk isn't uniform across the population, we
12 feel, but we really can't separate a person ahead of time as
13 being at higher risk or lower risk.

14 We suspect that there are people who are at a higher
15 risk of having a child with a kind of defect and other people
16 who are at a lower risk. But a priori a woman who is
17 pregnant has a 3 percent chance of having a baby with a serious
18 problem.

19 And while we don't have any definite information on
20 Agent Orange, we would -- I guess our general feeling would be
21 that it would be unlikely to do anything like double that risk.
22 It might conceivably add a little to it.

23 So we would guess the background risk is likely to
24 be more important than any possible risk that might be
25 associated with Vietnam service.

1 We are also very careful to identify that as an
2 opinion, and not to be based on any substantive research.

3 MR. CLELAND: On the subject of the CDC and birth
4 defects, didn't the CDC announce recently that in their studies
5 of birth defects that a couple of chemicals seemed to stand out
6 as having the capability of enhancing the chance of birth
7 defects? One of those chemicals was alcohol and the other
8 one was cigarettes?

9 DR. ERICKSON: Well I think that press release
10 was based on an article we had in CDC's Morbidity and Mortality
11 Weekly Report about a year ago in which we described trends in
12 birth defect incidence in the United States over the past
13 decade.

14 What we saw at that time was that some defects
15 were going up a little bit and some were coming down. Most
16 were remaining stable.

17 The idea that this new chemical environment has
18 caused a massive increase in the incidence of birth defects
19 does not seem to follow.

20 On the other hand, in that article we pointed out
21 that there are a number of factors -- some of which, like
22 alcohol, have been around for generations, eons, which are
23 probably at the root of at least some of these problems.

24 MR. CLELAND: I just thought I would mention that
25 because it did hit the papers. Would you like to say anything

1 else before we go on?

2 CHAIRMAN HABER: They are proposing a study -- they
3 have gotten a group together of some 250,000 births dating back
4 to 1968 from which there are about 5,000 abnormalities, and
5 they are proposing a study to look at the veterans among that
6 group and correlate the veterans' exposure with abnormal
7 babies.

8 I think this is one of the most hopeful things
9 -- eventualities that we can see towards answering this thing,
10 in addition to our own epidemiologic study. It sounds like a
11 very good idea.

12 MR. CLELAND: I don't know much about the scientific
13 validity or protocol on that. Is that a scientifically valid
14 and acceptable methodology?

15 DR. ERICKSON: Well it is -- yes, yes, I would say.
16 It is a variant on the way we pursue things on a routine basis
17 in Atlanta and you will find people who don't like the
18 approach we use. But generally I would say it is accepted.

19 Certainly if the study does go forward it will be
20 commented upon, I expect, by a wide variety of people. Before
21 it starts we would hope we might get some concensus of
22 scientific opinion on the validity of the methodology.

23 MR. CLELAND: The reason I ask that is because in
24 dealing with Vietnam veterans in general, and with the Agent
25 Orange item in particular, we in the VA have got to do

1 preliminary things that are not full blown scientifically
2 valid studies. And we have to live, in effect, with those
3 preliminary conclusions because, in effect, the moment they
4 become announced it is taken in an emotional atmosphere as if
5 it were a full blown scientifically valid study.. "A VA study
6 reports today that..."

7 Particularly was this true on the fat biopsy study. We took
8 about 30 or so veterans -- and I am not even sure whether there
9 was any valid mix at all -- the number, I am told, was not
10 scientifically valid -- and we tried to do the dioxin examination
11 and found that dioxin could be discovered in the fatty tissue
12 in small levels of parts per trillion.

13 And yet, in effect, that became announced
14 as a definitive VA study that insinuated
15 Vietnam veterans have a higher risk of all the bad things that
16 stem from dioxin exposure than anybody else.

17 Now you ask somebody in the scientific community
18 about that and they say, "No, it didn't say that at all. It
19 just said that you could find dioxin in fatty tissue. That is
20 it."

21 But that gets lost in translation when it ends up
22 in terms of a news report. So we in the VA now -- and I have
23 talked to Dr. Custis about this -- we are very leery of half-
24 way studies.

25 We have concluded that we are going to do all out,

1 full blown, scientifically valid studies because, in effect,
2 you end up spending years explaining and qualifying a study
3 if it is not scientifically valid -- if you can't stand behind it all the
4 way and live with it. So that is the reason I asked the question.

5

6

7 DR. ERICKSON: I doubt that there has ever been a
8 perfect study done of anything. Maybe Dr. Moore might

9 comment on the feelings of the scientific group which reviewed
10 this proposal, because I have a certain set of biased opinions.

11 MR. CLELAND: Dr. Moore, do you have any comment?

12 CHAIRMAN HABER: Dr. Moore is the Chairman of the
13 Scientific Panel of the White House Task Force and the Deputy
14 to Ms. Bernstein who is the Chairman of that. He is also a
15 member of our Advisory Council.

16 We saw him first, Mr. Cleland.

17 MR. CLELAND: All right.

18 DR. MOORE: Well, the proposal Dr. Erickson had
19 outlined was discussed in some detail, in fact it was discussed
20 almost a better part of a full day by a group of appropriate
21 epidemiologists who were brought in to augment the scientific
22 panel.

23 They found merit in doing this study. We have to
24 presume that their judgment has some scientific validity as to
25 what it can do and can't do. But aside from that,

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1 when you are dealing with an emotional issue -- and certainly Agent
2 Orange in Vietnam is an emotional issue -- I think that up front, whether
3 it is that study or anybody else's study, you have to flat state that
4 this is what you hope to learn from that study, and you also have to state
5 what that study won't tell you. I think that is where we get into trouble
6 sometimes. Some people get frustrated with the results of a given study
7 because it doesn't answer the question they wanted answered -- but it
8 wasn't designed to answer the question they wanted answered; it was
9 designed for something else.

10 The design of Dr. Erickson's proposed study is rather simple --
11 Is there an increased incidence of malformations as a consequence of
12 having service in Vietnam? It will not answer a question with respect
13 to Agent Orange exposure, so if the question you want answered is Agent
14 Orange, that study isn't going to do it.

15 MR. CLELAND: My problem is that you can say that, and he can
16 say that, but then when the study is done, they come and talk to me and
17 ask me, "Does that mean Agent Orange is....one way or another?" Suppose
18 the study came out positive. Their assumption automatically is Agent
19 Orange. It might have been the malaria tablets we took, instead of
20 Agent Orange, or a host of other things.

21 Now I understand the point. Unfortunately, I don't have ten
22 minutes on the evening news every night to communicate that to about
23 40 million households out there. From my point of view, I hope that
24 all of you are sticklers for those kinds of things throughout this
25 discussion, because whatever study you come up with, I am stuck with it.

1 In effect, the rest of us are stuck with it. We all want to know if this
2 is a good scientific thing. Is this something we should seriously believe,
3 or is this just something that was designed for something else? That is
4 why I caution you against half-way or limited-value studies. Whatever
5 comes up in those studies is automatically taken and expanded upon by
6 everyone concerned on all sides.

7 The one thing I have been saying is that we in the VA are going
8 to follow the facts, wherever the facts lead us. Unfortunately, we don't
9 have any facts to even discuss or argue over at this point in regard to
10 the actual experience in Vietnam. As Ron pointed out, that is cold
11 comfort. I like that phrase. It is about the way it comes across, and
12 I would get killed for offering only cold comfort, but that is where I am.
13 I am existing wherever the level of scientific inquiry is studied. That
14 level, in effect, is controlled by the scientists, not by Administrators.
15 We have to live with whatever that level of scientific inquiry really is.
16 That is why I made the point about was this something that had some
17 scientific validity -- did it fulfill some base requirement of the
18 scientific approach?

19 Yes, Ron?

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MR. DE YOUNG: It might help to add another element to it and the scientists will have to decide whether or not this is scientific. But as an additional resource to Atlanta's population, the Air Force has a program called CHAP, C-H-A-P, Children Have a Potential.

And it is an education and rehab and training program for disabled and learning disabilities children of Air Force personnel. And if these people could be included in the study we may have an idea as to -- we would have three different groups of people.

Those who were veterans but without Vietnam service but service on Air Force bases. Those Air Force veterans with

1 Vietnam service could be easily identified out of that group.
2 And then we would have the Atlanta civilian population as well
3 that those gentlemen brought forward. And it would be a much
4 smaller group, I am sure.

5 But maybe to the vets it would look like a more well
6 targeted study in addition to the 5,000 civilians in Atlanta
7 that we are talking about, because it is dealing directly with
8 the veteran population. Possibly that would be of help.

9 MR. CLELAND: Well I don't know. I am sure they
10 heard your remarks, Ron. I just wanted to make a point that it
11 is awfully tough to live with half-studies, partial answers,
12 and so forth, because I and the rest of us in this inquiry

13 have to try to understand them first of all, and then try
14 to explain them to the public, which is quite emotionally
15 involved.

16 Yes?

17 DR. HONCHAR: Yes --

18 MR. CLELAND: Pardon?

19 CHAIRMAN HABER: Dr. Honchar.

20 DR. HONCHAR: I am Dr. Honchar from the National
21 Institute for Occupational Safety and Health.

22 I would like to -- with regard to the two questions
23 as you pose them -- continue with a theme that was raised
24 earlier, which is the importance of separating the issue of
25 the effects of the components of Agent Orange and the problems

1 that the veterans are experiencing at this time.

2 Let me just briefly address the first part of this.
3 What is known about the health effects of Agent Orange com-
4 ponents? With regard to carcinogenicity, we have evidence
5 about carcinogenicity from animal studies and some very pro-
6 vocative papers that are currently under review from a number of
7 different quarters; papers from Europe indicating a carcino-
8 genic risk from phenoxy herbicides to humans through epidemi-
9 ologic studies.

10 With regard to birth defect risks, animal data has
11 indicated that materials that were present in Agent Orange do
12 have a teratogenic potential..

13 The big leap that must be made from this data to
14 the veterans goes over a stream which is a bit muddy at this
15 time with regard to specific exposure information for the
16 veterans.

17 I believe that it is asking a lot to expect the
18 veterans to be patient and wait until all of the data is
19 collected about Agent Orange and the leap is made. Perhaps
20 the solution to this that I would like to suggest is one which
21 is basically -- or I should say hopefully -- being approached
22 by the VA at this time, and that is,

23 to make a characterization of the
24 veterans from Vietnam. Do they have problems at this time, as
25 they are complaining? This can be done only by looking at

1 a large representative sample and characterizing the problems
2 as they have been described.

3 After that is done then, basically, the problem --

4 MR. CLELAND: Could I respond to that?

5 DR. HONCHAR: Sure.

6 MR. CLELAND: I think that there has been general
7 acknowledgement and some of our studies have indicated that a
8 certain number varying between 20 and 40 percent -- depending
9 on whose phase you want -- do have certain problems --
10 psychological problems, readjustment problems, emotional
11 problems, family problems.

12 There are a lot of problems -- nervousness, sleepless
13 nights -- but we have, in effect, dealt with this through the
14 understanding -- the better understanding of the post-traumatic
15 disorder -- exposure to life-threatening situations.

16 We now pay compensation based on these kind of
17 things, and we now have a readjustment counseling problem. So
18 it is not so much "Do Vietnam veterans have problems?" -- "Do a
19 certain group exhibit a certain symptomatology in regard to
20 service in Vietnam?"

21 My question really is -- and that is the reason I
22 singled out two medical questions -- not "Do Vietnam veterans
23 complain about nervousness, sleepless nights and other things
24 that could easily derive from psychological problems?" -- but
25 medical problems.

1 I am trying to reach -- to question -- direct impact
2 on the more sensational medical question. For instance,
3 chloracne is generally accepted. We are not talking about a
4 skin rash here, we are talking about some of the more
5 emotionally volatile medical problems that have been alleged
6 to be incurred from Agent Orange.

7 I specifically mentioned cancer and birth defects,
8 and that is why I am trying to pinpoint what the state of the
9 art is in the scientific community on cancer and birth defects.

10 You mentioned animal studies indicating that dioxin
11 was carcinogenic. I would be interested, if that is the
12 general conclusion of the group. I know it is bandied about
13 and written about in the articles, but that is one of the
14 reasons I asked the question.

15 So you feel that -- in your mind that is clearly
16 established?

17 DR. HONCHAR: Yes, but I guess the question, as you
18 phrase it, can be answered in a number of different ways. The
19 question can be viewed as, "Do Vietnam veterans with exposure to
20 dioxin have a higher risk than normal of contracting cancer or
21 siring malformed children?"

22 Or the question can be asked, "Do people who have
23 spent time in Vietnam during the war -- do they have a higher
24 risk of contracting cancer or siring malformed children?" Do
25 you understand what I am saying?

1 The two questions have entirely different answers.
2 One assumes known information about exposure. It would assume
3 information about exposure, but actually even can't be answered
4 unless there are specific -- very specific -- data about
5 exposure available.

6 The second question, I think, is one that should be
7 addressed, and it can be addressed through studies of the
8 veteran population. Once it has been established that there is
9 a greater cancer risk through studies of the populations or, in
10 fact, as CDC is attempting to do at this time, that service in
11 Vietnam proves to be a risk factor for siring children with
12 birth defects.

13 Then, basically, I think there would be more ground
14 upon which to begin to address the complaints of the veterans.
15 The issue of Agent Orange is another one altogether and, in
16 fact, it may be the problem here.

17 But waiting for the definitive final scientific
18 study to come from Agent Orange is perhaps not the most timely
19 and compassionate position to take at this time with regard to
20 the veterans.

21 MR. CLELAND: Well, we are moving on the epidemiological
22 approach. Is that consistent with some of your thinking?

23 DR. HONCHAR: Well, again, at this time I and others
24 are really not sure what approach that study will take. I
25 think there is a great potential there for, again as I said

1 earlier, characterization of the population.

2 MR. CLELAND: Anything more today on birth defects?

3 DR. HONCHAR: Not specifically, other than to give my
4 scientific support for the study that Dr. Erickson has proposed,
5 again with the understanding that it is not a study that would
6 tie birth defects with Agent Orange specifically, but with
7 service in Vietnam.

8 MR. CLELAND: Thank you. Yes, sir?

9 DR. PLIMMER: I am Jerry Plimmer from the Department
10 of Agriculture.

11 It is rather difficult for me to make comments on
12 whether essentially studies -- epidemiological studies -- I am
13 a chemist and my experience is purely in handling chemicals.

14 I got into this area over 25 years ago when we
15 started working on carcinogens -- identifying carcinogens in
16 tobacco smoke and mineral oils. There we were seeing those
17 positive correlations that we could say there were populations
18 at risk and there was good evidence of lesions in specific
19 areas.

20 As chemists our job was to identify what was
21 responsible. Later on when we came along to the dioxin problem,
22 we worked for several years in the lab analyzing dioxins,
23 identifying them, studying their effect on the environment.

24 I think, in looking at this from a scientific
25 point of view over the last ten years, we have identified more

1 and more of these stimulæ which produce cancers much
2 more diffused throughout the environment.

3 One way I became concerned about these things --
4 I go home and talk to my brother-in-law who works for the
5 nuclear energy industry, and he becomes concerned about similar
6 problems that come along to him.

7 We are working in agriculture where a lot of people
8 are at risk, and I think we have all had these concerns about
9 the chemical stimulæ to which we are exposed.

10 The Vietnam veteran may have had a particular ex-
11 posure combined, also, with a traumatic experience. It is very
12 difficult to relate these now to his position and how he stands
13 in the both medically -- and also there is this concern with
14 his situation.

15 I feel that we are getting a lot of pressure from the
16 press -- television particularly -- to look at situations that
17 are occurring around us. I think many of them we need to take
18 care of,

19 but I don't know how these affect particular individu-
20 als or groups of individuals. It is rather difficult to
21 answer someone who comes up and says, "This problem is
22 related to such-and-such a factor in my past."

23 In that case I am like the rest of us. I have got to
24 go to the epidemiologist and say, "We found these chemicals
25 and this man has been exposed to such-and-such a stimulus. How

1 does he compare with a peer group or how does he compare with
2 a group of individuals who have been similarly exposed or
3 ones who haven't been exposed? How can we look at interacting
4 stimulae?"

5 I think this is one of the most difficult
6 problems we face. Now I hope that these studies planned here
7 will address these issues. I haven't been to meetings of the
8 committee before, so I am not up-to-date on the status of the
9 studies,

10 but I know that it takes much more than just the
11 identification of the chemicals to predict the effects.

12 MR. CLELAND: Is there anything you would like to
13 add to that in terms of birth defects?

14 DR. PLIMMER: No. But I know that, for example, we
15 were talking about the PCB problem -- this came up -- poly-
16 chlorinated biphenyls --

17 MR. CLELAND: Of which dioxin is one or not?

18 DR. PLIMMER: No.

19 MR. CLELAND: It is another group.

20 DR. PLIMMER: Polychlorinated biphenyls are not a
21 group of pollutants. We discussed a little bit earlier
22 the occurrence of the chloracne in the Japanese victims of
23 Yusho oil poisoning.

24 I think the Swiss had looked at the livers of
25 victims of Yusho oil poisoning and found in those

1 polychlorodibenzofurans several years after the event.

2 So this is what I mean by groups of associated
3 stimulae. The polychlorodibenzofurans are closely
4 related to TCD and the dioxins. So we have a stimulae which
5 has spread throughout the world which is going to show effects
6 like chloracne and their chemical distribution is pretty
7 widespread.

8 There is evidence in seals, for example, in the
9 Baltic and in the United States, that polychlorodibenzofurans
10 are present in fatty tissue.

11 So this kind of evidence of almost global pollution
12 by related compounds is being brought to light continuously.
13 And, again, I would say this is what I implied by mixed
14 stimulae.

15 MR. CLELAND: Again, you draw no particular conclusion
16 on the question of birth defects.

17 DR. PLIMMER: No.

18 MR. CLELAND: All right. Yes?

19 DR. SHEPARD: I am Dr. Barclay Shepard and have just
20 been designated as the Chief Medical Director's Special
21 Assistant on Herbicide Orange matters.

22 I would answer your question by prefacing my remarks
23 by saying that I, too, am a Vietnam veteran and for 10 years
24 following my tour in Vietnam took care of -- either personally
25 took care of or was related closely with phsycians taking care

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1 of those active duty members of the Navy and Marine Corps who
2 served in Vietnam.

3 I think to answer the question we have to take two
4 approaches. We have a scientific approach which is extremely
5 important, but as it has already been indicated it is one which
6 will take time, a lot of detailed work, and will not produce
7 the answers that the average veteran wants to hear in the time
8 frame in which he wants to hear them.

9 That doesn't say that those are not important questions;
10 they are extremely important and probably will form the basis
11 of the ultimate answer.

12 I think we have another approach to take and that is
13 that we have, in fact, a large human laboratory of those
14 people who were exposed in Vietnam. The degree of that ex-
15 posure is very unknown

16 if you should ask a veteran, I would dare say, even
17 a veteran who was in a combat troop, whether he accurately
18 knows the extent to which he was exposed. Nevertheless, we
19 have these large numbers of individuals who were exposed to
20 some degree -- or may have been exposed to some degree.

21 We are working actively on that large human labora-
22 tory to determine -- and hopefully in a more expeditious
23 fashion, albeit probably a less scientific fashion -- what
24 or if there is an increased incidence among those individuals
25 of malignancies and birth defects.

1 As I said, we are collecting these numbers. We
2 currently have approximately 10,000 in our registry. We are
3 analyzing those data and, hopefully, within the next few
4 months we will come up with some preliminary information, at
5 least, as to whether there is, in fact, an increased incidence
6 among these individuals.

7 We are also revising our questionnaire to perhaps
8 streamline the process so that we can gather this data more
9 rapidly -- process it more rapidly -- and come up with, perhaps,
10 more answers more rapidly.

11 To go back to the original question, we don't know
12 the answers to the questions. We don't think that there is a
13 higher incidence of either cancer or birth defects among these
14 veterans. If there had been, I think we would have known about
15 it by now.

16 MR. CLELAND: Higher than normal?

17 DR. SHEPARD: Yes, sir.

18 MR. CLELAND: That is what you meant?

19 DR. SHEPARD: That is what I meant. I am sorry.

20 MR. CLELAND: That we would have known by now in the
21 sense that for 15 years we have been treating Vietnam veterans
22 in our hospitals and we have patient treatment files, we have
23 a cancer registry -- these kind of things -- and if there had
24 been any particular symptomatology, probably under normal
25 circumstances it would come to somebody's attention?

1 DR. SHEPARD: Yes, sir. As I say, it isn't a very
2 scientific answer, but I think it is a reasonable answer for the
3 time being. We are nailing down that question as rapidly
4 as we can organize our registry and extract the data from it.

5 MR. CLELAND: Isn't it true that we will treat the
6 symptom if an individual comes in and the individual alleges
7 Agent Orange caused their problem? Whether it is a skin rash,
8 or cancer, or whatever, we deal with the symptom right away -- I mean,
9 we deal with the disease or disability right away.

10

11 DR. SHEPARD: That is correct.

12 MR. CLELAND: That is correct?

13 DR. SHEPARD: Yes, sir.

14 MR. CLELAND: Paul, do you want to say anything?

15 CHAIRMAN HABER: Well, just to re-echo what Dr. Shepard
16 said, Mr. Cleland. I think the answer is the
17 answer you gave the House and Senate -- the jury is still out.

18 I think we have to be compassionate. We have to
19 treat veterans who come to us with various symptoms and
20 evidence of disease and we have been doing that.

21 We have had some 10,000 folks come to us
22 either alleging disabilities, coming for hospitalization, or just
23 wanting reassurance, which is also important.

24 I think the studies we talked about ---- epidemio-
25 logic studies, the research study of literature, the studies

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1 the White House Task Force contemplates, the study I hope
2 the CDC will undertake, a study that the National Forest
3 Products Association is also undertaking --

4 MR. CLELAND: What is that? I am unfamiliar with
5 that.

6 CHAIRMAN HABER: They talked to us and are soliciting
7 our support for a study to be done in Oregon about forest
8 workers who will be exposed to herbicides very like Agent
9 Orange -- a prospective study to determine whether or not there are
10 disabilities and an increased number of birth defects and/or
11 abortions.

12 I think it would be good to have that study done
13 as well. I think the important thing is that we have to be
14 ever alert to the possibility that there may be something there
15 and we have to look at it.

16 We have to continue to enlighten our own people as
17 to the possibilities and we are doing that, and educating them
18 in the possible disabilities. I think this is a vexing time
19 for the whole country.

20 I think that the Veterans Administration has the bulk
21 of this problem on its shoulders and, in a sense, on your
22 shoulders, Mr. Cleland. I keep saying that because I think that
23 a great many of the problems associated with the Vietnam War
24 have come to focus on this issue and we have to deal with that.

25 I think it is a trying time for all of us. We

1 have to be forthright. We have to convince veterans that we
2 have no stake in stonewalling, and that the Veterans Administration
3 wants to see that veterans get redress for their problems as
4 promptly and as equitably as possible. I am sure that the
5 Congress supports this.

6 I think that the readjustment counseling program you
7 talked about takes care of a lot of the psychological problems
8 that veterans have, and so we are responding to the needs of
9 Vietnam veterans.

10 MR. CLELAND: All right. Thank you, Paul.

11 Dr. Schepers?

12 DR. SCHEPERS: Mr. Cleland, your question is, does
13 Agent Orange contain a carcinogen and can it cause birth
14 defects? In animals, yes, dioxin can cause cancer of various
15 kinds and it can cause birth defects. In human beings, we
16 don't know.

17 MR. CLELAND: Actually, my question was in regard to
18 the Vietnam veteran.

19 DR. SCHEPERS: I am coming to that. When we know
20 that a chemical can cause cancer, we must naturally consider
21 that it can cause cancer in man also. When so many experiments
22 point to TCDD being carcinogenic in such small doses, it makes
23 it an unusual carcinogen.

24 It therefore becomes a lot more dangerous proposition.
25 There are innumerable things in nature that are carcinogenic.

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1 Some occur naturally and some are made by man. They
2 are all around us. But when they are not unusually carcinogenic
3 we just take it as one of the many things that the veterans may
4 encounter.

5 Here we have a situation where veterans have a unique
6 experience in that a group of them was selectively exposed to
7 TCDD in a way that the rest of the population was not.

8 This makes them a special group that needs to be
9 studied and the epidemiological study will undoubtedly help
10 solve that.

11 MR. CLELAND: When you say that the rest of the
12 population was not, does that mean that the spraying of farm
13 lands and so forth --

14 DR. SCHEPERS: That is slightly different, yes.
15 There are other groups that have been exposed in other ways.
16 The Vietnam veterans were exposed in a special way.

17 We don't know as of now whether the one time that a
18 plane flew over a platoon of soldiers is an effective exposure.
19 That needs to be proven. That is a special way. There are
20 farm workers who use the materials day by day and they have
21 different forms of exposure.

22 The possibility that these same Vietnam veterans
23 have come back to America from Vietnam and then being re-
24 exposed in their jobs or in their environment, that also needs
25 to be explored. We don't know the answers for that.

1 But we do know that some were exposed to an unusual
2 chemical in some manner and therefore we cannot dismiss it.
3 Then what do you say about the veteran who gets cancer? To
4 attribute cancer to one single carcinogen, when you have a
5 human being before you with a cancer, is the most difficult
6 thing possible to ask a doctor to do.

7 Almost all doctors will back away from giving an
8 answer. A single exceptional situation is, for instance, the
9 asbestos workers, where you can find the asbestos in his lung
10 and you can find the cancer in his lung and you will still find
11 that 50 out of 100 doctors or maybe 70 out of 100 doctors will
12 back away from saying, "I will blame that asbestos for the
13 cancer," because he will say, "I also notice the man smokes
14 and I also noticed he lives in a smokey city with a lot of smog
15 in it, so I am not going to say."

16 So it is much more difficult to say it with regard to
17 the Vietnam veteran and dioxin. However, we are doing research
18 here in the Veterans Administration's Central Office on whether
19 there are unusual numbers of cancers in our Vietnam era
20 veterans. We are pursuing that research. It is not finished.

21 If we find unusual numbers of any particular organ
22 or unusual types of cancer which have not been seen before,
23 like in the case of the asbestos story again -- a mesothelioma,
24 which is a special type of tumor -- we will have a clue.

25 I am currently busy with that, as I told you

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1 before. The four organs -- the four target organs -- that
2 we are particularly concerned^{with} are the human testicle, the human
3 liver, the human brain, and the human thyroid. We are ex-
4 ploring those more specially, and with the help of the medical
5 administration people we have been pulling in the files pro-
6 gressively of those Vietnam era veterans whom we know developed
7 cancers of that kind to see if there is anything unusual about
8 those people.

9 We cannot say today that we have an answer. My
10 estimate is that it will take probably another two years to
11 bring us closer to being able to say anything positive.

12 We cannot say no, either. We are not in a position
13 to say no. In my advices to Mr. Peckarsky on cases, we have
14 always said to him, "We cannot say yes and we cannot say no,
15 either -- we can say maybe because we have to look to the future
16 for answers."

17 Now on the question of birth defects. Of course the
18 animal experimentation can show that if you expose a female
19 animal to the chemical, birth defects occur. Many chemicals do
20 that. Dioxin is not --

21 MR. CLELAND: The female animal?

22 DR. SCHEPERS: The female animal. Our soldiers were
23 mostly men. There were some women in the field also. We do
24 not know whether an effect on the male testicle
25 can be transmitted through to the female. We do not have that

1 answer yet. There is some animal experimentation now in pro-
2 gress to test that, but it is a very difficult thing to do.

3 You have to do long-term breeding tests with animals
4 through two or three generations to see if you get that effect.
5 Again, we cannot say no, but we cannot say yes either. So we
6 have to wait and see. That is why we need this committee
7 and we need all this research.

8 MR. CLELAND: Well said. On the subject of breeding
9 and birth defects, the Air Force testified that down at Eglin
10 Air Force Base they had an area that had been sprayed. I
11 think I am saying this correctly, / ^{referring to} the testimony of Major Alvin
12 Young before the House Veterans Affairs Committee a couple of
13 months ago.

14 The area at Eglin Air Force Base had received more
15 than 200 times the amount of Agent Orange spraying that any
16 other area in Vietnam would have received because this was the
17 testing area.

18 They had 70 generations of rats there on the land
19 that they observed with no malformations other than the norm,
20 and this was with small traces of dioxin in the tissue of the
21 rats.

22 So this continues to be quite a difficult area for us
23 to evaluate because what evidence there is seems to not be
24 conclusive one way or the other.

25 I appreciate your analysis.

1 Doctor?

2 DR. LINGEMAN: Dr. Schepers covered it very nicely
3 and I think I relate to that. I am constantly, on a daily
4 basis --

5 MR. CLELAND: For the audience, could you tell us
6 who you are and who you represent?

7 DR. LINGEMAN: I am Dr. Lingeman with the National
8 Cancer Institute. I deal almost daily with causes of cancers
9 in individuals in whom we are asked whether a given chemical
10 or radiation caused a particular cancer.

11 It is extremely difficult to deal with this on an
12 individual case. It is difficult and frequently impossible to
13 establish a cause-effect relationship except in instances of
14 unusual neoplasms such as the vinyl chloride-associated angio-
15 sarcomas which were first noted a few years ago.

16 As I said, we are constantly facing the problem that
17 we are emersed in this huge sea of environmental carcinogens.
18 And we are still in the midst of the biggest cancer epidemic
19 in medical history -- lung cancer attributable to cigarette
20 smoking. We haven't seen the top of the mortality curve yet
21 in the cigarette-lung cancer epidemic. Despite the statistics,
22 we can't scare young kids enough to make them stop smoking.

23 We also lived through the saccharin episode several
24 years ago. When it was reported that saccharin caused bladder
25 cancer in rats, the FDA was concerned because of the law which

1 states that no carcinogen in any amount can be present in
2 food. This is the so-called clause.

3 Hysteria went up among thousands of diabetics who had
4 used large amounts of saccharin over a long period of time.
5 The Cancer Institute, in cooperation with FDA, began an epidemio-
6 logic study about two or three years ago, and within a year or
7 two they had an answer. There was no evidence that saccharin
8 consumed by humans in ordinary amounts had any effect on the
9 cancer rate.

10 So in answer to the question as to wheter an epidemio-
11 logic study can provide a definite answer about a cause-effect
12 relationship of a cancer to a definite chemical compound, it
13 can in some situations. With saccharin we were fortunate because
14 it had been used for about 50 years and we had a large, readily
15 identifiable population to study.

16 This allayed a lot of fears in a lot of people. Now
17 saccharin still could have effects that haven't shown up yet.
18 We all have to learn to live with this possibility. I still
19 drink Tab, recognizing that I am taking a risk. Do I want to
20 be obese, or have heart trouble, or get diabetes? I don't know.

21 We all must face the facts that many desirable things
22 are hazardous. So I would say, Mr. Cleland, to this veteran,
23 "Be patient. We don't know the answers yet. If we do prove
24 that you developed a dioxin-related disease in Vietnam, we
25 will do something about it. We have to face this uncertainty
and we all have to live with it."

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1 As far as birth defects, which is a very frightening
2 thing also, as Dr. Erickson said, at least three percent of
3 newborn infants are going to have congenital defects. Whether
4 there will be an increase in such defects in offspring of
5 veterans exposed to TCDD may be difficult to determine. We may
6 end up only with a marginal situation at best.

7 I can recall the German measles epidemic in 1964-1965,
8 in which a large number of children whose mothers developed
9 German Measles during certain stages of their pregnancies
10 developed a rather specific syndrome. Prior to that it had
11 been known that German Measles caused blindness, and a certain
12 kind of cardiac defect. These defects fit into a definite
13 syndrome. And when this happened again in 1964 -- for some
14 reason the virus reappeared -- it seemed to be more virulent.
15 It seemed to cause a wider spectrum of birth defects.

16 Great numbers of these children were deformed during
17 a two-year period. The cause was very obvious. We merely
18 asked the mothers of these infants, "Did you have German
19 Measles?" Some of them had non-clinical disease without a rash,
20 but most knew whether they had the disease or were exposed to it.
21 And antibodies to the virus could be measured. The problem
22 was resolved rapidly. It was proven by virus isolation that
23 the rubella virus caused birth defects. But this is not the case
24 in the majority of instances. Now we have a vaccine.

25 For the majority of children who are born with cardiac

1 and other defects the cause is never known.

2 One other thing I would like to mention is cleft
3 palate, which is the most frequent defect that was seen in
4 mice which were fed 2,4,5-T contaminated with dioxin.

5 Cleft palate also occurs in offspring of mothers who
6 receive drugs for epilepsy. Epilepsy is a bad condition and
7 it is likely that it is worth the small risk.

8 So, again, you weigh the benefit and the risk. I
9 think that perhaps I might ask a veteran, "Is it possible that
10 Agent Orange saved some lives?" The point I am making is that
11 there are many hazards in the environment in addition to
12 Agent Orange and it is not exactly clear why this particular
13 one has been singled out for such great attention.

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1 MR. CLELAND: All right. Thank you very much.

2 Dr. Moore?

3 DR. MOORE: Well, at the risk of being a bit glib,
4 after hearing all of the rhetoric, I don't think I can add
5 anything to my answer to the veteran who asks, "I was in
6 Vietnam. Am I at an increased risk of cancer?"

7 My answer is, "I don't know."

8 MR. CLELAND: Birth defects?

9 DR. MOORE: Same answer. I don't know.

10 MR. CLELAND: Thank you very much.

11 Dr. Murphy?

12 DR. MURPHY: I am from the University of Texas but I
13 am speaking just as a toxicologist in this discussion. Back
14 to your original question, my answer would be close to what
15 Dr. Moore said.

16 But I think that if addressed by one of the 2.4
17 million veterans, "Is my chance greater?" I would probably
18 say, "Probably no greater -- just with that information -- no
19 greater than mine, and I am not a veteran."

20 But if he then went on to say, "I was in the spraying
21 area and I spent six weeks in clothes that had been saturated
22 with this material," then I think I would probably be inclined
23 to say on the basis of that -- on the basis of current knowledge
24 that, "Yes, I think you probably would have some increased
25 incidence of the possibility of cancer."

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1 But perhaps no more than a lot of others. This
2 increase would be no more than that increase contributed by a
3 great variety of things we do and probably some of the things
4 that this veteran does as well, because there are -- as has
5 been pointed out -- many sources of cancers.

6 With regard to the birth defects, again, if it is the
7 2.4 million -- and that is all the information -- I think I
8 would say, "No more than the rest of us."

9 If the more specific case were cited, I think I would
10 be inclined to say, "I don't know. There is a lot of work that
11 hasn't been done to understand the possibility. What we know
12 now would suggest there is very little likelihood because even
13 though we know these materials can be teratogenic in animals,
14 as always that information is based upon studies in pregnant
15 females."

16 I guess, in summary, where we stand -- in listen-
17 ing to the discussion, the things that I feel reminds me of two
18 cliches. One is that you can't prove the negative and,
19 secondly, that all knowledge is historical. There is a
20 lot of work to be done;

21 but if you have to answer a question today you base
22 your answer on the knowledge you have, which is history.

23 MR. CLELAND: Thank you very much.

24 DR. MURPHY: Thank you.

25 MR. CLELAND: There was of course, a specific

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1 group that did breathe it, fly through it, smell it, get it on
2 their clothes, and so forth, and dispense it, and those were
3 the Ranch Hands.

4 That is a pretty definable group of about 1200 Air
5 Force pilots and crew members.

6 DR. MURPHY: On that one -- this has come up in dis-
7 cussions of this committee before, as to whether they, however,
8 really were the most likely to have had the highest and most
9 sustained exposure. So I really wouldn't know whether that is
10 the highest exposure or not.

11 MR. CLELAND: Sure.

12 Colonel Thiessen?

13 COLONEL THIESSEN: Yes. Thiessen is my name and I
14 represent the Department of Defense. Notwithstanding my uniform,
15 I am a physician.

16 I must say that your hypothetical veteran -- he is
17 probably not that hypothetical either. Asking those questions
18 is very much like any patient that wants to know why he has
19 what he has, or is there a chance that he gets what he is
20 afraid of.

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1 The question is not so much an objective
2 scientific answer to a question, because that is really not
3 what he is asking. He is not asking a scientific question as
4 to the relationship between herbicide orange and cancer or
5 birth defects.

6 He is asking, "Whatever I have now can I ascribe that
7 to something else that is not subject to my interference that
8 happened notwithstanding me?"

9 After everything he has gone through in Vietnam,
10 "Why me, again?" Even if he doesn't have anything at all, it
11 is just a fear of getting it. What kind of an answer do you
12 give to a man with respect to cancer and birth defects that are
13 both so extremely common?

14 One out of every four in this room will develop a
15 cancer. One out of every six of us will die. We are all
16 white, middle class with a good income -- maybe a little less,
17 but, basically, that is all it amounts to.

18 It is easy to be objective about it if you don't have
19 it. I can tell you that. I am sure as soon as I have cancer
20 I will not be objective about it anymore. And I think it is
21 the nature of the animal.

22 But the problem with herbicide orange, as I see it,
23 is that it is not one issue -- it is two. There is a
24 scientific issue and there is an emotional concern among
25 Vietnam veterans. Those are two different issues.

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1 You don't solve one issue with the other. If your
2 best epidemiologic study indicates, for example, that yes,
3 there is some difference in mortality experience and
4 morbidity experience between Vietnam veterans and other
5 people, what are you going to tell your hypothetical Vietnam
6 veteran?

7 That he has a probability of one in 25,000 that he
8 happens to be one of those Vietnam veterans who will develop
9 this or has developed this? What good does it do him?

10 Do you see what I mean? The question, in my mind, is
11 not so much whether or not there is a scientific relationship.
12 That is an important question that has to be answered and it
13 will be answered eventually.

14 But the more important question is how does that
15 help the Vietnam veteran who has a personal concern? How do
16 you address that personal concern?

17 It is my feeling that it is not scientific
18 and has to do with presenting an attitude of helpfulness --
19 of wanting to help the Vietnam veteran in solving that problem.
20 That is not necessarily by telling him, "Well we are doing an
21 investigation and five years from now we will have an answer"
22 -- because you will never have an answer. I can tell you that--
23 --you will never have an answer.

24 MR. CLELAND: How would you handle that second
25 problem?

1 COLONEL THIESSEN: I would handle it this way. I
2 simply have to tell him that -- there is a difference here --
3 does he have it or does he not? If he doesn't have it, my
4 answer would be, "Don't worry. Simply stop worrying. You will
5 make it worse by day in and day out worrying about what may
6 happen to you. It may never occur and chances are it will
7 never occur."

8 Even if herbicide orange is carcinogenic, chances still
9 are that whatever cancer he gets more than likely is caused by
10 some other factor that we don't know either. All right?

11 If he has cancer or if one of his children has a
12 birth defect, again, my feeling would be that the best answer
13 probably is that -- but that is a probabilistic answer and I
14 know that wouldn't appeal to any patient -- it wouldn't appeal
15 to me, probably, if I have it either -- that chances are that
16 his cancer, the birth defect that we are talking about, has not
17 been caused by anything related to Vietnam.

18 That is my opinion. That is a value judgment -- it
19 may be wrong, but I think it is pretty accurate.

20 MR. CLELAND: Mr. Thompson?

21 MR. THOMPSON: Max, I represent the Disabled American
22 Veterans. First I would like to say I am certainly deeply
23 interested in this subject matter. I have spent approximately
24 18 months in a Marine line company in the northern part of
25 South Vietnam.

1 I think it is the kind of questions that most Vietnam
2 veterans ask. Not only them, but their wives as well. In the
3 last year I have handled hundreds of calls to our national
4 headquarters.

5 And the first thing I try to do is realize that it is
6 certainly a sensitive area and, as Ron alluded to a little
7 earlier, I think that we have to be concerned with the way we
8 handle this, the way we counsel with them, and the way we talk
9 with them.

10 It is an extremely sensitive matter and an important
11 matter to them. The first thing I try to tell them is just
12 exactly what everybody else said here at the table -- more or
13 less the jury is still out.

14 The scientific community is still investigating
15 medical data is being correlated. I try to take it a step
16 further. I try to be as informative as possible.

17 I remember I attended a conference last year -- I
18 believe you attended and Ron was in attendance -- at Crystal
19 City, and I remember Ron getting up and talking about we have
20 scared people out there. And this is true.

21 However, I think that we can calm some of those fears
22 by being informative. Let those people know what the scientific
23 community is doing. Let them know what the VA is doing. Let
24 them know what the current regulations -- regulatory criteria,
25 DVB and DM&S, et cetera, are and what they can do -- whether

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1 they can go to the out-
2 patient clinic, the VA medical center, what have you. I think
3 that is a key to counseling with these people. Naturally it is
4 not entirely what they want to hear, as we have all discussed,
5 but at least you are being informative.

6 I also try to take it one step further. I had an
7 opportunity in being with the DAV to work with the Board of
8 Veterans Appeals for approximately six years doing administra-
9 tive review cases and the appeals cases .

10
11 Especially on cancer cases I am concerned with the
12 young Vietnam veteran in making sure that he files that claim --
13 maybe not only for exposure to Agent Orange, but also getting in
14 and having the studies done to see if that cancer did, in fact,
15 have its onset while he was in the service, and going through
16 the Armed Forces Institute of Pathology for opinions, et cetera.

17 I think it is important that the individual get in,
18 file his claim, get it on record, get examined -- whether the
19 case is denied or not, at least it is on record. And that is
20 the way we look at it.

21 MR. CLELAND: Yes. Thank you very much. That is
22 where we are, too. We really have, at this point, developed a
23 three-point approach to the whole thing.

24 First is examination. We have tried to appoint an
25 Agent Orange Coordinator in our hospitals and our outpatient

1 clinics, and any examination on Agent Orange or alleged
2 Agent Orange problems becomes part of our permanent Agent
3 Orange register. We encourage the vet to file a claim if
4 there is any question at all.

5 The second is the treatment. We will treat the
6 problem as best we can and not wait to find out later.

7 Thirdly, we are trying to be aggressive in our research effort.

8 One item I think that might help -- we are just
9 about ready to put out a little quick, down and dirty Agent
10 Orange brochure that, in effect, summarizes the research --
11 summarizes where we are and what the guy can do about it --
12 the actions he can take. I think that will be helpful. It
13 is interesting to note, to me, that out of the 10,000 that
14 have come for examination, more than half have come out of
15 curiosity, not out of bringing a symptom to the VA.

16 We have done a little quick, down and dirty
17 analysis of the phone calls we get at DVB and, again, a majority
18 of those ask questions about it, and a majority of those are
19 stimulated by radio and television stories about Agent Orange.
20 There is an information need and I think a pretty serious one.
21 I think that you are right on target with the DAV and we try
22 to provide information. Hopefully, this brochure will help
23 us all.

1 Well, I wanted to go around the table and ask the
2 question that is always asked me, and I am not so much sure I
3 have quick, down and dirty answers. I may still be left with
4 some of that cold comfort, I guess.

5 DR. BRICK: Hopefully it won't be as cold.

6 MR. CLELAND: Cold. Maybe we all will resort to some.
7 But until we are able to have a little more scientific basis
8 for saying what we are saying I think that we are still going to
9 be put in a difficult position in explaining the Agent Orange
10 question.

11 So I think that -- I know that I would encourage
12 you all to move forward in the scientific arena as rapidly as
13 possible and continue to advise us as to what we should do.

14 I want to thank all of you for your time. I
15 have enjoyed getting to know all of you and hearing what you
16 have to say, and you all have a good, tough mission here.

17 I will now excuse myself and leave you all to the
18 previous discussion. Thank you very much.

19 CHAIRMAN HABER: Thank you, Mr. Cleland. If you have
20 any further words of guidance or inspiration to us we would be
21 glad to hear it.

22 MR. CLELAND: No. Thank you very much.

23 CHAIRMAN HABER: Thank you.

24 Doctor Levinson, do you want to continue
25 going through the group? Then we will have questions from the

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1 floor.

2 DR. LEVINSON: Perhaps I had better move quickly
3 because of the shortness in time. We are continuing with the
4 development of the registry and as of March 31st approximately
5 10,000 veterans had received examinations in our VA facilities.

6 The major goal of this program is now to -- two
7 goals. One, to computerize the information and to develop the
8 suitable control population so that the results can be appro-
9 priately interpreted.

10 And, two, to change the operating format so that in-
11 formation gathered will be more helpful. Ms. Kilduff, do
12 you have anything to say about this program?

13 MS. KILDUFF: No, I can't add anything.

14 DR. LEVINSON: We are proceeding in these tasks. The
15 next matter I would like to raise -- it seems Mr. Peckarsky has
16 left. I wanted to ask if there were any further reports on the
17 DVB program.

18 As I understand it, they have had approximately 1600
19 claims filed, the number is rising very slowly, and no new
20 veterans have been declared service connected for Agent
21 Orange exposure.

22 Yes, sir. Is there a question? I am sorry.

23 MR. DE YOUNG: Yes, I wondered if there was a dead-
24 line or a target date for the return on that analysis you
25 mentioned.

1 DR. LEVINSON: I hesitate to give one because of the
2 inponderables of getting material through -- coded and compu-
3 terized --

4 MR. DE YOUNG: I am assuming there will not be --
5 based on the Administrator's comments about partial studies,
6 there will not be an interim study on that. Or will that be a
7 progressive type of study?

8 DR. LEVINSON: This is not -- I think we have to make
9 a distinction. This is not a study. It is a mechanism for
10 gathering data for keeping in touch with the veterans who have
11 come for examinations, so that if anything new is learned they
12 can benefit from it and to offer suggestions to people who are
13 doing studies as to where they should receive -- for example,
14 we will look at all the individuals in that group who have skin
15 lesions, and if any of them are discovered to have chloracne
16
17 they will be studied further, undoubtedly, to see if they have
18 any liver or nervous system diseases. And if something is
19 found or suggested, the presumption would be that somebody
20 would then perform a study that would attempt to relate this.

21 In no way is the registry a study. It should not be
22 considered that.

23 MR. DE YOUNG: Excuse me. Are we still talking a
24 matter of months, Dr. Levinson? Is there some sense of this
25 registry --

1084 DR. LEVINSON: My guess is yes, a matter of months.

2 Doctor LeGolvan, do you want to say a few words about the
3 registry?

4 DR. LE GOLVAN: Yes. It has already been alluded to
5 by Dr. Lingeman and others that a registry at the AFIP at
6 present has 38 registered cases of which 30 are surgical
7 material, seven are autopsies, and one is seminal fluid.

8 As Dr. Lingeman has said, the process for evaluating
9 these cases goes through the various areas of the AFIP. We get
10 a report every month on the cases that have been processed,
11 reports go back to the station. The number is
12 slow but probably will pick up.

13 We also hope that the dermatological work probably
14 can be coordinated and put in the registry at the AFIP as we
15 have mentioned before.

16 CHAIRMAN HABER: All right. Doctor Levinson, is there
17 anything you want to add?

18 DR. LEVINSON: No.

19 CHAIRMAN HABER: All right. Then that concludes the --

20 DR. MURPHY: Doctor Haber?

21 CHAIRMAN HABER: Yes?

22 DR. MURPHY: Can I just ask a question?

23 Dr. Schepers mentioned when Mr. Cleland was
24 here about the studies in the VA Central Office. Is this part
25 of the survey or part of the --

1 DR. SCHEPERS: A separate survey. We are going over
2 the patient treatment files which are on computer and we will
3 be pulling the statistics. At the present time we are
4 analyzing statistical things and purifying them which is
5 enormously difficult.

6 We are pulling in the individual cases to
7 see who represents which statistic. And then having found that
8 person we, through administration personnel, go back to the
9 person to find out what was his war experience record and what
10 was his work experience record.

11 That takes an enormous amount of time to purify. We
12 have purified certain tumors. For instance, tumors of the skin
13 have not increased, tumors of the blood-forming organs have not
14 increased. You know there is no use pursuing these. There is
15 no increase in leukemias in this age group. There is no
16 increase in skin tumors --

17 DR. MURPHY: In this age group?

18 DR. SCHEPERS: Right. There is no increase in the
19 sample of the population we are looking at.

20 DR. MURPHY: In where?

21 DR. SCHEPERS: In those. The ones that do seem
22 worthwhile pursuing further are the testicles, the liver, the
23 brain, and the thyroid, but we have no data yet.

24 DR. MURPHY: Why do those seem worth pursuing?

25 DR. SCHEPERS: Because they are not totally negative.

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1 DR. MURPHY: They are not as negative as the --

2 DR. SCHEPERS: We don't know whether the differences
3 between their unnegativity -- if I can refer to it in that way--
4 represent Vietnam War veterans. We don't know what they repre-
5 sent, so we can't speak on it.

6 But we know that there are differences in the
7 incidence of the tumors of the liver, of the testicle, and of
8 the thyroid, and of the brain. Whereas, there are no
9 differences in population age groups for tumors of other organs.
10 So those need to be researched.

11 DR. MOORE: Doctor Schepers, what I am missing is
12 when you say there is an increased incidence of testicular
13 tumors or something like that -- as compared to who?

14 DR. SCHEPERS: In age groups.

15 DR. MOORE: Which age groups? The U.S.A.'s mass
16 population?

17 DR. SCHEPERS: No, just veterans. We are just com-
18 paring age groups of veterans by years.

19 DR. HONCHAR: You mean veterans from all wars?

20 DR. SCHEPERS: Yes.

21 DR. MOORE: All right. Thank you.

22 CHAIRMAN HABER: All right. This concludes a review
23 of the Steering Committee and I would like now to throw the
24 floor open to questions or comments from the group including
25 discussion among the panel participants.

1 Yes?

2 MR. GOLINKER: Dr. Haber, you mentioned earlier this
3 morning that there were problems with the Ranch Hand studies
4 but Colonel Thiessen didn't mention any of them. Could you
5 tell me what they are, sir?

6 CHAIRMAN HABER: Well, I would rather defer to
7 Colonel Thiessen or Major Brown.

8 COLONEL THIESSEN: The problems of the Ranch Hand
9 Study in what respect? The problems with the National Academy
10 of Sciences Review you mean?

11 MR. GOLINKER: My question was to Dr. Haber.

12 COLONEL THIESSEN: That is what I was referring to.

13 MR. GOLINKER: You didn't mention any of them. I
14 thought maybe you --

15 COLONEL THIESSEN: I don't have any information on
16 it.

17 MAJOR BROWN: The way they are reviewed?

18 MR. GOLINKER: Dr. Haber, you were the one who
19 mentioned the problems. Do you think they are?

20 CHAIRMAN HABER: I beg your pardon?

21 MR. GOLINKER: You were the one who raised the subject--

22 CHAIRMAN HABER: No. The problems that I referred to
23 relate to the NAS review. But that review is still not
24 finalized -- is that right?

25 MAJOR BROWN: Correct.

1 CHAIRMAN HABER: And that is the problem I had
2 reference to.

3 MR. GOLINKER: Can I ask you another one, please?

4 CHAIRMAN HABER: Please.

5 MR. GOLINKER: The other question I have -- the
6 Congressional inquiry which you had defined for us and
7 Mr. Cleland of the five studies in Europe. Can you tell me
8 who reviewed them in your Central Office, or was it the
9 Administrator?

10 CHAIRMAN HABER: A number of people reviewed those.

11 MR. GOLINKER: Can you tell me who they were, please?

12 CHAIRMAN HABER: I can't give you their names off-
13 hand, but we can find out. A number of people reviewed those.

14 MR. GOLINKER: Were any of them epidemiologists?

15 CHAIRMAN HABER: I can't answer that question off-
16 hand.

17 Yes?

18 MR. DE YOUNG: I have a couple of items that I would
19 like to see included possibly for discussion today or possibly
20 for a future agenda.

21 The first is one that was on an old agenda that I
22 raised from the floor a matter of months ago. The question
23 of canines in Vietnam. What happened to the guard dogs?

24 COLONEL THIESSEN: That question was answered.
25

1 MR. DE YOUNG: Well it was answered verbally. .It
2 was answered verbally and on top of that new information has
3 come back which makes me question the answer I got.

4 Major Young told me that it was a virus, it was well
5 documented, and the Air Force was satisfied -- that the case
6 was closed -- that it was not herbicides or any other unknown
7 causitive agent.

8 But in the meantime I have had more calls from dog
9 handlers. This time one of them was from a sentry dog handler
10 who said that his dog was diagnosed as having IHS -- Idiopathic
11 Hemorrhagic Syndrome -- which was also referred to as Tropical
12 Canine Pancytopenia.

13 And it was at the word pancytopenia that my
14 radar went off because this is what the literature for
15 Dr. Allen's rhesus monkeys describes as the cause of death
16 for many of those monkeys -- pancytopenia -- a depressed
17 blood system.

18 And I spoke to Dr. Allen about it. I spoke to a
19 couple of other toxicologists and veterinarians about it. They
20 were questioning -- once again, I won't say they said, "Oh,
21 yes, it was herbicide," because they didn't.

22 But there was enough doubt in the subject and in our
23 conversations on the phone that, once again, the door in my
24 mind is open -- what is going on with these dogs?

25 I was promised by Major Young that we would get the

1 documentation on that. It has not been forthcoming , and I
2 would request the committee's help in obtaining and reviewing
3 the documentation that DOD can provide on all guard dogs that
4 were in Vietnam, with an eye at solving that question for the
5 veteran community from an objective source and not from the
6 Air Force or DOD.

7 Secondly, the use of herbicidal agents similar to
8 those -- the same as those in Vietnam have surfaced in Korea
9 and that, I think, should be made a matter of public record
10 not only for the committee's purposes but for the veteran
11 community's purposes.

12 That is one of the reasons I am mentioning it. I
13 think it expands our realm of inquiry because we are dealing
14 not only with Vietnam but with Korea as well.

15 This may be of interest to people who are interested
16 in study sites and populations once again. And I do have the
17 papers which I will submit to Dr. Haber for inclusion and
18 distribution to the members which we obtained under a Freedom
19 of Information Act request.

20 It cites Agents -- let me quote from this very
21 briefly for a second -- "Herbicides used: Orange, Blue, 2,4-D
22 and a soil sterilant called Monuron"-- M-O-N-U-R-O-N.

23 This chemical is totally unknown to me and I would
24 appreciate any members of the committee's short comments on
25 what the devil Monuron is and what it does to the human system,

1 if that is known. I understand that some soil sterilants of
2 some sort -- described as semipermanent soil sterilants -- were
3 also used in Vietnam and Monuron possibly was among them. So
4 it probably is a direct target of our inquiries.

5 I am curious. The surfacing now of documented
6 evidence which was once a year ago only hearsay evidence from
7 one crazy veteran who was at one time in a penitentiary on the
8 West Coast -- that is where this came from -- is now documented
9 by a Department of Defense paper.

10 And that doesn't make everything else that is anec-
11 dotal true, but one out of one is not bad. We are in the
12 process of checking out the rest of the anecdotal reports we
13 have heard and will keep you posted as time goes on.

14 We have had anecdotal reports on Panama, on bases in
15 Germany, on various other places around the world. I would
16 like to see, personally, full disclosure on the use of herbi-
17 cides, and the use of phenoxy herbicides in specific, around the
18 world by the Department of Defense.

19 Then maybe the epidemiology people can get a study
20 population together, because I have a suspicion that your
21 testing on fat biopsies was partially confused by the fact that
22 some of those guys were exposed outside of Vietnam, and I
23 have no certainty that that is the case.

24 But we do know that 2,4-D and other chemicals are
25 used as common grounds management technique by the Air Force

1 around air bases. Why not T in the 1960's?

2 And so we have data that is confounded. But I think
3 we need full disclosure on these things. Specifically,
4 possibly Dr. Moore, through his White House Committee affilia-
5 tion can proceed with --

6 CHAIRMAN HABER: May I interrupt, Mr. DeYoung, to
7 point out that we are well aware that one of the confounding
8 factors in this is that the herbicides are used so widely that
9 military personnel in other parts of the world may be exposed.

10 But, of course, that has to be taken in context with
11 the fact that everybody around is exposed, whether they are in
12 the military or not, and that the numerous examples of world
13 literature exposure attest to the fact that the herbicides are
14 widely used in right-of-way railways, transmission systems, in
15 manufacturing, in road maintenance and so on.

16 So it is a very complicated problem. Nonetheless,
17 we will endeavor to follow-up with your suggestions.

18 MR. DE YOUNG: The reason I think it is a little
19 more pertinent to this issue is because the lines of culpability
20 and responsibility are much more unclearly drawn in the veteran
21 community.

22 If their exposure happened while they were in military
23 service it is a very clear and --

24 CHAIRMAN HABER: That is not my point. I am not
25 denying that. I am saying that if they were widely found in

1 the universe then the difficulty in attributing that to
2 exposure during service is compounded. That is my only point.

3 MR. DE YOUNG: Yes.

4 COLONEL THIESSEN: Maybe I can shed a little light on
5 dog fatality in Vietnam. Actually it was published in the
6 Journal of the American Veterinary Medical Association in
7 1969 -- a case report of inadvertent malathion poisoning
8 which occurred in 24 scout dogs of an American Infantry
9 Platoon.

10 They were dipped in a concentrated malathion
11 dipped, believe it or not, in a malathion concentrate
12 solution for tick control. All the 24 dogs died.

13 And I am sure there are -- in talking about anecdotal
14 evidence, I am sure there is more anecdotal evidence if you
15 look long enough. However,
16 incidental situations don't really help us solve the
17 general problem that we are discussing around the table, I
18 don't think.

19 Whether or not you mention another pesticide, I am
20 sure we could come up with a list of 25 pesticides that were,
21 at one time or other, used incidentally or generally. It is
22 all known. There is nothing secret about it.

23 You don't need an inmate to produce anecdotal
24 evidence. It is all there, Ron. You can have it if you ask
25 for it. Believe me. And for heavens sakes let's forget about

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1 these dogs now.

2 CHAIRMAN HABER: Another question, please?

3 VOICE: Yes, Dr. Haber. I just address this to the
4 panel. In one of the position papers it seemed to indicate
5 that malathion was sprayed in Vietnam as an insecticide --

6 COLONEL THIESSEN: Yes.

7 VOICE: -- and also DDT.

8 COLONEL THIESSEN: Probably. Yes, DDT and malathion
9 were rather extensively used.

10 VOICE: Were there any other insecticides that -- I
11 mean is there a list of insecticides that were used?

12 COLONEL THIESSEN: I don't know -- I can't produce
13 it offhand, but it is there.

14 VOICE: Could that be submitted to the committee?

15 COLONEL THIESSEN: Sure.

16 VOICE: Thank you very much.

17 CHAIRMAN HABER: Yes?

18 VOICE: Dr. Haber, I have a video tape which was aired
19 Monday evening. It is produced by CBS News from Chicago by
20 Mr. Bill Curtis who has done two previous documentaries on
21 Agent Orange.

22 This one is the third in a series and has film footage
23 of a recent trip to Vietnam -- the first American journalist
24 allowed into the country -- and interviews with Dr. Ton-That-
25 Tung in Hanoi and with American physicians who are working on

1 the Nitro, West Virginia dioxin contamination studies. So as
2 soon as we have the transcript I will submit that to the
3 committee.

4 If possible, and if anyone wants to see this, we can
5 get some equipment. The tape is available.

6 CHAIRMAN HABER: I mentioned earlier that if possible
7 we will see it today. If not, I would like to ask Dr. Shepard
8 to make provision at some subsequent meeting to have
9 that shown along with the films, Ron, that we are developing.
10 But I will ask and see if that is possible.

11 Are there any other questions or comments from the
12 floor?

13 (No response)

14 MR. DE YOUNG: I have one more item which I was not
15 quite finished with when I was interrupted.

16 CHAIRMAN HABER: All right.

17 MR. DE YOUNG: The Australian veterans community,
18 according to a report in the New Asian News from Tokyo, has been
19 extremely interested in Agent Orange, needless to say.

20 I read one section of this report, "One independent
21 survey done in the state of New South Wales revealed that one in
22 four of the children of 50 Australian ex-servicemen were de-
23 formed."

24 I think we need some communication with the organi-
25 zations in Australia, because if this data is indeed correct it

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1 is, needless to say, extremely significant. I will provide
2 you with a copy of this and whatever checking can be done
3 through this source I think should be begun.

4 I think we need some close international cooperation
5 and although this may not be the forum to do so, it certainly
6 would be for the veterans community, I think.

7 CHAIRMAN HABER: Yes, as a matter of fact we have
8 had communication with a Mr. Medberry, the Chairman or Executive
9 Secretary of the Australian Repatriation Commission, which is
10 the equivalent of the Veterans Administration.

11 We have forwarded copies of the Swedish studies to
12 the New Zealand Embassy, and the Administrator's testimony.
13 We have also had contact with our State Department -- Mr. John
14 Knowles -- so that there is a two-way communication, both
15 with our people in Australia and those people here.

16 Mr. Medberry spent several weeks here, Mr. DeYoung,
17 informing himself about all the complexities of the Agent
18 Orange problem. I understand they are going to undertake
19 an epidemiologic study in Australia as well, and, of course,
20 we will be privy to the results of that. I would hope that we
21 have an opportunity to look at the protocol and to determine
22 the results.

23 If there are no further questions, I would like to ask
24 Dr. Shepard to sum up for us and to give us one or two further
25 instructions.

1 DR. SHEPARD: In your packages have been included the
2 five studies alluded to at various points here. These studies
3 are foreign studies -- four of them Swedish, one from West
4 Germany -- which deal with this issue.

5 We would appreciate the members of this committee
6 reviewing those and providing us with any thoughts they
7 have on the applicability of these studies to our deliberations
8 here and to our on-going studies.

9 We would appreciate getting reactions to these
10 articles, particularly from the scientific community and the
11 epidemiologists, so we can incorporate them in our thinking.

12
13 In conclusion, let me say again that I look
14 forward to working with this group. Mr. Layne Drash and other
15 members of our staff, I am sure, will be more than happy to
16 be available to any of you at any time in an effort to share
17 information, coordinate our efforts, and in any other way it is
18 possible to be helpful to you.

19 I have no further comments, Dr. Haber.

20 CHAIRMAN HABER: Unless there are any further
21 questions or comments I think we will adjourn. I am told that
22 the projectionist is here and equipped to show the video tapes
23 now.

24 Are there any of you who would like to stay and see
25 that?

1 DR. MURPHY: Can I ask -- is Dr. Shepard's phone
2 number the same as yours?

3 CHAIRMAN HABER: No. What is your phone number,
4 Barclay?

5 DR. SHEPARD: My present number won't help you
6 because it is not going to be my telephone number very long.
7 If you will wait a second I will get it for you.

8 Mr. Drash's number is 389-3517.

9 CHAIRMAN HABER: 389-3517. I don't see any great
10 manifestation at this time of interest in the films. Are there
11 those who want to stay and see it?

12 DR. MURPHY: I want to see it.

13 CHAIRMAN HABER: I suggest
14 if no more than one or two want to see it now
15 we will schedule it at one of the
16 meetings. I think that would be appropriate along with
17 those other films.

18 Can I see a show of hands? Who will stay to see it?

19 (A showing of hands)

20 All right. Well there are a few then. All right,
21 we will show it now.

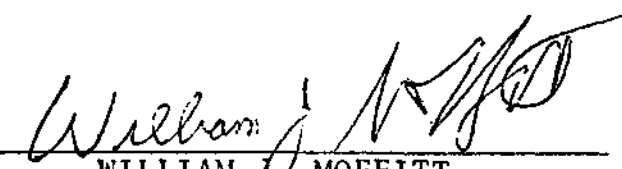
22 I hereby declare these proceedings adjourned.

23 (Whereupon, at 11:57 o'clock a.m., the meeting in
24 the above-entitled matter was concluded.)


25

C E R T I F I C A T E

This is to certify that the foregoing proceedings before the Veterans Administration, Advisory Committee on Health-related Effects of Herbicides, Wednesday, April 23, 1980, were had as herein appears and that this is the original transcript thereof.


 WILLIAM J. MOFFITT

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.


 BARCLAY M. SHEPARD, M. D.
 Chairman
 VA Advisory Committee on Health-
 Related Effects of Herbicides

July 8, 1980

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Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

**(Fifth Meeting
August 6, 1980)**

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VETERANS ADMINISTRATION

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ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

- - -

Veterans Administration Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C.

Wednesday, August 6, 1980

The above-entitled meeting convened, pursuant to notice, at 8:30 a.m., before DR. BARCLAY M. SHEPARD, Chairman.

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P R O C E E D I N G S

1
2 CHAIRMAN SHEPARD: Good morning, ladies and
3 gentlemen. Welcome to our VA Advisory Committee on
4 Herbicides. We are very pleased to have you all here.

5 We are also pleased to have here our Chief
6 Medical Director, Dr. Donald L. Custis, who will open the
7 meeting. His very busy schedule will not allow him to
8 stay for the entire meeting, but we are very happy he
9 was able to spare some time to welcome you all.

10 DR. CUSTIS: I must apologize. I am on the
11 agenda for later today, but my schedule got turned around.

12 I did want to express the appreciation
13 of the Department and the Agency for your generous
14 contribution of time and talent. We very much are in
15 need of your advice and help.

16 With the development of new initiatives and new
17 investigative efforts, I am beginning to get a little more
18 encouraged and optimistic that we might be seeing the be-
19 ginning of the unraveling of this puzzle.

20 We welcome new ideas and suggestions from this
21 Committee. I assure you that we will respond positively
22 whenever possible. I urge that the Committee not hesitate
23 to bring these ideas to us.

24 The Administrator, Mr. Max Cleland, will be seeing
25

2.

1 you mid-morning.
2 Something came through my office yesterday which I anticipate
3 will be discussed by Max Cleland when he addresses you. I am sure that
4 he would not mind if I give you a brief introduction to this matter.
5 I am referring to a letter from Senator Cranston that is
6 addressed to the Administrator. I would like to read a paragraph to
7 you.

8 "I am enclosing copies of reports by the President's
9 Interagency Work Group on Dioxin and the Office of Technology
10 Assessment on reviews I requested of the four Swedish and the West
11 German epidemiological studies of workers exposed to dioxin in those
12 countries. The reports discussed the implications of those studies
13 as they relate to possible effects on human health of exposure to
14 dioxin--the toxic contaminant contained in Agent Orange. Specifi-
15 cally, Dr. John A. Moore, Chairman of the Scientific Panel of the
16 Interagency Work Group (IAG), states that 'In spite of the reservations
17 that are generally associated with these case-control epidemiology
18 studies...the studies show a correlation between exposure to phenoxy
19 acid herbicide and an increased risk of some forms of cancer. Indepen-
20 dent verification would further validate these studies.' OTA states
21 that Dr. Richard Remington, Dean of the School of Public Health,
22 University of Michigan, who reviewed the five studies, concluded that
23 the three case-control studies carried out on Swedish workers are
24 '...among the most carefully conducted investigations of their type
25 that I have ever seen. In toto, the Swedish work is credible if not
fully conclusive.' OTA also indicates that these three studies would
be very useful in the process of designating the mandated VA study."

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Later in the letter, Senator Cranston observes that the Agency response to his initial inquiry about these studies tended to accord them less credibility than these expert reviewers are now doing.

This is what I am thinking of: "I believe that the VA must have a constructive response to the increased possibility evidenced in these three studies that soft tissue sarcomas and malignant narcomas are related to exposure to dioxin, keeping in mind, of course, the necessity for further studies before any positive conclusions about any cause and effect relationship can be made."

As I say, I would not be a bit surprised

1 that Mr. Cleland will be asking for your analysis and
2 opinion regarding these studies.

3 Dr. Suskind, are you presenting these studies
4 in the agenda today?

5 DR. SUSKIND: I will introduce the discussion.

6 DR. CUSTIS: Thank you so much for helping
7 us and have a good program today. Are there any
8 questions I may respond to before I go?

9 (No response.)

10 CHAIRMAN SHEPARD: We have a very full agenda
11 this morning. I would like to proceed as rapidly as
12 possible.

13 I have just a few opening remarks to make. A number
14 of the standing members of the Committee could not be
15 here. Some of them have representation. We are happy
16 to have Dr. Pat Honchar here representing NIOSH;
17 Dr. Walter Rogan representing Dr. Moore in NIEHS;
18 Dr. Charles Thompson from DAV; and Major Phillip Brown
19 from the DOD.

20 I would like to take a moment to read a letter
21 from Dr. Thiessen who was a member of the Committee
22 representing the Department of Defense.

23 "Dear Dr. Shepard, as General Augerson would
24 have told you, I am approaching the end of my Army
25 career and consequently near the completion of my

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1 tour as a member for DOD on the Veterans Administration
2 Advisory Committee. I had hoped to be able to attend
3 the August 6th meeting but am, at that time, heavily
4 involved in transferring my responsibilities to my
5 successor, Colonel Morton.

6 "I would like to thank the many officials at
7 VA Headquarters that I have had the pleasure of consulting
8 with for their kind attention to my -- not always
9 positive -- advice. I am quite impressed with the
10 professionalism and real concern for the veteran that
11 I have encountered. I would appreciate if you would
12 convey my appreciation especially to Drs. Haber,
13 Schepers and Castellot.

14 "I wish you and the Advisory Committee the very
15 best in your efforts to resolve, to the benefit of the
16 veterans, the extremely complex problems related to
17 Herbicide Orange use in Vietnam. I am sure that I will
18 read about the activities of the Committee in the popular
19 and scientific press for a long time to come but do hope
20 sincerely that they will finally result in an unequivocal
21 determination as to the hazards of Orange and TCDD."

22 We are happy to have had Dr. Thiessen's
23 counsel and wish him well in his future. We will ask
24 the Department of Defense to appoint a replacement to
25 fill his vacancy.

1 We are very happy to have Dr. Raymond Suskind
2 with us today for the first time. His very busy
3 schedule at past meetings has not enabled him to attend,
4 but we are most pleased he is with us today. We are
5 very much looking forward to his participation.

6 We are also very happy to have Dr. Adrian
7 Gross with us. He was not able to attend our last
8 meeting.

9 At the close of our formal agenda, we will
10 have some time for written questions and answers. Those
11 of you who wish to address the Committee in the form
12 of questions, if you will please write out your
13 questions and hand them to Mrs. Williams during the
14 course of the session, we will devote some time at the
15 end of the session to answer your questions.

16 Please feel free to write those out and
17 present them.

18 For those of you who were not able to view
19 the video tape that was presented at the close of the
20 last meeting, we will present that again. Those of you
21 who would like to stay and watch this video tape, this
22 is the one Bill Curtis of WBBN-TV in Chicago made. It
23 is the third in his series. It is called "Agent
24 Orange, View from Vietnam."

25 I would just like to bring you up to date on

1 some of the activities that have been going on at the
2 Central Office and throughout the Agency.

3 REPORT ON CHLORACNE TASK FORCE

4 CHAIRMAN SHEPARD: I would like to refer to the
5 efforts of the Chloracne Task Force which is very ably
6 headed up by Dr. Kenneth Halprin, an eminent
7 dermatologist in Miami and on the staff of the VA
8 Hospital there. He has done some remarkable work in
9 putting together some educational materials for VA
10 physicians and health care providers to enable a more
11 accurate and precise diagnosis of chloracne which as you
12 know is one of the hallmarks of exposure to dioxin.

13 In addition, he is putting together a
14 consultant group who will be available for examining
15 individual cases of chloracne and cases where the diagnosis
16 may be in some question. We are looking forward to his
17 contributions.

18 We hope that the educational material will
19 be available before long so we can start circulating
20 it and bring our health care staff up to date on that
21 matter.

22 REPORT ON LITERATURE ANALYSIS

23 CHAIRMAN SHEPARD: As many of you know, we
24 were mandated by Congress in P.L. 96-151 to conduct
25 a search of the literature, an analysis of the literature

1 on herbicides and dioxins. We are doing this by contract.
2 The proposals are in and we are now formulating a
3 selection committee to choose the contractor who seems
4 to be the most qualified to conduct this analysis.

5 This will obviously be much more than just a
6 bibliography of the literature. This will be a complete
7 analysis of the literature so the final product will be
8 a document that I think will be very useful to anyone
9 interested in this field and will serve as the basis of
10 ongoing research and investigation.

11 REPORT ON AGENT ORANGE REGISTRY

12 CHAIRMAN SHEPARD: As many of you know, we
13 have been engaged for almost two years now in the
14 Agent Orange Registry which is an effort to encourage
15 all Vietnam veterans who believe they may have been
16 exposed to herbicides and who may feel they have suffered
17 some health effects as a result of that exposure.

18 We now have approximately 26,000 veterans in
19 that registry. We are rapidly processing the data. We
20 are inputting the data from the examination and
-21 laboratory studies of those individuals. We hope
-22 to make some conclusions in the not too distant future
23 as to what this data shows.

24 In order to facilitate this process, I have
25 asked a group of people from the Agency under the

1 direction of Dr. William Page, who is a biostatistician
 2 to organize what we have come to call the Data Analysis
 3 Task Force and will pull together people of various skills
 4 in the areas of biostatistics, biometrics, and ADP
 5 technology, to really get to work and make use of the
 6 data we have gathered.

7 I would like to introduce Dr. William Page
 8 who will speak to you about the progress of this task
 9 force.

10 REPORT ON DATA ANALYSIS

11 DR. PAGE: Thank you, Barclay.

12 There is not a great deal more for me to say
 13 about the task force. The task force was set up to
 14 try and pull together some pieces of different types
 15 of data analyses. I would say the major task of that
 16 group has been to look at the registry data.

17 We are in the midst of getting it into a
 18 form that we can analyze it in. We will be reporting
 19 the results as they become available.

20 I suppose the other task would be looking at
 21 the VA's health records. I believe you mentioned that
 22 in some of your previous meetings. We expect also to
 23 be analyzing hospital discharges and things of that sort.

24 I think it is an important step to get all
 25 these people together, the data processing people,

1 the biostatisticians, and the program people, to get to work
2 and analyze these data and get them out to the public.

3 CHAIRMAN SHEPARD: There is one thing I think
4 is important to mention. We are in the process of
5 revising some of the mechanics of our registry. It has
6 become fairly evident that the questionnaire that has
7 been a part of that process needs some updating.

8 Bill's committee is working on that. We want
9 to make sure that the data we have is as accurate as
10 can be obtained. We are in the process of editing some
11 of the data. We want to develop an accurate method by
12 which we can get back to all veterans in the event
13 something comes along as a result of the many studies
14 that are being directed towards determining the health
15 effects of the herbicides.

16 We want to make a strong point to the effect
17 that we are making efforts to stay in touch with the
18 concerned veteran population. We will be working hard
19 to maintain that contact.

20 Another mandate of P.L. 96-151 was the
21 epidemiological study. Dr. Hobson is here to bring you
22 up-to-date on the status of that study.

23 REPORT ON THE EPIDEMIOLOGICAL STUDY

24 DR. HOBSON: There are people here who know
25 almost as much about the status of this as I do. There

1 has been a considerable amount of discussion.

2 As you know, this was mandated in the law. It
3 was mandated as a study of the individuals who had been
4 exposed to phenoxy herbicides.

5 There have been a number of suggestions made
6 lately but because of the difficulty of identifying
7 individuals who have specifically been exposed to these
8 phenoxy herbicides and because there were multiple
9 exposures and multiple experiences in Vietnam, the study
10 should really investigate what is the outcome of the
11 Vietnam experience as a whole.

12 We are not really at liberty to abandon the
13 study of the phenoxy herbicides in view of the mandated
14 work we are required to do. On the other hand, it seems
15 to me we may be able to design an epidemiological study
16 that will compare the experience of those people we have
17 reason to think were exposed to phenoxy herbicides with
18 the experience of veterans who were in Vietnam but not
19 so exposed in contrast to the veterans of that era but
20 never in Vietnam.

21 We may be able to encompass both. I am
22 phrasing this tentatively because the design of the
23 study will not be done until the contract is let. The
24 contract is for the design of the study and therefore
25 we have no protocol and no design at the present time.

1 The request for proposals was answered. A
2 panel has been formulated. The panel raised some questions
3 which required answers before they came to a final
4 conclusion. These answers have been obtained. In the
5 meantime, it became the vacation period and it was
6 impossible to reassemble the panel until after the
7 middle of this month.

8 We will reassemble just as quickly as we
9 possibly can after that and the contract process will
10 proceed from there.

11 Only after the contractor has begun work and
12 has come up at least with a tentative design for a
13 possible study will we be able to give you any estimates
14 whatsoever as to the time the study could be completed,
15 how much money it is going to take, what personnel
16 specifically will be involved and so on.

17 CHAIRMAN SHEPARD: Thank you.

18 Mr. Guy McMichael, the General Counsel for
19 the Veterans Administration, has been taking an
20 increasingly active role in our work with the Agent
21 Orange issue. We would like to have him speak about his
22 role and the VA Policy Coordinating Committee.

23 REPORT ON VA POLICY COORDINATING COMMITTEE

24 MR. McMICHAEL: Thank you, Dr. Shepard.

25 The Agent Orange controversy, to no one's

1 surprise, is an issue of great concern to many of us
2 within the VA. Increasingly, the need for greater
3 coordination of the Agency's activities has become
4 apparent.

5 There has been no one central focal point
6 throughout which all Agent Orange related activities
7 flowed. There was no one Agency official who was fully
8 cognizant of the many activities and programs that were
9 either ongoing or under consideration.

10 In an attempt to correct this deficiency,
11 the Administrator this past May established an Agent
12 Orange Policy Coordinating Committee. The principal
13 charge given to the committee has been to integrate
14 and monitor Agent Orange activities, provide advice
15 and recommendations to the Administrator as to future
16 Agency actions and to coordinate Agency activities with
17 those of other concerned Federal, state and veteran
18 organizations.

19 The committee as currently constituted is
20 comprised of representatives from the Department of
21 Medicine and Surgery; Department of Veterans Benefits,
22 principally the Compensation Pension Service and the
23 Veterans Assistance Service; the Information Service;
24 Studies and Analysis Service of the Office of Planning
25 and Program Evaluation; and the Office of General Counsel.

1 We attempt to meet on a regular basis and
2 have a free and open discussion.

3 We have found that there is an increasing need
4 for coordination, both between our two departments, the
5 Department of Medicine and Surgery and the Department
6 of Veterans Benefits. My office has been increasingly
7 involved, through litigation which deals with the
8 Agent Orange issue, Freedom of Information requests,
9 congressional inquiries and hearings which our office
10 handles.

11 In the area of litigation, we have questions
12 about our proposed contracts which have required
13 coordination. We have had litigation dealing with our
14 Agent Orange program guide and sufficiency and the process
15 by which it was developed.

16 We obviously are in a process of attempting
17 to provide information dealing with the Dow Chemical case
18 that is pending. There is some consideration that perhaps
19 Federal tort claims might be filed against the VA in
20 connection with Agent Orange which has necessitated
21 the involvement of our office.

22 Another issue which concerns us is the
23 increasing amount of Freedom of Information requests.
24 These requests seem to be directed to everybody and
25 his brother. An attempt to touch all bases to make sure

1 we obtain all relevant information has required some
2 attempt at coordination so that we can in fact obtain
3 all documents that are being requested.

4 Other things that the committee has been
5 looking into are the question of information distribution
6 of our Agent Orange brochure; response to various media
7 inquiries as to what the Agency is doing, and as I
8 mentioned earlier, the congressional interest in this
9 matter is a continuing one and one that continues to
10 grow.

11 We seem to be confronted with a number of
12 hearings and a number of congressional inquiries all of
13 which place a premium on our getting as much information
14 as possible so we can be as complete as possible in our
15 responses to those inquiries.

16 We also find that a number of states have
17 taken an increasingly interest in Agent Orange and
18 just keeping track of those states that are interested
19 in the question and that are requesting information
20 from us and that are seeking some kind of guidance is
21 another matter we have been directing our attention to.

22 Finally, we hope that the coordinating committee
23 is useful in gathering all relevant information to be
24 transmitted to the interagency committee upon which
25 both Dr. Shepard and I serve. We use this committee as

1 a method of gathering and disseminating to the interagency
2 committee all relevant information and we also hope to
3 be able to use this as a method of transmitting
4 information developed by the interagency committee to
5 all interested elements within the Veterans Administration.

6 CHAIRMAN SHEPARD: Thank you.

7 I think that is very helpful. I feel it is
8 most important that we proceed in an organized and
9 coordinated effort which in an issue such as this with
10 all its sensitivities, with its scientific complexities,
11 and other aspects of the issue, is not always easy to do.

12 There seems to be a flurry of activity relating
13 to the media and often short deadlines in order to
14 complete assignments.

15 I think it is a real benefit to everybody
16 involved in this issue to have Mr. McMichael serving
17 as a focal point and helping to keep this thing in some
18 semblance of coordinated progress.

19 We would like to move on. I am glad we are
20 a little ahead of the schedule. I am sure I have not
21 allowed enough time in some areas.

22 We would like to now introduce Dr. Adrian
23 Gross from the Environmental Protection Agency who will
24 lead the discussion on the Agency's ongoing hearings
25 relating to phenoxy herbicides.

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1 I think these are most important because they
2 are really getting at the root of many, many problems
3 and I think the body of testimony that is coming out as
4 a result of these hearings will be most important in
5 trying to assess many of the complexities and in some
6 cases, somewhat differing opinions that may be held in
7 various quarters.

8 I would like to introduce Dr. Adrian Gross
9 from EPA. Dr. Gross?

10 REPORT ON ENVIRONMENTAL PROTECTION AGENCY HEARINGS

11 DR. GROSS: I would like to introduce to the
12 Panel a member of the audience. We are privileged and
13 fortunate that he came here. His name is Professor
14 Nathan Matel. He is one of the foremost statisticians
15 and epidemiologists in the world who has done some work
16 in connection with dioxin and human effects.

17 He was interested in what goes on here and I
18 took the liberty to invite him to participate.

19 As to our assignment, Dr. Spencer and I thought
20 this Advisory Committee deserves nothing but the best
21 and traveling first class. Rather than us give you a
22 status report from the hearings, we have asked our lead
23 counsel, Ms. Dorothy Patton, to come and she runs the show.
24 She supervises dozens of attorneys; maybe not dozens but
25 they seem like dozens. She handles this whole case

1 herself.

2 I was pleased she consented to come and address
3 the Panel. You will also agree that the EPA counsel is
4 better looking the VA counsel.

5 MS. PATTON: Thank you, Dr. Gross.

6 First I want to apologize to Dr. Shepard
7 and Dr. Gross for arriving late. I understood it was
8 to begin at 9:00 a.m. and I was to begin talking at
9 9:10 a.m. I do apologize for coming in late. I certainly
10 did not intend to do that.

11 CHAIRMAN SHEPARD: We are glad to have you.

12 MS. PATTON: We have a very long period. It
13 is going to go for about two years. Rather than trying
14 to go into any details, I would like to give you a broad
15 outline of the hearing, the entire hearing, and perhaps
16 if anybody has any questions on matters that relate
17 directly to your interest here, I will be glad to
18 answer them.

19 The Agency's hearing on 2,4,5-T and Silvex
20 is being conducted pursuant to Section 6B of FIFRA.
21 That is the shorthand for the pesticide law, the
22 Federal Insecticide, Fungicide and Rodenticide Act.

23 Under Section 6B, the Agency is required to
24 consider both risks and benefits when considering
25 cancelling a pesticide. For your purposes, I think only

1 the risk issues are of interest so I am going to focus
2 on that part of the case right now.

3 At the present time, we are in the middle of
4 the risk case. The Agency began presenting witnesses
5 on risk issues in March. We completed our presentation
6 except for three witnesses on July 7th.

7 In the middle of July, the U.S. Department of
8 Agriculture began presenting its witnesses and U.S.D.A.
9 will conclude its presentation and EPA will also conclude
10 its presentation of its direct case in the middle of
11 September.

12 Beginning toward the end of September, the
13 Dow Chemical Company will begin to present its case on
14 risk. We expect Dow's case plus a few other parties
15 who are proponents of pesticide registration will
16 conclude sometime in November, perhaps early December.

17 In any event, the case on risk for EPA and
18 Dow and all the parties should be completed by the end
19 of the year.

20 In January sometime and continuing until
21 probably May or so, the case on benefits will be
22 presented. After that, there will be a briefing.

23 We have a hearing that is going to last for
24 at least a year when one considers both the risks and
25 benefits part of the case.

1 I think the things of interest to you are the
2 risk issues. I would like to broadly outline the Agency's
3 overall organization and presentation.

4 We have presented close to 60 witnesses
5 beginning in March. When Dow makes its presentation
6 it will probably present 40 or 50 witnesses.

7 Our witnesses and their testimony fall into
8 four basic subject matter areas. The first subject
9 matter area is toxicology, animal toxicology. We had
10 testimony on three different subject matters. One was
11 carcinogenic effects. The second was teratogenic effects
12 and the third was the effects on the immune system in
13 test animals.

14 The animal toxicology data falls into these
15 four broad categories in terms of the presentation that
16 our witnesses have made.

17 The second subject matter area concerns
18 epidemiology. There we have had two sets of testimony,
19 one on the Alsea Study on reproductive effects in
20 the Pacific Northwest and the second is the cancer
21 studies that have been developed using populations in
22 Germany and Sweden.

23 The third subject matter area deals with
24 exposure issues. In this third subject matter area, we
25 have presented testimony on what we have looked at on

1 traditional or classical chemistry, the environmental
2 fate, the environmental behavior of 2,4,5-T, silvex and
3 TCDD.

4 The fourth subject matter area is tangential
5 to the third one, that is it concerns exposure but it
6 is a different approach than the more or less textbook
7 approach to environmental fate questions.

8 The fourth subject matter area was based
9 on what we call use case histories. For the Agency's
10 purposes and the cancellation hearing, we must focus
11 on the use of the pesticide and 2,4,5-T and silvex have
12 uses in several different sites, forests, range, right
13 of way pasture, and so on.

14 The fourth area concerned the development of
15 information that is usually termed "anecdotal" in the
16 sense that we looked at Agency records and the records of
17 certain state agencies where individuals had reported
18 they had been exposed to the pesticide. Their reports
19 in the cases we used in the hearing concerned the
20 information that had been developed by state agencies
21 on the consequences of spray drift and on some cases,
22 direct application to private property.

23 This was a situation where the pesticide had
24 moved beyond the application site and had found its way
25 onto non-target property.

1 The use case histories involved testimony
2 from state officials, sometimes EPA or other governmental
3 officials, who had investigated these reports and had
4 found two kinds of evidence of pesticide contamination
5 of non-target property.

6 One kind of evidence was residue information.
7 These were situations where individuals had asked state
8 agencies to investigate places on their property where
9 they believed the pesticide had drifted and in fact the
10 investigators did find and did report either water
11 residues or residues on garden vegetation on other
12 crops or plants that were growing on the property.

13 The second kind of information was plant
14 pathology information. Official investigators from state
15 or other agencies had taken plant specimens and had
16 identified the damage reported there as being damage
17 attributable to phenoxy herbicides.

18 The use case histories were intended to
19 document or to provide documentation for something most
20 pesticide workers are familiar with, the idea of these
21 anecdotal stories.

22 In case histories, these
23 stories were documented by official reports made at the
24 time of the incident. The case histories did not involve
25 claims of health effects, even though some of the

1 individuals making the report initially had gone to the
2 state or had gone to EPA asking for investigation because
3 they claimed they were experiencing health effects,
4 because documentation of those kinds of effects is very
5 difficult, we did not attempt to have the witnesses
6 present that kind of information.

7 The information we presented concerned
8 exclusively the information on plant damage or on
9 chemical residues.

10 Those are the four kinds of information our
11 witnesses have presented. We expect Dow will be
12 presenting the same kind of information, coming from
13 the other side, of course, in the same general subject
14 matter areas with the exception of the case histories.

15 When the case is complete, the Administrative
16 Law Judge who is hearing the case will recommend a
17 decision to the Administrator and sometime subsequent to
18 that, the Administrator will make a final determination.
19 After that, either side may appeal to the courts.

20 That in a nutshell is what we are doing.
21 That gives you a general framework of the Agency's case
22 and what the presentation is all about.

23 I will be glad to answer questions which deal
24 with the issues that are closest to your interest, if
25 you would like.

1 CHAIRMAN SHEPARD: Thank you very much.

2 My comments earlier about questions do not
3 apply to the Committee. I am very anxious for the
4 Committee to feel free to ask questions at any time
5 during the course of the agenda. I think it is very
6 important that as a Committee we get involved in
7 discussions.

8 I would like to ask Ms. Patton if there will
9 be anything done in the way of evaluating any of the
10 scientific data, any of the testimony relating to the
11 scientific data, prior to the final report?

12 Is there going to be any analysis of any of
13 the testimony prior to the final report?

14 MS. PATTON: No. The way the hearing is
15 structured, the way a legal hearing is structured
16 generally in this regard, there will be a brief writing
17 so both sides will write briefs in which they present
18 and to the extent the record allows it, analyzes various
19 portions of the written and oral testimony.

20 In terms of any outside source or even the
21 Judge making any kind of comment about the hearing or
22 about the course of the hearing, that will not occur
23 until he recommends a decision to the Administrator, or
24 it should not occur, let me put it that way.

25 CHAIRMAN SHEPARD: Thank you. Dr. Brick?

1 DR. BRICK: With reference to the case reports
2 you mentioned, has there been any pattern of similarity
3 in case reports? What are the varieties if I might be
4 so bold to ask of these case reports?

5 MS. PATTON: There are several varieties. They
6 do have very common patterns. The varieties go to the
7 use areas, that is, we have reports from the different
8 use sites for chemical. The forest reports from the
9 Northwest are the best documented and that apparently
10 is because of political awareness in the Pacific
11 Northwest. The people out there are very concerned about
12 the pesticide and the result is when they see the
13 helicopters spraying near their property, they make
14 reports.

15 One of the situations about the Pacific
16 Northwest and if you have ever visited the area, it is
17 very apparent, the private property, the farms and homes
18 of people, are immediately adjacent to forest spray areas.
19 The mountains are very steep. There are forest sites
20 and they are spraying there and the property is
21 immediately adjacent to the places that are being sprayed.

22 There is opportunity for drift. The people
23 report that.

24 We find the same thing in the rice use areas
25 in the South, although we do not have as many reports. We

1 have reports on right of way spraying applications, where
2 very often the reports are made directly to the
3 applicator. That information has been acquired in some
4 cases through discovery of the pesticide applicators.

5 The common ingredients are the drift
6 phenomenon. The individuals sometimes see it, sometimes
7 they smell it, other times they see the damage a day or
8 two later or a week or so later. Because they understood
9 or learned that spraying was going on in the area, they
10 then made the report and the officials came out and
11 identified it as phenoxy specific damage or identified
12 it as having residue.

13 Each of the cases we presented, we were able
14 to locate the applicator and the labels that were applied.
15 These were applied for the most part under proper use
16 conditions.

17 In most cases, drift went anywhere from a few
18 hundred feet to several thousand feet. It depends upon
19 the area. We do not have drift going more than two or
20 three miles. We do not have reports of it in our case
21 histories. There are other reports of drift going
22 further than that, but not in our case histories.

23 DR. BRICK: I guess there is one problem with
24 this business of case reports. Being an academic
25 physician, a case report means something different than