medical facilities, or some combination of the two. There is some still questions that need to be answered.

MR. WALKUP: Then, assuming some turnaround time in redeveloping an RFP, selecting a contractor, and so on, that would take us into 1989 or 1990 or something like that, another three to four years?

DR. SHEPARD: I hope 1986 - 88 time frame we'll have --

MR. WALKUP: Okay. Then the three to four years were not on top of the pilot study?

DR. SHEPARD: Yes. Yes. I'm sorry. 1985. It would be probably '88 - '89.

MR. WALKUP: Okay. Thank you.

DR. SHEPARD: Are there any other comments from other members?

MR. LeVOIS: I just hope that those times can be shortened somewhat. I have been operating under the premise that the full blown study, once it begins, could be conducted on such a scale that it would only take about two years to conduct the full study.

I don't know whether that's feasible, but I think, looking at the Ranch Hand experience, they're trying, and very reasonably so, to keep the data collection period within a couple of years, so that you don't run

1 into other confounding factors. You don't want your
2 subjects at the end of the study to be four years older
3 than your subjects at the beginning of the study, for
4 instance.
5 So, I don't think that we want a four year,
6 full scale study. But, this is all rather difficult to
7 tie down. I just will assure you that we'll continue to
8 push for a shorter time frame.
9 MR. WALKUP: We definitely support that. Just
10 one other series of questions, if I may. I know I've taken
11 a lot of time, but our chances are infrequent.
12 On the brochures, I understand --
13 I wanted to clarify where we're at in mailing these to the
14 people who've taken the exams, already, who are on the
15 Registry. Have those been mailed or are there plans to
16 mail them to everybody? Where are we?
17 DR. SHEPARD: If they haven't started,
18 it's about to happen. I don't know exactly. That
19 particular effort is not being handled directly out of our
20 office. We've been cooperating with the Office of
21 Public and Consumer Affairs. They've taken the lead on
22 this initial mail out, in the development of the automated
23 mailing lists.
24 Our efforts have been directed towards a
25 follow-up, a very brief questionnaire to each of the veterans

1 who are currently in the Registry; and, also to get a
2 good, recent address.
3 So, there are really two parallel efforts going
4 on. And, between those two efforts, hopefully, everybody
5 in the Registry will soon get, at least, copies of this
6 information. And, then, of course, there are efforts
7 going on to develop other information packets.
8 MR. WALKUP: Has the questionnaire gone out yet,
9 then?
10 DR. SHEPARD: No. But, it's about to go out.
11 I mean -- it's cleared OMB and it's -- I think -- in the
12 final stages of printing; so, it will go out in
13 two fashions. The hospital will be provided with those
14 mailing addresses that we think are accurate, and so that
15 they can actual label -- so they will be able to put these
16 labels on the letters to the veterans.
17 In those areas where they have evidence that the
18 veteran has come in for an examination, but he is not one
19 that has a mailing label, the hospital will develop its
20 own methodology for getting the best possible mailing lists.
21 It should be getting out there soon.
22 MR. WALKUP: Okay. I hadn't gotten mine yet
23 that's why I was asking.
24 DR. SHEPARD: Okay.
25 MR. WALKUP:

1 My final question
2 relates to that that has the Privacy Act notice been filed
3 for this system of records that's
4 generating the mailing?
5 DR. SHEPARD: Ah, I --
6 MR. WALKUP: Or, maybe that would take
7 a little bit --
8 DR. SHEPARD: The Privacy Act?
9 MR. WALKUP: Under the Privacy Act, there's a
10 requirement that notice be filed in Federal
11 Register, stating what's contained in a system of records
12 that's being used; to let people know what --
13 what records are being maintained and used by the federal
14 government for a specific purpose.
15 DR. SHEPARD: Okay. That's a legal question.
16 Is Mr. Conway here? Okay. The question relates to
17 whether or not we have published in the Federal Register
18 a new system of records relating to the mailing
19 address of the individuals in the Registry. I suspect
20 that this has been cleared by general counsel; whether or
21 not it meets the test for a new system of records, I think
22 is the way --
23 MR. WALKUP: Under the Privacy Act.
24 MR. CONWAY: We are not considering this to be
25 a new system of records, but rather it comes under the

existing system of records that now exist for medical records. It's not a separate system. It's a part of the medical records system -- a subset of it.

MR. WALKUP: Then, a veteran identifying in a claim, his general medical records would be also identifying his Agent Orange examination records. Is that correct?

MR. CONWAY: I'm not sure I understand the question.

MR. WALKUP: In filing a claim, we're required to identify the particular record -- the particular set of records, out of 60 or so, that could be maintained.

MR. CONWAY: Filing a claim under the Privacy Act?

MR. WALKUP: No. A claim for compensation or what are requests for health care, whatever, with the Veterans Administration; we're required to identify the system of records in which information relating to that claim might be contained. And, my question was if in just identifying our general medical records, we also are identifying our Agent Orange examination records. Are those kept in the same box?

MR. CONWAY: The Agent Orange examination records is a part of the medical records of the individual, maintained by the station where he had that examination.

1 And, when he transfers to another
2 regional area, covered by a different medical center,
3 those records would go along with him. So, it is part of
4 the same medical records. It's not a separate record,
5 maintained independent, and separate and apart from the
6 main medical record of the individual veteran.
7 MR. WALKUP: Okay.
8 MR. CONWAY: That's why we have said that the
9 records, addresses, and so forth, are -- medical records
10 system of records that we have already had a notice in the
11 Federal Register for.
12 MR. WALKUP: And, then, it's just a copy of that
13 part of those records that's maintained in the
14 central Registry. Is that correct?
15 MR. CONWAY: I don't -- it's a copy of --
16 there's not really a copy of the medical record.
17 Dr. Shepard can probably speak to what exactly it is that
18 we have here. But, the Agent Orange examination, as I
19 said, is part of the major -- the complete medical record
20 of the veteran. It's not a separate record.
21 It's only separate in so far as we have data on
22 who has, among all the medical records that we have in the
23 VA system, who among those have had the Agent Orange
24 examination. I don't know if I'm answering the question.
25 MR. WALKUP: Yes, I think you are. Thank you.

1 DR. SHEPARD: We don't have two separate --
2 there isn't an Agent Orange medical record system and an
3 everything else medical system. A veteran comes in for an
4 Agent Orange examination. He's never been there before.
5 They will establish a record for him, but it will be the
6 same kind of a record as if he had come in for acute
7 appendicitis or an outpatient visit, or whatever.
8 There isn't a separate system of medical records
9 developed for the Agent Orange. Fred said
10 there's an identifier in a separate card file. Anybody
11 coming in to the VA is suppose to have a three by five
12 card filled out on the individual indicating if he has had
13 the Agent Orange examination.
14 And, that process is
15 in the process of being automated here.
16 MR. WALKUP: Thank you.
17 DR. SHEPARD: Any other comments or questions
18 for Mr. Walkup from the Committee? We now have a few
19 minutes, and I entertain questions from the floor. I have
20 already been provided some questions.
21 COMMENTS AND DISCUSSION
22 DR. SHEPARD: The first one is: Could the
23 Advisory Committee please comment on a
24 recent award of 58 million dollars
25 for the 1979 chemical spill from the ruptured

1 tank car in Sturgeon, Missouri. Specifically, what bearing
2 will the recent verdict have on herbicide-related law suits
3 filed by Vietnam veterans; and does the Committee plan to
4 review transcripts from the trial?
5 First of all, I would remind you -- those of you
6 who are not familiar with the details of this case
7 -- the tank car contained 30,000 gallons of orthochlorophenal,
8 which is not a herbicide. It's an organic solvent, alleged
9 to contain 22 parts per billion of TCDD, presumed to be
10 2, 3, 7, 8-TCDD. So, that's the only relationship to --
11 to Agent Orange that I'm aware of.
12 From what little I gleaned in the last few days
13 as a result of this, orthochlorophenal has
14 some toxic potential with probably five Cs of toxic
15 potential for herbicides. I don't know that from a
16 personal study, but that's - I think reasonably
17 good information.
18 First of all, we do not have the details of the
19 health status of the 49 -- or 47 railroad workers
20 -- for whom this verdict has been rendered. So, we don't
21 what their problems
22 are medically. So, we can't answer the question as to
23 what relationship this will have to Vietnam veterans.
24
25 The second question: Does the Committee plan to

1 review the transcript of the trial? I'm not sure that we
2 would task the Committee with reviewing the transcript of
3 the trial. I'm sure that there'll be some interest in our
4 general counsel's office --there already has been -- as
5 to the details of the trial.
6 Mr. Conway, do you have any comments further on
7 that?
8 MR. CONWAY: The newspaper accounts only came
9 out last Friday, and we have been trying to get more
10 detailed information as to what exactly the nature of the claims
11 by the workers was, what the nature of the verdict made by the
12 jury was, whether it was a special finding or a general
13 finding, what was the nature of the evidence that was presented
14 in the case; and, we are trying to track that down.
15 But, it's not a reported decision, in the sense
16 that it's not in the books someplace that we can go and
17 look up and read the court's decision. It's a jury
18 verdict at the lowest trial court level. And, we're having
19 some degree of difficulty in tracking down who would we
20 talk to about the trial. And, we're trying to get in
21 contact with the Clerk from the court's office and see
22 whether a transcript has been prepared thus far, and if
23 so we will try to obtain that transcript and the evidence
24 that has been presented, the exhibits, and so forth.
25 Once that is all done, we will analyze that and

1 make any recommendations that we feel are appropriate to
2 the Chief Medical Director and Chief Benefits Director,
3 and ultimately to the Administrator, as to whatever impact
4 this particular court case has on the agency's policies.
5 As Dr. Shepard -- I'm sure -- would agree with,
6 that we're very much interested in this particular case
7 because it is relevant, in so far as they're both related
8 to dioxins. And, whatever information we can get that will
9 shed more light on the issue and help us prepare a
10 comprehensive and fair policy, we're going to pursue.
11 Beyond that, we have nothing further to say at
12 the time.
13 MR. LeVOIS: I think that one constructive
14 line of evaluating this, even before we have an
15 opportunity to review transcripts, which I understand sometimes
16 take months to prepare and are several feet thick, would
17 be to talk to, I think, Dr. Bertrum Turno who was quoted in
18 the Times and also interviewed on television yesterday
19 morning. It might be very useful for us to consult with
20 him and learn from him what scientific work, if
21 any, he did.
22 We don't know, really, without good information
23 about the trial and his role in the trial and whether or
24 not background surveys of the health problems in that
25 population, among workers who didn't participate

1 in the cleanup, were conducted. We just don't know what
2 was done, what kind of scientific evaluation was conducted.
3 But, we should pursue Dr. Turno, I think, and try and learn
4 from his experiences there.
5 DR. SHEPARD: Any other comments or questions
6 from members of the Committee? It's obviously an
7 interesting case. It has some repercussions, I think,
8 in our activities, and it behooves us to be
9 knowledgeable,as Maurice and Fred have indicated,in the
10 area.
11 I would just like to caution making a brisk link
12 between this and Agent Orange, because I think the
13 circumstances of exposure, certainly the chemicals
14 involved, and so forth, are somewhat different.
15 I hope that answers the question.
16 This next one: Could we obtain a brief summary
17 of the physiologic testing for exposure and reaction to
18 2, 3,7,8-TCDD performed, indicated under further study,
19 including fat isomer analysis, liver enzyme study, serum,
20 cholesterol, and triglyceride, --, lymphisite impairment,
21 chromosome studies, nerve conduction, velocity, et cetera?
22 That's a long question. Yes. We'll be happy to share any
23 information that we have with anybody in that regard.
24 We as we've already alluded to, a fair
25 amount of this has been referred to in the literature

analysis -- this comes from Dr. Shetka: I hope we've provided you with a copy of the JRB two volume work.

Let me just say that we don't have an additional great source of information. I know Al Young has been collecting reprints as they occur, and probably has one of the best reprint libraries, at least, on this subject. And, I'm sure he'd be happy to share that information with you.

As I said earlier, we are in hopes of awarding a contract for an update of the literature analysis; and, particularly we want a more in-depth evaluation of the human studies that have been conducted. We need to have those fleshed out.

But, we certainly will be happy share any information.

In light of Illinois and Mississippi Commissions testimonies, will this Committee actively consider observer or member status for state commissions/ agencies? This comes from Ruth Leverett from the New York State Dioxin Commission.

It's a good question, Ruth. I think that there might be some virtue to establishing an interstate organization. It's not that we don't want to -- and we have, and you know -- cooperated with states in a number of areas.

I think it might be better for the states to take this on as their own initiative. And, as I say, this is not in any way a ducking a responsibility that we have. But, I think that the states would find, perhaps, that their effectiveness was enhanced if a little bit of distance was put, institutionally or systematically, between your organizations and the federal government.

I just follow very quickly to say that I don't want to suggest that we won't be very happy to cooperate in any way that we can in terms of information sharing. But, in terms of the VA or any other specific agency in the federal government consciously establishing an interstate grouping might not be the best way to go.

That's just a personal opinion, although it's not only my opinion. I have heard others say the same thing. But, I don't think that the last chapter has been written on that subject.

In terms of representation, on this Committee that issue has not been looked into in any great depth. If there are some persuasive reasons for doing that, I'd be happy to hear them. And, I certainly would be happy

1 to hear comments from the Committee
2 as to whether or not there should be systematically state
3 representation, not if -- if the states do organize an
4 interstate body or association, or what have you, then I
5 think it would be entirely appropriate to have somebody
6 from that interstate association to be
7 represented here.
8 I think it would be difficult for us to choose
9 which state should be represented on this Commission;
10 and, now some 30 states which have active Agent Orange
11 commissions of one kind or another. And, I think it would
12 swell this body if we attempted to have
13 each state represented officially, to a point where we
14 might find it difficult to conduct business.
15 Other comments from members of the Committee?
16 Can I assume that silence is tacit agreement?
17 The next question: In regards to your mortality
18 studies, how are we going to determine Vietnam service
19 when so many records were destroyed in the St. Louis fire?
20 Jim King from Illinois.
21 It's my understanding -- and please correct me
22 if I'm wrong -- that the -- the St. Louis fire involved
23 World War II veterans records. And, I think Vietnam
24 veterans pretty much escaped that conflagration. But, I
25 may be wrong. Yes, sir?

1 MR. JAMES KING: Not meaning to argue with
2 Dr. Shepard, but we've had several of our witnesses who
3 appeared before us claimed to have had trouble supporting
4 a claim because they have been told that their records
5 they requested were destroyed in the fire in St. Louis.
6 DR. SHEPARD: Okay. That's a question.
7 Obviously, it needs an answer. As I say, I was laboring
8 under the impression that if there were Vietnam veterans
9 records destroyed in that fire, that they were very few
10 in number.
11 Now, that isn't to say that there may --
12 MR. KING: Maybe we just run into those few.
13 MR. LeVOIS: There are a couple of people
14 in the audience who are experts, both in DOD and in VA
15 records. Would anyone care to comment on whether or not
16 Vietnam veterans records were destroyed in that St. Louis
17 fire?
18 DR. SHEPARD: Let me call on Mr. Richard
19 Christian, who is heading up the Army Agent Orange Task
20 Force. Dick?
21 MR. RICHARD CHRISTIAN: My answer is short and
22 sweet. By and large, most of the Vietnam era records
23 are in place in St. Louis. There are a few. The fire
24 encompassed records up until 1959 -- 1916 to '59. So, we
25 pretty well have the Vietnam era covered. There may be

a few, as you say. But, those can be dealt with by reconstructing ones records.

DR. SHEPARD: would it be appropriate, then, to suggest that any state agencies which have impression that the record on a given constituent is not available as a result of the fire, or for any other reason; that information could be made known to us or to you; and maybe some effort could be made at determining why that record isn't available.

MR. CHRISTIAN: They can contact me personally and we'll follow up.

DR. SHEPARD: Thank you very much, Dick. Does that answer your question?

MR. KING: If we run across any more of these, we'll be glad to give you the man's name so that you can assist him.

DR. SHEPARD: Fine.

There's a certain amount of loss of records that occurs from time to time. I'm sure there's a certain percentage of records used that simply get lost in the process of moving around, or whatever.

But, it's my understanding that that is pretty much at a minimum.

Okay. I have a question now from the National Veterans Law Center: At the February 25, 1982 VA

1 Advisory Committee, you said that with regard to --
2 protocol, within two months we should have a final product.
3 What is the status of the protocol review at this time,
4 some six months later?
5 Okay. I think I answered that question
6 earlier. If you're asking for excuses, why we went from
7 two to six months, I'm not going to get involved in
8 that. But, I think you've been given an accurate
9 description of where the status is. It's being reviewed
10 by the National Academy of Sciences; and
11 we hope to have their report in about three weeks.
12 In the meantime, we are working on the final
13 fine tuning of the protocol for the pilot study and hope
14 to have the contract awarded early in the next calendar
15 year, if not before.
16 MR. LEWIS MILFORD: If I could follow up on that
17 a second, when will there be a decision made as to who will
18 conduct the study?
19 DR. SHEPARD: The full study?
20 MR. MILFORD: Yes.
21 DR. SHEPARD: Probably some time during the
22 course of the conduct of the pilot study or
23 towards the end of the pilot study.
24 MR. MILFORD: Who will be conducting the pilot
25 study?

1 DR. SHEPARD: That will be done by contract.

2 MR. MILFORD: Other than Dr. Spivey?

3 DR. SHEPARD: Dr. Spivey association with this

4 effort, at least in this phase, has been

5 terminated.

6 MR. MILFORD: So, it could be an entirely

7 different contractor?

8 DR. SHEPARD: It will be.

9 MR. MILFORD: You're sure it will be?

10 MR. CONWAY: We're going to be issuing a

11 separate RPF, requesting proposals to be submitted by

12 potential contractors, who wish to conduct the pilot study.

13 Whomever -- we don't know who that will be, until we get

14 the proposals submitted.

15 It may or may not be UCLA. It may be some other

16 organization. There's no prior selection or determination

17 as to who is going to be qualified to bid or who is not

18 going to be qualified to bid.

19 And, we won't know who -- even the pool of

20 contractors -- potential contractors will be until after

21 we get the responses to the RFP.

22 DR. SHEPARD: Excuse me. -- First I think the

23 question -- the problem of identifying cohort of exposed

24 veterans has been a critical issue, I think -- a critical

25 issue since Congress ordered the VA to do an

1 epidemiological study almost two years ago. Question: A
2 year ago -- during Senate hearings, re Dr. Spivey's protocol,
3 critics of the Agency called for independent
4 epidemiologists to develop such a protocol, rather than
5 having the Defense Department go ahead without
6 expert assistance.
7 Now, we are told that the VA has just begun to
8 develop the protocol with the work group. How does the
9 VA defend the extraordinary inability to anticipate the
10 scientific difficulties that others saw all too clearly
11 years ago? Also, what prompted the VA to decide now that
12 epidemiological help was needed to develop an exposed
13 cohort?
14 Well, I think that-as I tried to indicate earlier--
15 that the process of cohort selection has been evolving
16 over some time now. And, part of that process has been
17 the elucidation of new information which colors the process.
18 So, what was thought to be an appropriate cohort
19 selection procedure a year ago, may no longer be all
20 together valid. I think that's part of the
21 explanation.
22 We also are hoping to have on board a group of
23 individuals experienced in the whole area of major
24 epidemiological research, as I also indicated earlier.
25 And, in the mean time, we have solicited expert opinions

1 from within the federal government and outside of the
2 federal government; this group and other individuals,
3 in order to grapple with some of these more difficult
4 questions as they related to sampling and cohort selections.
5 MR. MILFORD: If I might follow up on that, it
6 will -- this December will be three years since Congress
7 ordered the VA to do the epidemiology studies. Since that
8 time and before that time, the question of who was
9 exposed was probably the most pressing issue. On that
10 point, the VA could have hired some three years later an
11 epidemiologist to conduct the work that needs to be done
12 to assist in developing this cohort. Now we are talking
13 now about a process that will take months into the future
14 to develop the cohorts -- a problem that has been around
15 for three or four years.
16 DR. SHEPARD: Well, it was hoped
17 that the UCLA contract would have answered most, if not
18 all, of these questions. I guess that may have been
19 somewhat unrealistic, but nevertheless that was our hope.
20 We thought we hired the best minds in the Country to do
21 that work for us.
22 And, without casting dispersions on the UCLA
23 effort, I think the complexity of the problem was not
24 fully anticipated. And, UCLA, I think, gave it its best
25 shot, but there are still some unanswered questions.

1 And, we had no way of -- of determining what
2 those unanswered questions would be when we awarded the
3 contract; nor even when the contract was completed, until
4 we went through this review process.
5 So, all I can say is that we are continuing our
6 efforts at cohort selection. We think we are a lot closer
7 to it than we were a year ago or even six months ago.
8 Dr. Hodder has been working very hard
9 grappling with some of these points that were not clarified
10 in the UCLA protocol.
11 MR. MILFORD:
12 What was the nature of the
13 new data that has just recently come to light that caused
14 you to get expert help?
15 DR. SHEPARD: That's
16 not the impression I tried to make.
17 What I said repeatedly this morning, I think, is
18 the whole process has been an evolutionary process. I
19 don't think there's any startling new data that has just
20 come to light. If there is any, I'm not aware of it. And,
21 I certainly didn't try to imply that that was the reason
22 for now having to recruit
23 expertise in this area.
24 MR. MILFORD: Well, I'd like to clarify this.
25 It seems to me that the same information which was

1 available months or years ago, that should have prompted
2 you then to seek the help that you're now seeking. Why
3 wasn't that done? Why do we have to wait probably another
4 year and a half before you figure out who was exposed?
5 DR. SHEPARD: Again, you have misunderstood
6 my -- I thought -- lucid attempted explanation. We hope
7 to have the cohort selection protocol -- the cohort
8 selection protocol -- the methodology to select the cohorts
9 for the study completed within the next six weeks, not a
10 year and a half from now.
11 MR. MILFORD: Then, how long after that will you
12 have your cohort selection?
13 DR. SHEPARD: I'm sorry. I didn't hear you.
14 MR. MILFORD: You have a protocol to do.
15 DR. SHEPARD: Yes.
16 MR. MILFORD: How long will it then be before
17 you confirm the ramifications -- of using the protocol?
18 DR. SHEPARD: I'm sorry -- the proper what?
19 DR. YOUNG: How long will it take to select the
20 cohort once the process is ready to start?
21 DR. SHEPARD: Okay. The expert on that question
22 is in the room; and, maybe I can call on -- once again
23 Mr. Dick Christian. He
24 hasn't seen the protocol. So, it'll be difficult for him
25 to answer exactly. But, I think he may be able to give

you a better ball park figure than I.

MR. CHRISTIAN: First of all, the Army Agent Orange Task Force is prepared to start right now. So that once we're given the order to seek these cohorts, we'll have them for the pilot study in six months.

MR. MILFORD: Thank you.

DR. SHEPARD: Are there any other questions from the floor? We still have a few minutes. Yes?

MR. MILFORD: I'd like to ask one last question.

DR. SHEPARD: Of course.

MR. MILFORD: I'd like to follow on the testimony of the gentleman from Australia and also to some extent the jury case that was cited last week. A recent Congressional report on the super-fund legislation, that is the legislation that dealt with--hazardous wastes and chemical exposure, has recommended to Congress that it's virtually impossible for people in cases of chemical exposure to prove individual cases of cause and effect. Their recommendation to Congress is that a series of presumptions be established on exposure. Any other system is unfair to the individual.

Has the Agency given any consideration to adopting a series of presumptions on -- exposure and causation -- to shift the burden from the veteran to the government like the Australian cases? And, does the Administration have any comment on whether the existing system is fair to veterans?

1 DR. SHEPARD: Your question is really outside
2 of my personal expertise. That is a claims adjudication
3 question that is really not under our purview
4 I'm, first of all, not personally familiar
5 with that document. Fred, are you? Can you shed any
6 light on that?
7 MR. CONWAY: My understanding -- correct me if
8 I'm wrong -- but -- in the proposal, it is pretty much
9 known what the result of exposure is. You just don't know
10 who, within the exposed population, in fact, experienced it.
11 Is that the one you're talking about?
12 MR. MILFORD: No. It deals with the same problems
13 as the exposure to chemicals and the cause is unknown.
14 It is recommended that the government establish presumptions
15 of causation and exposure so the
16 individual himself or herself does not have to bear the
17 burden of proof. It's that question that exists in this
18 case. The question is whether the VA is doing anything to approach that?
19 DR. SHEPARD: I'm not quite clear, Lew. Who
20 made the recommendation? Is that in the statute --
21 established super-fund legislation?
22 MR. MILFORD: I think it's irrelevant who made
23 it.
24 DR. SHEPARD: Well, it isn't irrelevant who made
25 it, I don't think.

MR. MILFORD: It's a mandated group that's made recommendations to Congress on super-fund. The point of it is it's a system of presumptions of shifting of burden to government rather than laying them on the individual. I think that's a fair system. Is it a fair system -- a fairer system than the one you do have now.

DR. SHEPARD: Well, as I indicated earlier, I -- I'm not fully familiar with that legislation or really that process. I can assume that somebody in the VA is aware of it and is taking that under proper advisement. But, I can't personally.

Are there other members of the Committee that have any knowledge of that or can shed any light on this?

Are there any other questions from the floor? If not, I thank you very much for your patience and indulgence. Okay.

(Whereupon, at 12:00 p.m., the meeting was adjourned.)

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

(Fourteenth Meetings)
November 30, 1982

March 1983 Washington DC 20420

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

Veterans Administration Central Office
Room 119
810 Vermont Avenue, N. W.
Washington, D. C. 20420

November 30, 1982

PENGAD CO., BAYONNE, N.J. 07002 · FORM 740

TRANSCRIPT OF PROCEEDINGS
VETERANS ADMINISTRATION
ADVISORY COMMITTEE ON HEALTH-RELATED
EFFECTS OF HERBICIDES

Veterans Administration Central Office
Room 119
810 Vermont Avenue, N. W.
Washington, D. C. 20420

November 30, 1982

The Committee met, pursuant to notice, at 8:30 o'clock, a.m., BARCLAY M. SHEPARD, M.D., Chairman presiding.

MEMBERS PRESENT:

BARCLAY M. SHEPARD, M.D., Chairman
Acting Director
Agent Orange Projects Office (10A7)
Veterans Administration Central Office
Washington, D.C. 20420

ADRIAN GROSS, PH.D.
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CALL TO ORDER AND OPENING REMARKS

DR. SHEPARD: Ladies and gentlemen, welcome to the 14th meeting of the VA Advisory Committee on Health-Related Effects of Herbicides. We're very happy to have you all here. We have a fairly full agenda, as usual, today, so I will proceed. I'm delighted that we have our usual full house of visitors and we're particularly pleased that as many members of the committee are present as could make it. We have, we are particularly pleased today to recognize the presence of a number of representatives of state Agent Orange organizations. They will be represented later on in the meeting by Robert Santos, who will speak on behalf of the relatively newly organized coalition, or association, of these organizations. I don't know whether they have an official title yet.

As you know, we've been working with the various state organizations in, I think, a close cooperative spirit and we're delighted to have you ladies and gentlemen here again this morning. Later on in the day the state representatives will be meeting with Mr. Alvarez to discuss some special concerns that they wish to bring to the attention of the administration.

We also will be hearing from Dr. Donald Custis, our Chief Medical Director, who will have some announcements to make which I think will be of interest to all of you.

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There have been a couple of last minute changes on the agenda. Unfortunately, Lt. Col. Brown from the Air Force was not able to be with us because of a conflict in schedule and the Air Force's Health Studies report will be given by Major Alvin Young.

At the last minute, Dr. David Erickson from CDC was unable to come, but he has sent his very able assistant, Dr. Joe Mulinare and he will give us the report on the status of the CDC Birth Defect Study. We are happy to have you here Dr. Mulinare.

For those of you who have not had a chance to do so, will you please sign in at the guest registry in the lobby to register your presence here. We're always interested to know who is attending our meetings and its very helpful for us to have that information. As usual, we will have a question and answer period at the close of the formal agenda and we would encourage all of you who have questions to write them down on a card. Don Rosenblum will circulate among you to provide you with cards and pencils and collect your questions so that we may have them at the end of the formal session.

I have an important announcement to make in that recently Dr. Raymond Suskind has sent in a letter of resignation. His very busy professional schedule has made it difficult for him to take an active role, as active a role

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in the activities of this committee and he felt that it would be best he resign from the committee. He has very graciously, however, consented to continue to be available on an as needed basis for counsel and advice. We certainly thank Dr. Suskind for efforts on behalf of the committee and his presence will be missed.

I see Dr. Custis has joined us and I think because of Dr. Custis' very busy schedule, I'll ask him to address the committee now. Good morning, sir.

DR. CUSTIS: Good morning. Well, its been a while since I last met with you and I was just anxious to do so today because of changes underway in the epidemiology study.

There are some things on my mind that I wanted to pass on to you.

First of all, I wanted to express my appreciation. I hope you are assured how much we have and do appreciate the help you're providing us and have given us over a long period of time. It doesn't seem possible that we've been split over the Agent Orange now for 5 years. I'm sure you're all informed about the pending transfer of responsibility for the epidemiology study to CDC.

Let me recapitulate for you. The VA came into more and more criticism, mostly for the time lag in getting

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on with the study. In fact, our credibility has been under challenge now for some time, as you all know.

The House Oversight Committee, probably stimulated by Congressman Daschle, reached a consensus that was expressed in a letter to the Administrator from Chairman Montgomery, suggesting that everyone's purpose would be better served if the responsibility for this study were passed to a non-VA agency and that there would always be, even at best, a perception of conflict of interest were the VA to continue as the responsible agent. The Administrator intitially was reluctant to agree, understandably. I'm sure, well, this has been expressed in the media by some individuals, the VA's willingness to transfer the study was interpreted as still another manifestation of the VA's lack of interest. Of course, that is patently not true.

But, to make a long story short, the Administrator did agree and I too agreed, that all things considered, whatever the ultimate outcome of that study, it would have greater acceptance if the VA were not involved. Those of you who attended the Congressional hearing which antedated this decision, will recall that representatives from CDC manifested some interest in doing the study or, at least, went so far as to say they could do a quicker job of it. CDC now is going to do the study. We have had a couple of

meetings with Dr. Brandt and Dr. Hardy discussing the nature of an interagency agreement. It hasn't been consummated yet mainly because Dr. Brandt's interest to have an informed estimate as to the resources required. The VA will have just one responsibility and that is to continue to be the vehicle for resources passing through our budget to the CDC towards this study. The reason for that is, that the VA committees in Congress are anxious to maintain jurisdiction over the study and with that budgetary arrangement, are assured of having that continued oversight.

Similarly, HHS is interested in such budgetary arrangement in order not to risk having to divert other resources to support the study. They are more assured of line item budgeting with this arrangement. I think we are close enough to an agreement that I would hope it would be signed before the first of the year.

Meanwhile, you've also witnessed over a period of time, different organizational arrangements within the VA regarding Agent Orange responsibility. When Chuck Hagel was Deputy Administrator, because of his interest and because of the Administrator's interest in providing Chuck with specific Agent Orange responsibility, a second office was created in the Administrator's staff. The simplest explanation for the current reorganization is that there

will be no continued duplication of responsibility. The sole responsibility for Agent Orange program will rest in DM&S.

We have been, for several weeks now, pursuing the recruitment of an epidemiologist to serve on a full-time basis. We have had the part-time services of Dr. William Woodward as an epidemiologist and also Dr. Susan Mather, but they have not had full-time assignments. We would like to acquire a well-qualified epidemiologist who will be available for employment on a full-time basis to assist us in our bio-medical research pursuits.

There is just one more thing I would like to address. One of our Advisory Committee members has recently asked to be relieved of his responsibility and he's written a letter explaining his reason for doing so. He said that he didn't think the Advisory Committee was able to accomplish its full potential simply because of the open meetings and the very popular attendance at these meetings. That if the nitty-gritty of the scientific aspects of Agent Orange were to be addressed, this was not the way to do it. On the other hand, I think you'll all agree that this serves a very valuable purpose, having these open meetings and having attendance from all of you who have your own constituencies.

I think the reasonable compromise is, hereafter, to keep this format, but to add to it an executive session. I hope you'll all understand the reason for my asking you to go into this type format. We cannot hold an executive session unless it is announced ahead of time in the Federal Register. The next meeting announcement will list an executive session. We'll see whether the expertise present around the table can address some of these problems in a little more depth and with a little more accomplishment than afforded by the open meeting that we've been experiencing so far.

I would be happy to receive any comments. I hope I have given you a satisfactory explanation for what it is we want to do.

MR. GROSS: Let me say something, because I think that's an excellent idea. In fact, in the past Dr. Shepard has, on occasion, needed the committee's advice on various problems --. I mean I could think of several instances that, in fact, this has been done in the past and worked very well and I think the open forum here very useful in that we get input from Veteran's organizations--individuals in the field and so on. It's very informative, but I also agree with you that those executive sessions where we can sort of let our hair down in the give and take

of science. I think that's an excellent idea.

MR. WALKUP: I think one of the roles of the Advisory Committee is scientific information and I can recognize what you're talking about. Try to give some chance for scientific dialogue in the course of analysis of what some of the proposals are and the things that you were talking about. Another role of the Advisory Committee, I think, is to give concerned veterans and Veteran's organizations the opportunity to have some input in the decision process that is taking place --. In a lot of ways what's happened here is because of those organizations and because of those things and I think there is a valid interest and role for that kind of input. And I would be concerned that by closing the meetings, some of that could be lost.

DR. CUSTIS: Let me say again, I hope I'm not misunderstood. I am not proposing the entire meeting be closed, but to continue like this and at the tail end of the meeting to go into Executive Session and to have a portion, a minor portion, of the meeting a closed session. I didn't mean to discontinue the open session.

MR. WALKUP: Could you be more specific about what agenda items would come up in the Executive Session?

DR. CUSTIS: I think you could answer that as well as I could. The research that we have underway, the scientific aspects of that research. You would be free to

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use scientific language not completely understandable to everyone attending an open session. I think you will be more free to give us your hard scientific opinions. If you find such arrangement does not lend itself to greater accomplishment, why that's up to you. As I say, this was precipitated by one individual expressing the feeling there was something missing in our utilization of the committee.

DR. WOODWARD: My name is Woodward. I'd like to speak to that point. I chair a committee, a lay committee, known as the Armed Forces Epidemiological Board. We have open meetings and minutes are kept. Also, there are smaller meetings, executive sessions. These smaller meetings are participated in by persons who possess knowledge of the pertinent problem. If there were no smaller meetings, we would not accomplish our task. Nothing is discussed in the executive meetings which is not open information. Minutes of the general session, the executive committee meeting and specialized --groups are recorded and published. I would certainly support the Chairman, Dr. Custis, in that much can be accomplished in a shorter time with smaller groups: certain problems cannot be fully discussed comprehensively in large open meetings even if scientifically-qualified persons are present.

DR. CUSTIS: Dick?

DR. HODDER: I think I may be able to clarify something here. First of all, you are proposing that the total committee participate in this executive session, right? Well, any time that you have a closed meeting, immediately there is a suspicion on the part of some, that material is being brought forth that the public should know. I believe that if you have the full committee participating in this, you have sufficient representation here of Veteran's interests that this suspicion should not be paramount and that the members present on this committee who do represent veteran's interests would be sure to make it known.

DR. CUSTIS: Plus the fact that as Dr. Woodward says, the minutes of the closed session will also be published. Yes?

MS. FARR: Gentlemen, my name is Sandra Farr. First, I apologize for my appearance. I've been driving from Atlanta all evening. I see a great deal of sympathy that you have toward the Vietnam veterans, but what about the widows and the children left behind? I just lost my husband in June with no insurance policy --, I get no benefits from the VA. I live off of the Social Security check and I have a 4 year old daughter to support. What about us? We have a right to something too. We'd like an education. I sat at home for 4 years and nursed my husband because he couldn't get service-connected to do this, to have the VA

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call me the day I buried him and say, can we deliver the hospital bed you requested? I think the process is a little too slow. I have a daughter that doesn't understand where her father is. I don't have the training or the money to go out and get the training I need to get a good job and I think I'm being treated extremely unfairly by the slowness of the process. I have filed appeals several times over. --from Atlanta, Georgia -- to try to get service connection benefits. I was turned down on the state level. For somebody that doesn't have anything, I was cut off completely and have been ignored. I have stacks of papers -- the VA here in Washington that say I'm entitled to nothing until I prove service connection. Why do I have to prove service connection? Why can't you prove that its not?

DR. CUSTIS: You know I think all of us listening to you have an empathy for what you're saying. There are avenues to--are you talking about Agent Orange now?

MS. FARR: Yes, sir, I am.

DR. CUSTIS: Tom?

DR. FITZGERALD: I deal with the Board of Veteran's Appeals. My capacity is representing the American Legion. And this is what we are pursuing, trying to obtain for the veterans a decision as to whether there is any relationship between Agent Orange and the illnesses that the veterans have brought forth as supposedly related to it.

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1 Unfortunately, the law is such that in this country a pre-
2 sumption cannot be made of a relationship, it has to be
3 proven to be definitely related. That is the whole work
4 that we're trying to do here in these committees, to prove
5 that there is some relationship or that there is no relat-
6 tionship. --
7 MS. FARR: What about our children? We have no
8 place to carry our children for testing.
9 DR. FITZGERALD: There are laws that are control-
10 ling the compensation and the benefits. I would suggest
11 that you work with your service organizations in Atlanta
12 to keep you posted as to what you are entitled to at this
13 point and what we are trying to get for you in the long run.
14 MS. FARR: The only thing I'm entitled to is to
15 appeal to you on this level. I'm not allowed to appeal
16 on the state level any further. I've appealed -- on the
17 state level.
18 DR. FITZGERALD: In order to appeal further --
19 MS. FARR: I don't have the money to come to
20 Washington and stay until --
21 DR. FITZGERALD: No, I understand your problem
22 and I'm very sympathetic to it, but what I'm trying to
23 bring to you is the realistic facts that govern the situa-
24 tion. In order to come to a secondary appeal before the
25 Board of Veterans' Appeal, you will have to bring forth

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more scientific information to confirm your claim. This is the whole purpose of what we're trying to do here, that is to see if there is scientific evidence to support your claim.

If we can get that scientific evidence, then you will be allowed to make a secondary appeal in the future and that's what we're trying to do.

MS. FARR: Is there anyone I can see today who can help me with this? I've brought all the information that has been requested this morning, which is correlation of animal testing of Agent Orange and correlation to what it does to human beings. My husband's autopsy results are astonishingly similar to findings that were found in 1969, '70 and 71 in published books. And a 26-year old man doesn't have a heart the size of 75% of his chest for no reason.

DR. SHEPARD: Excuse me, madam. I have a special session at the end of the agenda for questions and answers, but beyond that I will be available to talk to you at the close of the meeting. Ok?

MS. FARR: Yes, sir.

DR. SHEPARD: Thank you. Again, I thank you very much. Does anyone have any comments? I'd like to move on with our prepared agenda now and call on Mr. John Hansen who will give us a brief comment on the recently concluded GAO report. John? Excuse me, by the way, I hope that all members of the committee received their copies and have had

a chance to look at them. You may have some questions concerning the report following John's comments.

MR. HANSEN: Thank you, Dr. Shepard. I appreciated your invitation to come before the committee this morning, to give you a brief summary of the GAO's recent report on VA's Agent Orange examination program. Because of time, I am not going to discuss the whole report, but I will focus on three of VA's Agent Orange related activities. Namely, examinations at VA medical facilities, the computerized Agent Orange registry and VA's efforts to provide veterans with information on Agent Orange and their health.

To assess VA's Agent Orange examination program, we visited 14 VA medical facilities around the country. There we interviewed about 100 physicians and we reviewed a randomly selected sample of about 1300 examination records. In addition, we obtained veteran's views on the examination program by sending questionnaires to about 1100 randomly selected veterans who were examined during 1980. We had about an 88% response rate to those questionnaires. The majority of the questionnaire respondants were dissatisfied with their Agent Orange exam. Generally, the veterans complained that their exams were not thorough, that they were provided little or no information on Agent Orange and that VA personnel showed little interest in their health.

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Although a comparison of a sample of the questionnaire respondents with their examination records showed the exams to be more thorough than the veterans perceived them to be, our discussions with VA physicians and a review of the exam records at the medical facilities we visited confirmed the veteran's complaints. Only one of the 14 facilities we visited was adequately following VA directives to gather additional information on past or present health problems reported by veterans.

Furthermore, most exam records lacked documentation that a complete medical history was elicited and that all body parts and systems were examined. Only 10% of the medical histories and 36% of the physical exams met VA's own standards for thoroughness. Two factors which may have contributed to this problem are the poor design of the exam forms and a lack of knowledge by some VA physicians conducting the examinations about the potential symptoms of exposure to Agent Orange or the objectives of the exam program itself.

Another factor relating to the examination thoroughness is the lack of a monitoring program to assure the quality of care provided veterans obtaining Agent Orange examinations. The VA Central Office had no monitoring program, and environmental physicians at the facilities we visited were not generally reviewing exam records for

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thoroughness, despite VA directives that they do so.

One area in which the VA has made some progress is in reducing the examination backlog. However, as of the end of July, 1982 about 46% of the 172 VA facilities still had more than a one month backlog of examinations. Since January, 1980, the VA spent about $3 million on the computerized Agent Orange registry. Although the registry was established to determine what health problems Vietnam veterans were experiencing, and to facilitate follow-up contact with those veterans who were examined, it cannot, in its current form, accomplish either objective.

The registry lacks specific information on veterans' health problems. As a result, the registry cannot tell how many cases of chloracne, soft tissue sarcomas or malignancies have been found in veterans examined. Nor can it describe the birth defects reported in veterans' children. Furthermore, VA's Inspector General, concluded that the registry contained inaccurate and unreliable information which compromised its value and integrity.

Because the computerized registry lacked veterans' addresses, separate mailing lists had to be developed so the VA could contact those veterans that had been examined. Although the registry's deficiencies could be corrected, the corrections would be costly and the data still could not be used as a basis for scientifically valid

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conclusions about veterans' health. Discontinuing the registry could save over a million dollars a year. About 80% of the veterans responding to our questionnaire were dissatisfied with the information the VA provided them.

Although VA has prepared informational materials such as pamphlets and videotapes, VA medical facilities we contacted by telephone did not generally offer to send us a pamphlet or tell us the videotape was available for viewing at the hospital. For example, only 24 of 112 VA medical facilities we contacted in our telephone survey, told us that the pamphlet was available at a VA hospital or offered to send us one. This is a franked pamphlet and all that you need to do is put a veteran's name and address on it. In addition, only 2 of the 112 facilities we contacted told us the Agent Orange videotape was available at the facility for them to review.

While VA had not effectively advised veterans of the availability of information materials they had prepared, state outreach efforts, on the other hand, have been much more successful in assisting and encouraging veterans to obtain information and an examination from the VA. Although VA established a requirement to provide veterans their examination results in 1981, many of those who were examined before that did not receive their results. We recommended that VA contact veteran's examined before

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January 1981 and tell them how to obtain their exam results if they did not receive them. The VA disagreed with our recommendation because they felt contacting these veterans and telling them how to get their exam results would cause undue alarm.

I would like, for a moment, to address some of VA's comments on our report. In their comments on the draft of our report, which are included in an appendix to the report, and in a more recent Agent Orange status report, which is a report the VA regularly disseminates, the VA has criticized our methodology, analysis and conclusions, suggesting that we used old data, and that the deficiencies we had identified, had long since been corrected. However, VA's comments were both inaccurate and misleading. For example, VA said that our report did not reflect corrective actions they had taken , such as the reduction of the exam backlog.

However, on page 15 of our report, we acknowledge the VA has made progress in accomplishing this objective. Furthermore, VA said that our report failed to discuss veterans' expectations of the examination, when we discussed this on page 31 of our report and explained that there is a need for the VA to better inform veterans of the exam's limitations. In fact, this was a recommendation that VA agreed with. VA said that we failed to discuss it in our

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1 report.

2 Although VA says that they have already taken
3 actions to correct deficiencies in the examination program
4 before our report was issued they failed to point out that
5 many of their actions were taken only after they received
6 a draft of the report. In an August 13, 1982 nation-wide con-
7 ference call, which was one week after they received a
8 draft of our report, and in a September 30, 1982 information
9 letter that was sent to all VA facilities, VA directed its
10 medical facilities to implement many of our recommendations.

11 VA also disagreed with our recommendation to dis-
12 continue the computerized Agent Orange registry and has ad-
13 vised us that they intend to expand the registry. Such a
14 decision should only be made after weighing the answers to
15 several serious questions. How much will it cost to expand
16 the registry? Will VA recode the 97,000 examinations that
17 have already been conducted and are in the registry? What
18 affect will the poor documentation of examination records
19 have on recoding? Will veterans have to be re-examined in
20 order to have their exams recoded and then put into the new
21 expanded registry? And, finally, since VA has made little
22 use of the registry to-date, what use does it intend to make
23 of an expanded registry? I'd be happy to answer any of
24 the committee's questions. Dr. Shepard --

25 DR. SHEPARD: Do any members of the committee

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have any questions or comments on the GAO report? Yes, Dr. Lingeman?

DR. LINGEMAN: I'd like to ask who the GAO examiners were, the ones who visited the hospitals and examined the hospital records and talked to the physicians and talked to the veterans. What were the qualifications of the examiners?

MR. HANSEN: None of them were physicians. GAO has a medical advisor with whom all our audit tasks were discussed. We basically took the standards VA set out in their own circulars, which discussed what the medical histories and the physical examinations should cover, including specific systems and specific parts of the body about which examining physicians should gather specific information. When we reviewed the records, we applied the standards that VA, themselves, had developed. We looked to see whether or not the specific medical history and physical exam factors they said should be covered were documented in the medical histories and the physical exams we reviewed.

We used a very liberal interpretation of coverage by VA physicians. If there was ever any question as to whether or not a particular item was covered, the physician who did the examination was contacted and the matter was

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1 discussed with him. If there was any doubt, the physician
2 was given credit for covering that item. Furthermore, we
3 discussed these results with the physicians at each of the
4 facilities we visited, as well as with the Chiefs of Staff
5 and the environmental physicians.

6 We feel that this represents a very conservative
7 view. Every benefit of the doubt was given to the VA phy-
8 sician. The standards that are set out in VA circulars
9 are fairly explicit. All I would think one needs to do to
10 see whether those standards were applied is to be able
11 to read.

12 DR. SHEPARD: Dr. FitzGerald?

13 DR. FITZGERALD: Mr. Hansen, I'd like to pursue
14 Dr. Lingeman's question. You have said that there were no
15 physicians represented but you did have a medical consult-
16 ant. You did not address the further part of the question
17 as to what were the qualifications of the individuals that
18 were doing this examination?

19 MR. HANSEN: Well, the qualifications of the in-
20 dividuals was that they were familiar with the standards
21 that the VA said should be met in the examinations.

22 DR. FITZGERALD: In other words, they knew about
23 the paperwork, but what were their qualifications as far as
24 going into a hospital and examining procedures in hospitals?

25 MR. HANSEN: Well, I'm not sure what you're

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1 referring to Dr. FitzGerald. We're talking about reviewing
2 the medical records where there are lists of medical
3 history questions, and determining what medical history information
4 was elicited, and whether they elicited the required information,
5 whether veterans reported health problems and whether follow-up
questions were asked. A
6 physical exam form lists 21 items at the top and says, de-
7 scribe each of these. All one needs to do is read
8 --

9 DR. FITZGERALD: That's not true, sir. That is
10 not true that all they have to do is read. They have to
11 interpret and that's what I'm getting at. In order for
12 your report to have validity, we have to know about your
13 interpretation and the ability of the individuals to inter-
14 pret and I think that's what --

15 MR. HANSEN: Certainly. Dr. FitzGerald, when
16 there was ever any question about any entry in a medical
17 record, that was not understood, we had the administrative
18 medical records staff and the physicians available to
19 us.

20 DR. FITZGERALD: May I repeat my question? What
21 were the qualifications of the individuals?

22 MR. HANSEN: The individuals were GAO auditors.

23 DR. FITZGERALD: Thank you.

24 DR. SHEPARD: Any other questions or comments
25 from the committee? Yes?

1 MR. WALKUP: I think we share some similar con-
2 cerns. We have for a while. Some of your information,
3 whatever its validity, concurs with some things veterans
4 have been concerned about for a long time. You are open
5 to the same criticisms that we are, I think, that your re-
6 port is basically saying no to what's been undertaken and
7 what was attempted was to generate some information about
8 something that people didn't know very much about before.
9 You're telling us all the reasons why it hasn't worked,
10 coming out of your report, do you have any recommendations
11 on how to generate the information that is being tried by
12 the registry? How can we get to the place that you're re-
13 ferring to? --
14 MR. HANSEN: Well, I think that in order to make
15 a decision on what should be done with the registry,
16 the VA has to take a serious look at the cost of
17 compiling the registry and the uses it intends to make of
18 it. Unless there is going to be some sort of use of the
19 data in an expanded registry that can justify spending
20 millions more dollars after 3 million have already been
21 spent, I would say that there is no alternative but to
22 discontinue the registry.
23 I would want to point out that we do not say the VA should
24 stop examining veterans who are concerned about Agent Orange.
25 On the contrary, we think that that should continue and we

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1 feel that that can be very productive, if the necessary
2 monitoring and quality assurance measures are taken to ensure
3 that the exams are thorough and timely.
4 DR. SHEPARD: Dr. Hodder?
5 DR. HODDER: Did you check back on the exams and
6 identify people with illnesses and then go back and see
7 whether those were missed?
8 MR. HANSEN: I'm sorry, I don't understand the
9 question, to see whether they were missed?
10 DR. HODDER: In other words, if you found that
11 veterans who had actual complaints, who had had the exams
12 and physical abnormalities and yet those were not picked up
13 by the exams. Did you find that out?
14 MR. HANSEN: No, we didn't question whether or
15 not the physician detected or missed a particu-
16 lar health problem in a veteran.
17 DR. HODDER: Because I think the thing that both
18 Dr. FitzGerald and Lingeman were getting at is that there
19 are two ways of looking at the quality of medical care.
20 One is process and one is outcome. Physicians, particular-
21 ly in physical exam situations, they're recording a large
22 volume of predominantly negative information and hence, take
23 short-cuts. And, if you evaluate the process of how good
24 at recording they are, I can almost guarantee you before
25 you start that you're going to have a very poor result.

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1 The real question is the outcome. When I looked at this,
2 did I find real things missed? Having done service physi-
3 cals, 80 a day, etc., you develop a shorthand of your own.
4 I think the real question is, do I pick up everything I
5 should pick up? I don't know that I can use an auditor's
6 evaluation of how complete a medical record is filled out
7 as a valid way of looking at the accuracy of the health
8 care.

9 MR. HANSEN: I think its important to note, Dr.
10 Hodder, that we did have physicians at 4 of the facilities
11 we visited who admitted to us they did not elicit a complete
12 medical history from the veteran. By the same token, be-
13 cause of the point that you made in doing a physical exam-
14 ination with a lot of factors to cover, many negative items
15 would not be caught. We focused on cases where the medi-
16 cal record indicated that the veteran reported a past or a
17 present health problem. The VA directives that were sent
18 out were very specific in the information that was to be
19 gathered in those cases and there were four particular
20 areas that they were supposed to explore. In two of those,
21 only 55% of the health problems indicated in the record had
22 any coverage and the other two, it was only a third. And
23 that was our primary focus as far as the thoroughness ques-
24 tion was concerned. Cases where veterans reported physical
25 problems and the directives that the physicians were

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provided indicated that it was important to gather additional information on these questions, rather than just the longer list. As far as abbreviations are concerned, we did have, again, access to all the physicians. We did have medical abbreviation lists. We had medical administrative staff working with us at each of these facilities. If there was any question or something we didn't understand, we went to whomever we needed to go to to get an answer. We'd go all the way back to the physicians, if necessary, and, in many cases, it was.

DR. HODDER: I guess I would sum it up by saying that, to me, what the result has done is suggest that it may be a problem. I don't think its confirmed the problem. Its like starting a hypothesis again. Now you would have to go back and start with known illnesses and see if those are, in fact, missed. I think you've documented a process problem and I would have to look to an outcome problem.

DR. SHEPARD: Any other comments or questions? I just would point out that we continue to deal with the GAO report. I thought it was important to bring it out at this meeting for the sake of the members of the committee, to afford them the opportunity to comment on it. I do feel that if the study would have been done in the manner which I originally suggested, that is that two groups of individuals be

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examined, those examined early in the process, where

information and directives are going to be relatively fresh and compare it to a group that were more recently examined, we might have had the opportunity to see if an improving trend

Unfortunately, that suggestion was not taken. I think that that is unfortunate. We have a report that is based largely on information that was gathered in the relatively early stages of our Agent Orange Registry.

Point number two, we've taken very seriously the recommendation that we discontinue the computerized We have decided not to concur with that recommendation and I'd also like to comment on the term that John has used in the matter of expanding the registry. I think that's a little misleading, particularly when he says that going to cost a lot more. My view is that the registry process, that's the process in which we will automate the information which flows from the examination process, will be streamlined, will be brought to more useful information. But, the encoding process will be much more streamlined, so in my view, we ought to see a decrease in cost. I don't know, that's just a hunch and obviously, we won't know that until we get the process underway. But, I think its probably not valid to make the assumption that if we continue the

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1 registry, its going to cost more money than it has cost in
2 the past. I view the automated portion of the registry as
3 very important and to that end, we've been working very hard
4 in streamlining it and making it a more useful effort. And,
5 on that point, I'm happy to announce that the revised regis-
6 try process is now in the hands of OMB for review and we
7 are hoping very much to get it out in the field before too
8 long.

9 The other part of John's concern about our address
10 list, we have now sent out the follow-up circular
11 that was disseminated in August of this year, in which we
12 will develop an automated mailing list and we'll also send
13 out brief health questionnaires. So, in the next few months,
14 we'll have what we think is good, valid information regard-
15 ing the current health status of veterans who have been in
16 the registry since its inception. I think that will give
17 us some information in terms of what the pro-
18 gress of the health of the veterans in the registry has
19 been since their initial examination.

20 DR. LINGEMAN: Dr. Shepard, I believe that the
21 Registry should be continued.

22 We need some record in the central office
for keeping a handle on diseases occurring in this group. For
23 example, do we have any soft tissue sarcomas
24 in the Registry? Those questions could not be answered
without some sort of Registry. The Registry
25 could be made more

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1 useable.

2 MR. HANSEN: Dr. Lingeman,

3 the registry wouldn't tell you how many

4 soft tissue sarcomas occurred in veterans. In fact, the

5 registry doesn't even tell you how many people have benign

6 or malignant tumors.

7 DR. LINGEMAN: There is some information to be

8 gained. I think if there have been a lot of soft tissue

9 sarcomas, I think some of them would have appeared in the Registry records.

10 MR. HANSEN: There's no way for them to get in,

11 Dr. Lingeman. That's precisely the point we're trying to

12 make. I think its also important to point out that when

13 VA went back and looked at the incidences of neoplasia

14 reported in the registry, three out of every four entries

15 in there were wrong.

16 DR. LINGEMAN: Then this needs to be corrected.

17 But I know of no other way to keep track, of diseases occurring in this group of veterans.

18 MR. HANSEN: As I pointed out, I think any deci-

19 sion on expanding, revising, continuing the registry need

20 to be made based on very careful cost-benefit analysis,

21 unless there are specific uses that are going to be made of

22 it to justify the cost, we would recommend that it be dis-

23 continued.

24 DR. LINGEMAN: I think it was probably conceived

25 and implemented in haste because of accusations that the

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1 VA was not doing anything. Now the VA is doing something
2 and I think it can be improved.
3 I know of no other way to do this to accomplish the job
4 The GAO has made its recommendation on how this be
5 the Registry could be improved.
6 MR. HANSEN: Well, our recommendation was to dis-
7 continue the registry because, although the problems could
8 be corrected, there was no demonstrated use of the informa-
9 tion.
10 DR. LINGEMAN: How
else will the information from the VA hospitals
11 who examine these veterans get back into a central information system?
12 MR. HANSEN: What is going to be done with the
13 information? That's the question.
14 DR. LINGEMAN: Well, you need to know what diseases
are occurring in these veterans as they are observed.
15 MR. HANSEN: We've been told by this panel and
16 others that the information in the registry is not adequate
17 because its a self-selected sample
18 which cannot be used for scientifically valid conclusions.
19 DR. LINGEMAN: It can be improved and it can be
20 made useful.
21 MR. HANSEN: I don't disagree that corrections
22 could be made in the registry. Its just a question of --
23
24 Well, since in the registry in its
25 current form most cases would require that anyone wanting

to look up specific health problems to go back to the veteran's medical record anyway, it would seem to me that the most important thing is that you have a method of contacting the veteran and being able to locate his medical record at the hospital. You don't need an elaborate registry with a lot of health and service information in it to be able to say that a particular individual was examined at this facility.

DR. SHEPARD: I think we'll have to move on. I think its been a useful discussion and I would like now to call on Dr. Betty Fischmann, who is the Chair of our Chloracne Task Force, to give us a report of her committee's activities.

DR. FISCHMANN: The newly reconstituted Chloracne Task Force of the Veterans Administration has the Chairperson directly responsible to the Director, Agent Orange Projects Office. Dr. Lawrence Hobson of Central Office, Clinical Assistant to Dr. Shepard will render assistance in initiating any of the goals of the task force.

There are three standing task force members and two new members. In addition, a program analyst, based at the Washington VA Medical Center, works full-time with the task force. Funding comes from Central Office and is currently $55,000 divided for medical, housing and travel funds

for special examinations of veterans with possible chloracne, salary for the program analyst, and supplies.

The Chairperson reports formally to the Director quarterly and informally as necessary. The program analyst reports weekly to an administration assistant of the Director. The task force will provide an analysis annually to Agent Orange Projects Office of special examinations for veterans with possible chloracne. The VA Chief Medical Director, Dr. Donald Custis, has given the task force members the following seven goals, tentatively identified as primary activities:

Task Force goal number one: To hold an initial meeting of the reconstituted task force and to conduct appropriately scheduled future meetings. The first meeting will be in New Orleans at the VA Medical Center on Monday, December 6, 1982, during the American Academy of Dermatology Annual Meeting. Subsequent meetings will be held at American Academy of Dermatology Annual Meetings. A second meeting will be held each spring at the annual meeting of the American Federation of Clinical Research, Washington, D. C.

Goal number two: Identification of additional VA physicians to act as dermatology consultants. There are 24 full-time dermatologists in the 172 VA medical centers and 29 part-time dermatologists. The cooperation of all 24 full-time and some part-time dermatologists will be requested as there are 28

medical districts in the VA medical system. Each consultant's duties will be detailed at the first Task Force meeting and will probably involve responsibility for dermatologic examinations of Agent Orange registry veterans, sending copies of examinations to the Task Force, updating procedures as required, advising the Task Force of problem areas, reviewing cases of skin diseases to determine veterans requiring special examination, maintaining close cooperation with the hospital environmental physician, checking that veterans have seen the Agent Orange video tape, are aware of Public Law 97-72, have had a rating for their skin problem and are notified in person and in writing of the dermatologic examination.

Goal number three: initiation of an ongoing review of rating decision sheets provided by the Central Office, Compensation and Pension Service (CPS) to determine possible chloracne cases and recommend selected claimants for special dermatologic examination. To date this ongoing review has been done locally here in Washington, D. C. The CPS forwards any ratings where skin disease is claimed for Agent Orange exposure. The review involves three steps: Step one: the rating decision sheets and, where these are not clear, claims folders are separated by a physician into two groups; (a) cases with any, even slight, possibility of chloracne, (b) cases with no possibility, such as clear cut warts. Step two:

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the claims folders, including compensation, medical and dermatologic examinations in possible chloracne cases are reviewed by a dermatologist familiar with the clinical history and diagnosis of chloracne. The dermatologist divides these cases into those where chloracne is not diagnosable and those where chloracne is likely enough to warrant a more detailed examination.

Step three: veterans with chloracne are offered a special examination by an internist and a dermatologist at one of 3 or 4 outstanding private clinics in the United States of America. The clinic selected will be the one closest to the veteran's residence. The cost of transporting, examination, accommodations and meals will be paid from Task Force funding. The program analyst sets up clinic appointments, transportation, accommodations and disbursement of funds to the veterans and clinics. To date, of 3,200 claimants, 13 have possible chloracne, review of cases is ongoing. Of the 13 veterans, we have been unable to locate 4. Their registered letters came back with no known address. Presently, their Congressional representatives and veterans' groups are trying to locate them. Of the remaining 9, 7 have completed their special examination this month and we await the clinic's report.

Goal number four: provide an analysis annually to the Agent Orange Projects Office of the special

examinations. The format for this analysis will be evolved at the first Task Force meeting.

Goal number five: review and analyze Agent Orange Registry data relating to types of skin conditions being reported by registrants.

Agent Orange data are retained in the medical record of the Vietnam veteran at the examining hospital. Approximately 100,000 Agent Orange examinations have been performed. A spot check of three major hospitals shows wide variation in the numbers of examinations; a Texas VA, 3,000, a Northern California group: 867, 1876 and 253. (The 1876 was felt to reflect the effect of the outreach program in that hospital's area); a Southern VA saw 897 and an East Coast VA 190. The number referred to dermatologists is up to the judgment of the examining physician. The Southern California VA has 897 exams and 893 were seen by a dermatologist at their request. At none of the 5 hospitals were any of those exams done only by the environmental physician, but by a larger group of out-patient divisions.

A major problem in the East Coast hospital is the large number of veterans who failed to show for their examinations. For example, in 1981, 695 veterans were scheduled and 540 failed to show.

Data transferred from these examinations to central computer gives total number of claims per month and divides them into claims with diagnosis confirmed,

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with diagnosis not confirmed, and no disability alleged.

It will therefore be necessary for the Task Force to evolve a system by computer or hand check to analyze the Agent Orange Registry examinations in the medical files.

Goal number six: provide support in the development of a protocol for the diagnosis of chloracne and other possible skin conditions related to herbicide exposure. Two Task Force members are currently reviewing chloracne literature and will report in New Orleans. A provisional questionnaire has been sent to Task Force members to formulate a detailed protocol for diagnosis of chloracne and other skin problems. The protocol will be forwarded to all environmental physicians and dermatological consultants. Thus, there will be comparable examinations for analysis and computerization.

The examination will incorporate new findings and old confirmed by the 3rd International Symposium on Chlorinated Dioxin and Related Compounds in Salzburg, Austria, October 12-14, 1982. New and confirmed findings are: 1) Chloracne may persist in 25 to 50% of cases, up to 30 years, as shown by the longest follow-up to date of an industrial accident. It was previously believed it cleared in a few years. 2) Porphyria cutanea tarda may result from low chronic exposure to dioxin as could have occurred in some Vietnam veterans. Therefore, screening of urine,

stool and any liver biopsy tissue will be done for porphyrins.

3) Hirsutism of the face and hyperpigmentation may be due to porphyria cutanea tarda. 4) Solar elastosis may have an accelerated onset, increased frequency and severity. 5) Skin cancer was statistically significantly increased in exposed Finnish workers. There was no trend for higher mortality in higher exposed groups. Skin cancer will be specially checked.

Dioxin is a co-carcinogen or promoter not a carcinogen in animal experiments. Therefore, veterans who were exposed to Agent Orange and are heavy users of tobacco which is a known carcinogen, or who are subsequently exposed to carcinogens at work or elsewhere shall be followed closely.

7) Dioxin persists in soil mostly in the top 8 cms. and down to 15 cms. Veterans who cleared herbicide foliage and this top soil from the sides of highways in Vietnam to prevent ambush, must be carefully screened and followed. 8) Atherosclerosis may be accelerated. Therefore, skin will be checked for Xanthoma.

Goal number seven: serve as a resource in the development of a monograph on chloracne. To ensure excellence of the monograph, leading national and international figures in the field of chloracne will be approached to

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contribute to the monograph as will be determined at the Task Force meeting.

In conclusion, the major focus of the Chloracne Task Force will be to resolve the health care issue of chloracne in the near future. Systemic toxicity rarely occurs in the absence of chloracne. Resolving the issue of chloracne can only be done by the above outlined aggressive, continually updated approach to locate veterans who may have had and still have chloracne. This is the group at risk from systemic absorption of the most toxic material ever synthesized by man. It is, therefore, the group of Vietnam veterans whose health must be monitored indefinitely. Thank you, Mr. Chairman.

DR. SHEPARD: Thank you very much, Dr. Fischmann. I think you'll all agree that Dr. Fischmann's Task Force has really taken on an ambitious program and we look to the future for some very interesting results. Are there any questions for Dr. Fischmann? Dr. Fitzgerald?

DR. FITZGERALD: Dr. Fischmann, do you anticipate that you will require many skin biopsies?

DR. FISCHMANN: We are requesting all the special examinations have skin biopsies done. At my own hospital, we are currently doing biopsies on any possible chloracne. The recent meeting brought up several suggestions that there may be ways to diagnose it by

histology. Dr. Suskind feels that there are certain features which may be present -- for one. So, we are going to set up a look at histology to see if it is possible to diagnose it by histology.

DR. FITZGERALD: That is the information that has been brought to this panel previously. Are you going to have a central point to which biopsies will be referred?

DR. FISCHMANN: Yes, we will be requesting copies of biopsies go to the Armed Forces Institute of Pathology to Dr. Irey.

DR. SHEPARD: Are there any other questions for Dr. Fischmann? Thank you very much. I'd like to now call on Mr. Peter Currier from AMVETS to give us his report. I apologize for the temperature. I understand they are trying to do something about it. We're in that in between season.

MR. CURRIER: I think has to do with your being from Maine also. Mr. Chairman, members of the committee, we appreciate the opportunity to appear before you My comments will be brief. They center around our concerns about recent developments and developments of the past. There has been much talk recently about the transfer of the responsibility for the study of Agent Orange and, on an ongoing basis, much talk about lamenting over the difficulty of the identification of the Vietnam veteran by

the Department of Defense and the Veterans Administration, among others. We, like other veterans organizations distribute information and consistently urge those who approach our field offices, posts, Departments, and National Headquarters to seek the examination as a means of determining any on going health problems and confirmation of any problems relating to Agent Orange.

Our concerns are that the Veterans Administration retain responsibility for the examination process because we feel that it is the only agency which is able to control the examination process. If this were left to the private sector, we feel there would be no mechanism for regulating examinations. We also feel that the mechanism for the identification of the Vietnam veteran has been with us for a number of years with the examination procedure. The Vietnam veterans in Veterans Administration Medical Centers regularly are hospitalized and sent home only to find in the newspaper an article about the Agent Orange issue, whereupon they pick up the telephone and request of the Veterans Administration an Agent Orange exam. We know personally of individuals who have done this, traveled back to their home, some 400 miles from the VA Medical Center and then are paid to come back to the Veterans Administration Medical Center and receive the examination. We think that this is somewhat illogical, and would urge the

Veterans Administration through this committee that upon entering a VA Medical Center, veterans be queried as to their participation in the Vietnam Conflict and be given Agent Orange pamphlets and asked to take the exam while hospitalized.

This we feel would add to the process of identifying the Vietnam veteran as well a giving him some piece of mind and avoiding the outlay of travel funds by the Veterans Administration over the long haul. We also feel that there should be some greater emphasis on the examination procedure itself by the Veterans Administration. Not necessarily by Central Office, but particularly at the local level.

We feel that, having canvassed our field offices, a greater emphasis should be made on an effort to accomodate Vietnam veterans who, but for work schedules, would take the exams. These individuals are unable to come in during business hours and would prefer to receive the examination either on an evening or during the weekend basis. We think that this is a great barrier to the number of exams that have been conducted, and we do not feel that this would overload the Veterans Administration system as have been the fears of some of the local VA Medical Center Directors.

We also feel that there needs to be a serious

consideration given to the overall anxiety on the part of the Vietnam veterans about the issue as relates to the claims procedure. We feel there are some veterans (we've heard of a few) who are considering filing claims for anxiety based on the Agent Orange issue and also that if not now this will become a reality in the future. We would hope that the Veterans Administration would exercise it's authority to encourage the Vietnam veterans to come forward, No. 1, and No. 2 to accommodate them by weekend and evening examinations. We feel this will aid in the identification of the Vietnam veteran and the provision of a ready roster for follow-up procedures and should be added to the registry which by the way we have heard much talk about. AMVETS is deeply concerned however that the registry process be maintained.

DR. SHEPARD: Thank you very much, Peter. Are there any questions or comments from the committee? I would just add that we now have in place a Vietnam service indicator in the Patient Treatment File, on the patient data card, that is the embossed plastic card that is issued to each veteran as he comes in for either an out-patient or in-patient visit and, in the last few months, that card has the Vietnam service indicated on it. Those of you who are familiar with those cards, the number 7 appears indicative of somebody who served during the Vietnam era. After the 7,

there now appears the letter V for anybody who actually served in the country. So, gradually, we are establishing various processes for identifying veterans who come into our VA medical centers' outpatient clinics as to whether or not they actually served in Vietnam. Hopefully, that process will enable us to make better use of the Patient Treatment File and begin to get a handle on what illneses are being experienced by the Vietnam veterans and then comparing them between those who actually served in Vietnam and those who did not. Thank you very much, Peter. I'd now like to move on and ask that Major Alvin Young, who is on detail with us from the Air Force, present an update on the status of the Air Force Health Study and give us some information that came from the Salzburg conference he attended in October.

MAJOR YOUNG: Let me start first with the literature issues. Not wanting to plug the Air Force, but we do have a new book out; it's called "Operation Ranch Hand, The Air Force and Herbicides in Southeast Asia". It's a historical document prepared by Bill Buckingham of the Air Force Academy. I have a flier available back on the back table so, if you are interested in the Ranch Hand program in Vietnam, the historical point of view, please order that. It's expensive, $8.50.

There is word of the 1981 Dioxin Symposium

publication. I've been telling you all along that that publication was forthcoming. Well, Plenum Press has finally got into gear and the publication is to be released the 7th of January. It's about a 600 page book on the latest knowledge we have of the chlorodibenzo-p-dioxins. A number of health studies, environmental studies, and exposure studies are in back. It will be coming out at around the first of the year.

The 1982 International Symposium on Dioxins and Related Compounds was, of course, held in Salzburg, Austria. Dr. Fischmann has already alluded to some of the information on chloracne that came out of that. I have prepared the 7 abstracts on the lectures of epidemiology for a handout. 40 more copies of the handout will be available in a couple moments in the back of the room for those that did not get it. Let me just say that there are industrial studies that are reported in here. Both the studies in England and one by Dr. Suskind for Nitro, West Virginia really provide us little more than the knowledge that Dr. Fischmann discussed about chloracne. We still don't get any indication of increased mortality, heart disease or cancer. So those issues have not been resolved. Industrial populations are quite small. The Air Force did talk about their mortality study at Salzburg and I'll mention it in a few moments in the up-date. Dr. V. Riihimaki from Finland talked

about a study of some 1926 men who had sprayed 2-4-D and 2-4-5-D in Finland. He saw no increase in cancers of a variety of types including the soft tissue sarcoma. The issue of skin cancer was brought up by Riihiamki and that really remains to be determined, but Riihimaki was concerned about skin cancer.

Dr. Alan Smith from New Zealand presented a poster session and I don't have the abstract for you here, but New Zealand scientists have been working on the soft tissue sarcoma issue for people who have handled routinely 2,4,5-T in New Zealand. That study has shown nothing at this time. I'm sure many of you are aware that the state of New York is conducting a soft tissue sarcoma study and some of the information on it is available in the Report to the Governor and Legislature, 1982.

So, although we didn't get any answers on soft tissue sarcoma, a number of large studies are underway. After I left Salzburg, I did have a chance to go to Denmark and to talk with the Danish Cancer Registry scientists over a very large study currently underway in Denmark. The Danes for many years, since 1947, have used large quantities of the herbicide 2-4-D and MCPA, which is methyl-chlorophenoxy acetic acid. Neither of these herbicides contain the 2,3,7,8-TCCD, the dioxin. But there has been a lot of allegations about 2,4-D the other half of Agent Orange. The Danish study is

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important because it is of 3500 people. Some 1800 who were heavily exposed during the years of herbicide production. There are 1700 people, who act as controls, that work in the business side of the herbicide-producing company. The Danish Cancer Registry is one of the oldest, most complete registries in the world. The study, then, will be looking at the issue of cancer in a population of individuals who worked with 2,4-D and MCPA. There are excellent records and that's the beauty of this study, good exposure data and excellent records on the people. That study should be out in the next year.

From Copenhagen I went to Amsterdam and met with Dutch scientists and looked at the study they have underway. They are currently working on a morbidity and mortality study of some 400 workers that since 1946 have worked and actually sprayed 2,4,5-T herbicide that does contain the TCDD. In the Netherlands, one of the big problems is a shrub that's very much like blackberrrys and these 400 individuals have had the responsibility of controlling this blackberry-type of bush for the past 25 years. It's one of those situations that was literally a job passed from father to son and so we have a very interesting population that the Dutch are studying. What we are saying is that the answers that we are seeking will probably come from a lot of little studies that are ongoing. I

wish we could say that all the studies were done. The Dutch have released one small part of that study and a flier, that I did put on the back table, talks about a scientific issue. The Dutch and the man that's responsible for some of the best work in the world on prophyrins is Dr. Strik. I met with him and he pointed out that in this case they have not seen a relationship of prophyrins to 2,4,5-T exposure. Recently, we've heard a lot of talk about the work of Dr. Cadario in Philadelphia. Dr. Strik who has been in contact with Dr. Cadario is of a different opinion about the impact of 2,4,5-T and dioxins on prophyrin metabolism. So, be aware that there is still a controversy about prophyrin metabolism.

I did have a chance to meet with a number of Italian scientists and I'd like to just take a moment to tell you a little bit about the frustration of Italians over the epidemiologic work at Seveso. Many of us had hoped that the Seveso accident, and all the ongoing studies since 1976, would give us an indication about dioxins and what to expect, what to monitor for in the population. I'm sorry to say, that it's been very disappointing for the Italians as well as for us. The problem has been, as you might suspect, the lack of support in trying to conduct long-term comprehensive studies.

Let me just go into some of the things they have

found. For example, they pointed out that they knew that TCDD was released in the accident, and they know about how much of the TCDD was released. In terms of population exposure, unfortunately, it was very patchy in terms of time of accident and distribution of TCDD and where the people were located. The population's mobility has impacted the study because of lack of definitive information on the population mainly during the first two weeks after July 10, 1976. Because of that, the Italians do not have good records on who were exposed and how much were they exposed.

In terms of markers of exposure seen during the last 6 years, they conclude that there may be some unknown dose related effects, but chloracne is the only marker they have consistently found. As to acute and short-term effects that have been monitored, it's resulted in too broad a spectrum of biochemical and clinical symptoms, and thus is no more than a sum of inconsistent information collected. They simply have not seen consistent information. For example, the issue of nerve conduction, they see some indication, but it's too inconsistent because of the small population size and the measure of exposure.

Their clinical and epidemiologic baseline data, i.e., what did they have prior to the Seveso accident, have been the big proglems with monitoring birth defects. They had very little good data on hand with which to compare any

increase, thus they simply have not been able to make any reliable conclusions. In terms of the health care structures, and the resources, they point out that they are materially sufficient, but there is scarce readiness to cooperate. And they have no epidemiologic tradition in Italy for such types of studies. Doesn't it sound familiar? One of the comments they did make that was interesting, and an issue now, is whether to continue with the monitoring (epidemiologically) in Seveso. The question remains whether the "don't worry, we always thought it would go like this" approach will prevail or the official, "go on, please try harder to obtain better coordination and compliance" position of the International Steering Committee and of the epidemiologic team. They further point out, based on evidence derived from prolonged, direct work in the field, repeated personal experiences, international meetings and critical readings of the published literature, the most serious consideration must be given to implications of this difference in attitude. The Italians are trying to decide whether to continue the epidemiologic studies. There's a very high cost in terms of dollars. They're questioning whether to put those dollars out and what kind of information would come from putting those dollars out.

So, its a rather dismal picture, I think, of what's happening now in terms of the epidemiologic studies

in Italy. I did meet with some of the English scientists and they have quite a number of studies in England going on but nothing concrete at this time.

On to the Air Force report. I have been asked by Colonel Brown to present to you the up-date of the Ranch Hand report, where we are with respect to the Ranch Hand epidemiologic study. I have asked for 40 additional copies of the up-date to be delivered here in a couple of minutes so that those of you who do not have a copy, we'll have one for you in a few minutes.

The following information is an up-date on the progress of the Air Force epidemiologic study of its Ranch Hand personnel exposed to herbicides in Vietnam, from 1962 to 1971. The study protocol was developed in 1979 for an in-depth epidemiologic investigation consisting of three integrated elements: the mortality study (death); a morbidity study (diseases, including birth defects in off-spring). Some of you have asked about, what does the Ranch Hand study include? It does include that. And 3) a follow-up. The protocol was subjected to extensive peer review during the 1979 and 1980 period. Final approval for the study was given in the fall of 1980 and the work was begun on the study.

The initial mortality phase of the study is nearing completion at this time. As of December 31, 1981, 60 Ranch Hand deaths had been reported with full documentation for each. We're talking about a population here of about 1260. 22 were killed in action; 18 accidental deaths; 3

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suicides; 1 homicide; 2 malignant neoplasms; 1 endocrine, nutritional, metabolic and immunity disorder; 9 having diseases of the circulatory system and 4 having diseases of the digestive system. These are the positives related to death now. The School of Aerospace Medicine at Brooks Air Force Base in Texas has heard of 7 more deaths for which they are now in the process of obtaining additional information. Data collection for this study continues on a daily basis. Although more extensive analyses and comparisons remain to be done, preliminary findings indicate that the overall crude mortality of the Ranch Hand and comparison groups have been very similar. Based on the deaths identified, excluding the 22 killed in action, no statistically significant differences in total death rates have been found between the Ranch Hand group and the comparison group. Both groups appear to have experienced significantly less mortality than a similarly aged U. S. white male population, indicating a healthy worker effect. I always knew Air Force people were in good shape. However, thus far, very few deaths have occurred in the study group, and these deaths represent only a very early assessment of mortality. The only preliminary interpretation that can be made from these data is that, thus far, the Ranch Hand group has had a mortality experience equivalent to that of an occupationally similar comparison group. Periodic reassessments of

the mortality experience of the groups will be made. Definitive conclusions must await the completion of the more detailed analyses and the accumulation of a larger number of deaths in the study groups in the coming years.

On September 18, 1981, Lou Harris and Associates were awarded a contract to administer the face-to-face, in-home questionnaires to the participants selected for this phase of the study. Of the original 2,486 subjects selected for this study, only one Ranch Hand and 4 comparison subjects could not be located. This location rate of 99.8% is very high, as you know, for an epidemiologic study. Interviews were also planned with the current and former wives of the subjects and with the next-of-kin of deceased individuals. These interviews were begun in October 1981, and terminated November 15, 1982. At the completion of the contract, November 15, 1982, 2,665 study subjects, 2700 current and former spouses, and 75 next-of-kin interviews had been accomplished.

The participation of the subjects has been very gratifying. 97%, 1,170, of the Ranch Hand subjects chose to participate in the questionnaire. 3%, 38, declined to participate in the questionnaire. As expected, comparison subjects participated at slightly lower rates, 92%, 1,495, of the selected comparison subjects completing the questionnaire phase of the study. All comparison subjects

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1 declining the questionnaire and/or the examination have
2 been or will be replaced with willing subjects, equally well
3 qualified for inclusion in the study. These substitute
4 subjects will all be interviewed and examined in the same
5 manner as other participants. This circumstance was anti-
6 cipated in the study design, and provisions for the substi-
7 tution were planned in the early days of the effort. This
8 substitution process will ensure that the largest numerical
9 set of data are available for maximum scientific validity.
10 The physical examination phase of the study is
11 proceeding well. On November 25, 1981, the Kelsey-Seybold
12 Clinic in Houston, Texas, was awarded the contract to con-
13 duct in-depth physical examinations and psychological eval-
14 uations of the participants. The examinations began on
15 January 12, 1982. As of November 24, last week, 2,153
16 examinations had been completed on 1,020 Ranch Hands and
17 1,133 comparison subjects. There are 137 examinations yet
18 to be accomplished. The physical examination contract is
19 scheduled to terminate on December 15, in a couple weeks,
20 so that those 137 are now scheduled or are being examined
21 between now and the middle of next month, Decem-
22 ber. Every effort will be made to accomodate all the in-
23 dividuals desiring to participate in the study. Each sub-
24 ject will thus be given the maximum opportunity to partici-
25 pate fully in this effort.

One problem due to a computer programming error has arisen since last year and it has been successfully resolved. Eighteen percent of the comparison subjects initially selected from computerized personnel records for the questionnaire and examination phases of the study were found to be inappropriate for inclusion in the effort.

Many of these individuals had already been interviewed and some had even been examined. All of these individuals were advised of the error and thanked for their assistance. Those who had not already been examined were offered a careful and complete physical examination at the Air Force expense at the Air Force medical treatment facility nearest their home. Other more appropriate subjects were entered into the study in their place. This over-selection, then, of controls did not affect the scientific validity of the study.

The next 7 months will continue to be very active. The contract for physical examinations will conclude in December, and interim technical reports will be issued in early 1983. A mortality report will be released in March, and preliminary reports on the data from the questionnaire and examination phase of the study will be available in the April-June time frame next year.

The initial round of questionnaires and physicals

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will be the basis for the remainder of the study. Follow-up examinations will be administered to the study subjects at the 3, 5, 10, 15 and 20 year points. Last week the Air Force School of Aerospace Medicine released to the public Air Force Technical Report-TR-82-44, "Epidemiologic Investigations of Health Effects in Air Force Personnel Following Exposure to Herbicides: Baseline Questionnaires". The questionnaires presented in the technical report are the field instruments used for the baseline data collection effort of 1981-82. The Air Force promised to release the instruments upon completion of the questionnaire phase. They have done so. This is available to the public for dissemination.

In summary, this study is proceeding only slightly behind schedule. But please note that this is due to the unexpectedly high and favorable participation rates, the eligibility problems and unique logistical and scheduling difficulties encountered in a study of this scope. The Air Force investigators look forward to continuing their association with the Veterans' Administration in their study efforts. Submitted by: Lt. Col. Phillip Brown, Office of the Air Force Surgeon General, Bolling Air Force Base, Washington.

DR. SHEPARD: Thank you, Al. I think the excellence of this study attests to the dedicated team of investigators located in San Antonio, Col. George Lathrop

and his associates who have done a marvelous job and are to be commended on their efforts and we have certainly enjoyed the close working relationship with this outstanding group of investigators. I would now like to call on Mr. Robert Santos, who will represent the State Agent Orange organizations. We are very happy to have you all with us today.

MR. SANTOS: Good morning and thank you very much. My name is Robert Santos. I am from the New York State Temporary Commission on Dioxin Exposure. I am the spokesperson for a number of commissions which are also here today with me and they are: Oklahoma, New Jersey, Illinois, West Virginia, Pennsylvania and Texas. A number of the other states that expressed interest in joining us, but were unable to make it due to transportation as well as scheduling difficulties. I'd like to point out that this is the second meeting that we have had. The first one being held in early October, and we are planning to continue to do this on a periodic basis in other locations.

And for those of you who are not familiar with the state commissions, I'd like to take a few moments just to explain our make-up and where we're coming from. The states presently active in this area range from Hawaii to Maine, from Georgia to New York -- There is Wisconsin, California, Kansas, Ohio, Hawaii, Connecticut, Massachusetts, Maine, Texas, Pennsylvania and the ones I mentioned earlier.

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1 As you can tell, we're not limited to any geo-
2 graphical area. We're not limited to any industrial base.
3 We are basically representing veterans throughout the na-
4 tion. The reason for us being created, which was started
5 about 3 years ago, -- New Jersey was the first state
6 commission to be created -- was obviously as a result of
7 dissatisfaction among the veteran population as well as the
8 workers in our respective states, who may have been exposed
9 to dioxin through manufacture, transport, or possibly acci-
10 dent. And it was dissatisfaction amongst this population
11 which was recognized by the respective state legislatures,
12 that certain activities being conducted either by the fed-
13 eral government or the private sector or the legal circles,
14 was not proceeding adequately or in a timely fashion.
15 As a result, they created these fact finding bodies
16 and our job mainly is to go out and address these certain
17 issues objectively. The membership of the respective
18 commissions varies from people who are just concerned citi-
19 zens to doctors, lawyers, scientists, elected officials,
20 members of the state governments, membership in the respec-
21 tive scientific circles - health departments, public health
22 departments, hospitals as well as I said, membership in
23 veterans' groups and other types of groups including unions.
24 The reason we came together as a group is that
25 for the past 2 years we have been struggling with certain

1 issues. As it noted earlier, you have been struggling for 5
2 years over the same issues. The veterans have been struggl-
3 ing for approximately 10 years over the same issues, and we
4 felt that it was time we all got together.
5 Being disbursed has advantages as well as a disadvantages.
6 Although getting together is difficult, we
7 know we represent a cross-section of the nation, and that
8 the respective expertise located throughout the commissions
9 together is an incredible array of personnel.
10 What we're doing now is trying to share our knowl-
11 edge with each other.
12
13 Some of the people in this room we've
14 seen testify for us at our hearings. We have done much as a
15 group. We conducted hearings, we received oral
16 testimony, as well as written testimony from both repre-
17 sentatives of the VA as well as the private sector, both
18 veterans themselves and independents. We are in the pro-
19 cess of having varied programs. Current programs are facili-
20 tating the referral of veterans to the Veterans' Adminis-
21 tration for their examinations. Others are facil-
22 itating the referrals of veterans to other types of organ-
23 izations that might be able to deal with other issues that
24 can't be addressed at this point. We are conducting public
25 service announcements throughout the states as well as

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eventually throughout the nation regarding this issue. There are 800 numbers that are being utilized now to reach out to veterans. So we can possibly be a resource down the line to anyone working on these issues in a concerted effort.

We will never forget the fact that we were created for a very specific purpose, out of dissatisfaction as well as a mandate to address this objectively. So, regardless of where the studies go, or where the money goes, we are doing the work, we will always serve as a basis for criticism as well as a focus of energy to reach out to veterans.

To that extent, we have issued collectively a number of reports -- we are encouraging other states to go out and create their own programs to address these issues. We are coming here today, we met yesterday and we'd like you to know that we realize that this is an Advisory group

We have heard, you know we all do at times, that advisory groups advise, they do not set policy. Well, we are not ignorant in that policy makers go to advisory groups and ask them for their information, ask them for their advice. We're not naive to think that people who sit on advisory groups do not expect to be listened to and do not expect to be heard. So, we're addressing you on both a personal and professional basis and we have decided amongst ourselves on two basic issues that we'd like to

bring out today. I always like to point out at this time that Dr. Anderson is here from Texas state commission who is working on a number of issues from a medical standpoint and we would like him to address this group for the last portion of our allocated time.

But at this point, we would like to address two things. One is the recent reports of the transfer of the study to CDC. We are under the impression that although that transfer has been conducted publically and politically also, as early this morning was mentioned, that we were under the impression that it was not yet official. That it has not yet been transferred officially. We have decided, as a group, that we endorse the transfer of the study to CDC. The issues that we based our decision on are probably the ones you've already heard -- that we don't need to go over. We would like to express two concerns regarding the transfer of the study. One is that autonomy is given to the CDC in terms of developing, implementing the study, and that it is essential that the proper allocation of dollars goes with that responsibility. If they are willing to accept it, then we should give them the money and not tie their hands at the beginning. The second issue is contrary to some stated opinions that the Vietnam experience factors should not be considered at this time. We feel it should be included in this new study conducted by the CDC. It's

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very important that regardless of the results they may come out with, whether they be neutral, positive or negative, whatever way you want to look at it, we feel that the Vietnam experience should also be included because of other factors that have been raised regarding other types of chemical exposure involved. And we do not want to spend a lot of money on one issue and find out that if the results come out one way, we have to start all over again.

The veterans have waited long enough. Also, we feel that we support the CDC, we feel that they are the most appropriate governmental agency, at this point in time, in the nation to handle this type of study. Although I will not preclude the states from conducting their own independent studies that are ongoing now and it would not preclude the states from focusing on those particular issues in a concerted effort.

The second point I would like to make this morning is that recently a bill has been introduced into the House by Daschle regarding the presumption of compensation based on a presumption of service connection for the disease of soft tissue sarcomas manifested in veterans who served in Vietnam during the Vietnam era. At our meeting yesterday, several states were able to make the decision, voted and those states who had representatives who could not make that decision shared their concern and they will go back to

1 their respective states. But consensus of opinion at the
2 meeting yesterday was that we support that particular bill.
3 We feel that, at this point in time, the presumption of
4 service connection for soft tissue sarcoma should be estab-
5 lished. We will be lobbying within our respective states.
6 We will be lobbying as a group. We feel that it is time
7 that the veterans get something out of this particular
8 issue. It is not simply an emotional piece that we are
9 deciding, we're basing this on recent reports that we have
10 read. We are basing this on a number of studies that have
11 been conducted. We are basing this on expectation that
12 there are some reports that will be coming out shortly that
13 will show a correlation -- and resulting in soft tissue
14 sarcoma. And at that particular junction, we are limiting
15 our support to that particular bill that addresses soft
16 tissue sarcomas. We are not addressing the other issues
17 related to it, although down the road the issues of retro-
18 activity will, I would say, have to be addressed. Again,
19 we are addressing this group in this manner, on only two
20 issues, but at this point in time we feel those are the
21 two we can -- come before you and make our claim.
22 Also, we will -- down the road again and address
23 other issues. We would like to continue the relationship
24 that we have established individually as well as in terms
25 of our respective states as well as the group, with

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1 the respective administration and the other groups that
2 have come before us and testified and we will encourage
3 that again in the other states to create programs to call
4 on your services to come before us. And I thank you for
5 your very gracious invitation to be here today and we will
6 send you a letter and express our statements again and we
7 would like to have you respond, in writing, to our objec-
8 tions, whether or not you will endorse our recommendations.
9 Now, although I know you are advisors, you still have that
10 power to affect policy and we expect that you do that and
11 we would like you to do it with us. That concludes my
12 remarks. Dr. Anderson is here from Texas --
13 DR. FITZGERALD: Mr. Santos, will you amplify what
14 you mean by Vietnam experience?
15 MR. SANTOS: Yes, that's a terminology that's
16 been floating around. What that infers to,as it is our
17 understanding,is that dioxin was not the only chemical
18 that Vietnam veterans were exposed to. There were a number of
19 things that we were exposed to. I am a Vietnam veteran and
20 I don't know what we were exposed to, but perhaps some
21 people in the room have an inkling and if we put them all
22 together we'd have a bunch.
23 DR. FITZGERALD: In other words, what you're say-
24 ing is you'd like other chemicals that Vietnam veterans were
25 potential exposures to be included in this?

1 MR. SANTOS: Yes, yes.

2 DR. LINGEMAN: Mr. Santos, do I understand you to
3 say you are on the verge of taking the position that you do
4 believe that there is a definite relation between soft
5 tissue sarcomas and exposure to herbicides? Did I under-
6 stand you correctly?

7 MR. SANTOS: As a group, that is what we --

8 DR. LINGEMAN: Do you believe that the scientific evi-
9 dence justifies payment of claims?

10 MR. SANTOS: Well, let's put it this way. As far
11 as scientific evidence goes as well as legal evidence goes,
12 there is always two sides to every issue. We don't fully
13 believe that the evidence will ever come in within a timely
14 fashion on either side of the issue to convince everyone in
15 this room or elsewhere. We do feel this is the right time,
16 at this point, to address that issue. It's probably a policy
17 decision for those who believe that there is correlation,
18 the answer is, yes. For those who don't believe there is a
19 correlation, the answer is, no. But, for those veterans
20 who do have soft tissue sarcomas, who have come forward, for
21 those who may still have them in their bodies and not know
22 about it, we feel at this time there is ample precedent. I
23 mean you go forward and look or go backward and look, there
24 are approximately, we understand, 40 different diseases that
25 now qualify for some disability. The government of

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1 Australia has awarded compensation. The recent court case,
2 I believe in Illinois, awarded $58 million in damages to
3 workers exposed to dioxin. We don't feel its the time or the place
4 for the government to wait any longer to make that decision.
5 If the courts have felt that, international governments have
6 felt that -- it is now the policy, it is time to set policy
7 along those lines.

8 Also, for those who are concerned about economic
9 factors, I do not know what disability rates will be, or
10 the frequency of soft tissue sarcomas, but I assume it's not
11 nearly as large, in terms of numbers of Vietnam
12 veterans. But to be quite moral about it, you
13 don't place a dollar value on it when these people have gone
14 forward to serve their country. One thing that you should
15 realize, that we have heard all along, we've never once
16 heard a veteran come in and complain about his service to
17 his country. They have only expressed concern about the treat-
18 ment they receive, or their dependents or the lack of treat-
19 ment for their dependents, about their cancers, about their
20 deaths. They've always asked for service,
21 they've asked for justification, some kind of moral indica-
22 tion that what they did and this is just a mere, mere minis-
23 cule step in that process. And that's what we're supporting.

24 DR. SHEPARD: Any other questions? Thank you.
25 Dr. Anderson from Texas.

DR. ANDERSON: We always have a lot to say in Texas. Dr. Shepard, members of the committee, its a real privilege to be here. I assume that most people in this room have become familiar with the diverse direction in which Texas went some 2 years ago when the legislature put into law the Texas program to assist our veterans who were exposed to Agent Orange. At first it was rather confusing to us in the Health Department as we were given the program, as to how we would approach this, but the law was very specific and said we would develop a joint program with the University of Texas system. I believe Dr. Bill Neaves from Dallas is here. He is the representative from the University side of our program. Ours is a joint program between the State Health Department and the University of Texas' 5 health centers.

The centers were very cooperative and promptly came back with protocols as to how they would approach the problem. Of course, these protocols had gone through their research approval committees, so we felt quite comfortable with them. We felt that we had several people on staff who could look at things objectively and that we would, the Health Department side of it, more or less collect the subjective data - the records of the veterans. The University of Texas Health Science centers would look at the problem objectively and from a more medical, scientific point of

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1 view. These studies which were developed, at first, were 6.
2 Since that time, we have dropped out the mortality study.
3 We ran the tapes through, we had those in the Health De-
4 partment. We had the identifiers and we just didn't have
5 enough numbers. The veterans that had died since 1960's,
6 after return from Vietnam, were in small numbers and signifi-
7 cance could not be found.
8 The primary cause of death I think most people in
9 this room could guess right now, was out on the interstate
10 highways of Texas. They were the right age group for that
11 type of death. Now the other protocols that we have, of
12 course, we're looking at birth defects in children. We
13 had ongoing in the state of Texas a reporting program, a
14 genetic program in the University of Texas system, which
15 the children in the State who are born with birth defects
16 are registered and are followed. For us, its a bit of a
17 retrospective study. We go back, ask the questions of the
18 parents. Was the father a veteran of Vietnam when you
19 entered the program and if you were; was he exposed to AO?
20 The next was a cytogenetic study which we are look-
21 ing for, of course, aberrations of chromosomes in
22 lymphocytes. We have a sperm study going in which
23 we are also looking at chromosomes. We have an immuno eval-
24 uation study at the University of Texas in Houston in which
they are doing a profiling of the immunocompetency
25 status of the veterans

1 who feel that their
immune status may have been compromised by
2 the induction of certain enzymes due to the
toxic effects of dioxin.
3 We're looking at a little more than just dioxins, of course.
4 The first effort is, of course, of dioxins because we tend
5 to know a little more about that and that's what's in the
6 newspapers anyway.
7 In the Health Department, we set up
the administrative program,
8 of which I was, of course, made the Director. I
9 have a very small staff of one other person and that's it.
10 They gave us a half a million dollars to spend over a 2
11 year period. We immediately went to work. Fortunately, I
12 had had 30 years military. I had been in Vietnam. I had
13 a background of some toxicology and occupational medicine.
14 We designed our programs to fit. We immediately said, "What
15 do we need to form the data, some information on our veter-
16 ans?" We got the questionnaires out, realizing our program,
17 a self-selected program, in which the veteran has to meet
18 several criteria other than just being a Texan. He must
19 have a medical condition which he feels is related to ex-
20 posure which is verified by a physician. And, to-date, we
21 have 280 in our program. I have reviewed the medical re-
22 cords on nearly 200 of these individuals. The medical
23 records and other records which we get consist of, first and
24 foremost, the questionnaire which, of course, is 3 or 4
25 pages which he filled out. We then ask him to fill out

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1 release forms for any and all types of medical records that
2 he has ever had. We go to St. Louis. We get his military
3 medical record. We get his personnel records, particularly
4 a history of any combat in his duty in Vietnam and other
5 places. We get a "prior to service" occupational history.
6 A history after service, any civilian hospital he has ever
7 gone to, any treatment that his family has received and if
8 they have children, if they feel have problems, and the
9 usual file, when I finally get it to my desk for review is
10 about 3" thick. It takes me several hours to review this.
11 What am I looking for as I go through it? Now, after I have
12 reviewed the personnel records, the medical records
13 (VA, military and civilian), I take a look at the possi-
14 bilities of his exposure in Vietnam. I also, at that time,
15 use, of course, the herb tapes, any other information I have, and
16 operational records of where units were. Fortunately, I
17 know where a lot of the units were over there. I can come
18 up with a gut feeling as to whether this individual was ex-
19 posed, not exposed, maybe exposed. Of course, where I was
20 I definitely was not exposed, an officer's club at Da Nang
21 was not exposed. But, I get this gut feeling. And then
22 we contact the veteran. Now ours is a one on one in most
23 respects. We get on the phone and talk with him. And
24 we ask him more questions. I talk to him about his outfit
25 and I say, who do you know around here who was in your

1 outfit? We'll talk to him. We pull in all this one to one
2 information the best we can.
3 We see who was in the 27th Marines. We want to
4 talk to some other guys who were in the 27th Marines. I
5 want to talk to as many as possible, if he was Navy and he was down on
6 the Mekong Delta on one of those gunboats, I want to get a
7 good feel for what it was like on a gunboat. And we've had
8 some Navy men that give us a very accurate description of
9 what the C-123 at 150', at around 120 or 30 miles an hour,
10 coming down the river spraying something to knock off all
11 the leaves on trees because they didn't dare run the boats
12 up and down the river without the leaves being off the
13 trees. They didn't like snipers. Well, that to me is a
14 pretty good indication that we're probably talking about a
15 herbicide. I don't think anybody in this room would prob-
16 ably disagree with me. We're talking about a herbicide.
17 We have 280 in our program now. We have a selections committee
18 made up of representatives of the University of Texas, more
19 or less the protocol directors, that meet about once every
20 month or two. And I present to them our cases as I discussed
21 with you. And we then will decide whether we will take the
22 individual into our studies. Now the University people are
23 concerned as to whether or not their study has been com-
24 promised. We know we have a lot of men who work in petro-
25 chemical companies. In Texas we have a number who work in

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1 agriculture, particularly in West Texas where we're still
2 using 2-4-5-T to knock out our mesquite. So we look at
3 all these factors. We eliminate and narrow down. As of
4 today, we have 29 individuals that we have selected, along
5 with controls who were men selected as non-Vietnam, hope-
6 fully a veteran, state-side who will compare in age and so
7 forth. In many cases a relative so they may share some of
8 the same genetic make-up.

9 We feel that we can, over a period of time, with
10 a sufficient number
of veterans feel a little more comfortable.
11 it. Now I know that the critics are going to tear into us.
12 We expect this. But, the fact is this, something is being
13 done. And that's what our veterans asked us to do. We
14 took the resources we had and we're doing the best we can
15 under the circumstances, to try to get into a really touchy
16 situation.

17 What do I look for when I go down through the med-
18 ical records? Well, to tell you the truth, I am, many times,
19 very disappointed. There is always good and bad. For in-
20 stance, the VA Agent Orange physicals; we always get them.
21 We have no difficulty at all getting them once we request
22 them, we get them. I'm very disappointed, at least from a
23 medical point of view, because they don't tell me very much.
24 I look through them primarily to get the history and to
25 see if they really have an occupational history which goes

1 back to when he was a young man, before he went into ser-
2 vice. What he's been doing afterwards. Of course, we have
3 already gone out and questioned him and got some of the
4 same information in our own questionnaire. I look particu-
5 larly for baselines laboratory procedures, both in the
6 military medical records and in the VA.
7 records. And, what do I really look for?
8 Of course,
9 we're looking for chloracne. We have, as one of the selec-
10 tion factors for selecting people for our studies, is the
11 presence of chloracne or a rash, which could be interpreted
12 as being chloracne or similar to it. Remember this, those
13 of you who have looked at military medical records from
14 that time period back in the '60's. Incidentally, I even
15 found my own handwriting in some of these men's records.
16 I was going along and I have trouble with doctor's writing
17 and all of a sudden, I read it beautifully. It was mine.
18 But, anyway, the word chloracne was not well known in those
19 days. Perhaps, a few industrial physicians and dermatolo-
20 gists used it, but most physicians didn't have it in their
21 vocabulary. So, you don't look for it. I look for liver
22 disease, liver disorder and the laboratory procedures that
23 were used at that time to try to get a baseline on the indi-
24 vidual. I look for neurological and behavioral changes that
25 people have recorded on individuals. Those that have been in

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1 combat, heavy combat, for instance are never the same again.
2 They do have certain changes and I think most of the psy-
3 chiatrists will support that.
4 I look for, in the individual and the family his-
5 tory, for porphyria cutanea tarda. We find this in our
6 population in Texas down around the petro-chemical plants
7 anyway, particularly among a lot of women.
8 So I look at the laboratory procedures in this man's
9 medical record. I look for results of porphyrin studies,
10 particularly uro-porphyrin excretions. I look for SGOT's.
11 Some of the fellows have had some problems so
12 they have done a SGOT. I look for billirubin studies, any-
13 thing that pertains to the liver and the enzymes. SGPT's
14 as well. We know that these are all things that are going
15 to increase when a person has been affected with a toxic chemical.
16 Now, industrial physicians are quite aware of this and they
17 use these tests pretty much around petro-chemical plants.
18 Bromosulphthalein test, the BSP. I look for, particularly in the older
19 men, whether they have had chloresterol studies done, the
20 tri-glycerides, any problems in their lipid metabolism,
21 total lipid studies are very important, toxicologically. We
22 know that lipid metabolism is early affected in many people.
23 We look at any studies on lymphocyte chromosome
24 aberrations and changes, that have been done. Now, I don't find most
25 of these. That's why I'm giving you a hard time. I just

1 don't find it in either the military or in VA physicals.
2 These things are not being included. In fact, in most
3 cases, and unfortunately the GAO, when they did their
4 study, didn't come down to any of our Texas VA hospitals,
5 they stayed in other places, but I find that as I go
6 through and I look at the things that can be done to evalu-
7 ate people and they're not being done in the laboratory.
8 Most physicians are very good at using a stetho-
9 scope and reading some X-rays and so forth, but when you
10 really get down to it, what has happened to his liver? It
11 takes an internist. Most general physicians don't want to
12 get this deeply involved. But those are the things
13 that I look for from a laboratory point of view to get a
14 baseline.
15 Now, in a few cases, I've found some answers. In
16 most cases, it's not there. Now, with the GAO report, I
17 read it. In fact, a couple times. I was quite interested
18 in it because they were saying some things that I could
19 agree with and also disagree. It became apparent to me
20 immediately that they were not physicians. I immediately
21 said, these people are not doctors, they don't understand
22 the way doctors think. That's alright. I took a look at
23 the report and I said, you know, this outcome that we're
24 after, what are we really getting, as physicians, when we
25 examine our patients? What do I find after I have

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1 reviewed the medical records of veterans? As a physician,
2 what do I see? What do I feel? And, let's face it, those
3 of us who are physicians many times establish our diagnosis
4 on such feelings. You just know they are sick, you know there
5 is something there, and you go after it. I don't think we
6 have gone far enough and that's why, in Texas, the studies
7 we are doing are important. Not that ours are going to be
8 that good. We may not have the numbers. We may not have
9 everything else. But, perhaps, somebody else that has
10 larger numbers can begin to expand this, to take advantage
11 of technology that exists today and do these things. To
12 study an individual who has been insulted with dioxins and
13 not study his sperm is wrong.
14 Those are the tissues which are most likely to
15 be early affected and will be permanently affected, 20
16 years later makes no difference. They still show the in-
17 sult took place and then move down the line into other body
18 tissues. Now, to get back to the VA, the
19 Agent Orange physicals, we have no trouble getting them.
20 They are a little short in content, particularly in the
21 laboratory back-up. I have no argument with the timing.
22 Our veterans seem to be able to go in, get an appointment
23 and get their physical within a reasonable period of time.
24 We require all of our individuals in our program to have
25 had the VA Agent Orange physical. Most of them have already

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had it. Now, I did run into a bit of a problem in San Antonio. We requested some medical records and they said that they had been retired and that the only way to get them was to declare an emergency and that they would be used for the treatment of the patient. I said, I will not perjure myself and compromise my medical ethics by lying. There is no emergency and I'm not going to use them to treat the patient, but merely to evaluate. I put it into a letter and sent it to the Regional office. They received it about a week ago. We will see what will come of it, but that's the only real problem that I have had with the retired records that had been sent to St. Louis or somewhere else where you retire your records.

I do have a problem with the AO registry. We requested the names and addresses, I think it was along about last June or something. We got a very nice letter back saying we'd someday get them. We haven't heard anything. We would like to, at some point in time, get the names of the Texas Agent Orange registry participants. I'm open to questions. I sure appreciate being here.

DR. SHEPARD: Thank you very much, Dr. Anderson. Are there any questions or comments from members of the committee?

MR. WALKUP: I just wanted to say thank you --

DR. SHEPARD: I will be meeting with Dr. Anderson

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later on today so we can over some of these particular points or any problems that are related to records or any other information. We're running a little behind schedule, so I think we better press on. Right now I'd like to call on Dr. Mulinare from CDC to give us an update on the Birth Defect Study.

DR. MULINARE: Dr. Shepard, committee members and guests, good morning. The CDC Birth Defects study is well underway. I might summarize for a few of you what we are doing. We are examining, interviewing 10,000 families in Atlanta. Approximately 7,500 of those families have a child with a birth defect and approximately 3,000 have children without birth defects. We are in the process of tracing and interviewing these families from records that we have from 1968 to 1980.

The interviewing process has been ongoing for the last 6 or 7 months and we're halfway through. We anticipate completing most of the interviews through next spring and summer and analyzing the results and having something in the late fall. For the most part, the activites that are ongoing right now -- as you can imagine, looking for people who are, we have records for back to 1968, that's 12, 13 years ago, tend to be rather difficult to find. The interviewing, itself, is going very, very well. There is no difficulty with questionnaires and we've had relatively few

refusals of the families that we've been able to find. To-date, we've interviewed 4,600 moms and 3,600 dads. We actually do conduct separate interviews for the mothers and the fathers, feeling that they may be able to give us different information about different questions that we ask. The reproductive histories may tend to be more accurately from the moms than from the dads. Any histories that we get about Vietnam experience most likely will be more accurate from the dads than the moms.

In order to make a comparison, to try to understand whether or not we're getting information from both moms and dads that are similar, we did run a few cross tabulations and one of the ones that Dr. Erickson has presented to the group in the past -- first, the number of participants in the study who have had Vietnam service. In the past we've been running about 12 or 13% and update, we also have found that approximately 12% of fathers are serving in Vietnam. Now this is within the estimate that we figured at the initiation of the study.

When we interview the moms, we find that the moms agree to the point that they say that approximately 10½, 10.6% of the dads did serve in Vietnam. So, we're getting information about service in Vietnam from the moms and the dads that's fairly close, fairly accurate. And the agreement, as I said, is very good. We are not doing

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1 any other analysis, but one of the things we are very in-
2 terested in is this agreement between moms and dads. Dr.
3 Erickson has looked at a couple of the cross tabs in the
4 past. One of the questions we asked of moms and dads is
5 whether or not this pregnancy was planned. I
6 thought I'd just give you the information that we got this
7 time when I ran the cross tabs the other day, just to show
8 you what we're finding.
9 The question asks the father and
10 mother separately, was this pregnancy planned.
11 And out of about 2200 or so, we found that both
12 moms and dads in 1100 cases stated, yes, both mom and dad
13 did plan the pregnancy. And in approximately 540 cases,
14 both mom and dad said that the pregnancy was not planned.
15 When mom responded and said, yes, the pregnancy was planned,
16 95 of the dads said, no, that it wasn't planned. How-
17 ever, when dad was asked and he said, yes, the pregnancy
18 was planned, approximately 200 of the moms said, no, the
19 pregnancy was not planned. This may be an article for
20 "Psychology Today".
21 We feel that the study is really going well. The
22 next half of the study is going to be more difficult than
23 the first half because, as you may realize, finding people
24 gets more difficult as you go through the study and we're
25 looking forward to trying to maximize mobility and to trace

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them, to trace people. Once we have found them, we've found that the people are very, very receptive to having the interview done and we look forward to the next several months as being ones that are going to require a great deal of work in tracing and finding these people. Thank you.

DR. SHEPARD: Thank you, Dr. Mulinare. Are there any questions? Dr. Lingeman?

DR. LINGEMAN: I just have a comment. I think it illustrates the ability of the CDC to do things well, to implement an epidemiologic study and get it going rapidly and get results soon. And I think that they should be relating to, if not required to do an epidemiologic study which the CDC is all geared up to doing it well, so --

DR. SHEPARD: Any other questions? I have one. Did you tell us, Joe, how many numbers you had done in each group?

DR. MULINARE: There were, we've completed 4,600 mom interviews and 3,600 dad interviews.

DR. SHEPARD: And that's in both the cases and controls?

DR. MULINARE: Yes, that's not separating cases and controls. That's all totalled.

DR. SHEPARD: I wonder if you could elaborate a little bit more on the apparent difference between fathers and mothers perception of service in Vietnam. Have you had

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1 a chance to track that down at all? As I heard you, you
2 said 12-13% of fathers reported they had served in Vietnam,
3 but only 10% of the mothers or the wives of those fathers
4 said it?
5 DR. MULINARE: I did do a
6 cross tab and its always difficult to interpret in the
7 middle of a study, but it will be easy what we have right
8 now. For service in Vietnam, when both mothers and fathers
9 said, yes, that dad served in Vietnam in 240 of the cases.
10 Both mom and dad said, no, that's an agreement that father
11 didn't serve in Vietnam in 44 of the cases. When
12 father said, no, he didn't serve in Vietnam, mothers said,
13 yes in 6 cases and when father said, yes, he did serve in
14 Vietnam, mother said, no in 8 of those cases. And if you
15 set that up as a table you could see that it's really fairly
16 good agreement, basically, lack of disagreement in that
17 situation.
18 The interpretation of Vietnam may vary. Some
19 experience has been that Thailand is included, and that
20 when asked certain questions about Southeast Asia and
21 whether a man served in Southeast Asia, some people had
22 interpreted that as being service in Korea or the Philippines
23 as well. But we still think that basically that the dis-
24 cordance in that particular table is rather minimal.
25 DR. SHEPARD: Fine. Thank you. Any other

1 questions or comments? Well, thank you very much, Dr.
2 Mulinare, for a very informative
3 presentation, and we wish you continued success. I agree with Dr. Lingeman, this is a very good
4 example of CDC's capabilities of the last few years, a good
5 epidemiological study. It's been quoted, I
6 think in the New York Times
7 and by the way there is a rather complete article in Today's Science section, that this is the
8 largest birth defect study ever conducted so, its a
9 pioneer effort.
10 We now, let's see, I think we ought to take about
11 a 5 or a 6 minute break and then I'd like to reconvene and
12 we can go over some possible comments from the members of
13 the committee.
14 (OFF THE RECORD. BRIEF RECESS.)
15 DR. SHEPARD: The meeting to order again, please.
16 We wish to have enough time to take questions from the aud-
17 ience. Prior to that there are two agenda items that I'd
18 like to cover. First of all, I'd like to hear from any of
19 the service organization representatives, if they have any
20 comments or questions or concerns of their membership that
21 they'd like to bring to the attention of the committee. We
22 normally have that on the agenda.
23 That's a very
24 important part of our effort. And, so I'd like to call on
25 Mr. Charles Thompson first to see if he has any words of

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1 wisdom to bring to us.

2 MR. THOMPSON: Well, I'd just like to reiterate

3 what my colleague, David Gorman said at the last meeting to

4 continue our efforts to objectively inform membership to

5 our magazine of the current events on the Agent Orange issue.

6 One other factor and we'll go on record here too, is the

7 fact that we -- have a correspondent with HHS about the

8 transfer of the epidemiological study to CDC in Atlanta

9 and we request this transfer take place as soon as possible.

10 That's about it for me.

11 DR. SHEPARD: Thank you. Mr. Sypko from the VFW?

12 MR. SYPKO: The only comment I have to say is,

13 you probably read it in the newspapers this week that our

14 position is fairly strong backing the Daschle bill on the

15 soft tissue sarcoma.

16 DR. SHEPARD: Fred Mullen?

17 MR. MULLEN: I just have a couple of questions.

18 At our last meeting it was mentioned that the VA allocated

19 about a dozen FTEE to augment the portion of the study that

20 they were conducting at that time or were going to be con-

21 ducting, and we are concerned that the sharing of informa-

22 tion with CDC, health related information, is of utmost im-

23 portance so the transition goes as smoothly as possible.

24 Dr. Custis expressed two points of concern regarding criti-

25 cism of the administration that has heretofore befallen our Agent

1 Orange Advisory Committee as well as the rest of the VA in-
2 volved in the different studies; and, also there is a question
3 of credibility. Well, it seems that the credibility ques-
4 tion is being resolved by the transfer of the -- epidemio-
5 logical studies to CDC, but there remains the subject of
6 the criticism of the administration. Since the epidemiological study is
7 going to be transferred to CDC, has the VA complied com-
8 pletely in supplying CDC with all the information that they
9 have available and since this is going to be a rather large
10 study, is the VA considering transferring any of the FTEE's
11 to CDC to help them get the study started?
12 DR. SHEPARD: Yes, two good questions. First of
13 all, we have transmitted already to CDC s
14
15
16
17 virtually all documents
18 that had been developed both by contract to UCLA and the
19 comments of the various review groups, the National Academy of
20 Sciences report, efforts that had been ongoing regarding
21 the cohort selection
22 process and so forth. So, I think its accurate to say that
23 we have already transmitted virtually everything that we
24 have, in terms of factual material, planning documents and
25 so forth to CDC. So there should not, now, be any delay in

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1 developing or finalizing that protocol as far as existing
2 information is concerned.
3 On the matter of the FTEE, we have yet to have a
4 request from CDC or an identification from CDC of the re-
5 quisite resources for conducting the study. So, as soon as
6 we have their input on the issue of resource requirement,
7 we will be in a position to respond to that request.
8 MR. MULLEN: Does it necessarily have to be re-
9 quested or couldn't we let it be known that certain FTEE's
10 will be available if they decide they need them?
11 DR. SHEPARD: The only reason for my hesitating
12 at all is that the process is perhaps somewhat more compli-
13 cated than the VA turning over FTEE's to HHS. It is my
14 understanding, and I'm not an expert in this area, but it
15 is my understanding that the transfer of FTEE between gov-
16 ernment agencies is under the control of the
17 Office of Management and Budget. So it is not simply a
18 VA to CDC effort. There are other agencies that have to be
19 involved in that process. I don't think that from the VA'S
20 perspective there would be any problem in responding to any
21 reasonable request on the part of CDC for both dollar and
22 personnel resources. I don't foresee any problems from
23 the VA --
24 MR. MULLEN: You're still involved in many studies,
25 like being involved with the Twin Study, with the EPA on the tissue

sample studies, and mortality studies. I believe that in those FTEE's allocated there were provisions for both junior and senior epidemiologists and a biostatistician. Now, are you going to retain any of those three FTEE's?

DR. SHEPARD: Yes, that brings up a point that I was trying to make earlier, but now that you've mentioned that, I'd like to clarify or elaborate a little bit on Dr. Custis' point about the organization of our office. I used to be designated as Special Assistant, Chief Medical Director. Our office is now known as the Agent Orange Prohect's Office and our mail symbol is 10A7. We have two sections within our staff. That is, an administrative staff and a program or a research/program staff. The latter is being augmented with 5 additional personnel consisting of the following: a senior epidemiologist, a biostatistician, a statistical programmer, an administrative officer with experience in dealing with research projects, contracts and so forth, and one additional clerical person. So, that's 5 FTEE's that have been approved, and the positions have been approved. The PD's have been classified. We are now in the process of recruiting all 5 of those individuals. They will be the core group heading up and monitoring the research efforts that will remain with our department.

MR. MULLEN: Thank you.

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1 DR. SHEPARD: Dr. FitzGerald? Do you have any
2 comments from the Legion?
3 DR. FITZGERALD: Nothing to report today.
4 DR. SHEPARD: Thank you. We did leave some time
5 on the agenda to discuss other research efforts that the
6 members of the committee might feel to be crucial and so
7 I'd like to spend a little time on that. Then we will
8 open up the discussion for questions from the floor. I'd
9 like to start the discussion rolling a little
10 bit. As I think I have reported in the past, we have been
11 working on and now awarded a contract to the JAYCOR Corpor-
12 ation to do a search of a random sample of some 15,000
13 Vietnam era veterans who are in our
Patient Treatment File.
14 The contract calls for a search of military records
15 established within this group of Vietnam era veterans who
16 actually served in Vietnam and who did not.
17 It appears to me that there would be an oppor-
18 tunity then to compare medical information on these two
19 groups of individuals. The question that has been raised,
20 and I would like comments from the committee on it at this
21 point, is it a statistically valid
22 procedure to compare these two groups given that these
23 are individuals who have eligibility for health care in VA
24 hospitals.
25 It's been suggested

there may be some kind of a bias by using individuals who are in the VA system, and that one could not, perhaps, validly extrapolate that to the general veteran population. We are grappling with this issue. In other words, to what extent can we validly base conclusions on comparison of two groups within the patient treatment files? That's one question that we'd like some help on.

On another issue is the matter of the soft tissue sarcomas that exist in the Patient Treatment Files. We are currently going through a search of the Patient Treatment Files and have come up with approximately 200 soft tissue sarcomas that have been identified as existing in Vietnam era veterans.

The coding system of the VA is such that you cannot distinguish the types of soft tissue sarcomas within this group. These are classified as connective tissue tumors. We will attempt, by means of going back through the medical records of the individuals in the VA hospitals, to identify the type of soft tissue sarcoma that these represent.

From there we would go to a search of the military records to determine which of these 200 some individuals actually served in Vietnam and compare them to a group that did and did not serve in Vietnam. But those are two efforts that we are currently embarked on

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1 using our internal VA medical information --

2 DR. FITZGERALD: Dr., how many cases do you think

3 you have of sarcoma to look at?

4 DR. SHEPARD: Out of 203 in the ICD-9, 171 series

5 which is connective tissue tumors.

6 DR. FITZGERALD: So you don't have too many to

7 distinguish in the sub-types?

8 DR. SHEPARD: No, about 200, 203 I think and that

9 includes all in the Vietnam era. As you know, the Patient

10 Treatment File gives a discharge diagnosis of any veteran

11 admitted to a VA hospital and those discharge diagnoses are

12 coded according to the ICD-9 coding system. Unfortunately,

13 the cell type is not coded so we have to go back and get

14 the cell type to distinguish --sarcomas from fibrasarcomas

15 from other soft tissue sarcomas, use the actual cell type

16 because these tumors have their own prevalence rates.

17 I don't feel its scientifically valid to lump all

18 soft tissue sarcomas together in any way and try and make

19 any meaningful conclusions from that.

20 MR. GROSS:

21

22 Does anybody feel

23 that this is an unexpectedly high number? -- What would be

24 the expectation based on?

25 DR. SHEPARD: We have not made that analysis as

yet. We did take a quick look at the soft tissue sarcomas in the registry and that did not suggest an unusually high incidence in the registry. But, there again, being a self-selected group one can't make very valid comparisons.

MR. GROSS:

I think it is important to leave oneself every opportunity for flexibility. One should add things together, break them apart, look at it in different ways. Remember when Dr. Irey was here, I believe last time, there was a problem that he had a large number of diagnoses, but only one or two entries in each one of these. Well, these certainly don't mean very much. It's nice to look at them separately, but then one should give oneself the opportunity

--

DR. SHEPARD: Yes. I think

one of the justifications for looking at them separately is, if in the Vietnam veteran group there is a marked difference in the prevalence rate within the group of soft tissue sarcomas, in other words, if the normal prevalence within soft tissue sarcomas, I believe, -- sarcoma, fibro-sarcoma - the two most common - if some other more usual soft tissue sarcoma appears to be at a higher prevalence within that group, then that might signal something. So that would be one of the reasons I would think you would want to look at cell type. --

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1 DR. HODDER: No, just maybe a comment on the fact
2 this is the exact kind of study that shows you why you have
3 to go to a cohort type of design because you're looking at
4 200 -- an unusual amount, and basically the answer is, you
5 can't tell. For two reasons, one, you don't have a compari-
6 son. Well, the first reason is, you don't have a denomina-
7 tor really that you can, at this point, use because you
8 can't use a known group who have served in Vietnam because
9 -- actively. The only, I guess, good comparison would be
10 to get, let's say, a Korean war cohort to get an idea of
11 the --. But, then again, you have to look at the frequency
12 of using the VA. So this type of study, while its inter-
13 esting, is very difficult to do. --
14 DR. SHEPARD: Thank you. Any other comments from
15 members of the committee or any other suggestions for addi-
16 tional research efforts? We might start thinking of it.
17 We're in the process now of building budgets and now is the
18 time to think about what we should be looking at in the
19 future. Yes, Joe?
20 DR. KEARNEY: I have two. These are in the form
21 of suggestions. I'm concerned that the epidemiology study
22 is again delayed. I won't go into all of the background
23 that's involved in the newspapers, but from a scientific
24 standpoint we have a further delay. We have more time now to
25 wait before we get a final answer and it must be difficult

for the politician facing his constituency to answer this question. It's difficult for the VA to answer the questions about possible effects. And certainly as a member of this panel when I go before the press it's difficult to answer these questions. But this doesn't say that things aren't happening in this world and every month I get 3 or 4 publications, articles, research articles about experiments done on a global basis. So, my suggestion is that we get a critical evaluation and conclusions on global research on dioxin exposure and adverse human effects.

We have the literature review done by JRB, which was good, but now I think we need to sit down, looking at the global literature and to group the studies under various health effects, birth defects, to summarize the number of studies conducted, the number of people involved and a critical assessment of those studies and sound scientific conclusions.

I don't know what it will tell us, but I'm concerned that the anxiety will continue to build because we have another for 8 years or 10 years of studies. This is hardly a satisfactory answer when people are concerned, as they are. So, I think we've really got to bite the bullet. I think we've got to do it, perhaps outside of this committee, to sit down and look at all the literature that is available to us. Its really rather large, and arrive at

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some interim assessment as to where we are. If we don't do that, I think we're going to see further anxiety, further frustration from all segments of society. That's a form of suggestion.

Number two, I would like to see us do more on the question of exposure. We live in a chemical world. I don't think it's outside the realm of possibility that in either a limited or global warfare that chemicals won't be used again. We may go through this same process 10 to 15 years from now. Hopefully, we won't. But, it seems that we have an opportunity to arrive at some numbers, some estimates on exposure to chemicals based on things like distance from the point of application, time in the zone of application, that is, if you're a combat soldier in an area that has been sprayed, what is the effect of the length of time you're in that zone and your possible dosage? The residual time of a person in that area, the residual time of the chemical, the effective particle size, a whole raft of useful information that could be useful to us in further designing the epi study, but in a larger context, it would be helpful to other segments of society where we have to make a risk-benefit assessment on exposure data. Our models are not as good as they should be. to get exposure in fixed wing aircraft and with helicopters, but a larger segment of the scientific community could use this data. I think it would

be a service if VA would pursue this to get some better information on what exposure is.

DR. SHEPARD: Thank you, Dr. Kearney. They are two excellent suggestions and you're quite accurate -- in the problems of exposure. We are going to have a meeting of the Agent Orange Working Group, I believe on the 15th of December, and at that time the latest work of the subcommittee of the Science Foundation on cohort selections and I think that we've pretty much come to some closure in that area and it should be an interesting meeting -- taking up that issue.

I certainly agree that the whole issue of chemical exposure is one that's important to the entire federal government. I would hope that other agencies would continue work, the ground work that's been laid by the Agent Orange Working Group and the science panels and pool our resources so that we can build on the foundations that have been laid in this regard. It's very important. On your first point, if you give me an opportunity to take a few minutes, to just bring you up to date in what we are doing in the area of literature analysis and so forth. You know the JRB effort that you referred to is now over a year old and we'll soon publish or request a proposal for an update of that with special emphasis on the human effects. I think that will be a

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1 very
useful effort. In addition, we've been approved, we've been funded
2 for four monographs, one of which will deal with the known
3 human effects of phenoxy-herbicides and other herbicides.
4 So there is going to be a monograph as well as the litera-
5 ture analysis.
6 Of course, we'll also be doing a monograph on
7 birth defects, genetic screening, genetic counseling, and
8 Agent Blue. Hopefully, as Dr. Fisch-
9 mann indicated,
we'll have a major monograph on chloracne. These, I
10 think, will all be relative firsts in the field and we are
11 very much looking forward to this effort. Yes?
12 DR. LINGEMAN: I'd like to say that the VA has
13 some capabilities within the system to do some things that
14 have not been done. I believe that Dr. Fischmann's report
15 illustrates that there is considerable scientific talent
16 within the VA -- I think there are certain other areas
17 that could be dealt with in a similar manner. Task
18 Force is a good word
or maybe one or more sub-committees. Some areas that
19 could be studied within the VA in small studies as opposed
20 to large ones would be the lymphoid system, the liver and
21 the nervous system. Within the VA I think there are some
22 good possibilities. Men with known service in Vietnam
23 could be subjected to intensive studies of the lymphoid
24 tissues. Another area
25 which could be done very well within the VA would be the

1 study of hepatatoxicity. I think we have evidence that the
2 VA has some excellent physicians on the staff that are
3 capable of doing intensive studies of the problems of such
4 exposed men.

5 The third area that I think could be studied in
6 this way would be the central nervous system. There might
7 be two possibilities. One might be an intensive study of
8 toxic neuropathies. This is an area that very little is actually
9 known, but I think the VA could make a great contri-
10 bution to the world literature on such an effort. There
11 are many excellent neurologists in the VA and I think, in
12 consultation with known experts in this area, a good study
13 could be planned.

14 The psychiatric aspects of dioxins also need to
15 be studied. There is no good psychiatric test for toxic psychiatric symptoms. This is an area that
16 has been relatively unexplored. I think its one that should
17 be looked into, particularly since anxiety appears to be a major symptom of people with
18 exposure to dioxin. The effects of anxiety itself should
19 be separated from direct toxic effects of dioxins. I think
20 this capability probably exists within the VA. If not, it that, again,
21 could be done by a contract with someone on the outside.

22 The fifth area I think needs to be resolved is
23 that of the soft tissue sarcomasand getting you and I -- Dr. Enzinger (STS). Experts, such as the AFIP's Dr. Enzinger, need to
24 be consulted more frequently. One
25 criticism of the

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Swedish studies is that all types of STS, visceral and non-visceral, were condensed together in a mixed bag that no one can make anything out of it. So, -- by the time you break them down into too many categories, you have something that may be meaningless. On the other hand, if you don't have some good reason for separating them, then perhaps you are justified in lumping them all together.

So these are my suggestions, that the VA could select target organs for studies of toxicity and study them intensively.

DR. SHEPARD: Thank you. Dr. Woodward?

DR. WOODWARD: In support of the comments just made, the National Academy of Sciences in 1952 sponsored a study of the -- effects of blood dyscrasia and chloramphenicol. I can tell you that the only reliable and analyzable data came from the Veterans Administration. Most of the other data was antedotal. The point is that the VA had good records, there was continuity of care, and it had the only available information regarding a reliable denominator and an answer pertaining to risk.

DR. SHEPARD: Thank you. Mr. Walkup?

MR. WALKUP: I guess a few comments about the limits of science I think as part of your question. A lot of what we've heard today has been about -- the limitations that we've got of even being able to apply the science that is available is the time-frame that's involved in getting

the answers. It is definitely going to create problems for the people. This is a strange Advisory committee with a dual role of scientific advisory plus advisory about the people. One of the most significant things, I think, that's come out of all the chaos has been what's happened with the CAC report. All the unanswered questions that are out there. What's happening with all of the state organizations, they're trying to find the answers too. And their frustration and the frustration of many veterans with us not being able to find the answers. You'd think at some point, it's the responsibility of this committee to respond to the question that was asked by those organizations today, a policy question not a scientific question, that, given the lack of information that we have been able to provide, at what point is it our responsibility to shift the burden of proof from the veterans who have no resources to be able to conduct these studies, if we haven't been able to conduct them.

And to take a policy action which says that until we are able to -- that information, its our responsilibity to attempt to respond to the needs. To some extent we've done that -- but specifically there were some recommendations that came out of that committee and the National Veterans' Task Force on Agent Orange is on record as supporting the recommendations that the state commissions

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1 came up with and I would like to endorse those and urge
2 other members of the committee to endorse those too, in
3 addition to the VFW's endorsement of the Daschle bill and
4 the DAV's endorsement of the movement of the epidemiologic-
5 al study to the CDC.

6 The recommendations of the state commissions
7 briefly were that this body endorse the transfer of the
8 epidemiological study to the CDC with adequate resources
9 to fund that study under the Vietnam experience factor.

10 Also that we support the bill under con-
11 sideration in the House of Representatives concerning the
12 presumptive disability for Vietnam veterans. The National
13 Veterans' Task Force on Agent Orange endorses those and
14 urges other members of the Advisory committee to do so also.
15 If we don't do that, I think our silence will mean that we
16 don't endorse this.

17 DR. SHEPARD: Thank you, a good point. Excuse
18 me, Dr. Fitzgerald?

19 DR. FITZGERALD: I would like to go back to Dr.
20 Lingeman's suggestion about the research studies. Basic-
21 ally, I agree with what Dr. Lingeman said, The strength of
22 the VA in research is in its cooperative studies because
23 of the vast organization it has and the distribution it has.
24 I think that this is where meaningful information is
25 going to come out rather than going into several small

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1 isolated studies. That, indeed, if you could develop a
2 cooperative study in the effects of Agent Orange within the
3 Veterans Administration.
4 DR. SHEPARD: Yes, I think that's a very good
5 point and I certainly will continue to encourage this kind
6 of effort. You know we went out with a solicitation for
7 research projects related to the effects of herbicides and
8 dioxin on animal studies primarily. We've got 10 good
9 studies going in that area. We need now to encourage addi-
10 tional clinical studies. Of course, the twin study will be
11 such a study. It will not be a cooperative study in a sense
12 that we will be using large numbers of VA facilities, but I
13 hear what you are saying. I agree that this is an area
14 that the VA has been able to make a major impact on the body
15 of scientific knowledge that was available to us. I
16 think we have an obligation to pursue them.
17 I'd like now to encourage comments and questions
18 from the floor. I have one question here from Mike Sutton,
19 from the VVAW and he says, Dr. Custis stated the minutes of
20 the Executive session will be published. The question is,
21 will you release the minutes of the last three closed
22 sessions of February, May and August? If so, when? If
23 not, why? Did we have three closed sessions?
24 I think we've only had one closed session, and
25 that was a session that related to the discussion of the

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1 UCLA protocol.

2 That meeting was in May. We did not make a transcript of that meeting in the sense that we do in these open meetings,

3 but there are minutes of the closed session. We did discuss the protocol and prepared some review comments

4 which have been forwarded to CDC along with the other

5 comments.

6 Yes, Doctor?

7 DR. FITZGERALD: I think to respond to that also,

8 that closed session, if you'll recall, was not for any other

9 purpose than to respond to the criticism of some of the

10 members of the panel that the entire questionnaire was not

11 made available to the members of the panel. The question-

12 naire had not been made public the same way as the Air

13 Force questionnaire had not been made public in order to

14 not hazard the study by having people respond to known

15 questions before they are examined. That is all that was

16 taken up in that committee. It was a chance for us, as

17 individuals, to examine that questionnaire and until the

18 actual examinations are done, I can only agree with the

19 fact that the study should not be hazarded.

20 DR. SHEPARD: Thank you, Doctor. I have a ques-

21 tion here from Jim Hebron from the New York State Temporary

22 Commission. "First, will the VA agree to allow the CDC to

23 have complete freedom to pursue the epidemiological study

24 as CDC sees fit?" I can assure you that the VA has no desire

25 or intention to manage, control, even monitor that study.

1 Dr. Custis feels very strongly about this and its very care-
2 fully written into the proposed interagency agreement that
3 the CDC will have complete autonomy in terms of policy and
4 management of the study. The VA's role will be that of
5 funding the study because the study was mandated legisla-
6 tively to the VA, so the VA still has some responsibility
7 in the area of providing the requisite funds, but other
8 than that, we have no intention to make any efforts to
9 influence the CDC in terms of how the study should be con-
10 ducted and when it should be completed.

11 The second question. "Will there be a guarantee
12 that the CDC will receive the necessary funding now and in
13 the future?" As you all know, that responsibility lies with
14 the Congress. We cannot guarantee what the Congress will
15 do. We can guarantee that we will put in our budget the
16 requisite funding. Whether or not the Congress will see
17 fit to provide those funds, of course, remains to be seen.
18 I would think that the Congress, because of its intense
19 interest in this whole issue, would probably see fit to
20 fund any reasonable request for the conduct of the study.

21 This is from Matt Kinnard of our
22 Research Service, here in Central Office --regarding Dr.
23 FitzGerald's comments. "After the preliminary review and
24 approval of the twin study, R&D has recommended that the
25 conduct of the study be done under the cooperative studies

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1 mechanism. There has already been some effort to use that
2 process." Are there any other questions from the floor?
3 Any comments, discussion? Yes, this is Colonel Brown from
4 Pennsylvania. Why don't you come on up?
5 COL. BROWN: In our discussion yesterday with
6 members of the HHS, a comment was made that the CDC, if
7 they take the study, this is not
8 a fact, they have a choice, they could refuse the study.
9 I questionned whether they thought they had the lux-
10 ury of ever turning it down with the country
11 pushing it in their direction. But the one was--that they
12 may not choose to use the UCLA protocol. Is that a
13 fact? That with all the money, the time, the 4 years of
14 discussions and reviews, must they stick to the design,
15 the UCLA design or do they have the luxury of saying, no,
16 we're going to throw it aside. We're going to use some
17 part of it, but that is not the way we're going to run the
18 study?
19 DR. SHEPARD: In answer to your question, Colonel
20 Brown, I really can't answer that question other than con-
21 ceptually. I don't think that there is anything binding
22 on CDC to use the UCLA protocol. I think, however, that as
23 a practical matter, a tremendous amount of effort has gone
24 in, as you suggest, I doubt that CDC will completely start
25 from scratch. I know that efforts are underway, have been

underway of reviewing the protocol and refining it and so forth. But, really, I don't know the answer to your question in terms of what they are planning to do. We have not yet seen their final proposal or even a preliminary proposal. I know they are working very hard on it and I hope that something will be forthcoming very soon.

I think it also is important to state that the VA will not be in the position of approving the protocol that CDC chooses to adopt. We are not going to be in the position of approving CDC's plans. We'll be interested in it obviously, we will fund the study, but it is important to point out that the VA is not going to be the one that will be the determinant of exactly what protocol will be used. Yes?

MS. GWALTNEY: My name is Linda Gwaltney. I'm founder of Agent Orange Victims of Atlanta. I founded it after my husband died in 1980 from non-Hodgkins lymphoma. I did a TV show for a year in Atlanta called "Bette's Forum" on cable about the problem of Agent Orange and other veteran's problems. I did it with two veterans and they died a month apart so our show had to be cancelled until we can start again. They both died from soft tissue cancer. All of these men I'm talking about are under the age of 40. The only thing we had in common was they were all in Vietnam. I have many friends in Atlanta that are widows and

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1 we have a lot of children between us. All we can do is beg
2 you, the panel, the people in the audience, look at it from
3 our side too. You hear the scientific facts, but listen to
4 the human side. Our lives are destroyed. Our husbands are
5 gone. Our children are dying or either they have birth de-
6 fects. It seems like there's no hope for the future for
7 us. What can we do? Can anybody guarantee us any hope?
8 What about our grandchildren? Will we ever have a night's
9 sleep again?
10 You know, what's going to happen to us? We're
11 not concerned just about ourselves. We're concerned about
12 our whole world. What is going to happen? We don't know
13 yet what's going to happen. In Atlanta we hear lots about
14 James Francen, the nursery worker, that his lungs were de-
15 stroyed by paraquat. They don't say allegedly destroyed by
16 paraquat. We hear, his lungs were destroyed by paraquat,
17 which is a herbicide. Now, why can't we be given the same
18 consideration? Is it because there is so much money at
19 stake? Money does not mean anything to us because even if
20 we win our compensation or anything, we have lost, we have
21 all lost. So, all we can beg you for is just some hope for
22 the future. Please, it's the most horrible nightmare. You
23 can't imagine what happens to these men when you're trying
24 to take care of them yourself and we're not nurses. We're
25 not qualified to take care of these horrible things that

are happening to us. So all we can do is just beg you, please listen to us and please look at each case and think of what's happening to our families and our future generations. Because it just doesn't affect us. Because we know what kind of chemicals are being used in the United States too. We have Love Canal, the forest industries out West where women have been told to plan their pregnancies around the spraying missions and things like that. Just listen to us and give us some kind of hope that the use of chemicals in the United States and in the world will be studied more before they're sprayed without knowing what can happen. That's all we can ask you for, just help us.

DR. SHEPARD: Thank you very much. I appreciate your coming here. We hope to have somebody from our veterans' Counseling Office here to meet with Melinda and your friend at 12:15. Is that all set up? We will have somebody here that can address your particular concerns in terms of -- Yes? Senator Carl Berning from Illinois.

SENATOR BERNING: Somewhat as a follow-up to this ladie's questions, I have a question that I'd like to pose. It represents somewhat of a consensus of questions from the various agents that formed commissions in the conference. Inasmuch as the scientific studies are projected to continue for anywhere from a year to 5 or 6 or 7 years and decisions affecting those people who are now suffering,

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1 apparently would require some political determination, our
2 question is simply this: if we assume a positive political
3 posture, and do appeal to the Congress, Congress members
4 individually of our states as well as collectively, will
5 the VA, if not actively join in our efforts, passively
6 refrain from attempting to interfere or block our efforts?
7 Recognizing there is quite a difference of approach between
8 the scientific solution and a political solution, we would
9 like to know if we can approach Congress
10 we aren't going
11 to be running into bureaucratic blocks. Would you care
12 to comment?
13 DR. SHEPARD: -- illusive treatment of a knotty
14 problem, Senator Berning, and you better than I are aware
15 of the political implications involved. I think that the
16 only thing I can really say
17 is when legislation is proposed by the Congress,
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19
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21 it is passed to the appropriate agency
22 for comments. That is a fairly complex process in many
23 instances and requires, I would say, the corporate wisdom
24 of an administration such as the VA. I think that one has
25 to look at those issues on a case by case basis and it's

1 difficult to generalize. I can give you a little bit of
2 example as to what has happened in the past regarding cer-
3 tain legislation. I am referring now to Public Law 97-72
4 which was proposed as an authorization for care to Vietnam
5 veterans who perceived a health problem resulting from
6 their exposure in Vietnam. I think the VA cooperated
7 rather promptly with the Congress in implementing that
8 legislation to the extent that we drew up guidelines which
9 we felt were reasonable in terms of what kinds of conditions
10 might be suspected as possibly being related to exposure to
11 Agent Orange and what kind of conditions by any rational
12 approach to the problem would be excluded as having been
13 not the result of exposure to Agent Orange.
14 A similar piece of legislation was passed relating
15 to exposure to ionizing radiation and guidelines for that
16 implementation were drawn up. So I think that in that in-
17 stance, we worked very closely with the Congressional com-
18 mittees and came up with a good solution to a rather com-
19 plex issue and I think that that's worked out reasonably
20 well. I would hope that reasonable legislation is proposed
21 that we would approach it, that the agency would approach
22 it in an open-minded fashion. But I think we'd actually
23 have to look at the language of the legislation before we
24 could make any comment on it.
25 SENATOR BERNING: Let me challenge that just a

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1 minute. We wouldn't want you to look at the language of a
2 bill, we want you to look at the concept. In other words,
3 help now versus a determination of possible help one year,
4 5 years, 10 years down the road. The position of you, the
5 VA or any other agency to whom a bill might be referred for
6 comment could either be bludgeoned into insensibility or
7 killed with kindness or just passively accepted as comment-
8 ed on with a bit of encouragement versus a great deal of
9 opposition and that's the sort of position we'd like to
10 have you take. Namely, you may have reservations, but if
11 the objective is something we cannot any longer avoid, in
12 my opinion. We hope that the conviction of those of us
13 who represent the various state's commissions is beginning
14 to make itself apparent to you gentlemen and ladies and
15 anyone else who has any interest in or obligation to this
16 problem. So we would, if you don't care to take a firm
17 stand, please keep in mind that, at least in my individual
18 personal conviction, this is going to be politically re-
19 solved and I don't mean partisan politically, a political
20 decision, a political answer and it's going to rise or fall,
21 to a large extent, on the degree of acceptance or resist-
22 ance by the people who influence the Congress and the bill
23 that's been referred to --
24 DR. SHEPARD: Again, my only response
25 is that we would remain in the posture of supporting

1 veterans' causes, that we, the agency, views itself as the
2 advocate of the veteran not as the adversary of the veteran,
3 so I think that the record stands very clearly that the
4 Veterans Administration does support reasonable legisla-
5 tion that will further the cause of veterans. Again, I'm
6 not an expert in this field. I don't feel comfortable about
7 speaking for the administrator on such issues. However, I
8 think, as a matter of principle, I think that reasonably
9 safely that the VA stands ready to support veterans' causes.
10 Are there any other questions or comments?
11 Well, we've come right down to the wire and I
12 appreciate all of your attendance and contributions. We
13 look forward to seeing you in about three months.
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Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Sixteenth Meeting
May 20, 1983

July 1983 Washington DC 20420

VETERANS ADMINISTRATION ADVISORY COMMITTEE ON

HEALTH-RELATED EFFECTS OF HERBICIDES

Veterans Administration
Room 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

May 20, 1983

The committee met, pursuant to notice, at 8:30 AM,

DR. BARCLAY M. SHEPARD, M.D., Chairman presiding.

MEMBERS PRESENT:

BARCLAY M. SHEPARD, M.D., Chairman
Acting Director
Agent Orange Projects Office (10A7)
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Washington, D.C. 20420

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CHARLES A. THOMPSON
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Washington, D.C. 20024

NOEL C. WOOSLEY
National Service Director
AMVETS
4647 Forbes Boulevard
Lanham, MD 20706

ALTERNATE MEMBERS OR SUBSTITUTES PRESENT:

(For IRVING B. BRICK, M.D.)
THOMAS J. FITZGERALD, M.D.
Medical Consultant
National Veterans Affairs
and Rehabilitation Commission
The American Legion
1608 K. Street, N.W.
Washington, D.C. 20006

(For JON R. FURST)
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Department of Human Resources
City of Seattle
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(CAROLYN H. LINGEMAN, M.D.)
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P R O C E E D I N G S

1 DR. SHEPARD: Good morning ladies and
2 gentlemen. I would like to call the meeting to order.
3 I appologize for the brief delay, but I think we can
4 get through our agenda comfortably this morning.
5 I would like to welcome you all to our 16th
6 quarterly meeting. It doesn't seem possible that
7 we've had that many meetings. Since our last meeting,
8 I had my third anniversary as Chairman of this
9 committee. The years roll by.
10 Anyway, it is always a delight to meet you and
11 have the opportunity to discuss issues with you.
12 I would just like to remind the committee and those
13 in the audience, that this committee is charged with
14 the responsibility of assembling and annalyzing
15 information which the VA needs to formulate appropriate
16 medical policy and procedures in the interest of
17 verterans exposed to herbicides during their
18 military service in Vietnam.
19 I think you will all agree that the Agent
20 Orange issue has not gone away. Perhaps, it has
21 even become more intense in some aspects, and I think
22 we still have a lot of work ahead of us. So,
23 although it has been over 4 years now since this
24 committee was first formed, the work is no less
25 important than it was in its early days.

I'm happy to report that since our last meeting we've had a 2 year renewal of our charter. As you know, this committee is chartered under the Federal Advisory Committee Act, and, as such, we have a renewal of our charter periodically, on a 2 year basis, and that renewal has now been granted for another 2 year period, to extend to April of 1985.

This meeting, as have all previous meetings, is open to the public and we welcome the presence and, at the appropriate time, the participation of those people in the audience.

For those of you who may be here for the first time, we remind you that there will be a period of time, following the formal agenda, in which we will solicit questions from the floor. In order to facilitate that process, we would appreciate you writing your questions down. Don Rosenblum, the very able executive secretary for this committee, has cards and pencils. Please write your questions down. That kind of makes the process flow a little more easily.

In order for us to have a record of attendance, we would encourage you all to sign our registry out in the lobby. We are very happy to have with us this morning, Dr. Mary Kornreich, who is a Ph.D.

1 toxicologist with the National Toxicology Program

2 She is sitting in for Dr. Carolyn Lingeman who

3 could not be with us today. We are very happy to

4 have you here, Dr. Kornreich, and solicit

5 your comments as they are appropriate.

6 We are also very happy to welcome, for the first

7 time, Mr. Noel C. Woosley who will be representing

8 AMVETS. Noel, nice to have you with us. Noel, as

9 I say, comes to us from AMVETS, and this is his

10 first meeting. He is the National Service Director

11 of AMVETS and served 12 years in the Army including

12 2 tours in Vietnam. So, I think it is certainly

13 appropriate that you be a part of our program.

14 As we talked about, at our last meeting, we

15 are implementing a slight change in our procedures.

16 For a number of reasons, which we talked about fairly

17 extensively last time, we have established 2 sub-

18 committees. One to be a subcommittee on

19 Epidemiology and Biostatistics and, Dr. Hodder has

20 kindly agreed to chair that subcommittee.

21 And, we also have a subcommittee on Public

22 Information and Education and that will be chaired

23 by Mr. Fred Mullen. These subcommittee meetings

24 will be held concurrently. The subcommitte on

25 Education and Information will remain in this room.

1 The subcommittee on Epidemiology and
2 Biostatistics will move to room 139 which is to your
3 left, across the lobby as you exit from this door.
4 Across the lobby, go up some steps, and it will be
5 on your left-hand side. And, we'll make those
6 changes at the appropriate time.
7 We have a number of announcements to make.
8 Among which are the fact that, at the encouragement
9 of the Administrator, a small group of us is going
10 to initiate an information outreach effort.
11 Starting next week, we will be going to Philadelphia
12 where we will spend 2 days. From there, to Boston
13 and then, the first few days of June, we'll be in
14 New York. And, the last several days of June, we'll
15 be out on the West Coast at Los Angeles and San
16 Fransisco and then returning by way of Houston and
17 Chicago.
18 We will be hitting 7 cities, 7 major metropolitan
19 areas. In all of
20 these areas there has been an increased level of concern and interest relating to
21 the whole Agent Orange issue. The purpose of this
22 effort is several fold.
23 First of all, it's part of an ongoing process
24 that was initiated a number of years ago. We feel
25 that it is a very important function of our office and

of VA Central Office to make every effort to keep veterans informed as to the progress of the issue, status of research, what the VA is doing, and

to make sure that our VA personnel are kept abreast of developments and, also, afford the opportunity for interfacing with a number of different groups.

Our agenda, principally and primarily, provides for, in each city, a meeting with some of the key staff of each of the medical centers in that metropolitan area, a fairly long session with VA employees from a number of the medical centers in each of the areas we will be visiting.

Also attending will be those VA officials involved in adjudicating claims and veterans counselors.

That will be, primarily, an update as to the status of research and program activities and will give us an opportunity to answer questions.

It will also give people in the field an opportunity to raise concerns for discussion purposes.

We've also scheduled very important evening sessions in each of the cities.

At this session, and it is specifically designed as an evening session to enable as many veterans as possible to come and have a dialogue with us,

we want, very much, to stay in close touch with all concerned Vietnam veterans, and we will have, at least 2 hours, that may stretch out to more than 2 hour sessions, and we are encouraging all Vietnam veterans who are concerned, who want to talk to us, who want information, to be part of that process.

This will be a somewhat less structured agenda. We want to devote most of the time to veterans' questions. We'll be giving some information update, but, it will be primarily an opportunity for veterans to bring their concerns to us and for us to answer their questions.

We also want, very much, to maintain our on-going relationship with all state Agent Orange Commissions and committees, so, there are times provided for doing that. We also want to stay in close in touch, as we have, with veterans service organizations.

So, we are encouraging the leadership of all veterans service organizations to be a part of this process. We have informed each of the centers involved of the program. We are also attempting to get the word out to all veterans through a variety of means. Through the media, the service organizations, and our readjustment counseling people; we are trying to

make this as a broad brush an effort as possible. We'll be reporting back to this committee, the result of these efforts and, hopefully, they will be salutary. Needless to say, we are informing the congressional members from the respective areas as well as the House and Senate Veterans' Affairs committees so they will be kept abreast of our activities.

It's a real pleasure to announce that we have awarded a contract to Clement Associates for an update of our literature analysis. As you recall, in October 1981, we completed the first literature analysis and critical review of all scientific literature on phenoxy herbicides.

Since that time, it has been estimated that some 500 new publications of significance to this issue have appeared in the scientific literature.

It is very important for us to keep this effort moving so we can bring together, between covers of several volumes, all the information that is available.

So we are very happy to have Clement Associates on board with this effort and, it gives me pleasure to announce that Dr. Carl Schultz and Mr. Wayne D. Reinehardt of Clement Associates are with us today.

I'm sure some of you may want to address questions

1 to them later on.

2 So we are very pleased to have these gentlemen with us this

3 morning.

4 Our other efforts are moving along well. There

5 is continued interest on the part of Congress and

6 state legislatures in the whole issue. We have had

7 two hearings recently. One, in the later part of April

8 on Mr. Daschle's bill, HR 1961, which would

9 presumptively service connect three conditions.

10 That is,

11 chloracne, prophyria cutanea tarda, and soft-tissue sarcomas.

12 I think that was a very interesting set of

13 hearings. A lot of witnesses provided testimony

14 and we will be looking at the results of that effort

15 as time goes on.

16 We had oversight hearings before the House

17 Veterans' Affairs Committee on the third of May,

18 and we, I believe, are scheduled to have hearings

19 before the Senate. That date has not been settled

20 as I understand it. But, we are anticipating, at

21 some point in the not too distant future, of having

22 hearings before the Senate.

23 Our various research efforts are going along

24 well. Our mortality study is moving along well and

25 Dr. William Page will report to us, or will report

1 to the Epidemiology/Biostatistic sub-
committee on the progress of
2 those efforts as well as other research efforts.
3 I think a very significant event that has
4 occurred since our last meeting, is the report of
5 the Australians on their birth defects study. We
6 have been asked by Senator Cranston, rather this committee
7 has been asked by Senator Cranston in
8 a letter dated
9 April 27
10 to review this study.
11 Now, let me just read Senator Cranston's letter.
12 I think some of you have that in your package.
13
14 Dear Dr. Shepard: As you know, the Commonwealth
15 Institute of Health University of Sidney, conducted
16 a study entitled, "Case-Control Study of Congenital
17 Anomalies and Vietnam Service." The report was
18 submitted to the Australian Minister for Veterans'
19 Affairs on January 24, 1983.
20 The study's conclusion, as stated in the
21 summary of the report, felt that, "there is no
22 evidence that Australian Army service in Vietnam has
23 increased the risk of the birth of a veteran's
24 child with an anomaly," is naturally of
25 great interest to the members of the U.S. Armed

1 Forces in Vietnam concerned about any excess risk
2 of parenting birth defective children. Thus, I
3 would very much appreciate the Advisory Committee's
4 review and comment on this study, particularly its
5 evaluation of the methods used and the conclusions
6 drawn from the data collected.
7 Thank you for your continuing cooperation with
8 the Committee.
With best wishes, Sincerely, Alan Cranston.
9 So, we had planned to do that anyway, but, it's
10 nice to have Senator Cranston's encouragement. So,
11 I would charge the committee to review that study
12 very critically, and, provide comments back to me,
13 if possible by the end of six weeks.
14 I think some of you may have already had a
15 chance to look at it. I'm not sure how many of the
16 committee were mailed copies of it in advance of
17 this meeting, but, I would very much appreciate each
18 of your comments by the end of the first week in
19 July.
20 I think it is very important. In that
21 connection, we have been informed that the
22 Australian government has appointed a Royal
23 Commission to study the whole Agent Orange issue.
24 We just received word, officially, from the government
25 of the Australia, that such a commission is being

1 assembled. As I understand the process, it will
2 consist, primarily, of a ranking senior judge who
3 will take testimony from a variety of experts and
4 then prepare a report.
5 Another event which will occur sometime this
6 summer, and we're not certain exactly of the date
7 yet, but, we've been informed that Dr. John Donovan,
8 who is the Senior Science Advisor to the Ministry
9 of Veterans' Affairs, is a member of the Commonwealth
10 and Institute of Health, will be visting the United
11 States.
12 And, so, we are looking forward to a dialogue
13 with him. We are hoping that we can set up some
14 kind of a meeting for him to brief us on the current
15 status of research in this area in Australia. I
16 think it might be nice if we can assemble those
17 members of the committee who can attend on an
18 ad hoc basis, not necessarily as an official committee
19 function, but, those of you who would be interested
20 in meeting Dr. Donovan, I think it would be very
21 helpful and useful,to all of us, to have such a
22 meeting.
23 Are there any comments or questions from the
24 members of the committee concerning efforts and
25 procedures on the matter of our subcommittee meetings,

1 or any other comments from the committee while we
2 are still meeting. We planned to reassemble
3 at approximately
4 the agenda calls for 10:30, but I think we will push
5 that up to about 10:45. So, if everybody will
6 reassemble here after our respective subcommittee
7 meetings at 10:45.
8 We will then have a report from the two
9 chairmen of the subcommittees as to the highlights
10 of their deliberations and then we will take questions
11 from the audience.
12 Now, are there any comments or questions from
13 the members of the committee now? (Silence) All right. That
14 being the case, I think we will now break up into
15 our subcommittee meetings. Let's say the
16 Information/Education subcommittee will remain
17 in this room to be chaired by Mr. Mullen and the
18 Epidemiology/Biostatistics subcommittee will
19 move to room 139.
20 Let me read the list of the members of the
21 committees for your information. I'm very sorry.
22 The following people will be on the Epidemiology/
23 Biostatistics subcommittee: Dr. Brick, in his absence Dr. FitzGerald,
24 Dr. Cordle, Dr. Hodder, Dr.
25 Lingeman, Dr. Kornreich in her absence, Dr. Moses.

The Education/Information Committee will be composed of Mr. Furst or Mr. Walkup who is representing him, Mr. Mullen, who will chair the committee, Mr. Sypko, Mr. Thompson and Mr. Woolsey.

(OFF THE RECORD UNTIL 10:45 AM)

MR. SHEPARD: I'd like to call the wrap up session of the final portion of our agenda to order. I am remiss in not having introduced to you, at the opening session, Dr. Patricia Breslin. Dr. Patricia Breslin, who comes to us from OSHA, is a very senior and experienced biostatistician. She is joining our research group. We are most delighted to have her as a full time member of our research team. I think we are very fortunate in that we have now Dr. Kang and Dr. Patricia Breslin, and, we will soon have a very experienced statistical programmer, who has had a lot of experience dealing with the ADP aspects of epidemiology. So, we are going to have a very nicely rounded out team. We are very fortunate have them.

I would like now to call on the chairmen of the two subcommittees to give us a brief summary of what went on during the two parallel sessions. First of all, Mr. Fred Mullen, would you give us a wrap-up on

1 what your committee discussed.

2 MR. MULLEN: Well, we had general free-for-

3 all and there was a lot of constructive criticism,

4 a lot of recommendations that went out, that came out

5 during our subcommittee meeting. And, a few of these

6 suggestions I would like to get into the record.

7 First of all, in the planned 7 city sessions, we

8 felt that it would be best if we had a service

9 organization representative there to evaluate the

10 process. And, Mr. Woosley, from AMVETS said he

11 has already made plans to have a representative of that

12 organization present. And, Mr. Thompson and Mr. Sypko

13 will get back to me this afternoon regarding

14 participation of their organizations.

15 We want to get this underway as quickly as

16 possible because of the imminence of the onset, or

17 beginning of the sessions. They will be giving us

18 feedback on each individual session as they progress

19 so we can refine, add to, or take away from, the

20 agenda of those meetings.

21 Also, the videotapes that are going to be made

22 of those meetings, or sessions, we are going to

23 try to get them out, not only to the VA, but to

24 service organizations as well so we can present them

25 to our service officers during our annual

1 conferences.

2 We felt that there should be more balance

3 reporting in the VA pamphlets. We discussed a lot

4 of negativistic reporting in the media. It's

5 rather one sided. We also felt that the VA reporting

6 was a little bit too positive.

7 We felt that both should give equal time to

8 different views on the issues.

9 DR. SHEPARD: Excuse me for interrupting.

10 Did you come up with any recommendations as to how

11 that should be implemented. I understand the problem.

12 Did you make any suggestions as to how we can deal

13 with the problem.

14 MR. MULLEN: No, we identified the problem.

15 DR. SHEPARD: I think we all recognize

16 the problem. Obviously, we welcome your observation

17 very greatly. I was just wondering if you had dealt

18 with some of the means of dealing with the problem.

19 Because that's very important.

20 MR. MULLEN: For instance, in the Agent

21 Orange pamphlets that are going out, Mr. Walkup, in

22 particular, pointed out that just

23 about everything that was being reported was the

24 positive results of certain studies and nothing

25 about the negative results of other studies.

1 And, we think that both sides of that coin should
2 be portrayed and let the veteran's self evaluate the
3 situation. Give him a little bit more insight. That's
4 all we had time to do on that particular issue.
5 DR. SHEPARD: It's a good point and I
6 hope that you can pursue that.
7 MR. WALKUP: There were a couple of
8 specific things along that line. One, was on
9 discussing the Agent Orange studies in Australia,
10 many veterans know that the compensation procedures
11 in Australia are different than they are here.
12 That wasn't mentioned in the article. What was
13 mentioned were the results of the Australian's studies
14 which reinforced the things that the Veterans
15 Administration position on not having adequate
16 information yet, about a number of areas.
17 DR. MOSES: How is the compensation
18 different? In what way that it would affect an
19 epidemiological study?
20 MR. WALKUP: Oh, the presumptive disability
21 has been given for veterans who were in Vietnam from
22 Australia, and, they are receiving compensation -
23 DR. MOSES: Just for having been there.
24 I mean, they don't have to be tied to anything?
25 MR. WALKUP: Well, it's a presumptive

1 disability, that, if a veteran dies of soft-tissue
2 sarcoma, his widow gets compensated for a service
3 connected item.
4 DR. FITZGERALD: I think it's a little bit
5 different than that. The situation in Australia is that
6 the burden of proof is upon the government
7 to disprove, instead of the opposite that takes place
8 in this country.
9 DR. SHEPARD: I would question whether or
10 not Australia has established any presumptive
11 conditions. As far as I know, that is not the case
12 here. If you have information, I would like to know
13 about it.
14 MR. WALKUP: Well, I think that's a
15 semantic difference that presumption means that the
16 veteran's point is presumed until proved otherwise.
17 DR. SHEPARD: Okay. I thought you meant
18 in terms of -
19 MR. WALKUP: More generic presumptive.
20 The way they operate is presuming that the veteran's
21 case is true until proven otherwise. The way we
22 are with Agent Orange is, we presume that there is
23 nothing wrong with you until you prove that there is
24 something wrong with you, in the case mentioned.
25 MR. MULLEN: All right. I figured we have

1 identified that there are definitely more difficulties
2 in the conduct of examination and attitudes of the
3 VA personnel in major metropolitan areas versus the
4 rural areas. We would like, perhaps, to have, in
5 future subcommittee meetings, a member of DM&S, in
6 particular, a quality assurance person here, to
7 consult and give us some insight into what and how
8 they are approaching this problem so we can
9 disseminate that information to our veterans.
10 Also mentioned, was the possibility of evening
11 exams or Saturday examinations for the Agent Orange
12 exams. A lot of veterans are in pretty bad financial
13 straits right now and they are very reluctant or
14 completely unable to take off work in order to
15 appear for an examination.
16 We would like to ask the VA to look into the
17 possibility of scheduling possible evening or
18 Saturday examinations. We also discussed expanding
19 the outreach efforts to other cities beyond the
20 seven that are presently scheduled.
21 We'd also like a member of DVB here during our
22 subcommittee meeting, in order to answer some of the
23 questions regarding compensation or adjudication of
24 these issues. In the registry mailing of the
25 information bulletins and Agent Orange pamphlets, we

1 think that there should be more use made of the
2 readjustment counseling available in the outreach
3 centers. And, I think, that if we were to also send
4 out a copy of IS-1 Fact Sheet, which gives the
5 addresses, or a separate listing of the addresses of
6 the outreach centers, these veterans may be more
7 aware of their presence and this would be more or less
8 an invitation to them to come in if they should have
9 any problems and seek help and advice.
10 Mr. Walkup asked if we could get a report on
11 differences of the veteran's data on exposure,
12 explaining the differences between VA and EPA as far
13 as exposure indexes, or, would you like to
14 explain that a little further?
15 MR. WALKUP: Yes. specifically,what I
16 was asking for was clarification on the issue
17 of differences in EPA and VA scope of responsibility
18 and procedures in dealing with Times Beach and
19 Vietnam. And, what I asked for, was a specific delination
of responsibilities.
20 You know, exactly what is the EPA's role and exactly
21 what is the VA's role vis a vis environmental
22 contaminents, and what are the responsibilities to
23 their respective populations for assistance or
24 compensation, and what are their responsibilities
25 for levels of burden of proof that are required before

1 they can take a specific action? We've come up against
2 that in generalities a number of times. I think we
3 need some specifics to deal with that.
4 DR. SHEPARD: I'm not sure that we should
5 necessarily respond to all of these right now because
6 I think we ought to get through your -
7 MR. MULLEN: We like to, if possible, we
8 would like to have that by the next meeting. We did
9 identify a problem that's been long lingering, and
10 that is, the veterans are rendering the same types
11 of complaints about the conduct and the attitude of
12 the Agent Orange examination and personnel.
13 They don't seem to be as widespread and we would
14 like to know what
15 the guidelines are for policing the Agent Orange examination for quality control between
16 different VA medical facilities. I think that would be
17 the purpose of also having a member of DM&S
18 Quality Assurance staff present at our future meetings.
19 That's all that I have.
20 DR. SHEPARD: Thank you very much, Fred.
21 I think we can take a few minutes to address some
22 of these issues. Dr. Hobson?
23 DR. HOBSON: I have a very minor, sort of
24 procedural matter. In the first place, I think your
25 idea of having various veteran's representatives

1 comment on each of the sessions in this outreach
2 program is an excellent one. But I want to explore
3 the mechanics of getting the information to
4 us. Because the team will be passing directly from one
5 city to another
6
7
8 any feedback should come to us very
9 promptly if you expect to change the presentations. All
10 I'm saying is that we ought--and we can, I think--settle
11 here how any comments are to come in; whether it's all to
12 come in to you and you pass it to us here in
13 Washington or whether it is to be delivered
14 directly to our office from each of the representatives
15 and, if so, to whom it should come so we can get it
16 out to the field team in as expeditious a manner as
17 possible.
18 MR. MULLEN: I did request that they not
19 wait until the entire series of sessions is over, but,
20 to make a report almost immediately following that
21 particular session and get it in as quickly as
22 possible. I don't know who you would want it sent
23 to, but, I think, it would be best in the hands of
24 the people who are going to be conducting those
25 sessions so they can police themselves as they go

1 along, but, at the same time, we ought to have that
2 information.
3 DR. SHEPARD: I would suggest two strategies
4 to the upcoming seven visit. We will be available.
5 Part of the agenda, as you know, calls for us to
6 interact with veteran service
7 organization leadership as part of the process. And, in
8 all but one of those cases, and I think there is a
9 scheduling conflict, but, in virtually every
10 instance, that session will be
11 at the end of that particular location's program.
12 So, there will be an opportunity to have a
13 wrap-up critique as we go along from place to place.
14 But, in addition to that, I think it would be very
15 good, as things are still fresh in their minds, of
16 whoever is going to be doing the critiquing, to call
17 back. Dr. Hobson will be here.
18 He is not going with us on the road shows,
19 so he will be here and can receive any
20 criticisms and then he will be in touch with us as
21 we go along. So, we can hear from two points of
22 view.
23 MR. MULLEN: I think Mr. Woosley has a
24 recommendation.
25 MR. WOOSLEY: One of the things that didn't

1 get mentioned, or maybe it wasn't worthwhile, and
2 I strongly suggest that the VA medical director and
3 the regional office director, make direct contact
4 with the service organization representatives in that
5 area and ask them to attend.
6 Okay. Now, fine, I called my people and said
7 I would sure like you there. I realize it is in
8 the evening but you can take some comp. time. But,
9 now I find that, all of a sudden, we are invited to
10 the daytime aspect of it as well. Now see, I wasn't
11 informed of that by telephone yesterday, so I was
12 just told there was a meeting from 7:30 to 9:30 in
13 the evening.
14 Now, if the VA medical director and the regional
15 director contact those people and invite them
16 specifically, then they will be there for immediate
17 feedback They can say
18 well, maybe you
19 should have done this.
20 And, one point you forgot, on the agenda, there
21 was no place for the veteran to be told how to
22 implement what you are going to tell him he can have.
23 DR. HOBSON: That has actually been taken
24 care of. Do you want to speak to that?
25 DR. SHEPARD: Part of the evening process

1 will be telling them how they get appointments for
2 the Agent Orange examinations, how they can file claims,
3 and other important information.
4 MR. MULLEN: Well, we got the opposite of
5 that during our meeting. We were told that there
6 would be a counselor available, but he was not
7 scheduled to disseminate any information or to
8 address these veterans, unless the veterans came and asked
9 for it. And, our suggestion was that the counselor be
10 afforded some opportunity to get up and tell these people,
11 as a group, how to proceed and give them some
12 direction.
13 DR. SHEPARD: Okay. Fred, do you want to
14 talk. Mr. Conway has been doing a lot of the
15 arranging, and he may have some comments on that.
16 MR. CONWAY: What we were discussing at
17 that meeting, I raised a question of the program
18 structure whether it was adequate or not. And, the
19 criticism was made that we didn't have anybody on
20 the program that would address the concern raised by
21 Mr. Woosley. And, I think it is very easy to
22 change things around a bit, and put somebody on the
23 program.
24 And, the other suggestion that was made, I
25 raised a question of whether we could get some feed-

1 back on the kind of information we're giving to
2 employees to see whether we are conveying the
3 message of empathy and understanding, compassion and
4 not apathy and not criticism and so forth.
5 And, the suggestion was made, or I raised the
6 question of whether it would be advisable to have
7 veteran service organization members at that
8 afternoon session. And it was the consensus of
9 the group that it would be a good idea. So, we
10 are going to now expand that -- a little bit by
11 getting invitations out.
12 As I tried to say, the program is a very
13 flexible one, and, it is one that we're trying to
14 put together that will be responsive to the needs of
15 the veterans and VA employees. In other words, we want
16 to get responsiveness, criticism and feedback.
17 DR. HOBSON: My plea really is--can we set
18 up a formal mechanism whereby each session's comments
19 can get back to the participants on the team
20 immediately so they have an opportunity to modify the
21 presentation? The best thing, if I may make
22 a suggestion, would be, that immediately following the
23 evening session the official representatives of
24 each of the veterans organizations get together with
25 the team and say, "This is what we think you are doing

1 wrong" or "This is what we think you are doing right."
2 There has to be pretty prompt response because the team
3 is going to be leaving almost immediately to go to
4 the next place and will want to get the criticism that they
5 can use at the next place.

6 MR. MULLEN: But, I think, as an advisory
7 committee, we ought to also get this information
8 because, if the VA is planning an ongoing series of
9 these sessions, I think, as an advisory committee, we
10 would be better able to pinpoint areas where there
11 may be potential problems, than those people that
12 are there immediately.

13 DR. HOBSON: I agree with that
14 completely. I was more concerned about getting the
15 immediate word to them so there could be a reaction.
16 Barclay thinks there may be a better suggestion for
17 doing that.

18 DR. SHEPARD: No. I think we should use
19 any means available to us to get the feedback. All
20 I'm saying is, that there is, in part of the structure,
21 an opportunity to do that feedback by service
22 organization representatives the day after the
23 evening session. So, that's sort of built into the
24 program already and I don't have a special mechanism.

25 MR. SYPKO: Fred, what we could do is

1 just ask them to respond immediately and then contact
2 us the next and then we can pass it on to you.
3 MR. MULLEN: Sure.
4 DR. SHEPARD: I think we need to bear in
5 mind too, although we've done this kind of thing
6 before, at other places, some time ago, we've never
7 done it exactly this way before and, consequently, we
8 are kind of feeling our way and seeing what
9 system will work the best. And, it probably will
10 work differently, better, in different cities. We
11 want to keep it flexible.
12 MR. MULLEN: All right. I missed one
13 point here, and that is, as Mr. Sypko pointed out, he
14 surveys VA hospitals for VFW, and he went to 4
15 hospitals, I believe, in the midwest. Only one
16 had an adequate display area and adequate pamphlets.
17 The other three did not. It may be a problem of
18 logistics getting them there, or, it may be a problem
19 that they are there and somebody just doesn't know
20 to put them out.
21 I think there ought to be some type of concerted
22 effort to specifically identify the type of display
23 that should be there and where it should be located
24 and, to make sure, that these publications get out
25 to the individual facilities.

1 Perhaps, through requiring them to respond upon
2 receipt or non-receipt.
3 DR. SHEPARD: Is Mr. Moen still here?
4 All right. Because there is a definite plan to
5 address that concern. It's part of Mr. Moen's
6 plan to respond to that specific complaint. So, I think
7 that's being addressed, or will be addressed.
8 I'm not sure
9 whether he mentioned it to you; they are going to have
10 posters in prominent waiting areas, clinic areas,
11 and so forth. The poster will have pockets
12 for pamphlets. Individuals then can mail back requests for
13 additional information, that kind of thing. So, that
14 will be, hopefully, part of the solution.
15 MR. MULLEN: But again, getting
16 them out to the hospital is one thing, but making
17 sure they utilize it is another, and I think that's
18 what we're mainly talking about.
19 DR. SHEPARD: We are intensifying that
20 effort. Thank you very much Fred. I'd like now to
21 call on Dr. Hodder to give a wrap-up of the
22 Epidemiology/Biostatistic subcommittee.
23 DR. HODDER: Basically, our subcommittee
24 looked at three areas. The first was the soft-tissue
25 sarcoma. Dr. Larry Hobson gave an excellent
28

1 succinct summary of the association of soft- tissue
sarcoma with phenoxy
2 herbicides, as published. He mentioned
3 that the Swedish study had the relative risk of five
4 to six times -- and we are obviously looking to see
5 how well this hold up.
6 The problem mentioned in the discussion were
7 with the study as well as the follow-ups and, of
8 course, as all case control studies, problems of
9 exposure, measurement and verification. Dr. Hobson
10 pointed out that the Swedish study, in several
11 follow-up articles, was pointed out to be methodologically
12 weak. Also, as in any study, we like to
13 see verification from other sources.
14 He specifically mentioned three areas. One,
15 that we would look in U.S. areas using herbicides
16 as evidence of a marked increase in this disease,
17 and he mentioned this has not been shown.
18 Second group was some studies that were done to
19 look at a similar type population in Europe.
20 Several of these studies were
21 negative but, again, they suffered from the same
22 methodological weaknesses.
23 And then, a third group, looking at the
24 occupational groups that manufacture the herbicides,
25 there is some support for an association with soft-

1 tissue-sarcoma. Dr. Moses summarized some of the
2 evidence for that. The Monsanto and Dow experiences
3 showing, -- -- somewhat higher than expected
4 instances of those diseases.
5
6 What we still don't know, in either designing
7 or interpreting studies, is the
8 difficulty caused by the long latency period, ten,
9 twenty years, which is, to me, an important aspect of the model.
10 What is exactly the model of the way this
11 disease works, is a specific carcinogen along the
12 line of the vinyl chloride
13 a promoter
14 Then, we would need to look at multiple
15 outcomes. Something -- like radiation or something
16 that would put a general increase in tumors.
17 The other side of that is the problem with
18 multiple exposures. The confounding problem--people not
19 only worked in TCDD, they were exposed to
20 many other chemicals, some of which we know are
21 carcinogens. So, we have both multiple exposure and
22 multiple outcome problems.
23 And, finally, the question of the heterogenicity.
24 How do we categorize these diseases correctly? It
25 was mentioned that we, although we can talk about

1 sarcomas, we don't know which of these belong together.
2 And, in fact, some people have included mangio
3 sarcomas apparently, and others have chosen
4 not to count such sarcomas. So we are without
5 a clear biological indication of a unity of the
6 group. We get into almost a
7 semantic problem.
8 Second part of the presentation on soft-tissue
9 sarcomas was Dr. Kang. He presented his protocol
10 which the committee commended him on as being
11 clearly written, well thought out. This is a study
12 of soft-tissue sarcomas presented to the AFIP between
13 1971 and '80, I'm sorry, 1975 and '80.
14 So far, 1100 people have been identified as
15 falling into that category. The discussion on
16 protocol really centered on the issue, again,
17 typical of the case control, a study of the problems
18 of control. What is the appropriate control group
19 comparison or the yard stick that we can use and
20 this -- considerable discussion.
21 Dr. Kang protocol was to take a local control
22 from the pathologist seeing the original case, he
23 would pick, by a selective method, another case from
24 his files, probably with a tumor, with a malignant
25 tumor, one with and one without malignant tumor.

1 The advantage of this would be, obviously, it
2 would be more representative of the population from
3 which the case came. However, you would sacrifice
4 control over the sampling process at the actual level
5 of picking it. And, it may not consider the pattern
6 of referral.
7 And, we talked about taking AFIP controls and
8 then there was a discussion, actually, perhaps both
9 were needed as has been done in situations where
10 we take population and hospital control , etc.
11 One issue that was not discussed was, again,
12 based on a need for comparability, was the question,
13 should we exclude military hospital patients or not.
14 That was not discussed this time.
15 The second area we looked at, and very briefly,
16 was the Australian study of the birth defects. I
17 mentioned, yesterday's meeting, the science panel
18 also discussed Senator Cranston's letter. And, a
19 member from the OTA specifically stated that she
20 felt we should think in both the terms of the validity
21 and the relevance. And, that was basically what we
22 used to discuss this morning, to use it as a way of
23 disclosing discussion.
24 The validity of the study, I think, is going to
25 take more looking at and more information. Both, Dr.

1 Houk, yesterday, and Dr. Breslin have made comments
2 that the information is incomplete to make it a
3 thorough assessment of the validity.
4 The relevance of the Australian study to the
5 policy makers in the United States, is another matter
6 and, perhaps, more important, and three areas of
7 concern there is, one, the paper itself says that
8 exposure of Australian veterans seem to be fairly
9 low. Dick Christian feels that this may not, in
10 fact, be the case, but, certainly, that will be a
11 very important in determining how relevant their
12 studies were in the first place.
13 But, secondly, we have to recognize the
14 perspective of the study. It's a limited look. It
15 looks at one aspect of it, i.e. congenital malformation
16 ascertained at the time of birth. And, must also
17 be recognized that this was not then meant to be
18 a definitive answer.
19 It may have been sufficient for the policy
20 makers but the question of relevance here, would
21 depend on what our people felt was important.
22 Then, the final presentation, Dr. Page presented
23 the Vietnam mortality study that is underway at this
24 time and reported to us what has been found to date.
25 They are in the process of tracking records and what

1 they have found after 15,000 records, that they
2 first identified.
3 When they looked at the record repositories they
4 were able to find the record and also that the subject
5 was eligible 85 percent of those.
6 Six percent of them, they were able to find the
7 record, but since they were only looking at Army
8 and Marine records, the person was not eligible,
9 either Air Force or Navy personnel.
10 And, nine percent were, so called, hard to find
11 category. There was, perhaps, some part of the
12 identifier missing, etc. It's not that these records
13 are absolutely lost records, but, that, on the first
14 pass, on using the routine method, these were not
15 found.
16 How much or how difficult,- how much will be able
17 to be found, or how difficult this will be is not
18 known at this time. But, nine percent is such a
19 large number that it will have to be broached, at
20 least, by sampling, as to how much effort and force
21 it will take to identify the remainder.
22 Twelve percent of the records were found not to
23 have the cause of death which will require going back
24 to the states. We mentioned also, that -- the
25 consultants that were fairly well known group of

1 Epidemiologists and Biostatisticians, made two
2 recommendations that they over sample the deaths in
3 late years and study size be increased to allow for
4 more powerful sub-group analysis.
5 DR. SHEPARD: All right, find. Thank you
6 very much Dr. Hodder for
the excellent summary. I'd like
7 now, to just spend a few minutes on evaluating our
8 new subcommittee process. And, I will throw this
9 open to the full committee in terms of how they
10 think the process went and, perhaps, -- --
11 whether it seems to be a good way to go and should we
12 continue it.
13 For those of you who served on Fred Mullen's
14 committee, if I could get some expression of opinion
15 as to the process and whether you think it is a
16 good way to go and should we continue it.
17 MR. Walkup : I have a question to
18 clarify the process. First, did I understand that
19 the biostat. subcommittee met yesterday, also.
20 DR. SHEPARD: No. Let me just clarify it
21 again. Dr. Hodder also sits as a member of the Agent
22 Orange Working Group Science Panel, and that's the
23 committee he was referring to. The AOWG and its Science
24
Panel are not
25

1 chartered under the Federal Advisory Committee Act
2 since all the members are Federal employees. The
3 structure of that committee is very different from
4 this committee structure and, therefore, the meetings
5 are not open.
6 Any other questions or comments?
7 DR. KORNPIECH: Since the subcommittee
8 system seems to work very well, people with
9 common interest working on the same problem, I
10 wonder if, perhaps, they have to meet more often
11 because it seems this agenda was very full with
12 programs -- and didn't allow much time for working.
13 The speakers were wonderful and it certainly
14 was the right starting point, but, perhaps, there
15 should be more time for committee work.
16 DR. SHEPARD: Yes, I have the same thought
17 If there was some way we could expand our
18 agenda to include time for more discussion. Maybe
19 we should consider spilling over into the afternoon.
20 We could take that up as a possibility. Any other
21 comments on the Education/Information subcommittee?
22
23 MR. WOOSLEY: I would agree with your
24 point for our group too. I found that talking out
25 loud, the specific area that the program speaker was

1 addressing brought up a number of other issues that
2 we needed to deal with. We were able to get to the
3 point of identifying some of the issues that we needed
4 to address next time and some of Mr. Mullen's
5 requests for information were to take us to that next
6 step.
7 So, it did seem helpful in that way. We had
8 a concentrated block of time to look at one thing,
9 we could start identifying issues, we could start
10 setting up an agenda for next time, but, we need
11 more time.
12 DR. SHEPARD: Do I infer from that, then
13 we ought to consider having a morning and afternoon
14 session? Would there be any strong objections to
15 our, at least, investigating that as a possibility?
16 I think that a number of other committees
17 that are comparable to this, do that. Some committees
18 meet for 2 days. I see no objection to
19 certainly looking into that.
20 MR. MULLEN: I think we ought to go to a
21 full day session simply because, while, in my
22 subcommittee we were able to address the immediate
23 problems, the things that needed addressing now, as
24 Mr. Walkup said, we couldn't get into the long term
25 evaluation of the problem. And, I think that we need

1 more to time to adequately assess our position on
2 the issues that we are charged with discussing.
3 DR. SHEPARD: Well, let's take that under
4 advisement and then if that's the wish of the committee
5 we will certainly look into the possibility. I see
6 no objection to it. I don't think the administration
7 will have any problem with it.
8 It's a matter of scheduling the rooms and the
9 time, and, if people feel they want to devote that
10 amount of time to it, we would certainly be receptive
11 to that.
12 Okay. Any members of the Epidemiology/Biostatistics
13 committee want to make any comments as to that
14 process?
15 DR. MOSES: Well, I thought it was quite
16 good actually. And, what I liked about it is,
17 there didn't seem to be any barriers. I've never
18 liked, in these meetings, sort of us sitting up
19 there and them sitting out there. I like the idea
20 that there is a lot of interaction between the
21 people sitting out listening to us.
22 And, I think that is very important. And, the
23 most important thing I think happened, is nothing
24 passed anybody by. They had a question about
25 something, we were able to stop and deal with it and

1 talk about it right then on whatever level. And
2 everybody participated. I think it is one of the best
3 meetings I've attended in this committee.
4 I like the idea of focusing, and, I'm also glad
5 that the public is there. In terms of
6 having a longer meeting, I think that might be a
7 good idea because, I think, there is going to be
8 more and more information to be evaluated.
9 We could have spend all of our session just on
10 soft-tissue sarcoma. I think the reproductive area,
11 we just talked about one study, if we had talked about
12 what is known and what's doable, I think that could
13 be another session. I, for one, if we are going to
14 continue to do this, I think we ought to find out
15 from the public people here too, how they feel about this
16 because they've been coming too.
17 But, I think it's good. I like the approach,
18 and I also think we do need more time. I agree with
19 the other committee.
20 MR. MULLEN: Yes, we found too, that it
21 was much more informal and spontaneous and there was
22 a lot more interaction. As Dr. Moses said, we were
23 able to stop and discuss a point and pick up where
24 we left off, and I don't think it causes any particular
25 degree of disruption. In fact, I think it was very

1 conducive to the general nature of our subcommittee.

2 DR. SHEPARD: Dr. Hodder, do you have any

3 comments?

4 DR. HODDER: Yes, I agree with Dr. Kornreich's

5 idea that we need more time. I felt just about the

6 time everything was getting interesting, I had to

7 look at the clock and stop and move on to the next

8 item. And, certainly the other point that Dr. Moses

9 brings up, there was a lot more interaction. I

10 think the points,both for us to clarify and advise

11 you better, and, also, I think, to make sure your

12 opinions are representative of the people sitting at

13 the meetings.

14 I think both of those are best served by more

15 time.

16 DR. SHEPARD: I'd be curious, I didn't

17 spend as much time as I would like to have in the

18 Education/Information meeting, was there very much

19 audience interaction?

20 MR. MULLEN: In our meeting?

21 DR. SHEPARD: Yes.

22 MR. MULLEN: Oh yes, there was. In fact,

23 I had to stop the questions for a while, but,

24 it worked out pretty good. We were really cutting it

25 close at the end there. But, I think, we could have

1 spoken for at least another half an hour
to 40 minutes
2 on each subject.

3 DR. SHEPARD: Well, that sounds good. I'm
4 delighted that it has worked out well. This is
5 exactly what we had hoped would happen. The fact that
6 you need and want more time, I think, is very
7 encouraging.

8 MR. MULLEN: I might add one more thing.
9 I think the topics that we discussed as opposed to
10 the topics we discussed in the other subcommittee
11 were much more easily dealt with by our subcommittee.
12 I'm sure that the people on the scientific panel
13 here, don't understand a lot of what is going on
14 as far as veterans benefits work.

15 And, I'm sure, we don't understand a lot of
16 the medical jargon that happens in their committee.
17 So, I think it gives us a little bit more of a free
18 rein.

19 DR. SHEPARD: Well, again, it is one of
20 the hoped for outcomes. I'm delighted it came out
21 that way. While I'm thinking about it, maybe we
22 could ask the two subcommittee chairman to
23 draw of their respective agenda
for the next meeting on
24 issues they would like rather than me set the agenda.

25 I feel it would be much more important to have

1 you people set the agenda and we can work together.
2 Obviously, in assembling that information, we provide
3 the backup and the mechanical support, but, I think
4 it would be very good for the subcommittee chairmen
5 to work with their subcommittees in developing these
6 rather than having me do it.
7 I'd be happy to help in any way I can.
8 MR. WALKUP: On Mr. Mullen's last
9 statement, I think that we do have a danger in
10 getting specialized in our respective areas, that
11 we stop understanding each other's jargon even though
12 we may be able to inform each other at some point.
13 I've sat through sessions before
14 so I can understand most of what you were talking
15 about when you were giving your report, but, I think,
16 after a couple more, I would not understand what it
17 was that your group discussed.
18 I don't know how to overcome that unless we had more
19 time. With more time it might be possible to
20 have more lengthy overviews of what it was that
21 each group discussed. Or, we might be able to send
22 observers to each other's group or something like
23 that.
24 DR. MOSES: One of the things, I think
25 what you are saying is very important,

1 If things do start to pile up, maybe,
2 one of the things we ought to do at one of our
3 sessions, is, discuss just this very thing. And,
4 just like you want to make sure you get feedback at
5 whatever you are doing, if we knew what particular
6 things people didn't understand or had problems
7 with and would like to know more about it, I think
8 that is one of the things that we could talk about
9 in the committee.
10 Maybe we use too much jargon. But, actually,
11 we use the same jargon all the time. But, I think,
12 that that is something that we definitely should consider.
13 I wish we could rearrange the table so
14 we could have better audience participation. I thought
15 that was really critical.
16 DR. SHEPARD: Okay. Any other comments
17 from the subcommittees?
18 MR. MULLEN: I have one more comment, Dr.
19 Shepard. I think this is the first meeting that I
20 remember where, other than specific organizations
21 expressing their beliefs of political views on this
22 particular issue, in the past we've all just been
23 involved in giving the perceptions of our particular
24 organizations to the committee. I believe this is
25 the first time we are going to actually have

1 participation in the field generated by this
2 committee and veteran service organizations and I think
3 that is crucial.
4 Sitting here and talking about it is one thing
5 and talking politics is another, but, actually
6 having involvement of our constituents in the field,
7 I think, is very crucial to maintaining the reins
8 on this whole situation, and, insuring that the
9 wishes and the advice of this committee is being
10 followed.
11 DR. SHEPARD: I thank you. That's a
12 good point. Before we move into questions, we ask
13 a quick recognition of a number of state
14 representatives who are with us today. As they have
15 in the past times, we have representatives from
16 New York, West Virginia, Illinois, New Jersey, Texas,
17 and did I leave anybody out. Excuse me, I thought I
18 said it, Pennsylvania, yes indeed.
19 And, I'm delighted that you are here, and we
20 want very much to keep you a part of the process.
21 For those states where we will be visiting, we want
22 very much your participation in that session where
23 we will have an opportunity to discuss your
24 particular issues as we go around from site to site.
25 I think that has already been established, and I hope

1 it will work out very well.

2 Okay. I have a couple of questions. One is

3 from a Mr. Wayne Wilson from -

4 MR. WALKUP: Excuse me, Dr. Shepard. At our

5 last meeting we recommended that someone from the

6 state commissions be appointed to this board. Could

7 you advise us of the status of that recommendation?

8 DR. SHEPARD:

9 Just to refresh your memories, the Administrator

10 agreed to receive the name of three candidates who

11 had had the endorsement of the states which have

12 established commissions. To the best of my

13 knowledge, he has not yet received that list of

14 candidates, so -

15 MR. WILSON: I sent that 2 weeks ago.

16 We have carbon copies to every state, so, he's had

17 it for, approximately 2 weeks, I believe.

18 DR. SHEPARD: Well, I checked on it

19 yesterday Wayne, and we have not received it. I

20 don't know what has happened to it. I was aware

21 that you had sent something because Ruth Leverett

22 from New York called me

23 and said that such a letter was on the way.

24 I have made considerable efforts to determine

25 where it is, but, as of yesterday, it had not come.

1 MR. WILSON: It hasn't come back, so-

2 DR. SHEPARD: Well, we'll pursue it. I

3 mean, it's not, by any means, a dead issue.

4 The Administrator has made

5 this commitment and he's still open on it. We just

6 haven't had any action or any names, yet, to act on.

7 So, we are still waiting. It may have come in in

8 the last 48 hours.

9 This is a question from Wayne. Is the physical

10 examination given Times Beach residents different

11 than that given to Vietnam veterans? If so, why?

12 I, for one, am not aware of the details of the

13 examination. I have the impression that the

14 examinations are not being done by any government

15 agency. I think they are being contracted out to

16 local physicians.

17 DR. CORDLE: They are being paid for the government,

18 but it is local physicians that are doing all of

19 the physicals.

20 DR. SHEPARD: So, I think it would be

21 difficult to answer because we don't know exactly.

22 My hunch would be that they are probably giving a

23 fairly thorough physical examination. Probably

24 doing indicated laboratory studies. Not too

25 dissimilar from what we are doing.

1 MR. WILSON: Can we find out how, possibly
2 by the next meeting, how dissimilar or similar they
3 are?
4 DR. SHEPARD: I don't know how we get
5 that information, Wayne.
6 MR. WILSON: -- EPA or someone on site
7 down there -- or CDC. Somebody has to be monitoring
8 it.
9 DR. SHEPARD: We can ask CDC if they have
10 any standard methodology or guidelines. I suspect
11 there must have been some guidance if this is a
12 contract or reimbursement. Larry do you have
13 some information?
14 DR. HOBSON: There were 2 or 3 on the
15 scene. We asked Dr. Houk yesterday at the meeting
16 precisely what they had done and what they found.
17 We got no answer. He said they were not prepared
18 to release it as yet. Therefore, we do not have
19 anything to report to you.
20 MRS. LEVERETT : I might have some bearing
21 on that also. I contacted CDC and was referred to
22 state epidemiologists in Missouri. I have been unable
23 to speak to the gentleman -- --
24 DR. SHEPARD: I'm sure the Department of
25 Health, at least as Times Beach is concerned, the

1 Missouri Department of Health has, in some way,
2 been involved in this. I don't know whether it has
3 been turned over entirely to the state of Missouri
4 to conduct these examinations or whether it is being
5 done by the CDC and the state of Missouri, I just
6 don't have that information.
7 We can certainly try and get if for you though.
8 It is an important question and we need to know.
9 Representative O'Connell from the state of
10 Illinois would like to address the committee.
11 MR. O"CONNELL: My name is John O'Connell.
12 I'm a member of the Illinois House of Representatives
13 and the chairman of the Illinois Agent Orange
14 Commission. I thank you for the opportunity to be
15 here.
16 Listening to the subcommittees and the committee
17 as a whole, I think you are on the right track,
18 particularly with regard to the outreach program.
19 However, I think you are stopping. I get the impression
20 that it will be a one shot approach to informing
21 the veteran.
22 One of the most salient responses that we have
23 gotten from our 8 hearings, public hearing throughout
24 Illinois, is there is a very deep gap, credibility
25 gap between the local VA hospital and the veterans

1 with whom they are to treat. The range of discussion
2 has gone from down right animosity, to a feeling of
3 lack of interest. It is our belief, that the VA
4 can make some very constructive changes in that
5 regard by making a permanent liasion committee, if
6 you will, or perhaps, the medical director, or a
7 member of his direct staff, the individual in charge
8 of the Agent Orange screening program, a member of
9 the local, traditional service group, and, certainly,
10 a member of the Vietnam veteran organization that
11 is not, perhaps, a traditional service group, but
12 does speak for the veterans in that area.
13 As I said, I think the outreach program is fine.
14 But, it is addressed at a one city, one stop scope.
15 And, you've got to develop a better
credibility
16 in your field offices, in your field hospitals.
17 It isn't there.
18 One other thing, this is on a personal matter,
19 you are having the Chicago session June 28th, 29th
20 and 30th, I believe, and you indicate there would be
21 meetings with the legislative commission. I might
22 point out, in terms of your scheduling, if, perhaps,
23 we could be scheduled at some other time.
24 That is our busiest session of the legislature.
25 We are in our closing week. We adjourn on June 30th,

1 and I can assure you, that no member of the
2 legislative committee, commission, would be able
3 to attend and we would desperately like to meet with
4 you and convey what we've been receiving from our
5 constituents. Whether that's possible or not, I
6 just raised the question.
7 DR. SHEPARD Maybe
8 we can work out something. Well, I certainly
9 appreciate your comments Mr. O'Connell. I think
10 the point is very well taken.
11 It would be my hope that, as a result of this
12 group of visits, and, I want to stress again, that
13 this is not an isolated effort, we are
14 trying this in various parts of the country and hope to see
15 how we can best handle it, we have
16 every intention of making it as part of an ongoing
17 process.
18 It isn't a one shot deal. What I would hope
19 to do in every place where we visit is, to encourage,
20 both veterans groups, and our VA leadership, to
21 develop a process for better interchange at the local
22 level.
23 I have done this, personally, in some areas and
24 it has worked very well. When I say, personally, I
25 mean, I visited VA hospitals and encouraged this kind

1 of a process to be put in place. And, in areas where
2 that has happen, it seems to have worked very well.
3 So, the concept is very sound, and that will be one
4 of my goals and that of my staff, to encourage that
5 same kind of process to be developed all around the
6 country. It is very important.
7 We are increasingly desirous, also, of getting
8 the readjustment counseling program involved in this
9 kind of liaison effort. And, they've already been
10 doing it, we want to encouage it, we want to give
11 them the necessary support, both, in their groups
12 and, have that support received at the medical center
13 level. So, there are lots of different areas that
14 we can work on and hopefully they will bear fruit.
15 I certainly appreciate your comments. I think
16 they are right on. Any other questions from the
17 audience? Yes?
18 MR. MILFORD: I have a question that's
19 really a follow-up. I think a point
20 that needs to be addressed by the committee is the
21 question of compensation. All of this, presumably,
22 is geared to lead tosome policy decision, some time
23 in the future, on medical care as well as
24 compensation, and, I think it would be important to
25 have a member of the committee, who is knowledgeable

1 about compensation policy and who can report to the
2 members of the committee and the public about the
3 standards for compensation decisions. In particular,
4 how all the scientific information that is being
5 discussed and will be discussed, perhaps, endlessly,
6 might be used to make policy in the future.
7 So, I would suggest that there be a member or
8 someone from the agency that can discuss that point.
9 In particular, following that, I think it might be
10 important, at least I would like to suggest, for
11 the committee's consideration, that material prepared
12 on that compensation policy, particularly with
13 respect to compensation policies in the past
14 be prepared. What I'm speaking about is the presumption
15 bill Congressman Daschle has introduced, and, the question raised by that bill
16 has to do with the agency's historical policy to
17 award compensation on the basis of presumptions in
18 the past.
19 I think it is important to take a look at, on
20 a scientific basis, those presumptions that are
21 now a matter of law. I think many people suspect
22 the scientific basis for those presumptions are
23 considerably weaker than the scientific basis may be
24 for Agent Orange compensation. So, I would suggest
25 that the committee, perhaps, resolve to ask the agency

1 for a report on that point.

2 The last point I want to make is I wonder

3 whether the subcommittee meetings will be transcribed.

4 I think, it would

5 be important to have those transcribed.

6 DR. SHEPARD: Let me answer your last

7 question. We did tape the subcommittee discussions

8 for purposes of being able to have a record of that.

9 We have not yet decided whether we will go to the

10 effort of having them transcribed. We can certainly

11 consider that. What I

12 originally thought we'd do was have the committee sessions

13 transcribed and have minutes of the

14 subcommittee meetings.

15 I think it is true that conversation

16 flows more easily and if you are going to make sure

17 that you catch every word that everybody says, both

18 from the audience and from the committee, that

19 becomes a mechanical inhibition to some degree to

20 all that goes on. But, we will certainly take that

21 under advisement.

22 It is a technical question whether or not we

23 can tape and transcribe every word that is said by

24 every person, because, not in every instance, people

25 don't identify themselves when they speak.

1 MR. MILFORD: Well, if I could just- I, as
2 a member of the public and a person involved in
3 this issue for several years, I think it is very
4 important to have a transcript of those materials.
5 I find minutes to be extraordinarily superficial
6 and, usually, filled with jargon of whomever is entertaining
7 that. Whether it be a scientist, lawyer, or a vet.
8 And, I find that it is much more useful to have the
9 actual information that is being used.
10 Perhaps if you ask people to identify themselves,
11 they should, in a meeting will help that.
12 DR. SHEPARD: It is certainly not an
13 insurmountable problem. We'll discuss it.
14 Yes, Wayne?
15 MR. WILSON : I just have two points
16 while we're talking about transcribing meetings.
17 I will certainly support what Mr. Milford said. I
18 travel down here, I'm one person and obviously I
19 can't be two places at one time, and there are
20 scientists and medicals folks back in New Jersey
21 who expect me to insure that they have a transcript,
22 all be it, two or three months later to look at.
23 And, that's another problem, is we are not
24 getting transcripts. As I understand it, the
25 transcripts of last meeting are still not yet

1 available. I just think that it is very important
2 to have these transcripts so we
3 can advise our commissions and our constituents and
4 have an opportunity to,hopefully, come here with
5 some questions in terms of following up from last
6 meeting. So, I hope we can improve on that.
7 It seemed to be very better in the beginning,
8 and getting kind of down hill as we go along --
9 DR. SHEPARD: We will certainly look at
10 that and see if we can speed up the process. Thank
11 you.
12 MR. MILFORD: Can I get an answer to the
13 first point?
14 DR. SHEPARD: Oh. I'm sorry. Give me
15 your first question again.
16 MR. MILFORD: It has to do with the report
17 or some information from the agency on the
18 scientific basis for prior presumptions which are
19 now in the law and form the basis for the basic
20 compensation decisions.
21 I think it is important to have that kind of
22 information so that the discusions about scientific
23 evidence has some meaning. That, without that, a
24 standard is really absent and it's impossible to have
25 an educated discussion about where this scientific

1 evidence may go.

2 DR. SHEPARD: I hear two aspects to your

3 questions. I hear that you would like the

4 commission to discuss and be aware of compensation

5 policies of the VA. And, I also hear you asking for

6 somebody in the VA who is knowledgeable in the VA's

7 compensation procedures and policies to address the

8 committee for purposes of informing them and the

9 public.

10 I see no problem with either or both of those.

11 I would have to clear that, obviously, with our

12 Department of Veterans' Benefits to see how they

13 felt about providing that kind of technical

14 information support. But, I think it is something

15 we could certainly look into.

16 Was that it? You had another question?

17 DR. LAMM: Dr. LAMM from CEOH.

18 I'd like to give a bit of

19 information on what I think is going down at Times

20 Beach. I think the basic situation there, is that

21 CDC has a contractor, has funds from the super-fund

22 project which have gone by contract down to the

23 state, the Missouri state Health Department where

24 Dr. Denny Donal is running the program there.

25 He has contracted with outside services, within

1 the state for providing the health examination and
2 has hired epidemiologists. And, in the process of
3 doing so, for the purpose of collection the health
4 examination reports which will then be collected in
5 either Jefferson City or the Saint Louis area
6 where they will be analyzed.
7 That whole process will be overviewed by the
8 Center for Environmental Health at the Center for
9 Disease Control.
10 DR. SHEPARD: That you very much for
11 that information. That's very helpful. Yes?
12 Mr. Conroy from West Virginia.
13 MR. CONROY : Dr. Shepard, just one quick
14 suggestion. I've received several inquiries from
15 various vet centers located around the state of
16 West Virginia, and these people are receiving
17 inquiries relative to Agent Orange, virtually, on
18 a daily basis. They've asked if it would be possible
19 for them to receive copies of the update of the
20 literature, the literature analysis, to make
21 available to clients that they see, as I've indicated,
22 on a daily basis? And, if it is a policy decision,
23 I think it is something -- -- that should be
24 pursued.
25 DR. SHEPARD: Yes. I'm not quite clear Chuck,

1 who it is that would like these?

2 MR. CONROY: Various veteran centers.

3 Vietnam Veterans Counseling centers that are located

4 around the state of West Virginia.

5 DR. SHEPARD: These are state centers you

6 mean.

7 MR. CONROY: These are VA centers.

8 DR. SHEPARD: Oh, VA centers. They are

9 available to the VA centers.

10 MR. CONROY : Well, the VA centers in

11 West Virginia haven't received copies of the analysis

12 of the literature they have requested.

13 DR. SHEPARD: I thought we had sent them,

14 but I may be in error. Let me just

15 remind you that these are very

16 technical reports and, I think, they would have

17 relatively limited usefulness to non-scientists.

18 This is a very detailed technical scientific

19 effort. Now, what you mentioned, is something that

20 we have been wanting to do, have been thinking about,

21 and that is to develop a somewhat less scientific

22 interpretation of, or summary, a lay language summary,

23 if you will, of the results of those studies, or

24 the results of those analyses. Certainly, some of

25 the key elements.

1 I think that is an important thing to do. We
2 are addressing that, in part, in our monograph series,
3 but those, obviously, have relatively limited
4 frameworks. They don't encompass all the literature.
5 But, I think it is an important question and
6 I think that increasingly we need to do that.
7 It is a matter of getting the requisite funding and
8 how it should be done, who should do it, and that
9 kind of thing. Your point is well taken.
10 But as far as getting
11 the literature reviews to Vet Centers, we have no policy that would prohibit them from being sent.
12 Any other questions?
13 MR. O'CONNELL: I'm sorry Doctor, I forgot
14 to mention one thing. Our Agent Orange Commission,
15 myself, and Commissioner Maiman, met with the
16 Illinois status for Women Commission. And, we
17 discussed the non-civilian participation in the war,
18 specifically, the Red Cross worker. And, the
19 Illinois Legislature has adopted a resolution to
20 Congress, asking that Congress include specified
21 civilian, non-combatants in all studies of the
22 Agent Orange question and all compensation that may
23 be afforded to such specifics.
24 DR. SHEPARD: If I may react to that, and
25 I invite the other members of the committee to do so

1 also. I think your motives are very high.
2 When you get down to including these groups, these
3 individuals, in studies, that begins to run a little
4 bit head on into some rather basic epidemiological
5 strategies and techniques.
6 I think it would be very difficult, for example,
7 to include a group of Red Cross workers along with
8 ground troops. I think that the Red Cross workers
9 would get lost in a larger group. And, I think,
10 what you would like to see is, what has been the
11 impact of females, or other groups of civilians,
12 serving in Vietnam, what's been the impact on their
13 health.
14 I think that if there are some specific groups
15 that need to be targeted, then I would strongly
16 urge that studies be structured so as to answer
17 those specific questions rather than, sort of melting
18 them in with a larger group. I think, we would
19 probably come out with not the information that you
20 want.
21 So, I would say, rather than including them in
22 existing studies, or proposed studies, that new
23 studies, addressing the specific questions should
24 be encouraged. I would solicit comments from the
25 rest of the committee to see if they agree with me on

1 that.

2 MS. MAIMAN: -- -- one of the points

3 we met with the White House on it yesterday, is the

4 inclusion of the Agent Orange testing and treatment

5 programs which exist. And, they supported our

6 contention that it really is

7 unfair to deny assistance to persons who experienced risk because of their service

8 to their country.

9 And, I think the Illinois legislation will take that

10 in consideration.

11 DR. SHEPARD: I think that's fine. I

12 see no problem with that at all. You used the word study, and that was what I responded to, not

13

14 in terms of providing examinations or screening,

15 and that sort of thing.

16 Is Mr. Christian here? I wonder, Dick, if you

17 would be willing to share with the group, because I

18 think it is an increasingly interesting point, or

19 a point that is going to get more attention. Just

20 a word or two about what your group is doing about

21 trying to identify female veterans.

22 You want to just give us a quick update on that?

23 MR. CHRISTIAN: We have identified close

24 to 4,000 women who served in Vietnam, 2,900 of those

25 were Army nurses and the remainder were in the Women.

1 Army Corps at administrative and logistical jobs.
2 There are no automated records that provide that
3 information to us. In fact, there were no records
4 kept at that time to distinguish gender. So, this
5 amounts to an extensive research of all the unit
6 morning reports from Vietnam.
7 We hope to have that project completed within
8 the next 12 to 18 months.
9 DR. SHEPARD: Thank you very much. I
10 think that this is an area that will be, as I say,
11 receiving increasing interest, and, I think that
12 what Mr. Christian just told you, that for the first
13 time, we are making, he is making an effort to
14 identify groups of females who served in Vietnam, as
15 a basis for doing epidemiology work.
16 Any other questions or comments? (Silence) Thank you
17 very much for your attention. Thank you.
18 (Meeting adjourned at 12:00 PM)
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22
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25

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Seventeenth Meeting
September 1, 1983

December 1983 Washington DC 20420

1 UNITED STATES VETERANS ADMINISTRATION

2 + + +

3 ADVISORY COMMITTEE ON HEALTH-RELATED

4 EFFECTS OF HERBICIDES

5 + + +

6

7 Veterans Administration Central Office
Room 119
8 810 Vermont Avenue, N.W.
Washington, D.C. 20420

9 Thursday,
September 1, 1983

10

11 The meeting of the Advisory Committee was called

12 to order at 8:30 a.m.

13

14 PARTICIPANTS:

15 BARCLAY M. SHEPARD, M.D., Chairman

16 GEORGE R. ANDERSON, M.D.

17 THOMAS A. FITZGERALD, M.D.

18 HENRY SPENCER, Ph.D.

19 RICHARD A. HODDER, M.D., M.P.H.

20 CAROLYN H. LINGEMAN, M.D.

21 MARION MOSES, M.D.

22 JOSEPH MULINARE, M.D.

23 FREDRICK MULLEN, SR.

24 GEORGE T. ESTRY

25 CHARLES A. THOMPSON

NOEL C. WOOSLEY

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P R O C E E D I N G S

DR. SHEPARD: Good morning, ladies and gentlemen. I would like to call to order the 17th quarterly meeting of the V.A. Advisory Committee on Health-Related Effects of Herbicides.

We're very pleased to have you all with us this morning, and as we announced at our last meeting, this will be an all day session. We will have appropriate breaks, however. It was, I think, the unanimous decision of the committee that the meetings be expanded to allow more time to go over various issues and reports.

As usual, this is a meeting which is open to the public. We would request that all attendees register their presence in the outer room so that we can keep record of who attends.

We will, as usual, have an opportunity for questions from attendees. If you would please observe our convention of submitting your questions to me in writing, Don Rosenblum will be happy to provide you with cards which will enable you to do that conveniently.

I have a few committee announcements to make. First of all, we received the resignation of Dr. Phil Kearney, very regretfully. Phil Kearney was a very faithful member of this committee and contributed immensely to its efforts. He will be sorely missed.

We have correspondence from the Department of Agriculture that the Department will continue to follow the activities of this committee very closely; however, they wish to withdraw as official participating members. I would hasten to say that, lest I mislead you, this committee is not composed of federal or non-federal agencies. It is composed of individual people who have been solicited for membership or have volunteered for membership for their own particular expertise and interests. So the fact that Dr. Kearney has resigned and the Department has chosen not to suggest somebody to replace him in no way hampers the committee's ability or the Administrator's ability to solicit somebody of Dr. Kearney's talents to be a member of the committee if that seems to be appropriate.

We're most pleased to have with us, not for the first time, because he's been here at many of our previous meetings, but for the first time as an official member of the committee, Dr. George Anderson from the State of Texas Department of Health. Dr. Anderson has very graciously expressed his willingness to serve as a member of this committee representing the interests and concerns of the Coalition of States, which have enacted Agent Orange related legislation. So we're most pleased to have you as an official member of the committee, Dr. Anderson.

As his alternate, the Administrator has appointed

1 Dr. Peter Kahn from New Jersey, and we're also pleased to
2 have Peter as an alternate member of the committee, and I
3 don't know whether Peter's here today or not.
4 He's been at the ACS meeting. Maybe he'll join
5 us later.
6 We're also very pleased to announce that Dr.
7 Joseph Mulinare has been appointed by the Administrator to
8 serve as an official member of this committee. We welcome
9 you, Joe. Dr. Mulinare is not a stranger to this committee.
10 He has appeared several times as an alternate for Dr. David
11 Erickson, who has resigned because of his very busy schedule
12 as the coordinator and director of the CDC epidemiological
13 study.
14 Dr. Mulinare, as you know, has been very involved
15 in the CDC birth defect study and is eminently qualified to
16 be a member of this committee, and we welcome his presence.
17 We have a full and, I hope, exciting agenda. We
18 are particularly pleased and honored to have with us today
19 two distinguished visitors from Italy, Dr. Umberto and Dr.
20 La Porta, who will be addressing both the full committee and
21 the subcommittee on -- excuse me -- I misspoke. Dr.
22 Fortunati and Dr. La Porta. I'm sorry. Umberto Fortunati.
23 Dr. Fortunati is a director of the Seveso project
24 and has a wealth of experience and background which, of
25 course, is of very vital interest to this committee and to

1 all of us involved in the whole Agent Orange issue because,
2 as you know, the accident at Seveso exposed large segments
3 of the environment to fairly heavy doses of dioxin.
4 It was a great pleasure for us to host Dr. John
5 Donovan of the Australian Department of Health. Dr.
6 Donovan is a senior epidemiologist-advisor to the activities
7 ongoing in Australia regarding the whole issue of Australian
8 Vietnam veterans exposed to herbicides during their period
9 of service in Vietnam.
10 It was a very helpful and, I think, important
11 interchange of information. I'm sure most of you know that
12 the Australian government has completed a birth defect study,
13 and Dr. Mulinare, I hope, will be prepared to make a few
14 comments about that study. Of course, it's of
15 considerable interest to both us and to him as the investiga-
16 tor in the CDC birth defect study.
17 Of particular interest, I think, is the fact that
18 the government of Australia has now appointed a royal
19 commission to look into the whole issue of the possible human
20 health effect of exposure to herbicides. The
21 royal commission will be headed up by a judge,
22 and they will begin their delibera-
23 tions, I believe, very shortly. So Dr. Donovan brought us
24 up to date in that regard.
25 I hope you've all -- I know that the members of the

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committee have copies of the agenda before them. We are also very particularly pleased to have with us representing the AMA, Dr. John Beljan. Dr. Beljan will report to us on the AMA Council on Scientific Affairs' activities regarding the programs and the work that the AMA has done to help put some of these issues into perspective.

I would like now to call on Dr. Beljan to give us a brief report on activities of his council. Dr. John R. Beljan.

REPORT FROM THE AMERICAN MEDICAL ASSOCIATION

DR. BELJAN: Thank you, Dr. Shepard.

It's my pleasure to appear today on behalf of the Council on Scientific Affairs of the American Medical Association, and I would like to begin by complimenting you on your efforts in this regard.

We, as you, are concerned about the concern of our several publics regarding dioxins and the other phenoxy herbicides. And the mission of the American Medical Association, as we see it, and particularly the Council on Scientific Affairs, is to try to present to its constituency the best possible scientific information relating to the topic so that they may then use that information in the proper way to manage and treat their patients.

A number of people, I believe are totally unfamiliar with the existence of the Council on Scientific Affairs, and perhaps it may be useful if I spend a minute or

1 two with you about that before I tell you what we are about
2 and we are up to at the current moment.
3 It was about a decade ago when the council was
4 established to provide a definitive organized forum within the
5 American Medical Association to look to state of the art
6 activities, questions of scientific nature, and to be a
7 resource body for the organization in the areas of scientific
8 concerns. Since that council was established, it has been very
9 active, and issued a number of reports which
10 have been, we feel, very useful to the practicing physician.
11 Approximately three or four years ago, as the
12 controversy regarding dioxin and Agent Orange arose, a
13 request was made to the Council on Scientific Affairs to
14 prepare a report on this subject for the purposes of guidance
15 to its physician constituency.
16 The council itself is a group of 11 members, who
17 are elected by the house of delegates. Almost all have
18 academic and/or scientific ties, and it also includes a
19 member of our resident physician group and our medical
20 student group.
21 We not only will prepare a statement for the
22 physician regarding scientific questions on a larger scale,
23 but also have recently developed a network which permits it
24 to respond quickly to other questions, particu-
25 larly in the area of technology or new applications, through

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1 our so-called DATTA panel, D-A-T-T-A, which is an activity
2 under the Council of Scientific Affairs designed to provide
3 fast turn-around for areas of concern to our constituents.
4 We operate by developing ad hoc panels of experts
5 in appropriate areas for our formal report. And our report on Agent
6 Orange and that task force is no exception.
7 Many of those members, in fact, often times as many
8 as half, are not formal members of the Americal Medical
9 Association, and they are selected solely in those specialty
10 or advisory panels for their expertise and recognition for
11 their expertise in the United States and, on occasion,
12 internationally.
13 So we do have, in each of the areas that
14 the council chooses to try to define the definitive and
15 state of the art picture, a series of
16 ad hoc advisory panels, which will broadly represent the
17 best thought in those areas.
18 We, at the present time, have a number of those
19 panels operating in a variety of questions, and my presence
20 here today is because I am the liaison from the council to our
21 ad hoc advisory committee on toxic substances, have
22 chaired that committee, and continue to chair it.
23 As a result of the concerns of the physicians of
24 the United States in requesting the council to address the
25 question of Agent Orange, I think you are all familiar with

1 the report that was developed by the association in October
2 of 1981.
3 We operate under the principle that we are not the
4 initiators of new investigations. We are not the sponsors
5 of scientific laboratory investigation as a funding or
6 support agency, but rather, we and our expert
7 panels are a series of individuals who are intimately
8 involved with the specific matter in their normal activities. Their
9 function is to survey the existing literature in the public domain
10 and to make the best reasoned judgments regarding that matter to
11 guide our physician population and the patients they serve.
12
13 That 1981 report, as you know, was a review at that time
14 of the current status of information regarding
15 Agent Orange and dioxin. It ultimately became probably
16 more of a position paper regarding dioxin than Agent Orange,
17 and our focus to the present has moved more in
18 the realm of dioxins, so that our subsequent report will
19 probably feature, even in its title, an emphasis on dioxins.
20 We have had considerable outside interest regarding our
21 activities. We've been asked on a number of occasions to
22 testify. We have been asked by our house of delegates to
23 update our report, and through and during the update of that
24 report to provide information in some kind of organized
25 way, which hopefully will continue to keep in perspective

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1 the overall problem of dioxins.

2 Our panel, which consists of seven individuals,

3 reconvened for the first time since our publication of that

4 report approximately two weeks ago. We are beginning to

5 tool up for an extensive review of the literature and other

6 information available to us at the present time,

7

8

9

10

11

12 We have decided that our most fruitful approach in

13 responding to the demand of the House of Delegates has been, and will be,

14 to concentrate on the important human epidemiological studies,

15 some of which are in progress, some of which have been

16 completed, and some of which will be completed, and

17 to bring to our house of delegates a report in the spring of

18 next year for their June meeting. This will be a revised report dealing with our update of

19 the information available to us about dioxins, Agent

20 Orange and related substances.

21 It will be our intent during that period of time

22 to try to provide information through the regular channels

23 of the American Medical Association. As you know, we have

24 submitted materials to JAMA and elsewhere, and will

25 continue to do that. We will continue to have our panel, the

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council, and others available to discuss the activities of where we're headed. In brief, our intent is to try to expeditiously and appropriately update our report of October 1981, and on the basis of that, attempt to put into perspective this entire problem.

With that, Mr. Chairman, I'll be pleased to respond to questions.

DR. SHEPARD: Thank you very much, Dr. Beljan. It was a very nice overview.

Are there any questions from members of the committee for Dr. Beljan?

I'd be curious to know -- you may have mentioned it and it may have slipped me --did you have a time frame in which you were going to complete your update?

DR. BELJAN: Yes. Our panel is planning to meet on a monthly basis, at least, through the remainder of this year, and we hope to have a final report of our activities about mid-spring.

DR. SHEPARD: I've spoke to Dr. Beljan a number of times, and it's my understanding -- correct me if I'm wrong, Dr. Beljan -- that your report will include a kind of a synopsis of the various research efforts that are currently underway, and by then those which may have been reported out, and give a summary of what the conclusions are?

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1 DR. BELJAN: That is correct. Yes. I have put
2 together a simplified synopsis of where we are at the time
3 that the report is concluded. I particularly appreciate
4 having the opportunity to visit with you today, and to attend
5 the meetings. It will enable me to get an impression of the
6 activities in which you're involved and the state of the art.
7 DR. SHEPARD: Are there any questions, then,
8 for Dr. Beljan?
9 Well, we certainly appreciate your being here,
10 Dr. Beljan, and as time goes on, I hope we can get together
11 frequently, and we welcome this relationship. Thank you
12 much.
13 Next, I would like to call on Dr. Umberto
14 Fortunati to give us an update on activities in Seveso and
15 discuss, perhaps, in some detail the health surveillance
16 program.
17 Your agendas were titled, Conclusions from Health
18 Studies Conducted in Seveso. This is a little
19 bit misleading. These will not be the reports of the health
20 studies. This will be an outline of the health surveillance
21 program. I would hasten to add that Dr. Fortunati is
22 not a physician; he's a PhD., chemical engineer. His
23 principal role in this whole effort has been that of dealing
24 with some of the environmental concerns surrounding the
25

Seveso accident has -- to minimize the potential for that causing any long-term health problems.

So, Dr.Fortunati, it's a real pleasure to have you with us, sir, and we're looking forward to your remarks.

OUTLINE OF HEALTH STUDIES CONDUCTED IN SEVESO

DR.FORTUNATI: Thank you, Mr.Shepard. On behalf of the Lombardi Goverment I'm representing here.

I wish to thank the Veterans Administration for the honor that has been granted to us to visit the United States and to look at the dioxin issue, which is a rather important one and very much being studied in these days.

To begin with, I wish to give a quick idea on what we've been doing in the last 3 years in Seveso. You probably know that the runaway reaction has taken place on July 10,1976 at the ICMESA factory in Meda, which is north of Seveso, and in such an accident were contaminated several houses and a wide territory downwind during about two and a half hours. The runaway reaction, lasted about this time, and when the contaminant was finally known, we have established a crash program to find out the extent of the contamination. And, ever since the Speciale Office established by the Lombardi Govern has coped with the consequences of TCDD contamination.

These efforts were made possible thanks to a law, a special law being voted at the Regional Parliement and in the law the appropriate funds have been allocated to take

care of the consequences of the contamination in the area. In the law a Task Force (about 140 people) has been put in condition to clean up the area, to take care of the social and damage refunding problems, and also of evaluating the contamination in the soil and the buildings and also, of course, in assisting in every possible way the population which was directly affected because, as you probably know, 735 people had to be relocated. They had to leave their homes and only about five hundred were brought back to their houses after one had a half years after the accident.

May I have the first slide?

This is a view of the polluted area. You can see how heavily populated it is. At the top is the ICMESA factory which caused the damage. On the left of the slide you see the highway connecting the Milano with Como.

Next?

This shows the subdivision and the three zones, "A" zone, contaminated, has been evacuated, the "B" zone, which has intermediate contamination, and the "R" zone, which --- has been established as a buffer area around the most contaminated area; around the Band A zones. The cloud followed a precise direction from North to the South. And we've stopped making the analysis where we could not find more dioxin in the soil.

Next?

I want to stress that our aim has been always to minimize the exposure of the population and of the reclamations workers.

The evacuation of population, whereven necessary, was used to minimize the hazard. To take care of the reclamation workers the Special Office has been very careful in screening them. About 30 percent of the applicants for the reclamation jobs have been discarded because they didn't have the physical requirements.

This is --- the Decontamination Unit which has been established to take care of the entering into the contaminated area and coming back, you know.

In the first place, the reclamation worker received the protective material. They enter and -- put on the protective suits, gloves, boots, mask. When they come back, after 4 hours, they -- after having washed the boots take away everything, and them wash themselves.

Besides the boots, which are washed by the workers themself also the mask, are recycled 30 times and are cleaned by the Personel of the Decontamination Unit.

Next?

This slide shows the kind of protective suits that we're using. They proved to be very effective, it's a

demonstration of how do we work in the contaminated area.

Next?

To keep down the dust we have been spraying continuously water to avoid the diffusion of the dioxin which as everybody knows, is bound to the soil. And this bind increases with time. The dioxin does not move from the contaminated area.

All around the contaminated area we built a fence 2.5 meters high. And this fence - which is of reinforced polyesther - has the purpose to reduce to a minimum the quantity of dust that may diffuse.

Next?

What solution was endly adopted?

The controlled landfill.

These 2 basins are -- of 160,00 cubic meter capacity and 80.00 cubic meter respectively.

Both are lined with bentonite, clay mixed with concrete and sand, lined with high density polyethlene, and then filled with contaminated soil.

Some precautions are adopted in setting the soil inside.

The most contaminated soil and the chemical

equipment are in the center and the less-contaminated around.

When we clean up the area, we accumulate separately the several layers of soil that have been scarified. The first layer is the most contaminated. It's separate. The second, again, is stored in a separate area. And the third layer also in a separate area. When we do fill the basins in the center are dischanged heavily contaminated materials, all around the less contaminated.

Next?

Here is shown the "A" zone, which is now about 50% percent decontaminated.

The orange square area, represents the ICMESA factory, and the two yellow basins are shown under. We had to make two basins not only one as we would have preferred in two different municipalities, Meda and Seveso, Both Meda and Seveso didn't want to accept the dioxin of the next municipality.

We were compelled, for "political reasons" to build two basins.

North of the ICMESA is the neighbor municipality of Barlassina.

A south are the Cities Cesano Maderno and Desio.

Monday, when we come back to Italy, we have to establish the contractual basis to build a park in the A zone.

All the area will be available for normal use after clean up work ended. The only places where we will not allow people to walk will be the two hills that will result after the filling of the two basins.

Next?

This slide gives an example of how we -- clean the soil, the method we have used, we dug, as you see, more than one meter in the most contaminated area.

The hip curbs the people working within the dirty area. After each passage with the spoon, it must cleaned carefully. Analysis must he done to check if the values that we had wanted to reach havein fact been reached and then start all over again, if we didn't.

Next?

This is the most contaminated part of the ICMESA factory. You can see two tanks where contaminated water is collected:in fact water is used to wash the protective material of the workers when they exit the contaminated area.

Next?

These are the most sophisticated protective units

that we have been using. They are under air pressure and so we need a decontamination unit just next to the polluted plant. We need to carry the air pipe, and for practical reasons the pipe cannot be longer than 25 meters.

If the pressure of the air goes below a certain limit the alarm system will ring so the workers, alerted, have to come out. Two valves in the back keep the pressure balanced.

Should the protective unit -- break, the air will flow outside and not vice versa. The reclamation workers are fully protected.

Next?

Four windows were opened between the contaminated and the uncontaminated part of the plant, through the safety glass we can follow minute by minute, the work inside the area and, -- thank to the comunication system, direct it.

Next?

These are the workers doing their job at the beginning of the decontamination work. You can see on your left-hand side is the reaction vessel wherefrom -- the runaway reaction that contaminated the area originated.

Now, all the plant has been carefully dismantled.

We put every piece in containers. The containers

will be put in the center of the largest basin, which has been shown before.

I think this is the end of it. Turn on the lights.

I wanted to emphasize the precautions we've been using in the Seveso area. We have no indication of any adverse effect to the health of the reclamation workers. The workers were examined before having the authorization to join the cleanup team. They are checked every month, if they are heavily involved in the work. -- After they give up the activity in the Seveso area the workers are checked a second visit is planned after 12 months.

Thanks to the protection that they've been using, we didn't have(any kind)of evidence of adverse effect.

About the health of the populations, if you permit, I will read something from an official document of the Special Office.

Five years after the TCDD accident, it is possible to see the final stages of the various projects that have been undertaken in an attempt to look for short-term human health detriments resulting from TCDD. Fears of multiple and massive manifestations of toxicity have not been realized. A review of clinical, laboratory, and epidemiological studies have revealed that so far the only evidence for a systemic toxic reaction have been the appearance of chlor-

acne in some exposed individuals.

Some marginal effects that could conceivably be linked to the esposure are still being analyzed.

193 children contracted chloracne. Screened very carefully by Professor Puccinelli -- Probably you Know the work done by Prof. Puccinelli.

Evidence currently available does not, of course, bear heavily on possible delays or later effects of carcinogens --

To date, no excess of death or a particular cause of death has been discovered in the all municipalities under surveillance, about 220,000 inhabitants. Case by review of the 25 deaths of people who used to live, in Zone A, according to codes from death certificates, show nothing suspicious.

We had some indication at first glance to have a sample, a geographic cluster of certain categories of birth defects. However, the scientific committee devising the procedure, they conclude that the data available thus far show no birth defects that can be unequivocally ascribed to TCDD exposure. The possibility of detecting an effect in the future diminishes as the body burden of TCDD declines.

The registry, will be kept up to 1996,(*) 20 years

(*) Reduced from 25 down to 20 years.

after the event. As expected, no cancer occurred which might be attributable to TCDD exposure. From studies of other environmental human carcinogens, we know that latent periods are longer for cancer from ionizing radiation than from immuno-suppressing drugs for renal transplantation.

It was necessary to carry on this analysis and it will be done carefully.

On the occupational health, non effect from TCDD has been found on the reclamation workers, soldiers or public service employees.

The workers exposure at the factory is independent of the runaway reaction to which they were not exposed, unless they happened to be downwind on that fateful Saturday.

You know, that the contamination was blown through the roof of the plant outside the ICMESA factory. People inside had practically no exposure.

We didn't have any chloracne among the workers.

We had soldiers for a few years to control that nobody could break into the contaminated area; they were changed every three weeks. No one, really, has been exposed for a long time. The soldiers are difficult to trace after they leave the Army. Studies on both adults and children today have not demonstrated any clear

association between health problems except chloracne from acute exposure to TCDD.

I would say in conclusion that the only finding, so far, that can with certainty be attributable to TCDD is the chloracne. But our Epidemiological Team is going to continue the effort and will follow the risk groups. A first group's made by the people who have been affected in the B+A Zone. A second is constitued by the workers of the ICMESA factory.

The people involved in the reclamation activity constitutes the 3rd group. These three groups will be followed and compared with reference groups to check whether any adverse effects in the longterm does appear.

Thank for your attention. If you have any questions, I will answer to the best of my knowledge.

DR. SHEPARD: Thank you very much, Doctor. Are there any questions from the members of the committee?

It certainly is a very important report and, as Dr. Fortunati has indicated, the Italian government is following up on these individuals. Of course, that's terribly important, and we in the biological sciences will be very interested in what those efforts reveal.

Any questions?

Dr. FORTUNATI: We would like to exchange information viz a viz the interested agencies in the United States because this will help to increase our knowledge and make more valuable judgment on the results.

DR. SHEPARD Certainly that's the case, and we would welcome such close association.

Dr. Fortunati will be here for the scientific subcommittee meeting and will be available for more questions at that time from the members of that group.

I would simply like to ask, if you have the information, Dr. Fortunati, you said there were 191 children?

DR. FORTUNATI: 193.

DR. SHEPARD: 193 had developed chloracne. Do you have any idea -- and they were all in Zona A, right? There was nobody outside of Zone A?

DR. FORTUNATI: No, Zone A and Zone B.

DR. SHEPARD: And Zone B. Do you have a rough idea what the populations were at the time of those two areas, A and B?

DR. FORTUNATI: I would say about 10,000.

DR. SHEPARD: 10,000.

1 DR. FORTUNATI: About equal the ones that were
2 nearest to the factory and the effect, I think, was the
3 combined effect of the mixture of chemical with the cloud.
4 And the dioxin. The dioxin was diluted in large quantity
5 and those possibly had dioxin by eating the vegetables
6 from the gardens. Each house has a garden and everybody is
7 cultivating vegetables.
8 So I think the TCDD assumption was through two
9 routes, by inhalating the cloud and by eating the vegetables.
10 DR. SHEPARD: Well, thank you very much for
11 that report. We're looking forward to your comments at the
12 subcommittee meeting. I'd like to call on Dr. George Anderson
13 from Texas to give us an update on various state activities.

REPORT OF STATE GOVERNMENT ACTIVITIES

14 DR. ANDERSON: As you most likely know, in the
15 18 or so states which have a program or commission, it's hard
16 to put together exactly what all of the states are doing.
17 Last evening we had a meeting here in town at which representatives
18 from New Jersey, West Virginia, Pennsylvania, Minnesota and
19 New York and, of course, myself met. We discussed our various
20 programs to some extent. However, we are knowledgeable — fairly
21 knowledgeable, since we've had a considerable amount of correspondence
22 back and forth over the last year or so.
23 At the meeting last night, we looked at ourselves
24 a bit. We felt that at times we had, or course, been accused
25 of prejudgment, which is understandable. The veterans'

1 organizations, which in most states actually sponsored or
2 put through the various state legislatures the various laws
3 setting up the programs, tend to make the state programs and
4 commissions advocates of the veterans. The VA, of course,
5 itself is an advocate for the veterans.
6 We discussed the VA Agent Orange registry. We
7 appreciate the mail-out of the registry to the states which
8 have requested it. I received mine in Texas two weeks ago.
9 There were some 4,400 names in our registry in Texas.
10 Because in the State of Texas the fiscal year begins the
11 1st of September, we didn't have the necessary postage at
12 that time to put out a mailout.
13 We discussed the GAO report and we feel pretty
14 much as a consensus, the group, that there should be a
15 follow-up to that report. We haven't heard very much and
16 we would like to have this done.
17 We would, as the follow-up perhaps, if a new
18 team is selected to make some visits, that a physician be
19 on the team. We were concerned because the report showed
20 more methodology than results. We are more concerned with
21 what has come out of the program than the way in which it
22 is being conducted.
23 We, as a group, encourage the veterans in various
24 states to contact the VA and take advantage of the Agent
25 Orange physical. That's all.

1 The individual programs have become more active.
2 Pennsylvania is rapidly moving. They are funded through
3 1984 and are going in for a three year extension, which they have
4 every expectation of receiving. They are developing their
5 mailing list, and shortly will be in contact with their
6 veterans. They have a questionnaire under development
7 which will be sent to the veteran. I think most of the
8 programs tend to use the questionnaire method of contact
9 with their veterans.
10 We have bad news, as well. The New York Commission
11 terminates as of the 30th of September. We have no more
12 to say on that than that.
13 The West Virginia program is rapidly developing.
14 The folks in that program paid a visit to Texas a month
15 or six weeks ago; spent two days with us. They met with
16 the six individuals at the University of Texas who are
17 carrying out the medical research of our program. And the
18 next day they came to Austin where they spent a day with us,
19 taking a look at how we are developing the epidemiological
20 component of our program.
21 Those of you who are not familiar with the Texas
22 program realize that it is a joint program between the
23 Texas Department of Health and the University of Texas
24 system. Three of the health science centers within the UT
25 system have developed protocols and are working very closely
26

1 with the Department. The department is the administrator of
2 the program. The University of Texas scientific
3 group who are in contact with the veterans, who carry out their
4 part of the studies, which are in a form of protocol which I
5 think, you are probably already aware of.
6 I received correspondence from the State of Hawaii.
7 I will read part of the letter which they sent to me. This
8 is from Will Rellahan, Ph.D., who administers their program
9 in their Department of Health. "We have established an
10 Agent Orange registry in which are stored reports of the
11 symptoms, diagnosis, and treatment of medical problems
12 which patients attribute to exposure to herbicides in
13 Southeast Asia. We have conducted a health survey in which
14 volunteers describe the conditions of their residence in
15 Southeast Asia, and indicate their estimation of the degree of
16 their exposure to herbicides during the period of
17 residence, and describe any subsequent medical problems
18 they remember. The result of this survey (to be published
19 in the fall of 1983) led the Hawaii legislature to extend
20 the life of the Agent Orange program until 1985,
21 and requested
22 the extension of Agent Orange health surveys in such a
23 way that a random sample of Hawaii Vietnam veterans popula-
24 tion would have it's health compared with that of a corres-
25 ponding sample of the remaining Hawaiian population.

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1 We have started the latter task. We are pleased
2 to be numbered among the states which have taken an active
3 interest in the problems of veterans in Southeast Asia
4 conflict. Our program, in addition, has included an
5 examination of the medical problems of refugees from South-
6 east Asia who might have been exposed to herbicides. Unfor-
7 tunately, so few of these people have volunteered for the
8 medical problem survey, that no conclusions can be reached
9 about their health relative to other members of the popula-
10 tion. Yours sincerely."
11 I also heard from the Illinois commission. They
12 are not here today at this meeting. They are planning
13 a meeting the 24th and 25th of this month, a meeting of the States
14 program and Commissions in Illinois. Which I am sure, Dr.
15 Shepard already knows about.
16 I'd like to, at this time, talk a little about
17 the Texas program. We are now two years old. It started
18 on September first, 1981, following the passage of our law
19 at that time. We were funded to the extent of $500,000 for
20 the biennium. Most of that money, I have to report, was
21 utilized. The program is a joint program between the
22 Texas Department of Health and the University of Texas. The
23 Department receives the money which goes on contract with
24 with the University to carry out their studies.
25 The veterans contact the Texas Department of
Health directly

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through their physicians. One of the requirements is that the veteran have a medical condition which he attributes to exposure to Agent Orange in Southeast Asia.

To date, we have over 400 veterans in our program. We anticipate, by next year at this time, we will be up to about 650. The veteran coming into the program, of course, fills out a questionnaire. We then, contact St. Louis at the repository and get his military records, both medical and personnel. We also contact the Veterans Administration if he has had an Agent Orange physical, and get a copy of that and all other medical records which are on file with the Veterans Administration.

We also contact all civilian physicians with whom he has had contact since Vietnam. We get all hospital records, if he were hospitalized. We build a very large file on each veteran. We then make an estimate of his exposure in Vietnam. I might say that we get good cooperation from Mr. Christian and his group in determining the exposure of these veterans.

An exposure index is developed, which actually amounts to primarily, was his unit in an area in which there was spraying activities during the time that he was there and of his account of the situation that took place while he was there. Many of them, of course, do present their version of what happened: backpack spraying, the use of helicopters,

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1 and various other methods that were used.

2 We have an advantage in our work, because we are

3 in direct contact with the veteran. We can discuss, at any

4 time we want to, any part of the questionnaire, by phone

5 call. Some of them come into our office , sit down,

6 and discuss things with us.

7 Once we have worked out the exposure index (and

8 not all of them, of course, were there when there was

9 heavy spraying) his case is presented to a selection com-

10 mittee in Houston at the University of Texas Health Science

11 Center; made up of six individuals who are carrying out the

12 various studies.

13 We determine whether or not the individual is

14 eligible. If he has been a welder, and worked at petro-

15 chemical plants, and worked in agriculture in Texas where

16 they use a lot of 2,4,5T, he is not eligible for our studies.

17 To date we have selected 85 individuals to study.

18 We also, at the same time, select controls. The controls

19 are selected several ways. Either through the buddy system

20 of the veteran, naming two or three individuals for us to

21 contact, and to look at as possible controls; through the

22 various veterans organizations; and through the Texas

23 National Guard, looking for individuals between the ages of

24 30 and 40 years of age. We have, so far, been able to draw

25 blood, and get a sperm sample on 44, which have been sent

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1 to the University of Texas. The reports are now coming
2 back to my office. This includes 44 veterans and appro-
3 priate controls.
4 We hope by the first of the year that we may be
5 able to break the code. Take a first look at the first 85,
6 to see what we're going to find. The studies that
7 we're primarily carrying out now are immune suppression
8 profiles, lymphocyte cytogenetics (chromosome breaks in
9 peripheral blood), and sperm studies (primarily looking for
10 Y bodies and other breaks).
11 The individuals at the University of Texas do
12 not know who the controls or veterans are. All
13 they receive, the only contact they have, is a sample of the
14 blood and sperm which they process. They're very anxious
15 to break the code. We will decide by the end of the year the
16 method we will use in breaking the code to see what we have.
17 Realizing these are pilot studies, which should give us some
18 direction, and we're particularly interested in developing
19 some methodologies for evaluating all individuals exposed
20 to toxic agents. And, as you know, Texas has a large popula-
21 tion which has already been exposed in the petrochemical
22 industry to the same agents. Our health department is very
23 interested in working out a program with the University of
24 Texas, as problems of Agent Orange and dioxin diminish,
25 to continue on in a civilian endeavor to carry out

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1 similar types of industrial toxic agent exposure studies.

2 We are funded this year for $300,000 and $300,000

3 for the second year of our biennium. Our legislature

4 is expected to continue the program until we have certain

5 resolutions. I believe that's about all I have to report

6 today.

7 DR. SHEPARD: Thank you very much Dr.

8 Anderson, a very nice run-down of the State activities.

9 And we're particularly pleased to hear more details on your

10 home state's epidemological efforts. Are there any questions

11 from members of the Committee. Yes, Dr. Moses.

12 DR. MOSES: Is this on, can you hear it? I was

13 just curious, you said in your sperm study you had 44

14 veterans and appropriate controls. I'm curious who those

15 controls are and how they were selected.

16 DR. ANDERSON: They were selected through the

17 buddy system, or through a veterans organization where

18 giving us the names of controls--

19 DR. MOSES: You mean they were selected by the

20 veterans?

21 DR. ANDERSON: They were only named by them. They

22 were not selected by them. We eliminate many of the

23 controls, because of their exposure occupationally to

24 various factors-- such as welding, agriculture, and so forth. These

25 are individuals who are not, were never, Vietnam veterans.

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1 Some of them are veterans who served stateside and in
2 Germany or other places. We matched them, of course,
3 through the usual match, age and the rest. We do the
4 best that we can. Controls are a very difficult thing. To
5 select a control, you have to go through several in the
6 process of selecting.
7 DR. MOSES: And I was also curious in the 44
8 veterans who you say--are they all from one geographical
9 area? Or, are they from all over the State of Texas, which
10 is huge?
11 DR. ANDERSON: They're all over the State.
12
13 DR. MOSES: I see.
14 DR. ANDERSON: We work very closely with our local
15 health departments in drawing the blood, and getting the
16 samples, and with project clinics and physicians; we'll
17 contact in any way we can to get the samples, and--
18 DR. MOSES: Is the same lab going to do all of
19 the samples?
20 DR. ANDERSON: --and the same lab is doing all
21 of the samples. The sperm studies are being done at the
22 Medical Branch at Galveston; the cytogenetics at M.D.
23 Anderson Cancer Center in Houston; and the immune suppression
24 studies at the University of Texas Health Science Center
25 in Houston.

1 DR. SHEPARD: Any other questions for Dr.
2 Anderson? You may have said it, George, but I didn't
3 catch it, how many people you're aiming at, in terms of
4 studies, subjects, and controls. Ultimately do you have
5 a cut-off point?
6 DR. ANDERSON: We hope to have an addi-
7 tional 50 added to our study during this next year: 50 to
8 each one of these three studies. This is due to funding
9 limitations: high cost. For instance, an
10 immune profile costs us $933.00, and then you have to
11 multiply it times two, because of the control. So our
12 contract with the University of Texas for the immune study
13 itself was $93,000 for that study alone. That will only
14 cover 50 veterans. Of course, just the shipping of the
15 specimens from throughout Texas to the University system (they must
16 get there within 24 hours from rather
17 remote areas) cost us a lot of money. The Federal Express
18 people are in business in Texas.
19 DR. SHEPARD: Well, thank you very much Dr.
20 Anderson. I hope you'll be available to meet with us
21 for a portion of, at least, the Science Subcommittee. Because
22 I'm sure there would be some more specific questions on
23 some of your testing procedures, and so forth.
24 I'd like now to call on Dr. Donald Barnes of
25 the Environmental Protection Agency, whom I hope, will give

us an update on what the EPA is up to in the dioxin arena. Morning Don.

EPA ACTIONS REGARDING DIOXIN

DR. BARNES: Morning Dr. Shepard, members of the Committee, and members of the audience. Environmental Protection Agency has been involved with dioxin concerns of a variety of types, since the early 1970s. Our initial focus was on the herbicide 2,4,5-T And this occupied our concerns through most of the decade of the '70s culminating in 1979 with our emergency suspension of certain uses of the herbicide, and initiation in 1980 of litigation to cancel all uses of the herbicide. That activity is ongoing at the present time. But since that initial effort focusing on 2,4,5-T the issue of dioxin as defined as 2,3,7,8-TCDD has broadened, as has the definition of the term dioxin itself.

We are now concerned about the presence of all 75 chlorinated dioxins in the environment. And increasingly concerned about the dibenzofurans, as well.

Given the recent changes at EPA in terms of the higher management in the past six months. There has been a refocusing of our activities in the area of dioxins and furans. The Deputy Administrator came in, and after about a month or so, saw that the concerns of dioxins and furans, had broadened well beyond the initial focused interest in 2,4,5-T. Subsequently we all received in that time period, a petition from citizens from the State of

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1 Michigan asking for a full-scale field investigation, is
2 the term they use. To investigate the potential pollution
3 which they were suffering in Southcentral Michigan.
4 In response to that citizen's petition, a cross-
5 agency effort was brought together under the direction of,
6 or at the behest of, if you will, of the Deputy Administrator.
7 And out of that, people began to see that if you're
8 talking about dioxin contamination, you're talking not
9 only about 2,4,5-T but you're talking about possibly incinera-
10 tion sources, and other types of activities as well.
11 In responding to that citizens petition, and with
12 the encouragement of the Deputy Administrator, the--manage-
13 ment of EPA has developed, what they refer to as a dioxin
14 strategy. This strategy has been formulated over the past
15 two or three months, and is now out for a limited outside
16 review. We hope that within the month of September,
17 this will be finalized and will be presented to the Adminis-
18 trator to allow him to make his decisions, and announcement
19 of whatever it is regarding the dioxin strategy.
20 Therefore, while I cannot speak definitively
21 about what the details of the strategy are, I think I can
22 mention some of the possible and probable complements of
23 that strategy. Our experience in Missouri and Newark and
24 other such places as that, have indicated to us that an
25 area of real concern is associated with dioxin, around and

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1 associated with the previous production of 2,4,5-T and 2,4,5-
2 trichlorophenol. The best of our information, these
3 chemicals are no longer produced in this country. However,
4 the facilities which had produced these in the past, still
5 exist. And there seems to be a need to, at least, go back
6 and check at several of these facilities to determine whether
7 or not there is harmful contamination.
8 This, if you will, was the source of contamination
9 in Missouri. Back in the early '70s, a manufacturing facility
10 that was involved with making 2,3,7,8-TCDD contaminated
11 materials, was the source of material which were then
12 spread over certain portions of Southern Missouri.
13 So, the idea is to go back and look at the finite
14 number of plants which were involved in those kinds of
15 manufacturing processes in the past. Associated with the
16 manufacturing is not only the site itself, but also the
17 question is what happened to those wastes. Again, this is
18 what the problem turned out to be in Missouri. That the
19 wastes were disposed of in what we were term now
20 euphimistically perhaps as a injudicious way of disposal.
21 The question is whether or not other facilities that
22 were involved in similar types of manufacturing had similar
23 problems with disposal of the wastes in the '70s. So this
24 activity is being focused in, under our Office of Solid
25 Waste and Response. There has been certain guidance already

1 sent out to the regions. The regional offices have a great
2 deal of autonomy in the structure within EPA. And guidance
3 is being sent out to try to coordinate this activity.
4 In addition, if you will, going to the next layer
5 of concern is, people have suggested that we might not only
6 want to look at people who not only manufactured it, but
7 people who formulated it into various products. Again, some
8 of our regions have already--and some independent states
9 have also taken activities--taken action to look into this
10 area.
11 Our concern here is to try to coordinate the
12 activities so that everyone moves along in a pretty
13 well coordinated fashion.
14 As a consequence of the response of the Michigan
15 citizens there was considerable interest in Congress that
16 the Agency somehow respond positively to the suggestion of
17 a full-scale, or full-field investigation. This has
18 resulted in bills introduced in Congress to encourage the
19 Agency to conduct, what has been termed, a National Dioxin
20 Study. And there is a certain portion of the strategy
21 that deals with this.
22 You know, what form should that take? And how
23 will it be dealt with, and so on? There is great Congres-
24 sional interest in this. And we are in the process of trying
25 to work out the details of it. Certain components of it,

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1 though, have been suggested in the past. And some of these
2 deal with 2,3,7,8-TCDD in terms of where it happens to be in
3 the environment in terms of air, water, fish, soil, and so
4 on. So, there's been some concern, that in the past, we
5 really don't know what the background levels are of this
6 particular chemical in the environment.
7 We do know that there are certain samples reported
8 at the American Chemical Society, yesterday; and there's
9 already appeared in the literature before, dust taken from
10 certain areas of the country which we don't necessarily
11 know to be associated with 2,4,5-T manufacturing and so on,
12 have been reported to contain trace amounts of various
13 chlorinated dioxins, not necessarily 2,3,7,8.
14 Part of our concern then would be, or one recom-
15 mendation has been to try to figure out what the background
16 levels are. Another area of concern, that has been
17 raised on the international scene, has been incineration as
18 a source of dioxin contamination. This would involve the
19 incineration of hazardous wastes, which we've looked at in
20 some regard; and incineration of municipal waste.
21 The Agency has a program ongoing to look at these
22 activities, but it might be a need to broaden this interest.
23 I know that this is an interest to various states, and
24 the City of New York and others who are involved in
25 building incineration facilities, then, that is determine to

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1 what extent there is a problem, and if there is a problem
2 how to minimize it and solve it.
3 In addition to these activities, which have
4 focused, will focus initially on 2,3,7,8, the broader
5 scale of looking at dioxins and furans is one which
6 we recognize as something we've got to deal with. And
7 there is an effort underway right now, to see if we can
8 sort of focus more clearly what activities we
9 would have in that broader arena.
10 The concern is not to get ourselves boxed in,
11 to just doing what seems to be the problem at the moment,
12 but to get ahead of the curve, and be able to address some
13 of those concerns that we think we'll be coming to us in
14 the future.
15 The strategy itself, as I say, is not yet a public
16 document. However, the Office of Water
17 and Environmental Protection Agency has a limited number
18 that are available to certain environmental groups, industry
19 groups, and other government groups. People in the Office of
20 Water and the Office of Solid Waste and Emergency Response
21 I believe, would be happy to answer general questions about
22 the strategy. You can look forward to it, as I say, coming
23 forward we hope, by the end of the month.
24 DR. SHEPARD: Thank you very much, Dr.
25 Barnes. I think, any questions from the members of the

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1 Committee for Dr. Barnes? Dr. Moses.

2 DR. MOSES: Yes, I'd be curious, I think this

3 is an excellent idea as far as looking at dioxins and

4 furans together. And I would be curious as whether or not

5 the Agency is considering the most widely used environmental

6 chemical now, is pentachlorophenol which has both

7 dioxins and furans in it, although not 2,3,7,8. Are there any

8 plans to include either pentachlorophenol

9

10 particularly since

11 about 40 million pounds a year are being used? And that

12 might be a rather important area to look at, at the same

13 time. Is that being considered?

14 DR. BARNES: It's not only being considered,

15 part of, if you lay this problem out, if you will, in terms

16 of an onion. At the nucleus the onion would have 2,3,7,8-TCDD,

17 and we have all the other dioxins, all the other tetras,

18 then all the other dioxins

19 and furans. And there are a limited number of

20 resources. So, the current thinking seems to be, well we

21 ought to try to focus where we see the bigger problem.

22 And where pentachlorophenol will hit, I am not

23 quite sure. I don't think, though, we would limit strictly

24 to penta, because there are other chlorphenols as well.

25 We see that as a--

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1 DR. MOSES: That's my next question.

2 That's the other question I wanted to ask you.

3 I thought you said that trichlorphenol is no longer

4 being manufactured. I assume you mean 2,4,5-trichlorphenol?

5 DR. BARNES: Yes.

6 DR. MOSES: Now, 2,4,6-trichlorphenol, which used

7 to have wide use as a germicide I assume, is being manu-

8 factured. And that's very, very widely used.

9 And I was curious about that statement. And is no 2,4,5-

10 trichlorphenol being made? Hexachlorbenzene is, I mean,

11 hexachlorophene is still being made, and this is the feeding

12 stock for it. I thought it was still being made.

13 DR. BARNES: 2,4,5-TCP, which is used in this country,

14 to--

15 DR. MOSES: Coming from ICMESA, used to.

16 DR. BARNES: No longer, no longer.

17 DR. SHEPARD: Any other questions for Dr.

18 Barnes? If not, I would now like to announce that the two

19 subcommittees will now meet. /The Subcommittee on Education and

20 Information will remain in this room. And the Subcommittee

21 on Epidemiology and Biostatistics will convene in room 139,

22 which is just down the hall. And let's try and convene

23 within the next six minutes or so. Then we will break for

24 lunch and reconvene at 1:50 or thereabouts. Thank you.

25 (The meeting was recessed, but did not reconvene until

/2:28pm, this same day, Thursday, September 1, 1983.)

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1 A F T E R N O O N S E S S I O N

2 2:28 p.m.

3 DR. SHEPARD: First of all, I'll call on Fred

4 Mullen, and ask him if he would give us a synopsis,

5 several highlights of deliberations of his subcommittee,

6 and then I will ask Dr. Hodder to do the same.

7 Following that I will ask Dr. Michelle Flicker,

8 on my right, to give us a run-down of what has been

9 going on, not as part of this Committee's actions, but

10 another very important deliberative effort. As

11 you probably know, the American Chemical Society has been

12 meeting here in Washington. That meeting has afforded the V.A.

13 the opportunity to bring some of the biggest minds in the

14 world together to discuss some of the aspects of a very

15 important study that we will be conducting in conjunction

16 with the Environmental Protection Agency. That is the

17 analysis of human adipose tissue for dioxin. And we'll

18 have a little more to say about that later. But Fred could

19 you kick it off for us, please.

REPORTS OF SUBCOMMITTEES

20 MR. MULLEN: We had another free-for-all. I think

21 it was productive in some aspects, informative in others.

22 But we did again, identify some very obvious problem

23 areas. There does not seem to be a V.A. policy in policing

24 the Agent Orange examinations that are conducted. The way

25 the examination is conducted now, there are certain routine

1 laboratory tests that are conducted. And other laboratory
2 tests that are conducted, if necessary. I think we have
3 reason to believe that there are examinations that should be
4 done which are routine, and are not being done, even when
5 clinically indicated; or, based on the medical history.
6 We were advised that at least one V.A. hospital's
7 accreditation is hanging in the balance, because of their
8 Agent Orange examination program. And we believe, that if
9 this, if the accreditation of an entire hospital, hinges on
10 the quality of the Agent Orange screening examination, that
11 you can find similar variances in other V.A. hospitals. I
12 think that you ought--that we ought to institute, if
13 necessary, another committee, in addition to the I.G.'s or
14 whatever, that goes out. Rather than wait for the I.G.'s
15 team to go out there and investigate a hospital, V.A. should have a
16 specific team go out and police specifically for the Agent
17 Orange examination.
18 Immediate, and I think everybody knew this was
19 going to come up, while the administration may have stated
20 a disclaimer as to the information reported to the various
21 media, that the statements made indicated that they were
22 the results of a review of data by the administration,
23 rather than a major study. In some instances the media
24 picked it up, and did describe it as a major study. But we
25 felt that the onus should be on the administration to either

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ask for a retraction, or to ask for clarification. And, if nothing else, buy space and inform the veterans that the information reported was erroneous, or taken out of context. CDC is experiencing, or is expecting to experience some difficulties in locating both veterans and cohorts for their study.

One article, in particular, indicated that there are a million people in the general population who have had exposure to dioxin, and 85,000 possible cases of dioxin exposure of veterans in the Agent Orange registry. I think this gives the impression that the administration and the government has already made up their mind that there is nothing here. And, if that is the case, why would a veteran want to take three or four days off of work, possibly lose his job to do it, or suffer loss of wages, if he has the perception that the Government has already made up their mind. Why participate in the CDC study? I think the onus is on the V.A. to clarify any errors that occur in the media, or misconceptions that are portrayed.

We found out that there is a definite need for dialogue between the Department of Veterans Benefits and the Department of Medicine and Surgery. It seems there are approximately 18,000 Agent Orange claims that have been filed. Roughly 24 percent of those, have no disabilities. But in 13,000 cases, where disabilities

1 had been diagnosed there are in excess of 500 malignancies.

2 DR. SHEPARD: 15,000 or 1,500?

3 MR. MULLEN: 13,000. I think the 1,300

4 you are referring to 1300 which are the claims that were allowed for

5 skin conditions. Am I interpreting this right? I believe

6 I am.

7 MR. WOODALL: In one--7,535 claims were denied,

8 there were--

9 MR. MULLEN: Of malignancies, I think that's

10 a, even though that may be a self-selected group that's

11 I think an inordinately high amount of malignancies for

12 such a small group of veterans. Additionally, and in earlier

13 dialogue between DVB and DM&S, I believe, DM&S supplied

14 DVB with the names of a thousand veterans, from the registry.

15 It only correlated with one name in the claims that had

16 been filed? So here you've got--

17 MR. WOODALL: One in ten.

18 MR. MULLEN: Oh, excuse me, one in ten. Okay,

19 one in ten. But still, there is

20 a great potential for increasing the numbers of the registry,

21 and the information in that registry. If you're talking

22 that only ten percent of those veterans are in that

23 registry, and vice versa. The one thing that

24 we really took umbrage at, is the fact that since those

25 veterans are not in the registry, they were rated without

1 the Agent Orange examination. Even though Agent Orange
2 is claimed. And there are circulars out that state that the
3 examination is to be conducted before the claim is raised.
4 DR. MOSES: If you're talking about the people
5 who have already filed, a disability--these claims?
6 MR. MULLEN: For compensation. 18,000.
7 DR. MOSES: --Are they the ones who have been, or
8 what did you say, they've been
9 MR. MULLEN: Some of those names are not incor-
10 porated in the register.
11 DR. MOSES: No, that I understand. I can see why
12 that might be the case. You made another point about they
13 decided what their Agent Orange exposure was, did you say?
14 MR. WOODALL: These claims were filed. They go
15 back to 1978, '78 and '79 so far. They've been examined,
16 but they were not subjected to the Agent Orange--
17 DR. MOSES: Oh, okay.
18 MR. MULLEN: And also, in V.A. law, if a veteran
19 has an examination, or a hospitalization, or outpatient
20 treatment, if he filed a claim within one year of that date,
21 should he finally receive benefits for that disability,
22 he can go back to the date of that examination, as the
23 date of the claim. The V.A. is not notifying these veterans
24 after their Agent Orange examinations that if they don't file
25 within one year, that the date they do file would be the

1 effective date of any benefits. So you've got 119,000
2 potential people, with the exception of the ten percent,
3 that have not been notified that if they had filed within
4 one year of that examination, their benefits would have
5 been retroactive to the date of that examination.
6 DR. SHEPARD: I think there's a confusion here
7 between, you hear me? I think there's some confusion
8 between the registry and the C&P process. As far as I know,
9 there is no, there is no formal link between the registry
10 process, and the claims' filing process. Both are totally
11 voluntary, on the part of the veteran. A veteran may or
12 may not wish to be included in the registry, if he is filing
13 a claim. And vice versa. Having the Agent Orange examina-
14 tion in no way obligates him to file a claim--
15 MR. MULLEN: No.
16 DR. SHEPARD: --or a claimant is in no
17 way obligated to become part of the registry. You know,
18 I think, that ten percent of the overlap is not very
19 surprising given the numbers. On the issue of
20 veterans being informed about the deadline on filing a claim.
21 There again, I don't necessarily see that it's incumbent
22 upon the V.A. to tell people that there's a limited time in
23 which they have to file a claim, if they go in for an Agent
24 Orange examination. I don't know if that's the point you're
25 trying to make, but that's the point I heard.

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1 MR. WOODALL: That, that came up in our meeting.
2 Two or three of the people here at the meeting believe
3 that this amounted to a claim, informal claim, the Agent
4 Orange examination. But, of course, it's not. For our
5 purposes, we would have to have
6 a formal claim, before it becomes a claim.
7 MR. MULLEN: Okay, but, if you don't file that
8 claim within one year of the examination, then you lose
9 entitlement to a year of benefits. Should the claim be
10 allowed? Under 3.157 if you have an examination, and you
11 file a formal claim within one year of that examination,
12 that examination is the effective date of your benefits.
13 DR. MOSES: Do you think people are having that
14 exam because they think it's a claim?
15 MR. MULLEN: No, but I think they ought to be made
16 aware of their potential entitlement.
17 DR. FITZGERALD: Marion, I think some of them do
18 think it's a claim.
19 DR. MOSES: That's what he suggested--
20 DR. FITZGERALD: And as a result of that, that
21 has come up in this body before, and the Veterans
22 Administration has subsequently been told to advise people
23 that there is a distinction between Agent Orange exam,
24 and filing of a claim.
25

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1 DR. FITZGERALD: Our organization has gone ahead
2 and advised them through our publications, that there is a
3 distinction--you understand now?
4 DR. MOSES: Well, I understand now.
5
6 But you think they really are confused.
7 MR. MULLEN: Certainly, certainly.
8 DR. SHEPARD: We have attempted, through a
9 number of initiatives, I believe, if I may jump in, to
10 make that, very clear. And in the Agent Orange
11 film, "A Search for Answers," you know, that goes back
12 aways, the distinction is made. The encouragement is
13 made, for those who watched the film, to--
14 I think I'm quoting it reasonably
15 accurately, if you think you have a disability, file a
16 claim. If you think you have a health problem possibly caused
17 by Agent Orange come in and have an examination.
18 MR. MULLEN: I don't see where it would be that
19 much trouble in the initial data base, to notify the man
20 of his potential entitlement at that point.
21 DR. SHEPARD: Okay, that was just one example.
22 I think in the Agent Orange Review, which we now have at
23 least three editions, I think the same point has been made.
24 Maybe DVB people would like to comment. Think as far as DM&S is
25 concerned, we have tried, as a Department,

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1 to encourage veterans, if they have any suspicion that they
2 have a claim to go ahead and file the claim. And, if you're
3 talking about a time limitation, then I'm not sure--Max
4 do you want to comment on this?
5 MR. WOODALL: Yes, one of the problems here, I'd
6 like to explain--
7 DR. SHEPARD: Why don't you come up to the table
8 and grab one of the microphones. Mr. Max Woodall, from the
9 Department of Veterans Benefits.
10 MR. WOODALL:
11 First of all, on the informal claim itself, generally
12 we're talking about the claim filed by the 526 or the
13 claim, with treatment--if possible, I'm not sure the Agent Orange
14 examination itself would constitute an informal claim.
15 Bob and I agreed I would have to research that. But I
16 think for the persons, particularly if you have a diagnosis,
17 in that case, they should file that claim as early as
18 possible.
19 MR. MULLEN: And all we're asking is that the V.A.
20 notify them at the time of that examination, that they
21 should, period. That's all we're asking.
22 MR. WOODALL: I think that's what some of the
23 people are upset about.
24 DR. MOSES: If they wish.
25 MR. MULLEN: If they wish.

1 MR. WOODALL: There was a general opinion here,
2 among three or four of the people, that that already costs
3 them the claim.
4 DR. MOSES: Yeah, that--
5 MR. WOODALL: And they wondered why these, why
6 the registry and the Agent Orange claim list didn't match.
7 Okay.
8 DR. SHEPARD: I think then that being the case,
9 as long as there's any continuing confusion then it is up to
10 the agency to help clarify that. And I certainly will
11 commit myself to working with the folks from DVB to do everything we can
12 to clarify that in any future publications.
13 MR. MULLEN: Another point that we made and,
14 according to Mr. Woodall, this has already been taken care
15 of. There were obviously a number of claims that were
16 denied without the benefit of the Agent Orange examination.
17 Mr. Woodall has advised me that in future ratings, if the
18 rating action does not contain a notation that the Agent
19 Orange examination has been done, there will be no rating
20 action done at that time. The rating will be deferred or
21 continued pending the conduct of the examination before
22 the man is rated as far as service connection, on a denial,
23 or an allowance. Is that correct?
24 MR. WOODALL: Yes. According with a
25 DM&S --examination

1 DR. SHEPARD: Let me hasten to point out that
2 there isn't any significant difference , in the
3 majority of instances, between a C&P examination and a
4 Agent Orange examination. Both are, presumably, fairly
5 complete physical examinations. They may emphasize or focus
6 on one area or another, as any appropriate physical examina-
7 tion does, depending on what the history suggests. So, I
8 just don't want to leave the impression in the minds of
9 people here, that somehow there is something very special
10 about the Agent Orange examination which might not be,
11 essentially identical to a C&P examination, or very similar
12 to it.
13 MR. MULLEN: It was also suggested that a lot of
14 people who are in the Agent Orange registry early on, were
15 under lumped diagnoses--from what I understand. And there is
16 a good deal of trouble separating that. Also there have
17 been strides--
18 DR. SHEPARD: Would you like me to respond to
19 that?
20 DR. MULLEN: If you'd like.
21 DR. SHEPARD: Certainly. That's true. And
22 that's one of the reasons why we've done a major revision
23 of the registry. We too were dissatisfied with the
24 specificity of the medical information that was being
25 reported. And we have now gone back and done a major Revision. I

1 hope you are aware, major revisions have now been in place
2 since March of this year, in which we are gathering much
3 more precise information. For example, we are
4 coding all diagnoses that are made during the process of
5 examination, both by name and by ICD9 code number. We
6 are noting specific kinds of consultations that
7 are performed. We are gathering much more precise medical
8 information. And will then soon be in a position to
9 analyze that a little more precise fashion.
10 MR. MULLEN: Since the techniques for Agent
11 Orange examinations have been updated and refined, since
12 the earlier examinations, we would suggest and recommend
13 that in the next Agent Orange review, there be incorporated
14 a letter, or article perhaps highlighting as you do in the
15 one orange block that's on there, that they can come
16 in for subsequent examinations as many times as they want,
17 if the need arises. And encourage them to do so.
18 Because not only would this assure them that
19 their health is being taken care of, but it would also
20 give DM&S a chance to update the information that's in the
21 registry, because as we've said, some of the earlier
22 participants, those diagnostic codes under ICD-9 are not
23 in there. We suggest and recommend that. And, I
24 think that's most of the things that have come up in our
25 discussion. We would like to answer as quickly as

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1 possible, on these recommendations.

2 DR. SHEPARD: Okay, recommendations, well, as I

3 see it, you've made some recommendations for changes in

4 policy. When you say an answer to them, you'd like to see

5 policy changes, I presume.

6 MR. MULLEN: Exactly.

7 DR. SHEPARD: I can't commit for the

8 administration.

9 MR. MULLEN: I understand. I'm not asking you

10 for an immediate answer. I realize that red tape is always

11 there. But we would like to have an answer as to whether

12 or not the committee proposes policy changes in this area, as

13 quickly as possible.

14 There's only one other thing and that was the

15 cancellation of the Seven City Tour. We understand that

16 there's going to be a film put out. And some of these

17 recommendations we would like to see displayed in that film.

18 So we request an opportunity, the service organizations, or

19 other people who are interested, or may have an impact on

20 the quality of that film, we would request before the final

21 edit is made, and the final cut and reproduction is made,

22 that we have an opportunity to screen that film. To make

23 sure that everything that we feel is necessary to insure the

24 veterans health, and his welfare is being given to him as

25 portrayed in that film. That's about all I have.

1 DR. SHEPARD: I'm sure Bob Putnam discussed
2 the film and the whole outreach effort in some detail.
3 Let me just point out for the benefit of those who
4 may not have been at that subcommittee
5 meeting, that the film to which Fred has referred is
6 primarily designed
7 for the edification of V.A. employees. It is not primarily
8 designed as a film for showing to veterans. Now obviously,
9 there's an overlap there. And I'm sure that the employees
10 pass the information on, and that is
11 obviously one of the thrusts of the film.
12 So I think we need to consider whether we should change the film, or
13 include some of the material that you've suggested in this
14 film, or whether a subsequent film, or parallel film should
15 be developed for purposes of showing to veterans and telling
16 them, assuring them, advising them in
17 terms of what they should do in relation to claims proce-
18 dures. And the fact that Agent Orange examination does not,
19 in and of itself, constitute a C&P--that kind of information
20 might more appropriately be dealt with in a separate--through
21 another medium. But we can discuss that.
22 MR. MULLEN: My problem with that is I was led to
23 believe that this more than being a film for the purpose of
24 edification, was more for the purpose of education of the
25 V.A. employees. And I think part of that education should be

1 the knowledge and the onus to, as I said, notify these
2 veterans that they should file a claim. If they don't file
3 within a year, they are dead. They can't get their benefits
4 retroactive to the date of that examination. These are the
5 types of things. I think the onus should be upon those people
6 who are reviewing that film, to pass this information on.
7 I was Chairing an Information and Education subcom-
8 mittee. These are information and education subjects, and
9 the information and education is primarily not for the V.A.,
10 but for the veterans. And, that's why we're making these
11 recommendations.
12 DR. SHEPARD: I understand, and entirely appropriate.
13 Don't misunderstand me. I'm just saying whether
14 they should be part of this film, or part of a different
15 film, we'll have to discuss. Any questions for Mr.
16 Mullen from members of the Committee? Any comments? We
17 will take questions from the floor at the appropriate time,
18 okay? I don't want to appear to be shutting you off, but
19 we will do that.
20 PARTICIPANT: Clarification points?
21 DR. SHEPARD: We'll come to that. Thank you.
22 Dr. Hodder, would you summarize the deliberations of the
23 Subcommittee on Biostatistics and Epidemiology.
24 DR. HODDER: We had a crowded agenda today, and
25 covered more or less the entire spectrum of studies,

1 including looking at a review and overview of published
2 literature. We looked at study design and formation of several
3 studies in progress, and we evaluated those completed ones.
4 Following them in the order they were presented: The first
5 was Dr. Anderson who briefly told us more about the protocols
6 he had presented earlier in the meeting. We've asked him to
7 present this further at the next meeting where we can give
8 it more time.
9 Dr. Fortunati continued his talk about the Seveso exper-
10 ience. A couple of new points were brought up.
11 Less than ten people out of
12 the original 183 with chloracne persisted with the disease.
13 And, I believe, he said no new cases have been discovered since
14 January of 1979. So there's not a continuing formation of new cases.
15 Also only minor plastic surgery was needed in these cases.
16 He also reiterated the spread of the dioxin was strongly
17 related to the soil.
18 The other point of interest he mentioned
19 was that the persistence of the people in coming back for follow-up
20 has fallen off. This perhaps suggests continued good
21 health although this needs further study.
22 Then Dr. Green presented an update of the solicited
23 in-house research studies. There was a considerable spectrum,
24 from very basic science studies and metabolism to
25 behavior studies and sleep studies. There were ten studies

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1 funded out of 36 .

2 Members of the sub-

3 committee asked for a list of all the studies so that

4 at the next meeting they could specifically ask questions

5 on points of interest.

6 Dr. Eisen, then, presented the V.A. identical

7 twins study. That study is similar to and reminiscent

8 of the post World War II studies by the National Academy of

9 Sciences. The objective stated was quite broad. The

10 primary objective would be to look at the impact of

11 Vietnam service on all aspects of health; specifically however,

12 herbicide toxicity and post traumatic stress syndrome will

13 be reviewed.

14 The key point, to most committee members,

15 was the ability of this type of design to overcome

16 many difficult problems with controls in epidemiologic

17 studies. He is going to look at both monozygotic and di-

18 zygotic twins and will look at all combinations of ex-

19 posure; both those where neither twin went to Vietnam;

20 where one went and one did not; and where both went to Vietnam

21 as internal controls for exposure.

22 Dr. Mulinare, then, discussed two studies. He

23 made some comments on the

24 Australian birth defects studies he had reviewed for several other groups.

25 The key points that he made were that this is

really a Vietnam exposure study and is not specifically addressed to Agent Orange. The other point of importance he made is that this is basically a sound study although it has some limitations.

He then summarized the progress and the conduct of the CDC birth defects study based on routine survelliance for birth defects. Dr. Mulinare was encouraged by the progress in the study. The goal had been to find 80 percent of the parents, and interview 90 percent of those. This would produce an overall 72 percent response. And it would be particularly important, obviously, to record military status service of the father in Vietnam. He expects preliminary results will be forthcoming sometime in winter or early spring.

In the next presentation, Dr. Hoar from NCI presented the studies of soft tissue sarcomas. Specifically the study is case control study, looking mainly at Kansas due to agricultural exposure. It's also taking advantage of a statewide cancer registry that Kansas has. And they're looking specifically at three groups. They're classifying the diseases as either soft tissue sarcoma, Hodgkins, or non-Hodgkins lymphomas. They have three controls for each patient, each matched by age and vital status.

Of particular interest to the subcommittee was the amount of corroborative information both in the

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1 effort being spent to recheck the biopsies, as well as efforts to
2 go back and actually classify by the amount of herbicide
3 used. Results are expected, perhaps in spring or summer.
4
5 Next two persentations were by Dr. Lavy and
6 Dr. Hood who presented monographs, first on--herbicides. And
7 Dr. Lavy spent a fair amount
8 of time going over some of the exposure studies that
9 were done. He showed some pictures that were taken of field
10 studies. Dr. Hood also discussed his monograph.
11 The purpose of it's mention was that a single source of cacodyl-
12 lic acid. Both of them have fairly similar outlines from typical
13 chemical properties, to the analyzing methods, production
14 usage, the human exposure studies, etc.
15 The final presentation was by Dr. Kenneth Sell of the NIH
16 Infectious Disease Institute who provided an
17 overview of the immune system in exposure to TCDD.
18 He said that in a review of the literature that animals
19 given a sufficient quantity of Dioxin will show a decreased T-cell
20 activity. The corrollary to that though, is even under
21 high doses, Mice showed a complete recovery at a
22 year's time. He then used this background to look at Dr. Ward's
23 study which supposedly showed decreased phyto hemoglobin stimula-
24 tion of the immune system. And decreased host response specifi-
25 cally in people exposed. He felt that

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statistically

you'd expect about five percent of control groups to be low. He did not show that. The control group was not typical of the general population, and he felt this was not a good comparison. Then he talked about studies that could be done and expected it to be difficult to show persistence of immunlogic defect in these animals. Using the model of the immuno-suppressed transplant patient, for example, it was difficult to show that persistence of the initial immunosuppression of people on these drugs. Long-term, low dose immunosuppressants is very difficult to measure in effect.

Using that as an analog, it would be difficult to show it's effect on animals.

Again one year later, even after very heavy intense exposure, those effects were not shown.

DR. SHEPARD: Let me just add a couple of comments from Dr. Sell's discussion. I think the bottom line impression he had of what was presented as Dr. Ward's work, information he had was that the conclusions that Dr. Ward seemed to be drawing in his discussions were not substantiated by the data that were presented. And Dr. Sell, I think, had the

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1 impression that conclusions were not only not substantiated, but
2 probably not valid. The reason I asked Dr. Sell to lead
3 this discussion is that a great deal has been made of the
4 Ward work. And I just wanted to put that into proper
5 perspective, so that somebody with Dr. Sell's knowledge and
6 in-depth experience could give us the benefit of his evalua-
7 tion and analysis of that work. Thank you very much Dr.
8 Hodder. Are there any questions from members of the Com-
9 mittee to Dr. Hodder or any comments by other people who
10 attended either of the two sessions?
11 Okay, now I'd like to call on Dr.
12 Flicker. Dr. Flicker is a very interesting person. She
13 is both a physician and a physical chemist. And she also
14 is one of our environmental physicians at our medical center
15 in Kansas City. And she, in addition to having seen a large
16 number of Vietnam veterans as part of the registry process,
17 has also managed to take out enough time from a very busy
18 schedule to play a very important role in
19 the cooperative studies we'll be doing with
20 EPA--that is the analysis of adipose tissue for dioxin.
21 And, Dr. Flicker was with Dr. Young and some of the chemists
22 discussing the analytical protocol, and perhaps some other
23 issues too. And, I'd just like Dr. Flicker to give us the
24 benefit of those deliberations. Thank you.
DIOXINS/FURANS IN ADIPOSE TISSUE STUDY
25 DR. FLICKER: Thank you Dr. Shepard. Can you all

1 hear me? I want to tell you what a thrill it is as a
2 physician in the field to be here actually seeing all the
3 folks who are responsible for the wise words that we field physicians receive in
4 published/ form. And they're actually very helpful. I've been
5 given lots of good advice from Dr. Shepard, Dr. Moses and I
6 got to read about Dr. Mulinare on the TWA flight magazine
7 on the way up here. So I really feel very privileged to
8 be among all these celebrities. I'm going to try just to
9 highlight the major features of what was a very
10 technical meeting.
11 I understand that you're all very familiar with
12 the V.A., EPA coordinated program for the analysis of
13 dioxin in human adipose tissue, and that you're also
14 familiar with it's purposes; mainly to see if there is
15 dioxin detectable in the world population; to devise standard
16 analytic methods for getting this measured in a
17 reprodicable way; to see if there are higher levels of
18 these dioxins and related chemicals, the furans, in Vietnam
19 veterans; and eventually to see if there's any correlation
20 of these levels with health effects; a tough set of goals.
21 It's very interesting that in the meeting, data were
22 presented from Canada and Sweden in unexposed populations
23 that-indeed, as we suspected, there is a significant and
24 measurable baseline level of TCDD and furans and higher
25 chlorinated relatives. This means that

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1 the dioxins and the furans are in the adipose tissue
2 of ordinary people walking around who were not either
3 in Vietnam or in industrial accidents. The sources of
4 these / substances were not only the phenoxy herbicides; there
5 are congeners, that is, higher chlorinated dioxins and furans,
6 that are speculated by Dr. Rappe, for example,
7 not to have come from the phenoxy herbicides, but
8 must have come from other sources such as flyash.
9 Also there were data presented suggesting a very
10 important principle: that the toxicity of the dioxins are
11 very much a function of other co-toxins to which the organism
12 is exposed. In other words, there is work now that shows
13 that teratogenicity of TCDD can be greatly magnified if
14 the organism is co-exposed to furans; and the furans indeed
15 are naturally occuring in greater frequency than some of the dioxins.
16 Also we are finding from the industrial accidents
17 a large population of higher chlorinated species. And
18 these principles, then, led the Committee and the group to
19 a consensus. It looks as if it might be much more meaningful
20 not just to analyze for dioxins, but also to try what is
21 called "pattern recognition:" to try to get relative concentra-
22 tions of these chemicals, not just with respect to TCDD, the
23 contaminant present in Agent Orange; but also to try to get
24 levels of other dioxins and furans. Which dioxins and furans
25 should be analyzed is a very important question. And that

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1 depends on what we're looking for.

2 Pattern recognition would have several

3 functions. First of all, given the political implications

4 of this project, it would give us a handle on the origins

5 of exposure. For example, Dave Stallings' group of the

6 EPA has computerized his patterns, and now pretty much

7 can tell you if a given pattern is from a fish source or

8 an industrial accident. So, that can help us distinguish

9 the source of exposure. We can run a stricter quality

10 control program if we do pattern recognition. And

11 basically, I think, those are the major features.

12 As part of developing our analytic

13 method, it is also agreed that we should consider getting

14 standards that are what is known as bioincurred. This is

15 because when we do extractions of dioxins from living

16 tissues, now that we know that there's a worldwide distribu-

17 tion of these chemicals; it's going to be difficult for us

18 to assess just how much of the dioxin we're extracting

19 is from an industrial accident or Vietnam exposure,

20 for example, versus that which was already the baseline

21 level in the tissue.

22 And Dr. Jim McKinney has suggested some ways

23 in which we can feed an animal of choice--a cow, a pig--

24 some radioactively labelled dioxin and dioxin relatives,

25 and therefore test our extraction and other analytic

1 techniques. Thus, we would differentiate the labelled from the naturally
2 occurring dioxins, should they have occurred even from
3 combustion sources.
4 Those are some of the major points. It may
5 interest you to know that so far we have collected nine
6 kilograms of fat, thanks to the EPA. This fat is slated to
7 become homogenized as a substrate on which to
8 develop our analytic methods.
9 So, in summary, the major points were that dioxins
10 and furans, as you all probably suspected, are everywhere.
11 That our analytic methods, then, must be such that we
12 can pick up these higher analogs of TCDD, in addition to 2,3,7,8-TCDD.
13 Thus, we'll probably need to use pattern recognition in our
14 analysis. And that indeed, this is a feasible study. Some
15 excellent work has been done by the statisticians in Dr. Joe
16 Carrie's group, showing that it is feasible for the sample
17 size that we're likely to have from the EPA archived adipose
18 tissue samples. We're likely to have a statistically mean-
19 ingful sample, and a statistically meaningful study, of
20 course, subject to a large number of variables. These
21 variables may indeed obligate us in the future to do a
22 prospective study, should they become too difficult, to control and assess, and too
23 open to too many variables and criticisms. Dr. Moses
24 obviously has thought of this! -- so that 's basically my
25 summary of the highlights of the meeting.

1 DR. SHEPARD: Thank you very much Dr. Flicker.
2 Are there any questions or comments from members of the
3 Committee?
4 DR. MOSES: I have two. First of all, are there
5 any plans, I realize the concern, as I say, of the Veterans
6 Administration is the men between a certain age group, in
7 a certain age group. But I feel that women can also
8 contribute, many ways in this world.
9 DR. FLICKER: I heartily agree.
10 DR. MOSES: And I feel that somewhere down the
11 line, conceptualizing this problem scientifically, that
12 fat from women, fat tissue from women, I think, needs to
13 be looked at. And I hope that maybe the V.A. could broaden
14 their sights, somewhere along the line. I guess you have
15 to get some early--
16 The second question related to the immune assays,
17 do you know what the status is on that, or what. You
18 say you mentioned Jim McKinney, and I know he's been very
19 interested in that?
20 DR. FLICKER: The details of the status were not
21 discussed in the meeting, to my recollection.
22 DR. MOSES: So, we've not gotten very far in that,
23 I guess?
24 DR. FLICKER: Unfortunately, you're right.
25 DR. MOSES: Thank you.

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1 DR. SHEPARD: Any other questions for Dr.
2 Flicker? Thank you again, good to have that report.
3 Now, I'd like to open up questions from the floor. Don
4 do you have some questions. Yes, you can come up, if you
5 please come up to the microphone and identify yourself
6 for purposes of the reporter, I'd appreciate it.
COMMENTS AND DISCUSSION
7 MR. KLEINGLASS: My name is Stephen Kleinglass,
8 and I'm from the Medical Inspector's Office within the
9 Department of Medicine and Surgery. I wanted to make one
10 bit of clarification to some statements that Mr. Mullen made
11 earlier on about the accreditation status of one of the
12 medical centers. That accreditation was referring to
SERP- accreditation, that we do internally to DM&S. It
14 came up when we went to a medical center and we were
15 reviewing the entire medical center for the quality of
16 care both in the patient-related areas, the allied health
17 areas, and the support services.
18 We specifically now, are looking at three areas
19 in addition with a stronger eye, so to speak. One of those
20 three is the Agent Orange program. We felt that at this
21 particular medical center the Agent Orange program was not
22 functioning as properly as it should. So we assigned a
23 provisional accreditation status to that medical center.
24 The medical center has one year from the date of the
25 receipt of the report to correct the deficiencies in the

1 Agent Orange program, to remove that provisional status.
2 I made the trip myself, and it's my indication that they
3 will successfully complete that project and be able to
4 remove the provisional status.
5 DR. SHEPARD: Thank you very much for pointing
6 that out to us. I would also like to supplement that.
7 The term accreditation means different things to different
8 people. I suspect, and please correct me if I'm wrong,
9 you were referring to VA accreditation, not JCAH accredi-
10 tation. The term hospital accreditation and normal parlance
11 suggests, Joint Commission on Hospital Accreditation,
12 and not an internal examination. I didn't want anybody to
13 get the impression that the JCAH would withdraw accredi-
14 tation from a V.A. hospital based on what's wrong with
15 the Agent Orange examination. But the point is well taken.
16 I don't mean to downplay the importance of that review.
17 And we certainly appreciate the efforts of our medical review
18 teams in doing this. I think it's a very important
19 adjunct to an ongoing quality control program. And we
20 salute their efforts, appreciate their comments.
21 Any other questions from the floor. Gee, that's
22 unusual. I think it's incumbent on me, perhaps, to make
23 a comment on the matter of some recent press that has
24 come out, regarding this large V.A. study. New York Times
25 picked up on a news conference held at the American

1 Chemical Society this past Monday and certainly suggested
2 that the V.A. had recently released a large study of some
3 85,000 Vietnam veterans. That has caused quite a ripple
4 effect, as you might suppose. What was being referred to
5 was some descriptions of the V.A.'s Agent Orange registry
6 about which you all know a great deal. It was not any kind
7 of a study. We have attempted to make disclaimers, but
8 those of you who know how the press operates, know that
9 disclaimers are often not effective. We will certainly
10 take under advisement, I won't but some people will I'm
11 sure, what the V.A. should do in regard to trying to set
12 the record straight, so to speak.
13 But just for the benefit of the people here in
14 this room, and for the purposes of the record,
15 it was nothing other than a description of some of the
16 data thatare contained in the Agent Orange registry, not
17 an epidemiological study report.
18 I'd be happy to answer any questions in that
19 regard if they occur to you. Any other questions, comments.
20 If not,thank you very much for your indulgence, and I think
21 it's been a good meeting. Appreciate your being here.
22 (Whereupon at 3:15 p.m. the meeting was
23 adjourned.)
24
25

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Eighteenth Meeting
December 6, 1983

February 1984 Washington DC 20420

VETERANS ADMINISTRATION

* * *

ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

* * *

Room 119
810 Vermont Avenue, N.W.
Veterans Administration
Central Office
Washington, D.C.

Tuesday, December 6, 1983

The meeting of the Advisory Committee was called to order at 8:40 a.m.

ADVISORY COMMITTEE MEMBERS PRESENT:

BARCLAY SHEPARD, Chairman

GEORGE R. ANDERSON, Member

THOMAS A. FITZGERALD, Alternate for Irving B. Brick

GEORGE T. ESTRY, Member

HUGH WALKUP, Alternate for Jon R. Furst

FREDRICK MULLEN, Member

CAROLYN LINGEMAN, Member

CHARLES A. THOMPSON, Member

RICHARD A. HODDER, Member

DONALD BARNES, Member

MR. SEDGWICK, Substitute for Noel C. Woosley

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1 P R O C E E D I N G S

2 CHAIRMAN SHEPARD: I would like to call the
3 meeting to order and welcome you to the 18th quarterly
4 meeting of the VA's Advisory Committee on Health-
5 Related Effects of Herbicides. It is hard to believe that
6 we have gone through 18 of these meetings now over the last
7 several years. I think it is, if nothing else, a tribute to
8 the fortitude of those of you who have been with the program,
9 both directly and indirectly.

10 I think it is safe to say we have managed to keep
11 our heads reasonably well above water, I think over the
12 previous months and years. It is always a pleasure for
13 me to chair these meetings, because I do think they do
14 provide an opportunity for the VA, as an agency, to get
15 input from a number of different sources, and also it is
16 probably the only meeting of its type in the Federal Govern-
17 ment in which we share information in a public forum.

18 So, once again, I welcome you all to this meeting.

19 A few housekeeping notes: This will be the third
20 meeting in which we have had meetings of two subcommittees.
21 Unlike the last two meetings, the Subcommittee on Bio-
22 statistics and Epidemiology will remain in this room, and
23 the Subcommittee on Information and Education will move
24 to Room 139, which is on this floor on the other side of
25 the lobby. So please take note of that at the

1 appropriate time, when we break up for our subcommittee
2 meetings.
3 As has been true in the past, this is an open
4 meeting. We would hope that all of you would register as
5 you come in. If you haven't done so, please do so, so we
6 can keep track and make note of your presence here. It is
7 very important to us.
8 We are very pleased this morning to have with
9 us Dr. John Gronvall, who is our newly appointed Deputy
10 Chief Medical Director. Dr. Gronvall comes to the VA after
11 a distinguished career in academic medicine and in the
12 field of pathology. Dr. Gronvall is a board-certified
13 pathologist,
14 and, most recently, was the
15 Dean of the Medical School at the University of Michigan at
16 Ann Arbor.
17 Dr. Gronvall first came to the VA as the Deputy Assistant
18 Chief Medical Director for Academic Affairs, and then on
19 September 18th of this year, was appointed to the position
20 of Deputy Chief Medical Director to assume the position
21 vacated by Dr. Jacoby, who has retired from the VA.
22 We are very pleased to have Dr. Gronvall with us
23 to address the committee and the audience.
24 Dr. Gronvall.
25

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REMARKS BY THE DEPUTY CHIEF MEDICAL DIRECTOR

DR. GRONVALL: Barclay, I thank you very much for the kind introduction. I appreciate very much the work of this committee. I should tell you that I view my function here as making several minutes of opening comments so that the audience and the committee can kind of quiet down and forget about the things that were going on a few minutes ago, and then really get down to work.

I primarily want to welcome both the committee and the audience to these deliberations in addition to thanking the committee. When I moved into the Deputy Chief Medical Director's office, I very quickly discovered that the concerns about the effects of dioxin on humans had a quite preemptory character unlike much of the other work that goes on in the Deputy's office.

So within a few days, it seems to me, I became completely immersed in Agent Orange, symbolically at least, if not actually. When Barclay just introduced me as the newly appointed Deputy Chief Medical Director, I was thinking back about all of the energy and effort that has gone into the Agent Orange issue in the past couple of months, and it felt like it has been a very long time that I have been dealing with Agent Orange. I have been very impressed by the work

of this committee and the research community, not only in the United States, but throughout the world, in regard to the number of studies now underway dealing with the effect of herbicides on human health.

I have been impressed with Barclay and his staff and the people that I have dealt with here, who I am very convinced are honestly seeking the best possible scientific information on this question, whatever that may be.

I know that from the outside many have been concerned that we had a predetermined outcome that we were working toward, and I think that is always a concern when you are dealing with a large governmental or bureaucratic organization.

Again, I would repeat, though, it has been very pleasing to me to gain the sense from inside the workings of the VA that to the best of my knowledge, there is no predetermined conclusion that we hope will come out of these scientific investigations.

Whatever the data are, we hope that once they are tested and accepted by the scientific community, those can then provide a sound basis for political and other social judgments about what to do about the problem. And our role certainly, and your role in working with us is to look for that underpinning of valid scientific information and judgment that has been developed to the point of consensus in the

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scientific community.

It is extremely critical, I think, for us to have advisory groups like this one who can bring a broadened perspective to us, review what we are doing, test what we are doing, and be certain that we are making progress toward that goal.

I have also been impressed with the Agent Orange Working Group. It has had now a change in chairmanship. Dr. Edward Brandt, who is the Assistant Secretary for Health in the Department of Health and Human Services, has just been appointed to chair the committee.

Ed Brandt is a very respected, distinguished, and effective health administrator on the federal scene. I think he is interested in, and committed to, the programs on Agent Orange, and will be a good chairman of that key committee.

The committee meets on the 15th of December. That will be the first meeting since Dr. Brandt assumed the chairmanship. So I think that we are going to have a strong coordinating point in the Federal Government to bring together, not only the VA, but all of the federal agencies that are working on herbicides, Agent Orange, and dioxin exposure.

In passing, I want to say a public word of thanks to Dr. Al Young, who has been part of Barclay's office, on detail here from the Air Force. I expect probably most

people in the audience know or have heard that Al is moving to the White House on the 1st of January. He will be in the Office of Science and Technology Policy, George Keyworth's office, the science adviser to the President.

This is a real loss to the VA because we will miss his participation here in Agent Orange issues, but we hope to capitalize on his move in the sense of having a knowledgeable and informed person on the Agent Orange question now being part of the White House staff. Hopefully, that added focus at the presidential level will hasten the progress that the country is making in coming to scientific conclusions about the effect of dioxin on humans.

Once again, welcome. It is a pleasure to have you here, and in spite of the preemptory character of some of the Agent Orange questions that we have been dealing with, it has been a pleasure for me to get deeply immersed in these questions, working with Barclay and his staff, the advisory groups dealing with veteran service organizations, the rest of the scientific community, and the Agent Orange Working Group.

I think we now see our way clear to a series of studies that will produce the information needed, so that the country can have a sound scientific basis on which

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1 to make political and social judgments.

2 So, again, I wish you well in this meeting, and

3 thank you.

4 CHAIRMAN SHEPARD: We appreciate your coming.

5 Just a couple of other notes. We have had some

6 change in the makeup of the committee, membership of the

7 committee.

8 George Estry, who is an appeals consultant

9 at the VFW and an alternate member of the committee since

10 March of 1983, has now been appointed as a full-fledged

11 member of the committee, and we welcome him to the committee

12 as a full-fledged member.

13 Dr. Adrian Gross, who served faithfully for many

14 years, representing the Environmental Protection Agency, has

15 resigned and his position has been filled by Dr. Donald

16 Barnes, who is a senior science adviser in EPA's Office of

17 the Assistant Administrator for Pesticides and Toxic Sub-

18 stances.

19 Don Barnes has had a long-standing relationship

20 to the whole Agent Orange issue in that, among other things,

21 he has been EPA's representative on the Agent Orange Working

22 Group, and has been working very closely with us on a number

23 of projects. We certainly welcome him to the committee.

24 I am sorry that he is not here yet. I suspect

25 that the weather may have delayed some members. I know there

1 are some in-town members who I expect will be along shortly.

2 Unfortunately, we got a call this morning from

3 Dr. David Erickson that the weather in Atlanta has

4 been very severe -- tornadoes, very heavy thunderstorms.

5 Apparently flights have been cancelled. So he will not be

6 with us today, which is a loss because we were hoping to get

7 an update on the status of the birth defect study, as well

8 as the progress of the plans for the large epidemiological

9 study of which he will be the principal investigator.

10 He expressed his apologies to the committee. He

11 will, however, be here for the Agent Orange Working Group

12 on the 15th, so we will be able to avail ourselves of his

13 counsel at that time.

14 Dr. Joseph Mulinare, who is now the principal

15 investigator for the birth defects study, has also had

16 apparently a health problem in the family, and I do not

17 think he will be with us this morning. We have not heard

18 for certain, but information suggests that he will have to

19 return quickly to Atlanta.

20 I think we will go on with our agenda and ask

21 Dr. Carl Schulz to talk a little bit about the status of the

22 literature review/literature analysis update. Carl Schulz

23 has been the program manager for the contract with Clement

24 Associates, and we have been working very closely with him,

25 and we are pleased to have Carl with us this morning.

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1 DR. SCHULZ: Thank you.

2 Clement Associates was awarded a contract by the VA
3 last April to update the literature review on the health
4 effects of phenoxy herbicides and their impurities. A
5 previous literature review, annotated bibliography, and
6 analysis of the literature was performed by JRB Associates,
7 and published by the VA in October of 1981.

8 Our job was to review the literature published
9 since that time, and create an updated, annotated bibliography
10 and a critical analysis.

11 We have completed the literature search and acquisi-
12 tion, and a draft of the critical analysis, and delivered
13 that to Dr.Shepard here at VA for VA review.

14 We hope to have their comments back by the end
15 of this month. We hope that we can incorporate any neces-
16 sary changes that might be required as a result of their
17 comments in January, and hope that we have a camera-ready
18 copy late in January sometime.

19 What I would like to do in the brief time I have
20 this morning is to highlight what the review has accomplished
21 and what we have found. I have prepared a handout, which
22 the members at the table have. There are 25 extra copies
23 back there, which are not enough to go around one to one,
24 but if you can figure an equitable way of distributing them,
25 members of the audience are welcome to have copies.

The scope of the review is such that we surveyed all literature available since the time of the JRB report, which was roughly mid-1981. We limited the review to phenoxy herbicide active ingredients and commercial formulations. That is 2,4-D, 2,4,5-T, and in some cases, MCPA, the impurities, mostly polychlorinated dibenzo-dioxins, and two other herbicide active ingredients,cacodylic acid and picloram.

We limited the review to health effects, and in this sense, it is a little more limited than the JRB review, because we did not discuss environmental distribution, analytical chemistry, and some of those topics.

We tried to obtain all information,published and unpublished, that is available to the public. We made as good an effort as we could to identify material that was unpublished, not yet published, and published in some rather unconventional resources.

I think we did a pretty good job of that. One of the problems in this area is it is such an active field of current research that there are many studies now, that we know of, that are complete, but we were unable to obtain the results of those studies because they have not been published, or they are being kept confidential for one reason or another.

So one of the legacies that we have is that our

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1 report will be outdated the day it is published.

2 The next page of the handout tells the number of

3 documents we found. We identified 452 total documents as

4 relevant to this issue. We were unable to locate copies of

5 three of these. I hope that by the end of January we will be

6 able to. Thirty-one of these documents were related to the

7 minor herbicides: cacodylic acid and picloram; leaving us

8 418 documents dealing with phenoxy herbicides and/or their

9 impurities.

10 This, to me, is remarkable that in a two-year

11 period, 418 documents have become available, showing the interest

12 in this field. 161 of these documents are what I call

13 secondary resources. No original primary research data are

14 included in them. They are reviews, news reports, comments,

15 and risk assessments, and so forth; leaving us 257 primary

16 literature resources.

17 Eighty-four of these 257 are studies of exposed

18 human populations, and 173 are studies in experimental

19 animals.

20 The next page breaks down the human studies, the

21 84 human studies. Of the 84 total documents representing

22 studies of human populations, 43 are studies of populations

23 of people who were exposed to phenoxy herbicides or dioxins --

24 as I will use the shorthand here, dioxins -- through occu-

25 pational exposure. Sixteen more studies are studies of the

1 Seveso population exposed to -- presumably exposed to dioxins
2 as a result of a reactor explosion in 1976.
3 In those two categories, there is an awful lot of
4 duplication. The same data are published in two or more
5 different documents, so it looks like there is more literature,
6 more information on these populations than there really is.
7 Twelve of the documents were other environmental
8 exposures where people were exposed through the use --
9 presumably exposed through the use of phenoxy herbicides in
10 the areas where they live.
11 Seven of the studies are Vietnam veteran studies,
12 many of these dealing with the Agent Orange registry. Six
13 are isolated case reports of a miscellaneous nature. About
14 a third of the occupational studies are involved with
15 absorption, distribution, and metabolism of phenoxy herbi-
16 cides and their impurities, and contain no direct health
17 effects data.
18 The experimental animal studies are broken down
19 on the next page. Of the 173 studies, only 4 of these
20 primarily involved determining cancer as an end point.
21 Twenty-four deal with reproductive toxicity
22 including teratogenesis, 26 with genotoxicity, 13 with
23 neurotoxicity, 10 with immunotoxicity, 21 with absorption,
24 metabolism, distribution and excretion, 19 with enzyme
25 induction, and 56 deal with other toxic effects, mostly

1 mechanism of action and miscellaneous topics.

2 I would like to point out here that of these animal

3 studies, I would estimate that at least three-quarters deal

4 with the toxicity of polychlorinated dibenzo-furans, mostly

5 TCDD, 2,3,7,8-tetrachlorodibenzo-dioxin, and very few deal

6 with 2,4,5-T, 2,4-D, or commercial formulations thereof.

7 I would just briefly like to mention some of the

8 limitations of the literature we looked at. Despite the

9 large volume of literature, my opinion is that this body of

10 literature is not of very good quality relative to bodies

11 of literature about other toxic substances.

12 Many of the human studies are very limited in what

13 you can do to interpret them, and in almost every case, the

14 exposure, what the people were exposed to that are studied,

15 is uncharacterized. This is very clear in some cases when you

16 get to situations where people sprayed undefined herbicides

17 and the active ingredients and impurities are unknown.

18 There is a lack of adequate control groups in

19 most cases. In the epidemiology studies, the study popula-

20 tions are compared to national populations, and so forth,

21 and the use or exposure to herbicides and impurities in the

22 control group is not determined and characterized.

23 Finally, in terms of the studies dealing with

24 cancer as an end point, epidemiologic studies, just as a

25 matter of the way things are, there hasn't been sufficient

1 time elapsed between exposure and time of the studies to
2 allow for sufficient latent period for most cancers to
3 develop. This is a more severe limitation on the negative
4 studies than on those that suggest positive outcomes.
5 The animal studies are likewise limited. Again,
6 the test substance in most of these studies is not adequately
7 characterized. If they test 2,4,5-T or 2,4-D in most cases, the
8 amount and distribution of dioxin impurities is not given.
9 Commercial formulations of known composition have
10 not been tested. The relative toxicity of the various
11 polychlorinated dibenzo-dioxin isomers have not been well
12 studies. In many of the animal studies, the routes of
13 exposure, intraperitoneal injection, or oral exposure are
14 not relevant to the routes that we are interested in from the
15 human exposure studies.
16 That completes my summarization.
17 CHAIRMAN SHEPARD: Thank you very much, Carl.
18 That was a very nice detailing of your efforts. We have
19 just received the draft document that Carl referred to, and
20 we will be reviewing it, and hope to get it into publishable
21 shape as quickly as possible.
22 I just want to hasten to assure everybody that our
23 role, VA's role, in reviewing this will not be in any way to
24 influence the excellent work that Carl has done in terms of
25 the scientific merit of the literature, or in any way the

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1 conclusions that have been drawn as a result of his group's
2 scientific review. It will simply be to review the work
3 from the point of view of whether or not it complies with
4 the terms of the contract
5 If we become aware or if we are aware of any citations
6 that were not included, that we think should have been
7 included, then we will have the opportunity to include them.
8 But I doubt that is the case, because Carl has
9 been working very closely with us, and it is not as though
10 he went off and did this in a vacuum. He has been touching
11 down with us frequently to assure the completeness. Since
12 Al Young, among others, has had a very complete library, has
13 been following the whole issue, probably as closely as any-
14 body in the world, it seemed appropriate that Al Young and
15 Carl work closely together to make sure that no omissions
16 were made.
17 You will all remember the embarrassment of the
18 VA when we were not as aware of
19 the Swedish studies as we should have been when they were
20 published. We certainly don't want to go through that
21 experience again.
22 The other point I would like to make is that in
23 regard to some of the limitations that Carl has so appro-
24 priately pointed out, I think he makes a strong point for
25 the fact that a lot more research is still needed in some of

1 the basic science areas. There is still an awful lot about
2 the toxicology of TCDD that we know nothing about, and that
3 remains a mystery.
4 I was at the Rockefeller University symposium
5 held the early part of last month -- excuse me -- the early
6 part of October, and there were some very reputable scientists
7 from all over the country in attendance there. They
8 share the concern about the baffling mystery of the toxicology,
9 why it behaves so very differently in different animal
10 species. It is almost a unique substance.
11 Are there any questions from members of the com-
12 mittee for Carl? Yes, Dr. Lingeman?
13 DR. LINGEMAN: Did you attempt to evaluate each
14 one of these reports separately? You made some statements
15 that overall quality of many of them was poor, but
16 will your report include your evaluation of the
17 individual report?
18 DR. SCHULZ: Yes. We have critically evaluated
19 every individual primary literature source. We might have
20 missed one or two, but we critically evaluated each one, and
21 the report is actually over 400 pages long. So it evaluates
22 the studies individually, and then tries to integrate all
23 the available information, including the pre-'81 information
24 as much as possible to arrive at our best estimates of the
25 state of knowledge in these areas at the present time.

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1 DR. LINGEMAN: Having not read the contract, I
2 would like to know how many people were involved in this
3 and what are their
4 scientific backgrounds?
5 DR. SCHULZ: A very good question. There were
6 four of us at Clement Associates, who are principal authors.
7 I was the project director. I am a board-certified toxicolo-
8 gist. The other three authors are a Ph.D. toxicologist, a
9 biostatistician, and a Bachelor's level biologist environ-
10 mental scientist.
11 Those four people contributed all the written
12 draft material. In addition to that, we had senior level
13 advisory review. The three reviewers were Dr. Kenneth
14 Chase, who is an M.D. occupational physician, Dr. Marvin
15 Schneiderman, who is a biostatistician epidemiologist, and
16 Ian Nisbet , who is a toxicologist,environmental scientist.
17 So, basically, those were the people involved in
18 the production of this document.
19 CHAIRMAN SHEPARD: Any other questions of Dr.
20 Schulz? Yes, Hugh?
21 MR. WALKUP: Dr. Schulz, has your review included
22 articles from Vietnam and eastern European countries?
23 DR. SCHULZ: As much as possible. We have included
24 several studies of occupationally exposed populations in
25 the eastern European countries, Czechoslovakia, and so

forth. In the Vietnam area, the major information was information that was provided at a symposium in Ho Chi Minh City, I believe early this year, January of this year.

Unfortunately, none of that information is published in a conventional scientific report form, but several different people who attended that conference summarized the data that were presented there, and we have reviewed that and included that information in our overall evaluation of the literature.

MR. WALKUP: At one point in your discussion you talked about some unincluded studies which were not reviewed because they were confidential for one reason or another. What were the reasons for those alleged confidentials?

DR. SCHULZ: The one big area is not data on the major herbicides, but much of the health effects data on Picloram is the company trade secret of Dow Chemical Company and in the files at the U.S. EPA, involved in the registration proceedings going on there, and we could only have access to summaries of that data, not the original studies.

There were other instances where we knew about studies that were going on and were completed, and we wrote to the authors and asked for preprints because they have not yet shown up in the literature.

In some of these cases we did get preprints, but in other cases they chose not to, which is their prerogative.

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1 MR. WALKUP: So they were only in the cases of
2 Picloram and professional confidentiality?
3 DR. SCHULZ: Right.
4 CHAIRMAN SHEPARD: Yes, Dr. FitzGerald?
5 DR. FITZGERALD: Doctor, you have indicated some
6 of the studies that are not appropriate in your estimation.
7 Will your report show any that you will advocate as being
8 outstanding or worthy of particular note of this committee?
9 DR. SCHULZ: Yes, I think that we have tried to
10 point out that the report is not negative in balance, that
11 we have indicated which are the more reliable and good
12 studies, but that I think depends on how the reader reads it,
13 because the report is generally critical from a scientific
14 -- it is scientifically critical.
15 CHAIRMAN SHEPARD: Are there any other questions of
16 Dr. Schulz?
17 I might just add that we are very privileged to
18 have Dr. Levinson with us today, who is on the agenda for
19 later on in the program. Dr. Levinson, I believe --
20 correct me if I am wrong -- attended the Ho Chi Minh City
21 symposium and has had many trips to Vietnam, so I think it
22 will be very interesting to hear his comments about that
23 symposium and other issues related to that whole effort.
24 We will be very much looking forward to Dr.
25 Levinson's remarks later on in the program.

1 Thank you very much, Carl. I am now in the process
2 of considering how we want to conduct this review. I cer-
3 tainly would want to involve some of the members of this
4 committee in that review process. As soon as we get some of
5 the material duplicated, we will share it with members of the
6 committee so they can look at it.
7 Thank you.
8 Next, I would like to call on Mr. John Sommer of
9 the American Legion to give us an update on the status of
10 the Stellman research effort. I use that term perhaps for
11 the lack of a better one. If there is an official title for
12 that, John, would you share that with us, please.

AMERICAN LEGION/STELLMAN RESEARCH EFFORT

13 MR. SOMMER: Thank you, Dr. Shepard.
14 My name is John Sommer. I am Deputy Director of
15 the National Veterans Affairs and Rehabilitation Commission
16 of the American Legion, and I have been asked to briefly
17 comment on the Columbia University and American Legion Study
18 of Vietnam Era Veterans. This will be very brief for two
19 reasons.
20 Number one, we have a pretest currently underway,
21 and we are aware that there are going to be some changes
22 made before the full test begins; and, secondly, because the
23 protocol and the questionnaire that we are using will be
24 considered this Friday by the Scientific / Advisory Board for the study. Therefore,
25 until they have considered and approved both of these

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instruments, I am not at liberty to discuss them.

The study is based upon a model that has successfully been used by the American Cancer Society in their Cancer Prevention Study II. It consists of looking at 15 ,000 members of the American Legion that served during the Vietnam era ; 7,500 that served in Vietnam, and 7,500 that served during the era but elsewhere during that period.

As I mentioned, there is a pretest currently underway in South Dakota. We have thus far experienced a very good participation rate. The study will be comparing the overall health of the group of individuals that served in Vietnam with the group that served elsewhere, and the health of their children . We will also be looking at specific issues, such as post-traumatic stress disorder, and some of the questions surrounding Agent Orange.

A very interesting part of the study will be to get the perception of the entire group of the benefits and services provided by the Veterans Administration, both through the Department of Veterans Benefits and the Department of Medicine and Surgery.

The full study will convene in February, and we expect to have a final report available the end of October or the beginning of Novemer of 1984.

That concludes my comments.

CHAIRMAN SHEPARD: Thank you very much, John.

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1 Are there any questions for Mr. Sommer of the
2 members of the committee?
3 (No response.)
4 CHAIRMAN SHEPARD: Thank you very much, John. I
5 look forward to the study, and hope it progresses well.
6 MR. SOMMER: Thank you very much.
7 CHAIRMAN SHEPARD: Next, I would like to give you
8 a very brief update on the status of the Agent Orange
9 Registry, about which I am sure you have heard a great deal
10 in recent weeks.
11 You may have seen the recent article that appeared
12 in the American Chemical Society's journal, the environmental
13 and science's publication that they put out, an article that
14 was authored by some of us here in the VA. That alluded
15 to some information arising from various studies and some
16 preliminary descriptions of the status of the registry.
AGENT ORANGE REGISTRY REPORT
17 Let me just quickly state that as of September 30,
18 we have conducted 125,649 initial examinations in the
19 Agency Orange Registry process. In the past fiscal year, we
20 have done 28,000 initial examinations and almost 8,000
21 followup examinations.
22 So you can see that the Agent Orange Registry con-
23 tinues. It has slowed down a little bit from its high point
24 of 3,000 examinations a month. We are down to just under
25 2,000 a month, that is, across the country. But, still, that

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1 is a significant number, and we are still encouraging
2 veterans to participate in that program.
3 Just to remind you, we did do a major revision to
4 the data input process in that we revised the code sheet
5 to make it much more specific in terms of medical information
6 derived from the physical examinations, the laboratory tests,
7 and so forth. So we have in effect since May of this year,
8 hopefully more precise data which will enable us to more
9 quickly get more precise information retrieved.
10 Again, I want to point out that this is not an
11 epidemiological study. It is simply a review, a health
12 screening process for any veterans who desire to avail
13 themselves of this service.

STATUS OF CDC EPIDEMIOLOGY STUDY

14 As I mentioned earlier, Dr. David Erickson, who
15 was going to be with us today to talk about two things, talk
16 about the CDC study and then focus a little bit on the plans
17 for doing a study of female Vietnam veterans, unfortunately
18 is not going to be with us today because of weather conditions
19 in Atlanta.
20 He did ask me, however, to state that the plans for
21 the study are progressing well. The protocol has been
22 submitted for review by a number of groups, including the
23 Agent Orange Working Group Science Panel. The review
24 comments have been collected and submitted back to the
25 investigators. So that process is moving along well. Mr.

1 Richard Christian, who heads up the Army Agent Orange Task
2 Force, is charged with the responsibility of identifying
3 cohorts for that study, and that process has begun.
4 It is my understanding that because of the relative
5 ease of selecting cohorts for the Vietnam experience study as
6 opposed to the Agent Orange study, which is a more complicated,
7 complex process, probably will result in the Vietnam expe-
8 rience study getting underway sooner than the Agent Orange
9 study, but I am not certain of that. I just mention that as
10 a possibility. And in the event that you should hear any-
11 thing to that effect, I want to very quickly emphasize that
12 it is not because of any lack of interest or desire on the
13 part of CDC to get on with the Agent Orange study.
14 It is simply that the identification of the cohorts
15 for the Vietnam experience study will be somewhat less
16 complex and therefore probably more quickly accomplished,
17 and that portion of the study may in fact precede the
18 initiation of the other study.
19 I suspect, however, that the two studies will be run
20 pretty much in parallel.
21 Because of the intense interest
22 in the whole issue of female Vietnam veterans, CDC has proposed
23 a study to address those concerns. I want to assure you that
24 that interest is shared by the VA, and to that point, I
25 would like to introduce to you Colonel Rossi, Colonel

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1 Lorraine Rossi, who is Chairperson of the Veterans
2 Administration Advisory Committee on Women Veterans. I hope
3 I have given the right name of the committee. We are most pleased to have Colonel
4 Rossi with us this morning.
5 Good morning.
WOMEN VETERANS
6 COLONEL ROSSI: Good morning. Thank you very much,
7 Dr. Shepard. I am sorry that Dr. Erickson couldn't join us
8 this morning. I was introduced as the Chairperson
9 of the VA Advisory Committee on Women Veterans. That is a
10 newly-formed committee appointed this summer by the VA
11 Administrator, recently approved as a Congressional Committee.
12 Our first meeting was held in September. Eighteen
13 members of that committee, 16 women, 2 men. Three of the
14 members of the committee are Army nurses, former Army nurses
15 who served in Vietnam. I am also a Vietnam veteran. So we have
16 four women on the committee who are Vietnam veterans.
17
18 At our first meeting, Dr. Shepard and Colonel
19 Young gave us excellent briefings on Agent Orange and
20 studies in effect. The women on the committee expressed
21 concern at that time that there seemed to have been
22 very little consideration of the women who served in
23 Vietnam, and the concern on the part of the committee that
24 because of the small numbers, as so very often happens,
25 women were excluded from the studies.

1 Not intentional on the part of anyone to exclude
2 the women, but because it was
3 estimated that only 2 percent of the population of veterans
4 were women, then that almost automatically excluded them from
5 any sample that was taken.
6 So special efforts have to be made. The VA has
7 recognized that, fortunately. CDC has recognized that now.
8 We need to continue emphasizing that it must take special
9 effort and special consideration to include women in the
10 studies, and of course, one of our main concerns would be
11 for the younger women who served in Vietnam
12 for any affects on their reproductive system.
13 So, again, I thank you today for allowing me to
14 speak, even in Dr. Erickson's absence, to let this committee
15 know about our committee. We have a
16 broad view of women veterans and some of the problems and
17 some of the issues facing the VA; one of the issues
18 that we have identified is the issue of women being included
19 in Agent Orange studies.
20 Thank you very much.
21 CHAIRMAN SHEPARD. Thank you very much. Are there
22 any questions of Colonel Rossi? Yes, Dr. Lingeman?
23 DR. LINGEMAN: I would like to know how many women
24 veterans served in Vietnam, and
25 what proportion were nurses as opposed to other occupations.

1 COLONEL ROSSI:

2 We have no exact answer to that question,

3 The closest

4 estimate is about 7,000.

5 The

6 majority would be nurses, most of them Army nurses

7 who served in many areas throughout the country.

8 Some, a smaller portion were enlisted women, mostly

9 Army enlisted women, but you also had some Marines and

10 Air Force.

11 DR. LINGEMAN: What age groups? Are most of these

12 nurses young women?

13 COLONEL ROSSI: Most of them were young women,

14 lieutenants and captains, and I would say under

15 35 years of age.

16

17

18 Some of the supervisory personnel in the senior grades

19 would be older.

20 MR. WALKUP: Is there any way for our committee

21 to open formal diplomatic relations with your committee, so

22 we know what you are doing, and to find out what is going on?

23 COLONEL ROSSI: We can work that out very easily.

24 CHAIRMAN SHEPARD: Yes, that was one of the reasons

25 that we invited Colonel Rossi and other members of the

1 committee to be here. We would like very much to do that,
2 and as Colonel Rossi indicated, Al Young and I briefed their
3 committee on our efforts and the whole area of Agent Orange,
4 so I think there is a good dialogue already started.
5 For those of you who may not be aware, Dick
6 Christian, whose name I mentioned earlier, who heads up the
7 Army Agent Orange Task Force, is also building a registry of
8 female veterans. That may not be entirely accurate. He is
9 trying to identify as many female Vietnam veterans as
10 possible from a variety of sources in order to have a group
11 of women for the purposes of the CDC study, and, I think, to
12 get a better handle on the evaluation of the character of
13 that universe, because there is relatively little that we
14 know, as Colonel Rossi has indicated, about the numbers.
15 Although we have a good sense that most of them
16 were Army nurses, we are not sure of some of the finer
17 details of the makeup of that group. So we very much look
18 forward to Dick Christian's efforts in this regard, so we
19 can get more definitive information.
20 Yes. Peter Kahn?
21 DR. KAHN: Colonel Rossi, the Red Cross and the
22 churches, and a number of other private agencies had
23 substantial numbers of women out doing health work and
24 refuge relief, literacy work, and what have you, all through
25 Vietnam. Many of them were there for more than a year. I am

1 sure it wouldn't be too difficult to track a lot of them
2 down through their private agencies.
3 COLONEL ROSSI: Thank you.
4 DR. KAHN: That would add to your numbers.
5 CHAIRMAN SHEPARD: Dr. FitzGerald?
6
7
8
9 DR. FITZGERALD: Are you identifying, at this
10 point, conditions unique to women? Are you at the point
11 where you can share that with us?
12 COLONEL ROSSI: Are you talking about in this
13 particular area?
14 DR. FITZGERALD: Yes.
15 COLONEL ROSSI: No. Our committee is an advisory
16 committee, where we can come to the Veterans Administration
17 or to, say, this committee, and ask that you include women
18 in your studies. We have not identified any specific areas
19 of concern other than that we know that there are some women
20 who have appeared and asked for physicals, because they are
21 concerned about the effects of having served in Vietnam and
22 the possible effects of that.
23 Does that answer your question?
24 DR. FITZGERALD: What I would be interested in
25 would be that indeed when the time is appropriate, that you

1 would draw to our attention any unique conditions that you
2 feel have been overlooked, so that we can follow through on
3 it.
4 COLONEL ROSSI: Fine, yes, we will do that.
5 MR. WALKUP: I think another aspect of that, Col.
6 Rossi, too, is that we have recently broken into two sub-
7 committees, as you heard, and one is looking into science,
8 which is often what you hear about our group, but we are
9 also trying to take a look at -- it is called education and
10 information -- but the services that people receive around
11 the issues of Agent Orange and related --
12 COLONEL ROSSI: Related.
13 MR. WALKUP: I would imagine that is something that
14 your committee is looking into and something that I think is
15 important for us to coordinate, or to let each other know
16 what sets of problems or --
17
18 -- or virtues you are coming up with.
19 COLONEL ROSSI: Yes, and one thing that we have
20 recommended, that there be an outreach to the women veterans
21 to let them know that there is concern and that someone is
22 looking out for them.
23 Thank you.
CDC BIRTH DEFECTS STUDY
24 CHAIRMAN SHEPARD: Thank you very much, Colonel
25 Rossi. We appreciate your being here. I would also like to

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1 announce that Dr. Mulinare, who will not be with us today,
2 was to have reported at the Science Subcommittee on the status
3 of the birth defects' study being conducted in Atlanta.
4 Let me briefly summarize the status of that study
5 since he will not be here to give you this information. Dr.
6 Erickson shared this information with me on the telephone
7 this morning, so it is fresh. All the data has been col-
8 lected. The interviews have been completed.
9 We are happy to report that CDC was able
10 to contact at least one member of the parent pair in 70 per-
11 cent of the cases which they were hoping to reach. That is
12 considered to be a very good average of a study of this
13 type.
14 So they are pleased that they got that level of
15 participation. As probably predictable, there is a higher
16 rate of locating and questioning the mothers than the
17 fathers. There are a variety of reasons for this, some of
18 which are obvious.
19 The father of the child may not currently be the
20 husband of the mother. That poses a problem. Some fathers
21 chose not to participate. Probably the most prevalent reason
22 for that disparity is that the mothers were the ones who were
23 registered at the time of the birth of the child with the
24 defect and also of the controls.
25 In the normal course of registering children, making

1 out birth certificates and hospital records, there is much
2 less information gathered on the father, for some reason,
3 than there is on the mother. So, in most instances,
4 the information available on the mother was recorded in the
5 hospital records, less information was available on the
6 father.
7 For example, Social Security numbers apparently are
8 not routinely recorded on the father in the hospital records,
9 and the mother does not always have a Social Security
10 number. We have gotten a lot of cooperation -- they have,
11 CDC has been very fortunate in a very high level of coopera-
12 tion through the Internal Revenue Service and the Social
13 Security system in tracking down the location of the parents
14 of the children, both the children with the defects and the
15 controls.
16 So I think that CDC is to be commended for an out-
17 standing job in locating them and conducting these inter-
18 views. The data, as I say, has been collected, and now is
19 in the process of being analyzed. I asked Dave this morning
20 when he hoped that the report would be finalized and avail-
21 able for distribution. He said early in the spring of
22 '84. So that is the target date, and we will be anxiously
23 looking forward to that report when it comes out, because I
24 think it will answer one of the very emotional concerns of
25 Vietnam veterans, that is, the risk of their having children

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1 with birth defects.

2 Any other comments from the committee? If not,

3 we will now break into our separate groups. The

4 Biostatistics/Epidemiology Group will stay here. The

5 Information/Education Committee will move down

6 the hall to Room 139.

7 I will turn over the chairmanship of this group

8 to Dr. Hodder.

9 (Advisory Committee recessed for subcommittee

10 meetings at 9:35 a.m.)

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AFTERNOON SESSION

(2:10 p.m.)

CHAIRMAN SHEPARD: It looks like our two committees finished up at approximately the same time, which attests to the skill of our able executive secretary, Don Rosenblum who puts agendas together very well, I think.

I would like to call now on Fred Mullen to give us a brief summary of the activities of his subcommittee, and then we can open up for discussion.

Fred?

REPORTS OF SUBCOMMITTEES

MR. MULLEN: Thank you very much.

First of all, I would like to discuss the literature review update. We were led to believe that some of the information that was used, some of the articles that were used were fairly accurate, but some of the information had to be, not pried loose from Dow Chemical, but they were cooperative if you can use a word that strong. In other words, there was other information out there, but because of certain skewed rules and regulations, could not be obtained and which may well affect the validity of some of the literature that is going to be used in the literature review update.

We also found that there was concern over the reference to gender in some of the literature, and we wanted future literature to not take into consideration sex

1 in deference to the women veterans. They feel that some of
2 the information is almost all geared toward the male. It is
3 male-oriented, when, in fact, there are women out there who
4 would fall into that same category, especially where they
5 refer in some of the birth defects studies, or genetic
6 defects studies, to fathering versus mothering a child as a
7 specific point.
8 CHAIRMAN SHEPARD: Excuse me, Fred. You are speaking
9 now about the literature analysis?
10 MR. MULLEN: I am going into the women's panel now.
11 CHAIRMAN SHEPARD: But your comments do not have to
12 do with the literature analysis?
13 MR. MULLEN: Not with the literature analysis, but
14 we would like to see that references in that analysis, when
15 it goes to print, include references to women veterans,and
16 not just all male-oriented language.
17 CHAIRMAN SHEPARD: Well, if you are talking about
18 the literature analysis, I think, in fairness to the con-
19 tractor, he can only deal with what is there. He is not
20 inventing literature.
21 MR. MULLEN: No, no. Well, you have a summary in
22 there. Anything that can be changed should be changed to
23 reflect deference to sex. Okay?
24 CHAIRMAN SHEPARD: Okay, if it seems to be slanted,
25 we will be sensitive to that.

1 MR. MULLEN: Well, it seems there was concern that
2 it slanted the opposite way right now.
3 We recommend that a pelvic examination is routine
4 in any Agent Orange examination conducted on a woman veteran,
5 and we would like to see that implemented in a guideline to
6 to go out. I don't think that is part of the routine examina-
7 tion of women veterans at this point.
8 CHAIRMAN SHEPARD: We can ask Dr. Mather when we
9 get to discussions on that point. I have a different
10 impression, but I may be wrong.
11 MR. MULLEN: Also, they said that less than 2 per-
12 cent of the Vietnam veteran population is women, which is
13 roughly 7,000, that served during various periods of time.
14 There is concern that some people think that this 2 percent,
15 a study of this 2 percent is going to skew the results of
16 the examination if they are included, if women are included
17 in the overall study.
18 In specific regard to birth defects, all preliminary
19 data seem to indicate that genetic defects are not transmitted
20 from male Vietnam veterans. If that is the case, then it
21 would seem that if there is an increase in genetic defects,
22 or birth defects in children, et cetera, that the women ought
23 to, in fact, be studied for that specific purpose, because I
24 don't see how you can come out with a valid birth defects
25 study if you only study one of the parents, if that was a

1 Vietnam veteran. From what I understand only the male
2 Vietnam veterans are being studied at this point. Is that
3 correct?
4 CHAIRMAN SHEPARD: If you are asking me, we have
5 to be very specific now what studies you are talking about.
6 MR. MULLEN: I am talking about the studies being
7 done in Atlanta.
8 CHAIRMAN SHEPARD: Okay. The CDC birth defects
9 study is a case control study. It is not a study of
10 veterans, either male or female.
11 We are not studying the veteran himself or
12 herself other than questioning both parents of the children
13 with the defects to see if there is a higher representation
14 of veterans in the group of parents of the children with
15 defects than in the group of parents of children without birth defects.
16 MR. MULLEN: But are they, in fact, using Vietnam
17 veterans for comparison in that study not at all?
18 CHAIRMAN SHEPARD: It is not a cohort study. It is
19 a case control study.
20 MR. MULLEN: But in the Australian studies they
21 did?
22 CHAIRMAN SHEPARD: It is the same, no.
23 MR. MULLEN: It is the same study?
24 CHAIRMAN SHEPARD: The Australian study is a case
25 control study.

1 MR. MULLEN: They are not going to include these
2 7,000 women in any type of birth defect study?
3 CHAIRMAN SHEPARD: I didn't say that. I said that
4 is why it is important to be very specific about what study
5 you are talking about. Now, in a cohort study, in which you
6 are looking for reproductive outcomes in the group of indi-
7 viduals, in this case veterans, who are being questioned,
8 examined, what have you, that will be done presumably.
9 Unfortunately, as I said, Dr. Erickson was not
10 able to come, and he would have pointed out to you that
11 CDC is proposing a separate study of female Vietnam
12 veterans. Most of us think that to simply have some females
13 included in the larger study as a chance occurrence would
14 not be a good way on which to base any conclusions, and if
15 we are going to do study of female veterans, it ought to be
16 a study specifically designed to answer that concern.
17 DR. LINGEMAN: This probably isn't the time to
18 ask the question or make a comment, but it is very possible
19 that during the interviews of the parents of these deformed
20 children, maybe some of them might turn out to be offspring
21 of female Vietnam veterans.
22
23 CHAIRMAN SHEPARD: I specifically asked Dr.
24 Erickson that question, and I said, "Do you know of any
25 female veterans who were the mothers of these children," and

1 he said, "Not to date." They have not analyzed all their
2 data. He said he can't answer that question. They haven't
3 analyzed that particular question. But just his general
4 impression is that there will be few, if any, mothers of
5 either the cases or the controls who were veterans.
6 MR. MULLEN: Are they planning a separate study
7 for female Vietnam veterans?
8 CHAIRMAN SHEPARD: Yes, precisely. That is in the
9 early planning phases. The protocol has not been written
10 yet, but CDC is proposing that, and Dr. Erickson will be up
11 next week to discuss that.
12 MR. MULLEN: What attempts are being made to
13 recapture -- this is another point -- to recapture the
14 registry data that were lost?
15 CHAIRMAN SHEPARD: I am not aware that registry
16 data were lost.
17 MR. MULLEN: Okay, or was not properly classified.
18 CHAIRMAN SHEPARD: Well, if you are asking me the
19 question, "not properly classified," if you are talking about
20 the first 85,000 --
21 MR. MULLEN: Yes.
22 CHAIRMAN SHEPARD: I would not necessarily agree
23 that it was not properly classified; it was not collected in
24 such a way that we can make very easy use of it. It was not
25 done for that purpose.

1 MR. MULLEN: If you can't make use of it, it is
2 lost, then, isn't it?
3 CHAIRMAN SHEPARD: No, the data are all there. It
4 is just not computerized in the most readily available
5 methodology in terms of retrieving specific medical informa-
6 tion. For example, we can't say the following diagnoses
7 appeared in the first 85,000.
8 MR. MULLEN: Are you attempting to --
9 CHAIRMAN SHEPARD: We are looking at ways in which
10 we can do that. Some of our environmental physicians have
11 expressed an interest in going back, and on a sampling basis,
12 to go back into the first 85,000, and try to retrieve the
13 information and recode it, as is now being done with a new
14 code sheet.
15 MR. MULLEN: Can we recommend that as you identify
16 those veterans, that you send out a letter and ask them to
17 come in for another examination, because the data base and
18 the examination technique has changed to some degree since
19 that time, and not only for the purpose of affording the
20 veteran another examination, but it would seem that it would
21 be a way of qualifying and updating that information that
22 was in the first 85,000?
23 CHAIRMAN SHEPARD: Okay. We will certainly take
24 that under consideration. I think that is a good recommenda-
25 tion.

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1 MR. MULLEN: Boy, what a lousy film, Barclay.

2 VOICE: I thought it was pretty good.

3 MR. MULLEN: It was pretty bad. As you know, some
4 of the veteran service organizations reviewed it. We were
5 somewhat assured that we would have a chance to review it
6 and have input before the final cut, which as you know did
7 not occur. It was already finished when we were told that.

8 Now the film has been released, and much to the
9 dismay of those people who did review it, and to the further
10 dismay of the people who were my subcommittee today. The
11 general consensus is that the film ought to be just scrapped,
12 for two reasons.

13 First of all, the film is totally condescending
14 toward Vietnam veterans. They are portrayed as fat and
15 bearded and sloppy and out of shape, and some of the
16 reference to them was bordering on the unsavory.

17 Second of all, the Administrator came out very
18 strongly at the beginning that this is a number one priority,
19 and then we have a little tete-a-tete in a coffee klatch
20 sort of situation, which was expressed by Hugh Walkup as
21 taking a totally opposite view of what the Administrator was
22 saying by portraying to those people viewing the film that
23 everything is on the up and up, it's hunky-dory. It does
24 not jibe. Nobody liked the film. It was not informative.
25 It was more of a public relations film than an information

1 or education film. It was the general consensus that it
2 was a piece of garbage.
3 There was also a recommendation that if it's being
4 used right now, that it be pulled back in until such time
5 as you get another film, or another method of educating your
6 people in the field.
7 It was brought up that the Subcommittee on Informa-
8 tion and Education was being used more as a public relations
9 tool than an information and education panel by the VA. I
10 think based on a review of that film the second time around,
11 I am totally inclined to agree with that.
12 I think the goals of the administration towards
13 information and education should be much more clearly
14 defined, and less glossy than what was portrayed in that
15 film.
16 A question. How many environmental physicians
17 are left out of the original environmental physicians
18 who were assigned in '79 or '80, approximately?
19 CHAIRMAN SHEPARD: If you are asking me, I can't
20 answer that right off the top of my head. I would say there
21 is probably an annual turnover rate of about 15 to 20 percent,
22 maybe a little higher, but that is pure guesswork on my part.
23 Is there some reason for --
24 MR. MULLEN: Well, it was a question that was
25 asked, and its importance perhaps could be expounded upon by

1 Mr. Walkup if he'd wish.

2 MR. WALKUP: I think it was raised from the

3 audience at the last meeting,which I did not attend

4 Apparently this question was raised, and so it was being

5 reraised to find out if that number had been found. But

6 behind that was the issue of -- I wasn't here, so I cannot

7 attest to it --

8 CHAIRMAN SHEPARD: I don't remember it having

9 been brought up.

10 MR. WALKUP: But that would be a useful number

11 because of the planning around the re-education or training

12 of the environmental physicians. With a 20 percent turnover,

13 it has been three years, that means that over half of them

14 have not received at least the same thing, and the other

15 half have received something that is three years out of

16 date even though they have been updated.

17 There was some concern about the delivery of train-

18 ing and uniformity of environmental physicians.

19 CHAIRMAN SHEPARD: May I just say a word about

20 that? We are continually updating our information. We have

21 a variety of ways of keeping our environmental physicians

22 informed, which is an ongoing process. It is true that it

23 has been a while since we have had a national educational

24 conference. It may have been brought up -- it was on

25 the agenda at your information meeting -- that we are working

1 toward having another national educational conference. That
2 would depend on the availability of funds,as to whether we
3 can do that or not. But in the meantime, we have, on a very
4 frequent basis, both by conference calls and by mailouts, have
5 been keeping our environmental physicians informed. So I
6 think it is accurate to say there is an on-going dialogue. So
7 I don't think that the environmental physicians would
8 necessarily be out of date because they hadn't attended an
9 educational conference per se.
10 MR. MULLEN: Along that same line, I think we
11 recommended at the last meeting that the VA put together a
12 team specifically designed to police the Agent Orange
13 examination of activities at each VA medical center to insure
14 uniformity and quality in those examinations.
15 Was that, in fact, forwarded to someone who could
16 possibly respond to that in a responsible manner?
17 CHAIRMAN SHEPARD: In response to the recommendation,
18 a couple of things have happened. As you may know, there is
19 a office in the Department of Medicine and Surgery
20 which does precisely that in terms of the overall quality
21 control monitoring aspects of that Department of Medicine
22 and Surgery.
23 We have had a couple of good briefings and meetings
24 with that group. We gave them a briefing on the Agent Orange
25 Program, and they gave us a briefing on how they operate. We

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1 are now starting to integrate. Nancy Howard, who is a member
2 of my staff, will be assigned as part of the inspection team
3 that goes out from Central Office from time to time to do
4 this.
5 In that process, she will get a much better feel
6 for how the inspection teams are actually doing the evalua-
7 tion of the Agent Orange Program. That is one way. The
8 other way is that we are re-examining the criteria by which
9 these SERP teams, as they are called, evaluate the local
10 program.
11 A third way is that there is an internal review
12 process, and we are taking a look at trying to standardize
13 how VA hospitals examine themselves in this regard. Yes, we
14 have taken up your recommendation and are acting on it.
15 MR. MULLEN: And the last thing. Apparently some
16 of the committee members in the audience are at odds about
17 the information that was relayed by the administration.
18 This regards our concern over the supposed comments of Dr.
19 Young in the media that was brought up at our last meeting.
20 We asked that the VA either ask for a clarification by the
21 press, or that a retraction be made. What was the final
22 action by the VA on Dr. Young's press release, the ones to
23 the Chemical Society?
24 CHAIRMAN SHEPARD: When you say "press," you mean
25 the reports of the interview or the press conference that

1 they had?

2 MR. MULLEN: The big hullabaloo we had last time

3 around.

4 CHAIRMAN SHEPARD: Right. Okay. A letter, as

5 you probably know, was sent by the Legion to the Administra-

6 tor, and that letter was responded to, and we can make copies

7 of that letter available to you.

8 MR. MULLEN: But from what I understand, the

9 Administrator did support Dr. Young's statement in the press,

10 or was a retraction effected?

11 CHAIRMAN SHEPARD: I don't know what you mean by

12 a retraction, Fred. If you are talking about how it was

13 dealt with in the press, I am not aware of anything that the

14 Administrator did directly with the press.

15 MR. MULLEN: What I am getting at here is I was

16 led to believe that the Administrator supported Dr. Young's

17 actions, and that the press more or less used poetic license

18 in reporting the news. Some of the audience participants

19 at the subcommittee were led to believe that, yes, the VA

20 did in fact ask for a retraction.

21 Now, for a point of clarification, I am just trying

22 to discern which happened.

23 CHAIRMAN SHEPARD: I am not aware -- and I can't

24 answer for all the Administrator does, obviously -- I am not

25 aware of anything that was done by the Administrator to

1 ask for a retraction on the part of the press. It is true
2 that the press did misquote Dr. Young in some respects.
3 The specific example that comes to mind is that in
4 talking about the Agent Orange Registry, that the impression
5 was made that the VA was planning to set up a control group
6 for the registry, and that clearly is not the case.
7 That is the first time I have
8 ever heard such an idea. I don't know where that idea
9 came from. I am sure that it wasn't Dr. Young, because he
10 doesn't have any such notion that we would be setting up a
11 control group. I think that was just a misinterpretation of
12 what went on.
13 I was not personally at the news conference, so I
14 can't say from personal experience, but I know that is one
15 example. A statement was made in the press.
16 It was not attributed to any one person, so I can't
17 even say where it came from. But that was clearly a mis-
18 statement, in the press, of the facts.
19 MR. MULLEN: Just two more items. We had a request
20 that someone from the VA Women's Advisory Group be made a
21 panel participant or a subcommittee participant. Since we
22 did reach that gap in our subcommittee today, we would like
23 to keep that ongoing by having a regular member on our
24 subcommittee from the Women's Advisory Group.
25 CHAIRMAN SHEPARD: We can certainly take that under

1 consideration. I am not sure how many vacancies there are
2 on the committee at the present time. I think we can effect
3 the same thing as we did today, and invite members of that
4 committee to attend our committee, and hopefully vice versa,
5 so that there will be the on-going dialogue, so I think the
6 result can be effected. We will certainly take your recom-
7 mendation -- I gather your recommendation is that we ask or
8 explore the possibility of having a member of the female
9 veterans Advisory Committee actually serve as a member of
10 this committee. Is that your suggestion?
11 MR. MULLEN: Yes.
12 CHAIRMAN SHEPARD: We will certainly look into
13 that.
14 MR. MULLEN: And last but not least, we do opt
15 for the lay language summary of the literature review. We
16 feel that it is necessary.
17 CHAIRMAN SHEPARD: Thank you. Any questions or
18 comments to Mr. Mullen?
19 (No response.)
20 CHAIRMAN SHEPARD: Very good. Thank you very much,
21 Fred. Dr. Hodder, can you give us a summary of our other
22 subcommittee's activities?
23 DR. HODDER: We had a fairly busy agenda despite
24 the inability of Dr. Erickson and Dr. Mulinare to be with
25 us. We still managed to run over to a certain degree. We

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had presentations which we had asked for last time on research efforts being done in the states' Agent Orange commissions or other organizations. We had reports from three today.

Dr. Anderson from Texas who had made a brief presentation last meeting, told us some more about what his state was doing. He mentioned that the program started really three years ago, and like many programs, was aimed at predominantly giving assistance to the Vietnam veteran, and was not set up for research.

However, as so often happens with health service organizations, or similar organizations, basic information is needed and research becomes part of the effort. He described six protocols that were done

or reviewed by the University of Texas, three which are particularly active now: a profile of immune systems, sperm counts and cytogenetics. He also mentioned a mortality study which had to be stopped; it wasn't feasible because of the small number and the fact that most people were dying of the expected diseases. There would not have been enough power in the study.

He shared with us some problems that other studies might run into, for example, the difficulty in finding controls. The problem with management information systems using different

1 computers, and he gave us somewhat unique ones that Texas
2 has and the state of Rhode Island does not -- which is the
3 large geographic area.
4 I will take these out of sequence and mention of presentation/
5 the other state presentations. Dr. Reiches presented the
6 Ohio program which I gather is just now gearing into its
7 public phase by sending out three pamphlets, two
8 of which go directly to the veteran.
9 One is just information to the veteran, a
10 simple education pamphlet with a brief questionnaire. A
11 second one, which gives more health information, includes
12 a more detailed questionnaire and physical form. This is
13 filled out by the veteran and
14 by his physician. And finally, a third/ mailing goes directly to all the
15 physicians licensed in the state. It gives the physician
16 background information on the health effects of Agent Orange and what the
17 study is attempting to accomplish.
18 She mentioned that at this phase, they are
19 particularly interested in public education, as well as
20 beginning a surveillance network. The Phase two study will
21 be $240,000 a year, and that is just being developed at this
22 point.
23 Finally, Dr. Peter Kahn presented three studies
24 that were being done at New Jersey: a mortality study which
25 will have controls who have not served in the armed forces

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1 and veterans not serving in Vietnam.

2 Therefore, they

3 have dual controls.

4 He mentioned that the state has the death cer-

5 tificate data coded already, which is an advantage, and they

6 can also identify veteran status.

7 A second study will be a preliminary look at soft

8 tissue sarcoma. He mentioned some of the difficulties

9 predominantly about the small size, and it would take probably

10 a longer time to get an adequate number of cases. However,

11 it should be at least able to be done, if nothing else, at

12 a higher risk factor or lower power. It may not be able to

13 get down to a 2 to 1 risk. The power may not be enough

14 for that. It may have to be a three- or four-fold risk to

15 be picked up.

16 Again, the advantage is that they have a good

17 cancer registry which is linked with the SEER network. A

18 very interesting study he talked about was

19 the possibility of identifying either dioxin or a product of

20 dioxin in the blood even considerably later after heavy

21 exposure. He related this back to studies in Japan, in which they found

22 traces of chemical 11 years later.

23 He plans a simple study, looking at 50 heavily

24 exposed individuals who were either sprayers or any other

25 military occupation that would have experienced heavy contact

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1 with dioxin. He would have two unexposed controls, one
2 a veteran who would not have been in Vietnam, and one who
3 had been in an area of Vietnam which had very little risk of
4 exposure.
5 He described the protocol of how this would be done,
6 including a fast to hopefully force breakdown of the lipids
7 and release some of this material into the blood.
8 From that phase of the states, Dr. Richard Green
9 presented some of the basic science research that
10 was being done in the veterans organizations, the veterans
11 hospitals. He had four basic samples or illustrations of
12 these research projects, actually representing 10 ongoing
13 projects out of 36 applicants that were chosen by a panel of
14 experts as being meritorious projects.
15 All of these started in August of '82. The first
16 one presented by Dr. Peter Sinclair was looking at Porphyria
17 cutanea tarda. He recalled for us that in the compensation bill, this
18 was one of three criteria for presumptive exposure
19 to dioxin.
20 The area that he is trying to study is the
21 mechanism by which TCDD would inhibit the enzyme system
22 going from the precursor ALA -- and I don't remember what
23 ALA stands for -- to hemoglobin. The chemicals block this
24 and force side production of uroporphyrins which are the
25 agent for the skin toxicity, and they would be looking into

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1 this. He is using a cell membrane system to do that.

2 The other studies presented, just quickly, are a

3 neuromuscular toxicity study being done in the Baltimore VA,

4 looking at behavioral and physiologic outcomes, and also

5 the biochemistry of some of the

6 transmitters.

7 Another study being done is on behavior and stress by

8 Dr. Shelton, and I don't remember where that is being done

9 -- at the Madison, Wisconsin, VA Medical Center. He is

10 using Rhesus monkeys.

11 A final one, Dr. Puhvel from Los Angeles presented

12 the biochemical aspects of Chloracne. She reviewed the

13 pathology of it, and presented the studies they are doing on the

14 enzymes in keratinization to explain Chloracne.

15 Then, we moved to case control studies, the soft

16 tissue sarcoma studies that Dr. Han Kang and his associates

17 are doing at the AFIP. He gave a quick summary of the pros

18 and cons of the association of STS with dioxin. Then, he

19 reviewed the study, which has been presented several times

20 here, and I needn't go into that.

21 What they have looked at is 5,015 cases of soft

22 tissue sarcoma; 440 of these would meet the criteria by time,

23 age, and male sex, and these will be looked into further. He

24 also mentioned that this study has been presented to the

25 AFEB and he discussed their comments.

He also presented the mortality study which is at the phase now of setting up the system to collect data, and then Dr. Kang stepped through the process of how the data would be handled to identify cases and get their records.

He then had two of the subcontractors in the study, Ms. Kokiko from Moshman , who explained the processing of the death record data, and Mr. John Ward from Westat, who talked about the approach they would use to verify military status. They presented the formats and the forms that they would use.

The final presentation was Dr. Annemarie Sommer who presented the outline of her monograph on birth defects, genetic screening and counseling. She talked about some of the principles of organizing the birth defects and how these would be organized and presented in her monograph, which will be available fairly soon, I gather.

CHAIRMAN SHEPARD. Fine. Thank you very much. Are there any questions, comments from members of the committee for Dr. Hodder?

MR. WALKUP: Did you learn anything more this time about what Agent Orange might do to humans, or did you learn anything more about when we might know something more about that? I had a hard time following a lot of what you were saying. Is there any outcome at this time that tells us something more?

DR. HODDER: No, I don't think there is something

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1 which -- first, today, what we were looking at was what
2 studies were in progress. It was more information gathering
3 for the committee than it was anything in terms of what I
4 guess you would call an outcome or a product.
5 I think we will be able to say something
6 more in evaluation of an outcome when someone is presenting
7 a final study, and saying this is what we conclude. I think
8 then the committee can perhaps review it and give a statement.
9 MR. WALKUP: That is what I thought I was hearing.
10 One other thing that I wanted to ask was Dr. Schulz, in our
11 committee and as followup to his comments earlier this
12 morning, in talking about the lay person's exposition of
13 updated literature review, said that he thought the time
14 had come when there were some things that could be said about
15 Agent Orange, about the general area that we are talking
16 about, some conclusions that have been reached; some things
17 that we can predict are going to be known within the somewhat
18 near future, the next five to 10 years; and some things
19 probably we will never known, and that science cannot give
20 the answers to many of the questions that are being asked of
21 it.
22 Do the scientific panel members agree with that
23 assessment?
24 CHAIRMAN SHEPARD: If I may put my two cents'
25 worth in. I think we have to be very specific again. It is

1 very difficult to generalize in an area that is as complex
2 as this in terms of speaking of specific studies. I wasn't
3 there when Carl gave that part of his presentation, but I
4 would agree that there are some things which we are close to
5 being able to answer, if not being actually able to answer.
6 It may be important to sift out those things
7 on which we can draw conclusions as of the moment, project
8 which studies will lend themselves to drawing conclusions,
9 and then probably cite some questions that may never be
10 answered.
11 But it is difficult for me to say, yes, that is.
12 To the extent that I have said that, then it is in agreement
13 with what was said earlier. I just speak for myself now, not as chairman of
14 the committee.
15 Dick?
16 DR. HODDER: I think that addresses really two
17 questions. One is the degree of certainty. Science never
18 really does give you anything with 100 percent certainty.
19 What we try to do is refine questions and hope that
20 our probability of being right gets closer and closer to a
21 certain level that we are willing to accept.
22 But the other thing that I think is important, at
23 least to me, in the papers that we have presented, is that we are
24 really not at a phase where we are trying to get definitive
25 answers. Since most of these studies are at a

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fairly early phase, we are really trying to make sure that there are not flaws in the design, which, when results come rolling in, are going to make them invalid. Certainly, if we can find out something in advance; you know, a lot of studies years ago, wouldn't let any of the information out about their design until they presented it, and then they find out that they have made a significant mistake, and many years of work would be wasted.

We are really at a very early phase, and not very many studies are completed. We are just trying to make sure that when these studies come to fruition, completion, that a key variable was not left out. That is why the ranch hand took so long to design and why so much time was spent on the CDC study.

MR. WALKUP: For the veterans and for our committee in particular, that is a very important question that keeps getting re-raised,and especially after seeing the public relations' video tapes that we viewed today. A point that the VA was continually making through those was that we were awaiting the definitive outcome of scientific studies. I think that has been the position for a long time.

I think that pretty soon we are going to have to bite the bullet and say,"No , we are not going to know some of this stuff, and we are going to have to deal with probabilities, and it is going to be a very long time," and start

1 telling people that and basing policy on what definitive
2 conclusions scientists have given us, which are going
3 to be a very long time, and that we are not going to know some of
4 it.
5 Thank you.
6 CHAIRMAN SHEPARD: I would like now to call on
7 Dr. John Levinson who has been patiently waiting. Dr.
8 Levinson has had a long-standing interest in the whole area
9 of health. He is an obstetrician and gynecologist from
10 the Wilmington, Delaware area. He is a consultant to the
11 Veterans Administration, and has a long-standing interest
12 in this area. I am very happy to have you here, Dr.
13 Levinson. AGENT ORANGE: A PERSPECTIVE ON RESPONSIBILITY
14 Dr. LEVINSON: Good afternoon. You should understand something
15 of my background if you are to understand my perspective
16 on today's subject.
17 At the age of 17, during World War II, I joined the
18 U.S. Navy, and served as an enlisted man. I was proud to do
19 so and thought my country treated me very well. Being a
20 veteran in those days was something special.
21 Today, I am a practicing physician in Wilmington,
22 an Associate Professor of Obstetrics and Gynecology at
23 Jefferson Medical School in Philadelphia, and serve as the
24 President of Aid for International Medicine, which I founded
25 in 1965 out of my interest in the medical needs in South

1 Vietnam.

2 Twenty years ago I made my first of 15 working
3 visits to Indochina, the majority self-financed. I have
4 worked in hospitals, I have worked in clinics, I have
5 taught surgery in Cambodia, Laos, South Vietnam. I have
6 taught surgery in North Vietnam, and I have done surgery
7 under combat conditions.

8 In 1967, I traveled with Senator Edward M. Kennedy
9 as a medical consultant for his Senate subcommittee to
10 South Vietnam. On January 8th, twenty years ago, I found
11 myself perched in a helicopter 2,500 feet above War Zone C
12 Below was a moon scape of bomb craters and defoliation
13 stretching for miles in all directions.

14 This was a shattering experience that I shall
15 never forget. Over coming days, reports filtered in on
16 fetal abnormalities and high rates of miscarriage from
17 Tay Ninh province. Regretably, we could not research these
18 allegations attributed to defoliating chemicals as we were
19 overwhelmed dealing with the massive problems of civilian
20 war casualties and the plight of milliones of refugees.

21 But I truly have never forgotten that day and
22 continue to search for answers. As you know, between 1961
23 and 1971, over 20 million gallons of herbicide were sprayed
24 around Indochina. Mounting protests from the scientific
25 community, citizen groups, and strong political pressures

are credited with halting this form of chemical warfare. In spite of approximately 2,000 scientific articles on herbicides, including phenoxy herbicides and associated dioxins, we have few firm conclusions as to the long-term effects on man and the environment.

Realistically, where are we in solving the puzzle? The millions of veterans of the Vietnam conflict have a right to expect that the Veterans Administration can answer their questions, give counsel, and proper medical care. It is apparent that many of their expectations have not been met.

In December 1979, mounting national concerns on Agent Orange disease processes, and on the inadequate responsiveness of the Veterans Administration led to the creation of the Presidential Interagency Work Group on phenoxy herbicides and contaminants to coordinate all federal research efforts and to study long-term health effects of herbicide exposure in South Vietnam.

Following dilatory handling of Agent Orange research by the VA, Congressional protests of 1982 led to the Centers for Disease Control in Atlanta to have the lead role in the federal research effort.

The Australian Senate report on Agent Orange studies failed to recognize most of the alleged effects of herbicides and other chemical agents on the 49,000 Australian veterans of the Vietnam conflict. A royal commission is

about to re-hear the data. However, they do acknowledge many emotional problems, psychiatric problems and general readjustment problems in Vietnam veterans.

The work of Dr. Van Tigglen in Australia and Holland in pursuing cerebrospinal fluid abnormalities related to dioxin raises the strong suspicion of toxic neurasthenia. These studies should be followed and enlarged upon by U.S. scientists, as we too have an overwhelming number of Vietnam veterans with emotional problems, psychiatric problems, and general rehabilitation problems.

Possibly there is an organic basis for the so-called post-traumatic stress syndrome that well may be the most significant medical problem to emerge from the Vietnam conflict. In good conscience there is no way we can afford to pass up on any potential leads to deal with these tragedies.

The often quoted Seveso accident in 1976 has been most carefully studied. A critical review of their data fails to substantiate early concerns of increase in birth defects, cancer and many other medical conditions. However, 200 cases of chloracne were found, and I find this hard to reconcile with only 10 documented cases in the 125,649 initial physical exams and the 29,775 follow-up examinations that were done through the end of September of this year for the Veterans Administration Agent Orange Registry.

1 In May of 1982, I spent two weeks in Vietnam as an
2 official guest of their ministry of health. My purpose was
3 to study the results of the chemical warfare. Although I
4 was impressed by the tremendous number of liver cancers in
5 Hanoi, by the increase of patients in hospitals in the south
6 with trophoblastic disease, and many other health allegations
7 due to toxic chemicals, I left with far more questions than
8 answers.
9 In January of this year, I returned and spent one
10 week reviewing medical records at the Tu Du Hospital in
11 Ho Chi Minh City. Unfortunately, the data collection is
12 so poor and there are so many variables, that serious doubts
13 cloud their conclusions. The following week, "The Inter-
14 national Symposium of the Long Term Ecological and Human
15 Consequences of Chemical Warfare in Vietnam" convened in
16 Ho Chi Minh City.
17 The conclusions of the symposium shed little new
18 light on the problems. Considering the tremendous population
19 shifts during and following the war, and the largely unknown
20 amounts of individual exposure to defoliating chemicals
21 makes research difficult. The overwhelming lack of laboratory
22 facilities and the limited understanding of the Vietnamese
23 scientists on how to gather raw data and how to do a proper
24 statistical analysis, makes all of their conclusions open to
25 serious question. A classic example is the 5 plus fold

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1 increase in primary cancer of the liver at the Viet Duc
2 Hospital in Hanoi. Is the increase really due to toxic
3 chemicals, or is it due to the fact that it is probably the
4 only hospital in the country that can do this type of
5 extensive surgery for liver cancer and hence they have more
6 referrals; or is it due to the fact that there is better
7 transportation now that the war is over, or is it due to the
8 fact that they have time for this type of surgery, or is it
9 due to Hepatitis B? It is known that Hepatitis B is endemic
10 in Southeast Asia, and that contracting that disorder
11 increases the chance of primary liver cancer approximately
12 300 times. With no laboratory facilities to document
13 Hepatitis B, how does one attempt to study any of this? We
14 cannot blame the defoliating chemicals without good hard
15 data.
16 Following the symposium, a group of U.S. scientists
17 offered to set up a bilateral research program with the
18 Vietnamese for further study on toxic chemicals and its
19 effect on man and the environment, in the hopes to benefit
20 the Vietnamese as well as ourselves.
21 I have discussed this with members of our Congress
22 and they have expressed great interest in the project. U.S.
23 industry has offered funding. Regretably, after 10 months,
24 the Vietnamese have not yet appointed a committee to work
25 with us. Private Vietnamese sources suggest that the political

1 rhetoric about the chemical warfare is more important to
2 them than a constructive approach.
3 In the weeks following the symposium, some members
4 of your committee met with several of the U.S. participants.
5 I was surprised that you only interviewed nonphysicians
6 and mainly individuals who had never been to Vietnam
7 previously to give you a better perspective on the meeting.
8 You could have done better.
9 Some five years ago, a VA medical director urged
10 me to offer my assistance in the Agent Orange research
11 because of my knowledge of Vietnamese medicine. After hours
12 of fruitless phone calls to reach key individuals, with
13 none of my calls ever being returned, I gave up my efforts.
14 Over recent months my frustrations have mounted
15 in trying to see what, why, and how the VA is helping our
16 Vietnam veterans. One of the several hundred VA outreach
17 programs is exactly next-door to my office, and daily I see
18 these distressed men seeking help.
19 Their perception of what the VA medical system is
20 doing for them is very, very poor. My own investigations
21 at various facilities and outreach programs where I have had
22 the opportunity to talk with physicians, psychologists,
23 nurses, and other personnel verify many of the veteran's
24 complaints.
25 Veterans complain of waiting for up to six hours

1 for a 15-minute history and physical by a physician. The
2 physicians claim they are too busy with routine matters and
3 they have little time.
4 If further consultations are necessary, men may
5 wait many months for an appointment and get only several
6 minutes with a specialist. Certainly, most chronic skin
7 rashes are not chloracne, and from a medical standpoint,
8 are not of great concern. But can't someone take a few
9 minutes to explain to an emotionally drained, scared, ex-
10 serviceman, who is now out of a job, what it is all about?
11 When the armed services needed recruits, their
12 questions were answered. Why not now?
13 In the summer of 1980, the Vietnam veterans in
14 Wilmington, Delaware, staged sit-ins in the hospital lobby
15 as a protest to the way Agent Orange exams were being con-
16 ducted. The hospital director responded intelligently by
17 appointing a special Agent Orange nurse.
18 This dedicated nurse spends 1 hour with a veteran
19 to learn where he served in Indochina, discusses where he may
20 have been exposed to toxic chemicals, and gets a good history
21 on his health problems.
22 Then, after his 10- to 15-minute physical and
23 various laboratory tests, he returns a month later to see
24 her, receives the reports, and discusses anything further he
25 may wish. Indeed, I have no first-hand knowledge of all the

1 VA facilities, but I think the approach in Wilmington is
2 unique, bears study, and might offer a little "humaness"
3 to your Agent Orange Registry.
4 Dr. Ronald Codario of Philadelphia makes much of
5 the elevated porphyrin levels in urine of the many hundreds
6 of Vietnam veterans he has studied. He feels these changes
7 are directly related to toxic chemicals and to a multitude
8 of symptoms.
9 As a scientist, I strongly question his data and
10 would like to suggest that tests of this type be included
11 with the VA Agent Orange physical exams. Codario receives
12 11 pages of coverage in the book, "Waiting for an Army to
13 Die - The Tragedy of Vietnam" by Wilcox.
14 This paperback contains much sensationalism, but
15 the distressed veteran and his family read it, and they tend
16 to believe it. The VA has an obligation to counter this
17 with good research and either prove or disprove him. When
18 will you seize this opportunity?
19 In July 1983, VA medical officials spoke in
20 Philadelphia on the Agent Orange physicals. Many of the
21 individuals that attended these talks felt they were
22 insulted, the manner of presentation was patronizing, and
23 the individuals from Washington really lack an understanding
24 on how the hospitals are handling the problem.
25 I am told that the "traveling road show" scheduled

1 to hit 9 cities was soon abandoned.

2 Clerks who enter the Agent Orange physicals into
3 the computer do not have codes for many of the vague signs
4 and symptoms, so the information is not entered. The symptoms
5 of depression, sexual problems or lack of libido cannot be
6 coded from one area of the Agent Orange Registry code sheet,
7 so how accurate will your data be?

8 On the November 21, 1983 Agent Orange conference
9 call, Dr. Shepard expressed concern because the GAO is
10 gearing up to re-study the VA Agent Orange Registry process,
11 coding, et cetera.

12 He pointed out they were very critical of the VA
13 in their first study. He stated that if the review was also
14 critical, excuses would not hold up, and the vulnerability
15 of the VA was discussed. Furthermore, he mentioned that the
16 VA was not getting out follow-up letters in a timely fashion.
17 The concern seems to be to protect the establishment, not
18 to learn what the problems may be with the men who fought
19 and survived in that miserable war.

20 At the same conference call, Nancy Howard complained
21 of the quality of the code sheets, of repetitive errors
22 and instructions not being followed. She complained that
23 some charts were sent in without history and physicals,
24 with no entry for neoplasia, and with complaints incompletely
25 listed. Many facilities doing exams were not using the

1 proper forms. She made a plea for total compliance.

2 Several people explained why various studies would
3 take longer than anticipated and the monograms and video-
4 tapes that were being prepared on toxic chemicals for the
5 veterans would not be available for many months to come.

6 As one of your professional staff said to me in
7 private, "We have been having these conference calls every
8 few months for years - they always promise things that
9 never come through."

10 I am sure I have upset some of you this afternoon,
11 but after my 20-year personal involvement in Indochina, I
12 feel I have the right to be heard at this forum. When one
13 has sweat, when one has cried, and when one has been shot
14 at in Indochina, you learn to talk very straight. I implore
15 that you move ahead rapidly with your studies and do them
16 well, and have a greater sensitivity to all the veterans
17 and particularly those with the post-traumatic stress
18 syndrome - which might possibly be Agent Orange-related.

19 In real straight talk, the Vietnam veterans have
20 gotten the short end of the stick. I feel they deserve a
21 lot better.

22 Thank you.

23 (Applause.)

24 I will be glad to answer any questions. I assure
25 you I can verify everything I have said.

1 CHAIRMAN SHEPARD: Thank you, Dr. Levinson.

2 Are there any questions for Dr. Levinson?

3 DR. ANDERSON: I have one. It relates to what

4 was brought up earlier here. Do you think that a pelvic

5 examination in a female Vietnam veteran would serve any

6 purpose unless the physician accomplishing it has certain

7 things pointed out to him to look for? Being a physician

8 myself, I like to have people say here is something to look

9 for, here is some guidance, just don't do a physical

10 examination. How do you feel?

11 DR. LEVINSON: Well, I am a little perplexed. I

12 think, as physicians, anyone doing a complete physical ought

13 to be able to make some basic judgments whether there is

14 normalcy present in the organs involved, and if there is

15 a problem, have a specialist see the patient.

16 But I indeed think every lady that is getting an

17 exam for this or anything else deserves a pelvic. We have a

18 lot of unanswered questions in the reproductive area, which

19 have not been researched at all well, and we have a lot of

20 accusations in Vietnam that I cannot prove. Their data is

21 just beyond any realm of trying to understand it.

22 I think it would be worthwhile.

23 CHAIRMAN SHEPARD: Any other questions or comments

24 of Dr. Levinson from the committee? We will open questions

25 from the floor in just a moment. Any other comments or

1 questions from the committee?

2 (No response.)

3 CHAIRMAN SHEPARD: Fine. Thank you very much,

4 Dr. Levinson. I appreciate your candor.

5 DR. LEVINSON: Thank you very much.

COMMENTS AND DISCUSSION

6 CHAIRMAN SHEPARD: The time has now come for us

7 to open up questions from the floor. If you would please

8 rise and identify yourselves so we can get your name.

9 While you are coming up, there were two questions that were

10 forwarded to me earlier.

11 I am not sure to whom this is directed, but let

12 me just read it anyway. "Hasn't Dr. Rappe from Sweden found

13 ways to isolate or detect degrees of isomers in dioxin?"

14 My knowledge would suggest that he has. I think the answer

15 to that question is yes, he has found ways to isolate and

16 detect degrees. When he said "degrees of isomers", I presume

17 that to mean differentiating one isomer from another. I

18 think that has been clearly established. I cannot speak

19 for Dr. Rappe himself, but I know that other analysts, other

20 chemists have been able to.

21 Jimmy?

22 MR. RICKETTE: That was my question.

23 CHAIRMAN SHEPARD: Maybe you can clarify it. Did

24 I answer it? The answer is yes, if you

25 are talking about distinguishing one isomer of TCDD from

1 another.

2 MR. RICKETTE: Yes, but I asked Dr. -- I can't

3 remember the name --

4 CHAIRMAN SHEPARD: Dr. Kahn?

5 MR. RICKETTE: Dr. Schulz, and I didn't feel it

6 had anything to do with information and education.

7 MR. MULLEN: He brought it up in his testimony.

8 MR. RICKETTE: Okay, but this is a scientific

9 panel. I think there are more people here that would be

10 better able to answer that.

11 DR. KAHN: I will answer the question. He does

12 have complete isomers, specific analysis for dioxins and dibenzofurans.

13 CHAIRMAN SHEPARD: The other question is "can't

14 the specific isomer of dioxin, that was used in Vietnam,

15 be still found in the bodies of Vietnam vets?" There are

16 some other questions, but the answer to that is yes. The

17 feasibility study which the VA engaged in did address that

18 question, and it is possible to isolate the 2,3,7,8 isomers

19 of TCDD, so the answer to that is yes, and it has been done,

20 and it has been done in other laboratories.

21 The chemist that did it for the VA under contract

22 was Dr. Michael Gross at the University of Nebraska. The

23 second part of that question, "or the soil in Vietnam?" I

24 don't know of anybody specifically who has analyzed soil from

25 Vietnam, but I know the technology exists for doing analysis

of soil, and it has been done by the EPA at Times Beach and other areas, horse arenas, and so forth. So the technology does exist for isolating isomers of dioxin and furans from soil.

The second question, "While Vietnam veterans are waiting for the answers, what are we supposed to do? We have been waiting since 1978."

If Vietnam veterans are worried about their health problems, there are a number of options open to them. They are eligible for the Agent Orange examination which we have talked about, and they also are eligible for health care.

Now, when you say, "What are we supposed to do," it is very difficult for me to answer that. I think, in general terms, I would say that Vietnam veterans should keep themselves informed as to the progress of studies, to avail themselves of the opportunities that exist within the VA and other agencies, the state agencies, and so forth. Our office is always available for discussions on any particular concern to veterans, so I think there is a lot that you can do.

I guess probably one thing that we all have to do is to be patient. These studies take a lot of time to do. I hope that Vietnam veterans would agree with me -- I am also a Vietnam veteran, as most of you know -- that if we are

1 going to do studies, they ought to be done well. It would
2 be inexcusable, in my view, to do bad studies simply because
3 we need to get the answers quickly. Studies of this type,
4 given the complexity of the problem, cannot be done easily.
5 Dr. Kahn can certainly attest to that. He has
6 been at it for some time now. It is not an easy question.
7 But I think it is also accurate to say that a tremendous
8 amount of effort has been put forward. The Federal Govern-
9 ment, the VA and other agencies, has expended a
10 lot of time, effort, and money in trying to get the answers
11 to these questions, so be patient. Ask questions. Hopefully,
12 we will be able to answer your questions as they arise.
13 MR. MARTIN: We have a few questions, Dr. Shepard.
14 My name is David Martin, Vietnam Combat Veterans Coalition.
15 I am an infantry combat veteran, so therefore I have a
16 question about exposure. I keep hearing about your Ranch
17 Hand. As an infantry combat veteran, you know, I have a
18 very hard core approach toward the term "Vietnam veteran."
19 I think I am, and I think Frank is, and I think
20 that 10 percent of us, who actually were out in the bush and
21 fought that war are the Vietnam veterans. You know, we
22 didn't change our clothes, we didn't shower at all for up to
23 two and three months, and we were in that area. We walked
24 through that area. In this videotape we heard about earlier,
25 it was talking about insecticide. I don't know how dumb Mr.

1 Walters thinks we are, but I can tell the difference
2 between insecticides and herbicides because when I walked
3 through an area that has been defoliated and the leaves
4 are falling, I don't assume that was an insecticide. I
5 assume that was a herbicide.
6 When I see the planes flying overhead within .5
7 meters from my position, and a few days later the trees are
8 defoliated, and I have to walk through that area and sleep
9 in it, and drink the water, you know, I didn't have access
10 to cold beer or canned soda, I drank that water, and I
11 slept on that ground, and I walked through that area.
12 Now, if I didn't change my clothes, and if I
13 didn't shower for like two months, and somebody back here
14 is expecting me to believe that a Ranch Hander who
15 went out on a /spraying mission for an hour, came back and
16 showered, changed clothes, had protective clothing, and also
17 had Vietnamese -- I know how the Air Force worked. You know,
18 I was in the Marine Corps, but I know how the Air Force
19 worked.
20 They had an indigenous population, the Vietnamese
21 handling that stuff, -- you know, I have a tough time believing
22 that, and if you have any further information on it, you
23 know, I wish you would inform me. But I think our exposure
24 index was a hell of a lot higher than any Ranch Handers were.
25 CHAIRMAN SHEPARD: Certainly, that is a concern,

1 and it is a concern of ours. I would hope you would agree
2 that it is different. Certainly your exposure was very
3 different from what the Ranch Handers were. Whether
4 it was more or less, I think it is going to be very difficult
5 to determine. I would hope that you wouldn't have the
6 impression that anybody in the VA thinks that you were not
7 exposed. Certainly the record is clear that the VA accepts
8 the fact that the ground troops in Vietnam were exposed,
9 and some of them were heavily exposed.
10 So I don't think that is anything that the VA
11 is trying to deny. I think the point we are trying to make
12 is two things. First of all, the exposure was probably
13 different, as you have already alluded to. Whether it was
14 heavier or not so heavy, or the comparison of the degree of
15 exposure, I think is a question that is going to be very
16 difficult to answer. I am not sure that we will ever be able
17 to answer it. That is one of the scientific questions that
18 we will probably never be able to answer, what was the level
19 of exposure of the ground troops in Vietnam in terms of the
20 amount of exposure, documenting that.
21 The importance of the Ranch Hand study is that we
22 can identify and have identified those people. We are not
23 trying to say that they were any more exposed, or that study
24 is any better a study than any other study. It is another
25 study. It's a group of people who were readily identifiable,

1 who had a fairly high degree of willingness to participate
2 in the study. So it was a group of individuals that lent
3 itself very naturally to this study, and fortunately, the
4 study is well underway. We are not making any judgments in
5 terms of the quality of this study and the quality of the
6 ground study.
7 MR. MARTIN: Concerning that, on this videotape
8 I just saw, you know, the priority of the ground troops,
9 you know, that Mr. Walters said that it was light exposure,
10 and he put down the Ranch Hand as heavy exposure, and I just
11 saw that like within the last three or four hours.
12 MR. RICKETTE: And they named specific areas.
13 MR. MARTIN: It was the videotape we saw this
14 morning.
15 CHAIRMAN SHEPARD: That the ground troops were
16 lightly exposed?
17 MR. MARTIN: That is a quote, yes, it is.
18 CHAIRMAN SHEPARD: I don't remember it.
19 MR. RICKETTE: I question that very much. Also,
20 Dr. Levinson touched on it, about the humanistic view. If
21 this Veterans Administration considers themselves what they
22 put right in front of their building in big bold letters
23 underneath the Veterans Administration, "To help he who
24 fought, did the battling, and his orphans and his widows,"
25 then why can't he give us the benefit of doubt instead of

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1 studying this damn thing to death? Eighty-six damn studies
2 going on right now, and you are talking about another one
3 with women. Now, how many studies do you need? I mean,
4 you know, a lot of us are sick. Some are dying. We are
5 dying slow deaths.
6 Let's talk about the humanistic point of view here,
7 what it does to a person's mental and physical conditioning
8 every day of their life. Let's talk about that. That is the
9 main point here. Every God damned person in this room except
10 Dr. Levinson, Dave Martin, and myself are missing the whole
11 God damn boat, because that is what we are talking about
12 here is human life.
13 If you call yourselves doctors, then examine
14 yourselves and examine what I am talking about, because I
15 am fed up to here. I have gone to the VA system through the
16 state of New Jersey. I have been to everywhere, and I am
17 sick, sick and tired. My family is sick of hearing about it,
18 and I am tired of talking about it.
19 That is all I have to say.
20 MR. MARTIN: Yeah, and we have been at this
21 since -- you know, like it hit the papers in '78, you know.
22 We are not all asleep. Even though like we live in dioxin
23 Jersey, noxious Jersey, you know, like still we are not that
24 dumb up there, and we read the papers, and we follow the
25 articles, and we watch the stuff on TV, and we buy the books,

1 and we hound our Congressmen and our Senators to death, and
2 we get all of the information we can, and we still find out
3 when we come to places like this, there is information that
4 is like either withheld from us either by incompetence, by
5 negligence, by design, or whatever it is.
6 Like Frank and I go out of our way to find out
7 this information. We go out of our way to research this
8 stuff. You know, it is like Marc Williams can tell you
9 from the New Jersey Agent Orange Commission, we go up there
10 and we are there all the time. We write letters. We are
11 all the time trying to find out information about this stuff,
12 and we come down here, and we find out stuff that we have
13 never even heard of, and we see tapes that irritate us, you
14 know.
15 We have been in this since 1978. You know, it is
16 like six years. '84 is around the corner. Except for the
17 fact that, you know, like Dr. Levinson said, you know, we
18 are a little bit scared about this, you know, and like, you
19 know, paranoia is a definition which you can argue about for
20 years, but, you know, whatever you want to say about it,
21 you know, like we are worried about it, and we are concerned
22 about it.
23 You know, it has been a long time, you know, since
24 I have saluted that flag or cared anything about that thing,
25 but yet the fact is that I put more communists in the grave

1 than anybody in this damn room, you know, and I did it
2 willingly, and I did my job. For like 10 years after that,
3 I kept my mouth shut, and I didn't have anybody. There
4 wasn't any vet centers. There wasn't anybody to talk to.
5 There wasn't any priest. There wasn't any ministers. There
6 wasn't any family. There wasn't any friends. There wasn't
7 anybody to talk to. There wasn't any psychologists.
8 You have, I have a Master's degree. I have got
9 six years of education. The college campuses in '70 and '71
10 wasn't too great to be at. You kept your mouth shut. In
11 '78, the only thing that broke my back, you know, in this
12 whole thing was Agent Orange. When I found out that no
13 matter what I could try and bury, or put under, or try and
14 just like forget about psychologically, you know, then I
15 have got to worry about a physical problem that might catch
16 up to me.
17 I would like to live to be 40. I would like to live
18 to be 45. I am still worried about my two little girls
19 which I will never see again. They are in Seattle, Washington,
20 for one reason or another. I worry about their health.
21 I worry about the two miscarriages from a
22 previous marriage. I worry about these things. I worry
23 about the genetic damage that maybe I put in the system
24 by having like two little girls. What is going to happen
25 to their kids, or after that? You know, this whole problem

1 is like, you know, it is like profound to a Vietnam vet,
2 a combat vet, an infantry vet. It is our life. Frank and
3 I do this like morning, noon, and night. We do it all the
4 time. We have been doing it and doing it, and yet all we
5 get from the VA is like a bunch of studies, or, you know,
6 like one of our other partners say, a bunch of rhetoric,
7 and that is all we get, you know.
8 And like, Dr. Shepard, I don't want you to take
9 this personally, but, you know, that is my opinion about the
10 VA, and that is my opinion about -- and the VA being one of
11 the largest bureaucracies for this country, unfortunately,
12 it has become my opinion about this government, and like
13 I go back to Dow Chemical and Monsanto and Hercules and
14 Hooker and Dupont and the rest of them, and Diamond
15 Shamrock, you know, and I think that they have pulled such
16 a massive con game on this country. They have like stripped
17 everything from it.
18 They have stripped our religion, you know, our
19 belief in our country, and now they are trying to strip
20 our physical well-being. I think if the VA wanted to do
21 something, it should go after Dow Chemical, and they should
22 make them pay. I don't care if they go out of business.
23 I don't think the American taxpayer should pay for it, and
24 I don't think Frank or I should have to pay for it. I
25 don't think my two little girls in Seattle should have to

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1 pay for it. I don't think their kids should have to pay
2 for it. I think Dow Chemical should have to pay for it.
3 That is all I have to say, sir.
4 CHAIRMAN SHEPARD: Any other comments or questions
5 from the floor?
6 DR. ANDERSON: I have one. When the state programs
7 met for lunch today, it was brought up that there were some
8 good presentations at the scientific panel this morning, and
9 we were wondering if chese are going to show up in the
10 general transcript or not, because we felt some of these
11 were worth being in there.
12 I know that Dr. Hodder's report will be in, but
13 if some of the presentations themselves will be included.
14 CHAIRMAN SHEPARD: You may have noticed that my
15 secretary was taking notes and transcribing most of the
16 proceedings of that. To the extent that we can capture
17 that, we will. These were not definitive reports. As you
18 know, these were status reports of these studies.
19 DR. ANDERSON: We realize that. Some of them were
20 good. They had some good material in them, and they should
21 be included. No criticism, though.
22 CHAIRMAN SHEPARD: I just wanted to be straight
23 about that, because we haven't been transcribing everything
24 verbatim in subcommittees. The reason for that is, in
25 part, by virtue of the fact that I think it provides for a

1 little freer flow of conversation, informality, so I think
2 we can share information a little more freely.
3 DR. ANDERSON: My thought was that some of this
4 might be lost, because it was good material.
5 CHAIRMAN SHEPARD: Well, the studies are all
6 ongoing, so that certainly the data that is accumulated
7 will not be lost. These studies are in progress. We will
8 have enough of that, and I think will be included in our
9 proceedings.
10 DR. ANDERSON: Thank you.
11 CHAIRMAN SHEPARD: Thank you very much for attend-
12 ing the meeting and for being with us.
13 (Whereupon, the meeting was concluded at 3:25 p.m.)
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Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Nineteenth Meeting
March 6, 1984

June 1984 Washington DC 20420

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON
HEALTH-RELATED EFFECTS OF HERBICIDES

Room 119
810 Vermont Avenue, N.W.
Veterans Administration
Central Office
Washington, D.C. 20420

Tuesday, March 6, 1984

1

2 The meeting of the Advisory Committee was

3 called to order at 8:30 a.m.

4 ADVISORY COMMITTEE MEMBERS PRESENT:

5 BARCLAY SHEPARD, Chairman

6 GEORGE R. ANDERSON, Member

7 DONALD BARNES, Member

8 THOMAS A. FITZGERALD, Alternate for IRVING B. BRICK

9 GEORGE T. ESTRY, Member

10 HUGH WALKUP, Alternate for JON R. FURST

11 RICHARD A. HODDER, Member

12 CAROLYN H. LINGEMAN, Member

13 JOSEPH MULINARE, Member

14 FREDRICK MULLEN, SR., Member

15 CHARLES A. THOMPSON, Member

16 NOEL C. WOOSLEY, Member

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2 P R O C E E D I N G S

3 DR. SHEPARD: Good morning, ladies and gentle-
4 men. I think we'll get started. We have a full agenda
5 as usual and we're very happy to welcome you to the
6 nineteenth quarterly meeting of the VA's Advisory
7 Committee on Health-Related Effects of Herbicides.
8 We're privileged and pleased to have some
9 distinguished guests with us this morning who will be
10 addressing you later on in the program. We would like
11 to acknowledge the presence of Mr. John Coombs and Dr.
12 John Matthews, colleagues from Australia; Colonel George
13 Lathrop who will bring you up to date on the activities
14 of Ranch Hand Study and a number of other distinguished
15 members of the committee. Welcome, one and all.
16 As is our custom, this meeting
17 is open to the public. We would ask that any, all
18 members of the audience please sign the registry.
19 As in the past, we will make time on the
20 agenda available for questions from the audience. We
21 would ask that the audience restrict their questions to
22 that question and answer period in order that we can
23 get through our agenda in an orderly fashion. We're
24 sorry to report that we have a resignation from Dr. Frank
25 Cordle who so ably served on our committee.

Dr. Cordle with the Food and Drug Administration, because of the press of other duties, has submitted a resignation and unfortunately will not be able to be with us. We have set a tentative date for our next advisory committee meeting of June fifth.

So if you will make a note of that, that will probably be the date of our next meeting. Just to bring you up to date on some recent activities, I'm sure you're all aware now that on the thirtieth of January the House passed the H.R. 1961, a Bill entitled Agent Orange and Atomic Veterans Relief Act which will provide disability and death allowance to veterans and survivors of veterans who served in Southeast Asia during the Vietnam era and suffered from certain diseases.

As you probably also know, this has been passed to the Senate for their consideration. On February the twenty-fourth, the investigators in the Air Force Health Study presented several briefings.

Included in those were a briefing to Congress, a briefing to representatives of service organizations over at the Pentagon and finally a full blown press conference later on in the afternoon also at the Pentagon.

I'm sure that you probably have seen the various

1

2 reports in newspapers and the media

3 following that series of briefings. We're

4 happy to announce that a member of our staff, Mrs. Nancy

5 Howard, has been asked to join our VA quality control

6 team in order to assure that we have some on-going process

7 for checking on our procedures for the conduct of the

8 Agent Orange registry examinations and related activities.

9 So she will be making the first of her visits

10 with our external review program later this month in West

11 Haven. I, myself, will be visiting over the next weeks

12 two areas, Chicago and Denver, and we'll be doing a similar

13 effort, meeting with our environmental physicians in those

14 areas and reviewing the progress of our Agent Orange

15 activities at medical centers in those two areas.

16 I'll also be going to Boston later on in the

17 month. The GAO review of our Agent Orange activities is

18 an on-going process and we've been having frequent meet-

19 ings with the auditors at GAO, so we're looking forward to

20 that progress.

21 During past meetings there has been some con-

22 cern expressed by some members of the committee as well

23 as interested individuals / attending our meetings concerning

24 our process for keeping our environmental position up to

25 date in the field and from time to time I have, I hope,

provided assurances that that is a very high priority item and that we are in fact continuing that process. A number of things have gone on and will continue in that regard.

As I have said many times in the past, we have had two major national educational conferences with our environmental physicians and we're planning a third. The date for that's not yet been set. We have bimonthly conference calls to our environmental physicians. Also an extensive mail-out program is on-going, in which we very frequently mail out not only the proceedings of this committee but other informational materials. So, we do keep in close touch with our environmental physicians.

It's very common for environmental physicians in the field to call us to ask questions about activities if they have any concerns or problems that they are dealing with. There's a very free communication between our office and the field.

In addition to that, as I've alluded to, we make site visits to our hospitals and that helps to keep the lines of communication open. In addition, and you'll be hearing more about this later on in the program, we are in the process of

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2 preparing two new video tapes dealing with Agent Orange,
3 one targeted primarily to veterans and their families
4 and the general public and also a second one that will be
5 designed primarily for our health care professionals in
6 the field. Our Learning Resources Center in St. Louis
7 is working hard on completion of those and we will
8 have a report from Mr. Jones later on to discuss the
9 details of that effort.

10 Finally, I would like to take this opportunity
11 to go on public record once again to commend the work of
12 our environmental physicians in the field because really
13 they are the ones who keep the program going. They are the
14 ones who really deal with veterans at the local level.
15 I think it's a tremendous effort that they have put forth
16 and in virtually every instance that program has
17 been going well.

18 I'd like at this time to call on our guests from
19 Australia to provide a report on the activities of the
20 Royal Commission and I would first introduce Mr. John
21 Coombs, an attorney who serves as the counsel to the
22 Royal Commission investigating the effects of herbicides
23 on Australian veterans and he is accompanied by Dr. John
24 Matthews, an epidemiologist who is working on several
25 studies related to this issue in Australia. John?

1

2 REPORT ON AUSTRALIAN ACTIVITIES

3 MR. COOMBS: The concerns and anxieties of Amer-
4 ican veterans who served in Vietnam are shared by Aus-
5 tralian veterans. Those concerns have developed out of
6 the past few years to a point where they are so real and
7 so genuine that they must be addressed at a governmental
8 level.

9 There have been for years studies in trying to
10 investigate the problems. There was a quite elaborate
11 birth defects study done by an epidemiological team in
12 Australia and there is just coming to conclusion a mortal-
13 ity study and the details of those studies are more
14 properly a matter for Dr. Matthews to describe to you.

15 The point of the studies did not, it seems,
16 allay the fears of veterans in Australia and in the lead
17 up to the 1983 federal election the Labor Party promised
18 a Royal Commission into the use and effects of chemical
19 agents in Vietnam to put, if you like, an independent
20 and judicial team together to inquire. After March 1983,
21 the Australian Government appointed Mr. Justice Phillip
22 Evert a Royal Commissioner to make such an inquiry.

23 Royal Commissions are a traditional way of
24 allowing the government to have investigations done at
25 arm's length from the government. The Royal Commissioner

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2 as his name suggests is appointed by the Queen's Repre-
3 sentative. He inquires independently of the government
4 and if I may say with respect to government, there's a
5 long tradition of Royal Commissions -- governments so the
6 general public feel confident when the Royal Commission
7 is appointed that it will diligently, separately and
8 independently inquire into whatever the politically
9 sensitive or difficult problem that needs inquiring into.
10 Mr. Justice Everts, who is a distinguished
11 federal court judge, he was before that a trial lawyer, a
12 barrister, specializing in about half of his practice
13 anyway into industrial medical and injury problems. So
14 well fitted for the task professionally and also himself
15 an ex-serviceman from World War II.
16 He was a submarine person. He was decorated
17 twice and he understands the way men who fight together
18 live and work. He began last May to put together a
19 team and he paid me the honor of appointing me his lead
20 counsel to conduct the collection, collating and presen-
21 tation side of a Royal Commission, part of which will be
22 done in a court type context, but most of which will be
23 done in a quiet, scholarly and investigatory kind of way.
24 We are looking in America at today's studies
25 that are going on here, and we hope to be able to give

some kind of definitive report in the form of findings and recommendations towards the end of 1985. It follows from what I've said, I hope, that I would not be prepared at this time to venture any conclusions at all.

We are about a quarter of the way, perhaps, along the track. The Royal Commissioner has not seen all that I have seen and we have formed no decided views at all. It's important that I stress that.

The time in America has been well-spent. We've had opportunities to deal with veterans' organizations. We've had opportunities to deal with the lawyers who are appearing for many veterans in the class action, and we've had opportunity to observe what research is being done on behalf of the Administration and the many independent studies .

And I'd like to take this opportunity to publicly thank Dr. Shepard and Dr. Young and very, very many other people, Dr. Linea, who have made us welcome, given us quite free and open access to all kinds of data which has been extraordinarily usefull. If you think it's appropriate, Dr. Shepard, I'd ask Dr. Matthews to describe the design and the results of the birth defects study and similarly the design of the mortality study which is not yet finished and the morbidity study which we hope

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2 to do.

3 It's important to remember that the Australian

4 population was way, way smaller, 50,000, in all

5 fields, was all that went to Vietnam from Australia, but

6 there are advantages in that from a study point of view

7 which Dr. Matthews will outline. But perhaps I ought to

8 say that we have in Australia a very homogeneous popula-

9 tion. Those who went to Vietnam are easier than a more

10 heterogeneous population to get control groups and the

11 like from.

12 DR. SHEPARD: Thank you very much. Dr.

13 John Matthews.

14 DR. MATTHEWS: Thank you. The three studies

15 that are either completed or in train or proposed in

16 Australia are firstly the birth defects study which was

17 initially designed by Dr. McClennan and concluded by Dr.

18 Donovan working with the Australian Veterans Health

19 Study Group in Sidney, Australia and that birth defects

20 study was very simple in concept.

21 What was done was to look up in hospital

22 records to identify infants with birth defects that were

23 identifiable in the records of the hospital where they

24 were born or in a certain number of cases in birth defects

25 registers and to select a control baby who was not subject

1

2 to any birth defects but born, if you like, the next

3 birth in that same hospital.

4 And the very simple question that was asked was

5 was the birth defect baby more likely to have been

6 fathered by a Vietnam veteran than was the control baby.

7 Now, the answer within the limits of the statistical

8 power of the study was no.

9 There was no more likelihood of the father

10 being a Vietnam veteran if the baby had a birth defect

11 than not. Now, of course, within some of the subgroups,

12 we presume due to chance, some of the subgroups, some of

13 the particular abnormalities were slightly associated

14 with veteran status, but overall, there was no evidence

15 to suggest any association between birth defects and

16 Vietnam veteran status as the father.

17 So within the limits of the study design, there

18 was a negative finding there. The other study that is

19 somewhat more straightforward in concept was a mortality

20 study based on the entire cohort of Australian draftees

21 from the Vietnam era.

22 And this was a study of about 44,000 Australian

23 drafteees. These are genuinely young men whose birthddate

24 came up in the the birthday ballot and they were drafted

25 into the army. Approximately somewhat less than 50

1

2 percent of those drafted ended up going to Vietnam and

3 the other somewhat more than 50 percent did not go.

4 And as Mr. Coombs said, the Australian popula-

5 tion is homogeneous socially and ethnically and we had

6 a good contrast between those who went and those who

7 didn't go, and very few differences between them when the

8 data are examined retrospectively. Now, that mortality

9 study followup is complete.

10 At the present time we are not able to say

11 because the analyses are not complete on any differences

12 in mortality between those who went to Vietnam and those

13 who did not go. That report will be available for the

14 Royal Commissioner and for government shortly, but at

15 present time that data, the data is unavailable.

16 The third study, which is at the design stage

17 is awaiting a decision from the Australian Government

18 whether they wish to proceed with it, is based on the same

19 concept of looking at draftees who went to Vietnam

20 versus the draftees who did not go. In this case, largely

21 for reasons of time and cost, we have selected a sub-

22 sample of draftees.

23 These will be draftees who were drafted from

24 one state, New South Wales, the most populous state in

25 Australia and the study center is in that state. Those

1

2 draftees who went to Vietnam will be invited for a

3 morbidity examination and,as will a control group of

4 draftee who did not go. Draftees living out of the state

5 will be invited to the study center in Sidney as

6 was done with the Ranch Hand Study. In concept,the

7 design will have many similarities with Ranch Hand and

8 will benefit from the experience of Ranch Hand.

9 We would hope that with a somewhat larger

10 sample size and with perhaps, again we hope, a higher

11 compliance rate both in the Vietnam and the non-Vietnam

12 group that we will have quite a tight study design, but

13 again, I must emphasize this study proposed to examine

14 5,000 men, 3,000 who went to Vietnam , 2,000 who did not

15 and to relate within the Vietnam cohort any outcomes

16 which may be observed to probability to exposure of

17 Agent Orange and that study is still on the drawing

18 board waiting for government approval before it goes

19 ahead. Thank you very much.

20 DR. SHEPARD Thank you very much. Dr. Matthews

21 will be available to meet with the epidemiology biosta-

22 tistic subcommittee later on in the program. While I'm

23 on that point, that committee, the/ subcommittee on epidemi-

24 ology and biostatistics will remain in this room.

25 The subcommittee on information and education

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2 will adjourn to the room down the hall for their respec-

3 tive subcommittee meetings.

4 MR. WALKUP: Excuse me, Dr. Shepard. Since

5 some of us apparently won't be here to be able to hear

6 their responses, would it be possible for us to ask them

7 some questions now or for them to come back this after-

8 noon for us to do some followup on the information they've

9 given us today?

10 DR. SHEPARD: Yes. If you have questions now,

11 feel free to ask them.

12 MR. WALKUP: Fine. One is the birth defects

13 study that you were talking about has apparently a couple

14 of subgroups where there was a statistical, statistically

15 significant difference which was found and you said that

16 was probably related to chance. Could you tell us what

17 those subgroups were and the level of the statistical

18 significance?

19 DR. MATTHEWS: I did comment that I was not

20 directly involved or I meant to comment that I wasn't

21 directly involved with that study and I would not want to

22 comment in this forum without refreshing my mind about the

23 exact details of the findings. But my understanding is

24 that at the subgroup analysis level, once you divide it

25 up and look at different birth defects, that there was

very little evidence that what was found could not be explained by chance.

In other words, if you're talking red pennies, green pennies, blue pennies and brown pennies, then looking at just one color then the chances that you get more heads than tails would be somewhat more greater than chance with one of the colors. Now, I don't want to be pinned down because I would wish to have the data in front of me as I wasn't directly involved in that study myself.

MR. WALKUP: Does the committee have copies of the study available to it?

DR. MATTHEWS: Yes. I think it would be possible for a copy of the study to be found this afternoon. I apologize for not having it with me now.

MR. WALKUP: We appreciate you coming. Perhaps you can't answer this question, either, but in the Ranch Hand Study which we'll be discussing later, apparently there were also some, some areas where there were some indications that there might have been some birth defects associated with Vietnam veterans as opposed to the control fathers. Have you had a chance to look at that information and do any comparisons between what was found in your study and what was found in the Ranch Hand Study?

DR. MATTHEWS: Well, I guess it's more proper

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for Colonel Lathrop to comment on Ranch Hand. I think it would be fair for me to say that my interpretation of Ranch Hand was that if one took consideration of the fact that Ranch Handers were more aware perhaps of the likelihood of the birth defects, then the fact that all the excessive birth defects in Ranch Hand were in the milder defects group corresponding to skin blemishes and skin tags. I would tend to interpret the Ranch Hand findings in terms of a greater ascertainment of those minor defects because of that greater awareness in the Ranch Hand group which may have led them, we know that the attendance rate for examination was greater in the Ranch Hand group than in the comparison group. So I would tend to think that those findings were reassuring as Dr. Lathrop and the study group themselves suggested because one of the problems with all epidemiologic studies as I don't have to emphasize in this forum is that they're not randomized experiments, these observational epidemiologic studies.

The data need to be interpreted in terms of whether you selected the sample correctly. Of course, that was done very well with Ranch Hand, but the thing you don't have complete control over is who attends and of those who attend, whether they remember and report in

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2 a comparable fashion. It's those two things that even

3 with the excellent design that Ranch Hand had they didn't

4 get 100 percent attendance in the two groups. Of course

5 you can't be assured that you've got comparable reporting

6 and I would feel that certainly the interpretation that

7 is very plausible is that those minor birth defects might

8 be arising from differential attendance and differential

9 reporting in the two groups.

10 MR. WALKUP: Thank you very much, Doctor. One

11 other question if I might of Mr. Coombs. Could you

12 review for us one more time the actions that the Austral-

13 ian Government is taking towards veterans who served in

14 Vietnam regarding their concerns about Agent Orange,

15 what sorts of treatment or compensation are available to

16 those veterans pending the outcome of these studies and

17 the Royal Commission?

18 MR. COOMBS: We have now the equivalent of the

19 bill that's before Congress at the moment. Vietnam

20 veterans are treated exactly as veterans of all wars.

21 There's a special statute that included them in the

22 rehabilitation and repatriation process.

23 They have, I think it's fair to say, somewhat of

24 an advantage over American veterans in this one limited

25 way, that if an Australian veteran establishes that his

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2 disability, that is measurable is

3 connected in a way, that can be described as more than

4 fanciful, to war service, then the onus, as it were, shifts

5 to the administration to show that it is not connected

6 with war service.

7 In other words, once there's a connection that

8 can be seen and it's more than just suing, the administra-

9 tion has the onus of disproving it to us.

10 MR. WALKUP: So in Australia were I to assert

11 that I was exposed to Agent Orange in Vietnam, my child

12 has a birth defect which in some studies has been shown to

13 be associated with exposure to dioxin or in some --,

14 then the onus there would be on the government to dis-

15 prove my case until that were disproved and I would re-

16 ceive compensation any my child assistance from the

17 government, is that true?

18 MR. COOMBS: Well, there isn't a provision at

19 the moment for compensation of the child because the

20 circumstance has never happened before and I know of no

21 legislation in the pipeline to do that. The area I'm

22 talking about is the area where there is a health defect

23 in the veteran himself.

24 And it's fair to say also that there has been,

25 as I understand it, only one claim specifically based on

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2 exposure to herbicide, that was a soft tissue sarcoma, that

3 was paid, but paid on the basis not of any admission that

4 there was any causal connection. Indeed, in the con-

5 text of the denial that there was any causal connection,

6 but an acknowledgement that it couldn't be proved beyond

7 a doubt that it wasn't connected.

8 MR. WALKUP: Thank you very much.

9 DR. SHEPARD: Are there any other questions from

10 any members of the committee for either Dr. Matthews or

11 Mr. Coombs?

12 DR. KAHN: I have one. Dr. Matthews, you didn't

13 tell us the overall predictive power in the birth defects

14 study. Do you remember that offhand?

15 DR. MATTHEWS: Yes. I think the target power

16 was to have about 80 percent power of detecting an in-

17 crease at risk of 50 percent. Again, I wouldn't like to

18 pinned down without looking at the original document and

19 I apologize but it wasn't a study that I was actually

20 involved in. But my recollection is that the study was

21 designed to have an 80 percent probability of detecting a

22 50 percent increase in risk in relation to exposure. Now,

23 I prefer not to be quoted on that.

24 DR. KAHN: I understand.

25 DR. SHEPARD: Thank you very much. I would like

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2 to thank the guests from Australia for being with us

3 today. They've had a very busy schedule. It's been a

4 privilege for us to be involved in helping them around a

5 bit.

6 As you all know, I'm sure, there's a very close

7 relationship between our government and that of the

8 Australians over this issue. I hope that we

9 all agree that it has been a mutual benefit

10 to share information and again have an open commun-

11 ication so that all aspects of this whole issue can be

12 viewed from many perspectives,and we can benefit from each

13 other's activity. So we thank you very much for being

14 with us today and wish you well in your on-going visits

15 and on your trip back.

AGENT ORANGE REGISTRY STATEMENT

16 A couple of other announcements. I'd just like

17 to make, draw to your attention a short document that our

18 office prepared. This has to do with a statement as to

19 the uses and limitations of our Agent Orange registry

20 process.

21 There's been a good deal of ambiguity about what

22 that effort can and cannot do in the way or providing

23 useful epidemiological information, so I would just call

24 this two page statement to your attention. I think

25 we've got handouts in the outer room for those of you not

on the committee who would like to see this statement. I hope that it puts in perspective the uses of the registry, why we feel it's important to continue the process, but also outline some limitations in terms of its use in epidemiological research.

Also, we have provided for you a handout that I alluded to earlier, concerning the various pieces of information that we have shared with our environmental physicians in our ongoing efforts to keep them abreast of developments. I'd like now to call on Colonel George Lathrop, a principle investigator on the Air Force Health Study, who has been in recent days, briefing various committees and groups. George is indefatigable, and we're very pleased to have him with us this morning to present the results of this important study.

I have handouts here for the members of the committee and there are a few additional copies available for those who would like to follow along. This is George's presentation. Colonel George Lathrop, United States Air Force.

RANCH HAND STUDY

COLONEL LATHROP: Good morning, ladies and gentlemen. John Matthews did such an outstanding job of presenting the birth defects section, I believe we should-

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2 UNKNOWN: You don't have a microphone on your

3 podium, sir.

4 COLONEL LATHROP: Well, we'll have to get one,

5 then. Good morning again. I represent three principal

6 investigators not with me this morning, Lieutenant

7 Colonel Bill Wolfe, Colonel Patricia Moynahan, and

8 Dr. Richard Albanese of our group.

9 As most of you are very familiar with the

10 background of the Ranch Hand Study, let me present a

11 quick overview of the background of the study and its

12 design. Dr. Shepard does have copies of this briefing

13 and has brought additional copies of the report for those

14 of you that wish one.

15 (Vu-graphs being shown) - See pages 120-129

16 COLONEL LATHROP: The Ranch Hand Study is

17 White House directed and has been reaffirmed now by two

18 separate administrations. The study protocol has been

19 reviewed extensively and,as a matter of fact,five times

20 since its inception.

21 The Ranch Handers comprise a very unique, study

22 population as they were unequivocally exposed to herbi-

23 cide. As a matter of fact, approximately 1000 times more

24 than that of the average ground troop. The study design

25 itself calls for three separate elements, a mortality

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2 study, the first report of which was released on 30 June

3 1983, the second study, a morbidity study or study of

4 disease that's the subject of this particular overview.

5 The morbidity study is composed of question-

6 naires and physical examinations keyed to the known

7 reported dioxin effects as well as to veteran complaints.

8 The morbidity effort has been conducted by contract by

9 two nationally recognized organizations, Lou Harris of

10 New York and the Kelsey-Seybold Clinic of Houston, Texas.

11 The third element of the design is that of

12 followup and we intend annual mortality updates for the

13 next twenty years and a repeat of questionnaires and

14 repeat physical examinations in years 3, 5, 10, 15 and

15 20 following the baseline effort. The major findings in

16 terms of the proposed clinical end points for dioxin were

17 the absence of cases of soft tissue sarcoma, porphyria

18 cutanea tarda and chloracne in the Ranch Hand group.

19 We did find one case of soft tissue sarcoma

20 in a comparison member. In the fertility/reproductive

21 area, no significant Ranch Hand findings

22 were noted for sperm count or percent defective sperm.

23 Perhaps of some interest to the elderly gentlemen here is

24 that we detected an increasing sperm count with age.

25 The bad news is that compliance to that

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2 particular specimen also decreased with age. In terms of

3 fertility and infertility, there were five separate

4 measures, and they were all essentially negative.

5 In addition, miscarriage, still birth and live

6 birth rates showed no differences between the Ranch Hand

7 and comparison group. It's emphasized that for severe

8 birth defects and moderate birth defects, there were no

9 significant differences.

10 Most of the findings in the fertility area are

11 based at this time upon unvalidated self-reports. Small

12 numbers are involved and most fertility/reproductive

13 findings are deemed preliminary at this time as they

14 await verification by birth certificate and medical

15 record reviews.

16 There is a clinically non-relevant aberration

17 for limited or minor birth defects that has unfortunately

18 skewed the overall findings to statistical significance.

19 This fluke is not judged to be of clinical significance

20 and let me illustrate these points both for birth defects

21 and for neonatal deaths with the next couple of slides.

22 When we make a distribution severe, moderate

23 and limited birth defects, this is the kind of distribu-

24 tion that appears when categorizing for service before Vietnam and after Vietnam. The

25 definition of a severe birth defect is one that is life

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2 threatening or produces a major handicap throughout life.

3 The definition of a moderate birth defect is one

4 that requires constant medical care throughout the indi-

5 vidual's life. A limited birth defect is defined as a

6 birth defect requiring absolutely no medical care whatso-

7 ever.

8 As you can see, before Vietnam, the distribu-

9 tions were reasonably similar. After Vietnam they are

10 essentially identical within the distributions: for

11 moderate birth defects, very similar; after Vietnam, a

12 slight shortage in the Ranch Hand group. But the great

13 disparity lies with the limited

14 birth defects, only 8 percent before Vietnam, and 32 percent

15 after Vietnam. It's this aberration that throws things

16 into statistical significance.

17 Now, one might argue that distributional

18 difference is not the true case and one ought to look at

19 attack rates. Indeed, the attack rates by the birth

20 defect categories shows identical findings.

21 With regard to neonatal deaths, the findings

22 were of exceptional interest, but again, we're into the

23 low number category. We have taken these low numbers

24 and adjusted them to rates per thousand. As you can see,

25 before Vietnam and after Vietnam the rates of 13.4 and

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2 16.8 are remarkably similar. In addition, that's

3 remarkably similar to the

4 pre-Vietnam comparison rate of 16.0 per thousand. Now,

5 there are no statistical differences with respect to those

6 three rates. However, all three rates significantly

7 differ from the 3.4 and that suggests the possibility of

8 under-reporting in the comparison group post-Vietnam.

9 Again, it's emphasized that these data are

10 subjective self-reports, mostly by the wives, that have

11 not as yet been validated by birth certificate or medical

12 record review. Further, please recognize the difference

13 between a stillbirth and a neonatal death is one second

14 of life and that there is a natural stigma attached to the

15 label of stillbirth.

16 Also, the difference between an infant death

17 and a neonatal death is one day of life. Thus the sub-

18 jective reports are critically dependent upon exact times

19 of death and we regard this as an issue most likely to be

20 repressed by parents.

21 Thus, there is substantial reason to believe

22 that some of these reported deaths are misclassified. In

23 view of these real concerns of the validity of the self-

24 reports, the statistically significant finding of an

25 excess of neonatal deaths in the Ranch Handers is not

viewed with alarm or even as a solid finding at this time.

For cancer there is no significant difference in the occurrence of systemic cancer, that is, non-skin cancer. The Ranch Handers are not developing unusual cancers in unusual sites nor are they developing cancer at a younger age.

No soft tissue sarcoma was found in the Ranch Hand group. However, we found significantly more skin cancer in the Ranch Hand group but it was not possible to adjust for sun exposure, the primary cause of these tumors.

Most of the skin cancers were of the non-melanotic variety and mostly of the basal cell type, a very innocuous form of cancer that is easily cured by surgical excision. Many of us here today, including myself, have one or more of these cancers right now and particularly those of us from the south who enjoy the out-of-doors or high altitude recreational sports.

The observation of an excess of basal cell tumors in the Ranch Hand group is not viewed in an alarming way since this happenstance must be adjusted for sun exposure, a process that will hopefully be accomplished sometime this year. Here are the rates for skin

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cancer using two separate comparison groups versus the Ranch Hand group and then a breakout of all the systemic cancers.

As you can see on the bottom, there are no significant differences. The percentages are very, very similar. There are some small aberrations that you will notice because we're dealing with small numbers, digestive system 0 versus 5, -- genitourinary differences. These differences again are reflective of small numbers and they are not statistically significant.

UNKNOWN: Could you explain the difference between the two comparison groups --?

COLONEL LATHROP: The original comparison group was those individuals initially identified before we discovered that there was an over-selection error. All those that followed thereafter within the study were labeled and flagged in a special way to avoid possible bias or misrepresentation within the analysis.

So several of the chapters within our report used original comparisons, others used all the comparisons. Essentially all the inferences made within the report are based upon the original comparison group.

With respect to liver findings, the Ranch Handers self-reported more liver and porphyria cutanea

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2 tarda- like symptoms. These reports, however, have not

3 been verified as yet by medical records reviews.

4 The symptoms were not confirmed at the physical

5 examination. In fact, no cases were diagnosed, nor were

6 the symptoms validated by three separate laboratory tests.

7 Numerous minor laboratory differences were noted. Let me

8 add that numerous minor differences have been detected in

9 the study, as expected, that are statistically significant,

10 but of absolutely no clinical relevance.

11 The liver tests fall into this category. Any

12 other interpretation is simply over-reading of the data.

13 The findings were reported for the sake of completeness

14 and as a possible guide to other researchers. More

15 verified miscellaneous disorders were in fact reported in

16 the Ranch Hand group. We're not clear as to the

17 significance of this,

18 but I can assure you that in a military population, the

19 diagnosis of a non-specific liver disease is often a mask

20 for alcoholic cirrhosis as that label in a

21 military population would essentially be career damaging.

22 We're in the process of planning several case control studies

23 to find out, if in fact, that's what happened.

24 The psychologic tests for the Ranch Hand study

25 were exhaustive. They lasted six and three quarter hours,

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2 consumed essentially one day, and were composed of six

3 validated test batteries. For the more objective tests,

4 that is, I.Q. Halstead-Reitan Performance tests, there

5 were absolutely no differences with respect to the Ranch

6 Hand and comparison group.

7 However, for the more subjective psychologic

8 tests, as expected, the analyses reflected the substantial

9 effect of the educational level on the test results. In

10 particular, questionnaire administered by Lou Harris, the

11 Cornell Index and the MMPI showed substantial Ranch Hand

12 differences with respect to a variety of deficits.

13 Some of these parameters included fear, anger,

14 fatigue, depression, hypochondria, mania, hypomania, et

15 cetera, again, all of them in the high school educated Ranch

16 Handers. Only the parameter of isolation was noted to be

17 significant within the college-educated group.

18 We view that the psychologic findings are of

19 genuine interest, but again, because of the highly

20 subjective nature, additional verification measures are

21 indicated and full consideration of the Post-Vietnam

22 Stress Syndrome must be accomplished. In terms of other

23 observations, there was a poorer perception of overall

24 general health by the Ranch Handers as determined by

25 questionaire.

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2 Two leg pulses were diminished in the Ranch

3 Handers. The significance of this is absolutely unclear

4 at this time, but since there was no correlation between

5 the central cardiovascular findings, that is blood

6 pressure, heart rates, heart abnormalities, we do not

7 interpret the pulse deficits

8 to be a sign of early heart disease or

9 atherosclerosis at this time.

10 Clearly, for the followup examination, a more

11 detailed Doppler-type measurement will be conducted. There

12 were essentially no differences with regard to the nervous

13 system, renal system, immune system, or blood system. Al-

14 though there were small test differences, they were not

15 judged to be of clinical relevance.

16 No meaningful relationships between exposure

17 and the dependent variables in this study were noted and

18 that's a major finding in this study. The effects of

19 classical risk factors such as age, smoking, alcohol,

20 educational level, maternal age, paternal age -- were

21 observed essentially throughout the study.

22 Repeated demonstration of these classical risk

23 factors lend great credence to the overall validity of the

24 study. In conclusion, we believe that this study measured

25 the true health status of the study population and its

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2 comparison population to the maximum extent possible.

3 All significant findings both positive and nega-

4 tive are being followed up at this time, that is a collec-

5 tion of appropriate records to confirm or reject the sub-

6 jective findings plus detailed planning for the next

7 examination. There is at this time insufficient evidence

8 to support a herbicide causality.

9 In total, we believe that these findings should

10 be viewed as reassuring to the Ranch Hand group. I have taken

11 some reasonable heat on that phrase in the last week or

12 so. I would like to reemphasize it. That scientific

13 report is approximately 350 pages in length. There has

14 got to be some way of summarizing that

15 with the population that the Air Force serves, the Ranch

16 Handers. The very fact that we did not find any of the major

17 proposed end points, the very fact that they appear to be

18 in remarkably good health for their age to us is reassur-

19 ing.

20 These people have been bombarded with a media

21 blitz since the day they flew those missions in Vietnam.

22 That's continued throughout the entire controversy to

23 this day. We look at the Ranch Hand population in a very

24 simple way. If there are adverse health findings, clearly

25

they deserve to know those. Likewise, if there is an absence of findings, they deserve the peace of mind that goes with that. We feel that the word "reassuring" is totally appropriate for the Ranch Hand group. That concludes my briefing, Mr. Chairman. At this time I will entertain some questions.

DR. SHEPARD: Thank you very much, Dr. Lathrop, that was excellent. Are there any questions from members of the committee? Dr. Lingeman?

DR. LINGEMAN: Colonel Lathrop, I'd like to congratulate you on a fine presentation. Concerning the questions I had planned to ask, most were already answered. However, I have two questions. One is that you noted that there were six genitourinary cancers among the Ranch Handers and two among the controls.

COLONEL LATHROP: In the originals.

DR. LINGEMAN: Yes. Can you tell me what the types were, where were they located, in the kidney, bladder or elsewhere?

COLONEL LATHROP: We had if I recall correctly and I would have to go back to the original report, somewhere on the order of three bladder cancers in the Ranch Hand group and two in the comparison group. We looked at

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2 the latencies of these. One of the Ranch Handers

3 in fact had a zero

4 latency for bladder cancer. There were two testicular

5 cancers in the Ranch Hand group and zero in the compari-

6 son and a couple of miscellaneous cancers.

7 DR. LINGEMAN: No kidney neoplasms that you recall, renal?

8 COLONEL LATHROP: Perhaps one or two, I don't

9 recall off the top.

10 DR. LINGEMAN: My other question concerns the

11 skin cancer.

12 COLONEL LATHROP: Yes?

13 DR. LINGEMAN: How many were there?

14

15

16 COLONEL LATHROP: Well, it was reflected on

17 the slide and I believe the figure was on the order of

18 35 in the Ranch Hand group versus 25 in the comparison

19 group. I know the other comparison group had an addi-

20 tional, that slides not reflected in there, Dr. Shepard.

21 But again, we're talking reasonably small numbers.

22 DR. LINGEMAN: Has there been a histopatho-

23 logic review of these skin cancers by a group of

24 experts on skin cancers? Were these

25 found on unusual locations on the

1

2 body?

3 COLONEL LATHROP: No. These were head and

4 neck basal cell carcinomas for the most part. Pathologic

5 review has not been conducted. Of the fourteen biopsies

6 taken from eleven patients at the physical examination,

7 no chloracne was diagnosed, but we really were after

8 basal cell carcinomas. Most of those were diagnosed on

9 a clinical basis or by verified medical records.

10 DR. LINGEMAN: Were these histologically

11 verified?

12 COLONEL LATHROP: Yes, but not by this particu-

13 lar study. They were simply excised and removed by other

14 medical facilities and we verified that fact by the review

15 of medical records. We're in the process of trying to

16 get our hands on those slides.

17 DR. LINGEMAN: Thank you.

18 DR. SHEPARD: Any other questions by members of

19 the committee? Hugh?

20 MR. WALKUP: Colonel, I think we do appreciate

21 your reassurances. The one thing that I know some con-

22 cern exists among the veterans' community around is nor-

23 mally when we've heard results of studies such as this

24 we've heard of not so much the reassurances as the needs

25 for further research in particular areas,and we're hearing

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this presented in a different format this time. Could you give us that statement in the format of what you found that indicates the need for further research?

COLONEL LATHROP: Well, there are major differences with respect to these two groups. That is, we found an aggregation of many differences, mostly in the subjective areas. It's problematic at this point whether those subjective differences are reflective of true disease or whether they're due to differential reportings, perhaps based upon media bias.

Very clearly they need adequate and proper followup. To us the findings to date simply reaffirm the fact that the study protocol is on target and should be followed. We would think it incredibly remiss for the government to drop the study at this point simply because we didn't find tremendously alarming things.

What we have simply done by virtue of the mortality report and baseline morbidity report is show that there have been no major problems in the past nor can we find major problems at the present. It does not preclude these conditions emerging in the future.

We clearly believe this to be the most heavily exposed military population that served in Vietnam. There are a variety of reasons why one might postulate

that some of the proposed end points would not yet be apparent because of latency issues and would take a few more years to develop.

If the protocol was followed properly, we have the opportunity of bracketing that time period to indeed determine whether those aberrant effects will emerge. So we feel that the Ranch Hand study is viable and should be continued.

MR. WALKUP: Are there specific areas, Colonel, that the Air Force is intending to conduct further research on as a result of this report outside of the original protocol?

COLONEL LATHROP: No, essentially not outside of the original protocol, but please recall that that document says that we will use the baseline physical examination and all subsequent examinations as a mechanism for fine tuning each and every examination. A good example of this is, how do we explain the pulses.

We really don't know. But clearly there are better measurement techniques involved than simply putting your hand on a pulse and we're going to in fact validate whether the pulse measurements are a real finding or an aberration found at baseline. So there's a lot of things to followup and do -- with.

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2 MR. WALKUP : One final question, Colonel. On

3 the liver cancers, you had mentioned that those might be

4 alcohol related.

5 COLONEL LATHROP: I didn't say liver cancers.

6 Those are liver disorders.

7 MR. WALKUP: Pardon me. And then later -

8 COLONEL LATHROP: Liver cancer would be a very

9 startling finding and would be an alarming finding,

10 believe me.

11 MR. WALKUP: Then later you indicated that the

12 effects of possible risk factors including alcohol were

13 observed throughout the study.

14 COLONEL LATHROP: Yes.

15 MR. WALKUP: Did you not do some investigation

16 into the relationship between the alcohol factors that

17 you identified at that point and liver disorders that you

18 referred to earlier and was there any relationship between

19 those?

20 COLONEL LATHROP: That's an area within the

21 report that we need to shore up more than we did. Indeed,

22 there are some adjustments or covariate / risk factor

23 analyses that need to be done. Those are in progress

24 right now to further explore the relationship between

25 alcohol and the liver findings.

DR. SHEPARD: Any other questions from members? Yes, Dr. Anderson?

DR. ANDERSON: The question always arises as to whether or not there's residual dioxin in fatty tissues, adipose tissues. Do you have any plans in the future of any fat biopsy work?

COLONEL LATHROP: When someone can give me a femptogram sensitivity test, that is, 10^{-15}, I will certainly consider it. My personal view is that we do not have adequate test sensitivity at this point. You're talking 10^{-12}, clearly which will not be adequate to draw out sufficient levels for anyone to make valid inferences in my judgement.

I will also point out, however, that we have prepared for this eventuality and have saved a variety of urine, blood and semen specimens on all these individuals and have frozen them at -70 degrees. If and when a test system is developed that has sufficient sensitivity, we will be able to haul them out and test them appropriately for dioxin.

My personal concern is that we've gone through a minimum of twenty half lives since the time of Vietnam and how can one really ascribe any positive finding to the Vietnam experience versus the dioxin that one has

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inherently picked up from the environment.

DR. ANDERSON: Thank you.

DR. SHEPARD: Any other questions from members of the committee? Okay. If not, I'd like now to -

MR. MILFORD: Can we have questions from the audience?

DR. SHEPARD: All right. We will waive our rule since Dr. Lathrop is extremely busy and will not be able to stay for the wrap-up session at the end so we'll entertain a couple of questions from the floor.

MR. MILFORD: During the press conference -

DR. SHEPARD: Will you please identify yourself?

MR. MILFORD: Sure. My name is Lewis Milford. I'm with the National Veterans Law Center. During the press conference and the disclosure of the Air Force test results, there seemed to be some disagreement between the civilian and the military investigators about the characterization of the study as "reassuring." One question is; was there such a disagreement about the use of the word "reassuring" to charcterize the study and if there was, could you explain the points of disagreement and the conclusions you reached?

COLONEL LATHROP: I personally don't view that there was any disagreement whatsoever among the principal investigators. The briefings that were prepared have

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2 total agreement and consensus among the four of us.

3 The report was obviously released over four

4 signatures. I don't view that there was any substantial

5 disagreement and that should speak for itself.

6 MR. MILFORD: There was, if I recall at the

7 press conference, one of the civilian investigators who

8 seemed to have some serious concerns about using that

9 word "reassuring." That was made very clear during the

10 presentation. Was that not resolved before or was that

11 something that you simply don't see as an area of contro-

12 versy?

13 COLONEL LATHROP: I don't view that as an area

14 of controversy whatsoever. I think that has been tremen-

15 dously misrepresented by the press.

16 MR. MILFORD: In what sense?

17 COLONEL LATHROP: In the fact that it's been

18 over-dwelled upon in several news presentations. I do

19 not view that there is any significant essential disagree-

20 ment among the four investigators, period.

21 DR. SHEPARD: Yes, Peter?

22 DR. KAHN: I didn't realize he wouldn't be here

23 this afternoon. How many soft tissue sarcomas would you

24 have expected based on standard national numbers in a

25 group that size?

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COLONEL LATHROP: Using national numbers, we would expect to see one soft tissue sarcoma over the next fifteen years. The fact that we've already observed one -

DR. KAHN: The fact that you've found it --.

COLONEL LATHROP: No, statistical power is only one side of the coin. I think people have a tendency to over emphasize this. The very fact that you have not seen a case is significant in and of itself and a good background for this is that the Dow and Monsanto studies with very, very small sample sizes have shown four, I think it may be up to five or six cases of soft tissue sarcoma.

We've not seen any in the Ranch Handers. The very fact that we do not see chloracne in the Ranch Handers and we've not seen soft tissue sarcoma suggests to us that the Ranch Handers, while heavily exposed, these and the other military personnel were not as heavily exposed as the industrial chemical workers in this country.

And that in itself should be reassuring to the Ranch Handers. So what I'm saying is, we appear to be seeing disease coming out of the industrial populations and thus far we're not seeing it coming out of the military populations.

DR. SHEPARD: In the back of the room, yes?

MR. MARTIN: Dave Martin, Vietnam Combat

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2 Veterans Coalition. I'm an infantry combat Vietnam

3 veteran. I have one question about the word exposed,

4 Doctor. What do you mean by exposed? Do you mean hours,

5 do you mean amount times hours, you know, what's your

6 exposure index? How do you determine that?

7 COLONEL LATHROP: Our exposure index within the

8 Ranch Hand study is based upon the average number of

9 gallons that an individual handled during his tour in

10 Vietnam and also considers the average TCDD content of

11 the particular herbicide. Unfortunately, this is a thea-

12 ter specific herbicide index and we've not yet been able

13 to translate this to an individual specific herbicide

14 exposure index. We have experimental studies with C-123

15

16 aircraft at Eglin Air Force Base in progress at this time.

17 We feel by this time next year we'll be able totally to

18 refine our exposure index.

19 DR. SHEPARD: Yes?

20 MR. FALK: Yes, I'm Allen Falk. I'm chairman of

21 the New Jersey Agent Orange Commission and my question was

22 very much along the lines of Mr. Martin's. One of the

23 problems we have in explaining the Ranch Hand findings to

24 the larger ground troop population is the assumption on the

25 one hand these studies feel that these are the most

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heavily exposed personnel, and yet you find because of a lack of chloracne and other findings that there's a low level of exposure. What I'm concerned about is, have you really studied what precautions were taken during the time of Ranch Hand to monitor exposure so that we can really get some type of valid findings on how Ranch Hand personnel do compare to the exposure of ground personnel? I don't think it's necessarily something that's been concluded so far that the Ranch Hand personnel were the most heavily exposed.

COLONEL LATHROP: I think you ought to talk to some Ranch Handers. They would convince you far better than I. These people crawled inside the herbicide tanks, 1,000 gallon tanks and cleaned them. Every time they changed herbicides they had to clean out the tanks.

The crew mechanics as they walked around the aircraft were exposed to the dripping flight booms on both wings. These people did not wear shirts. They wore khaki pants. If you'd see some of the films that Dr. Young has, these folks were loading the herbicide onto the 123 aircraft with hoses breaking and spraying about them.

These people were drenched in it. The question that always arises is how were our pilots exposed because they obviously didn't maintain the aircraft. We've done

experimental studies within these aircraft to show that as they were sitting in the cockpit with their windows open, they were significantly exposed.

The reason that they flew with the windows open is that it was awfully hot in Vietnam and secondly when bullets came whizzing through that plane they would rather catch one without having the glass shatter all over them. So they flew with the cockpit windows open. This created a venturi tube action within the fuselage of the aircraft that drew the herbicide vapors from the back of the aircraft up front and out the cockpit windows. These pilots oftentimes got out of the aircraft with their flight suits dripping.

Now, recall the Canadian aircraft that caught on fire just a month or so ago and recall the commentator's descriptions of how that fire moved from the back of the aircraft straight forward. This is precisely the draft current that is created in an aircraft; it goes from back to front and this is how our pilots became exposed.

MR. FALK: But were there regulations that -

COLONEL LATHROP: No, there were no regulations.

MR. FALK: As far as gallons?

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2 COLONEL LATHROP: No. They viewed this as an

3 innocuous substance. There are memoranda in existance

4 that clearly show no precautions were felt necessary at

5 that time. It was an innocuous substance. These folks

6 were heavily, massively exposed to that compound, not to

7 the degree that the chemical workers were, however.

8 DR. SHEPARD: One more question. Yes?

9 MR. WILLIAMS: Dr. Shepard, my name is Mark

10 Williams. I'm the Chaplain of the American Legion Post

11 512 in South Jersey. I'm also the Outreach / coordinator for the

12 New Jersey Agent Orange Commission. I have two questions

13 for you, sir. One is, I understand you talked about peer

14 review of the Ranch Hand study. I believe from what I've

15 read that the Ranch Hand study is an excellent study, no

16 question in my mind about that. I think we're looking at

17 the wrong group, however.

18 COLONEL LATHROP: I will debate that with you

19 substantially.

20 MR. WILLIAMS: And I'm sure you'd win the debate.

21 I have others that would debate you -

22 COLONEL LATHROP: My counsel to all of you who

23 would doubt the Ranch Hand exposure is please talk to

24 these gentlemen. You can talk to me all day long and may

25 not believe me, but talk to the Ranch Handers.

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2 MR. WILLIAMS: Colonel, I have had calls from
3 anonymous colonels in the Air Force in McGuire Air Force
4 Base who have given me information that they would not
5 give me their names so let's not talk about -
6 COLONEL LATHROP: There is no such thing as an
7 anonymous colonel.
8 MR. WILLIAMS: American Legion, as a member of
9 that organization, I understand they viewed hundreds of
10 thousands of feet of the actual Ranch Hand spraying
11 operation and noted somewhat to the contrary that you
12 mentioned before that most pilots and navigators, flight
13 crew to be separated from that, but those on the flight
14 deck were actually going on board and coming off these
15 planes not such as drenched as what we were led to
16 believe. I would have to understand that the people who
17 actually reviewed that at the American Legion would be
18 more knowledgeable than I and possibly they're--. But
19 the second thing is, what did the National Academy of
20 Sciences and other organizations say about the Ranch Hand
21 study? Wasn't there some kind of dissention among some
22 other professionals that it was not as good a study as
23 we may be led to believe?
24 COLONEL LATHROP: I think the National Academy,
25 the National Research Council of the National Academy

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2 previously published its viewpoint on the Ranch Hand study

3 design. You're certainly welcome to ask those individuals

4 for a copy of that. There was a minority report,

5 however, that also

6 should be read with the same vigor which the main report

7 is read. The primary objection centered about the fact

8 that the Air Force was conducting this study and its pri-

9 mary recommendation was that the study be contracted out.

10 Indeed, as you have just seen, we followed that recommen-

11 dation to the letter.

12 MR. WILLIAMS: So there was some dissension

13 about the Ranch Hand study protocol from some scientific

14 group?

15 COLONEL LATHROP: The National Academy focused

16 on statistical study power of the mortality study which in

17 our judgment is an incredibly small point to dwell upon.

18 We clearly recognized and even heralded within the proto-

19 col that we have suboptimal statistical power for mor-

20 tality.

21 We did, however, have excellent, absolutely

22 excellent statistical power in the morbidity study that

23 we've just reviewed now.

24 MR. WILLIAMS: And your comment about the

25 American Legion reviewing the film, were you aware of this

1

2 and has anybody contacted the -

3 COLONEL LATHROP: My comment to you sir, is

4 again, talk to the bulk of the Ranch Handers. Clearly on

5 many missions when they did not take hits, where the

6 tanks did not leak and when the hoses did not rupture,

7 I'm sure their exposure was minimal.

8 However, to this day you can go to Wright Patter-

9 son Air Force Base and find a 123 aircraft by the name of

10 Patches, the most wounded aircraft I believe ever to have

11 flown; walk inside that aircraft and you will smell the

12 Herbicide Orange to this day. There is no way of getting

13 those vapors out of the aircraft. So in a vapor sense,

14 people are exposed when they're in the aircraft even

15 though they're not being hosed down.

16 MR. WILLIAMS: Those on Operation Mule Train,

17 did they have anything to do with the Ranch Handers?

18 COLONEL LATHROP: I'm not familiar with that.

19 DR. SHEPARD: Dr. FitzGerald, you have a

20 comment?

21 DR. FITZGERALD: Yes. I'd like to ask the

22 gentleman where he's referring to the American Legion

23 making this review of the film?

24 MR. WILLIAMS: I have been told that the Ameri-

25 can Legion reviewed film here in Washington of pilots,

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2 flight crews, navigators and handlers going in and out of

3 the aircraft and apparently hundreds of thousands of feet

4 of this film looking at the individuals and I don't know

5 if it was taken by the Air Force or some group and their

6 comment as I have heard and seen in print was that many of

7 the people on the flight deck when they went in, came out

8 the same way, they were not as Dr. Young alluded to

9 yesterday, if there's a burst valve in the back or if they

10 take a round and there's some spray going up in the plane,

11 it will go through in this total effect, but that didn't

12 happen very often.

13 COLONEL LATHROP: Again, talk to some Ranch

14 Handers with a different point of view.

15 DR. FITZGERALD: I'd just like to say that, you

16 know, I represent the National Office of the American

17 Legion and I'm unaware of this.

18 MR. WILLIAMS: You have not seen this?

19 DR. FITZGERALD: That's right, sir.

20 MR. WILLIAMS: And what is your position there

21 because I would like to find out who has given me this

22 information?

23 DR. FITZGERALD: I would be glad to research it

24 for you if you will give me some information on that.

25 MR. WILLIAMS: And your name, sir?

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2 DR. FITZGERALD: Dr. Thomas FitzGerald.

3 DR. SHEPARD: All right. One more. This is

4 the last one because we must move on.

5 MR. FEINSILBER: Colonel, have you discussed the

6 possible effects on your findings of the fact that 13 per-

7 cent of the Ranch Handers chose not to participate in your

8 study?

9 COLONEL LATHROP: The study participation in the

10 Ranch Hand study is one of the highest ever observed in a

11 national health study like this. Participation was just

12 phenomenal. We hope to drive it up even higher next time.

13 Approximately 95 percent of all individuals made the com-

14 mitment to us as they exited the Kelsey-Seybold Clinic to

15 participate in the next round of examinations.

16 We believe that the 13 percent that you're

17 talking about are mostly those that were discontented with

18 the military or separated individuals; and probably the

19 most likely explanation, are still on active duty,

20 actively participating in flying duties. We know as a

21 matter of fact 14 percent of both of our groups are

22 still actively flying either military aircraft or com-

23 mercial aircraft. Pilots notoriously do not like

24 to be examined

25 in the event that a minor defect is disclosed that could

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2 conceivably compromise their occupation. Our personal

3 guess is, and we did not fully analyze this, that the

4 majority of our non-compliants were pilots.

5 However, I can point out to you that during the

6 time that we did the examination that a number of Branif

7 pilots had joined the study.

8 DR. SHEPARD: Thank you very much. I'd like to

9 move on now and call on Dr. David Erickson from CDC to

10 give us an update on the status of the epidemiological

11 study. Dr. Erickson.

12 CDC EPIDEMIOLOGY STUDY

13 DR. ERICKSON: Thank you, Dr. Shepard and good

14 morning to some people I haven't seen for a year or so.

15 CDC at the moment has four components to its efforts in

16 studying the health of Vietnam veterans and I would like

17 to make clear that CDC, while it has some responsibilities

18 for reporting to the VA on these matters, is operating as

19 an independent agency.

20 The VA has no control over the design, the

21 conduct or the analysis of our study data. The four com-

22 ponents of our effort are first a birth defects study

23 which has been ongoing for some time now and which is

24 winding down and a brief description of our progress on

25 that study will be given by Dr. Mulinare shortly.

The other three components of our efforts are the following: first, what we are calling an Agent Orange Cohort study; second, what we call a Vietnam Experience Cohort study, and lastly a what we are calling a Special Cancers Case Control study. The two cohort studies and the cancer study are, I would say at the moment, just getting underway.

We completed draft protocols for these three studies last May. They underwent a fairly extensive peer review process during the summer. There were four independent scientific reviews, one by an ad hoc committee of CDC epidemiologists who work in the program areas outside of our own The Office of Technology Assessment scientific review was done in the summer.

A special meeting of the scientific oversight committee which was assembled for the Ranch Hand study also reviewed our study protocol and lastly, the Science Panel of the Agent Orange Working Group, interagency working group, reviewed our study protocols. Moreover, we solicited the opinions of some fifteen veterans' groups representative of national veterans groups for comment on our protocol.

Those reviews were completed in September, and we made a revision of our protocol which we believe takes

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account of most of the suggestions and criticisms received during the reviews. The two cohort studies will have three phases.

First, it will look much like the Ranch Hand study. There will be a mortality phase, mortality follow-up phase for all individuals included in the two cohort studies. There will be an interview phase and that will be done, the interview will be done with approximately 18,000 men who are a part of the Agent Orange study, 12,000 men who are a part of the Vietnam Experience study.

Then there will be an examination phase on a subset of those 30,000 men. In total we project that we will have a two to three day examination done in a central location on 10,000.

Finally, the Special Cancer study will be a case control study. It will depend upon the cooperation of a variety of cancer registries around the country. We are hopeful that we will include roughly 400 cases of soft tissue sarcoma, 1300 cases of lymphoma and roughly 200 cases of primary liver cancer and 200 or nasal and nasal pharyngeal cancers.

The sarcoma and lymphoma part of that case control study were what was recommended by CDC in its draft protocol. The primary liver cancer and the nasal

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2 and nasal pharyngeal cancer are the cancers which were

3 added to our protocol as a result of the review.

4 CDC has lots of expertise in epidemiology

5 and certain laboratory capabilities and infectious disease

6 clinical expertise. It's pretty short on expertise in a

7 lot of the areas which are important to these studies and

8 therefore we have made liberal use of consultants to

9 advise us particularly in four areas about what kinds of

10 things we have to do.

11 Those four areas are neurology, psychology,

12 immunology and hepatic diseases. In each of those areas

13 we have hired roughly four to five top national consultants

14 to provide advice as to our specific directions in those

15 areas.

16 An important issue in our mind is the fact that

17 we have obtained I believe it's called a certificate of

18 confidentiality which allows us to promise men who parti-

19 cipate in these studies that we will keep the data which

20 they provide to us under absolute confidentiality. This

21 goes quite a step further than the usual provisions for

22 privacy which are given under the Privacy Act of 1974.

23 Indeed, it goes so far that data which will be

24 given by the participants will not be available even to

25 surviving next of kin after the death of the participant.

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2 We are in the process now of reviewing proposals from
3 potential contractors for the interview phase of our
4 cohort studies.

5 We expect that hopefully that a contract will
6 be let in August this year, somewhere around that time,
7 and that pilot study interviews and main study inter-
8 views will begin relatively promptly after that date. We
9 are about to release an RFP for our examination phases
10 and the letting of the contract, performance of the
11 examinations will follow roughly six months after the
12 interview contract is let.

13 There's only one further issue I would like to
14 mention. As a part of our birth
15 defects study, every woman who was interviewed as a part
16 of that study, some 8,000 in all, were questioned about
17 whether they had ever been in Vietnam for any reason,
18 any particular way that they had served in the military
19 there. The two cohort studies and the Special Cancer
20 study which we are undertaking now specifically exclude
21 women.

22 We specifically excluded them for a variety of
23 reasons which I'd be glad to go into in a later session.
24 Basically we felt that if women veterans should be
25 studied, they should be studied in

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2 numbers sufficient that inferences could be drawn about

3 women and that our other plans which are designed to

4 provide the best answer for ground troops serving in Vietnam

5 would not provide us with very many women.

6 At the moment we are investigating the feasi-

7 bility of doing a study of women and expect to make some

8 recommendations on that issue this spring. Thank you.

9 DR. SHEPARD: Thank you very much, Dr. Erickson.

10 One question occurred to me, it may have to other members

11 of the committee. You described very nicely the two

12 cohort phases. Is it your plan to award the contract for

13 the examination and the questionnaire process to one

14 contractor , or will there be

15 separate contracts for the two phases?

16 DR. ERICKSON: We anticipate that there will be

17 a single contractor to perform interviews for both of the

18 cohort studies. We are uncertain at the moment whether

19 there will be one or multiple contracts with which to

20 perform the examinations for both of those studies.

21 If there are multiple examination contractors,

22 they almost certainly will not be split up on study

23 lines. The reason that we are uncertain about the number

24 of contractors for the examination phase is we are un-

25 certain whether anybody out there in the private sector

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2 will have the capability of giving us the throughput that

3 we need to maintain the schedule that we have set up for

4 ourselves.

5 Finally, there will be many other contracts so

6 there will be contracts, independent contracts signed with

7 each of the cancer registries which agree to participate

8 in the Special Cancer study. There will be a contract in

9 effect with the private sector firm to obtain controls

10 for that study.

11 In other words, the cases will come from

12 multiple registries around the country. The controls will

13 be gathered from those same geographic areas but by a

14 central contractor and lastly, there will be four con-

15 tracts for that study for pathology review.

16 There will be an independent review of patho-

17 logic materials from the cases of the four different

18 types of cancer. There will be specialists in liver

19 cancer. There will be specialists in sarcoma and so on.

20 DR. SHEPARD: Thank you. Any questions from

21 other members of the committee? Dr. Erickson informs me

22 that he also will not be able to be here for the wrap up

23 session, so I would again waive our usual rules and take

24 questions from the floor at this time. Would you please

25 identify yourselves for the purposes of the Recorder? Yes?

1

2 MR. FALK: Allen Falk of the Agent Orange Com-

3 mission in New Jersey. The specs for the interview phase

4 of the cohort study, is that for personal interviews or

5 telephone interviews?

6 DR. ERICKSON: It will most likely be done over

7 the telephone. Now, there are some unknowns in the equa-

8 tion here. Our preference will be to do them all over

9 the telephone. If our pilot study suggests that we are

10 unable to get sufficient participation or that there are

11 other problems that arise from doing interviews over the

12 phone, then we may have to shift gears.

13 MR. FALK: Our experience is that there is

14 great reluctance for some of the personal questions that

15 are part of these studies to be answered over the phone.

16 DR. ERICKSON: Yes. Well, as Dr. Mulinare can

17 tell you, we've had extremely good luck in talking with

18 veterans and non-veterans in our birth defects study on

19 very personal matters and that's been CDC's experience

20 generally. But if, as I say, if we do run into problems

21 in the pilot study, that's the purpose of the pilot

22 study, we may well have to shift gears.

23 MR. FALK: I'd just ask how long you propose

24 the telephone interviews will be?

25 DR. ERICKSON: No more than an hour. That's, in

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our experience that's pretty long but we find that if there is a personal interest on the part of the individual that they will persist and stick with you. Yes, sir?

DR. LAMM: Dr. Lamm, consultant in epidemiology and occupational health. Two questions. First question, would you define what the entry criteria are for admission to the Agent Orange Cohort and the Vietnam Experience Cohort?

DR. ERICKSON: Entry criteria for the Vietnam Experience study is relatively simple and straight forward. These will be men who served in Vietnam or the United States or Korea or Germany during the late sixties and very early seventies whose rank at discharge was not higher than E-5, who were in the Army. I think that about covers it.

For the Agent Orange study, we are still in the process of working with the Agent Orange Task Force, providing much help on matters of selecting individuals for the study. We're firming up the criteria for the choice of individuals for the Agent Orange study.

I can only give you the criteria in sort of broad outline. We will take all units, combat units which served in III Corps in '67 and '68. The daily records of each of those units will be reviewed and locations of the

units recorded.

After all of that is done, we will match the locations of the units on a daily basis with the locations of Ranch Hand and other herbicide applications. Then those units which have the highest number of encounters insofar as the records available today can tell us will be part of the possibly exposed or probably exposed group and those units which have the lowest numbers of encounters according to the records today will serve as the cohort at the other end of the exposure scale.

Finally, a third cohort will be chosen from an area in Vietnam where there is arguably evidence that no herbicides were used whatsoever.

DR. LAMM: So you will have three subcohorts in the Agent Orange -

DR. ERICKSON: Right.

DR. LAMM: With approximately 6,000 interviewees per and basically a high, low and none?

DR. ERICKSON: Right.

DR. LAMM: With respect to your case control study, do I understand that the controls will be non-cancer controls rather than using other cancer controls?

DR. ERICKSON: They will be non-cancer controls.

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2 The controls will be derived from the geographic areas

3 which the registries which participate in our studies

4 serve and those controls will be derived by the method of

5 random digit dialing which I believe you're familiar with.

6 In the process of our peer, of the peer review

7 of our protocol, there were people who suggested that we

8 ought to use, quote, diseased, unquote, controls. And we

9 were willing to go along with that suggestion but we

10 wanted some advice as to just what kind of diseases would

11 be eligible for the control group.

12 And I guess I can summarize it by saying the

13 people, peer reviewers who made the suggestion could not

14 come up with suggestions for what type of valid disease

15 control would be, and so we're back with dealing only

16 with normal controls, non-cancer.

17 DR. LAMM: What information will be acquired

18 -- control? Will it be a record review with respect to

19 the case? Will there be interviews? Will the work

20 histories be obtained and will -- a position that in

21 cases where you are dealing with relatives and kin of

22 deceased and in the controls you'll be dealing with living

23 people?

24 DR. ERICKSON: Interviews will be done. There

25 will be some record review, of course and confirmation of

1

2 the histopathologic diagnosis. But the major data

3 gathering will be as a part of an interview and that

4 interview will go over the occupational history and so

5 on.

6 Our specifications will require rapid reporting

7 by the cancer registry so that we don't anticipate having

8 deceased cases will be a particular problem except for the

9 liver cancers. And our plans at the moment are that for

10 liver cancer and for other deceased cases that next of

11 kin will be interviewed in abbreviated form, not as de-

12 tailed as living cases and that next of kin of controls

13 identified by the random digit dialing method will be

14 interviewed in a proportion similar to the proportion of

15 the cases which are deceased.

16 DR. LAMM: So the cases are then prospectively

17 registered rather than retrospectively -

18 DR. ERICKSON: Summer '84 on.

19 DR. SHEPARD: I think in the interest of time

20 we better move along. Dr. Erickson and Dr. Mulinare

21 will be here for the Science subcommittee, so those of

22 you who have additional questions, perhaps you can be part

23 of that committee meeting. I'd like to now call on Dr.

24 Joseph Mulinare who, to give us an update, you can stay

25 where you are,Joe, on the status of the birth defect

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2 study.

3 CDC BIRTH DEFECTS STUDY

4 DR. MULINARE: Thank you, Dr. Shepard.

5 In a word the birth defects study is in its analysis

6 stage, but I thought I'd just spend a minute and give a

7 brief outline of what we've done up to date for those

8 people who haven't been aware of what's been going on with

9 the study.

10 We began this study three years ago and the

11 interviewing for this case control study started in the

12 spring of 1982.

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20 The interviewing of the case

21 controls, interviewing of parents of children who had

22 birth defects and parents of children who did not have

23 birth defects started in May of '82 with anticipation of

24 completing interviews in about thirteen months. As we

25 were coming to the close of our interviewing phase, we

1

2 found that we were not getting, we were not finding

3 people as quickly as we were and we felt that we needed

4 to extend our interviewing sessions for several more

5 months to come up to the standards that we had established

6 for our study, that is, a location made of 80 percent and

7 interviewing approximately 90 percent of those who we

8 located.

9 In the fall, '83, we did come up to those

10 standards for the mothers who had children with birth

11 defects and we also had others, the controls that did not

12 have children with birth defects. Our analysis started

13 after collecting the final data tape in about December of

14 '83 and we are now in the process of that analysis.

15 The analysis is rather complex as you might

16 well imagine. We're using several advanced statistical

17 techniques, and we're in the process of doing several

18 ongoing analyses right now.

19 We anticipate that taking into account the need

20 for checking and rechecking our data to be sure that we

21 are confident of the results, plus the need to have

22 certain reviews that are just necessary for the papers and

23 the report to be published to complete the study in six

24 to twelve weeks. And if there are any questions I'll be

25 glad to try to answer them.

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DR. SHEPARD: Any questions from members of the committee? If not, fine. Thank you very much, Dr. Mulinare. I would like now to recess the full committee and divide up into our subcommittees. The epidemiology and biostatistics committee will stay here and the information education committee will adjourn to room 139 down the hall. Thank you.

(Whereupon, at 10:13 a.m. the meeting was adjourned to reconvene into committees.)

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2 AFTERNOON SESSION

3 DR. SHEPARD: I think we must reconvene and
4 get through the remainder of the agenda if we get started
5 now. I'd like first of all to complement the chairmen of
6 our two subcommittees. I think they've done a marvelous
7 job of chairing these two important subcommittee acti-
8 vities.

9 I think that it's a demonstration of a continued
10 interest that the attendance at these meetings continues
11 and it's to the credit of the subcommittee chairmen that
12 they've been able to make those subcommittee meetings as
13 productive as they have been. I'd like first to call
14 on Dr. Hodder to give us an overview of the activities of
15 the epidemiology and biostatistics subcommittee. Dr.
16 Hodder?

17 EPIDEMIOLOGY AND BIOSTATISTICS SUBCOMMITTEE

18 DR. HODDER: The first two presentations were
19 basically amplifications of the presentations that had
20 been made already that morning. Dr. Erickson in talking
21 about the CDC studies brought up a question that had been
22 raised before about female veterans, the women who had
23 served in Vietnam and updated us on the status of that.

24 The first question of course being the feasi-
25 bility. There were initially concerns that it would be

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very difficult to locate most of these women, particularly those who had changed surnames after getting married.

To their surprise, using Social Security Numbers, they were able through IRS to locate a fairly good percent. Joe, do you know the percentage on that? Was it 60 percent?

DR. MULINARE: He didn't mention it today. Over 60 percent.

DR. HODDER: And that was in part due to the way the IRS handled particularly secondary names. They would require only Social Security Numbers for that person. It was mentioned there were roughly 7,000 women who served in Vietnam of which 5,000 were nurses and that prompted further discussion about alternate ways of finding cases.

Specifically, Steve Lamm mentioned a study, I think it was by a Dr. Hanican, that was as a possible way of doing case control studies on these women. The other point mentioned on the question of women was whether it was necessary to do a separate study for women, the specific area where it would be, was in the study of fetal loss or in gender specific cancers. However, since most women were nurses, the

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2 exposure would be quite different from combat veterans.

3 They would be exposures around hospitals. In that case,

4 it would not be an Agent Orange

5

6 but rather a Vietnam experience type of study if it is

7 feasible to do it. There was a followup question on

8 soft tissue sarcoma raised at that point which I will

9 incorporate later.

10 Dr. Matthews continued his discussion of the

11 Australian morbidity study. He amplified particularly

12 some of the questions on the selection of cases; how

13 they would be looking, and what they would be looking for.

14 Specifically, he was separating the consequences of

15 exposure to war from / characteristics of the type of person who would go to

16 war.

17 That's the main reason, for example, that they

18 have chosen to look at draftees rather than career

19 soldiers They feel this is as homogeneous a group as

20 possible. They will be able to separate the post-war syndromes

21 that are common following any war from

22 war exposures. Also, as in the Ranch Hand study, they

23 will be able to adjust for associated variables like

24 cigarettes and alcohol that may be used differently in

25 that population.

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2 He feels that the interest in Australia is

3 predominantly for Vietnam experience, not just Agent Orange,

4 and that they feel comfortable that their groups, at least

5 in the mortality study are quite comparable.

6 The next presentation was a new study where

7

8 Dr. Kang reviewed the VA in-

9 patient file for patients with soft tissue sarcoma between

10 1969 and 1982. He used the ICD-171 Code as his initial screen,

11 finding 418 cases. In looking at those

12

13 who could have been Vietnam vets, when he looked through

14 the pathology, he found 394 where he could get the

15 pathologies; of those 234 were confirmed case soft

16 tissue sarcomas, and 151 were considered not likely to be

17 a soft tissue sarcoma.

18 Then he was able to link these records

19 up with the St. Louis Personnel files to finally come up with a cohort of

20 214 people with soft tissue sarcoma with a military

21 record. Then he was able to look at

22 the proportion of those who had been in Vietnam; 37

23 percent of those people had been in Vietnam; 61 percent

24 non-Vietnam; 2 percent in Thailand.

25 He then looked at another cohort of people

1

2 from the in-patient file, this time 14,000 people,

3 to see if the proportion who served in Vietnam was

4 similar in both groups. And in essence

5 the proportion was about the same.

6 The proportion of people with soft tissue

7 sarcoma and with RVN experience versus people from the VA in-patient file,

8 in general, seemed to be roughly the same. However, that was a

9 relatively preliminary report. There still are some things that

10 need to be done and Dr. Kang will follow up on these.

11 For example, he will check for latency and see if there's been a

12 change in frequency of diagnosis as time has gone on.

13

14 Dr. Williams presented studies on soft tissue sarcomas in

15 central east Michigan. He's very early on in planning

16 those studies but he discussed with us some of the

17 difficulties of ascertainment of case as well as diffi-

18 culties in choice of residents and how to define the

19 cases relative to your controls.

20 DR. SHEPARD: Thank you very much. Any

21 questions for Dr. Hodder? Okay. I'd like next to call

22 on Mr. Mullen to give us a synopsis of the Sub-committee that

23 he chairs.

24 EDUCATION AND INFORMATION SUBCOMMITTEE

MR. MULLEN: Thank you, Dr. Shepard. We had

25 two guest speakers in our subcommittee, one covering the

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2 upcoming films or proposed upcoming films and the other
3 covering the library system here at the VA to include the
4 video library.

5 Danny Jones spoke with us about the two films
6 that they are putting together at St. Louis. One is
7 geared to the veteran,his family and veterans' groups and
8 another which talks in more scientific language aimed at
9 the clinicians. And we didn't believe that the way in
10 which the VA was proceeding with this was proper since
11 that the most frequently recorded difficulty lies in the
12 inability of the intake personnel or the environmental
13 physician to show the sensitivity,compassion or expertise,
14 and particularly expertise with regard to the intake
15 personnel,which is causing somewhat of a mass displeasure
16 among Vietnam veterans who are going for the Agent
17 Orange exam.

18 We felt that the film for the clinicians should
19 be put together last if at all and that a film educating
20 the intake personnel and the environmental physician
21 should be put out and tested and then followed up by a
22 film aimed at the concerned veteran and his family,
23 explaining to him what he is to expect when he goes for
24 an Agent Orange examination. We felt that the film geared
25 in this direction would have been more effective than

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2 written material as sometimes it's tended to be pushed

3 aside and would give more of a review of the actual hands

4 on technique that could be inferred from written material.

5 Mr. Jones said he would look into that and of

6 course -- and get back to us with a final decision about

7 what's going to be done. The second presenter was -

8 DR. SHEPARD: Excuse me, Fred. I wonder, while

9 it's still fresh in everybody's mind, maybe I could

10 follow on. We did, during the break in fact, have a meeting,

11 and it was decided that we would accept the recommenda-

12 tion of your committee and we're going to go along those

13 lines.

14 What's going to happen next is Dan Jones and

15 his group in St. Louis will put together a questionnaire

16 that he will circulate among members of the committee and

17 we'll ask other veterans' groups to take a look at it and

18 also to make comments, additional items that might be

19 included with the film and very shortly thereafter put out

20 an outline of the contents of all three films again for

21 comment so that that will then form the basis of the

22 script for what we now are planning to do in terms of

23 three films, one geared to the veteran, one geared, I'm

24 not listing these in priority order just for the sake of

25 completeness, one geared to the veterans and veterans

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2 families; one geared to, as you say, intake staff of VA

3 medical centers and regional offices; and the third, for

4 more scientific treatment of the various research efforts.

5 So taking your recommendations in hand and proceeding

6 along those lines.

7 MR. MULLEN: Thank you, Doctor. I appreciate

8 that.

9 MR. FALK: He just made your day.

10 MR. MULLEN: Sure did. The second speaker was

11 Ms. Jean McVoy from the VA Central Library here who gave

12 us an explanation as to some of the written and video

13 tape material that's at the disposal of various veterans

14 and veterans groups to include copyright material from

15 various TV series that are not Agent Orange specific, but

16 geared more to the overall Vietnam experience.

17 From what I understand, these, some of these

18 can be on loan, but most of them are in three quarter

19 inch format so you'd have to have more or less specific type of

20 equipment. She said there is a master on all of these

21 kept, I believe, at St. Louis or thereabouts, and you can

22 get a copy of the film for somewhat under $100 and

23 virtually any format you want, to include 8mm and 16mm

24 films.

25 We did ask Ms. McVoy to recommend that those

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2 VA facilities having the Agent Orange film,

3 Agent Orange--Where Do We Stand, not to show the film

4 anymore, and again I'm sure this would have to be, this

5 recommendation would have to be passed onto higher

6 channels to get it okayed. But again, we're just reregis-

7 tering our displeasure with that film and again, reitera-

8 ting our request that it not be shown anymore.

9 We talked also with Mrs. Nancy Howard who is

10 going out with a SERP team to West Haven, and we have a little

11 difficulty with that, too, because I think we mentioned

12 in past meetings that you tend to find a little bit more

13 of a problem with staff in a major urban area at VA facilities

14 than you would find in smaller, rural areas where the

15 community is small enough where virtually everybody knows

16 everybody. And in a situation like that, you're going to

17 receive very few complaints which has in fact been veri-

18 fied through polls taken by various service organizations.

19 Most of the difficulties in the Agent Orange

20 screening examination program tend to lie in the major

21 metropolitan areas. And while we see the assignment of

22 Nancy Howard as a foot in the door and a foot in the

23 right direction in accordance with our past recommendation,

24 we felt that the system would be best served by looking in

25 those areas where you have the most complaints, and

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2 therefore can adjust your audit criteria accordingly.

3 By looking at a worst case situation and improving

4 that, there's bound to be a trickle down effect and you

5 can be covering more than one hospital at the same time

6 whereas if you go into a rural setting you might not

7 find anything wrong and you're not going to be able to

8 adjust your criteria for further inspection of other

9 facilities.

10 So while we do appreciate her assignment to

11 SERP, we do feel that it should be rearranged a little

12 bit for a better service system.

13 DR. SHEPARD: Can I just comment on that, just

14 so that it's very clear. This is the first of what I

15 presume will be a number of visits, and as I announced

16 earlier this afternoon, I am leaving for

17

18 Chicago to do some of the same kinds of things that

19 she'll be doing in West Haven.

20 I will then be going to Denver and also to

21 Boston. So I think we've got, we're trying to cover the

22 waterfront as quickly as we can given the limited staff

23 that we have. But again, this is one, you know, of a

24 series of visits she'll be making and I don't think there

25 was any intent to confine it.

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2 MR. MULLEN: No, no. I didn't mean to imply

3 that.

4 DR. SHEPARD: No, I know.

5 MR. MULLEN: Well, while you are going to

6 Chicago and Denver and then later on, Boston, I'm sure

7 that you have a list of your so-called worst case Agent

8 Orange screening program, those places where you're having

9 most of your major complaints. Is Chicago, Denver, Boston

10 among those?

11 DR. SHEPARD: Well, your question implies that

12 we have a list of VA hospitals that are not doing a good

13 job,or the implication is there. I don't, I'm not aware

14 of any such list. I'd be happy to receive that list.

15 MR. WILSON: We'll gladly give it to you.

16 DR. SHEPARD: Okay.

17 MR. MULLEN: I was referring to, as I mentioned

18 earlier in administrative procedures, if a case goes

19 to the Board of Veterans Appeals and it's not adminis-

20 tratively correct or there's lack of administrative due

21 process, the regional office will be notified and they

22 will be given what we call a variance, okay, which is

23 more or less a demerit and later on their service is

24 rated upon that. Now, by you going out to these three

25 places, you're just going out there to look it over.

1

2 You're not going out to grade. Or are you

3 going to make recommendations to SERP for the updating of

4 the criteria?

5 DR. SHEPARD: Yes, the latter. We want very

6 much to formalize the criteria or to more formalize the

7 criteria against which hospitals are rated on this issue.

8 So we want to develope a scheme for judging the quality

9 of how the programs are going in individual hospitals.

10 So this effort will be largely that, to see

11 what's there. To see what ways we can, what methodology

12 we can use for actually evaluating the program. But it

13 will be both. I mean, we will be evaluating the programs

14 and then establishing more criteria for further evalua-

15 tions at other hospitals.

16 MR. MULLEN: Okay. This is old business and

17 new business and that is the registry data. I understand

18 within the past couple of months you've made some inroads

19 to get the information out to reclassify it from the

20 85,000 misclassified diagnoses that were in the registry

21 from early on. Is that correct?

22 DR. SHEPARD: You say misclassified diagnoses?

23 MR. MULLEN: Okay. Let's just say not fully

24 useable.

25 DR. SHEPARD: Okay. Maybe it would be helpful

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2 if I gave a brief update on what's going on. Roughly, /85,000

3 examinations were conducted using the former

4 code sheet which has now been replaced with a new code

5 sheet.

6 And by the new code sheet, I think, were somewhere

7 around 15,000 examinations using the new code sheet. The

8 process for doing the examination and so forth and

9 recording the results of the examination in the patient's

10 record, in the veteran's record, has not substantially

11 changed over the years.

12 So the basic information is still there as it

13 has been. The only thing that has really changed is the

14 way in which we enter that data into computerized registry

15 data base. Now, one of the major differences that has

16 happened is that we are asking that the actual diag-

17 nosis and the code, the ICD-9 code, is incorporated in that

18 input process which was not the case in the previous one.

19 MR. MULLEN: It was ill-classified.

20 DR. SHEPARD: Pardon me?

21 MR. MULLEN: Was it ill-classified? I mean,

22 what prompted the change to a new code sheet?

23 DR. SHEPARD: Very simple. We were not able in

24 any kind of automated way to access the information. So

25 it's not a question of accuracy. We just put it into a

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2 computer in a more retrievable and meaningful way.

3 MR. MULLEN:

4 Have you attempted to go in and reclassify and

5 reinput any of the old material?

6 DR. SHEPARD: No.

7 MR. MULLEN: Are there plans to do that?

8 DR. SHEPARD: No.

9 MR. MULLEN: So if the purpose was to put the

10 diagnoses in under ICD-9 and all you had before was the

11 diagnoses and I don't know if there's a copy of that

12 diagnostic code in the rating schedule or not, which is

13 less specific.

14 DR. SHEPARD: It has nothing to do with the

15 rating schedule. These are medical records,not -

16 MR. MULLEN: Okay. Now, when you want to access

17 this material to determine rates of occurances for speci-

18 fic types of diseases, I would assume that's why you're

19 putting it into ICD-9.

20 DR. SHEPARD: Not really.

21 MR. MULLEN: Well, isn't that the purpose of

22 this registry to have this material accessible?

23 DR. SHEPARD: Only in part, Fred. As we've

24 said many, many times, the principle purpose of the

25 registry remains, as it was in its infancy, to

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2 provide a mechanism for concerned veterans to

3 get an examination, get their questions answered, hope-

4 fully, and be placed in a way in which we can follow up on

5 examination, share information with them and so forth.

6 As a spinoff we thought it would be a good idea

7 to get some kind of a feel for the kinds of problems the

8 veterans were experiencing that was, in a general way, part

9 of the previous input process. We felt that it would be

10 nice to know more precisely what kinds of, what diagnoses

11 are being made or confirmed in the field.

12 And that's what caused us to make the change.

13 But that is not the principle purpose. It never was and

14 can never really be the principle purpose for the registry

15 because it is a voluntary self-selected group of veterans.

16 So it is not for the purpose of comparing the health of

17 veterans in the registry with any other group of

18 veterans.

19 It's to get a feel for the kinds of problems

20 that these veterans are experiencing. Very little in the

21 way of analysis will be made of this data because it's

22 not data that can be analyzed or compared readily to any

23 other group because the makeup of this group is not

24 easily defined.

25 MR. MULLEN: So that 85,000 is the way it is

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now and it's not going to change?

DR. SHEPARD: The records are there; the information is there. If at some point in time we needed to have that information, if there was a very persuasive reason for having that information, we could reaccess that information, but it would be a hand count kind of thing

We would have to be persuaded that there was a very good payoff for doing that.

MR. MULLEN: So when we discussed this last time, I thought that we were led to believe that there was going to be some effort to go back in there and get those names in order to update that information and perhaps send a letter out advising them that they could come in for a new examination.

DR. SHEPARD: Okay.

MR. MULLEN: Now, is that abandoned?

DR. SHEPARD: It was discussed. We did discuss it. We looked into it and we thought that the benefit of doing that would not warrant the effort and the expenditure of resources that that would take. In other words, we don't think we've learned very much more information that would be of value to us or to the veterans.

Now, in terms of coming back for another

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2 for another examination, a veteran can always come back

3 for another examination. There's no limit to his coming

4 back for an examination if there's something -

5 MR. WILSON: They don't know that.

6 DR. SHEPARD: Let me clarify that. For admin-

7 istrative reasons we have not allowed repeated initial

8 examinations.

9

10

11 But there's never been anything said about a

12 veteran coming in for a followup examination. In fact,

13 many veterans have been reexamined a number of times and

14 have been counted as followup examinations.

15 MR. MULLEN: So he can come in and request an

16 Agent Orange examination, he will get an examination, but

17 even though it's in the same nature as the initial exam-

18 ination, it's considered a followup rather than initial

19 so it won't go down as two initial examinations.

20 DR. SHEPARD: That's basically correct, but the veteran will not necessarily receive another complete examination.

21 MR. WILLIAMS: Dr. Irving in Philadelphia told

22 Ms. -- and she says no, you may not go back for reexamina-

23 tion. Would you please convey this to her?

24 DR. SHEPARD: They can receive followup examinations but the initial exam will not be repeated. Obviously,

25 there is some confusion.

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2 MR. WILLIAMS: I'm sure there is, and as long

3 as it's clarified, that's all.

4 MR. MULLEN: Okay. We had a couple questions

5 that I was a little bit confused on. One of them is from

6 a gentleman who raised the issue of special studies with

7 programs for minorities groups, Blacks and Hispanics, or

8 an explanation as to how the scientific community was

9 integrating them into the studies presently

10 being undertaken to include CDC's epidemiology studies

11 and I can't answer that.

12 I asked him to refer to the scientific panel,

13 and I'm not going to touch on that any more. There was

14 also a request by a panel member that we set up,as a

15 future agenda item,an update on implementing, or update

16 on the Agent Orange resolution or proposed legislation

17 HR-1961 and implement a start up program due to the

18 impending passage of that bill by the Senate and I don't

19 know, I don't feel that that's necessary because I think

20 the mechanisms are already in place to deal with that.

21 But if perhaps Mr. Walkup would like to expound on that

22 a little more, I don't know another answer to give him.

23 Perhaps someone else could answer that.

24 MR. WALKUP: Well, that was mine. My concern

25 was twofold. One, in case the legislation or other

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2 legislation were to pass, what does the Veterans Adminis-
3 tration have in place to be able to implement that. And
4 the other is, what is the Veterans Administration position
5 on that and other bills that have been there.

6 I'm sure you've been called upon to testify
7 about those bills at different times. I think it would
8 be useful for the members of the committee to know the
9 VA's position on that legislation. So 1961 is one of
10 those, but there are other pieces of legislation which
11 have been and undoubtedly will be in the hopper. I think
12 it would be useful for our subcommittee to at least know
13 what the Veterans Administration is doing about them.

14 DR. SHEPARD: I don't feel it's appropriate for
15 me to address that issue at the present time. It's
16 really sort of outside the purview of this committee, but
17 I think if you're concerned about what the VA's position
18 is vis a vis the various pieces of legislation, that it
19 would be appropriate to address such a request to the
20 Administrator and get, find out what the Agency's position
21 is on the legislation.

22 In terms of implementing legislation that
23 already exists, I don't think there's any pat answer to
24 that. Various pieces of legislation have been passed over
25 the years and depending on the nature of the legislation

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2 various implementation strategies have been employed.

3 The one I know most about, because I was inti-

4 mately involved in it, was Public Law 97-92, and it's my

5 recollection that that, the implementing instructions were

6 not fairly promptly following passage of that piece of

7 legislation. Anything else for me?

8 MR. MULLEN: Yes. I have one other inquiry

9 from the floor from a state rep asking why our subcommit-

10 tee is not advising VA to change their stated position on

11 HR 1961 and use our subcommittee as a lobbying organism

12 and I didn't feel that that was appropriate and I didn't

13 address the question any further. I believe that, as full

14 committee chairman, if you would kindly state the

15 function of this panel for the benefit of those who are

16 not distinctly clear on it, I would appreciate it very

17 much.

18 DR. SHEPARD: Okay, I'd be happy to. I think

19 that the committee was originally set up in order to pro-

20 vide advice to the Agency on matters related to health

21 problems that might be ascribed to herbicide exposure.

22 I agree with you. I don't think it was ever

23 the intent nor do I think it would be an appropriate

24 mission of this committee to act as a lobbying effort to

25 influence legislation or even influence the Administrator

1

2 as to how he or the President ultimately should respond

3 to legislation.

4 There are other mechanisms for doing that. I

5 think it would subvert the real intent of this committee

6 to get involved in that kind of an effort. But I think

7 it's a legitimate question, but that's my personal view

8 on the matter, and I'd be happy to entertain any questions

9 on that point.

10 MR. WILSON: I'm the one who brought that

11 question up.

12 DR. SHEPARD: Excuse me, we're still on the

13 committee.

14 MR. MULLEN: I have nothing else.

15 DR. SHEPARD: Okay. Are there any other

16 questions of the committee to Mr. Mullen concerning his

17 subcommittee's deliberation? Okay. We now have time

18 for some questions from the floor so lets open it up.

19 Yes?

COMMENTS AND DISCUSSION

20 MR. WILLIAMS: Dr. Shepard, I just want to

21 clarify some misquotes that I made and some misunder-

22 standing that Dr. Thomas FitzGerald made to the Veterans

23 Administration. I don't know, is Dr. FitzGerald here?

24 from the American Legion.

25 DR. SHEPARD: Unfortunately, he had to leave.

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2 MR. WILLIAMS: Okay. He has since seen Mr.

3 Sommers who made the quote in his office at the American

4 Legion so apparently he did recall something. Mr. Conray

5 from West Virginia went through the archives on the ninth

6 floor. Jean McVoy gave us a nice tour of

7 what was up there, so he went up and dug it out and there

8 is a statement by the American Legion, John Sommers, De-

9 puty Director, to the House Science, Technology and

10 Subcommittee on Environment that he has reviewed not

11 hundreds of thousands of feet as I had said, that was

12 erroneous, but official Department of Defense films

13 showing operations of defoliation and supposedly no heavy

14 exposure to the crew.

15 Sommers pointed out that for several years the

16 Air Force has made a number of presentations stating that

17 they, the Ranch Hand people were the heaviest exposed

18 due to Agent Orange because they flew with cargo hatches

19 and windows open. And after reviewing the film he found

20 out that none of these windows were in fact open in the

21 films that he viewed.

22 And he testified again that he believed that

23 the people who were sprayed the heaviest were the soldiers

24 doing the backpacking in open trucks spraying the pari-

25 meter. And he goes on to state that the idea was is that

1

2 I did misquote the hundreds of thousands of feet, but

3 they have reviewed it.

4 It was not a study. It was a review, and Mr.

5 Sommers is quite concerned about the fact that the Air

6 Force is still using the statement that they were the

7 heaviest exposed veterans of the war. He says and I

8 believe that that's even considered -- at this time.

9 DR. SHEPARD: Well, I don't know how you would

10 settle that question other than doing studies, and I don't

11 know at this stage of the game how that could be possible.

12 I think that Dr. Lathrop's comments were based on his

13 extensive discussions with members of Ranch Hand group.

14 I don't think that seeing film footage neces-

15 sarily disproves that Ranch Handers were heavily exposed.

16 I think that, based on what I've been told, a large number

17 of them were. I think what's being said, it's my under-

18 standing, as an identifiable group of people, that they

19 were probably the most heavily exposed group that

20 served in Vietnam.

21 MR. WILLIAMS: And that's probably an incorrect

22 statement. It's some people's opinion.

23 DR. SHEPARD: Well, as an identifiable group

24 of individuals. Now, I'm sure nobody would say, would

25 quarrel with the statement there may have been other

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2 people who were not Ranch Handers who were more heavily

3 exposed than some Ranch Handers. I think that's quite

4 conceivable and I've never heard anybody in the Air Force

5 say that that's also, you know, not true.

6 That's why I was very careful to say that as an

7 identifiable group they were probably among the most

8 heavily exposed. Yes, Wayne Wilson?

9 MR. WILSON: I don't recall, just to clarify

10 what Mr. Mullen said,using the word lobby and I certainly

11 understand the distinction between lobbying and what the

12 supposed role of this committee is. You know -- and I

13 have been coming down here for about three years and

14 really don't enjoy coming down here any more.

15 You know, I recognize that this is to be an

16 advisory committee. I see that in some way those that

17 are not part of the scene here should have some way of

18 having some imput. I wrote in our Commander's Update

19 that I had talked to two or three members of the committee

20 and found that there was little interaction between

21 meetings other than some cursory review of some documents.

22 Now, we had, Mark and I, and some of the other

23 states had made some I think valuable suggestions in

24 terms of advice to the veterans part of this committee.

25 And I know Mr. Mullen passed that on to you folks. The

1

2 point I want to make is this, finally, is that the advice
3 that we give and the recommendations and advice that Mr.
4 Mullen and his representatives give never seems to come
5 to pass.

6 You know, when we talk about notifying 85,000
7 Vietnam veterans, we're not just saying that to say that.
8 We believe it's important that they know that they may
9 have a second exam or perhaps they should know that some
10 of the data they put in in 1978 or early 1979 may not be
11 good data, okay.

12 And so we never seem to get a clear answer nor
13 is the advice taken. When are we going to see, you know,
14 I remember this committee, Mr. Mullen and Mr. Woosley
15 saying that they wanted to see that film that the VA put
16 together.

17 And I remember sitting right here, correct me,
18 Mark, if I'm wrong, and saying that you guys were promised
19 that you would get a chance to see that film before it was
20 edited and before it was released, and you did not. I
21 still have not seen that film, and I know there are people
22 in this room who have not seen this film.

23 And you know, we want to come here and have some
24 very small successes in terms of the veterans we serve
25 by the hundreds of thousands outside of Washington. And

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2 I have said that I believe that perhaps I've been coming
3 down here too many years to too many advisory committee
4 meetings because it's not clear to me as a Vietnam
5 veteran who works every day in this business what the
6 role of this committee and if their advice is really
7 sought.

8 And I'm not sure, my boss is here, and I'm not
9 sure that I may just ask him, Allan, I'm not sure I want
10 to come back here anymore because I'm not, I don't really
11 feel that those of us who travel many thousands of miles
12 to come here, I don't think anyone really cares about our
13 advice. And we don't have enough -No, Mr. Mullen, Mr.
14 Walkup, Mr. Woosley, I work with 100,000 Vietnam veterans
15 in the State of New Jersey.

16 Fred has called me once. I have called you
17 once. Mr. Woosley has never called me. Dr. FitzGerald
18 doesn't like me. He has never called me. And you know,
19 I have to wonder. I come here. I think that I have a
20 right to speak and to be a part of the process, not a
21 member of the committee, sir.

22 But we have no contact, okay. It's like, it
23 seems like it's very staged anymore. Now, maybe this is
24 my perception and maybe what you ought to do is ask some
25 of the Vietnam veterans that run programs what their

1

2 feelings are. I don't speak for them. I'm telling you

3 what my feelings are.

4 And I'm very disappointed that we don't seem to

5 have a free flow of dialogue and bringing to fruition

6 some of the things that Vietnam veterans outside of the

7 crystal palace here want. And I'll bet you, maybe you

8 ought to ask the Vietnam veterans whether 85,000 letters

9 should be sent to guys that were previously examined

10 under the screening exam and see what they say.

11 Maybe you shouldn't ask me or Mark or Mr.

12 Credle. Maybe we're not as objective as we used to be.

13 But I think at some point other people have to have a role

14 in this business.

15 And I'm not just going to sit on the veterans

16 because I'll tell you. None of you doctors and none of

17 you scientists have ever called, either. And I'm going

18 to tell you one more time, I'm going to invite an open

19 invitation to anyone of you, anyone of you at the

20 expense of the State of New Jersey, is that all right, to

21 New Jersey and spend a couple of days with our Commission

22 and we believe we're in the trenches and with our Vietnam

23 veterans and their families.

24 I invite anyone of you at State expense to come

25 up. At least it will be money well spent for us, and I

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2 think you'll get to see some of the things you don't see

3 in this room. And I think this committee ought to think

4 about perhaps maybe holding some meetings in some of

5 these Commission states.

6 Apparently, it would be more convenient for Mr.

7 Walkup to travel to Minnesota than all the way to Washing-

8 ton. So these are what's very much on my mind. These are

9 the things we're talking about.

10 And I'm going to leave here today, and I know

11 other people will, very frustrated with what takes place

12 here anymore. Okay. Thank you.

13 DR. SHEPARD: Thank you, Wayne. It is a frus-

14 trating issue, there's no question about it, and I'll be

15 the first to admit it and I think you. I share many

16 frustrations. Just for the record, however, you will

17 recall that I did spend a day in New Jersey with the

18 Commission.

19 I consider that a very fruitful and very

20 educational effort. Maybe it's time to do it again. I'll

21 be happy to certainly consider that. I haven't received

22 an invitation from you, but I would be happy to -

23 MR. WILSON: We would prefer that you not come.

24 I would be interested in some of these other members of

25 the committee, actually.

1

2 DR. SHEPARD: Okay. Then I would suggest you

3 write them.

4 MR. MULLEN: I do have a recommendation. Since

5 you're not going to go into the registry and recode the 85,000 diagnoses that are

6 in there and in spite of the fact that I've heard that

7 a lot of Vietnam veterans are not getting their Agent

8 Orange newsletter, I think that's the exception rather

9 than the rule, it would be very simple to put a blurb

10 in the next newsletter that goes out stating you are

11 entitled to another examination if you haven't had one

12 and that would dispense with that because even though

13 the 85,000 diagnoses may not be classified under ICD-9,

14 I would venture that most of the addresses are still

15 intact. And that would put an end to that.

16 DR. SHEPARD: Okay. Yes? Dr. Hodder?

17 DR. HODDER: I'm just curious as to why would

18 you want to go back into the 85,000. If a

19 project came up where that it would be of benefit to do

20 that I could see it, but is it worth taking the time -

21 MR. MULLEN: If I'm not mistaken, that was one

22 of the main gripes of GAO and Capitol Hill when they

23 first undertook to look at that. They were dissatisfied

24 with the classification of diagnoses, was one of the com-

25 plaints, and I thought for that reason and since the VA is

1

2 undergoing another GAO study of the registry, that that

3 would be of prime importance.

4 Not only that, I passed on this recommendation

5 to the full committee through the recommendations of my

6 subcommittee and that's how I answer that.

7 MR. WALKUP: I think some of the concerns that

8 veterans have after this has been discussed for a while

9 is probably misinformation more than anything, and what

10 Fred's asking you is to get something clarified. I think

11 some vets are concerned that maybe this means that they

12 didn't get a good exam the first time; that they didn't

13 look for the right stuff or something like that, or that

14 somehow their name got lost and that something else

15 happens, nothing's going to happen to them.My name got

16 lost. I don't get the newsletter.

17 MR. WILSON: Me, too.

18 MR. WALKUP: Those kinds of things happen .

19 You know, at one point we were

20 going to redo the 85,000, and then we weren't. That kind

21 of information gets out a lot of different ways, and if

22 it just gets clarified, just tell people this is how it

23 is now, this is what's happening, then at least

24 people know that they can go back for a followup

25 reexamination which some people apparently are being told

1

2 that they can't have.

3 MR. MULLEN: There's another thing here. Be-

4 tween and during lunch break between subcommittee and full

5 committee, I stopped to talk to Mr. Woodall in the hallway

6 and he told me within the past couple of months there has

7 been an effort to go in and codify those diagnoses. So,

8 you know - what is the story.

9 MR. WILSON: Is that right, Mr. Woodall?

10 MR. WOODALL: Yeah. I talked with them, you

11 know, about three months ago, before the holiday break

12 and we've got some problems in that early part. We've

13 got some address problems. We've got some -- that people

14 don't receive their newsletter and saying what is the

15 problem. I think there's a large number out there that

16 have some concerns about our '78 and '79 reviews.

17 DR. SHEPARD: Well, we'll certainly look into

18 it. I would like the input of the state organizations

19 on that point.

20 MR. WILSON: Mr. Mullen brought this point up

21 on September first.

22 DR. SHEPARD: Wait a minute. Now, you're not

23 hearing me. I didn't say that it's a new, the point's

24 never been raised before. What I'm asking for is addi-

25 tional input into where the confusion may lie in

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2 terms of running this on the part of the VA to

3 reexamine any veteran who is concerned or continues to

4 be concerned. Number two, the misconception about somehow

5 if they weren't in the first 85,000 then something, the

6 examination wasn't thorough, or we've done something dif-

7 ferent to change the process; somehow, they need to have

8 a new examination because the other one wasn't as good

9 and that's why we changed the process.

10 You see, I can understand how those misconcep-

11 tions are there, but they really aren't valid. We have

12 not changed the examination process per se.

13 MR. WILSON: Yes, you have.

14 MR. WILLIAMS: The intake is different, Doctor.

15 DR. SHEPARD: Well, not substantively we have

16 not changed it.

17 MR. WILSON: Okay. And you were not required to

18 notify veterans before 1981.

19 DR. SHEPARD: That's not part of the exam.

20 MR. WILSON: That's important. '78, '79, '80

21 veterans were not required to be given the detailed

22 results of their exam, and many were not. That's important.

23 That's a problem that veterans still have very much so

24 and that and they never received the results. Now, you

25 know, this is something, this is not new to you, Barclay.

1

2 We've discussed this for years now.

3 DR. SHEPARD: That's an after the exam fact.

4 That's not the exam itself.

5 MR. WILSON: It's very important.

6 DR. SHEPARD: Okay. I don't doubt, I don't

7 question that point.

8 MR. WILSON: When do we ever pin something down

9 here? That's what I want to know.

10 DR. SHEPARD: Okay. I'd

11 like to call on Chuck Conroy. I'm going to call on Chuck

12 Conroy because he has an interesting piece of information

13 I think should be shared. Chuck is the representative

14 from the State of West Virginia.

15 MR. CONROY: Chuck Conroy,coordinator for the

16 State of West Virginia Agent Orange Program. I like

17 Wayne have been coming here,not as long but for the last

18 couple of years now, and I've heard a lot of dialogue

19 relative to the satisfaction or lack thereof with the

20 VA's Agent Orange exam.

21 Most of you know that in our West Virginia

22 Agent Orange Program we are advising veterans that we

23 would like them to initially go to the VA to receive

24 their Agent Orange screening examination. There were some

25 veterans on our advisory committee that voiced the

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2 concern that we would have a substantial number of

3 veterans that would balk at going through the VA.

4 I thought it would be interesting to provide

5 to the committee, an update on our report. As of this

6 morning, we've mailed out 27,000 of these

7 brochures, one to every state Vietnam veteran. As of

8 this morning we've had 3893 responses requesting testing.

9 Of those 3893 respondents, 76 as of this

10 morning have balked at going to the VA. In other words,

11 they have said that they will in no way, shape or form go

12 to the VA. This represents, if my math serves me right,

13 approximately 2 percent of the West Virginia Vietnam

14 population.

15 So I thought I would like to present that

16 information and let the audience and committee draw

17 whatever inferences they'd like from that. Thank you.

18 DR. SHEPARD: Thank you very much. Yes, Dr.

19 Lingeman?

20 DR. LINGEMAN: Having attended

21 these meetings and having been a member of this commitee for four

22 years, I have noted that the committee has received

23 concrete proposals for scientific studies.

24 For example, we have a protocol

25 for the epidemiologic study we can look at, and we can

1

2 evaluate and we can make specific recommendations.

3 But the some/ of the nonscientific members of the panel and some /of the people

4 who sit in the audience complain constantly /about what the VA

5 isn't doing. It seems that there is not a united effort

6 on the part of all these various groups, including

7 the different state groups, and those members of veterans

8 groups that sit on this committee. / It seems to me that

9 all of these different

10 groups could present some sort of a proposal that we

11 could act on as a committee, that all of you would agree

12 on, perhaps Mr. Mullen could

13 serve as a chairman to represent all these groups.

14 In other words, instead of bringing up one point at a

15 time and arguing and complaining about it, a

16 written protocol could be prepared stating the complaints and specific

17 recommendations about what should be done

18 so that they can be evaluated systematically by the committee.

19 MR. MULLEN: They're in the minutes. They are

20 listed.

21 DR. LINGEMAN: But the / recommendations are so fragmented over a

22 period of time. There's never any agreement on what

23 should be done.

24 MR. MULLEN: We have to keep hitting away at

25 the same problems over and over and over and we get one

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2 and the rest slide and then we get one the next time and

3 the rest slide. And that's the problem we're having. We

4 have been complaining about intake examinations for the

5 longest time, yet there's still discrepancies and

6 difficulties out there in the VA centers.

7 If there weren't, the VA would not be sending

8 out inspection teams. And they would not be trying to

9 assemble a standard set of criteria with which all the

10 intake centers must comply. And you know, Dr. Lingeman,

11 we've been complaining about that for a long time, but

12 we get nowhere with it.

13 We're only asking for certain things and it's

14 the same thing over and over and over. But they're of

15 record. They are of record, and I don't think that it's

16 as fragmented as it may seem because I think all veterans

17 groups no matter whether they're the traditional service

18 organizations or the individual Vietnam veterans groups

19 that are out there in the audience, we all want the same

20 things.

21 We want a little equity and we want this

22 equity doled out in the proper manner. We have to answer

23 questions every day. We deal with the veterans one on

24 one. All we're looking for is the answer to give these

25 people. Yes, they said they're going to do it.

1

2 Well, two things have happened that have been

3 concrete. One, we asked for a routine pelvic examination

4 at our last meeting and that just came out,

5 routine pelvic and breast examination for all female

6 veterans.

7 Barclay acceded to one of our requests for

8 rearranging the film formats or the method of release

9 and he's also stated today, yes, you can have another

10 examination. But these are three concrete things that

11 have arisen out of our sub-committee meetings, three. And

12 I've been coming here as long as you have, Dr. Lingeman.

13 DR. LINGEMAN: Well, why can't this all be put

14 together in one document and why can't it include what

15 has already been done --

16 MR. MULLEN: For a simple reason. First of all,

17 different veteran service organizations have different

18 political preferences. Some are more conservative than

19 others. Some take different stands on the Agent Orange

20 issues than others.

21 Some are for the legislation paying compensa-

22 tion; some are against. When you've got those different

23 types of ideologies, it's hard to please everyone and

24 you know, you can't, you have to solicit from each

25 individual organization a list of what's to be done and

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2 then have someone compile the most frequent and the most

3 practical recommendations and that's the only way it

4 can be done.

5 DR. LINGEMAN: Isn't that what the CDC did when

6 they wrote the protocol for the epidemiologic

7 studies? This proposal was subjected to review by many

8 individuals and scientific groups. The CDC

9 had lots of input and finally they, the people who are

10 responsible said okay, this is the protocol.

11 MR. MULLEN: Where was it put together, though,

12 Dr. Lingeman?

13 MR. WILSON: CDC.

14 MR. MULLEN: At CDC, in one central location.

15 We're from all over the country. We don't have one

16 individual area of study. We don't have the same area

17 thus we can't get our ideas together.

18 MR.WALKUP: I think she's got a good idea.

19 It could be that it might be a good start

20 to recommend that the Veterans Administration hire a

21 consultant group to attempt to investigate problems that

22 we've raised and that other vets have raised and recom-

23 mend -

24 MR. WILSON: That's like asking, you know -

25 MR. WALKUP: Wait a minute. No , I think it's

1

2 the same thing and that we come up with a protocol of

3 concerns and a schedule of how those could be investi-

4 gated and alternatives to resolution.

5 DR. SHEPARD: Excuse me, just a minute.

6 I've got an important appointment ; I've got to leave

7 now. Dr. Hobson will take over. I just did want to

8 make this point, that if any state organizations,

9 commissions or veterans groups have knowledge of any

10 veteran who is not on the mailing list, if they will

11 please give us the name and address of that veteran, we

12 will make certain that the veteran does get on the mailing

13 list.

14 To my knowledge,nobody has provided us with that

15 information,and we have always stated very clearly that

16 we're open to receive any kind of information updating.

17 In fact, we've repeatedly requested veterans to maintain

18 their names on the mailing list,and if it isn't done

19 through the local VA hospital, we will do it in this

20 office. Thank you very much. Dr. Hobson will take over

21 for me because I have to leave.

22 DR. HOBSON: Is there anyone else who would

23 like to raise any points either from the

24 audience or from the panel?

25 MR. MULLEN: I would like to make just one

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2 closing remark and let you finish up and that is that

3 it's easy to sit down in a group and talk things out,

4 okay, when you have a common goal. You have a common

5 goal. You're goal was to put together a protocol with

6 certain end points, okay.

7 We can't do that for the simple reason it's

8 almost logistically impossible. You know, we can't make

9 conference calls. Even if we could, I doubt if you would

10 get us all in one place at the same time because of our

11 varied duties.

12 The fact remains, the VA asked service organi-

13 zations long ago, long ago including the VFW which I

14 was working for at the time, to go out to your membership;

15 get us a list of all the problems that you've got and

16 we did. I think VFW came up with almost 50,000 responses.

17 We put it together, gave it to the VA. Nothing

18 happened. And the same problems still exist. So while,

19 you know, it has merit, I think it's logistically impos-

20 sible because it involves policy rather than science.

21 MR. WILSON: Let me just say one thing, too,

22 Dr. Lingeman. We have made countless recommendations.

23 You know, we don't want to come here just to criticize

24 and complain. We have made countless recommendations

25 that would include our common objective, to serve Vietnam

1

2 veterans and their families at levels that deal with

3 intake or examinations or notifications following exams,

4 the kind of basic stuff while we wait for the science to

5 be done.

6 I can tell you, and I have the documents to

7 prove that those recommendations have generally fallen

8 for the most part on deaf ears. Now, I have heard Mr.

9 Mullen talk for almost three years now, and he's absolutely

10 correct when he says that there have been many, many,

11 many recommendations and suggestions, whatever you want

12 to call them, made through the chair and I can show you

13 in reviewing the transcripts of these meetings, countless

14 occasions with the veteran representatives and the other

15 people, and the followup was never implemented on those

16 even rudimentary types of suggestions that would improve

17 the things, the basic things that we have difficulty with

18 the VA.

19 As an example, 60 percent I understand of the

20 environmental physicians today were not participants in

21 the program at Silver Spring. So we have three fifths

22 of the people examing veterans today who were not part of

23 that original group and may not be as up to date according

24 to the veteran organizations as the original group of

25 people.

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2 The VA says that they don't have the money to

3 bring them in until possibly 1985. Now, you know, I have

4 to question that considering some other reports that we

5 have. So we aren't getting satisfactory answers to some

6 of the questions that are raised. I recognize the

7 chairman, Mr. Falk.

8 MR. FALK: Thank you. I feel I have to comment

9 on my impressions because I don't have the personal

10 frustrations that Wayne and some of the rest of you do

11 have. I haven't been coming down through the years. The

12 Commission in New Jersey has been sending Wayne and Peter

13 and Mark and we've been getting reports from them back,

14 but I think it was at the stage where I did want to see

15 for myself what was happening.

16 I am very concerned as to why -- mainly con-

17 cerned with science today. I'm not a scientist or doctor.

18 I'm an attorney, but I purposely chose the scientific

19 subcommitee to sit through because again, the feeling

20 that I get back in New Jersey dealing with the veterans

21 is that time is running out on answering the question.

22 The science that I heard here today broke down

23 to two parts. One is the CDC study and the long term

24 studies are still a long way away. The second is the

25 studies that are complete, the Ranch Hand and the STS

1

2 studies at this point can be summarized as the Colonel

3 said, basically by reassurance.

4 And it seems to me that like it or not that is

5 where you and the VA is heading in the short term, and

6 even to the long term, until the CDC studies and some other

7 studies come back; and I think you have a real problem on

8 your hands because the veterans are not going to accept

9 that type of reassurance attitude for the next two years.

10 The science tests will have to move faster and the

11 answers have to come along with a level, if there's

12 going to be reassurance, it better be reassurance that

13 the veterans can look at and accept and I don't think

14 you're going to have that level of acceptance.

15 DR. HOBSON: Why do you think we won't have it?

16 MR. FALK: I think there are too many other

17 indications from accepted scientific areas that there are

18 problems in these same areas. With the soft tissue

19 sarcomas, I didn't come up the soft tissue sarcoma area

20 as a problem area. The scientists and the veterans de-

21 fined that as an area to put in the studies.

22 There was a good science indicator that there

23 is a problem with soft tissue sarcomas. I sat through the

24 science meeting here and found that the VA studies

25 apparently conclude that not only is it not a substantial

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2 problem but the studies that they have show there are

3 less Vietnam veterans with soft tissue sarcomas than non-

4 veterans.

5 I don't think the veterans are going to accept

6 that science. I can't give you a valid scientific com-

7 parison as to all the other studies that are out that

8 challenge that finding, but if you go up on the Hill and

9 say our conclusion is that there is absolutely no soft

10 tissue sarcoma problem, I can tell you from my experience

11 that veterans are not going to accept that scientific

12 conclusion.

13 DR. HOBSON: Let me correct one thing. The

14 results that we have do not show that there are less. It

15 shows that we were not able to demonstrate more. That's

16 all.

17 MR. FALK: Well, the numbers I heard here were

18 actually less amongst the Vietnam veteran group even

19 though you didn't come out and make that statement, that

20 was the -

21 DR. HOBSON: This becomes a matter of inter-

22 pretation of science and the scientists' interpretation

23 is that it did not show any difference between the two

24 groups. That was all. Yes?

25 MS. KOPYSTENSKI: Now that the Supreme Court has

1

2 cleared the way for the class action suits, they'll begin
3 selecting the jury on May seventh. And part of the class
4 action suit provides not only for a super fund for Vietnam
5 veterans but --. It also allows for the VA to be
6 reimbursed. Now, if the VA contends that there are no
7 problems, the VA cannot put in on the veterans' behalf
8 for reimbursement. What is going to happen within the
9 next let's say two years? Is the VA going to suddenly
10 find that our children are birth defected, I'm a wife,
11 that our husbands are dying miracuously, you understand
12 that? Or are you going to forego the billions of dollars
13 on the reimbursement list?
14 DR. HOBSON: I do not know what the VA policy
15 is about any reimbursement. I do know that we will
16 follow what the science shows and we'll report what the
17 science shows and that's as far as we can go.
18 MS. KOPYSTENSKI: In other words, you will not,
19 we are allowing in our class action suit for the VA to
20 assume, as a third party, the reimbursement of any treat-
21 ment provided to the veteran.
22 DR. HOBSON: I'm sorry. I am not a lawyer and
23 I would not make that policy under any circumstances.
24 I cannot answer your question as to what the VA is going
25 to do in that respect. Are there any other questions or

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2 comments? If not, it's a little past our time.

3 MR. WALKUP: I did have one. You wanted to

4 finish up the health notices. We can drop that. But I

5 wanted to follow up on the issue of race which was

6 raised in our committee with the -- numbers from the

7 other side.

8 The issue was raised that specifically during

9 the blood pressure and possibly the effects of sickle

10 cell anemia that Black veterans health experience might

11 be different from the total population when we're looking

12 for health effects of herbicide. Is that something, and

13 we've seen in the protocols that race is something that's

14 asked about.

15 Is there any kind of control that is happening

16 in these studies, any subgroups that are happening in any

17 of these studies to look at differential health defects

18 for Black or Hispanic or Asian or veterans, vis a vis

19 White veterans since I assume that White veterans would

20 be the ones who come out the majority of the time?

21 DR. HOBSON: The studies that I know about are

22 all designed to be analyzed in terms of race. There is

23 an attempt made to get a balance, a racial match if you

24 wish, between the control groups and the ones for Vietnam.

25 The data are analyzed in terms of race. They are in

1

2 the Ranch Hand study for example. So the answer is it is

3 not being ignored at all. It's being looked at.

4 MR. WALKUP: That's a selection factor to make

5 sure that there's no -- groups?

6 DR. MULINARE: Let me put another perspective

7 on it. I'm not sure that it is going to answer your

8 question, but in order to be in the armed forces, you have

9 to be free of certain illnesses or diseases. A Black

10 veteran who has, let's say, I'm not sure and I'd have to

11 ask and find out, but if someone who has sickle cell

12 disease would actually be inducted into the Army.

13 Those kinds of diseases are taken into consider-

14 ation on that basis, that they're not part of the study

15 because it would be very difficult to find veterans who

16 did not have sickle cell disease five minutes before, he

17 wouldn't become a veteran in essence. Is that the kind

18 of question that you're asking about?

19 MR. WALKUP: In part. I think - Let me put it

20 another way in terms of how it was expressed. Is race

21 a selection factor so that you have experimental and

22 control groups paired on race so that race goes away as

23 a factor, or is there, are there interaction effects that

24 are looked at after the outcome? Can you say that there's

25 no statistical difference based on race after the study is

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complete?

DR. MULINARE: I don't believe the studies are matched analysis. There's a -- match. Say, for the birth defects study, we did match in a way,and I'll explain this as we get the results later on when we have the results.

But there are two ways to deal with these problems. You can deal with them at the beginning of your design and match for them and then eliminate that as a problem in your subsequent analysis. Or what you can do is contruct a sample that's large enough so that later on, once you do your analysis, you can take in factors like race, sex, age of the person, a whole number of factors and still have a sample size that's large enough to give you statistical results.

So there are two ways of dealing with it and it just depends on what the trade-offs are in your study.

MR. WALKUP: Which are you doing?

DR. MULINARE: We're doing a little bit of both. Seriously, in the birth defects study there is very serious consideration as to whether or not we should match. It's always felt that it's better not to match and then deal with those kinds of situations in your analysis, as long as you have large enough numbers. But there are

1

2 considerations initially where you want to be sure that

3 you do take into account those kinds of factors and since

4 we know at least for birth defects that there is some

5 hint that some birth defects are more common among certain

6 ethnic groups than others, we try to take that partially

7 into account initially before we did the study as part of

8 the design.

9 MR. WALKUP: It sounds like you answered my

10 question. You told me what I wanted to hear. Now, let

11 me say it back to you. I'm not sure I heard it right.

12 You are attempting to make sure that we've got some, we

13 are somehow approximating the distribution of Vietnam

14 veterans in the same proportions or roughly as those who

15 served when you get to an experimental group and also

16 that there are sufficient numbers going into those groups

17 so you can look at possible effects that are attributable

18 to race if they are indeed that?

19 DR. MULINARE: Yes.

20 MR. WALKUP: Okay.

21 DR. MULINARE: And remember that there are two

22 different types of studies we're talking about. We're

23 talking about case control studies where we are choosing

24 our study sample on the basis of birth defects, and

25 then there are cohort studies where we're choosing our

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2 study subjects on the basis of exposure and we have to

3 take that into account.

4 And then you deal with these other confining

5 factors. And when I listened I thought I heard you

6 saying what about the Black Vietnam veteran who has

7 sickle cell disease, has he been taken into account and

8 I say put that in perspective of the type of men who went

9 through physical examinations. We found that you won't

10 find those men in the Army.

11 They may be in the Army and in fact they're in

12 the Air Force, but I don't know if that was a criteria

13 to be used to eliminate them from being drafted for Vietnam.

14 I don't know. You could answer that better than I

15 could.

16 DR.HOBSON: Did you have a question, Doctor?

17 DR. CREDLE: A question or maybe a comment

18 regarding Black and Third World Vietnam Agent Orange victims?

19 DR. HOBSON: You'll have to talk louder.

20 DR. CREDLE: I raised that question and one of

21 my concerns is not only the process of a study

22 but another part is reporting the results of the study.

23 For example, you talked about the Ranch Hand Study but you mentioned

24 nothing about ethnic identity of the people who were

25 involved in the process. I have a major problem with that because

1

2 my assumption from where I sit as an administrator at a

3 university where I know some of the details of what we are

4 talking about, but in my view as a Black

5 veteran, I know that veterans like me, will look at who's giving the

6 report and scrutinize who's around the table. The results are that I

7 would say, well, wait a minute, they're talking about someone else,

8 they're not talking about me.

9 And so my concern would be the other part of the report

10 as well. Not only the report, but what's coming out of it, such as who's involved. And I

11 think we need to do that all along. You know, we've got

12 the same kind of problem of credibility when the final

13 report is in. It's already hard enough getting Vietnam veterans

14 to come into the VA system.

15 You can imagine what it's like getting Black

16 Vietnam veterans to come into the system. It is harder to

17 talk about the Hispanic veterans and the VA system, which is another issue

18 because most of us assume that Hispanic veterans speak American and

19 they don't, not necessarily, you know. Some of them speak

20 Spanish. We don't have a mechanism to get in touch with

21 them and I don't think, you know, money is being provided

22 for that once the report gets out. So I'm having all

23 sorts of problems with what's happening with this process.

24 DR. HOBSON: The report that Colonel Lathrop

25 gave this morning was a very abbreviated report of the

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2 whole thing. The written report

3 does make comparisons of Black and non-

4 Black and quite extensively. One of the reasons we did

5 not go into it was that he was not able to demonstrate

6 any significant differences between the Black and the

7 non-Black veterans in this particular study.

8 And generally speaking, that's what's done

9 when you try to give a report in a short time. You only

10 mention the things that come out positive. You don't

11 mention the things that come out negative.

12 DR. CREDLE: I'm saying that that is a crucial

13 mistake particularly with this issue and we're talking about

14 30 percent of the combat veterans. I mean, that's a very signi-

15 ficant number and you've got to speak to them on this issue as well.

16 DR. HOBSON: Don't worry. It will be said. It

17 was not said here because he was condensing the talk. I

18 heard him talk yesterday and he did mention it, as I recall,

19 so it depends on the circumstances. We're going to have

20 to cut this short pretty soon because there are people who

21 have to leave. Yes?

22 MS. KOPYSTENSKI: I have a question.

23 When the

24 test results come back that for example, Dr. Kahn and

25 the New Jersey Commission are doing which is extensive and

1

2 painful for the veteran involved, the testing process,

3 when the CDC tests come back, what is going to happen if

4 it is found that all those fears are recognized? Is the

5 VA going to do a study on the results of those tests, or

6 is some action going to be taken?

7 DR. HOBSON: Now, you've mention when the

8 results come back, and if it's proved. That's the crucial

9 point.

10 MS. KOPYSTENSKI: Is the VA going to recognize

11 that proof?

12 DR. HOBSON: If the proof is there, now that

13 means scientific proof, not proof in your own mind or my

14 own mind or somebody else's own mind, if there is a con-

15 sensus that this is an effect, I can't imagine under any

16 circumstances that Congress would not compensate the

17 veterans and I can't imagine that the VA would oppose it

18 at all. We never have when there was any kind of medical

19 consensus to show that an effect was a consequence of

20 military service. I don't imagine it will begin here,

21 either.

22 MS. KOPYSTENSKI: And the children?

23 DR. HOBSON: The issue of children depends on Congress.

24 That we have no control over. That becomes a Congression-

25 al matter because we have no authority to compensate

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children, asside from providing education and health benefits.

MS. KOPYSTENSKI: If the scientific data is there -

DR. HOBSON: If there is a general scientific medical consensus, the answer is, the VA would back it. I have every reason to think so. Certainly I would, personally. Any other questions? If not, I'm sorry, we're going to have to cut it off.

(Whereupon, at 2:25 p.m. on Tuesday, March 6, 1984, the meeting was adjourned.)

AIR FORCE HEALTH STUDY
(PROJECT RANCH HAND II)

AN EPIDEMIOLOGIC INVESTIGATION OF HEALTH EFFECTS IN AIR FORCE PERSONNEL FOLLOWING EXPOSURE TO HERBICIDES

BASELINE MORBIDITY STUDY RESULTS

BRIEFER: GEORGE D. LATHROP MD, PhD

EPIDEMIOLOGY DIVISION
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235

AIR FORCE HEALTH STUDY

- WHITE HOUSE DIRECTED
- EXTENSIVE PEER REVIEW
- UNIQUE STUDY POPULATION
- STUDY DESIGN
  - MORTALITY
  - MORBIDITY: QUESTIONNAIRES, PHYSICAL EXAMS
  - FOLLOW-UP

STUDY RESULTS

- NO SOFT TISSUE SARCOMA (STS), PORPHYRIA CUTANEA TARDA (PCT), OR CHLORACNE DIAGNOSED IN RANCH HANDERS

FERTILITY/REPRODUCTIVE

- MOST FINDINGS BASED UPON UNVALIDATED SELF REPORTS
- NO SIGNIFICANT RANCH HAND OR OFFSPRING FINDINGS FOR:
  - SPERM COUNT, OR DEFECTIVE SPERM
  - FERTILITY/INFERTILITY (5 MEASURES)
  - MISCARRIAGE, STILLBIRTH, LIVE BIRTH
  - SEVERE BIRTH DEFECTS
  - MODERATE BIRTH DEFECTS

PRE VERSUS POST ANALYSIS OF REPORTED BIRTH DEFECTS (BY SEVERITY)

		PRE	POST	
RANCH HANDERS				
SEVERE	Y	51	32	P = 0.46
	N	1672	885	
MODERATE	Y	32	22	P = 0.35
	N	1691	895	
LIMITED	Y	7	26	P < 0.0001
	N	1716	891	
ORIGINALS				
SEVERE	Y	50	18	P = 0.18
	N	1385	726	
MODERATE	Y	27	20	P = 0.22
	N	1408	724	
LIMITED	Y	10	10	P = 0.13
	N	1425	734	
ALL COMPARISONS				
SEVERE	Y	62	34	P = 0.46
	N	1980	1275	
MODERATE	Y	40	34	P = 0.22
	N	2002	1275	
LIMITED	Y	20	18	P = 0.29
	N	2022	1291	

NEONATAL DEATHS

(UNVERIFIED SELF REPORTS; MEDICAL RECORDS, DEATH CERTIFICATES PENDING)

RATE/1000

	RANCH HAND	COMPARISON
BEFORE RVN	13.4	16.0
AFTER RVN	16.8	3.4

CANCER

- NO SIGNIFICANT DIFFERENCE IN THE OCCURRENCE OF "SYSTEMIC" CANCER
- NO SOFT TISSUE SARCOMA FOUND IN RANCH HANDERS
- SIGNIFICANTLY MORE VERIFIED SKIN CANCER IN RANCH HAND GROUP
    - NOT ADJUSTED FOR SUN EXPOSURE

LIVER

- RANCH HANDERS SELF REPORTED MORE LIVER AND PCT-LIKE SYMPTOMS
  - NOT VERIFIED AS YET BY MEDICAL RECORDS
  - NOT CONFIRMED AT PHYSICAL EXAM (NO PCT)
  - NOT SUBSTANTIATED BY LAB TESTS
- SEVERAL MINOR LAB TEST DIFFERENCES
- MORE VERIFIED MISCELLANEOUS DISORDERS IN RANCH HANDERS; SIGNIFICANCE UNKNOWN

PSYCHOLOGY

- NO GROUP DIFFERENCES IN IQ OR PERFORMANCE TESTING
- ANALYSES REFLECTED KNOWN SUBSTANTIAL EFFECT OF EDUCATION ON PSYCHOLOGICAL TESTING
  - SUBJECTIVE MEASURES SHOWED SIGNIFICANT GROUP DIFFERENCES PARTICULARLY IN HIGH SCHOOL EDUCATED PERSONNEL (QUESTIONNAIRE, CORNELL INDEX, MMPI)

CONCLUSIONS

- STUDY MEASURED TRUE HEALTH STATUS TO MAXIMUM EXTENT POSSIBLE
- ALL SIGNIFICANT FINDINGS ARE BEING FOLLOWED UP
- INSUFFICIENT EVIDENCE TO SUPPORT HERBICIDE CAUSALITY AT THIS TIME
- FINDINGS TO DATE SHOULD BE REASSURING TO RANCH HANDERS
  - NO CHLORACNE MEANS LOW EXPOSURE VERSUS CHEMICAL WORKER POPULATIONS
  - NO MAJOR CLINICAL HEALTH PROBLEMS
  - OVERALL GOOD GENERAL HEALTH FOR AGE

MINUTES

SUBCOMMITTEE ON EPIDEMIOLOGY/BIOSTATISTICS

Richard A. Hodder, M.D., M.P.H. (Walter Reed Army Institute of Research), Chairman of the Subcommittee convened the meeting at approximately 10:30 a.m., Tuesday, March 6, 1984. Other subcommittee members and alternates present were: George R. Anderson, M.D. (Texas Department of Health); Donald Barnes, Ph.D. (Environmental Protection Agency); Thomas A. FitzGerald, M.D. for Irving B. Brick, M.D. (American Legion); and Carolyn H. Lingeman, M.D. (National Institutes of Health). Barclay M. Shepard, M.D., Chairman of the full committee and Director, Agent Orange Projects Office, also was present, as were a number of other individuals in the audience. The meeting was open to the general public. Recognizing that the meeting began slightly behind schedule, Dr. Hodder requested that the speakers be brief in their presentations.

CDC EPIDEMIOLOGY STUDY AND WOMEN VETERANS

Dr. J. David Erickson, Centers for Disease Control (CDC), Atlanta stated that since everybody at this subcommittee meeting was also present at the full committee session, he would only go over the highlights of what CDC is currently undertaking. Last Spring, CDC decided to evaluate the feasibility of studying women veterans. They decided to defer the study. They were concerned about the fact that after women left the service, in many cases, they would be changing their names due to marriage. With the help of the Agent Orange Army Task Force, they put a small sample of women veterans' names through the Internal Revenue Service process and found women veterans can be found as easily as male veterans. IRS has changed their process and now CDC can get female veterans' addresses by having only their Social Security number, even if husband is primary filer, in the case of joint tax returns.

CDC is now trying to decide how such a study of females can be done. They may begin using records in Federal Records Center in St. Louis. They will send a team to St. Louis to assess feasibility of pulling up samples of women veterans. CDC has computer tapes of all records located at the Records Center.

Another issue that concerns CDC now is what is a suitable comparison group for a number of women Vietnam veterans. They would welcome any suggestions from committee in that regard.

AUSTRALIAN ACTIVITIES

Dr. John Matthews, who spoke about various Australian studies during the full committee session, touched on the highlights of these efforts in the subcommittee meeting. He indicated that Australian scientists believe they should restrict their studies to draftees and not men who enlisted. There is good evidence that Australian soldiers who volunteered are different from general population. Literature shows that after all wars there is a certain pattern of morbidity for a period of time, deaths being due to various causes. The compensability of war-related disabilities is different in Australia than United States.

In men of Vietnam era, there will be studies on things that may be war related as well as Agent Orange related. 44,000 Australian persons served in Vietnam; one half of that figure are being studied. They are still gathering data. No results are available at this time. They will also be looking into cases of men who died from alcohol and smoking.

PATIENT TREATMENT FILE/SOFT TISSUE SARCOMA REVIEW

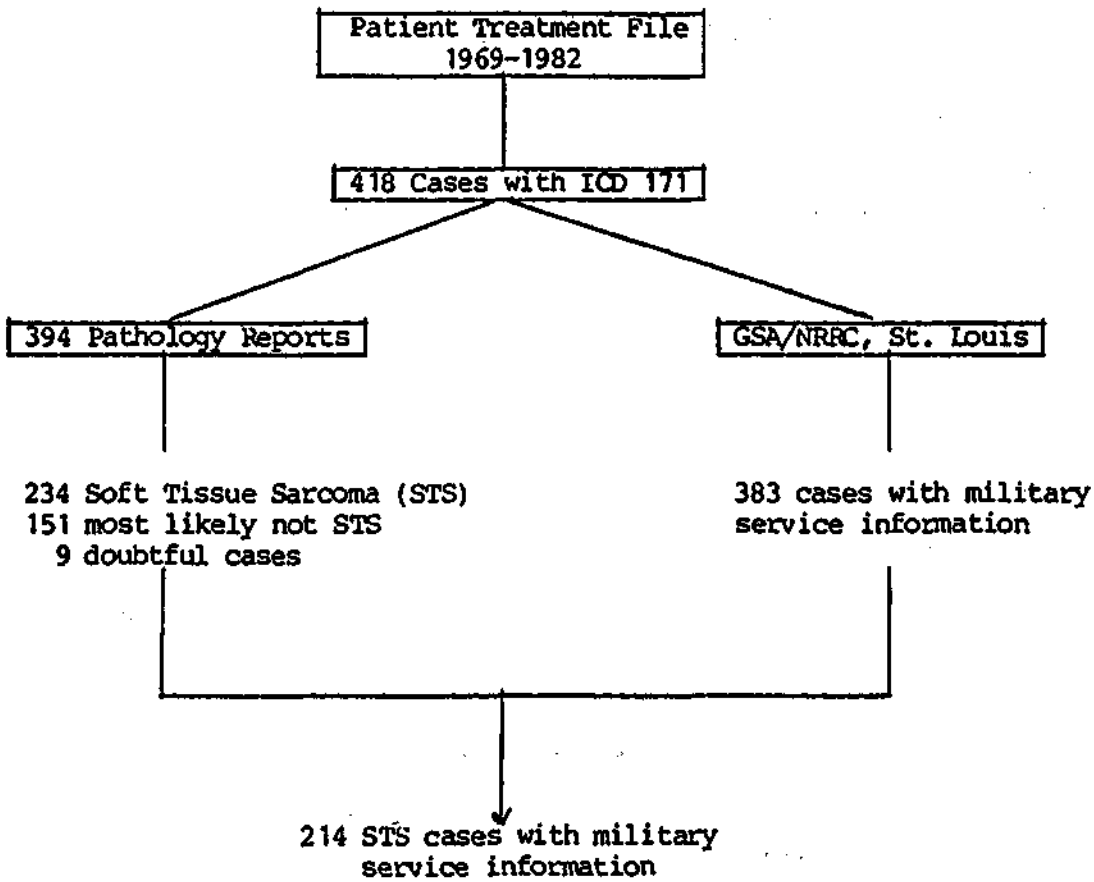
Dr. Han K. Kang of the VA Agent Orange Projects Office presented a review of soft tissue sarcoma cases for Vietnam-era veterans in the Patient Treatment File from 1969-1982. He reported that 36 percent of the soft tissue sarcoma cases served in Vietnam; whereas in the overall patient treatment file, 41 percent of Vietnam-era veterans served in Vietnam. These figures suggest that for Vietnam-era veterans in the VA medical facilities, the frequency of soft tissue sarcoma among veterans who served in Vietnam is not greater than that among those who did not. (A copy of the slides presented by Dr. Kang is attached).

SOFT TISSUE SARCOMA STUDY IN CENTRAL EASTERN MICHIGAN

Dr. Daniel E. Williams from the Center for Environmental Health Sciences, Michigan Department of Public Health then described a soft tissue sarcomas study in Central Eastern Michigan. Dr. Williams distributed a handout detailing the study (see attached). He stated they are looking at an eight county area. This area is a mixture of rural and city. An eight county area was chosen with idea that major population centers in Michigan are near Lake Huron and the population is generally stationary for long periods of time.

The meeting was adjourned at approximately 11:45 a.m.

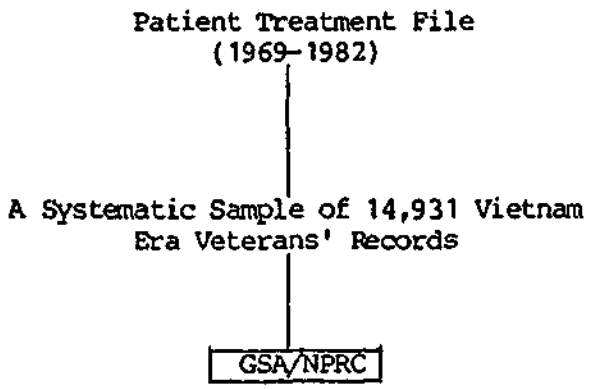
SELECTION OF SOFT TISSUE SARCOMA CASES



Soft Tissue Sarcoma Type
By Military Service Status

Type	Non Vietnam	Thailand	Vietnam	Total
Fibrosarcomas	22	2	10	34
Synovial Sarcomas	17	2	8	27
Rhadomyosarcomas	16	-	8	24
Liposarcomas	16	-	9	25
Undifferentiated Sarcomas	8	-	7	15
Leiomyosarcomas	8	-	11	19
Malignant Hemangioperi-cytomas	10	-	2	12
Malignant Schwannoma	4	-	5	9
Dermatofibrosarcoma Protuberans	3	-	6	9
Malignant Fibrous Histiocytomas	4	-	2	6
Kaposis Sarcoma	5	1	2	8
Epithelioid Sarcoma	4	-	2	6
Embryonal-extragonadal	1	-	1	2
Alveolar soft part	3	-	-	3
Angiosarcoma	3	-	1	4
Mesothelioma	3	-	1	4
Malignant Mesenchyoma	-	-	2	2
Other	4	-	1	5
Total	131	5	78	214
Percent	(61.2%)	(2.3%)	(36.5%)	(100%)

A Systematic Sample of Vietnam Era Veteran
Patients in the PTF



13,496 Vietnam era Veterans with military information

Non-Vietnam	7,679	(56.9%)
Thailand	273	(2%)
Vietnam	5,544	(41.1%)
Total	13,496	(100%)

Comparison of STS Cases and PTF Patients for
Vietnam Service Status

		STS	PTF	
Vietnam Service	Yes*	83 (39%)	5,817 (43%)	5,900
	No	131 (61%)	7,679 (57%)	7,810
		214 (100%)	13,496 (100%)	13,710

* Including service in Thailand

		STS	PTF	
Vietnam Service	Yes*	78 (36%)	5,544 (41%)	5,622
	No	136 (64%)	7,952 (59%)	8,088
		214 (100%)	13,496 (100%)	13,710

* Excluding service in Thailand

Comparison of STS Cases (ICD 171) and PTF Patients for Vietnam Service Status

		STS	PTF	
Vietnam Service	Yes*	145 (39%)	5,544 (41%)	5,689
	No	230 (61%)	7,952 (59%)	8,182
		375 (100%)	13,496 (100%)	13,871

* Excluding service in Thailand

A STUDY OF SOFT TISSUE SARCOMA IN CENTRAL EASTERN MICHIGAN

BACKGROUND

Data suggesting an excess of STS cases

1. Mortality data from " U.S. Mortality Rates adn Trends, 1950-1978" and "Midland County Soft and Connective Tissue Cancer Report, May, 1983"
2. "Midland County Cancer Incidence, 1979-1982, MDPH"

OBJECTIVES

1. Determination and confirmation of sarcoma cases within the eight counties to determine incidence.
2. To associate place of residence, occupation, dietary habits, personal habits, and other variables with sarcoma cases utilizing case control design.
3. To assess study methods in terms of efficacy, cost, and alternatives.

DEFINITION OF SARCOMA CASES

1. Histological diagnosis of malignant cell origin arising in a variety of organs
2. Cases to be found by pathology report review
   A. Compare physician, oncology nurse practitioner, nosologist interpretation
   B. Compare to routine tumor registry coding
3. Pathological confirmation
4. Clinical follow-up to confirm that the sarcoma diagnosis continues

SELECTION OF CONTROLS

1. Population controls utilizing a random selection of phone number
2. Hospital controls without malignancy

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Center For Environmental Health Sciences
Michigan Department of Public Health
405 W. Greenlawn
Lansing, MI 48910 (517) 372-6425

Subcommittee on Veterans' Education/Information

Mr. Fredrick Mullen, Sr. (Paralyzed Veterans of America), Chairman of the subcommittee, convened the meeting at approximately 10:30 a.m., Tuesday, March 6, 1984. Other subcommittee members and alternates present were: Mr. George T. Estry (Veterans of Foreign Wars); Mr. Hugh Walkup (National Veterans Task Force on Agent Orange); Mr. Noel C. Woosley (AMVETS); and Mr. Charles Thompson (Disabled American Veterans). Officials from several state Agent Orange commissions were also present, along with Col. Lorraine Rossi, who chairs the VA Advisory Committee on Women Veterans.

Old Business

Mr. Mullen read a list of statements/recommendations which the Subcommittee on Veterans' Education/Information made at the last full committee meeting on December 6, 1983. These included:

1. A question regarding the literature review update--can we get more information from DOW? The answer was no.

2. References to gender in Agent Orange studies--mothering/fathering children (in the Literature Review/Analysis) and future VA publications.

3. Requirement that female veterans be given pelvic exam as part of routine Agent Orange exam.

4. Feasibility of a study on women veterans.

5. Reclassifying/recovering registry data.

6. Report on progress of videotapes.

7. Asked that VA stop showing film "Agent Orange: Where Do We Stand?"

8. Educational conference for Environmental Physicians.

Mr. Marc Williams of the New Jersey Agent Orange Commission stated that he had received no answer on his question at the last Advisory Committee meeting regarding how many of the original Environmental Physicians are still serving in that capacity, and also stated that he was examined several months ago for an Agent Orange exam by a non-physician. Mr. Mullen responded that he had received from the VA information regarding who attended the various educational conferences and he would be happy to share this with Mr. Williams or anyone else.

9. It was announced at today's meeting that Ms. Nancy Howard of the Agent Orange Projects Office will be serving as a member of a SERP team, and that Dr. Shepard will be traveling to Chicago, Denver and Boston in the near future and will be observing the Agent Orange programs at these hospitals.

10. The matter of adding women to the panel--a representive from the Advisory Committee on Women Veterans, perhaps--was brought up. (Colonel Lorraine Rossi who chairs that committee was invited to attend today's meeting.)

11. Report on Literature Review Update and discussion of possible lay language summary by Dr. Carl O. Schulz of Clement Associates. (The subcommittee recommended at the 12/6/83 meeting that the lay language summary be written.)

Mr. Hugh Walkup stated that members of the subcommittee had received a handout on the Agent Orange registry, but that he did not understand its function. He also asked what had been decided on his question at the last meeting about having a transcript of the subcommittee meetings typed up and distributed to the members. Mr. Donald Rosenblum explained that the Agent Orange Registry statement was an attempt to clarify information regarding the Registry including its purpose, uses and limitations. He also stated that we were taking notes at the meetings, but there would not be verbatim transcripts, and that the subcommittee members could get copies.

Mr. Williams asked what exactly will be done about the original 85,000 exams and what he should be telling veterans as to whether they may or may not request a second examination.

Progress Report on New Videotapes

Mr. Danny Jones of the Regional Learning Resources Center, VAMC St. Louis, Missouri, was present and discussed the status of the planned Agent Orange videotapes. He stated that the first tape that they are considering making will be for veterans, veterans' families, and concerned individuals. The second film will be for the scientific field. There is also a possibility for a third tape or information of some sort to be made for environmental physicians and VA employees, to include handling of veterans when they first come to a VAMC. He stated that a determination is now being made as to what may be relevant, and they are using comments and suggestions made by committee members and others regarding the prior tapes, "Agent Orange: A Search for Answers" and "Agent Orange: Where Do We Stand?" He stated that an outline of the first videotape, for veterans and their families, will be sent out for comments hopefully by the end of March. He would like it to cover such things as how to apply for benefits, how to get an Agent Orange exam, and how to get on the registry, and that it will look at specific VA studies, and will use interviews with researchers, veterans and veterans groups.

Mr. Jones anticipated that the tapes should be ready by the end of the calendar year.

Mr. Mullen stated that he felt it would be nice to have tapes for veterans groups, families and clinicians, but he felt that most problems are intake problems--lack of sensitivity, need of quality control, etc. He felt that the order of production of the tapes should be changed and that there should definitely be a tape made for VA employees and Environmental Physicians and that it should have top priority. He felt that the information for these people should definitely be a videotape rather than written information.

Mr. Walkup made a motion that the subcommittee recommend that the priorities of the films be reversed, and that the first film made should be for the information of VA personnel. Mr. Woosley seconded the motion, and all were in favor.

Library Efforts

Ms. Jean McVoy of the VACO library was present and discussed information which is presently available in the library concerning Agent Orange. She presented a handout (see attached) on audio visuals which are available on Agent Orange and also the Vietnam War. She stated that the libary is looking for a commercial production on Agent Orange but cannot find one that is scientifically accurate. She stated that the VACO library has a catalog on all audio visuals in the network, and has suggested that field stations do the same with their collections.

Mr. Mullen asked if the VA allows copying of in house films. Ms. McVoy stated that the library has bought most of the videotapes and that they cannot be used in Beta or VHS machines, and that it is illegal for the VA to copy them, but they can be purchased from GSA. Ms. McVoy advised that there is presently a film in every district titled "A Gift From Mrs. Tim" which deals with insensitivity of hospital staff, and suggests that all hospital staff take a look at it.

Discussion of Veterans' Concerns

Mr. Williams again asked what is going to be done about the original 85,000 exams and stated that he had been examined by a non-physician.

Mr. Mullen stated that on December 6 the question was asked at the full committee meeting what efforts are being made to redefine or reclassify the information on these original exams. It was asked if the VA will send out letters to identified veterans recommending that they come back in for a second exam. It was also asked if veterans are not getting the Agent Orange Review can it be assumed they are not on the Registry?

Ms. Nancy Howard of the Agent Orange Projects Office stated that there are many highly mobile veterans, who move around a lot, and that these veterans should be advised to report their change of address to the nearest VA facility.

Ms. Howard also informed the subcommittee that she will be making her first SERP visit the week of March 12 through 16 in New Haven, Connecticut. She stated that she will be auditing MAS and will be looking specifically at the Agent Orange Program. She stated that there is specific criteria for conducting Agent Orange exams and that she will be checking to see that this criteria is being followed. Mr. Mullen asked what happens if the guidelines are not being followed. Mrs. Howard stated that the service receives a report recommending corrective action. If the matter is of a serious nature it is referred back to Central Office Medical Administration Service.

Mr. Woosley stated that small medical centers are not the ones that are having problems, that in small hospitals for the most part veterans are pleased with their exams and the physicians, but it is entirely different in the larger stations, and he felt that the ones where most problems are should be the ones being audited.

Mr. Estry asked if Mrs. Howard would be looking at the qualifications of the environmental physicians. Mrs. Howard informed him that she would not.

Future Agenda Items

Mr. Mullen asked if anyone had items to be put on the agenda for the next meeting, tentatively scheduled for June 5, 1984.

A member of the audience asked what efforts are made to contact veterans groups that are "not traditional" veterans groups.

Another member of the audience asked how someone from the "Network" would petition the panel to have a member represent them. Mr. Mullen advised her that they would have to submit a name for consideration and that it would have to go through the Administrator.

A question was also raised by a member of the audience as to the lack of minority participation. He also stated that blacks have health concerns that whites do not have, such as sickle cell anemia and a higher incidence of high blood pressure, and wanted to know if studies were being done to show how exposure to dioxins affects the health of blacks compared to whites. Mr. Mullen advised him that all meetings are open to the public, and that outreach centers deal one-on-one with all ethnic minorities. He also stated that minorities are not being excluded from the studies, but that he did not feel it necessary to break down the studies as far as ethnic minorities. Mr. Walkup suggested that this question should be raised to the scientific group at the full committee meeting.

Mr. Walkup stated that an item to be included on the agenda should be an update on procedures used to implement existing legislation. In case 1961 passes, what is being done now to implement it? Mr. Mullen stated that there is nothing to implement. Either a veteran has one of the three disabilities or he doesn't--it's cut and dried.

The meeting was adjourned at 12:00 noon.

AUDIOVISUAL AND PRINTED MATERIALS AVAILABLE IN THE VA LIBRARY NETWORK (VALNET)

Audiovisuals

1. Agent Orange: a search for answers, Veterans Administration, 1981, (videocassette), All Health Care Facilities
2. Genetic counseling: a practical demonstration of a counseling session for parents of a Down's child, 1978, (videocassette), District
3. Practical aspects of genetic counseling, United States Army Medical Department, Fort Sam Houston, 1973, (videocassette), District

Audiovisuals in Production

1. Agent Orange: clinical update (audience - hospital staff), estimated completion date December 1984, (videocassette), All health care facilities
2. Agent Orange: update (audience - general public) estimated completion date December 1984, (videocassette), All health care facilities

VA Video Digest

#3, Special report on Agent Orange, 1983, (videocassette), All health care facilities,

Audiovisuals on the Vietnam War or Vietnam War era

1. Anderson platoon, Films Incorporated, 1969, (videocassette), Regional
2. Front line, Filmakers Library, 1979, (videocassette), Regional
3. Frank, a Vietnam veteran, Fred Simon Productions, 1981, (videocassette) Regional
4. Good morning, Vietnam, Foxhole Production, 1978, (videocassette) Regional
5. Hearts and minds, BBS Productions, 1974, (16 mm), Regional
6. Spooks and cowboys, gooks and grunts, CRV Television Network, 1976, (16 mm and videocassette), Regional
7. Vietnam: ten thousand day war, Information Television Productions Limited and Cinequity Funding, Inc., 1980, (26 videocassettes) Regional
8. Vietnam: a television history, Public Broadcasting System, 1983, (videocassette), Regional
9. Vietnam memorial, Public Broadcasting System, 1983, (videocassette), Regional
10. The war at home, Catalyst Films/Madison Film Production Co, 1979, (videocassette), Regional
11. Warriors' women, Dorothy Tod Film, 1981, (videocassette), Regional
12. Young veterans program, Veterans Administration, 1982, (videocassette), Regional

Print materials

All print materials listed below have been delivered one copy to Library Service at each health care facility

1. Birth Defects, Genetic Services, International Directory, 7th edition, 1983, The National Foundation - March of Dimes
2. Case Control Study of Congenital Anomalies and Vietnam Service, Australian Government, 1983 (ordered but not yet received)
3. Chemical Sythe: lessons of 2,4,5-T and dioxin by Alastair Hay, Plenum Publishing Corp., 1982
4. Clinical Genetics and Genetic counseling by Thaddeus E. Kelly, Year Book Medical Publishers, 1980

AUDIOVISUAL AND PRINTED MATERIALS AVAILABLE IN THE VA LIBRARY NETWORK (VALNET)

5. Continuing Education Conference on Herbicide Orange (2nd : 1980 : Washington, D.C.), Proceedings from the 2nd Continuing Education Conference on Herbicide Orange, Veterans Administration, Department of Medicine and Surgery, 1981
6. "Cytogenetic Diseases," Clinical Symposia, volume 35, no 1, 1983. CIBA Pharmaceutical Company
7. "Dioxin," Chemical and Engineering News, vol 61, no 23, June 6, 1983, American Chemical Society (two copies sent to Library Service at each medical center, one for the medical library and one for the patient library)
8. Genetics in medicine by James S. Thompson and Margaret W. Thompson, 3rd edition, Saunders, 1980.
9. Human and environmental risks of chlorinated dioxins and related compounds edited by Richard E. Tucker, Alvin L. Young and Allan P. Gray, Plenum Press, 1980
10. Operation Ranch Hand: the Air Force and Herbicides in Southeast Asia 1961-1971, United States Air Force, Washington, D.C., 1982
11. Review of the literature on herbicides, including phenoxy herbicides and associated dioxins, Veterans Administration, Department of Medicine and Surgery, 1981
12 Vietnam: a history by Stanley Karnow, Viking Press, 1983. (The order is in process)

Regional delivery level means one copy is in the Library Service at each of the 7 Regional Medical Education Center host hospitals. The regional libraries are in Birmingham, AL, Cleveland, OH, Long Beach, CA, Minneapolis, MN, Northport, NY, Salt Lake City UT, and St. Louis, MO.

District delivery level means one copy in Library Service at a designated library in each of the 28 VA medical districts. The district libraries are located in Togus, ME, Buffalo, NY, Northport, NY, Lyons, NJ, Pittsburgh, PA, Perry Point, MD, Salem, VA, Durham, NC, Augusta, GA, Tuskegee, AL, Lexington, KY, Miami, FL, Cleveland, OH, Battle Creek, MI, Danville, IL, Wood, WI, Chicago, IL, Minneapolis, MN, Little Rock, AR, Waco, TX, St. Louis, MO, Topeka, KS, Des Moines, IA, Denver, CO, Prescott, AZ, Long Beach, CA, Palo Alto, CA, and Vancouver, WA

All health care facilities delivery level means one copy is in Library Service at each medical center. VA medical centers with two divisions have one copy for each division.

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Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Twentieth Meeting
June 5, 1984

September 1984 Washington DC 20420

1 VETERANS ADMINISTRATION

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5 Advisory Committee

6 on

7 Health-Related Effects of Herbicides

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13 Veterans Administration
Central Office

14 Room 119
810 Vermont Avenue, Northwest

15 Washington, D. C.

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21 Tuesday, June 5, 1984

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25

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25

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1 P R O C E E D I N G S

2 CALL TO ORDER AND OPENING REMARKS (8:35 a.m.)

3 DR. SHEPARD: Good morning, ladies and gentlemen.
4 We will begin our meeting. As usual, we have a fairly
5 full agenda, so I would like to get started.

6 We are delighted that not only are most of the members
7 of the committee here this morning, a very dedicated
8 group of individuals who have provided a tremendous amount
9 of help to the VA in sorting through some of the intri-
10 cacies of this complex problem and issue, but we are also
11 very appreciative of guest speakers and members of the
12 audience who have faithfully attended these meetings, and
13 have from time-to-time asked probing questions, which we
14 welcome. We believe that it is part of our responsibil-
15 ity to keep veterans and the general public informed as to our
16 activities.

17 We very much endorse the open-door policy, the
18 open-window policy, if you will, and so we appreciate
19 your attendance at these meetings.

20 This is the 20th quarterly meeting of the VA
21 Advisory Committee on Health-Related Effects of Herbicides,
22 since its establishment in April of 1979. It doesn't seem
23 possible we have been going that long.

24 Today's meeting will be open to the public, as
25 usual, including subcommittee meetings. Please note that

1 the subcommittee meeting on epidemiology and biostatistics
2 will remain in this room, and the subcommittee on education
3 and information will move to Room 139 at the appropriate
4 time in the agenda.
5 In order to have a record of attendance, we ask
6 that all visitors make their presence known by signing
7 the log book in the entryway.
8 We have set some time aside at the close of the
9 meeting, as has been our practice in the past, for questions
10 from the floor.
11
12 Please write down your
13 questions and give them to Don Rosenblum during the course
14 of the meeting, so that they may be presented in an
15 appropriate fashion at the appropriate time.
16 I would like to announce that Dr. Irving Brick
17 recently retired from the American Legion. We are very
18 happy to announce that Dr. Thomas FitzGerald, a long-time
19 public servant with a distinguished career with the VA,
20 who has been acting as Dr. Brick's alternate on this
21 committee, has now become an official member of the
22 committee. We are very glad for that, Tom.
23 We certainly wish Dr. Brick well in his retire-
24 ment, and hope that we can hear from him from time-to-time.
25 We have tentatively scheduled our next meeting on

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1 September 12th, which is a Wednesday, September 12th. It
2 is a tentative date, we will inform you as we firm up that
3 date, and of course, it will be published in the Federal
4 Register, as usual.
5 You may be wondering about the lights and the TV
6 camera, this is not a media event, at least not planned
7 to be a media event, as has happened occasionally in the
8 past. But the purpose of the camera today is to
9 record portions of this meeting for possible use in the
10 video tapes that the VA is producing
11 to update both veterans and VA staff personnel on the
12 activities of this committee, and the progress of the
13 whole Agent Orange issue.

OLD BUSINESS/RECENT ACTIVITIES

14 I would like to clarify a few points that have
15 come up over the course of the last several meetings, just
16 to clear up the record, in case there are some doubts in
17 the minds of individuals who have been attending our
18 meetings, as well as members of the committee.
19 The first point covers the issue of our bi-monthly
20 conference calls. These regular conference calls allow
21 the Central Office Staff, that is the Agent Orange Projects
22 Office, and related staff members who are in the Central
23 Office, and officials at various VA health care facilities
24 to share information and concerns regarding various aspects
25 of the Agent Orange issue. Typically, such calls include

1 timely announcements, formal presentations by Central Office
2 staff, and a question and answer period.
3 When we see problems that seem to be system-wide,
4 or questions, we utilize the conference call mechanism to
5 eliminate or minimize such difficulties and to answer such
6 questions. I hope that no one here will misinterpret the
7 purpose of the calls.
8 Again, I want to commend our field facilities on
9 the job that they have done during the past six years. We
10 have had a few problems, but overall the services have
11 been provided in an outstanding manner.
12 A point on the registry examination, there has
13 been some confusion at some recent meetings regarding the
14 initial and follow-up examinations. I want to clarify this
15 matter. When a veteran first visits the VA medical
16 center for an Agent Orange registry examination, he or she
17 is asked a series of questions relating to possible
18 exposure to herbicides in Vietnam. A medical history is
19 taken, a physical examination is performed and base-line
20 laboratory tests, such as X-rays, urinalysis, blood tests
21 are obtained. Consultation with other physicians are
22 requested, if the examining physician, in most cases the
23 environmental physician, or a designated member of the
24 staff, feels that such consultation is medically indicated.
25 This was the procedure in 1978, is the procedure

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1 today, and has been in the intervening years. The examin-
2 ation is the same today as it was then, there have been no
3 substantive changes in the way the examination has been
4 performed, or the way the medical history has been taken.
5 Veterans who need follow-up examination will not
6 necessarily receive the full comprehensive examination.
7 Veterans can receive only one initial examination, but can
8 receive an unlimited number of follow-up examinations.
9 Data from the follow-up examinations are included in the
10 computerized registry, but they are included as follow-up
11 examinations.
12 So, in our monthly reports and in our statistical
13 reports, we get the number of initial examinations, on the
14 cumulative basis, and the number of follow-up examinations.
15 So, we really receive two sets of numbers.
16 The process that has changed and evolved over the
17 years is the method of coding the information from these
18 examinations. But I just want to emphasize that the
19 original purposes of establishing the registry are
20 essentially no different today, than they were when the
21 registry was first established, and the process is not
22 very different, except in that the information is
23 coded in a different manner. That is we have developed
24 a new code sheet that we have referred to from time-to-
25 time. But that does not suggest that either the purpose

1 of the registry process has changed, or that the process
2 itself has changed significantly.
3 On the matter of the literature review, I am very
4 pleased to report that the analysis and the annotated
5 bibliography of recent literature on Health Effects of
6 Herbicides was published by the VA in April. I hope
7 most of the members of the committee have received their
8 copies, it will be Volume 3 and Volume 4; Volume 3 being
9 the critical analysis of the literature on herbicides and
10 related compounds, and Volume 4 is the annotated biblio-
11 graphy.
12 You will note that there is a somewhat of a change
13 in the format, and we hope this is a change for the better.
14 The bibliography is a much more succinct volume, and it is
15 just that, a bibliography. But it has a coding system to
16 indicate what areas that particular
17 citation covers.
18 We feel that this is a good step, because it
19 provides in a relatively short volume, the bibliography
20 and the highlights of the contents of each of the items
21 listed in the bibliograph. The major critical review, of
22 course, Volume 3, is essentially the same as has been done
23 in the first effort back in 1981.
24 For further information, see the flyer in your
25 folder or the hand-out on the table. For those of you in

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1 the audience who wish to obtain copies of the literature
2 review and analysis, instructions on how to obtain those
3 are provided.
4 In addition to the scientific review, we are
5 developing a lay-language summary which was a recommenda-
6 tion of our education/ information subcommittee. This has
7 been completed, that is the first draft of it has been
8 completed and is now undergoing editorial review to insure
9 that the language is appropriate for the audience for whom it
10 was designed. This is, as I said, a lay-language summary
11 of the results of the scientific review and analysis.
12 Hopefully, those will be ready in the next month,
13 or two, for distribution.
14 The monograph series. As you may recall, the
15 committee has received presentations from each of our
16 monograph authors, namely, Drs. Lavy, Hood, Sommers. Each
17 of these monographs -- a draft of each of these monographs
18 has been completed and has been reviewed for technical
19 accuracy. They are currently being
20 reviewed and edited.
21 The first monograph should be published in
22 approximately three to four months; the others will be
23 available later on this year, or early next year. A fourth
24 monograph on chloracne is now getting underway after
25 several unavoidable delays.

1

2 As mentioned at the last meeting, Mrs. Howard, of

3 my staff, went on the first of her SERP trip, which is an

4 acronym for Systematic External Review Program, a quality

5 control program that has been ongoing in the VA for some-

6 time. She made a visit to our VA Medical Center in West

7 Haven, Connecticut, and she will be going on additional

8 visits in the future. Some of these visits will be to large

9 cities' facilities and stations with considerable Agent

10 Orange activity.

11 Last month she also visited our VA Medical Center

12 in Fayetteville, North Carolina, and will be going to a

13 number of the medical centers, in addition to her SERP

14 responsibilities.

15 I have visited Boston, Chicago and

16 Denver for the purposes of acquainting myself on how

17 various medical centers are handling the Agent Orange

18 issue. My reaction to those visits has been

19 very favorable. By and large, the VA medical centers are

20 doing a very good job at handling the Agent Orange examin-

21 ation program.

22 Some of you, I guess the members of the committee,

23 have been given these consent forms. The purpose of this,

24 and please fill them out, is to obtain your

25 consent to use the materials which are being videotaped

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1 for the purposes of the tapes that I indicated earlier.
2 So, if the members of the committee will please fill out
3 those before leaving.
4 We are happy to have the people who
5 are developing these videotapes with us this morning, and
6 later on in the program we will be hearing from Mr. Dan
7 Jones.
8 We have continued to cooperate with the Women's
9 Advisory Committee, Women's Veterans Advisory Committee,
10 and have provided that committee with updates regarding
11 our Agent Orange related activities.
12 Some of you will be aware of the fact that recently
13 our office has been moved from this building to a nearby
14 building, namely the Shoreham Building, on the corner of
15 15th and H Streets. Our telephone number also has changed. We still
16 have an FTS number, but for those of you who need to keep
17 in touch with us, and have not been informed of this change,
18 I would suggest you jot this number down. It is still
19 Area Code 202 and the
20 FTS number is,as is the commercial number, 376-7528. So,
21 those of you who want to get in touch with us, please be
22 aware that we now have a new telephone number.
23 My deputy, Dr. Lawrence Hobson, is still across
24 the street, immediately across the street, and his number
25 has not changed, it is FTS or (202) 389-5534.

1 I am sure that many of you have heard about the
2 ongoing litigation, there may be some questions in your
3 minds concerning this. This is a matter, really, between
4 the Justice Department and the courts in New York, and my staff
5 have refrained from getting ourselves involved, to the
6 extent that we have been able to, from the details of the
7 litigation.
8 But I am sure that those of you reading the papers
9 and listening to TV will have noted that a
10 settlement has been proposed in New York. It is my under-
11 standing that the judge will conduct a series of hearings,
12 not only in New York, but around the country, for the pur-
13 pose of determining the reaction and appropriateness of
14 the settlement question.
15 We have received a number of calls from veterans
16 concerning the status of their position, with regards to
17 the class action suit, and particularly as members of the
18 class. I think this is because some veterans have
19 been under the impression that somehow there is a connection
20 between being in the Agent Orange registry and being in the
21 class.
22 I just want to make it clear here, as I have tried
23 to make it clear to the veterans who have called us on this
24 issue, that there is no real connection between the Agent
25 Orange registry, or being in the registry and being in the

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1 class. There was a point in time in which the court re-
2 quested names and addresses of individuals on the registry,
3 because that is among the larger of registries of Vietnam
4 veterans who certainly are concerned about Agent Orange.
5 It was a means of getting in touch with these individuals.
6 The court did request names and addresses of individuals on
7 the registry. And it is my recollection that they mailed
8 out a letter to these individuals, simply pointing out
9 their opportunity for opting out of the class, if they did
10 not choose to remain in the class.
11 To the best of my knowledge, that is the only
12 connection between the registry and the court action that
13 is going on in New York.
14 I just wanted to clarify that point.
15 Mr. Fred Conway, of our General Counsel's office,
16 is here and may be willing to answer any questions later
17 on, during the question and answer period, if there are
18 those of you who want to address questions to him.
19 You may also have heard that last month, that is
20 on the 22nd of May, the Senate approved H.R. 1961, after it
21 was amended to include the text of S. 1651, as amended,
22 the Veterans Dioxin and Radiation Exposure Compensation
23 Standards Act. The purpose of the Senate passed legisla-
24 tion is to insure that VA disability compensation is
25 provided to veterans who were exposed during service in

1 armed forces in the Republic of Vietnam to herbicides con-
2 taining dioxin, or to inonizing radiation in connection
3 with atmospheric, nuclear tests, or with the American
4 occupation of Hiroshima or Nagasaki (and dependency and
5 indemenity compensation is provided to survivors of such
6 veterans) for all disabilities arising or subsequent to such
7 service that are connected, based on sound scientific and
8 medical evidence to such exposure; and for all deaths
9 resulting from such disabilities.
10 Again, Mr. Conway and I wish to amplify, or answer
11 questions regarding this recent piece of legislation passed
12 by the Senate. It is my understanding that this will pro-
13 bably go to conference because of some differences between
14 the House and Senate versions, but we will follow the
15 course of that action with interest.
16 That concludes my opening remarks.
17 I would now like to call on Dr. John Beljan,
18 representing the American Medical Association, Council on
19 Scientific Affairs, who, as many of you know, has been
20 involved in the Agent Orange issue for sometime now, and
21 has been developing an update of analysis on that issue.
22 John, it is a pleasure to have you here this
23 morning.

UPDATE FROM THE AMERICAN MEDICAL ASSOCIATION

24 DR. BELJAN: Thank you, Dr. Shepard.
25 I noticed that Dr. Shepard gave me 15 minutes on

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1 the program, and I think that is related to my private life
2 as a Dean of Medicine. I do not intend to speak that long,
3 sir.
4 I would like to bring you up-to-date on the
5 report that is in process from the American Medical
6 Association. You will recall that in 1980 and '81, the
7 Council on Scientific Affairs of the American Medical
8 Association was asked by its constituency to develop a
9 paper summarizing at that time the medical effects of Agent
10 Orange. That was subsequently published in a document
11 that has been widely circulated in 1982. It was subsequently
12 published in an abbreviated form in the Journal of the American Medical Association
13 as a result of that investigation of 1981 - 1982.
14 You will also recall that the Missouri Delegation
15 requested that the report be updated following some of
16 the publicity related to the Times Beach affair, and con-
17 cerns of practicing physicians, particularly in
18 Missouri.
19 As a consequence of that request, the original panel that
20 developed the report of 1981-82 was reconstituted and
21 met initially in the summer of last year. It has subsequently met on
22 a monthly basis until April. It has asked a variety of
23 people who have testified before your committee, and others,
24 to bring us up-to-date in a small group setting, regarding
25 most of the human epidemiological work going on related to

1 dioxin/Agent Orange studies.

2 We are currently in the process of developing the

3 first draft of our revised report. We will be meeting

4 at the end of this month, in camera, as a full panel to

5 debate and/further revise the first draft. Our intent is to have

6 a paper completed in time for the fall meeting of the

7 Council on Scientific Affairs, and trust that the report

8 will be/subsequently adopted at the December meeting of our House of

9 Delegates.

10 I think it is fair to say that we do not see any

11 major alterations at this time from the con-

12 clusions of our previous report, but one can always be

13 surprised in the process of discussion, drafting, and/editing. However,

14 we believe that the report will be out in December and will

15 become public information at that time. And our bottom

16 line will be that we do not believe that it will contain

17 any surprises.

18 DR. SHEPARD: Thank you very much, Dr. Beljan.

19 Are there any questions from members of the

20 committee to Dr. Beljan?

21 (No response.)

22 DR. SHEPARD: I know from personal experience,

23 he has done a very thorough job, he and his committee.

24 I was privileged to present material updating the VA's

25 activity in this area at a meeting that he held at his

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1 committee in Chicago several months ago, and I know that he
2 has called on a number of experts in the field since that
3 time. So, I have the strong sense that Dr. Beljan and his
4 committee have done a very thorough job in preparing this
5 report, that has left no stones unturned, I believe, in
6 terms of achieving additional information.
7 Yes, Dr. Barnes?
8 DR. BARNES: I was wondering whether I might ask
9 whether or not you have included in your examination of
10 2,4-D in this document?
11 DR. BELJAN: Not in depth, no. It is primary a
12 dioxin paper.
13 DR. BARNES: Are you broadening the scope to
14 deal with dioxin and herbicides?
15 DR. BELJAN: No, we have tried to maintain our
16 frame of reference to dioxin. It all started out as
17 Agent Orange and then dioxin, and we have tried to contain
18 this, because as you know, one can keep opening many, many
19 doors. We wanted to develop a report directed at this
20 particular agent, and in some kind of timely way. We
21 believe our report thus came out timely; our membership probably does not.
22 MR. WALKUP: Doctor, in previous editions of your
23 report you gone to some length talking about the effects
24 of tobacco and alcohol, as well as Agent Orange and dioxin,
25 in your revised edition there are a number of places where

1 things had not been updated and there were still references
2 to studies that were as of 1981, which were then completed
3 by 1982 or 1983.
4 What sorts of things are you doing to insure that
5 the quality of the next report is better than the last
6 two?
7 DR. BELJAN: Our intent, of course, is where
8 studies have been completed, to include them in the report,
9 and to weave in those things that have been related in
10 prior reports into our current work.
11 MR. WALKUP: I guess I was asking more specifically,
12 what sorts of areas have you identified that have created
13 some of the criticisms that came with the previous reports,
14 and what have you done to correct those problem areas?
15 DR. BELJAN: Those that have come to our attention
16 have certainly been addressed and have been updated. If
17 there are other concerns about the report of which we
18 are unaware, we would be grateful to have them. There have
19 been criticisms of any report, and we recognize that, how-
20 ever, where there has been criticism in print, or elsewhere, that
21 criticism has been addressed.
22 We have Mr. Wheater in the audience, who is our
23 staff officer for this report. Bob, do you have anything
24 further to add to that question?
25 MR. Wheater: The only major objection that we

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1 heard was that of picloram, which has been changed. The
2 correction was issued in 1982, officially in JAMA, and a
3 revised printing of the document has been made since then
4 to reflect that change.
5 This was the controversial study of Reuber.
6 MR. WALKUP: Do I understand the VA and AMA feels
7 that with that exception, the previous reports have no
8 problems and essentially are proceeding on the same basis?
9 DR. BELJAN: I think that is a fair assessment,
10 yes.
11 DR. SHEPARD: I haven't discussed this, Dr. Beljan,
12 but if it would be helpful, or useful in your view, I am
13 sure the members of the committee would be happy to review
14 the manuscript with that in mind, if you think that would
15 be helpful. I just throw that out as an offering to the
16 committee, I trust the committee members would be willing
17 to do that, if that would be helpful to you.
18 DR. BELJAN: Thank you.
19 DR. SHEPARD: Any other questions for Dr. Beljan?
20 (No response.)
21 DR. SHEPARD: Thank you very much.
CDC BIRTH DEFECTS STUDY
22 The next item on the agenda was to have been a
23 presentation by Dr. Joseph Mulinare, who is working on
24 the CDC Birth Defects Study. Unfortunately, there has been
25 a health problem in Dr. Mulinare's family, and he is unable

1 to be with us this morning.

2 I had a good conversation with him yesterday, and

3 also with Dr. David Erickson, who initiated the Birth Defects

4 Study, as you will recall. We are very sorry that Dr.

5 Mulinare can't be with us this morning, but I think I can

6 summarize the status of that very important study. It is

7 essentially as follows: The study has been completed, the

8 data has been collected, has been analyzed and the report

9 has been prepared.

10 The results of this study will be presented in

11 two fashions: first of all, it will be submitted as a

12 medical journal item to a medical journal. It will appear

13 in a medical journal as a scientific report. Obviously,

14 such journal articles do not contain all the data, or all

15 of the methods, or the intricacies of the study, and so

16 forth, that is a much more complete document.

17 So, in addition to the article in a medical

18 journal, there will be a detailed report issued by CDC,

19 analogous, I suspect, to the Ranch Hand Report which was

20 a voluminous report on all the details of how the study

21 was conducted, the data that was gathered, the method of

22 analysis, some of the analytical results -- much more than

23 would appear in a normal journal article.

24 As part of the review process, the manuscript and

25 the report were submitted to the Agent Orange Working Group,

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1 for review and in turn submitted to the special advisory
2 committee that was established by the Chair of the Agent
3 Orange Working Group, for the purpose of reviewing
4 and monitoring such research efforts.
5 This is the same committee that reviewed the
6 Ranch Hand Study. As you many recall, Dr. Moore was the
7 Chairman of that committee for most of the time that it
8 was acting as an oversight committee for the Ranch Hand
9 Study. With Dr. Moore's new appointment to EPA, he
10 resigned that chairmanship, and the new chairman of that
11 committee is Dr. Robert Miller, an epidemiologist at the
12 National Cancer Institute.
13 Dr. Robert Miller's committee has reviewed the
14 Birth Defects Study report, and has completed that process.
15 Now the manuscript of the article that will
16 appear in a medical journal has been submitted to the
17 Editorial Board of the Journal of the American Medical
18 Association. They are currently reviewing the article,
19 the report, and hopefully, will act upon it favorably,
20 that is they will decide to include it as a journal article
21 in JAMA.
22 Precisely when that occurs is difficult to pre-
23 dict at the moment, but we certainly hope that it will be
24 within the next six weeks.
25 The detailed reference report that I mentioned,

1 the other form of the report, is also ready for publication
2 and by agreement with the editorial board of the JAMA,
3 assuming that they will agree to publish the article, the
4 detailed report from CDC will be published concurrently,
5 that is as close as can be predicted, the two reports will
6 appear at the same time.
7 We hope, as I say, that we will have the results
8 of this sometime in the next six weeks. It is a little
9 bit difficult to predict when you are dealing with an
10 editorial board of a journal of the reputation of the
11 Journal of the American Medical Association, to know
12 exactly when the editorial board will agree on the content
13 of the article. As I say, I hope it will be sometime in
14 the next six weeks, or so.
15 I would be happy to answer any questions, if you
16 may have them.
17 Yes, Dr. FitzGerald?
18 DR. FITZGERALD: Barclay, is it your intent to
19 have copies of the CDC Report for the members of the
20 committee?
21 DR. SHEPARD: For sure, yes. You will see it,
22 however, no sooner than it appears in JAMA.
23 DR. FITZGERALD: I understand that.
24 DR. SHEPARD: We will certainly get copies of the
25 full report. I haven't seen

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1 the report. It has been purposely conducted in this way,
2 I think, to minimize any opportunity for anybody influenc-
3 ing the contents. It has been a very carefully conducted
4 scientific piece of research and its publication as such
5 I believe has been in the appropriate fashion. Except
6 for the investigators themselves, I suspect that very
7 few people know the results of that study, and appropriately
8 so, until it appears in the Journal.
9 DR. KAHN: Speaking of the reports, I don't think
10 we ever got copies of the Ranch Hand Study -- there was
11 a box around, but the box evaporated, and most of those
12 never got to all members of the committee.
13 DR. SHEPARD: I certainly don't have a large
14 supply. I would suggest the people who want copies of the
15 Ranch Hand Study, who have not gotten them, submit that
16 request to the principal investigators in San Antonio.
17 We did not have a large number of reports. And
18 if that is a problem, please let me know, and we will see
19 what we can do about getting copies.
20 Did everybody on the committee get a copy?
21 (Affirmative reply.)
22 DR. SHEPARD: So, we did supply them to members
23 of the committee.
24 I, personally, feel that that is probably the
25 extent of our responsibility. We cannot, I think, take on

1 the responsibility of distributing copies of somebody else's
2 work to large groups of people. It was submitted, we did
3 make arrangements to have enough copies for us.
4 Any other questions on the CDC Birth Defects
5 Study?
6 MR. WALKUP: Is it correct then that the papers
7 you are speaking of have been reviewed by no one, except
8 within CDC, the Agent Orange Working Group, and the Board
9 of the American Medical Association who participated?
10 DR. SHEPARD: To the best of my knowledge, I know
11 that Dr. Erickson, from time-to-time, during the course of
12 the preparation of the protocol and other times has shared
13 the strategy of the study, the manner of the conduct of
14 the study with groups of veterans, and, of course, this
15 committee. It is a matter of public record again, and again
16 and again, Dr. Erickson and Dr. Mulinare have reported on
17 the study.
18 In terms of a critical review of the results of
19 the study, I believe that is correct. To my knowledge, no
20 other groups have reviewed it.
21 Any other questions or comments?
22 (No response.)
23 DR. SHEPARD: Thank you.
24 Next, I would like to call on Dr. George Anderson,
25 to give us an update on the activities of our various

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1 state Agent Orange Commissions.

2 STATE GOVERNMENT ACTIVITIES

3 DR. ANDERSON: I come to you with a bit of a
4 common cold, so with my raspy voice, and I am also suffer-
5 ing from seven hours of jet lag, I flew in yesterday from
6 Helsinki.

7 Texans do things in a big way, I came to this
8 meeting by way of San Francisco, Shanghi, Peking, Moscow,
9 Lenigrad and Helsinki and New York. So, if I tend to
10 wander, it is because I am not quite rested yet.

11 When I was contacted to present some information
12 from the various states, either 21 or 23 programs, depend-
13 ing on definition, I sent out a memo and I have the results
14 back from a number of the states, not all of them of course,
15 since the programs are in various states of development
16 and activity.

17 I thought what I might do is give a short summary
18 from each one of the responses, and then end up discussing
19 a bit of what is happening in Texas, to close.

20 I received from Al Wendt, from the State of Iowa,
21 a rather short report in which he wanted to be
22 recognized at this meeting. He says they are continuing
23 their activities and those are very much like those of many
24 of the other states in which they, of course, develop a
25 registry and get some basic data on the veterans within the

1 state, and then take it from there.

2 The public awareness program is moving along, they

3 are getting a lot of cooperation from the media. They are

4 sending out many news releases, radio and television public

5 service announcements, even though their program is still

6 quite new.

7 Eligible veterans are contacted by means of the

8 survey exposure questionnaire which he sent me a copy, and

9 they use a self-addressed stamped envelope to get it back.

10 And this, of course, is always important, many of our

11 veterans prefer this.

12 The information is collected, reviewed and the

13 data transferred for analysis to their computer data bank.

14 They hope to have a final report on their first year activit-

15 ies shortly. It is questionable at this time whether con-

16 sideration will be given for extending the program beyond

17 the 30th of June of this year, because of funding con-

18 straints. He will continue to keep us informed.

19 The great State of Wisconsin, a letter from Donald

20 Laurin, who is the field investigator. He states that

21 they are developing their veterans health update, and

22 they are hoping to get a cohort mortality study down the

23 road. They have 58,260 Vietnam War veterans in the state,

24 with 171,000 Vietnam Era veterans. They are going to study

25 the groups together with a proportionate mortality ratio

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1 analysis.

2 Beyond that they are not extending their studies

3 much further at this time. It is nice to know that they

4 are active, in view of the fact that a year or two ago, we

5 weren't sure if they were going to continue a program in

6 Wisconsin.

7 The State of Kansas, we heard from Dr. Donald

8 Wilcox. Although the Kansas statute pertaining to Veterans

9 Agent Orange Assistance Program was initially identical

10 to the one passed by Texas, the Kansas legislation amended

11 it and thereby eliminated a requirement of the state to

12 provide the veterans with fat tissue biopsies, genetic

13 counseling and screening. In addition, the conduct of

14 epidemiological studies was made elective, rather than a

15 mandatory responsibility of the State Department of Health

16 and Environment. And no funds have been appropriated for

17 such a program during the past two years.

18 As a results, reports by veterans to this depart-

19 ment of possible injuries subsequent to exposure to Agent

20 Orange have been extremely meager, only 20 have been

21 received, despite the fact that over 2,000 forms were

22 distributed to veteran organizations and other groups

23 throughout the state.

24 In summary, except for an annual report to the

25 governor and legislature required by statute regarding the

1 current status of various scientific studies being con-
2 ducted by the federal government on the effect of exposure
3 to Agent Orange. The program is not highly successful
4 in Kansas.
5 Without money, people just don't get things done,
6 and we are all quite aware of that.
7 The State of Connecticut, Vietnam Herbicide
8 Information Commission, this is being done at the Veterans
9 Office of Southern Connecticut State University.
10 "Dear George, Reference your request" and so forth,
11 March 24th, '84, Vietnam Herbicide Information and Medical
12 Outreach Conference, and he attaches some brochures con-
13 cerning their conference held in Connecticut.
14 On the same date, the Physician Hospital Reporting
15 System announced in Connecticut, and also attached are
16 their forms. As you know, their program is still very new,
17 just getting started.
18 On April 18th, the Agent Orange Registry List for
19 Connecticut was received at the VA, over 800 medical
20 questionnaires were sent to newly identified Vietnam
21 veterans. On April 25th, the current figures on Connecticut
22 Vietnam veterans who have completed medical questionnaires
23 and May and June, articles are being written by medical
24 subcommittees for two monthly publications in Connecticut.
25 And the Commission meets every six weeks, funding for our

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1 third year has been approved by the Governor, for the same
2 amount as this year, $120,000.
3 That concludes the State of Connecticut.
4 The State of West Virginia, I believe Chuck Conroy
5 is here today, but I will present what he gave to me. The
6 usual opening, "Please find enclosed a brief update on our
7 activities", they are attempting to get the kinks out of
8 their program, and moving along more rapidly than I thought
9 they would.
10 He had received a copy of our preliminary studies,
11 of our pilot clinical studies. Todate the West Virginia
12 Department of Health has received requests for medical
13 testing for possible health-related effects of Agent
14 Orange exposure from 4,221 state Vietnam veterans. This
15 means that approximately 16 percent of West Virginia
16 Vietnam veterans have requested these services. In order
17 to register for medical testing services available under
18 our program, the veteran simply completes and returns the
19 postage paid portion of the enclosed brochure, which he
20 attached copies. They have mailed out 27,000 of these
21 so far in the state.
22 If the veteran objects to being tested by the VA,
23 which is Phase I of our testing protocol. They so indicate
24 on the card, and arrangements are made to have them tested
25 in an alternate facility; todate only 84 veterans, or

1 approximately 2 percent of our responses, have refused to
2 be tested by the VA.
3 Upon receipt of their request for testing, provid-
4 ing they have no objections, we arrange an appointment for
5 them to receive an Agent Orange screening exam through the
6 VA Medical Center closest to them. Our office arranged for
7 over 1300 of these examinations over the past 18 months.
8 After receipt of the VA exam, we then forward the
9 Veteran Consent Form enabling the VA to release copies cf
10 the examination results to the West Virginia Department of
11 Health and a medical questionnaire to complete, additionally
12 copies of medical records from private physicians, the
13 veteran is visited .
14
15
16 Once we have received the veteran's medical
17 records from the VA and their private physician, they have
18 completed their medical questionnaire, we then forward
19 these documents on to our Health Department Epidemiologist,
20 she then assures that are required exams, lab work, X-rays
21 and so forth have been performed and are included with the
22 veteran's medical records.
23 After all of these medical records are gathered,
24 they are abstracted by a health department epidemiologist,
25 noting abnormal test results and so forth, and made a

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1 matter of record. They review the medical records, similar
2 to the way we do in Texas in our program, and build a file,
3 which then is very useful. They have a complete packet.
4 We now have complete packets, meaning all relevant
5 medical records and medical questionnaires from 25 percent
6 of our 4,000 veteran respondents, and hope to begin
7 schedulling appointments at state medical schools next
8 week.
9 Perhaps they may have already done this, because
10 his letter was dated April 18th.
11 To encourage participation in the program, Governor
12 Rockefeller has recently issued an Executive Order granting
13 administrative leave to all state employees who are Vietnam
14 veterans for the purpose of obtaining these examinations.
15 He also urged employers in the private sector to initiate
16 a similar leave policy for their employees.
17 They have also recently amended a mortality study
18 to determine how many West Virginian Vietnam veterans had
19 died since the conclusion of that war, the cause of death,
20 and so forth.
21 Finally, we are considering the feasibility of
22 conducting a birth defect study, similar to the one con-
23 ducted by the State of Texas.
24 And that completes West Virginia.
25 Chuck is here, he can make any additions, if you

1 would like, to his report.

2 DR. SHEPARD: I will recognize Chuck Conroy, if

3 you have any additional comments to make.

4 MR. CONROY: Thank you, Dr. Shepard.

5 No, that's basically it, although we have commenced

6 our testing now at our state medical facilities, we have

7 todate closer to 2,000 of the 4500 that are in the memo,

8 and we anticipate being able to test approximately 1800

9 veterans during our first year of testing.

10 We have received another fiscal appropriation

11 from our legislature for $200,000; we have also received

12 roll over funds for the unexpended funds that we have this

13 year. So, we are commencing our testing efforts with

14 approximately $400,000 in state monies. And we have

15 received outstanding cooperation from the VA, in terms of

16 obtaining these medical records that are referred to in

17 the report to Dr. Anderson.

18 We have four VAs in the State of West Virginia, and

19 just the quantity of medical records we have been receiving from

20 from the VA, we know that there are people involved at the

21 VA level that are just doing nothing but Xeroxing medical

22 records for the State of West Virginia, and we certainly

23 appreciate the cooperation we have received from the VA

24 thus far.

25 DR. SHEPARD: Thank you very much, Chuck.

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1 I was curious myself on the morality study, do
2 you have any feel for when that might be completed?
3 MR. CONROY: We have just commenced it now, I am
4 told by our computer people that it shouldn't take that
5 long because we do now have a master death tape that we
6 can bump against our 27,000, so they tell me it shouldn't
7 be more than a month, or so that we should have the results
8 of that.
9 DR. SHEPARD: You say you do have a master tape?
10 MR. CONROY: Yes, we do, it was just created last
11 July.
12 DR. SHEPARD: That should be very interesting.
13 Any questions -- oh, you are not through yet.
14 DR. ANDERSON: I am not done.
15 That was the extent of the states that responded
16 to my request. I note that there are other states repre-
17 sented at the meeting here, Terry Hertzler from Connecticut
18 is here, he may have something he may want to say.
19 MR. HERTZLER: We are Pennsylvania.
20 DR. ANDERSON: Oh, Pennsylvania, I'm sorry.
21 MR. HERTZLER: Briefly, I apologize for not
22 replying to Dr. Anderson, but we have been very busy lately,
23 trying to get an extension on our program. Legislatively,
24 there are currently two bills in Pennsylvania to extend
25 this, one for two years, and one for three years. Our

1 primary goal is establishing a registry of Pennsylvania
2 Vietnam veterans, which we expect, hopefully, will include
3 the 200,000 veterans in Pennsylvania. This will be accom-
4 plished by survey questionnaires scheduled to go out
5 in October of this year.
6 The Governor has done some TV PSAs for us and
7 so far we have distributed 250,000 informational brochures. We
8 expect to get another 50,000 out in the next couple of
9 weeks. The primary thing that we have just
10 finished, has been an educational program for physicians
11 in the Commonwealth of Pennsylvania. We held two seminars
12 late last year in which we had attendance from some of the
13 physicians in Pennsylvania's various medical functions.
14 We just got from the printer's two weeks ago a
15 manual we have been working on, which will be mailed this
16 week to physicians in Pennslyvania. Our primary mailing
17 is going to be about 9400 general practitioners, family
18 practice, internists and osteopaths in the Commonwealth
19 which will give them a background of the Agent Orange
20 problem, because we seem to get a feedback from some of
21 the veterans that due to their problems that they may have
22 encountered at the VA, or heard about the VA, have gone to
23 their own family doctors for some treatment and some of the
24 doctors are not familiar with the problem.
25 So, we have developed this manual, I have a limited

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1 amount of copies here which I will give the Chairman at the
2 break to distribute to the committee members, and then
3 additional ones to different state commissions.
4 DR. SHEPARD: Thank you very much.
5 DR. ANDERSON: I think Jerry Bender from Minnesota
6 is here.
7 MR. BENDER: Thank you.
8 The State of Minnesota, within a couple of weeks
9 will have a mailing to veterans. You will recall, four
10 years ago we had a major (inaudible). What we have done
11 now is run a cross-index between the most recent tax list
12 on the State of Minnesota and our computerized list of
13 57,000 veterans. We will be sending out current informa-
14 tion to these people. We hope to do this on an annual
15 basis.
16 As for those veterans on our old 1973 list, who
17 don't appear on there now, we hope to have some cooperation
18 from the Veterans Administration and the Internal Revenue
19 Service, so we can get a current address on these people.
20 What I intended on doing was setting up a system in
21 Minnesota that will accommodate the veterans for the next
22 half dozen years, until Minnesota has completed its control
23 study.
24 What we have done is set up a scientific panel
25 with noted scientists and medical people from the University

1 of Minnesota, the Department of Health, and also Mayo Clinic
2 we can use these people for the local source for the
3 analyses to study these people.
4 More importantly, we have been training people,
5 or had an ongoing effort to train the County Veteran
6 Service Office in the State of Minnesota, there is one in
7 each county, they serve as local contacts in a number of
8 areas. I think we have a very well trained network for
9 about 100 or so people throughout the state who are familiar
10 with the basic issues on Agent Orange, and also with some
11 of the latest updates.
12 I think basically what we have done in the last
13 couple of years is set up a system that is going to work
14 very well.
15 DR. SHEPARD: Thank you very much.
16 I would be pleased to welcome any other repre-
17 sentatives of the state Agent Orange commissions at this
18 time.
19 DR. KAHN: Peter Kahn. I am from New Jersey.
20 Our project for the death rate study is moving along rather
21 slowly. We have the disadvantage not having been a bonus
22 state, so cross-checking from the master tape has been a
23 real problem.
24 A second project to look at the possibility of
25 a study of soft tissue sarcoma is also still being looked

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1 at for feasibility. We don't know if we have the numbers
2 to do it.
3 The project that I mentioned here sometime ago
4 of an attempt to find out whether a small number of
5 heavily exposed men have dioxin in their blood at levels exceeding those in appropriate
6 controls is now in case selection, and we should be
7 putting our first men in the hospital for medical testing soon.
8 Our outreach operations continue at a fairly
9 high rate. We have held, for example, in the last couple
10 of weeks, a series of hearings around the state to gather
11 information for the Commission from Vietnam veterans about
12 the proposed settlement of the class action suit. This
13 information will be transmitted to the court, since
14 obviously 89,000 vets in New Jersey can't go there.
15 That about does it. If anyone has any questions,
16 you can see me after the meeting.
17 DR. SHEPARD: Any other state Agent Orange
18 Commission representatives here that would like to be
19 recognized?
20 (No response.)
21 DR. SHEPARD: If not, thank you -- oh, are you
22 going to tell us about Texas?
23 DR. ANDERSON: I will tell you about Texas.
24 DR. SHEPARD: Leave the best to the last.
25 DR. ANDERSON: It is not that I am a gentleman, I

1 just like to let everybody else come first.

2 Our program is undergoing a slight amount of

3 modification. Our Advisory Committee, which was established

4 under the amended law in our last legislature met for the

5 first time in March of this year. We, of course, in our

6 first meeting like that, you don't get an awful lot done,

7 mostly meeting the other people and getting them familiar

8 with the program, up-to-date.

9 Fortunately, at that time Dr. Guy Newell,

10 who is chairman of that committee, and also heads the

11 University of Texas System Committee on Agent Orange, did

12 have a report. And I think he sent copies of that report

13 to you, Dr. Shepard, covering our studies todate, our

14 pilot studies.

15 Our sperm study has shown nothing and we are in

16 the process now of dropping that particular study. We

17 were looking for Y-bodies, using florescent microscope

18 techniques, but it didn't show anything. We had, of course,

19 controls and we just didn't find anything.

20 The study, birth defects study in Dallas, has

21 been a difficult story, because we did not go retrospective,

22 we made a prospective study. We have now reached the point

23 at which the Vietnam veterans are not reproducing themselves

24 much anymore, they are reaching that 40-year group, and we

25 feel that their productive years of children are in the

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1 past, and we are now looking at the possibility of a retro-
2 spective study of going back and seeing if we can't locate
3 the children.
4 The study on the cytogenetics we are continuing
5 into our next year. Our fiscal year is the 1st of September,
6 which means that come the 1st of September we will have
7 revised protocols and will write new contracts for those
8 studies. We will continue with the cytogenetics, it is
9 very equivocal at this time as to whether or not we have
10 found much. But knowing the mutagenic potential of dioxin,
11 we did not want to drop that particular study. So, we
12 are continuing it. We have tested 69 veterans with 50
13 controls todate in that study.
14 The immunological profile studies are showing us
15 something we didn't expect. As you know, each university
16 system develops their own controls for their particular
17 procedures, and they have in the University of Texas, of
18 course, used staff and students of the university primarily
19 to establish their controls, and they use them against
20 patients in the hospital as methodology controls.
21 We found that our matched controls in our studies,
22 which of course were matched to age, to occupation, and
23 several other factors, except for one thing, they did not
24 serve in Vietnam. We had coded to the extent that the
25 researchers at the University of Texas did not know the

1 veterans from our controls. We had 69 veterans and 50
2 controls in the study at the point in time when we broke
3 the code. We had 13 individuals who had abnormal T-cells,
4 in other words low active T-cell counts and a few other
5 factors which were very questionable, primary in the total
6 T-cell count and the active T-cell count, subset. We did
7 not know who these were, amazingly when we broke the code
8 all 13 were veterans, which meant that we had a significant
9 finding.
10 Now, the problems we have is going back and sort-
11 ing through at this point in time to eliminate all of the
12 variables that we possibly can, to see how significant
13 our data on this is. We will continue that study in the
14 next fiscal year. We are not saying that we have a positive
15 finding, since it is a pilot study. It is giving us
16 direction to go, so we will be continuing that study and
17 possibly adding some other parameters to it.
18 The problem now in adding other parameters is
19 we must go back to the 69 original, plus the 50 controls
20 and all new controls that we select, and add these particular
21 parameters.
22 As you know, we dropped our mortality study two
23 years ago, when we found that it was not showing any
24 significance as to the cause of death, compared to anyone
25 else.

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1 We did not get going in the dioxin analysis of
2 fatty tissues for several reasons, one reason was that we
3 felt that we would not go after any individual, unless
4 we found some other clinical indications, such as laboratory
5 findings, which would indicate that he had an exposure of
6 a chronic nature in which he might still have residuals in his
7 fatty tissues.
8 We have collected only one sample of fat from a
9 veteran, and that is from a deceased Navy veteran, who
10 died from cancer in San Antonio. We have not analyzed that
11 specimen because on analysis of his risk factor we deter-
12 mined that he was not at high risk from exposure to start
13 with.
14 As we go into revising our protocols, we are now
15 looking at some enzyme studies, liver enzyme studies of
16 various types, and thinking of adding some subsets of
17 T-cells. We are going to change our birth defects study
18 and try to make it retrospective, if possible. And add
19 one or two other parameters, if it looks like it might
20 show us something.
21 We are still funded close to $300,000 a year, we
22 are now working on our next budget for the following two
23 years. We have a bi-annual budget. And it looks good, our
24 legislature and many of the members are still supportive
25 of our program. It would appear that we will be funded for

1 two years, beyond our current funding, which does not expire
2 until September of next year. It still looks good for
3 three more years of study.
4 The Department of Health is charged with an
5 epidemiological study, separate from the studies which the
6 University of Texas system are carrying out. We have
7 collected data now on nearly 600 veterans, medical data
8 and complete files. We have 1600 veterans in our program,
9 which means that we still have 1,000 more to put into the
10 system, collect the data. It takes anywhere from six
11 months to a year to develop a file on a veteran, so that
12 we can then at that point decide whether or not we will
13 put him into our clinical studies.
14 We hope to add at least 175 more during the next
15 year into our studies. At the present time we have 99
16 veterans selected for study, of which I believe some 85
17 have already had the specimens drawn and submitted to the
18 laboratory. The biggest problem we have, and an area
19 which we will probably receive a considerable amount of
20 criticism is in the selection of our controls. It is a
21 very difficult thing to do and those of you who have done
22 research and used controls know exactly what I am talking
23 about.
24 That concludes my report. I am open for questions.
25 DR. SHEPARD: Thank you very much.

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1 Do any members of the committee have questions
2 from Dr. Anderson?
3 DR. BARNES: Dr. Anderson, when you were referring
4 to the immunological studies that you had done at different
5 universities, was there implication to what you said that
6 there was variation between the controls of the different
7 groups?
8 DR. ANDERSON: I understand your question, the
9 T-cell studies were all done in the same university, by
10 the same group, and the controls were all selected by the
11 same committee and were geographically distributed around
12 the state from the areas from which the veterans came. So,
13 we tried to eliminate as many variables as we could.
14 We have not gotten a mix of laboratories nor indivi-
15 duals in the program. The ones that started will continue
16 straight through to the end.
17 DR. SHEPARD: Are there any other questions for
18 Dr. Anderson?
19 MR. WALKUP: Doctor, I would like to beat a dead
20 horse with you for just a minute, if I can. Do any of the
21 states receive funds from the Veterans Administration, or
22 any other agency of the federal government?
23 DR. ANDERSON: Not to my knowledge. I don't
24 believe any of them have.
25 MR. WALKUP: Do you feel, or for what reasons do

1 you think it is appropriate that the states have activities
2 working with veterans on Agent Orange, to what extent is
3 that a state or local responsibility, as opposed to a
4 federal responsibility? And why have states taken that on?
5 DR. ANDERSON: Of course, I am not in the political
6 scene in our state, I am with the State Health Department,
7 and I tend to want to stay out of the political side of it.
8 As to whether or not -- and I can only speak for Texas,
9 our legislature prefers to set up a state program, or not,
10 is in response from pressures from the various organizations
11 within the state, not from the Health Department, or the
12 scientific communities. We are only responding to a law
13 which was put into effect in response to veterans.
14 We are, by law, advocates of the veterans, we
15 have set up our program as an assistance program to the
16 veteran. Our job is to assist the veteran in filing his
17 claim and so forth, consistent with the law.
18 DR. SHEPARD: Any other questions of Dr. Anderson?
19 I have one question, Dr. Anderson. I think I
20 heard you say, correct me, if I am misquoting you, that
21 you are undertaking a mortality study, which you discon-
22 tinued because it wasn't showing anything. I am wondering
23 why you did that, it seems to me it is important to conduct
24 studies, irrespective of what they show, in order to
25 determine if anything is coming forward. Maybe I didn't

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1 understand you correctly, please correct me, if I am mis-
2 interpreting what you said.
3 DR. ANDERSON: Most studies of this nature, when
4 they are epidemiological studies, start out with a mortality
5 study, to take a look at those that have gone on before
6 to see what happened. So we have the mortality tapes, of course, in
7 our department, and we pull them out and we check the
8 cause of death of veterans, starting in 1967, '67 or '69.
9 And we could go up through 1979. So, we took about a
10 10-year span and we ran them through and we found that
11 these veterans compared favorably with the total deaths
12 of comparable males, same ages and so forth, in our state
13 statistics which we had already done in conjunction with
14 the Department of Public Safety.
15 They died from the same causes, mostly automobile
16 accidents, homicide, suicide and the usual cause of death
17 among 20-year old people. At the same time we realized
18 that in the State of Texas they had revised the death
19 certificate in 1979, and had left off the veteran identifier
20 as to the war in which he served. So, we now lost an
21 identifier which made it difficult for us to pull veterans
22 out, since 1979.
23 So, with those two problems facing us, we dropped
24 the study at that point in time. It cost us $5,000 just
25 to run the tapes to find that out. We just felt we had

1 other places we wanted to put our money.

2 DR. SHEPARD: Thank you very much, Dr. Anderson,
3 for your very complete report. It was very helpful.

4 I would now like to call on Dr. Betty Fischmann,
5 who heads up our Chloracne Task Force. Dr. Fischmann, as
6 you know is the Chief of Dermatology at our VA Medical
7 Center here in Washington, and has been working very hard
8 on this whole issue.

9 Dr. Fischmann.

VA CHLORACNE TASK FORCE

10 DR. FISCHMANN: Dr. Shepard, Advisory Group,
11 members, ladies and gentlemen.

12 In July 1982, the Veterans Administration Chief
13 Medical Director, Dr. Custis, reinstituted the Chloracne
14 Task Force, or CTF. The CTF consists of a chairperson,
15 and six members. All are prominent dermatologists, and
16 include internationally recognized authorities on acne,
17 dermatohistopathology and dioxin research. In addition,
18 the CTF has sought advice from American and European
19 chloracne experts.

20 Dr. Custis gave the Task Force seven objectives:
21 one, formation of a network of dermatology consultants to
22 the CTF in the 172 VA medical centers throughout the
23 country; two, establishment of a group of nationally
24 known private clinics, non-VA affiliated, to offer special
25 examinations to any veteran on the Agent Orange Registry

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1 where chloracne was suspected. three, establishment of
2 chloracne diagnostic criteria; four, to update dermatology
3 consultations in the Agent Orange Registry examinations; five,
4 to report on the types of skin problems in the Republic
5 of Vietnam veterans on the Agent Orange Registry; six,
6 to continue medical education for CTF dermatology con-
7 sultants; seven, to act as a source of information for
8 authors of the chloracne monograph.
9 The CTF has made significant progress as follows:
10 The nationwide network of CTF dermatology con-
11 sultants has been established, there is one in each
12 of the 172 medical centers, except those where no derma-
13 tologist is available. In the latter centers, the environ-
14 mental physician is appointed. Key reprints on chloracne,
15 systemic effects of dioxin toxicity in humans and lists
16 of chloracnegens are forwarded to each consultant.
17 Contracts have been established with non-VA-
18 affiliated nationally prominent medical clinics over the
19 USA for special examinations of Republic of Vietnam
20 veterans whose skin problems are chloracne or possible
21 chloracne. Those veterans are offered in-depth physical
22 examinations, environmental studies and laboratory examin-
23 ations.
24 To-date 17 veterans have accepted these special
25 examinations. Transport, accommodation and medical costs

1 are funded by the VA Agent Orange Project Office.

2 No definite case of chloracne has been diagnosed.

3 However, in threecases, the possibility that severe cystic

4 acne in service was related to dioxin exposure in Agent

5 Orange could be neither excluded, nor implicated. Copies

6 of the special examination reports are forwarded to each

7 veteran, to the environmental physician of the Veteran's

8 center for inclusion in the Agent Orange Registry, to the

9 veteran's private physician, if he has one, and to the

10 Chief of the VA Compensation and Benefit Department.

11 A new format for dermatology examinations for

12 the Agent Orange Registry is nearing completion.

13 The bibliographies on Chloracne and Dioxin, "Re-

14 view of Literature on Herbicides, Including Phenoxy

15 Herbicides and Associated Dioxin" Volumes III and IV,

16 have been forwarded to the confirmed authors of the

17 Monograph on Chloracne; also instructions to the authors.

18 A report on skin diseases found in the Agent

19 Orange Registry has been completed at the Washington, D. C.

20 Medical Center. Among 909 veterans, 179 had skin problems,

21 there were five histories of acute contact dermatitis cases

22 from sprays thought to be Agent Orange. There was one

23 case of chloracne in a bulldozer operator exposed to recently

24 sprayed and burned foliage and recently sprayed soil.

25 The commonest skin problems were fungal infections

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1 56; acute (11) and chronic (45) dermatitis; acne vulgaris
2 22; cysts, 18; acneiform dermatitis, 10; and eczema, 11.
3 There were up to three cases each of many common and some
4 rarer skin diseases.
5 Benign skin tumors were five lipoma and two other
6 tumors. Skin malignancies were five basal cell epitheliomas,
7 one squamous cell epithelioma; one melanoma; and one
8 cutaneous T-cell lymphoma; a total of eight cutaneous
9 malignancies.
10 Since the first 909 Agent Orange registrants,
11 there have been an additional two cases of chloracne, one
12 case of porphyria cutanea tarda and two cases of chlor-
13 acne from California. In addition, in the whole VA, there
14 are 17 cases of service-connected chloracne; of these one
15 is a case from the VA Medical Center and the remaining
16 sixteen are being collected for review by the Chloracne
17 Task Force.
18 In summary, at this time there are eight cases of
19 chloracne where dioxin exposure in the Republic of Vietnam
20 or to chemicals in a service research center in the US,
21 can neither be implicated, nor excluded. There are an
22 additional 16 cases to be reviewed by the CTF.
23 The CTF has established criteria for the diagnosis
24 of chloracne. These criteria were mailed to the CTF
25 consultants in the 172 centers on September 1, 1983.

1 Recently there have been two new findings, first
2 the Ranch Hand II Study has shown a statistically signifi-
3 cant increase in skin cancers, predominantly basal cell
4 epitheliomas, in the Ranch Handers. This finding has not
5 yet been corrected for sun exposure, the usual cause of
6 basal cell carcinomas. While awaiting this further analysis,
7 the CTF will advise the field consultants to do thorough
8 checks for skin cancers on Agent Orange registrants.
9 Secondly, in the National Cancer Institute
10 cutaneous T-cell Lymphoma Study, there are seven partici-
11 pants who are Republic of Vietnam veterans. The significance,
12 if any, of this cluster of cutaneous lymphoma is not known
13 at present.
14 Recently, at the VA Medical Center in D. C.,
15 the Agent Orange Registry was thoroughly re-
16 viewed by the General Accounting Office. They expressed
17 concern about follow-up on the registry. In the Dermatology
18 Section they were unable to locate two skin biopsies which
19 had been requested during the Agent Orange exam. We were able
20 to verify that these biopsies had been done and appropriate
21 therapy instituted.
22 The Chairperson had two days of deposition for the
23 Agent Orange Class Action. Again, questions by the lawyers
24 made it clear that there is concern about follow-up pro-
25 cedures for health problems found in the Agent Orange

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1 examinations in the country.

2 The CTF meets bi-annually, there have been four
3 meetings, the last in May 1984. The CTF decided to again
4 stress to the Agent Orange Projects Office its strong
5 recommendation that the records of veterans on the Agent
6 Orange Registry prior to October 1980, when chloracne was
7 coded for the data base, that these records be analyzed by
8 contract. It is important any cases of chloracne be
9 located, as these are the Republic of Vietnam veterans who
10 have had systemic absorption of a toxin and whose health
11 must be monitored for life.

12 DR. SHEPARD: Thank you very much, Dr. Fischmann.

13 Are there any questions from members of the
14 committee of Dr. Fischmann?

15 Yes, Dr. Lingeman?

16 DR. LINGEMAN: Congratulations, Dr. Fischmann,
17 on a very complete and interesting report.

18 My question concerns the procedure for reviewing,
19 you said that when a case of possible chloracne is called
20 to the attention of the Task Force, that these are reviewed
21 by the Task Force. Can you tell us more details about
22 what materials are used in this review, and how it is
23 conducted?

24 DR. FISCHMANN: When a case is brought to our
25 notice, we locate the medical center of the case, request

1 the Agent Orange Registry records, the patient's clinical
2 records, the service records and all of these are initially
3 reviewed.
4 On review it is sometimes clear that there is no
5 possibility that the case is chloracne. In that case, we
6 may go no further.
7 If there is a question in our mind, because often
8 there may not be a good description of the skin lesions,
9 sometimes there will be just the diagnosis , then
10 we always request the medical center to recall the patient
11 to be seen by the Chloracne Task Force consultant derma-
12 tologist, and to verify against the new criteria for
13 diagnosis the current diagnosis.
14 We may, of course, request further things like
15 skin biopsies and more detailed histories of exposure or
16 subsequent exposure, et cetera.
17 DR. SHEPARD: Any other questions for Dr. Fischmann?
18 Yes, Dr. Barnes?
19 DR. BARNES: I must confess a little confusion
20 on the numbers, let me just see if I have them straight.
21 On page 2 you talk about that in the whole of the VA there
22 are 17 cases of service-connected chloracne, now that
23 includes all veterans, not limited to Vietnam, is that
24 correct?
25 DR. FISCHMANN: That is correct, it is chloracne,

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1 and at this point not having reviewed those, I am not sure,
2 I think they are all Vietnam veterans, but I am not quite
3 sure.
4 DR. BARNES: We recognize those as confirmed
5 diagnoses?
6 DR. FISCHMANN: No, we are about to check them
7 to confirm those diagnoses. These recently came to our
8 attention.
9 DR. BARNES: Okay. Then in the following para-
10 graph it says there are eight cases of chloracne, which
11 can either be implicated, in which dioxin can neither be
12 implicated nor excluded. Is that part of the 17?
13 DR. FISCHMANN: No, only one of those is part of
14 the 17. The eight are all Republic of Vietnam veterans and have
15 had exposure to Agent Orange.
16 DR. SHEPARD: Any other questions of Dr. Fischmann?
17 DR. KAHN: Dr. Fischmann, is it the Task Force's
18 continuing belief that the systemic exposure -- that
19 chloracne is a necessary consequence of systemic exposure
20 only?
21 DR. FISCHMANN: The Chloracne Task Force believes
22 that in the instance of dioxin toxicity, not PCBs, for
23 instance, only in dioxin that chloracne is a necessary
24 finding to be able to say that some systemic problem is
25 related to exposure. In all of the literature there have

1 only been two cases of laboratory workers who, two years
2 after they had worked with dioxin, when three people got chloracne
3 two years afterwards . Two of the workers (without chloracne) had systemic
4
5 problems. And this is the only instance in the record that
6 I could find.
7 One would want to know what all the other exposures
8 of those workers had been.
9 DR. SHEPARD: As you know, if I may just comment
10 or add to that question, there is some block of consensus
11 among dermatologists familiar with chloracne, or experts
12 in the area of chloracne, as to whether or not the develop-
13 ment of chloracne is a necessary hallmark of dioxin
14 exposure. Some people feel very strongly that it is.
15 Dr. Kenneth Crow of England, for example, has
16 spoken many times on this subject, and have written
17 extensively on it and he believes that if you look at even
18 very subtle changes, that this is the most sensitive
19 indicator of systemic reaction to chloracnegens, I don't
20 know that he has made the distinction between dioxin and
21 other chloracnegens, but he certainly has made that
22 statement. I think I am accurate in that reporting.
23 I don't think that is universally held opinion,
24 however, so there is some controversy over that point.
25 And I don't know how that controversy would get cleared up,

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1 but it still is an open question.

2 DR. FISCHMANN: I would like to make perfectly

3 clear one point, what is not known at this time is what

4 low-grade, long-term exposure may do. Now, coming in that

5 category could be birth defects, because doses much lower

6 than those which can give experimental animals and

7 humans toxic manifestations, doses

8 much lower than those required for toxic manifestations

9 may give you birth defects.

10 And the same thing with something like cancer,

11 which is shown in the experimental animals, and is suggested

12 in the work now in dioxin as a possibility.

13 So that one could not have chloracne and still

14 have some long-term effect.

15 DR. SHEPARD: Yes, Dr. Hodder?

16 DR. HODDER: I am still not clear on the report,

17 on the question you made. You have found 17 reported from

18 service-connected chloracne, but you have not confirmed

19 yourself? You have found reported 17 cases of chloracne,

20 but you have not confirmed those?

21 DR. FISCHMANN: These are cases of veterans who

22 applied for compensation, for a rating, for their skin

23 problems and the rating examination stated they had chlor-

24 acne, and the rating board has made these people service-

25 connected. They are all currently service-connected for

1 chloracne, the 17. Of those, only one -- I am only
2 familiar with one, and we are currently collecting the
3 records from the other 16.
4 DR. HODDER: Did you confirm that one as chloracne,
5 or --
6 DR. FISCHMANN: Yes, that is the one from the VA
7 Medical Center.
8 DR. SHEPARD: Any other questions from members of
9 the committee?
10 (No response.)
11 DR. SHEPARD: Thank you very much, Dr. Fischmann,
12 for your report.
13 Next, I would like to call on Mr. Joseph Carra,
14 from the Environmental Protection Agency, who will give us
15 an update on the status of our joint VA-EPA analysis of
16 Dioxin and Furans in Adipose Tissue.

RETROSPECTIVE STUDY OF DIOXINS AND FURANS IN ADIPOSE TISSUES

17 MR. CARRA: Good morning.
18 As Dr. Shepard mentioned, this is a joint study,
19 a collaborative study between the Veterans Administration
20 and the Environmental Protection Agency. Basically, the
21 way this study started was that
22 the Veterans
23 Administration is trying to take advantage of specimens
24 that have been collected by the EPA for many years, since
25 1970, adipose tissue specimens that the EPA has collected,

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1 and in a number of these we still have archives of some
2 of the specimens.
3 And I will go through that in a minute. So, the
4 idea is for us to take advantage of the large number of
5 specimens that the EPA has on-hand, to determine what the
6 background levels of dioxin are in adipose tissue collected
7 from the general population, and then to compare that to
8 the adipose of specimens that we have from Vietnam veterans.
9 And then to analyze the results of that, to assess the
10 potential differences and factors that are associated with
11 the differences, other than veteran status.
12 The mechanism that we are going to be using for
13 this is the National Human Adipose Tissue Survey, or NHATS
14 for short. This is a national network that has a statistical
15 basis for it, at least in the initial stages of the design.
16 And it is designed to get a statistically sound estimate
17 of residues in human adipose tissues, residues of selected
18 chemicals and pesticides.
19 About 1,000 specimens, adipose specimens, are
20 collected annually for the EPA by medical examiners and
21 pathologists in selected standard metropolitan statistical
22 areas across the country, and they are sent then to EPA
23 for chemical analysis. Those specimens for which
24 we have remaining material, we archive, we store the
25 specimens.

1 EPA has operated the adipose tissue network since
2 1970, and we have been archieving the specimens remaining
3 after analyses for future work, as I mentioned before.
4 Because this is something that we have been doing
5 since 1970, and we continue to do to this day, what
6 I am going to be talking about is taking advantage of the
7 archives specimens, but it should also be kept in mind
8 that this network also has the potential for being used
9 for prospective analyses, as well.
10 And we would want to see how this retrospective
11 analysis goes before we would even entertain the idea of
12 using it for prospective work.
13 As I said before, there is a statistical basis
14 to the adipose tissue network, and I will just
15 go over it quickly, so you will understand where these
16 specimens come from. We have stratified the country into
17 nine geographic areas, coinciding with nine census divisions.
18 We then have selected, on a statistical basis from two to
19 seven SMSAs, Standard Metropolitan Statistical Areas, from
20 each census division for a total of about 40, what we call
21 primary sampling units.
22 From each of these primary sampling units we
23 select one or more hospitals, or medical examiners from
24 each of these SMSAs and then we give the hospital patholog-
25 ists who are cooperating with this network, or the medical

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1 examiners, information on the specimens -- the kinds of
2 specimens that we would like to have from each of them.
3 And that is based on census information, demographic informa-
4 tion. So, we ask for specific age, sex, and race distri-
5 butions from each of these participants.
6 The adipose tissue we get from the pathologists
7 and medical examiners, for the most part, I think between
8 70 and 80 percent, are from cadavers, the remaining are
9 from surgical patients. There are detailed protocols as
10 to what -- as I said, demographic characteristics of
11 the specimens we would like from each participant,
12 but also we specify how we would want the tissue supplied
13 to us, how it is to be sent. And we also indicate to the
14 pathologist and medical examiners that we prefer things
15 like traumatic deaths, so we don't have problems in inter-
16 preting some of the information.
17 Remember now, the purpose of the EPA network has
18 been to get a handle on the general population over the
19 years, and to track trends of pesticides and other chemicals
20 in the general population.
21 The activities that have been going on with respect
22 to this study have come in three basic parts. One is
23 method development, that is chemical method development.
24 We have worked on developing a suitable method for analyzing
25 dioxins and furans in adipose tissue, in the lower parts

1 per trillion range. I will get into a little more detail
2 on that in a moment.
3 The information retrival area, a big effort here
4 is to determine the veteran status of the contributors
5 of the archived samples. And this is something, again,
6 I will get into in a little more detail.
7 And the third area, study design, is to see
8 whether we would be able to have adequate sample sizes to
9 be able to look at differences between Vietnam veterans
10 and tissue from other than
11 Vietnam veterans,
12 We have proposed, the EPA and another branch in
13 EPA that I work with, has proposed an analytical method for
14 the analysis of adipose tissue. It was initially planned
15 only to analyze for 2,3,7,8-TCDD, but in meetings of experts
16 to review the protocol, the experts recommended that pro-
17 tocols be expanded to include the other dioxins and furans.
18 The method would use high resolution capillary
19 gas chromatography, mass spectrometry and selected ion
20 monitoring techniques, for those of you who are familiar
21 with the chemistry. It allows for both low resolution
22 mass spec and high resolution mass spec, depending upon
23 the particular laboratory instrumentation that would be
24 available.
25 We feel very strongly that this method would have

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1 to be evaluated, the proposed method is only a method on
2 -- basically, a method on paper that has been tested, pre-
3 liminarily in the laboratory where this initial pro-
4 posal, originated, a contract laboratory to EPA. So, we feel that the
5 method has to be evaluated by an intra-laboratory rugged-
6 ness testing, intra-laboratory validation study, preferably
7 following the AOAC methods for doing ruggedness testing
8 and validation.
9 In the information retrival area, the data base
10 that we were working with, the EPA adipose tissue file,
11 contains 21,000 records. These are just the records now,
12 with the laboratory information, birth date of the person
13 from whom the specimen came, the sex and race. No name or
14 social security number was ever collected in this file
15 because there was no need, Based on the initial purpose of
16 the adipose tissue network, we did
17 not have names or social security numbers.
18 We also have an archives inventory. So, of the
19 21,000 records we have found that we have 8,000 specimens.
20 So, the first limiting factor is that we only have 8,000
21 specimens of the original 21,000, and that is because for some
22 of the specimens there was no material left after the
23 initial analyses that were done on a routine basis.
24 We have institution codes with those archive
25 inventory records. We have patient ID numbers that are

1 unique to this EPA adipose tissue network collection. And
2 we have patient initials and we have specimen collection
3 dates.
4 So, the problem we confront, first of all, is
5 in order to identify whether the specimens come from
6 Vietnam veterans or not, we need some identifier, other
7 than simply a patient ID number that is unique to this
8 study. We need something like a social security number,
9 or a name.
10 So our approach has been to, first of all, look
11 through our files, being that we do have the birth date,
12 and to find potential Vietnam veterans; and what we are
13 looking for is, in this study, males, born between 1937
14 and 1952. So, we looked first to see what archived
15 specimens we had that came from males born between those
16 dates. That is our potential Vietnam veteran pool.
17 Then we went and contacted the institutions from whom
18 we got these specimens originally to obtain the
19 social security numbers, or lacking social security numbers,
20 to obtain names, so that we could then get social security
21 numbers.
22 And then we would check these against Veterans
23 Administration and former DOD files, that I think now
24 reside with the GSA, records to determine Vietnam service.
25 So that is the basic approach of collecting the specimens

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1 and
categorizing them as to whether they were Vietnam -- speci-
2 mens from Vietnam veterans, or not.
3 What we then wanted to do was get an idea, as I
4 said before, as to whether we would -- what kind of a sample
5 size we would have out of this, and what we would be able
6 to do with that sample size -- would it give us any informa-
7 tion, what would be the limits that we could go with the
8 sample size we would have.
9 So, we looked at some simple analyses that could
10 be done, in order to assess the design limitations that we
11 had. One basic thing we could do was compare, obviously,
12 Vietnam veterans to non-Vietnam -- to those who were not
13 Vietnam veterans. We wanted to see how many we thought
14 we could get of the Vietnams, how many of the specimens
15 would be Vietnam veterans, how many of the specimens we
16 would have remaining and try to get as much of the
17 social security information from the institutions as we
18 could, to get an adequate sample size.
19 The basic design we were looking at to assess
20 sample size was to say that we would take each Vietnam
21 veteran, and we would match a veteran with at least one
22 Vietnam Era male that was not a Vietnam veteran, based on
23 age and possibly race. Of course, multiple matching is
24 probably going to be possible; that is we would be able to
25 have for every Vietnam veteran more than one, call

1 it control, for purposes of this discussion.

2 We would then analyze the dioxin levels from the

3 specimens that we had in the archives, and then analyze

4 the potential differences in the average dioxin levels of

5 these two groups.

6 So, the question we posed for ourselves is what

7 ratio of dioxin levels between the Vietnam veterans and

8 controls is detectable, given the likely sample sizes and

9 likely variability that we would encounter in this analysis.

10 We looked at various factors to assess this, the sample

11 size that we would expect, the false-positive and false-

12 negative rates that we thought would be allowable, the

13 analytical measurement problems that we know we will en-

14 counter with this kind of an analysis, and some other

15 factors.

16 We then calculated, based on various sample sizes,

17 sample sizes of having Vietnam -- specimens from Vietnam

18 veterans ranging from 30 up to 60, to 120. And we looked

19 at what power we would have to do some statistical tests,

20 given that we had those sample sizes.

21 We found that for false-positive -- assuming a

22 false-positive rate of about 10 percent, and a false-

23 negative rate of 10 percent, and having an

24 overall variability from sources like measurement error,

25 the analytical measurement, that was in the moderate to

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1 high range (which is being conservative for what we would
2 expect) with a sample size of about 30, we could detect
3 the difference of about a ratio of 2.4, that is levels in
4 Vietnam veteran specimens that were 2.4 times the control
5 group.
6 That was assuming a one-to-one matching. If we
7 can get up to a two-to-one, or three-to-one matching, we
8 get that down -- we could detect a doubling of the average
9 level of dioxin in Vietnam veterans.
10 If the sample size increases to 60 Vietnam veteran
11 specimens that we have, then the ratio that we can detect can
12 go down to about 1.7. And if we can get up to 120, the
13 ratio that we could detect would be about 1.2.
14 As I said, we did this analysis with the expecta-
15 tion that we would have moderate to high variability,
16 primarily from measurement error.
17 Let me jump on to where we are right now, as far
18 as the number of specimens that we have identified and the
19 number of Vietnam veterans that we have identified. We
20 had 520 specimens eligible for this study
21 on the basis of age and sex, and the fact that
22 we had the specimens in the archives. So, we have 520
23 specimens in our archives that meet the eligibility
24 requirements. We have 470 of that 520
25 that now have been identified by social security number,

1 or name. We have thus far identified 80 of these as being
2 veterans, using the Veterans Administration BIRLS file, and
3 I don't really remember what BIRLS stand for.
4 So, we have identified 80 there, and of that we
5 would expect -- and these records will then be taken by
6 the Veterans Administration and be sent to the GSA, who
7 holds the old Defense Department records, to determine
8 whether these veterans served in Vietnam.
9 We expect anywhere between 30 and 50 of these 80
10 would be Vietnam veterans.
11 The 80 we look at as being the minimum number of veterans and
12 the corresponding 30 to 50 also being a minimum, and we
13 think that the DOD records may provide that many more
14 veterans than we ascertained through the BIRLS files.
15 So, we are not just taking the 80 veterans and
16 sending them to the DOD files, to see which ones are
17 Vietnam veterans, we are taking all of the 470 that we
18 have names and social security numbers for and taking them
19 and running them all through the DOD files as well, because
20 we suspect that there may have been some that we missed
21 by just looking at the BIRLS files.
22 So that is why we expect more than 80, as the
23 total number of veterans and more than 30 to 50 of the
24 Vietnam veterans, but that is the status right now of those
25 numbers. So, we have the potential of detecting somewhere

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1 between a doubling and a tripling. If there is a doubling
2 or a tripling of the average level of dioxin in adipose
3 tissue, we would expect to be able to detect that from the
4 numbers that we have now, we would probably get down to
5 below, between one and a half and two times, being able
6 to detect that kind of ratio, if we get a greater number
7 of Vietnam veterans as we expect to, when we go through
8 the DOD files.
9 DR. SHEPARD: Thank you very much for a complete
10 detailed report.
11 Are there questions?
12 DR. ANDERSON: Will you make an attempt to corre-
13 late these individual Vietnam veterans with the organizations
14 in which they served, as to whether or not they were highly
15 exposed, or essentially dioxin treated area?
16 MR. CARRA: Yes, I think we are going to be giving
17 this information to the Veterans Administration, and they
18 have the military -- I don't know what the file is called,
19 but there is a file that has down to a squad --
20 DR. SHEPARD: Yes, we would use the same method,
21 using the services of Mr. Richard Christian's group, now
22 known as the U.S. Army and Joint Services Environmental Support
23 Group, that is doing the
24 exposure identification for the big CDC study.
25 MR. CARRA: Now, there is going, of course, to be a

1 limitation in doing that, a great limitation by the fact
2 that we will be dealing with sample sizes that will allow
3 some crude comparisons. But when you start getting into
4 breaking things down into really fine -- a greater number
5 of cells, we will likely not have more than about 60 to
6 80 Vietnam veterans to work with.
7 DR. ANDERSON: How many grams of fat is critical?
8 MR. CARRA: The specimens in the archives that
9 we have have at least two grams and most of them have
10 between five and 10 grams.
11 DR. ANDERSON: Do you think that is sufficient?
12 MR. CARRA: Yes, the protocols that were developed
13 by the Midwest Research Institute for us, would give us
14 down to levels of detection in the one to 10 parts per
15 trillion range for specimens that were of the size that we
16 are talking about here, around five grams, and even lower
17 than that. We think we could get down to parts per trillion
18 range.
19 And the calculations that I gave you before,
20 of the ratios of detecting differences are
21 really what we are after. Those calculations took into
22 account that we would have some limitations with the
23 analytical method.
24 DR. FITZGERALD: Mr. Carra, I am confused, have
25 you established an average national norm finding in the

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1 specimens you have?

2 MR. CARRA: No, these specimens have been analyzed

3 for a number of pesticides and organic chlorine chemicals

4 in the past, over the last 14 years, DDT, DDE, Beta BHC,

5 aldrin, deldrin, PCBs -- a number of chemicals; dioxin was

6 not one of those chemicals. And so part of this analysis

7 is going to give us a background level.

8 So, I talked about one particular thing, of

9 comparing the Vietnam veterans to the general population

10 values. If we had problems with the number of Vietnam

11 veterans' specimens that we had and some confounding

12 factors, like the one Dr. Anderson mentioned, where they

13 might vary widely as to the exposure that you might expect,

14 we would still get out of this study an idea of the general

15 population values that we could expect for people in this

16 age group, from the adipose study.

17 DR. FITZGERALD: And that would be broken down

18 by geographic areas?

19 MR. CARRA: It could be broken down by geographic

20 areas, especially since we will have a large number of

21 non-Vietnam veterans -- we will probably have about 400

22 or so, non-Vietnam veterans. So, we will probably be able

23 to get a fairly good geographic stratification with that

24 number.

25 MR. WALKUP: I would like to follow-up on Dr.

1 Anderson's question concerning the separating of the people
2 out from the Vietnam veterans group. Do I understand
3 correctly that you are going to include all Vietnam veterans
4 who are identified, who are known for the study you are
5 talking about, and possibly breaking them down into cells
6 by the period of service and the unit they were in, regard-
7 less of whether they served in Vietnam during the time
8 when the spraying was going on, or in areas where the
9 spraying might have occurred?
10 MR. CARRA: I think it would be useful to get an
11 idea of the levels of exposure that -- the different levels
12 of exposure that the people may have had. And to the
13 extent -- the more detailed you can be in doing that, the
14 better. The only major misgiving I have about that is the
15 sample size that we are dealing with, it is probably going
16 to be -- the statistical analysis--my guess is that the
17 statistical analysis would be one of comparing the major
18 groups, and possibly coming up with a categorization that said this was the
19 high exposure group and this was the low exposure group.
20 This would be making a crude categorization within the
21 Vietnam veterans' specimen group, and that's about it.
22 You start getting any finer, and then what you are doing
23 is looking at things on a case-by-case basis, which would
24 be very useful, but it is not going to yield any statistical-
25 ly defensible results.

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1 MR. WALKUP: But it does sound as if there will
2 probably end up being people included in the group who had
3 no possibility of exposure.
4 MR. CARRA: That were Vietnam veterans, yes,
5 that is a distinct possibility that we will have Vietnam
6 veterans who, by looking at the files we have, would be
7 assumed to have no exposure to dioxin, or Agent Orange.
8 But the thing we have to look at is how those people com-
9 pare to -- we will have general population numbers, too,
10 where these people had no service in Vietnam, and we would
11 want to compare these low, or no exposure Vietnam veterans
12 to the general population values, to see whether there is
13 a difference there, because that might indicate that even
14 if there was no exposure that you could identify through
15 these files, that maybe just being there was enough to
16 make a difference.
17 DR. SHEPARD: If I may just add, or the subsequent
18 exposure, or previous exposure might have resulted in
19 detectable levels.
20 I would like to just make sure that everybody
21 understands that
22 for some of the individuals it may not be
23 possible to identify an exposure level, because their
24 records may not be complete, for a variety of reasons; it
25 may not be possible to determine what the likelihood of

1 exposure is in every instance. An attempt will be made to
2 do that, but we can't predict at the present time, since
3 we don't know who these individuals are. We haven't
4 searched through the personnel records yet to determine
5 what units they were attached to. So, it is a little early
6 to predict what we will be able to say about it.
7 DR. LUMB: I have two questions.
8 1. In the material you have available which might be designated back-
9 ground material: that is, people who have not been exposed to
10 concentrations of TCDD, such as one might expect to find in a factory,
11 but who may have some TCDD due to normal background levels
12 in the atmosphere? Am I right in assuming that you have not
13 tested such material and therefore, do not have a base line of what
14 might be called a normal TCDD level in a population existing under
15 normal circumstances?
MR. CARRA: That is one thing that we are concerned
16 about, and we are going to be analyzing as well. But be-
17 cause we have measured these specimens for other things,
18 we are going to analyze -- when we analyze the specimens
19 for dioxin, we will analyze them for some of the other
20 chemicals again, to see whether we can detect any deteriora-
21 tion in the levels and use that to adjust our results.
22 DR. LUMB:
23 2. Do you have any information available about material which has
24 been kept for some considerable time and then tested again? In
25 other words, does the TCDD level change? Does degradation take place
on storage?

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1
2
3
4
5
6 MR. CARRA: No.
7 DR. LUMB: That would give a handle --
8 MR. CARRA: What we are relying on is to be able
9 to look at these other chemicals that we have analyzed
10 previously, and we can get a complete profile on the
11 organo-chlorine pesticides. And we would make the assump-
12 tion then that these would degrade similarly.
13 DR. KAHN: I could, perhaps, field that last
14 question a little bit. There is very good evidence that
15 the metabolism of dioxin in the mammalian systems proceeds
16 with great slowness. These things are being stored frozen
17 at -80 degrees, so the likelihood of degradation is very,
18 very small.
19 MR. CARRA: That's what we expect, but we are
20 concerned about that. We do want to check it because
21 specimens that have been stored for this long, also, could
22 have undergone a lot of episodes that we may not know about,
23 may not have documented. So we are going to have to be
24 very careful.
25 DR. KAHN: I hope they all are in glass jars.

1 MR. CARRA: Yes, they are. They are what we would
2 consider to be very carefully preserved; whether in 14 years
3 now they have undergone any thawing and then re-freezing
4 due to power failures, or things like that, that is one of
5 the concerns that we have. We don't think it is going to
6 be a problem, but we have it in the back of our minds that
7 it is something we are going to have to pay attention to, because
8 that is the first question that people are going to have,
9 and reasonably so.
10 DR. HODDER: Just a quick question. In relation
11 to the fact that you have already studied these people,
12 have you looked at the comparison of the small sub-set with
13 the other people for what you have already looked at? In
14 other words, are they unusual, compared to their exposure
15 to anything else?
16 MR. CARRA: Most of our effort has been spent in
17 developing the method and in getting the social security
18 numbers and/or names from the institutions. This has not
19 been a trivial exercise. We have had to go back to these
20 institutions and beg them to get us social security numbers,
21 and we have been working with the VA, with their BIRLS files.
22 That is really where we have put most of our effort, we
23 have not, to this point analyzed -- but that is something
24 that is very easily done. Once we have these specimens
25 that we are going to be working with identified, we have

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1 a complete data file, automated data file that has all of
2 the information by patient ID number and all of the other
3 chemicals that were found in these specimens.
4 So, we can do that, and we will.
5 DR. SHEPARD: Thank you very much, Mr. Carra.
6 We are running a little behind schedule, so I am going to
7 ask Dr. Kang to give you a brief description of a
8 planned study, using the services of Armed Forces Institute
9 of Pathology.
10 On the agenda we also have Dr. Irey, and I would
11 like to have Dr. Irey give us his report during
12 our scientific Subcommittee meeting on epidemiology. So, if that
13 is all right with Dr. Irey, Dr. Hodder, I would like to
14 make that minor change in the agenda.

VA/AFIP PATHOLOGICAL EVALUATION OF MALIGNANT NEOPLASMS IN PTF

15 DR. KANG: Thank you, Dr. Shepard.
16 The research plan I am discussing this morning is
17 a joint effort between Veterans Administration and AFIP.
18 We heard this morning that there are massive research
19 efforts ongoing by the state and federal government. For example, CDC is
20 conducting a large-scale epidemiological study consisting
21 of three segments: Vietnam experience, Agent Orange
22 exposure and then selected cancer case control study.
23 Of course, the Veterans Administration is conduct-
24 ing a morality study, and a case control study for soft
25 tissue sarcoma.

(For vu-graphs used by Dr. Kang see pages 148-154).

1 As a parallel effort, we decided to review the
2 VA in-patient medical records to see whether there is any
3 difference between Vietnam veterans and non-Vietnam veterans
4 with respect to their reasons for admission into VA hospitals.
5 There has been some discussion in the scientific literature
6 that people exposed to phenoxy herbicides may have -- they
7 may be at higher risk of developing soft tissue sarcoma,
8 lymphoma, and possibly liver cancer.
9 As you know, it takes about 20 years to have
10 cancer to develop, if it is caused by environmental
11 chemicals. It has been almost a decade since the last
12 American troops withdrew from Vietnam, and about 20 years
13 since the first massive Agent Orange exposure occurred in
14 Vietnam. So, we are proposing to study the Vietnam Era
15 veterans who have been treated in the VA hospitals with a
16 cancer diagnosis.
17 We would like to compare Vietnam veterans' cancer
18 patterns with their counterparts in the VA hospital. We
19 recognize that all Vietnam Era veterans with a cancer
20 problem have not come to VA medical facilities for treat-
21 ment. However, the question has been raised many times,
22 do Vietnam veterans treated by VA hospitals present
23 different or unique health problems, as compared to the
24 non-Vietnam veterans ?
25 After a preliminary VA in-patient medical record

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1 review, we have decided to focus on malignant neoplasms.

2 This is a review of 13,000 medical records among Vietnam

3 Era veterans. This is a kind of diagnosis, the reason for them

4 being admitted to the VA hospital.

5 If you look at the bottom line, out of 13,446

6 Vietnam Era veterans in VA hospitals, roughly 58 or 60 per-

7 cent did not serve in Vietnam, and 41 percent served in

8 Vietnam. And if you look at different disease categories, starting

9 from infectious and parasitic disease, These proportions seem to

10 be true for each disease category.

11 In other words, the reason for being admitted in

12 the VA hospital is independent of service in Vietnam.

13 Incidentally, this is the medical record of VA in-patients

14 between 1969 and 1982.

15 We also sampled recent medical records of Vietnam

16 Era veterans, we sampled about 1,000 and looked at the

17 reasons for being admitted to the VA hospitals. Again,

18 a similar pattern seems to maintain, roughly 60 percent of

19 the in-patients during FY 83 did not serve in Vietnam

20 and about 40 percent served in Vietnam. And then the

21 breakdown by individual disease category is similar, 60-40, with a

22 few exceptions.

23 This is the number of the cancers among Vietnam

24 Era veterans in 1981, broken down by primary sites. This

25 is the kind of question we would like to address with

1 this joint effort between the VA and AFIP. We would like to know
2 whether Vietnam Era veterans who have been hospitalized
3 in a VA medical facility -- the histopathology and anatomic
4 site of cancer among the Vietnam veteran is significantly different
5 from the non-Vietnam veterans and whether cancer frequency
6 among Vietnam veterans is higher or lower, compared to non-Vietnam
veterans.
7 We are going to take advantage of VA patient
8 treatment files and AFIP expertise in pathology. This is
9 the study procedure as we envision it at this point. The VA
10 Agent Orange Project Office will develop a roster of
11 cancer patients among Vietnam Era veterans treated in VA
12 hospitals. And we will send that list to each VA medical
13 facility and ask them to provide us with tissue specimens
14 and pathology reports. So then VA Agent Orange Project
15 Office will serve as the central point; and the VA patholog-
16 ist service will represent VA, and monitor the compliance.
17 The VA medical centers will select appropriate
18 tissue specimens, the pathology report and
19 forward it to the Agent Orange Project Office. The AFIP
20 will review the tissue specimens for the pathological diagnosis
21 and the Agent Orange Task Force will determine the Vietnam
22 service status, and also Agent Orange exposure likelihood
23 of these individuals.
24 So, AFIP will determine the pathological diagnosis
25 without knowing the veteran's service status, and the Army

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1 Agent Orange Task Force will determine the service status
2 without knowing the diagnostic status of that individual.
3 And all of this information will be forwarded to the
4 Agent Orange Project Office, which will do a statistical
5 analysis.
6 This is the kind of sample size we need to make
7 some determinations. For example, if you want to determine
8 the 50 percent excess of a specific cancer, and if the cancer
9 proportion is only one percent of overall cancers, we will need over
10 10,000 cancer cases in each group. And if the proportion of
11 cancer is 5 percent,
12 you would need
13 about 2,000 cancers from each group; and if it is over
14 10 percent, of course the sample size goes down to 916.
15 At this time we are proposing to take a sample
16 of 2,000 in each group; 2,000 Vietnam Era veterans and
17 2,000 non-Vietnam veterans.
18 The kind of analysis we would like to do, is a
19. simple analysis: looking at differences in histopathology and
20 anatomic sites between Vietnam and non-Vietnam veterans; and
21 looking at the pathology and anatomic site by Agent Orange exposure likeli-
22 hood. And finally, as a by-product of this effort, we
23 can compare the VA diagnosis to AFIP diagnosis.
24
25 DR. SHEPARD: Any questions?

1 (No response.)

2 DR. SHEPARD: Dr. Conway will be attending with

3 Dr. Irey the meeting of the subcommittee on biostatistics

4 and epidemiology, so if there are further questions, I am

5 sure they will be happy to answer them at that point.

6 We said that Mr. Fred Conway, of our General

7 Counsel Office might be available for questions relating

8 to the litigation and the recent legislation.

9 Since Mr. Conway will

10 not be available for the entire time -- he has an important

11 meeting he has to attend, and will have to be leaving for

12 it fairly soon -- would it be all right with you, Fred (Mullen)

13 to have Mr. Conway available to the opening portion of your

14 subcommittee meeting, to answer any questions that people

15 may have in that regard?

16 MR. MULLEN: I see no problem with that.

17 DR. SHEPARD: That being the case then, let's

18 adjourn to our separate subcommittee meetings. The

19 Committee on Education and Information will adjourn to

20 Room 139, down the hall.

21 (Whereupon, the meeting was recessed for members

22 to attend the subcommittee meetings, and will reconvene at

23 1:00 p.m.)

24

25

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1 AFTERNOON SESSION

2 (12:55 p.m.)

3 DR. SHEPARD: We will return to our agenda. And

4 the first item on the agenda is to hear reports from the

5 activities of our two subcommittees. And I would like

6 first to call on Mr. Fred Mullen to give us an update on

7 what occurred in the process of his subcommittee. Fred.

8 REPORTS OF SUBCOMMITTEES

9 MR. MULLEN: We need time -- it seems that the

10 last three subcommittee meetings that I chaired have started

11 between 20 minutes to 35 minutes late. And I think one of

12 the reasons for this -- and I think I have somewhat of a

13 consensus on it -- is that in the full plenary session in

14 the morning we are hearing primarily a scientific reporting

15 which I think should be done during the scientific sub-

16 committee panel. Likewise, we have guest speakers in our

17 subcommittee who do not get a chance to present because

18 the issues they are dealing with do not directly deal with

19 scientific issues.

20 During the meeting it was brought out that these

21 people come from a long way away, to come down here,

22 and given the time schedule that is pre-planned in the

23 agenda, they don't have enough time to get their questions

24 answered, which we believe should be done. If there are

25 guest speakers dealing with scientific issues, and they

1 have a prepared text, I think what they should do is make
2 the text a handout, if they are going to give a presenta-
3 tion, and then briefly summarize.
4 If it is considered of importance to the veterans
5 here in the audience, they could pick up the handout and
6 ask questions at the appropriate time, after the presenter
7 is finished.
8 What it boils down to is we just don't have enough
9 time to get our meeting in, because the majority of the
10 morning is taken up with scientific issues and then you
11 have a scientific subcommittee afterwards. And we don't
12 have the benefit of that time.
13 There are numerous issues that have to be addressed,
14 not only dealing with the litigation, the outreach centers,
15 the claims process, et cetera, et cetera.
16 Another thing that we wanted to bring to your
17 attention is, I think Don has satisfactorily answered this,
18 because there are some minutes being taken at our sub-
19 committee meetings, and what is planned for the future is
20 that the minutes from our subcommittee meeting, as opposed
21 to the full committee transcript, will be attached to the
22 full committee transcript to send out as an appendix, so
23 everyone will get it.
24 DR. SHEPARD: From both subcommittees?
25 MR. MULLEN: From both subcommittees,

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1 One of the issues that was brought up is the more
2 or less subpoenaing of the medical records and names from
3 the Agent Orange Registry. There is some confusion there
4 about the Privacy Act, and I think Fred Conway covered it pretty
5 well. The Privacy Act does guarantee privacy and con-
6 fidentiality of all of your public records, however, a
7 court of competent jurisdiction has the right to subpoena
8 those records, and so can your congressman,
9 if it is for a good cause.
10 Fred Conway is going to get that straightened out
11 for us, go down to the Justice Department and get us some
12 answers before our next meeting.
13 I touched on the issue of conference calls. We
14 believe that we have a pretty extensive Agent Orange out-
15 reach program, with well over 100 centers, and you have
16 172 VA medical facilities. You have a lot of veterans
17 going into these centers seeking counseling, not only on
18 post-traumatic stress, but on Agent Orange issues as well.
19 And the reason they are turning to the Vet centers on
20 Agent Orange issues is because of the reluctance of a
21 great number of those people to submit themselves to
22 examination at a VA medical facility.
23 However, it came out during our meeting that the
24 directors of the outreach centers are not privy to these
25 conference calls. They may have questions out there in

1 individual centers that need to be answered as well, in
2 order to make the overall Agent Orange screening and test-
3 ing program that much more effective.
4 We would suggest that someone from the Office of
5 the Director of the Outreach Program be included in those
6 conference calls, at least a subordinate, in order that he
7 can get some information out to the field, and help these
8 people in these outreach centers.
9 I think that is about all we touched on, but the
10 main issue was time. And we don't think that scientific
11 methodology makes -- to explain scientific methodology to
12 the lay veteran is going very far, it is just eating up
13 time. And I think we are more interested in grass roots
14 issues.
15 If they want to be in on the scientific, analytical
16 issues, they have that option.
17 One other thing, I suggested to Don that we have
18 more or less an open-ended agenda, because we don't know
19 what issues these veterans are going to bring in from the
20 field, whereas the scientific panel knows what studies are
21 going on, and knows what issues are going to be presented
22 and spoken on. If there was just a summary of the latest
23 data, or statistics arising out of these studies, I think
24 that would suffice to satisfy the veterans' curiosity,
25 without knowing how they arrived at it through an

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1 epidemiological approach.

2 I think that's about it, unless you have something.

3 DR. SHEPARD: Any comments, or responses from any

4 of the members of that committee?

5 Do any of the members of the committee want to ask

6 questions of any members of the subcommittee?

7 (No response.)

8 DR. SHEPARD: I would like to respond in a couple

9 of areas, if I may. I certainly agree, Fred, as time has

10 gone on, I think that your committee does need more time,

11 open-ended time, unstructured time, if you will, so that

12 questions can be raised and answers can be obtained, to the

13 extent that answers are available.

14 I take the responsibility for not counseling the

15 scientific presenters in the open plenary session, if you

16 will, to confine their comments to basically summary

17 comments, and then address particular, more detailed

18 scientific questions -- reserve that for

19 the scientific subcommittee.

20 In some instances we have done that, and I think

21 it has worked very well. I think we, perhaps, in today's

22 agenda perhaps we are not as cautious in doing that as we

23 might have been. So, I apologize for that, and I apologize

24 for running over a little more. We had a few more items

25 to deal with of a general nature, than we often do.