DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
National Center for Toxicological Research

Ranch Hands Advisory Committee
September 7, 2006
Rockville, Maryland

Certified Verbatim Transcript

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Dr. Robert Sills
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FINAL MEETING OF THE RANCH HANDS ADVISORY COMMITTEE
September 7, 2006
Rockville, Maryland

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Opening Session

[CONVENE 8:33 A.M.]

M. STOTO: Is everyone ready to start? We're getting close to 8:30, so maybe we should get underway. Good morning, everyone. I'm Mike Stoto. I'm the chair of the Committee. I'd like to begin by asking everyone on the Committee and then the others attending the meeting to introduce themselves.

I'll begin with myself because I have a new job. And so I'm still the same person, but I have a new job at Georgetown University, a Professor of Health Systems Administration and Population Health, as of about two weeks now. David, do you want to go next?

D. JOHNSON: Yeah.

M. STOTO: Remember to turn the microphone button on.

D. JOHNSON: I'm Dave Johnson with the Florida Department of Health, Division of Environmental Health.

R. TREWYN: Ron Trewyn, Kansas State University.

R. SILLS: Robert Sills with the National Institute of Environmental Health Sciences.

M. STOTO: Sandy?

S. LEFFINGWELL: Sanford Leffingwell, with HLM Consultants, formerly CDC.

E. HASSOUN: I'm Ezdihar — I am Ezdihar Hassoun and Professor of Toxicology, the University of Toledo, Ohio.

J. ROBINSON: Julie Robinson, Branch Chief, Air Force Health Study.

K. FOX: Colonel Karen Fox, Principle Investigator, Ranch Hand Study.

M. STOTO: Len?

L. SCHECHTMAN: I'm Leonard Schechtman. I'm with the FDA National Center for Toxicological Research, Executive Secretary of the Ranch Hand Advisory Committee.

M. STOTO: And maybe we can go through the audience? Does somebody have a microphone? There it is.

C. BROOKS: I am Clark Brooks with the *Greenville News*.

J. BROOKS: Jeanne Brooks, the *Greenville News*.

M. OWENS: Maurice Owens, SAIC.

W. GRUBBS: Bill Grubbs, SAIC.

M. YEAGER: Meghan Yeager, SAIC.

J. MINER: Jay Miner, Operational Technologies, support of the acquisition efforts for Ranch Hand.

M. BLANCAS: Manny Blancas, Operational Technologies, working for Program Management in support of the Air Force Health Study.

D. SUPERVILLE: Darlene Superville, *Associated Press*.

M. PAVUK: Marian Pavuk, SpecPro, in support of Air Force Health Study.

S. McCARTHY: Sheila McCarthy with Exponent.

F. ERDTMANN: Good morning. My name is Rick Erdtmann. I'm the Director of the Medical Follow-up Agency of the Institute of Medicine.

D. BUTLER: David Butler, Institute of Medicine.

K. CAMPBELL: Kim Campbell, Food and Drug Administration.

M. STOTO: Okay. Thank you, everyone. I think that Paul Camacho from the Committee will be here shortly. Anyone else on the Committee coming? I think that's it. Okay. Len, would you lead us through the administrative items?

L. SCHECHTMAN: Okay, just a couple of housekeeping items. I'll be sending around a sign-up sheet for everyone at this table. There's also a sign-up sheet for everyone else in the room at that front table. We'd appreciate it if you filled out the information, and your affiliations and contact information as well.

In addition, just to make mention, we will also be having a working lunch today. So we'll have just a few moments to gather our nutritional supplements and we'll continue to work through that lunch period. We will also have public comments that'll take place beginning approximately 11:30 today.

M. STOTO: See if anybody would like to make a comment?

L. SCHECHTMAN: Yes, and I'll turn it back to the chair, Dr. Stoto, at this point.

M. STOTO: I just would like to ask whether anybody currently present plans to make a comment during that period? Okay. Yes, I see Clark Brooks is one. Was that — was that it? Okay. Thank you. We do the conflict of interest?

L. SCHECHTMAN: Okay. I'll now read the conflict of interest statement for the meeting. The following announcement addresses the issue of conflict of interest with respect to this meeting and is made a part of the record to preclude even the appearance of such. Based on the agenda submitted for today's meeting, all special government

employees have been screened for the — for their financial interests related to the topics at hand. FDA has determined that all financial interests and firms regulated by the Food and Drug Administration present no potential for a conflict of interest at this meeting.

In the event that the discussions involve any other products or firms not already on the agenda for which a participant has a financial interest, the participants are aware of the need to be excluded from further participation. Such an action will be noted for the record. In the interest of fairness, all other guest participants are asked to address any current or previous financial involvement with any firm whose products upon which they wish to comment.

M. STOTO: Okay. Thank you very much. Anything anybody would like to add about that? As I've — as I've said before, this is — the nature of this Committee doesn't naturally lead to conflicts of interests in the way that other FDA advisory committees do, but I believe that this is an important thing for the FDA and other government agencies. And I'm — I — we need to take it seriously.

Okay. Well, today is the last meeting, we believe, of the Ranch Hand Advisory Committee, which has existed for — how many years? — 25, 30 years?

L. SCHECHTMAN: Twenty-five years.

M. STOTO: Twenty-five years. And the focus will be on the closeout of the Air Force's efforts and the transition to some custodian for the — for the information. And we'll actually begin with that item today.

Review of Previous Meeting Minutes

M. STOTO: But before we get into that, I'd like to look at the minutes from the last meeting. I've had a chance to review these, and I believe that corrections have been made, and I think the Air Force did as well for technical reasons or technical issues. No?

Well, there wasn't that much — as much technical material in this one as there has been in the past. So at this point, I'd like to ask whether anybody has any corrections, suggestions, additions, complaints, praise? Praise — let the record show that the minutes were well done. So is there a motion to ...

R. TREWYN: Move approval.

M. STOTO: Okay. Dr. Trewyn. Second?

E. HASSOUN: Second.

M. STOTO: Dr. Hassoun. Okay. All in favor, please say yes or ...

RHAC MEMBERS: Yes.

M. STOTO: I think it's unanimous. Thank you.

Update on the Air Force Health Study Custodian

M. STOTO: Okay. Now Rick, would you like to come up to the — to the table? We have with us Dr. Rick Erdtmann.

F. ERDTMANN: Where would you like me to sit?

M. STOTO: Maybe how about over there? Wherever you like; this is fine if you — if you like it.

F. ERDTMANN: No, that's fine. I can sit here and see everybody.

M. STOTO: Yeah. Rick is the Director of the Medical Follow-up Agency at the Institute of Medicine, National Academy of Sciences. We had hoped that Mark Brown from the VA would be here — maybe he still will be here — to talk about these issues.

But in any case, the — what I — what I asked Rick and Mark to address is the legislation that's pending in the Congress that would authorize and appropriate money for a custodian for the Ranch Hand materials and records, basically following the recommendations of the report that the — that the Institute of Medicine did earlier this year. Okay.

F. ERDTMANN: Well, I'm very pleased to be asked to comment and chat with you a little bit. I would like to first of all, again, acknowledge that in a — in the room is David Butler, who was the study director that worked with the committee that created the report that you're all very familiar with. So if you ask me any hard questions, David gets to answer them. I think there's a couple of other members of the staff that may be joining us in progress.

I think before I say a couple of comments that I had prepared for this occasion, it just dawned on me what you just said, Mike; that this was the last meeting of 25 years of effort and 25 years of oversight for a very, very important research asset: the Ranch Hand materials. And that just struck me as an awesome occasion and I suspect that many of the people on this Advisory Committee were here for many of those years.

And so I'm not part of the government, but as a public servant, I will say, you know, as a private citizen, thank you for volunteering to advise the Air Force on this very, very important subject.

I already introduced myself. My name is Rick Erdtmann. I'm the Director of the Medical Follow-up Agency, which is an epidemiologic research center, which is part of the

Institute of Medicine. About three months ago, the Medical Follow-up Agency was incorporated into a new study board at the Institute of Medicine, called the "Board on Military and Veteran's Health." And so we actually then will have two oversight groups: the Board and the Medical Follow-up Agency Advisory Committee which will oversee the work of our agency.

Not knowing exactly what it is that you were interested in knowing a little bit more about, I have not prepared a long statement. But I am here to answer any questions that I can help you with to try to understand. But I would like to just take a few minutes to say something.

The Air Force Health Study was, as it was preparing to wind down and close out, Congress commissioned the IOM to do a study to try to answer some very important questions. The two major questions were: is there continuing value of this research asset? And if there were, where would be an appropriate home for the — for these research assets?

So the committee determined after a year and a half or after a year and 15 months — how long was it, David, about a year? About a year.

D. BUTLER: A little more than a year.

F. ERDTMANN: A little more than a year. After a lot of meetings and a lot of deliberations, the committee determined that the Air Force Health Study research database was, first of all, unique, and second of all, had enormous future potential as a research entity, as a — as a research set, and that they offered several options for where an appropriate home could be for this material.

They were reluctant — purposely reluctant to make a specific recommendation about which of those options that they had discussed. There were eight options. They

were reluctant to say which of them they felt was the best option. So it went back — the ball was then back in Congress' court to make that decision. So the Congressional staff and members considered the report and went through a decision-making process to decide on the best option.

They had a meeting with me and members of — selected members of my staff, and discussed our interest in becoming a custodian of these materials, and whether or not we'd be willing to accept that if asked. And we indicated that we were very interested in taking on this responsibility. We had, of course, to get approval from our governance and our leadership, which we went ahead and got.

But there were those discussions. And then after those discussions — and we presumed that those discussions were with other possible homes as well — but anyway, after that discussion, there was an authorization bill, the 2007 Defense Authorization Bill, which indicated a transfer of these assets from the Air Force to the Medical Follow-up Agency.

Now whether or not that will happen is still to be determined. I mean, there has to be an appropriations following this authorization bill that would allow monies to be used for this purpose. We believe that'll happen, but we don't know this for sure at this point. But if these funds were appropriated to support this transfer, we will work closely with the Air Force during the coming fiscal year — fiscal year '07 starting in next month — to transfer these assets in a safe, seamless and swift manner.

And really that's all, Mike, I wanted to say as far as my knowledge of how this all came about and where we are at this point in time as of today. But there may be some questions that the advisory group would have of me or David that we could answer for you.

M. STOTO: Rick, first of all, thank you. My understanding of the status of the appropriations is that there is language in both the House and the Senate bills that have passed those bodies, but it hasn't been — but the overall bills haven't been reconciled and signed by the President yet. Is that right?

F. ERDTMANN: I believe that that's true. And then, of course, even after the authorization bill is fully signed into law, you have to — it has to be followed by appropriations language and bills that give money toward that. And so I ...

M. STOTO: So I'm — now I'm confused. Which has — the authorization comes first.

F. ERDTMANN: Right.

M. STOTO: And has the authorization been ...

R. TREWYN: Normally.

M. STOTO: Or normally.

F. ERDTMANN: Yeah. If it's a hot item, sometimes the appropriations come before the authorization.

M. STOTO: So which one is — which one is pending between — with the same language in the House and the Senate?

F. ERDTMANN: Well, the authorization bill is the most mature at this point. And it talks — it has — it has very clear language of transferring the assets from the Air Force to the Medical Follow-up Agency. It even talks about potential monies that would be needed to do that.

M. STOTO: Okay.

F. ERDTMANN: But the authorization bill itself doesn't authorize the appropriations of those funds.

M. STOTO: Right, but has the authorization bill been passed or that's the one where that's pending?

F. ERDTMANN: Well, do you know the answer to that?

M. STOTO: Yeah.

K. FOX: No. To our knowledge, it has not been passed.

F. ERDTMANN: Yeah.

M. STOTO: The authorization has not been passed?

K. FOX: That is correct.

M. STOTO: Okay.

F. ERDTMANN: My belief is it's — it is — it is very mature and probably will be, but I ...

M. STOTO: Right.

F. ERDTMANN: ... don't believe it actually has been passed yet.

M. STOTO: Okay, and so is there any appropriations language at all at this moment? I mean, this is — this is something that theoretically should be done this month, right? Yeah.

F. ERDTMANN: Of course, you know, there's going to be a lot of — I'm sorry — there's going to be a lot of activity now that Congress is back in session and ...

M. STOTO: Yeah.

F. ERDTMANN: ... things will start happening, but ...

M. STOTO: Right.

F. ERDTMANN: ... I don't ...

M. STOTO: And it's unlikely the Defense Department will go out of business on September 30th.

F. ERDTMANN: Yeah. That's — that is very true.

M. STOTO: Yeah.

F. ERDTMANN: And I have not heard of any change in heart from anyone on the Congressional staff that — about this topic, so I think that's still the intent.

M. STOTO: Okay. I guess there's still though the issue is whether this is Veterans legislation or Defense legislation?

F. ERDTMANN: Well, I think — I think we may see some follow-on legislation after the — after the materials are transferred because right now they are owned by the Department of Defense.

M. STOTO: Yeah.

F. ERDTMANN: And so the Department of Defense would have to be authorized and funded to transfer this to some other agency. Then the question is if this asset, this research asset were to be used for future research, who would pay for that? And whether or not there would be a separate Congressional line item or whether or not the Congress would ask the Department of Veterans Affairs to fund this for the future and then, you know, to fund the IOM to do this work, it's not — it's not known at this point.

M. STOTO: Yeah.

F. ERDTMANN: And that's something that maybe Mark could, if he's here this morning, might be able to have some insight about. I don't know, but he probably wouldn't be able to answer that either because there's several ways that that could happen. But I don't think it'll be coming to the Department of Defense. After you transfer this, you're done. Isn't that right, Karen?

K. FOX: That was our understanding and all that ...

F. ERDTMANN: Yeah.

M. STOTO: That there would be — and some funding in the next fiscal year to transfer the assets and that would be the end of it for the ...

K. FOX: With the — there should — in the authorization bill, the versions that are out there that we've seen, it does talk about the Air Force, Department of Defense needing to come up with some money to allow this transfer, the closing of — for the Air Force side to be done. But again, no money has been exactly — but the Air Force is planning as best they can to continue to do this, what we think is going to happen.

M. STOTO: Right.

K. FOX: We understand that things don't happen and we are trying. The Air Force has tried to come up with some money to allow some of this to be transferred. We are attempting to do that.

M. STOTO: I think it's fair to say that the Committee ...

K. FOX: We can see the writing on the wall.

M. STOTO: Right. The Committee recognizes how difficult it is for the program staff to deal with the uncertainty of this situation too, so I'm sorry for putting you in a — in a — in a — in a tough spot. But ...

K. FOX: But we ...

M. STOTO: ... we're not — we're ...

K. FOX: ... do not expect that we will close and turn off the electricity to the freezers on 30 September.

M. STOTO: That's the key question.

K. FOX: Okay. We do not expect that to be happening.

M. STOTO: Right.

K. FOX: Okay, so we expect that there will be somebody to make sure the electricity is running. Okay.

M. STOTO: Okay.

F. ERDTMANN: But I think the answer to the other part of your question was if there were a research interest in using this asset, who would be the funder for that? And I think Congress would have to make a decision on that: whether there would be a line item appropriations or they would ask the VA to do this with — maybe with a plus-up to then transfer to the IOM perhaps.

M. STOTO: Well, one of the things that this Committee has said in the past — and I think that the committee that David worked with also said that — was to distinguish between the cost of maintaining the asset and the cost of doing research with that asset.

The second one, that actually doing research, is something that could be funded by NIH, or could be funded by lots of other agencies, foundations and so on. And that really the issue is making sure that some entity is funded to maintain the materials and I think it's an important distinction to keep on ...

F. ERDTMANN: On the record. There are actually three elements of cost that were described in the report as necessary to make this research asset used. One is to pay for maintenance of the data and, you know, management of the data ...

M. STOTO: Yeah.

F. ERDTMANN: ... the security of it, the actual management of proposals coming in and out, whatever. And then the second item would be for managing new research and that has a variety of different resources or sources. And then the third element of cost is the cost of maintaining the biological specimens and those were segmented in the report. It discussed it and described it in fairly high detail.

The second piece, as I mentioned, is the research piece. And I think it was very novel that the committee indicated that one of the things that they were a little bit concerned about is whether or not, you know, there were — that we needed to market this thing. We needed to get the attention and we needed to have some seed money to get people interested in doing new research on this cohort.

And so they had recommended a certain amount of money. I think the report indicated, I think it was $250,000 for a three-year period, three successive years, as seed money to encourage research. Now that is not going to take you too far with highly complex epidemiologic studies, but it certainly can attract interest and there are other sources of funds.

If a — if a great idea was put together using this seed money as really pilot project money that could then roll into a very, very huge study that may be funded by the VA, or NIH, or some other federal agency or some other foundation. That's kind of the way it's being looked at right now.

M. STOTO: Yeah. Would someone else on the Committee like to raise a question? Ron?

R. TREWYN: Yeah. it's certainly not uncommon for there to be some disconnects between authorizing bills and appropriation bills. And if there isn't someone sort of shepherding the thing along and making sure that it gets into the — into the appropriations language, that can be a problem.

And I would assume that your office probably can't take an active role in that, so is there — is there any — do you know of any entity that is going to try to ensure that in fact this happens? That if it winds up being authorized, that the appropriation will take place?

F. ERDTMANN: I don't think that there is a designated organization that has that responsibility. I would think that there would be a human cry from the veteran's service organizations if this did not happen. And I would be — I would be disappointed if there wasn't a reaction from the veteran's community about this.

Maybe there's even a role for this Advisory Committee to kind of, as its last hurrah, to encourage such a move to make sure that this actually does stay on the critical path. But that's not for me to say. But I don't think there's any designated cheerleader out there. We certainly would be the biggest cheerleader, but we really are not in the position to do that.

R. TREWYN: Well, I think, you know, many years ago on this panel, we would always have almost all of the veteran's service organizations represented in the audience when these — when these meetings were going on. And the fact that that isn't happening as this is winding down, I do believe there would be, you know, an outcry. But it's, again, it is something and I think maybe we ought to discuss.

I — and I don't know what we would do as our last act, but because I do know that there have been cases where authorizing and appropriations don't link up and the appropriation of the money is the most critical in this case. So we ought to — we ought to at least consider whether there is a role for the Committee.

M. STOTO: Let's come back to that. Sandy, do you have a question?

S. LEFFINGWELL: The comment that the records and samples are currently property of the Air Force kind of led me down a somewhat troubling line of thought. This is a government possession that perhaps has some commercial value.

And I'm wondering if pharmaceutical industries would pay to have limited access to any part of this and if that would fund some of the necessary efforts to go on with other types of research? I wish Dr. Camacho were here. I suspect the veteran's organization

would have some very serious problems — would have some very serious concerns with that.

M. STOTO: He's here.

R. TREWYN: Be careful of what you wish for.

F. ERDTMANN: So if I understand your concern, although it wasn't a question, maybe I can comment on it. Your concern was that the — there might be access to the research database by a pharmaceutical company. And you were wondering whether or not because it was a government asset, that whether it could be shared? Or what — I'm not — could you indicate again what your — what your — what your concern is?

S. LEFFINGWELL: I was wondering rather specifically could the government offer to provide some type of access to this material in exchange for a monetary fee that the government could then reinvest on the research?

F. ERDTMANN: Yeah. I think one of the advantages of having this transferred from the Air Force to a non-governmental agency is to avoid such a problem. And, of course, the Medical Follow-up Agency, although chartered by Congress in — under Abraham Lincoln, is a private non-profit organization and non-governmental, so I think it eliminates that risk.

Although I will tell you that we don't envision future research being done by private entities without careful scrutiny because — and we want to make sure that the — that the utilization of this research is toward the benefit of advancing knowledge of veteran's health care and to secondarily, advancing knowledge of health outcomes in — for the general population.

We are not trying to advance the agendas of pharmaceutical companies, *per se*. So any research efforts in the future will be carefully looked at by advisory boards and groups to make sure that we do research of high merit and value.

M. STOTO: No. I heard in his — in what Sandy said, both a concern and an opportunity, that perhaps the private sector use of the resources could provide for them being accessible to others. And would that be precluded with the IOM?

F. ERDTMANN: Absolutely not. No, that wouldn't be precluded. We would just have to make sure that that was fully acknowledged as to what — where the funds are coming from and how much of the funds, what portion of the funds are being used in that — in that fashion.

Just like other health medical researches, there's always the statement in the thing, you know: "Fifty percent of the — of the research monies came from so-and-so" and what investigators were being paid by that pharmaceutical company. So same kind of a thing would apply in this case, but I just wanted to make the statement that we wouldn't just make this an asset for anyone just to come in and just use as willy-nilly. It would be carefully monitored.

M. STOTO: Okay. Ron?

R. TREWYN: Just one other question based on the name change that you mentioned right up front with military and veteran's health since I know that, you know, Agent Orange isn't the first time that some issue of health in veterans or it's not the last time, certainly with Persian Gulf issues.

But the military is also supposed to be tracking health. Is there — and are struggling with how to do that. I got called on to a committee to try to work on that. And I was wondering if, in fact, there is in the plans for your group to actually try to facilitate studies with military personnel as far as health impacts?

F. ERDTMANN: Yeah. Let me just clarify the part of what your — first part of your statement. We really don't have a name change. What we — the Medical Follow-up

Agency is — continues on, but it's now incorporated within a larger entity called the "Board on Military and Veteran's Health."

The Board on Military and Veteran's Health is like many other boards within the Institute of Medicine: interested in a portfolio of study areas or focus areas to do its work. And ours is very special and very, very specific to look at the military and the veterans. And we use both words because we don't want this just to be seen as after someone's been in the military and now they're sick, you know, why is that? That is too narrow a focus.

We want to look at the military experience from the time that someone is even being accessed into the military to the time that they go through the military, and then become a veteran, and then have acute and chronic problems, and then eventually die. And we want to know about, and understand and advance knowledge at all phases of that military life cycle. And that's the concept of this new board: very broad and not focused on just epidemiologic studies. It goes beyond that.

R. TREWYN: Well, I do believe there was some legislation a few years ago that — mandating that the military track deployments and whatnot. But I don't know that that's ever been funded inside the military to actually do that and that's why ...

F. ERDTMANN: Yeah.

R. TREWYN: ... I thought this group might.

F. ERDTMANN: Yes. I'm sorry. I didn't really answer that part of your question. You know, I can't really speak for the military. I'm — although I've 30 — I spent 30 years in the military and as a medical officer. But I can tell you because I've been through many, many other committee meetings and events that the DOD has done an awful lot to increase their knowledge about deployment health.

And they have special survey instruments that they're keeping close track of and they're developing new ones all the time. And you're aware of the "Millennium Cohort Study" that they're doing. So the DOD has come a long way in trying to understand the deployment health effects, and tracking them, and documenting them and keeping records of them. So I applaud them for that, but there's always questions that emerge that sometimes need help from outside agencies like us.

M. STOTO: Other questions or comments? Paul, before you arrived, we — Rick started talking about the status of legislation that would authorize and appropriate funds for the Institute of Medicine's Medical Follow-up Agency to be a custodian for their Ranch Hand Study materials. And the bottom line is we don't know exactly where that stands, although people think that it seems likely. Do — are you aware of — turn your mike on, please.

P. CAMACHO: No. I'm not — I'm not aware of where it's going. It's just been, frankly, confusing. I haven't seen anything solid or heard anything solid.

F. ERDTMANN: There is some solid legislation, statutes in the — in the authorization bill, but that's not — that's not all the way. And so we had introduced the idea that there could be a role for the Advisory Committee to help at least ask questions about whether or not this will stay on the critical path for a final decision. And I — hopefully ...

M. STOTO: Hi, Mark.

F. ERDTMANN: ... it will and we believe it will. And we're hoping and we are looking forward to that opportunity should it arise.

P. CAMACHO: The last conversation I had was back, actually quite a while ago. I asked the committee — some people on the committee and they said they were following it, but they hadn't come to an agreement with the majority side.

M. STOTO: Which committee?

P. CAMACHO: The Veteran's Affairs Committee about what they were thinking of doing.

M. STOTO: In the — in the House and the Senate?

P. CAMACHO: In the House. In the House ...

M. STOTO: The House, yeah.

P. CAMACHO: ... about what they were thinking of doing about it. It's been a hard — it's — I'm afraid that people want to walk away. That's what I'm afraid of.

F. ERDTMANN: Well, before you came or just as you were coming and sitting down, I think we made the comment and someone asked me what would — who would — who would be kind of the watchdog for this. And I didn't know whether there was a specific entity.

But I think that the veteran's service organizations as a whole would be very disappointed to learn that after 25 years of work and $174 million worth of effort spent on this, where there was clear expert advice to continue on working, getting some good information from this asset, that the government would decide not to do it, not to support it. I think there would be an outcry. I can't guarantee that, but I would think that there would be a problem.

P. CAMACHO: Well, what's going to — my doomsday scenario is that nobody's really going to step up to the plate, and everybody's going to cry and point fingers if it's gone too far. And they'll point fingers at us as well.

F. ERDTMANN: Well ...

P. CAMACHO: We've talked about it.

F. ERDTMANN: ... we are stepping up.

P. CAMACHO: We are limited on what we can do.

F. ERDTMANN: I can tell you that the Medical Follow-up Agency is stepping up to the plate. We are ready to receive. All we need is a baseball.

M. STOTO: Well, at that moment, let me introduce Mark Brown from the VA — Veterans Affairs — who's come.

M. BROWN: How are you doing?

M. STOTO: Mark, I'll ask you to say a few words in a — in a moment, but let me let you know what has happened before you got here. Rick gave us a briefing and we had some questions about the status of legislation that would provide for the Medical Follow-up Agency to be a custodian, at least on an interim basis, of the data and materials from the Ranch Hand Advisory Committee — or rather, the Ranch Hand Study. And they've expressed their interest and willingness in doing that.

And the Air Force understands that something is likely to happen and they're not going to turn off the freezers on October 1st. But what is not clear — and maybe you can help us with and I'm not sure, maybe not — is the status of that — of that legislation and the role of the Department of Veterans Affairs. And part of the problem, I think, is that there are these two separate departments of the government: Veterans and Defense. And this legislation that you're talking about is coming out of the Veterans ...

P. CAMACHO: Yeah.

M. STOTO: ... committees, not the Defense committee. Yeah, and ...

F. ERDTMANN: It's out of the Defense committee, isn't it?

M. STOTO: Well, that — okay. That's the — that's the question. Is it in the Defense authorization bill?

M. BROWN: Yes. Right.

M. STOTO: Okay, but not in — but there's no appropriation bill for the Defense Department. But it's — but it's — but the — but the Veterans Affairs Committee and the Department of Veterans Affairs probably has limited sway when it comes to Defense activities.

M. BROWN: You've never said a truer statement.

M. STOTO: So Mark, welcome.

M. BROWN: Right. Thanks.

M. STOTO: And if you could enlighten us on any of that or other things you'd like to say, please go ahead.

M. BROWN: Well, first of all, that point that the Department of Veterans Affairs has little sway on the — on the DOE's appropriations is a true, true statement. I apologize for being late. I was — I was arguing with the — I went to the 5600 building, you know, which is I — what I know as the FDA building where I thought this — I was busy arguing with them this morning that they should let me in the building.

And they said, "Well, who's your contact person?" And I said, "Well, Mike Stoto." And they said, "Never heard of him." And anyway, they finally said, "Well, you're in the wrong building anyway." So I'm glad to be here.

Mike asked to — me to talk a little bit about what VA's thinking is about this, the whole issue of the future of the Ranch Hand Study. I'm happy to be here to do that, but it sounds like you've already had — you know, the discussion has already moved to a certain direction. I'd say I, in thinking about this just as I came over here, there's really just a couple of points that I'd like to make.

First of all, as you probably all know, we were asked by Congress to fund this study that Rick and his folks did here — the committee that — it was one of your committees in your — in the Medical Follow-up Agency.

F. ERDTMANN: Well, actually, it wasn't our specific committee because it would've been a conflict of interest.

M. BROWN: Was it?

F. ERDTMANN: It was another — it was another part of the IOM.

M. BROWN: Another part of the Institute of Medicine?

F. ERDTMANN: Yeah.

M. BROWN: But is — anyway, they completed the study, the disposition of the Air Force Ranch Hand Health — the Air Force Health Study. And the legislation that set that up came through my office because I have a lot of — I have a lot of studies that — I'm responsible for a lot of studies that we do with the Institute of Medicine, including with the Medical Follow-up Agency.

And really through, the legislation didn't ask — it didn't — it just asked us to sign the check really. It didn't ask us — there was no — we had no responsibility for doing anything with the final report. Sometimes when Congress asks us to do a study, to pay for a study, we have to then say, "Well, what are we going to do about it?"

Well, the legislation will say we have to — the Secretary of Veterans Affairs, within so many days, has to send a letter to Congress saying what our response is going to be, what — how we're — what are we going to do and how are we going to implement any policy issues that may have come up in a study.

This — the legislation that set this up didn't ask for our opinion at all. It just said — it just said "you pay for the study and then — and, you know, we'll see what happens." But

obviously, we've been following it very closely because the Ranch Hand Study, I think, influences the Department of Veterans Affairs. And the — and the most important way is it's been a study that's been used for another set of studies that we used the Institute of Medicine for, also required by legislation.

And that's the Agent Orange — "Vietnam Veterans and Agent Orange Health Studies" that have been going on since 1991. And they biennial, every other year, we get an update where the Institute of Medicine goes out and looks at all the literature related to Agent Orange, and dioxin and other herbicides that are used in Vietnam and the health effects that they have on humans.

And then the — that legislation that set that process up requires that VA respond to that, respond to the findings of the Institute of Medicine about health effects in — that might be related to veterans and come up with presumptive health connections where we'd then have to say that Vietnam veterans have the benefit of a — of a presumption of a health effect if the Institute of Medicine has found something.

And based on that, I'm sure most of you are familiar with that process. Mike here, in fact, was actually the original — one of the original project directors for the first one or two studies that was — that came out, the one that really set the ...

M. STOTO: The first one.

M. BROWN: Just the first one?

M. STOTO: Basically the first one.

M. BROWN: It really set the — it really set the model for how we do this. And it's — those studies review not just — I think it's important to understand though that those studies don't evaluate just health literature of Vietnam veterans. They do do that, but they also evaluate the relevant health literature for any population. And a lot of the studies, you

know, if you've seen one of these books, they're quite thick, several inches thick. They review thousands and thousands of studies.

And most of them are not of veterans; they're of people who were exposed to dioxin or herbicides in industrial accidents, for example, or who worked in plants where these chemicals were used and manufactured, so they were exposed occupationally. And only a very few of the studies really are directly of veterans. Most are of these — of civilians who were exposed in other types of contexts.

So the Ranch Hand Study has always been important too in that process in my mind because it's one of the few studies that actually is looking at these health effects in Vietnam veterans, in the target — in the audience of interest. And in that sense, it's very — it's been — it's unique. It's not — there's nothing really else quite like it.

So we funded this — we funded this study that's, you know, well, what's — what are we going to do with the Ranch Hand Study? It's run out. Its statutory timeline has run out. And I — you know, the Air Force is looking for — now for some way to, you know, close it out or, you know, thinking — people are thinking, "What are the next steps to do with this?"

And when we got — when we got this Institute of Medicine report, I mean, we couldn't help but notice that one of the suggestions that it mentioned was that the VA could — I mean, it was — it was looking at it from the standpoint, well, who could take — you know, it made the point that there's future — there's value in this data.

It's a — it's a big resource, so who should take custody of it? I mean, they also made the point that it probably shouldn't be continued. I think it's fair to say they said it — that it shouldn't be continued in its present form, but somehow it should be continued; that this information — there was a repository of health information, a repository of biological

samples that had value for future studies and that it should be therefore maintained, and therefore, it needed a custodian.

And it mentioned — of course, we couldn't help but notice at VA — that it mentioned as one of the possible custodians VA. And so, you know, that, of course, we were thinking, "Well, you know, how would we do that?" And I think in our thinking about this really, we didn't come up with any points or concern. We had some concerns and I'll get to that in a minute, but we didn't really come up with anything that wasn't really already in the — in this IOM report.

We — our — they did a pretty good job, I think, of covering the pluses and minuses of who — what would be involved in this hypothetical custodian who might — who might take on that role. And I think one of the points that they made that you — one of — one of — one of your members just made just now was that that custodian should have some enthusiasm for doing this; that other — you know, it's not going to just — the value of this data set isn't just going to automatically become used just because it's inherently valuable. You know, somebody's going to have to be interested in it enough in taking that — in taking in on.

And to tell you the truth, after doing some soul searching about this within our own research institution, we had — we had some concerns about this idea. And I'll just go through those concerns a little bit and, you know, you can — some of the concerns were more important than others, but I'll just go through the list that we were thinking of.

The first concern we had was of the Department of Veterans Affairs has a — we have an Office of Research and Development; that we have a research budget that it's been around $400 million a year in our appropriations. And that research is focused by — it's, I mean, it's dwarfed by NIH, for example. It's a small research budget. It's dwarfed by

NIH. It's dwarfed by DOD's — Department of Defense's research budget, but it's targeted. It's a very targeted research.

We target — it's targeted specifically at veteran's health issues, so we do a lot of research on mental health, on substance abuse, on things like prosthetics, on rehabilitation, on medical conditions that have at least some or maybe a very strong connection to things that are clearly related to these issues that we have to deal with when we treat veterans who are, after all, the audience that we are responsible for.

It's also — and a lot of people don't know this — it's strictly intramural. We only fund VA employees. We — it's not an — it's not like — it's different than NIH in that sense that we don't — we don't fund extramural research. We — our funding is purely intramural, exclusively intramural and I think that's tied to this issue that it has to be connected. We — we're paying VA, you know. Our typical researcher is a clinician who also is doing research at some institution where they're — and they're seeing patients and they're also doing, you know, health-related research, so it's very tied to veteran's health issues.

So when we're thinking of taking on some — something with a big price tag, you know, it's a concern. Just our research budget is not large. One of the issues that if, you know, follow what's going on in VA research, we're probably not any different than what you see in NIH or any other institution that has a lot of independent researchers.

We always are getting into trouble for research problems with IRB approvals that aren't being adhered to, and problems with protocols that aren't being adhered to properly, or informed consent issues that come up. So there's always — unfortunately, there's always every couple of years some spectacular scandal that takes place where something really awful or some researcher just, I don't know — I don't know what, you know, happens.

Researchers just go berserk or something, and do something terrible and it comes back to haunt us. And so we're very, very sensitive now, I think it's fair to say, to following proper procedures for doing the research. And one of the, of course, the issues that we're very, very concerned with is informed consent.

And there was a — there was a concern that if we were to be the repository — and really, this issue would apply to anyone. It would apply to Medical Follow-up Agency or anyone else; that there's an issue that there's going — we think — it's our opinion and I think that the IOM report reflects this concern in a — in a — in a limited way that there's going to be an issue in transferring the data out of — out of the Air Force, of transferring all that materials to some other agency, whether it's VA or any other agency, because we — it's our opinion that you're going to have to have — you're going to have to re-consent every person who's involved. And I don't know.

For those who are deceased, I don't know. Their families — I'm not sure about that. But the — what the headache that we see is that what's likely to happen is in this, there'll be this interim period where you'll have some proportion of it. You know, 30 percent of the people who you ask will say, "Okay. You know, transfer my data to whomever," and 70 percent won't answer.

And then it'll be sort of — it'll sit there and you'll have this — you'll have what is now a nice, reasonably coherent data set sort of split between two agencies and that's going to be a real problem, I think, for anyone trying to do research with it. Maybe ultimately that'll be resolvable, but I think for a while that's going to be a serious issue.

The other problem that we thought about, and this relates really just strictly to VA, and that was the concern that this study, I think it's fair to say, the Ranch Hand Study has been controversial from the beginning.

And advocates for veterans, people, those in the veteran — the veteran world, those Vietnam veterans who were — who's — who the study was designed to help understand and help them understand what the health issue — health issues might be related to herbicide exposure in the — during the Vietnam war have had a lot of, I think, misgivings about how the study was conducted, and the openness and transparency of the study.

And I think, you know, this Committee was set up really to help with that process. And I think it was — that is very effective, setting up this Committee to sort of be the honest broker as it were, and I think that that's been very helpful. But I think, nevertheless, there's been a — sort of a stigma of having to do with the credibility and the independence of the — of the Ranch Hand Study itself and the ability of the Department of Defense or Department — or Air Force to do a fair job trying to research this issue.

Whether or not — I'm not arguing that this is a fair criticism. I just — it's just a perception. And our concern at VA was that if we inherited this data set, we inherited this project somehow, that we would then be the recipients of some of that angst as it were. And also, we — there would be an expectation from — on the part of veterans and their supporters that we were going to be able to magically do something.

We're going to, you know — I mean, I think that there are — this is a large group of veterans out there who think that, you know, in different hands, the Ranch Hand Study would've, you know, it would turn open — it would open up doors. There would be all kinds of health effects that would be associated with exposure to Agent Orange that haven't been previously associated with it. I don't personally believe that really, but I think a lot of people have that perception.

And if we inherited that project, that there would be this expectation that we would do all kinds of things with that. And if — and if we couldn't live up to that expectations — that

expectation, that it would — it would be a problem. It would be — we would be, you know, people — it would lead to unhappiness with our agency. So we were — we were concerned about that.

Then the third thing I think we were concerned with is the generalizability. And I think the Institute of Medicine report gets into this issue and that is that, you know, as I mentioned, our research program is not large and it's very targeted, very consciously targeted at veteran health issues. I mean, some of the health issues that we look into spill over into the civilian sector; that — there's no question about that.

But we have to remember that's our primary focus; has to be veteran and veteran health concerns. And there was a concern that the Ranch Hand population, it would — it would be difficult. There would be some problems in trying to generalize from that population to veterans in general. It's kind of an unusual population. It's, you know, basically a bunch of overweight white guys, you know, who are kind of old, and happened to serve in Vietnam and ...

M. STOTO: Isn't that true of many veterans?

M. BROWN: ... we were — oh, but the thing is if you were going to look at a — if you were going to look at — if you were going to do a study of — it's not even representative — it's not representative of veterans in general, but it's not even representative of Vietnam veterans.

And so there was a concern that, you know, how would one use a population like that to look at veteran health issues? Now I'm not saying that there may not be a way, but it was a concern. You know, most — if you were — normally, you know, if you were going to do a study on veterans, you would try and pick something that was — represented some population.

Now having said all that, the last point I want to make is that — well, actually two more points. One thing that occurred to us that you could use this data for that it would be, in my opinion and in the opinion of other — some of our other public health people and epidemiologists that work at VA, is that it would be helpful to continue — there's a mortality study. There's a component of the overall study that's just looked at mortality, and that's fairly easy to do and not particularly expensive.

And I think it occurred to us that one of the things that one might do with a study like this is to continue at least the mortality component of it. It would be — it wouldn't be that expensive and you might find something interesting. You might find, you know, who knows what you might find by doing a cause-specific mortality study on this group? And, you know, given the huge investment in this, that it seems to me that would be — it would be a mistake not to follow it up on that basis, for someone to follow it up on that basis because it would be fairly — it would be low-hanging fruit to pursue that I think.

And then the final point I wanted to make is that our VA research program, our intramural research program is — it's investigator-originated research. And so, I mean, sometimes we'll send out requests for proposals where somebody in VA has an issue, a health issue that we want to pursue. But much of the research that we fund is our — is based on proposals developed by and originated by the investigator himself or herself.

And so the information about this study, I think, has gotten pretty well advertised at this point. I mean, this database has gotten pretty well advertised. I think if the Medical Follow-up Agency takes possession of it as they have with — actually, I mean, there's nothing that — in principle, there's nothing new for the Medical Follow-up Agency. They have been the repository for many databases that were originally generated for some purpose by the Department of Defense looking at military populations.

So this is — it's not — it's not new in that sense. And our investigators would be free to — I mean, I mentioned some drawbacks, I think, in trying to work with this study. But, you know, what do I know? I mean, there's — there may be some sharp investigators out there who can see this resource and think up some clever — something to do with it. I, you know — and more power to them.

If we — if we get proposals like that, then they would be — they would go — they would be considered just like any other proposal that we get from researchers and funded based on its merits, based on the merits of the — of the proposal. So I think that ultimately, that's what's going to happen.

Now my impression is — to get back to the original question about the status of this legislation — I hadn't really reviewed that in some time, and I haven't looked at the — that history and I don't really follow Congressional affairs. But my pretty strong impression was that it was a pretty done deal; that this — that this was, you know, I mean, the devil, of course, is in the details.

But that, you know, the study is going to be closed out at its — at the date, the legislatively defined date and that the Medical Follow-up Agency will be then the new custodian of this information. I mean, you know, if somebody here knows more about what Congress is doing, I — if I'd been asked that question ahead of time, I would've, you know, made some contacts and asked about that.

But as far as I — my understanding is of at least a few months ago that they — that was pretty clearly what was going to happen. With that — with those — just those few remarks, that's — those are the points I wanted to make. And I'd be happy to try and answer any questions about what VA is thinking about this study.

M. STOTO: Okay. Thank you, Mark. I think Dave wants to make a comment.

D. JOHNSON: As I listened to the discussion, I kind of ask a question for clarification. Is this — it seems we're coming to the end of the Air Force Study, I thought, or are we? And we're talking about closing that study because it's come to an end. And then we were recommending though that the material, the data and the samples be kept for potential further studies that would come.

So in the discussion though, it starts to become blurred to me as talking about continuing the study, and picking up on the study and going forward with it. I guess my question is, I wanted to clarify are we talking about closure of the Air Force Study — closure? Then all these other discussions about what to be done with the data is sort of a different discussion if we — if it's decided to keep the sample and the material for further potential research.

And so if we are talking about closure, what is the closure document that the Air Force — what document says, "Well, this is the study. This is the limitations of the — of the findings. Here's our — here's the findings. Here's the strengths of the findings." This is the closure — you understand my question?

M. STOTO: Yeah. I think that — I think it's a good question and I think that it — the problem is the unclarity in the word "study." To some degree, the study is the men who are the subjects and who have participated for a long time too. Another aspect of the study is the staff at the Air Force who have — and their contractors — who have designed instruments, followed these men, paid for them to be examined, and analyzed the data, and presented it in a variety of places, and so on. We probably are considered in that — in that as well.

I mean, to other — to other people, the study is the documents: those blue reports that come out every five years that we've reviewed here, or the reports that come out in

journals, and so on and so forth. And also, the study might be considered to be the materials that have been generated through that process.

So I think — and I think that what the IOM report has said is that the materials that were generated through that process seem to have value beyond the original intent and that there ought to be some opportunity to make them accessible to researchers in a variety of fields. In fact, some of the benefit may be for things unconnected with herbicides, dioxin, veterans at all.

I mean, we've made the case that, you know, that just studying a couple thousand men as they grow older become — they've always been white. They — but they get fatter and older. That's of interest to science and there may be value there. So I think that what's at issue here is the arrangements that can and should be made too so that the materials generated through this process become accessible to others. Is that — is that fair? Go ahead, Paul.

P. CAMACHO: The — this Committee — well, "I have," I should say. As a member of this Committee, I anticipated this being the last advisory board meeting. We have, I think, clearly expressed our concern that we as a Committee think that the materials should find a home; that the plug should not be pulled; that there is value in these materials.

So, but we have no authority, or power or wherewithal to say, "You take this." We made the suggestions. We wrote the letters. I thought that today we were going to — this was it. And we know that the 31st — the 30th ...

M. STOTO: 30th.

P. CAMACHO: ... that September 30th, yeah, that September 30th, it's — that's the end of the — of the Ranch Hand Study and we were talking about some closure issue here.

We'd love to — I'd love to see those studies find a home and, but it's — and we did what we, I guess, what we could as a Committee.

And several of us did individual things, and called the House Veteran Affairs Committee, or what we did as individuals, and have called and tried. But it's sort of like we're little — we're just pawns in this whole, you know, this whole project here. I don't see what we can do beyond today.

M. STOTO: Yeah. Well, let me just say a couple of things. One is that we'll be — another aspect of it is research projects that have begun, but have not yet been published. And we'll be talking about that later this morning. Mark, would you like to respond?

M. BROWN: Yeah. I really just want to echo what the two of you just said. I mean, my understanding of that Institute of Medicine report that was actually, you know, intended to try and look at options for what to do with what — to think about the future of this study and the future of the materials that make up the study.

And I think my impression is that the IOM — Institute of Medicine report was pretty clear in saying that they don't — they did not support the idea — they didn't — they did not — they did not recommend or suggest that the report be continued in its present form. I mean, they were clear about that. They didn't think it should be — I mean, because that was — obviously, that was one option; that you could just keep running the study as a — as a — as an ongoing epidemiological study and they didn't recommend that.

But as Mike said, they said that this material had value, and it should be maintained and used for other purposes, for other research purposes. And I think the other point that you made, Mike, is also important; that they didn't — I think that they were very farsighted in thinking that the potential uses of the Ranch Hand material were probably broader than just

the original intent, which was very specific: to study, you know, herbicide health effects in this Vietnam veteran population.

That, I mean, they mentioned the issue of a geriatric study looking at just — a longitudinal study of a segment of the American population as they age and to see what kinds of health issues might turn out with that. So I think that the future of the study, I think that their thinking was that it had value for purposes that we may not even, you know, have imagined yet; that — but if you — but if you made it available to researchers out there, that something might come out of it.

M. STOTO: Go ahead. Go ahead, Dave.

D. JOHNSON: Again, and I think you've clarified that "study" means different things to different people. When we keep talking about the future of the study, it gets a little bit confusing because the study is, we think, we're bringing to closure. This — I mean, the Air Force Study, so I know that it's just maybe understanding what's meant when you say "study," but ...

M. STOTO: Yeah. I think that we should talk about the future of the materials that were generated by the study. Okay. I don't think — I don't think there's any question that the study will be continued in the sense that people will continue to be examined, and monitored and so on. I don't think that's in the cards.

M. BROWN: The Air Force.

M. STOTO: What? Oh yeah. Go ahead, Paul.

P. CAMACHO: Let me ask — let me ask Dr. Erdtmann?

F. ERDTMANN: Yeah.

P. CAMACHO: What do you think we can do to help you get possession and maintenance of this? What could we practically do?

F. ERDTMANN: Well, I'm not sure that there is much. I think you're right. I think that this is an advisory group that has advised the Air Force for 25 years. I had proposed the possibility — just before you came in, Mark — that perhaps this advisory group could again reiterate its conclusion that there is value in this research set, not — the study is completed. You're done your duty.

You recognize that this may have further utility in future research and that this could then be serve — this could be a possible — in the form of a letter perhaps to the — to the appropriate Congressional office indicating that you would recommend that there be further opportunities for utilization of this data set without — not continuing the study, but — and that's, I think, that's all you could probably do.

P. CAMACHO: Essentially, we've done that. We've done — essentially, we've done that twice, but we can't go straight to Congress. We have to go through ...

F. ERDTMANN: Oh, that's right. You ...

P. CAMACHO: ... the FDA.

F. ERDTMANN: That's right. You would — you — this would go through the FDA.

M. STOTO: Well, I don't know. We — we've now written letters to the Secretary of Defense, and Veteran's Affairs and, you know, what are they going to do? Disestablish us if we do something wrong?

F. ERDTMANN: Good point.

M. STOTO: But I think there is value in reiterating in that and I think that I would — I would — I think there's a couple of points to be made, you know. One is that — exactly that there's — reiterate the point that there's value in these materials and that arrangements should be made in the national interest for them to be — for researchers to continue to have access to them.

And the other point I'd like to reiterate — and I said it earlier before you came in, Mark, and I'll say it again now — is that is to distinguish between two different sets of costs and the IOM puts them into three categories. But one cost is the cost of doing the research itself with these materials. And these are things that there's established mechanisms through NIH, other government agencies, foundations and so on to pay for, perhaps even VA for intramural researchers.

The second category is the cost of maintaining the specimens, and of maintaining access to the specimens and the — and the data. And that's something that if the Medical Follow-up Agency were to take on, someone would have to pay it to do.

F. ERDTMANN: That's right.

M. STOTO: I think we need to be very clear about that. And, I mean, and I think that a government agency needs to do that because it's really in the national interest. And the question is what's the right government agency to do that?

F. ERDTMANN: Are you asking me as a — that as a specific question?

M. STOTO: No. I'm not asking you as a question. I'm ...

F. ERDTMANN: Was that rhetorical or were you asking ...

M. STOTO: No. I'm assuming that's true.

F. ERDTMANN: Yeah, absolutely. As I mentioned before, that the Medical Follow-up Agency is not a governmental agency. All the work that we do is based on project funds that we get from some sponsor.

M. STOTO: Yeah.

F. ERDTMANN: So you're absolutely right there. We would not be able to maintain these specimens unless additional funds were provided to do that. And I think that it's very

likely, since we at the National Academies don't have a serum repository or a specimen repository, we would have to work out an agreement with some partner.

We would — we would look for a federal partner to do that: either the Department of Defense, a serum repository, or CDC, or NIH, some other federal agency. But if we could not find such a partner, then we would have to go to the private sector, which would be probably the least desirable. But we could find a home for these — for these specimens, but it would require funds to do that.

M. STOTO: Yeah, and I guess I would just add that since the Veterans Affairs Committees in the Congress are the ones that are showing the most interest in this, even though it may not be a lot, I think that the possibility that the Veteran — Department of Veteran Affairs be funded by the Congress to contract with the IOM to do the maintenance activities is something that might be considered as recommendation.

P. CAMACHO: What — what's the — what was the projected cost of maintaining the specimens per year?

K. FOX: 250K.

P. CAMACHO: $250,000?

K. FOX: Yes.

M. STOTO: Well, that was — that was the specimens, but also was the maintenance, the access.

F. ERDTMANN: Yeah. The cost of maintaining the database and the staff to manage it would depend on whether or not you're — the custodian was a private organization like the Medical Follow-up Agency or a federal agency like the VA or DOD because of the way in which there are appropriated funds to pay for staff.

In other words, you're not going to have to — if this were given to the Department of Defense, an individual's salary was already paid for by that department. But if we were to do this, we would have to get those funds to pay for salary time to get someone to manage the materials. So there would higher expense for us to do this and that was made clear to those when we talked about our acceptability of doing this kind of work.

M. STOTO: Well, what was the order of magnitude of that?

F. ERDTMANN: Well ...

M. STOTO: It was less than $1 million per year, wasn't it?

F. ERDTMANN: It was about $1 million a year to do everything to manage this. That was ...

M. STOTO: To manage and the specimens?

F. ERDTMANN: The specimens, the seed money. And the money was about — I think it was about 1.2 a year to do all three of those functions.

M. STOTO: Okay. Go ahead, Mike.

M. BROWN: Well, we looked at those figures very closely too, of course, because we had the — some of the same thoughts. I think that a couple of things struck me about that report. One thing is that the Institute of Medicine, the committee that did that study suggested that this — seemed to suggest, I think, that this information, this database would be so valuable that it would be self-supporting; that researchers would pay to get access to the biological samples, and the data, and that they — that that would make it self-supporting.

I'm skeptical about that, but that was their idea; that it would be — that, you know, you would — whoever — they weren't thinking at that time that the Medical Follow-up

Agency would necessarily be the recipient, but who — their thought was whoever got this data would be a real cash cow.

M. STOTO: But even if that were true, that wouldn't be true for the first couple of years until people found out about it.

M. BROWN: Well, I don't know, but that's ...

P. CAMACHO: Well, that has to be cleaned. The database needs a lot of cleaning, and the fields and ...

M. BROWN: Well, alright. Well, we don't ...

P. CAMACHO: ... all that. That's a huge ...

M. BROWN: Well, we looked at the — yeah, that's interesting, you know. The Air Force has some closeout costs that could maybe cover some of that if it — if there's going to be an addition, but I don't know what they're thinking. You know, may I — maybe a person from the Air Force can talk about that?

But the other point I wanted to make is we already pay a — there's already statutory language that requires DOD and VA jointly to pay the Medical Follow-up Agency to maintain the other databases that they already have: the twin studies and oh, I can't remember. It's a long, long list of databases. And we give them now about, combined, about half a — well, not exactly a half million dollars a year to maintain that, so there's certainly a precedent for doing that. I'm not sure if — what the details are.

I mean, the thing is we don't like this very much because this money comes out of our medical care dollars. This money is money that we would otherwise use for taking care of patients. Congress is very unlikely to give us — they'll — what they'll do is they'll authorize, but they won't appropriate it. That means that we'll have to use existing funds to

cover things like this and that money would come out of our medical care budget, not our research budget.

And so that would be, you know, I mean, we'll see what happens. I mean, you know, obviously, you know, you have to weigh all these things. It's going to — this — I don't think — I think — I think that the Institute of Medicine was overly optimistic in how self-supporting this database will be. So yeah, somebody will have to come up with a way, a means of supporting it.

M. STOTO: Other questions or comments? Does someone from the Air Force want to say something about ...

K. FOX: The study ends on the 30th of September 2006. And we are — we would be happy if we get the consent from our study participants to transfer this data to another agency because we do believe it is a rich and treasure. And we think it should be used.

M. STOTO: Okay. Thank you.

M. BROWN: Can I just ask a follow-up question? I think there is, as I understand and correct me if I'm — if I've — if I'm — if I — if I misunderstood this, but there are some closeout monies identified, targeted for the Ranch Hand — for this Ranch Hand Study? Does the Air Force have any plans for doing any — some kind of wrap-up or something, some way of consolidating the data, you know, maybe along the lines that the Institute of Medicine report suggested to try and ...

K. FOX: As we reported once before, we are already doing that. And we will — in the summary of transition activities, we will go over what we're doing. But we are already following what the Institute of Medicine already asked.

M. STOTO: Okay. Ron?

R. TREWYN: I mean, I — there seems to be a lot of separation here in these discussions between, you know, the — maintaining the data versus maintaining the specimens. And clearly, the specimen maintenance is going to be the high dollar item, I think, in this because, I mean, everything from freezers and everything else, it isn't that the Air Force is going to send all of the equipment and everything over. There are substantial costs and it would be questionable, you know, even if the 1.2 million will do it.

I was involved years ago in the Cooperative Human Tissue Network out of the National Cancer Institute and some of the — running one of those programs and the sort of the maintenance of biological specimens in a reasonable form is not cheap: personnel, equipment, supplies and whatnot. And so it's more than just electricity. There's going to be some high-end costs and I think, you know, hopefully if that's — if it's going to be maintained, then that would, you know, I'm sure that's being worked, but it's not going to be a cheap endeavor.

K. FOX: The authorization bill, the versions say that we are allowed to give our equipment over to the gaining facility, so we are planning to do that.

M. STOTO: Okay.

R. WEIDMAN: Mr. Chairman, can I just make one comment?

RECORDER: Use a microphone, sir.

M. STOTO: No, there's a — there's a time for that. Yes, Rick?

F. ERDTMANN: Yeah. I agree with what Mark said about the VA's position and how they look at this. I do want to mention that a part of the idea would be that this arrangement, to have a custodian look at this database and use this database would be time limited to about a five-year period.

And that if the — this could not be self-sustaining, then the idea would be to actually mothball this into using or into having a database. Perhaps it would be like any of our other databases that may not get used for many, many years, but it would — we wouldn't have an active use. We'd go into kind of a passive use status ...

M. STOTO: Yeah.

F. ERDTMANN: ... or even to the archives. But it would be — there would be a certain period of time where we would look to see if there was interest. If not, we wouldn't have to sustain these costs, you know, odd, you know, forever. So it is time limited and there would be a review and evaluation process at the end of this five-year period to look to see what its utility, its continuing utility was. I just wanted to make sure that was clear.

M. STOTO: Sandy?

S. LEFFINGWELL: Dr. Brown's comment that this was thought perhaps to be eventually a kind of a cash cow gets back to the idea I had earlier. Is this something that would have commercial value? Now a related problem here, in general, federal agencies must survive on appropriated funds. Any revenues they generate in the course of their activities get returned to the Treasury and cannot be spent by the agency. Is that true of Institute of Medicine?

F. ERDTMANN: Well, yes and no. We're — again, I want to clarify. The Institute of Medicine is a private non-profit. It's not a governmental agency. If we were to receive funds from DOD, VA or as a Congressional line item funding, if we were not able to spend that in the — in the — in the fiscal year that it was given to us, we would have to return it to the — to the U.S. Treasury. That's — that is part of our requirement to do that because we're non-profit. We can't keep any of the — any profits from our funds.

M. BROWN: But you could keep it if people were willing to contract ...

RECORDER: Microphone.

M. STOTO: Mark? Yeah.

M. BROWN: If my understanding, Rick, and correct me if I'm wrong, is that you could — if independent researchers wanted to give you funds to be able to get access to a certain database, that you could — that the Medical Follow-up Agency could accept that and use that to defray your costs during that period, fiscal year?

F. ERDTMANN: Absolutely, yes. My comment was only limited to federal funds that we receive, but private funds are not required to be returned to the Treasury obviously.

M. STOTO: Okay. Paul?

P. CAMACHO: Is there any — is there any sense of — I'm looking at the — an authorization bill. I know appropriations is another story. Did VA or OMB ask above and beyond what they asked for? Did they ask for help? Did they go — did you go to the — did the VA ask for money, additional monies for this?

M. BROWN: No.

P. CAMACHO: Did OMB suggest anything?

M. BROWN: No. I don't think ...

P. CAMACHO: There's been no champion ...

M. BROWN: Well ...

P. CAMACHO: ... agency champion that you know of?

M. BROWN: ... normally for something, you know, we wouldn't go to OMB for a request for $1 million. We — or we wouldn't go to our appropriators for a request like that. We would just probably eat it.

P. CAMACHO: Why? And yeah, it's so you can't — there's no way you can ...

M. BROWN: We don't ...

P. CAMACHO: You'd have to take this out of patient care? There's no other ...

M. BROWN: Yeah, and I mean, well, I mean, a couple of things could happen. Our appropriations committee, if it became clear that we were going to — also don't forget the decision about what to do has only — I mean, it's just recently kind of come together about what was going to happen.

The original IOM report when it came out suggested several possibilities: one of which was that the VA could become the sole — the sole custodian of this — of this data. But they also suggested it could go to the National Archives. They've suggested that — they mentioned Medical Follow-up Agency. They had a number of suggestions. It wasn't exactly clear what — which of these suggestions or some combination of them might fall in place.

Once we realized that we have a potential liability like this, I mean, I suppose we could go to our appropriators and say, you know, "Can you give us an extra half million dollars?" But we wouldn't. I mean, they, you know, that — they don't think — that's roundoff air in their thinking. They don't think in those kinds of figures.

M. STOTO: Well, but they — but they could put language in the ...

M. BROWN: They could. I mean, that's, you know, a lot — you would think ...

M. STOTO: You would spend it, or add more or ...

M. BROWN: All right. All right. All right. You would think that they would — there would some kind of coordination and that the appropriators would say, "We see here that our agency, you know, Department of Veterans Affairs is going to get stuck with this cost, so we'll kick in an extra half million dollars, you know, in their — in their appropriations." But it just doesn't work like that. It just doesn't work like that.

M. STOTO: Well, one thing that we might consider as a Committee is to write to the Veterans authorization and appropriations committees; and essentially endorse the IOM findings; and say that it's in the national interest that someone pay for the cost of maintaining the materials, and access to materials and the data for a time limited period to see whether it really does make sense, so ...

P. CAMACHO: You want to reiterate the letters we have in our past? So the last letter of this or the last statement of sorts of this Committee would be to forward such a letter?

M. STOTO: Right, but to a different addressee.

P. CAMACHO: Addressee.

M. STOTO: Yeah. No one has ever responded to my letters.

P. CAMACHO: All I know is that we — all I can tell you, sir, is that this Committee did talk about this since 2004, at least 2004, maybe 2003. I mean, you could see the handwriting coming on the wall. And we talked about this and ...

M. STOTO: Yeah. We talked about the idea about ...

P. CAMACHO: And we spent some time on it.

M. STOTO: ... getting an IOM study and perhaps we were — had some influence in having that happen. We talked to the staff and the committee members as that study was organized, and carried out, and reported out and so on. And so we've been — this has been our — one of our major activities for the last couple of years.

P. CAMACHO: I'd like to say, as much as I know you're in the — down between a rock and a hard place, that agency, as much as people will say, "Well, you gave that — all those materials to the VA. Who knows what's going to happen now?" But if you don't take them, "Well, see? The VA didn't even care and they allowed the thing to die."

M. STOTO: Right.

P. CAMACHO: So I don't think you have — in a sense, if I was a — I don't think you have a choice because you're going to be damned if you do and damned if you don't. But I think you're going to be more damned if you don't.

M. STOTO: And if the — and if the VA were to ...

P. CAMACHO: And it's — and if it's roundoff air, people are going to point that out to you and they're going to say, "This is small potato money."

M. STOTO: Yeah.

P. CAMACHO: And why — you should ...

M. BROWN: It's roundoff air for the U.S. national budget. It's not roundoff air for VA's budget, but I take your point. But I think — but I think that it's going to be very difficult to lay the blame for — if something really goes wrong at VA's feet. I think that there's a lot of players involved with this issue and we're just one. And I think, you know, having said that, I mean, I — but I agree with you. I think that we're very concerned.

I'll just put it this way. We're very concerned that we're seen as doing the right thing with this study. I mean, I think that the problem, of course, is trying to figure out, you know, how exactly should this be — should this play out? And obviously, we have, you know, we — from VA's perspective — we have a lot of research priorities obviously.

We have, you know, many other groups of veterans that we are focusing on now. We're very focused now, for example, on veterans coming back from Iraq, and Afghanistan and looking at mental health issues. We're trying to initiate some research in this area, so obviously, it's a critical area. And so we're stuck, you know. The other rock and the hard place that we're stuck between is too is trying to prioritize all these things.

But obviously, you know, we have to — we have to — we have to be fair and equitable across the board. We can't, you know, we can't be seen as, you know, not taking steps that would be beneficial to veterans when we could have. I mean, that's clearly — that would be unacceptable.

M. STOTO: Dave?

D. JOHNSON: This may go without saying, but I — if — when the material, it's decided how it's going to be kept and maintained, there needs to be an ongoing process or workgroup that looks at, like annually at least, that looks at how has it — does it — do we still think this is worth the cost of keeping it?

What has been done to — how has it been used? What are some ways that we could promote using it if it hasn't been used so there's an ongoing assessment of the value and promotion of the use of it in some way? And I imagine that goes without saying, but I don't know. Someone said something about five years, you know. We'll look at it again in five years, but I think it needs to be an ongoing assessment of this.

M. STOTO: I'd like to ask Rick what the IOM said about that and ...

F. ERDTMANN: And David, correct me if I'm wrong because I may not have this right. But I believe at the end of the five-year process, there was supposed to be a committee-type advisory group that would look at what has happened, and advise Congress as to what the, again, whether there was even more future potential, or whether it was probably diminished and not worth continuing on? But David, is that close to what the committee said? I don't want to ...

D. BUTLER: There. That is correct. The committee suggested three years of seed money funding and suggested that at the end of five years, a reevaluation take place of whether there was continuing merit in making the data available for analysis. It was their

feeling that after five years had passed, that would be sufficient time to evaluate whether there was further interest in the research community in using the data and specimens. And if so, then different and additional provisions would have to be made. To get back to the other comment, the ...

M. STOTO: David, before you go on, did the committee say who should do that review, that five-year review?

D. BUTLER: No. The — I'm — I have the text marked here and it simply says: "It therefore believes that it is appropriate to revisit the question of support for further work after the committee's recommendations have been implemented and have had time to play out in the research realm. A five-year commitment should be sufficient to establish whether the AFHS resources have value and relevance as a resource."

M. STOTO: Okay. Thank you.

D. BUTLER: As to oversight, if the Medical Follow-up Agency is designated as the custodian, as Rick indicated, the Medical Follow-up Agency has not one, but two separate oversight boards of outside researchers and experts who already evaluate the range of epidemiologic studies that are conducted on other data assets that the agency maintains.

M. STOTO: Okay. Thank you. Dave?

D. JOHNSON: Well, it just seems like maybe five years is too long to wait to assess the, you know, the use of it and what better ways to use the data. I don't know how — you don't want to spend a lot of money on it, add to the cost even, but there needs to be some sort of a process that — an ongoing process at least annually to look and see is anybody using the data? How can we use the data if it's not being used? That's just a suggestion.

P. CAMACHO: But isn't the — excuse me — but isn't the maintenance and the cleanup, the database cleanup to get the fields so that another researcher, an outside

researcher can come in and certainly within a month or so have a conception, you know, of what's what in this data table and where all the fields are over all the years? Because they changed field names; there was a big issue about cleanup, was there not?

D. BUTLER: The report mentioned that. The report made several recommendations for how the data might be organized and formatted to facilitated future research and ...

P. CAMACHO: Maximum access.

D. BUTLER: ... Colonel Fox indicated she would be speaking more about the study's work in that direction.

P. CAMACHO: Certainly, that — I mean, that's a — that's a — to get that ready is certainly a, I would think, a year anyway, right?

M. STOTO: I guess I would — I would say that ...

K. FOX: No.

M. STOTO: ... the IOM made its ...

P. CAMACHO: You don't?

M. STOTO: The IOM made its recommendation to look at it in five years and they made their recommendation. And, you know, that may be right or wrong, but they made it. So I don't — I don't think it's ...

P. CAMACHO: Which is nice.

M. STOTO: We — I mean, I — we take your suggestion and presumably, the oversight groups at the — at the Medical Follow-up Agency would look at it to some degree and on a — on a — because that's what they do, but ...

F. ERDTMANN: Sure. I certainly wouldn't want to second-guess the committee of experts. But clearly, the idea, the bottom line was there needs to be an evaluative process at some point.

M. STOTO: Yeah.

F. ERDTMANN: Five years seemed to be reasonable. These are complex epidemiologic studies that take a lot of planning just to get things through approval. IRB takes sometimes months if not a year, so it takes a while to get these things going. And I think it probably would take about five years to make evaluation, but it was an arbitrary, I think, suggestion.

M. STOTO: Yeah. Okay. Anything else? Sandy?

S. LEFFINGWELL: Do we know if the directors of CDC centers or of NIH's institutes have been asked to seriously consider having a hand in this? And if so, what their response was?

F. ERDTMANN: I don't know the answer to that. I mean, I don't know whether or not they were approached by the Congressional staff. I know that there were eight options as I mentioned earlier and as Mike — Mark mentioned. There were eight options considered in the report and the CDC, NIH was one of them. And I don't know whether or not they were approached formally or not.

M. BROWN: Yeah, if they were, I didn't hear about it.

M. STOTO: I do know that folks from both those agencies were — came to the workshops, and the committee meetings and expressed a potential interest in that to some degree. And I suspect that was factored into the IOM's recommendation, not about the arrangements that would be made, but about the potential value of the — of the data and materials. I know that because I was there at the same time.

S. LEFFINGWELL: I was thinking we have the comments from Dr. Brown earlier about the relative budgets of NIH and VA. And perhaps a half million dollars is roundoff air for NIH.

M. BROWN: Right.

M. STOTO: Yeah, and NIH does have a tradition of maintaining research databases and samples in a variety of areas. Karen?

K. FOX: Off the record, CDC, we've talked to them at the dioxin conference. So some people are — they are aware of the specimens and have expressed an interest, but I do not know if they have contacted the Institute of Medicine as yet to further that discussion.

M. STOTO: Yeah. Of course, it — the IOM really isn't in any official place to receive a contact, I suppose.

M. BROWN: You know, I suspect — I think the — I suspect that, and this is a speculation on my part, but I would suspect that CDC would look at this as really a military and veteran health issue, and that therefore, not in their bailiwick. If, as the IOM report — this IOM report that we're talking about, their suggestion that this database has a lot of value for civilian — looking at civilian health issues, you know, above and beyond its military and veteran health aspects, then I think, you know, one possibility I could imagine is after this five-year trial period as it were, it turns out that — it pans out as being a — the gold mine that the IOM committee itself would look at this data seemed to think was there for doing studies that would have relevance to civilian populations. Then CDC might suddenly get very interested.

M. STOTO: I think we should talk about it as having relevance to human populations as opposed to military versus civilian.

M. BROWN: It's — I agree, but the trouble is you have different agencies, you know, with different responsibilities. So inevitably, you know, it gets parsed out as it's "military veteran" versus "civilian," you know. But, of course, you know, it's a human population.

M. STOTO: That's why I say "human" because presumably, every agency of the government is concerned about human.

M. BROWN: I'm not sure.

M. STOTO: But if we label it as one or the other, it doesn't — okay. I propose that we take a short break now. We'll come back and we'll hear from the Air Force on a — on a variety of issues and then we'll talk about the status of collaboration. And then we come back later and decide whether we as a Committee want to do something that takes all the stuff into account as kind of our final letter. Does that make sense? And I hope that you two and others can stay with us for a while. Okay. Let's take a ten-minute break.

[BREAK 10:07 A.M.-10:27 A.M.]

M. STOTO: Let's get started, everyone, again please. I want to call the meeting back to order. And it looks like Colonel Fox is going to be the briefer.

Update on the Air Force Health Study Closeout Activities

Dioxin 2006 Conference

K. FOX: Okay. Hang on. Let's keep on going. Okay. What I was supposed to talk about was summary of — we just got back from "Dioxin 2006" in Oslo Norway. We had two poster presentations: one was on the mortality in U.S. Air Force veterans of Operation Ranch Hand. We — I think we briefed that last time; that was through 31 December 2003.

We also had a poster concerning the viability of stored serum specimens. That, again, was briefed last Ranch Hand Advisory Committee. And our oral presentations is because this was our last dioxin presentation, we summarized the Air Force Health Study, did an overview on that.

And then we also reported on the congeners that we had run. We — I think we briefed you on the 16 and — or 20-some odd previously and then we had another 8 — we had — CDC ran 800. And we did a presentation on what was seen there and it was mostly unchanged from what we had shown before. So that was what we discussed at "Dioxin."

R. SILLS: Karen, could you give us a sense of the interest following the presentations, especially of the oral presentation, the poster sessions? And the reason I'm asking is just to, first to get an additional sense as to how people in the dioxin world view this work. And were there discussions about new studies or additional use of this information?

K. FOX: They were all concerned about, I would say, that the study was ending. I think they — and they were interested in what was going to be done with the study, the data. And we expressed that we were hoping that it would be taken up with — another institution would be overseeing the study and that the data would be available.

And when we were asked if — to try to do any collaborations, we — I pointed them to that it would have to be with a new organization that was overseeing it. So I think there was interest, but also that they realized that we were no longer going to be presenting on it.

M. STOTO: How many people typically go to these meetings? I'm trying to get a sense of how big is this community of researchers?

K. FOX: A lot depends on when it's — Oslo has been the number one most expensive city in the world of — I think CNN did that one poll. It was about 800 this time.

Toronto, I believe the year before, was about 1,200. Next year is in Tokyo, so we'll see how — I would expect around 800 to 1,000 usually about.

M. STOTO: Okay. Well, that's a pretty substantial number of people and this is just dioxin.

K. FOX: Yes.

M. STOTO: Yeah. Okay. Thank you.

K. FOX: I'm ready to go on to the next topic.

M. STOTO: Any more questions on "Dioxin '06?" Okay. Then go ahead, please. Thank you.

Technical Reports and Manuscripts

K. FOX: Okay. As far as technical report and manuscripts, the — because of our time limit, we wanted things that had not been published yet to at least be put — not published in other civilian journals and all that we at least have it somewhere published so that people could have access to it. So the Air Force Health Study Compliance Report that we talked about last time has been turned into a technical report that can be available.

The "Third Source Causation: An Alternative Explanation for the Check Mark Pattern," this was briefed to you guys a long time ago and it was turned into a technical report so that people could have access to it. "A Matched" ...

M. STOTO: Where are — where are these — can I ask where these technical reports reside and what ...

K. FOX: I believe it's the Department of Defense. DTS is what it is, "DTIC," and it's available. Anybody can then pull it up and have access to it.

M. STOTO: On the web?

K. FOX: I believe it is on the web.

M. STOTO: And that will continue to be the case after ...

K. FOX: Yes. Once it's published, then it is — yes, it is available.

M. STOTO: Okay.

K. FOX: Yes. The third one was "A Matched Analysis of Diabetes Mellitus and Herbicide Exposure in Veterans of Operation Ranch Hand." Again, this was previously reported. And then our mortality study that we just did through 31 December 2003, that was also turned into a technical report so that it could be made available.

Manuscripts that we've contracted with SAIC: "Serum Dioxin and Memory Among Veterans of Operation Ranch Hand," that's done by Dr. Cary and that's been — going to be submitted to a peer-reviewed journal. And the "Nerve Conduction Study Data Verification and Review Report," which was done by Dr. Albers, will be submitted as a technical report. Now both those topics have not been briefed and I would like Dr. Pavuk to come on up and he will be briefing those two reports now.

M. STOTO: I'm — I — at one point, I want to discuss the status of these things and the things that aren't on here.

K. FOX: That's the next topic ...

M. STOTO: Okay.

K. FOX: ... after this.

M. STOTO: Okay. So we'll hear the briefing now.

K. FOX: Yes.

M. PAVUK: Thank you, Dr. Fox. Good morning, Dr. Stoto, everyone. I will try to be brief here to let Dr. Fox to move to other topics. As she said, this was done in collaboration

with Dr. Cary. There was a previous paper published in 2001 in collaboration with CDC, Dr. Drue Barrett, that evaluated cognitive function in Ranch Hand veterans.

That one used the data from 1982 examination. And the major finding of this paper was a memory deficit in immediate and delayed recall on the logical memory sub-test of the Wechsler Memory Scale. That scale includes some other sub-tests as the visual reproduction and associate learning sub-tests. And there were no differences reported there.

In the — in this current assessment, we have re-analyzed the memory data from 1982 with the addition of some other veterans that had dioxin measurements made in 2002. And we have also analyzed memory assessment data from 2002 for Wechsler Memory, or a revised version was used, and used standardized results from those tests to compare the results for 1982 and 2002 data.

There were slightly a smaller number of veterans that participated in 2002. Examination of the dioxin levels do not refer to levels in '82 or 2002. They just refer to participants that participated in 1982 and 2002. This is the result of analysis of logical memory immediate recall of 1982 data. You can see that the difference of adjusted means in the high Ranch Hand category contrasted with comparison data. The results for adjusted means on the immediate recall logical memory scale of the result for high category is lower than comparisons. And this is statistically significant as was in the original paper published in 2001.

In delayed recall, there's also a decrease in the low and high categories. But in contrast to the data — or to the analysis done in 1982, that this one is not statistically significant, although there is still a decrease in the adjusted mean scale results. In 2002, we do not see the decrease. As I mentioned, there was a different scale used.

This is Wechsler revised version and that's why the adjusted means are slightly different, higher. But we do not see any more the differences or the decrease in the — in the high Ranch Hand category in the memory function. And similarly to immediate recall, the same we see for delayed recall for 2002 results where we do not see the differences or decrease in the high Ranch Hand category.

Comparing the differences between paired standardized 1982 and 2002 scores, as I said, those were two different instruments. So they were standardized and the adjusted mean difference score was calculated. The difference of means is the subtraction of the adjusted mean difference scored in Ranch Hands relative to comparison.

I should point out that the positive difference of means indicates an adverse effect to Ranch Hands relative to comparisons. As you may see there, the difference is negative for Ranch Hand low and high. So in a sense, we see a relative improvement of memory functions between 1982 and 2002.

So in conclusion, re-analysis confirmed the finding of earlier reports for 1982 data that there was memory deficit in immediate and delayed logical memory recall in the high exposed Ranch Hands. The results of the 2002 data didn't show the deficits that we — memory deficits that we observed in 1982 data. And the comparisons of standardized memory scale between 1982 and 2002 didn't show the indication of memory function deterioration in Ranch Hands relative to comparisons.

When we looked at the enlisted ground crew Ranch Hands — the highest dioxin exposed group — the results were consistent with the results of other Ranch Hands, meaning that we've seen the memory deficit using 1982 data. But we didn't see the memory deficit for 2002 data.

So the results of the study indicate that Ranch Hand veterans are functioning normally in regard to immediate and delayed memory function. And the 1982 examination found small memory deficits in the highest exposed veterans. The 2002 examination does not indicate that the memory deficit is apparent at this point or using 2002 data. And the — we do not have the exact answer on specific neurological mechanisms related to the cause of 1982 deficits in these veterans. Thank you very much. Questions?

M. STOTO: Okay. Any — let me see if there's any comments or questions about that, those findings? So I guess the bottom line is that when you repeated the study 20 years later, you didn't find the same effects?

M. PAVUK: We didn't find the memory deficit in — on the memory ...

M. STOTO: And that could either be because whatever was happening in 1982 wore off or because it was a fluke in 1982?

M. PAVUK: It seems that, you know, that's why there were re-analysis, you know, of the data for 1982. So it doesn't seem that '82 was fluke. It seems that it was visible there. Although the different deficits appear to be small, the differences in the results of those scales.

M. STOTO: Well, 5 percent of the time we get a significant result when there's nothing going on by the definition of it.

M. PAVUK: That's correct.

M. STOTO: Yeah.

P. CAMACHO: Could there — could there have been other confounding variables, maybe behaviors done in 1982? I — done maybe 30 years later, you drop these off 20 years later?

M. PAVUK: Certainly. I mean, we have used extensive, very many factors for adjustments that are listed at the bottom of those tables relating to very many factors. And we tried to be consistent using the same factors for '82 and 2002. But as you correctly pointed out, the lives of the veterans in the 20-year span changes significantly.

So in — but I think the bottom line, that we do not see real big deficits in the memory function at this point. The other paper evaluated all cognitive functioning in the veterans, not just memory. The focus on the one that was positive there and tried to, you know, have a second look.

M. STOTO: Okay. Thank you. Why don't you go on to the next one?

M. PAVUK: The next one is the "Nerve Conduction Study Data Verification Review Report" done in collaboration with SAIC and Dr. Albers at Ann Arbor. In this study, we didn't try to re-analyze the data from the previous exams. But also the background, there was a paper published in 2001 that did find some increase in probable and confirmed peripheral neuropathy among Ranch Hands with higher dioxin levels.

The idea here behind the study was that in '97 and in previous examinations, the electrodiagnostic of peripheral neuropathy that is — can be done by nerve conduction study was not performed, was not available. And this nerve conduction velocity studies are the most sensitive, or better say, most specific studies that can diagnose peripheral neuropathy.

So for the participants of 2002 exam, we selected 60 Air Force Health Study veterans with clinically evident peripheral neuropathy that then used nerve conduction velocity study results to confirm the presence of generalized peripheral neuropathy. Out of the 60 veterans that had clinically evident signs of peripheral neuropathy, 56 were found to have peripheral neuropathy electrodiagnostically confirmed using the nerve conduction study.

Four participants were found to have no evidence of generalized peripheral neuropathy on this reclassification. Forty-six of the veterans showed signs of conduction slowing, meaning that axial neuropathies or toxic neuropathies caused by toxicants usually do not cause the conduction velocity slowing. They cause the amplitude changes, but not the slowing. And the diabetic peripheral neuropathy is characteristic by conduction slowing on the conduction studies.

So in conclusion, the review of the nerve conduction study results established a diagnosis of generalized peripheral neuropathy in 56, that is over 90 percent of the 60 Air Force Health Study participants based on conventional criteria. And of those 56, 46 or 82 percent had the evidence of generalized peripheral neuropathy characterized by conduction slowing, which may indicate the diabetes mellitus or impaired glucose tolerance in those veterans.

And the presence of the substantial conduction slowing is in contrast to the finding associated with most forms of "toxic," that means "non-diabetic" neuropathy. There was also an influence of age on this population as the average age was almost 70 years old. And aging influences results of the clinical neurological testing and nerve conduction studies, although these effects are not well understood. And the report also includes some more detailed results when age matching was used on this data.

M. STOTO: Thank you. Any comments or questions from the Committee on this one?

M. PAVUK: As I mentioned, the 60 veterans were not randomly chosen. Those were the first 30 Ranch Hands and comparison veterans and that were evaluated. So it's not very plausible to make inferences about the whole group that attended 2002 exam.

This was just to illustrate that the really nerve conduction velocity studies are superior or form of diagnosis of peripheral neuropathy.

M. STOTO: I guess I was interested in the point you made about diabetes on the — on the previous slide. I mean, because I recall having had a question like that in the — in the — in the past, you know. How much of the peripheral neuropathy is due to the finding that we have already seen ...

M. PAVUK: Right.

M. STOTO: ... of diabetes?

M. PAVUK: Yes. I mean, this was — this was also the questions that reviewers had with the — when the paper was published in 2001; that in the high Ranch Hand groups or, you know, where you see the risk, there was 70, 80 percent of people with diabetes.

And Dr. Albers didn't have the data on diabetes available. I mean, he was blinded to who was Ranch Hand and comparison. But yes, I mean, the high proportion of conduction velocity slowing shows that really what drives the peripheral neuropathy is more the diabetes than maybe a toxic effect of dioxin. But this was not the study to evaluate that in any analytical manner.

M. STOTO: I guess I would be interested to know of these — the people who have confirmed peripheral neuropathy, how many of them had diabetes, or glucose tolerance — intolerance or something like that?

M. PAVUK: That would be the logical next step in development of the report or if we would have data for all participants that had peripheral neuropathy; this is just that less than half of all those that had clinically evident neuropathy. But I do not have the results here.

But just to give you an idea, I did have a quick check of how many people did have: of those 56 with peripheral neuropathy, 34 were diabetic. So it's over 60 percent that were diabetic. And 18 of 28 Ranch Hands were diabetic and 16 out of 28 comparisons were diabetic. So it is very substantial proportion.

M. STOTO: And there might be others with pre-diabetic ...

M. PAVUK: Right. This includes — this "diabetic" means they had either impaired glucose tolerance on the test or diagnosed diabetes.

M. STOTO: Dave, did you want to ...

D. JOHNSON: Well, I could just — would ask maybe if you — could you summarize your summary here once more? I mean, I'm not sure exactly what your conclusion's saying there. I mean, you found 93 percent with peripheral neuropathy.

M. PAVUK: Well ...

D. JOHNSON: That's pretty significant. What ...

M. PAVUK: ... that just means that the clinical criteria that were used to classify a veteran with peripheral neuropathy, in those clinical criteria, were absent Achilles reflex of normal pinprick and of normal liberation at the ankle. If you had two of those present bilaterally, two out of three, you were classified as having peripheral neuropathy. So that is the clinical version of this classification.

And then when you used those 60 people and you apply electrodiagnostic criteria, you confirm the diagnosis in 56 out of 60 veterans. So it was pretty good. The — it shows that the clinical criteria were pretty good in diagnosing these veterans with peripheral neuropathy. It's confirmed electrodiagnostically.

D. JOHNSON: So what do you think caused half of the people to have peripheral neuropathy?

K. FOX: I don't think that was ...

M. PAVUK: That was ...

K. FOX: ... really the purpose of the study.

M. PAVUK: We didn't really — the ...

K. FOX: The study, it wasn't random. The 60 weren't randomly picked. It was to see if our diagnosis, clinical diagnosis of peripheral neuropathy was validated with the nerve conduction velocity. We only had money to do 60. So you — to go much further than that, you really can't do it. But we had an expert, subject matter expert, look at them blinded to see if he could see something toxic or if it — and it doesn't look like it was that.

It looked like it was slowing. And he's raising the questions of aging and then possibly looking at the diabetic. But again, the 60 were not selected well enough to do that next step. It was to try to confirm was our clinical cutoff of peripheral neuropathy supported by nerve conduction velocity and I think that's what we're saying; that yes, it was.

D. JOHNSON: Yes, it was. But just as a quick review, in the study itself, did we find significant peripheral neuropathy?

M. PAVUK: In using the '97 data, yes, there was some association there in the — in the high Ranch Hand, but it was questioned. And I think there were some letters to editor at that time too that, you know, that there was such high proportion — 70 or 80 percent in — or that had diabetes. So it was questioned whether really dioxin was underlying cause of increased risk of peripheral neuropathy.

K. FOX: And 2002 did not show that again.

M. STOTO: Ron?

M. PAVUK: Yes?

D. JOHNSON: Thank you.

R. TREWYN: Just curious, was peripheral neuropathy examined clinically in '82 in the first go-round of the exams? I'm just curious from the standpoint of could there have — if at that point, maybe some toxic effects if that showed up, might have been more expected early on?

K. FOX: I — I'm pretty sure. I'd have to get back with you to be positive, but I think the — this was standardized testing that was done throughout '82 because it's a clinical exam. And so yes, I think so. But I don't know what the results. I don't know. I — sorry.

M. STOTO: Okay. Thank you. But it was the — it was the '97 report that found an excess ...

M. PAVUK: Right.

M. STOTO: ... amount of glucose?

M. PAVUK: But it was — it was a paper published that used '92 and '97 data. It — so it probably didn't use the '82 and '87 data, but it was — it probably was evaluated.

M. STOTO: Okay.

M. PAVUK: Thank you.

M. STOTO: Thank you very much.

External Collaborations

M. STOTO: Now I asked that this next item be put on the agenda — you can come up as we get started — because of the following concern. We spent a lot of time — we have spent a lot of time in this Committee reviewing those five-year cycle reports that come out with the blue covers and so on. And that's an important component of the Ranch Hand Study.

But many of us have felt that that analysis — that it was kind of an old-fashioned analysis and may not be the most up-to-date and best way to analyze the data. And we've been comfortable with continuing that because there have been a whole series of papers that have been published in the scientific literature that used different methods to analyze the data, you know, like these two we were talking about here, and like the ones that showed — looked at excess cancer, and impaired diabetes analysis and so on.

And so we've been comfortable with these five-year cycle reports because there have also been these papers published in the scientific literature. I think that for many of us in the — in the scientific community, those papers in the literature really are more valuable than the five-year cycle reports to be honest. That's the one, although the veteran's community may see it differently.

And so the concern that I had, and I want to make sure that we address, is that all of those reports, those analyses that have been done see the light of day because there's a very important component of the study. You know, the earlier discussion this morning was about how to make sure that things continue to be done in the future, but this part is about making sure that the work that has been initiated is completed in the sense that it's made available to the scientific community.

K. FOX: So for external collaborations, we discussed with Dr. Michalek prior to his retirement to review — we reviewed all the list of all the collaborators. Dr. Michalek at that time indicated that all collaborations were closed. We ...

M. STOTO: What does that mean?

K. FOX: That there was no more. He was not collaborating with anybody else on this with — concerning Ranch Hand data.

M. STOTO: That he was no longer collaborating with others?

K. FOX: That there was — that it was — as a principal investigator, he was involved with all the other collaborations that were going external and he told us that there were no more external collaborations. We then got a list of all the former collaborators throughout the 25-year history. We sent a letter, a formal letter to them notifying them of the study's closure and to return or destroy the Air Force Health Study data sets or biospecimens that they still have.

This was in support of what the Institute of Medicine also said; that we needed to close out and get hold of everything because we then would need to get permission from all these study participants to allow us to give the data set to the IOM. We had this — the letter was reviewed by our Air Force legal advisors. We sent out — there were, for electronic data sets, we've had 45 collaborators and we had four specimens and all.

When we had non-respondents, we sent a certified follow-up letter. I've got to pull out the numbers. About 39 — 36 have responded, have said that — of the data sets have responded and they have said that they have destroyed it or they never — they don't have any data sets to begin with. The — and we are still — we are working with six of the others, still doing collaborations with them so that — so we know that they have the data sets.

We've gotten feedback from two out of the four specimens and they're still working on that. Our letter to these — to it prompted a response from Dr. Gupta saying that he would like to — he had something that he wanted to collaborate on with us. And then additional collaborators contacted the Air Force Health Study: Dr. Gough, former member of this Committee; Dr. Boyle and Dr. DeVito.

We entered into collaborative efforts with Dr. Gupta, Boyle and Dr. Gough because they met our requirement that we needed to have this ended by 30 December — 30 September 2006.

M. STOTO: So that means that they agreed to do the analyses and destroy the data by that period?

K. FOX: Yes.

M. STOTO: Presumably, they ...

K. FOX: And to publish it.

M. STOTO: And publish it?

K. FOX: Yes.

M. STOTO: How? That seems unlikely.

K. FOX: They've done it.

M. STOTO: They've done it? Okay.

K. FOX: So I — if they can do it, it can be done.

M. STOTO: Okay.

K. FOX: Because Dr. Gupta has — his — it's going — this topic, "Anthropometric and Metabolic Factors and Risk of Benign Prostatic Hyperplasia: Prospective Cohort Study of Air Force Veterans" is going to be published in *Urology*.

M. STOTO: So it's been submitted and accepted, but ...

K. FOX: Yes.

M. PAVUK: It hasn't been accepted.

K. FOX: It hasn't — it's been submitted.

M. STOTO: Submitted? Okay.

K. FOX: Dr. Steven Boyle, he's done two papers: "The Relationship" — "The Relation of Hostility, Anger and Depression to Five-Year Increases in Lipids and Lipid Proteins," and that has been submitted to the *International Journal of Behavioral Medicine*.

And “Hostility, Anger and Depression Predict Increases in C3 Over a Ten-Year Period,” that’s been submitted to the *Brain, Behavior and Immunity*.

Haws — Dr. Haws, this is with Dr. Gough, he — they did a study on, “Are Dioxin Body Burdens Surrogates for Other Risk Factors in Association Between Dioxin and Diabetes?” That was a 2006 abstract and was presented at the Dioxin 2006. And then they’ve also have a paper, “Evaluation of the Association Between Serum Dioxin Levels and Type 2 Diabetes in Air Force Veterans Occupationally Exposed to Herbicides in Vietnam,” and that’s to be submitted to the — have been submitted to the *Environmental Health Prospectives*.

M. PAVUK: To be submitted.

K. FOX: To be submitted. We have looked at it and cleared it to be published. Dr. Frame, we had a discussion — I think it was two Ranch Hand Advisory Committees back — that she has three publications and that’s on sleep disorders and dioxin level. And we are — it’s been cleared for publication. Unfortunately, we’ve been told that she’s been sick and has been out of office for almost nine months. And we were — are still getting a hold of her, but they have been cleared for publication.

M. STOTO: But they haven’t been submitted yet?

K. FOX: We are not — we do ...

M. PAVUK: I think that one paper ...

RECORDER: Sir, you’re going to have to go to your mike. I cannot hear you.

K. FOX: She’s submitted one paper.

M. PAVUK: I think — I think one paper was reviewed. I think one — I know that one paper was submitted, and reviewed and I — and I presume accepted for publication in

Journal of Epidemiology on sleep disorder as a metabolic syndrome and dioxin levels. But that's the one. I don't know. I don't have information on the others.

K. FOX: We are still trying to get hold of her.

M. STOTO: Okay.

K. FOX: She has other priorities at this time.

M. STOTO: Right.

K. FOX: And I believe that's the ...

M. STOTO: Well, the one that's not on the list is the cancer study that Dr. Michalek has briefed us on a number of times, which a number of us, I believe, is a very important study.

K. FOX: Dr. Michalek was given numerous opportunities to enter into a contract, a relationship with us. He did — elected not to do that and he never applied to be an external collaborator with us.

M. STOTO: You know, I have heard from him that he would like that paper to be published.

K. FOX: He has never talked to the people that needs to be talked to to do that.

M. STOTO: Okay. Let me put it another way. Given that that analysis has been done, it has been ...

K. FOX: The Air Force Health Study is ending 30 September ...

M. STOTO: May I ...

K. FOX: ... 2006.

M. STOTO: Excuse me. Let me finish my question. Given that that analysis has been done, it's been presented to this Committee; it's been presented to the Institute of

Medicine. I understand it's referred to in that — in that report. It's a matter of public record at least with respect to the minutes of this Committee.

And I think the slides — is it possible, and so in other words that no more data analysis needs to be done; no more access to the original data presumably. Would it be possible for Dr. Michalek to publish, to write up those results and publish them? And that this is a question both from your point of view and from the Committee's — and the Committee — asking the Committee to give advice about that question.

I understand the need to close the study when you say you want to — when the law requires it. I understand the need to — for no one to have access to the individual subject's data. That's an important privacy, confidentiality issue. But given the situation here that we have an analysis that's been done, been publicly presented, what's the position of the Air Force? And to the Committee, what should the position be with respect to getting that into the scientific literature?

K. FOX: Dr. Michalek has not contacted us, has not requested to be a collaborator with us. We tried to enter into a relationship with him, for him to write those papers. He did not do that. He elected not to pursue that and he did not ask to be a collaborator with us. And he is more than welcome to work with the new custodian to get permission to report on it.

M. STOTO: Ron?

R. TREWYN: Yeah. Let me just jump in because I, you know — and I recognize this is a — this is a somewhat different environment. But it's certainly not uncommon when one has funding from a federal agency to do research, that after the end of the funding period that one is still working on writing up publications and materials, getting manuscripts out, sort of standard practice.

If the data has been collected as part of a study, and again, then one has to ensure that you have all the appropriate coauthors who were involved in the study. I guess I'm curious what the differences are in this situation compared to what I think most academic researchers would be involved in where you just, you know, you write up the results whenever you can get to them, hopefully soon. But I guess I'm not familiar enough with the restrictions here to be able to do that, why that couldn't be done?

K. FOX: We have gotten — we've sent 45 letters out and it seems like everybody else can get — and has agreed to do this. And we had people agree to get it. We have a timeline that we had to do. And the person that we are talking about did not — did not enter into an agreement to do this timeline that we have.

He is more than welcome to talk to the Institute of Medicine if they are the new custodians to complete this. But he has not — he did not enter into an agreement with us. He was given the letter for external collaboration.

D. JOHNSON: Is there any question as to whether or not he received the communication from you and ...

K. FOX: No, there is no ...

J. ROBINSON: No doubt.

K. FOX: ... question.

J. ROBINSON: He and I have communicated verbally, via e-mail and he is fully aware of the mechanism to collaborate with the Air Force. He's also aware of the clearance requirements for anything that's published. He's just ...

D. JOHNSON: So was his indication he didn't want to go forward with it?

J. ROBINSON: He never pursued it.

M. STOTO: I want to pursue this clearance thing. As, you know, most universities have pretty strict rules about entering into a research contract that would not allow them to publish the results. Sometimes, many universities will say the sponsor has the right to review them for a certain amount of time, but ultimately the decision to publish resides with the university and with the PI. Was that an issue; that there was a — the issue between the Air Force and the University of Texas with respect to clearance?

K. FOX: Not that we know of.

D. JOHNSON: Are all the other author — potential authors been communicated with and cleared? Is this the — is this the one exceptional situation here? Everything else has been resolved?

K. FOX: That is correct.

D. JOHNSON: Okay.

R. TREWYN: I was certainly, at least had the impression that the difficulty was a University of Texas Health Science Center at San Antonio issue with language in that was — that was forwarded. If that's not the case — because hasn't — since he is employed by the University of Texas, it was my understanding that it would've been a — been a standard sort of thing that all universities — we have DOD grants at Kansas State and those sorts of — the restrictions that are in place are pretty standard and Mike already alluded to those. And so I was just curious, at least it was my understanding that that's where there were stipulations; that the — as a public institution, Texas would not agree to. But that may be incorrect.

K. FOX: I do not know, but he did not enter into an agreement with us.

R. TREWYN: Let me ask one other quick thing then. Do you know if the other — with most — there are many other academic investigators that you had on this list that you

just had up there. Are those agreements with their institutions as is, you know, would be standard as employees of those institutions or are those agreements with them as consultants, using their consulting? Any idea if those are individual agreements or are those institutional agreements?

J. ROBINSON: These have been collaborative efforts between the individual. So Dr. Gupta wanted to do a study on a certain topic. He came to us, presented his hypothesis, what variables he needed. Our scientific group reviewed that and concurred that it was worthwhile finishing his research.

R. TREWYN: So the contract is with him as an individual?

M. STOTO: Well, that — I think I want to pursue this. I think this may be important. I mean, these university restrictions are triggered when there's funded research. And, I mean, have these other things you talk about, have they been — have they — people receive funding from the Air Force to do — no?

K. FOX: No.

M. STOTO: For Dr. Michalek, would he have received funding from the Air Force to do his work?

J. ROBINSON: If he had been ...

K. FOX: If he had been through — we were trying to do it through an SAIC contract and with the same contract that Dr. Albers — the two studies that you just were shown that were done through that — that we were trying to attempt to go through that to fund him.

M. STOTO: Okay. I mean, I think that may be the difference, not with Albers, but with the other — well, I mean, obviously at this moment, we probably can't resolve this now. But I think that I would like to express my own point of view and see if others join me about

the importance of getting those particular results, the cancer study published in the scientific literature.

I mean, I think that there were some interesting and potentially important findings in those. You — maybe Ron, you can summarize them? But the — I'm not sure who we're recommending to, but I think we're expressing an opinion in this — in this case.

R. TREWYN: Yeah. I mean, there were two of the publications that we've talked about a lot in here in the past: 2004, 2005. There were some publications that were gotten out that didn't wind up in the — in the final report, but showed some cancer effects. But then he had some additional data — by however it was analyzed — that during his presentation in 2005, I think, that was beyond what came out in those 2004, 2005 publications.

And because those showed some significant cancer outcomes and because the data that he presented showed some significant cancer outcomes, we had certainly discussed that, you know. Getting that out in the literature was going to be important, talked about it at the time.

But I know we had also talked about at least in sort of a, "Gee whiz, it would really be nice if utilizing the sorts that were used on however those were — the cohorts were pulled together that then showed significant results, it would be nice to have seen that, you know, done some re-analysis and some of the other health effects." And clearly because of the timing and whatnot, that was not done.

And hopefully, it is another reason though why one would hope that those sorts of things could be done in the future. But again, it really is, you know, if the data is all there — the tables, the graphs, *et cetera*, *et cetera* — it really is a shame that that is not being put out. Because if it doesn't show up in any of your technical reports and still doesn't then

show up in the — in the peer-reviewed literature, that's really a loss of something that was done as part of this study.

M. STOTO: Yeah, and when it — frankly, when it shows a significant finding and it seems to have been suppressed, that doesn't add credit to the study.

K. FOX: I also — I've got to say something about that analysis. I — I'm sorry. I think that analysis — I think there was two things he talked about. He talked about the cancer and he talked about the diabetes. And he did it by year of spraying and number of days of spraying.

And I — I'm afraid I don't think there was a hypothesis before he started crunching the data because he picked two different times, lengths of spraying, and he picked different years to show that there was a significance. So I have — I have some problems with what — but we were willing to enter into an agreement because we heard what you were saying at the meeting and he did not go into a meeting.

But I really think that data needs to be looked — pursued further with a peer review. And he is free to do that with a new — we don't have the time now and he's free to do that with a new ...

M. STOTO: Custodian.

K. FOX: Institute of Medicine is who I'm hoping it ...

M. STOTO: Custodian.

K. FOX: The new — the new — the ...

J. ROBINSON: Custodian.

K. FOX: ... custodian.

M. STOTO: Well frankly, that ...

K. FOX: Thank you.

M. STOTO: Frankly, that comment troubles me because it suggests that you disagreed with the analysis and that contributed perhaps to the reason that ...

K. FOX: No, it did not.

M. STOTO: Okay.

K. FOX: It did not contribute to the thing.

M. STOTO: I know, but ...

K. FOX: We tried for many, many months to enter into a ...

M. STOTO: Okay.

K. FOX: ... meeting with him.

M. STOTO: Now I ...

K. FOX: And we would've openly if — he knew about the collaborator's thing. We would very happy to have him collaborate with us on that and he did not.

D. JOHNSON: So was — I think your comment about questioning whether or not you put it into the report had some — you know, you're ...

K. FOX: No. We — the final comprehensive report which we will talk about only deals with the six physical exams. The ones that got turned into technical reports are peer-review journal articles. That is what the comprehensive report covers ...

D. JOHNSON: Right. Well, I'm not sure ...

K. FOX: ... as of 31 December 2005. We had to cut a date off. I can't keep it going.

M. STOTO: I recall the comprehensive report was to summarize the cycle reports and things in the literature that had a bearing on this. And this is one of the things that if it had been in the literature would be in that comment section.

K. FOX: It would be, but it was not put into the literature.

D. JOHNSON: Well, I don't think I perceive that there's — the Air Force suppressed it though. I mean, that comment was made "it seems suppressed." And I don't see — I — what I hear is that they — that the study is ending, and they put out the appropriate requests, and they didn't get the response that was needed. And so, I mean, they don't really have any options at this point to — other than to proceed the way they're suggesting. I mean, I don't understand. I don't think they're suppressing anything.

M. STOTO: Well, I — maybe I shouldn't have used that word. I — what I'll say is this; is that the story I'm hearing here and the story that I've heard from Dr. Michalek are inconsistent. And I don't know what the facts are, but that concerns me.

D. JOHNSON: However, I — the Committee hasn't heard these comments that you're referring to from Dr. — that's one thing ...

M. STOTO: Right.

D. JOHNSON: ... that's missing here.

M. STOTO: Right.

D. JOHNSON: What is — what is his position on this?

M. STOTO: I — yeah. It is missing.

R. TREWYN: One thing I would like to raise though, and a — and a real concern with this, is okay. He has been told to destroy the data?

K. FOX: Yes.

R. TREWYN: Okay. The raw data and the analyzed results?

K. FOX: No.

R. TREWYN: No, so the graphs ...

K. FOX: Just the data that ...

R. TREWYN: ... table, okay, the raw data?

K. FOX: Yeah. He has ...

R. TREWYN: So he will be retaining all of these results that he got that he reported on?

K. FOX: Yes.

R. TREWYN: You also — the Air Force also has copies of all of that, of the crunched data, I assume, and will be retaining that in some manner? Or, I mean, I would certainly assume if it was done, that part ...

K. FOX: We have the data sets, yes.

R. TREWYN: As analyzed?

K. FOX: We — I — we can't answer that.

R. TREWYN: I ...

K. FOX: We have — we have the original data.

R. TREWYN: No, and I understand that.

K. FOX: Okay.

R. TREWYN: Yes. No, clearly, yes. No. I guess, but I would hope that again, everything that was — all the analyses that were done if — especially if there were significant findings, that that would be retained somehow by the Air Force as part of this; that it would — even if it has not made peer-reviewed publications, has not made a technical report, that that would be retained so the new custodian would have that material as well. So again, it doesn't now have to be re-analyzed; that it's there somehow for the record and could be accessed.

K. FOX: The new custodian will get the data on the personnel that grant us a consent form to pass on that information.

M. STOTO: So in other words, the data, in the form that they were analyzed, will not be available?

K. FOX: May not. I do not know. We have not ...

M. STOTO: Well, almost surely someone will say — will not consent. Yeah.

R. TREWYN: And what's frustrating about that is this was done under the auspices and during the timelines of the study, so it really should not have to then be subject to an additional beyond September 30th of 2006 approval and consent. If it's the data that was collected and analyzed as part of this project where you already have consent, starting over shouldn't be necessary. And so I'm really concerned that this really might be lost in the process.

S. LEFFINGWELL: Did you have occasion to discuss your concerns about the study with Dr. Michalek?

K. FOX: No, I did not. I — we — some of us — we have the technical report. I had not seen what he had briefed beforehand.

M. STOTO: Let me — let me say that I'm not endorsing the analysis or the results. I'm just saying that I think it's important that everything that's done by a credible scientist gets to see the light of day.

S. LEFFINGWELL: Except that we must consider the possibility that Dr. Michalek has had second thoughts and doesn't want to go forward with this.

M. STOTO: That's not what he told me. He told me that he very much wants to go forward with it.

S. LEFFINGWELL: He needs to state that publicly.

M. STOTO: Yeah. Like I said, I don't know what — clearly, there's a — there's a — there's a disagreement between what we're hearing and what I've heard from him. I don't

know what the facts are. I don't think we're going to get to the bottom of them today and I'm not sure there's anything that we can do about it.

But I personally want to go on the record as saying I think it's important that the analyses beyond the five cycle reports that have been done and presented to this Committee see the light of day; that they're available to others who want to review them, and evaluate them and see what they think contributes to the — to the findings.

R. SILLS: Since the — since there's been a lot of discussion on this, is there a mechanism for the Air Force to contact Dr. Michalek, and ask him for the information and maybe ...

K. FOX: We do not — the study ends in less than 23 days.

R. SILLS: Right, but the issue here is these are important findings that need to be considered and if there could be some discussion with Dr. Michalek so that we could — so the Air Force or somebody else could get this data and report it. I mean, I'm just trying to figure out how we could just move beyond, you know, talking among ourselves to talking directly with him. And if we — if the Air Force has this data in hand, then it could be transferred, or it could be utilized, and it could be reported.

M. STOTO: For instance, one thing that might be done in 23 days is to say — is to give Dr. Michalek permission to publish the data as presented to the Ranch Hand Advisory Committee; that not to maintain the individual level data, but to — but to — but to — but to publish the summaries, the statistical summaries, tables, regression analyses and so on that have already been presented.

K. FOX: It needs to go through the Air Force. Air Force has a process to do publications and he — Dr. Michalek, having been a member and a principal investigator

with this study for that long, knows the process and he has not entered into an agreement with us.

M. STOTO: Okay.

P. CAMACHO: I think the — what's the status of that, those tables that were presented to us? Is that some kind of classified data? I mean, is it — I — and then you used another word. I don't want to create too much of a monster, but you said, "And you would have to go out and get the permissions from the participants." You used a phrase there.

K. FOX: The — when you read the Institute of Medicine's report ...

P. CAMACHO: Yeah.

K. FOX: ... part of the process for us to turn over our data to the Institute of Medicine is that we are required to get a consent form from all study participants; that all ...

P. CAMACHO: And that's what they meant by the split data?

K. FOX: Yes.

P. CAMACHO: Okay. Thank you. Then now that ...

K. FOX: Then the Institute of Medicine then will have to go and re-get another consent form from all these people so that they can then analyze the data.

P. CAMACHO: What's the status of ...

M. STOTO: But that — but that applies — that applies to the individual level data and I think that makes a lot of sense. What we're talking about is tabular data and related summary statistics that have already been presented in a public meeting.

K. FOX: It's in the public ...

M. STOTO: Turn your mike on, please.

K. FOX: It's in the public record of ...

P. CAMACHO: Of this meeting.

K. FOX: ... at this meeting.

M. STOTO: Right, so the — so ...

P. CAMACHO: So anyone could do anything they want with that material?

K. FOX: That is correct.

M. STOTO: So if a newspaper reporter wanted to publish that as an article about that, he could do it?

K. FOX: If he so desired.

R. TREWYN: And if anybody can, Dr. Michalek can. It was just said it's been presented in a public forum. So if he wants to put that material together and publish it, what was just stated is he should have the right to do it post-September 30th.

K. FOX: That was not what was stated, but he has the right. It's already published, so he can do that. But if he's going to write and publish it someplace else, he does not have — he has not gone through the appropriate channels. We have appropriate channels to release. This has been going on for 25 years.

R. TREWYN: I — and I will just say it was one of the reasons, and where we are right now, it was one of the reasons why I think at least some of the members of the Committee argued all along that all data that had been put in tabular form should have been made part of the reports that were put out as part of this so then there is a permanent record of all it.

And we are now at a point with a — at least a small piece of this where it may or may not ever wind up beyond having some PowerPoint figures without then the necessary text to interpret may never get utilized.

P. CAMACHO: I don't understand the problem myself. If this is — if I've — you're telling me if I find a piece of public — somebody's suggesting that if I have a piece of public data here, "Look, this is public data," I can't utilize this in any kind of study or paper I want or newspaper article or newsletter?

M. STOTO: You could do that. The question is could — can you publish it in a peer-reviewed journal?

P. CAMACHO: Right.

M. STOTO: And the people who might say no are the editors of the journal.

P. CAMACHO: Yes.

M. STOTO: Or the ...

P. CAMACHO: But nobody from the outside can come out.

M. STOTO: Or the — or the coauthors or the Air Force.

P. CAMACHO: Why the Air Force all of a sudden? Why do the — why do — if it's public data, how do ...

S. LEFFINGWELL: You could publish that part that was ...

AUDIOVISUAL TECHNICIAN: Microphone.

R. TREWYN: Microphone.

M. STOTO: Sandy, microphone.

S. LEFFINGWELL: ... didn't have any new explanatory text, but have that go through review.

P. CAMACHO: That's like, well, I — it's beyond our business. But it's like saying, "Here's the published paper and now I can't talk about it anywhere."

S. LEFFINGWELL: Well, like saying, “Here’s two tables. Now here’s the dictionary I’ve written around it.” You can’t do that. He can republish what he said here in the Committee precisely, but that’s not ...

P. CAMACHO: Well, this is the last meeting of this Committee and this study ends on the 30th.

M. STOTO: Well, I think that we’ve gotten as far as we can get on this. I would just like to end this by saying that I personally feel that there’s value in having every bit of analysis see the light of day and that I think that the Air Force should take every step that it can to facilitate this particular analysis becoming accessible in the scientific literature.

J. ROBINSON: And as part of the record, we have made every attempt to do so.

M. STOTO: Thank you. And we’re not going to resolve this.

Public Comment Period

M. STOTO: But we — but it is time now to take comments from the public at 11:30 and we have anybody who would like to do that? Okay. Rick, you want to ...

K. FOX: You’re asking somebody that had a hard enough time getting it started?

M. STOTO: Yeah.

R. WEIDMAN: Yeah. No, that’s fine. I just — I wasn’t concerned for me so much as I was concerned with breaking your little equipment. That’s why I was an Army medic and not an Air Force technician.

First of all, I want to again thank — and as I have publicly on behalf of the members, and officers and board of Vietnam Veterans of America and all the previous boards and officers of Vietnam Veterans of America — thank those of you who have served, in some

cases, numerous terms on this Committee, for your service to — not only to veterans who were exposed to herbicides in Vietnam, but frankly, it's a service to the — to the nation.

And we're grateful to you for having done this and for all your vigorous efforts, not just when you actually come together for meetings, but at those done at home in your study and contemplating some of these rather serious issues. A number of things were mentioned today about the budget process. And it is, in fact, a common tactic that any research into conditions, exposures, maladies that may have been caused by military service that VA says this will take away from patient care dollars.

What was neglected to say, the budget process does work in a cumulative basis. And each department within the — area within the VA comes up with figures and that then goes through, including in the Veteran's Health Administration, and that's compiled and broken down and then VA submits to Office of Management and Budget.

That usually happens in July of each year for the request that will go forward the following February for the fiscal year hence. In other words, the FY'2008 budget, there — they — it has already been submitted and they'll get pass backs next month from Office of Management and Budget, the first cut, and then they'll proceed.

The problem is that if the Administration and the VA asks for X number of dollars for research into Agent Orange, or in the Gulf War illness or into anything else and the Congress does not provide it, shame on the Congress. But if VA doesn't ask, then shame on VA. Shame on VA. And we happen to know for a fact that VA didn't even request of OMB these additional dollars to take care and fund the ongoing MFUA activities: of maintaining the twins database, the World War II database, *et cetera*.

Vietnam Veterans of America testified before the IOM committee and that was doing the consideration of where might be the proper repository for the data and the

biospecimens. And we testified very hard in favor of the Medical Follow-up Agency and not in favor of any governmental entity. Because frankly, the track record over the last 30 years plus is not great for them being "neutral territory," if you will, and custodians that will be arbiters; only asking is this a valid researcher, legitimate researcher, and is this a valid legitimate research institution that is asking to use this data?

We do have confidence, however, in the Institute of Medicine and the Medical Follow-up Agency. And that's why we strongly recommended that to that panel and believe that of the recommendations of that panel, there were eight considered, but really only three recommended. And that we recommended strongly to the Armed Services committees and to the Veterans Affairs committees that it be the Medical Follow-up Agency.

The language that is now in both the House Defense Authorization Act and the Senate Authorization Act — in fact, Paul, it does work the same as appropriations. It will mean $850,000 go to the Air Force for continuing the cataloging and transfer work. It does authorize the Air Force to transfer freezers and that kind of thing, custody of them. And it does authorize up to $200,000 be transferred to MFUA to do the preparatory work for accepting the data and biospecimens.

Frankly from our point of view, we would hope that the biospecimens, that a relationship be worked out with a valid institution in the greater Washington area: whether that be Johns Hopkins, Georgetown, George Washington University, University of Maryland, James Madison, or whatever the case, or George Mason, but any of the major institutions, or Howard University, for maintaining the biospecimens because they do not have room at the Keck Building at 500 Fifth Street to do it.

They are set up, however, to maintain the several levels of security necessary on all of the data. And so that's the place that we believe where the data ought to go. And I

would hope in your recommendations, and it certainly would be within your purview, is to recommend that be the repository for the biospecimens.

The real problem, and it's not a question of questioning anyone's integrity, whether Colonel Fox or anyone else in the Air Force. It's simply the nature of the institutions that they respond to priorities that are given from the Secretary level on down: whether it be Secretary of the Air Force, Sec Def or Domestic Policy Council. And therefore, we need to make sure that it is scientific decisions that are made in an unimpeachable manner. And MFUA certainly has demonstrated that kind of unimpeachable integrity for over 70 years through thick and thin, through funding and not funding.

The job of the veterans service organizations, and I'm going to presume to speak not just on behalf of the Vietnam Veterans of America, but the Legion and all the other VSOs that are deeply interested in what happens to this, technically $140 million worth of effort and data. But actually, it's much more than that and I think most of us who've been involved know that.

I mean, the Air Force has spent way beyond $140 million in order to come up with this cache of material and data that is potentially valuable and it can be "mined," if you will, not just for veterans, but for others many decades into the future. And MFUA is a place to do it. It's our job to make sure that that five years of funding after September 30th FY'2007 is there, one, and two, that there be seed money.

The IOM panel recommended a quarter million dollars a year for three years in seed funding. We think that is way, way, way too low and we will be pushing hard for several million at minimum. Why? The reason for that is really very simple. Out of the tens of billions of dollars that the Institute of Health — National Institute of Health has, they do not

have a single veteran-specific study. Now this is something that my organization plans to start addressing in a public way and with the Hill in the 110th Congress.

We did not give up our citizenship when we took that step forward pledging life and limb in defense of the Constitution of the United States against all enemies foreign and domestic. And they fund cohort studies and epidemiological study of folks from Taiwan to France to Algeria to you name it. But they won't fund studies of American citizens who've put themselves on the line in defense of our nation. We have a real problem with that and we're going to take that on.

But at the moment, those dollars aren't there. So we're recognizing reality and having to make sure that the earmarked dollars are set aside for scientists — whether they be from Duke University, or University of Texas, or University of Pittsburgh or wherever they may be from, even the University of Massachusetts, Paul; we'll go that far — that those are available for valid, legitimate, reputable scientists and those institutions to apply for those funds.

Generally, what we — what we favor is RFAs and not RFPs where people can come in with their hypotheses, *et cetera*, and where that data and all the data, including all the analysis. And I want to second that which Dr. Stoto mentioned earlier. It is our belief that the public paid for it. We bought it. You were their custodians of it and all of the analyses in addition to all the data are, in fact, the property of the American people for legitimate uses. And legitimate uses would be with those reputable scientists as I mentioned before.

So we will, I can assure you, Mr. Chairman and all of you, that we aren't going to sleep on this one. You'll notice that we keep coming back, and coming back and coming back. And it is, as much as I personally enjoy seeing you all, it's the mission that is paramount to us because there are many people, our folks are dying 20 years too early.

I could show you, and you can go online and look at our "tap" section. And you will still see that the average age of those who are dying, who are our members, all of whom are Vietnam era veterans, is still in the 50s. We're dying 20 years too early of the diseases of aging and the research has not been undertaken by the VA to do the National Vietnam Veterans Longitudinal Study. Even though they're mandated by law to do it, they have shied away from it. Now they're saying they're not going to do it; they didn't think it was a good idea.

Only the VA, if you think about it, can get away with saying that the federal law is just a cute idea; that they're not going to — and suggestion that they're not going to obey. If I did that, I would go to jail. If you did that, David, you would go to jail. But the VA is getting away with it and the only way to enforce it is through the appropriations process. And I can assure you that we're working on that for the FY'2007, working very closely with Senator Kate Bailey-Hutchinson and Senator Feinstein. And we'll be working with their counterparts on the House side, Mr. Walsh and Chet Edwards from Texas.

That deal is not done, but we think it will be done by October 1 to force them to obey the law. That's all we're asking them to do. But the fact that you have to go through that extraordinary effort to get people to not only do what's right, but also to obey what is in black letter law is the reason why we believe the repository has to be neutral turf, and namely, the Institute of Medicine.

We don't always agree with the Institute of Medicine, but we do believe firmly and agree with the overwhelming majority of the scientific community and the public that they're fair; that they're honest; and that they're an institution and individuals of unimpeachable integrity.

The — we have expressed this concern with the data not being available publicly before. And I know, I understand and appreciate the perspective of this Committee in taking it off the web once it got put up on the web, but, and recommending that that happen. However, our hope is that once it goes to MFUA, all the materials, including the analyses, will then be made available to any and all individuals who need it.

One more comment; that it would be appropriate for this Committee, in terms of you asked, Mr. Chairman, whether it'd be appropriate to write to the committees on the Hill. I can tell you that in my conversations with those folks that they would welcome it. They have tremendous respect for this Committee. They have tremendous respect, frankly Colonel Fox, for you, and your folks, and your contractors and the efforts that you've put forward as do we.

We often have disagreed with you in the past, but we appreciate you, and we do respect your efforts and thank you for them. That kind of a letter would be very well received, particularly getting into specifics of recommendations and commenting on the IOM study, which was extremely well done in our viewpoint.

Secondly, it would be appropriate, it strikes us, for you to communicate to the National Institute of Health, as well as to the Labor HHS Committee and to the Labor HHS Subcommittee on Appropriations in both the House and the Senate the need for requirements for making dollars available for doing veteran-specific research the same way as one of you may, as an example, Dr. Johnson may choose to do a study of Native Americans who reside in West Virginia. And they would fund it, but they wouldn't do it of in-country Vietnam vets, or in-country operation and during freedom vets, or you name it.

We think that that's nonsense and that it would be greatly appreciated by us, but also, I think well received to make that note to responsible officials on the Hill as well as

directly to NIH, number one. And number two, something that you should know is Agent Orange has obviously been a great concern as are Gulf War illness, as are those who are atomic veterans, *et cetera*.

You should know that research and development section of the Department of Veterans Affairs does not have a single study going on ionizing radiation; does not have a single study going on the effects of Agent Orange. And the efforts on Gulf War illness research is only because of earmarked dollars that can't be used for anything else that were specifically mandated, directed and oversight performed by the Congress.

So one of the recommendations, if I may suggest, is not that they take over being the repository of the data. But one of the things that would be appropriate for you to do is to write to both the Secretary of Defense, and to the Secretary of Veterans Affairs as well as to the Secretary of HHS and say:

"We have recommended and it is now our understanding that the Congress is going to have the Institute of Medicine Medical Follow-up Agency be the repository of data. It is incumbent on you to make dollars available for legitimate scientists and legitimate research institutions to be able to utilize that by submitting RFAs, and then going to that neutral repository, and securing the data, and the copies of the analysis work and tables, *et cetera*, that has gone heretofore which the American taxpayers have paid."

Like I say, I think it's much more than $140 million. I suspect that overall total, not even counting each of your valuable time, is probably closer to a quarter billion dollars over the last 25 years. This whole thing about being seen as doing the right thing is one thing. It is much better from the point of view of many of us to do the right thing and then people will see you as doing the right thing.

The problem with much of what has happened in this area and other environmental exposures is the concern with people trying to put forth a profile where they're seen as doing the right thing whether they are or not. And so I know that this Committee has tried to do the right thing all the way through and I commend you for it.

And I would urge you to take these additional steps in exercising your prerogative. And I might say, this is your last opportunity to capitalize on the — on the reputation that you have deservedly built by dent of your hard work and what you have done before in order to "leverage," if you will, additional action on the part of the Congress and of the Executive Branch to make sure that these efforts have not gone for naught.

I want to thank you again for the opportunity, and to appear here today, and to sit in and observe your deliberations. And once again, I think you for all your efforts.

M. STOTO: Thank you, Rick. I'm going to make sure I understand your — I think you made three recommendations. And then I'll just throw it open to comments and questions from the floor if that's okay with you.

R. WEIDMAN: Yes sir.

M. STOTO: What I heard was the following: one is that you suggest that we essentially endorse the IOM study, and more specifically, endorse the choice of MFUA as the custodian.

R. WEIDMAN: That is correct, sir.

M. STOTO: Okay. Second one is that we support NIH funding of veteran studies.

R. WEIDMAN: That's correct.

M. STOTO: And then third is that we urge that the Department of Defense and Veterans Affairs support research based on the Ranch Hand Advisory — of the Ranch

Hand Study, not just making the data and materials accessible to people, but actually support the research itself. Was that what you said?

R. WEIDMAN: That's correct, sir.

M. STOTO: Okay.

R. WEIDMAN: And concomitant with that is not just writing to the Executive Branch, but to the appropriate and responsible officials on Capitol Hill.

M. STOTO: Okay.

R. WEIDMAN: Because sometimes if you do that, it's amazing how reasonable people can be once you have their attention.

M. STOTO: So I'm not sure those are all within our scope, but we'll discuss them. I think they're important ideas to discuss. Let me see if there's other questions or comments from the Committee to Rick now? Paul?

P. CAMACHO: It was discussed by the VA official here, Dr. Mark Brown, about the research dollars. I never really understood the maze of the Veterans Affairs Agency, never. Now recently, I heard that Dennis Duffy, who was in charge of data, that they actually stopped some research and policy unit out of the VA. Have you ever heard of anything like that? Do you know of anything of that?

R. WEIDMAN: They stopped the National Vietnam Veterans Longitudinal Study. There was a contract. It was mandated by the Health Care Improvement Act of 2000 that they go back to the 19 — mid-1980s study of National Vietnam Veterans Readjustment Study and that they repeat that going back to exactly the same population: which is veterans who served in Vietnam, veterans who served in the military during that cohort group, but did not serve in Southeast Asia, and non-veteran cohort.

And all together, including over-sampling, we paid in 1984 dollars — George Gallup — $1.1 million, which is a good chunk of change merely to select a cohort and the over-sampling, to make over-sampling of African Americans and Latino Americans.

And they took every in-country Vietnam veteran woman they could find and then got a commiserate sample of era vets and non-veterans in order to have all three groups so that your control group — and there may have been something in the military itself that affected people's health.

And were supposed to go back and replicate the readjustment study having to do not just with psychosocial readjustment, and PTSD and other mental health problems, but also looking at physiological data and to essentially do a complete mortality and morbidity study.

That contract was proceeding along. And Dr. Roswell, then Undersecretary of Veterans Affairs, started complaining that $17 million contract with Research Triangle Institute was not going well and started bitterly complaining that RTI was not a reputable institution; it was ripping off VA. No kidding. This is what he said.

And we pressed him on it and wanted a meeting on it with him. And instead of meeting with us, in order to avoid meeting with us because I went to the Secretary and — Secretary Principe — and said, "We want a meeting on this." He suspended the study and then he turned around and canceled the study. And he turned it over to the IG and said, "I can't talk to you. It's in the hands of the IG. RTI has committed fraud."

And there it rested from October 2003 until September 30th, 2005 when the IG finally issued its report, IG report, in regard to a study, the final results of which were due to the Congress October 1, 2005. Now if that doesn't sound like a put-up job to you, it certainly did — it was a remarkable coincidence to us. And they still have not started that study. So

we're not going to give up on that because we're bound and determined that the VA obey the law.

Why is this important? Because it's a mortality and morbidity study, we think they canceled it because they don't want to know what they think they're going to find. And at one point, they said, "We can't do the study because we can only find 400 of that 2,000-plus sample."

To which our response was: "If you can't find 85 percent of the statistically valid random sample of Vietnam veterans after 20 years by — and you have full use of the IRS, full use of every other federal agency, if you can't find them, that means they're dead. In which case, let's call a press conference. We'll join with you to announce that 85 percent of these folks have died of this statistically valid random sample, nationwide sample."

We're going to continue to press on that. Why is this important? It is important because unfortunately, it reflects an attitude that they don't study what is germane to "veteran-ness," if you will, of the people whom they serve. Most of the study, they don't have a single Agent Orange one going.

They are — they do not take regularly a military history to test it against the null hypothesis of other studies they do with the veteran's population within the — within the hospitals. And that's important because if you don't test it against the null hypothesis, then you're doing bad science in our view.

Same thing is true, I would suggest, when you look at the nationwide statistics on prostate cancer. And when the National Cancer Institute does those — funds those kinds of studies, they don't ask, "Did you serve on active duty in the U.S. military? And if so, did you serve in Vietnam or in a DMZ in Korea?"

And if you don't ask that, you're not testing against the null hypothesis in those who are 55 to 65. And therefore, you're doing bad science the same way as you come into a town where one of the major employers is an asbestos factory or asbestos mine. And you don't ask people what they do for a living and to account for that potential exposure, you're doing bad science. And VA doesn't ask because they — and we believe it's probably too harsh a judgment — but that they don't want to know.

The primary purpose of that 500 million, and incidentally, the VA, the Administration asked for less money for next year than they had this year in research and development dollars. And it was increased after all of us in the major veteran's organizations and military service organizations pushed hard to get more dollars back in there. That shows you where it ranks in the Pantheon; is that they wanted a reduction of dollars.

But even of the dollars that are there, it is used primarily, quite frankly, for physician retention for those in the affiliated medical schools who also practice in VA hospitals. And so that's why much of the research has nothing to do with the "veteran-ness" of the people whom they're studying. That's a — that's a dollar 25 answer to a nickel question and I apologize for going on so long, Dr. Camacho.

M. STOTO: Ron?

R. TREWYN: I'll try to make this one quick and because ...

M. STOTO: Well, the problem isn't with the question. It's with the answer.

R. TREWYN: Question. It's going to be the answer. Okay. Well, I think this one — this one may require a three-word answer. We'll see if we can get it. Okay. If — okay. For the Institute of Medicine's folks to be the custodians of the data, okay, this arm of it to do this, they will need funding that needs to come through some portion of government to do that.

R. WEIDMAN: That's right.

R. TREWYN: The basic points you've just been making would suggest to me that that should not be through VA; that again, if they are not enthusiastic about this even as a pass-through entity that it might be better to have those dollars go through some other agency. If that is correct, what — where should those dollars go? And if it's not correct, what are your thoughts?

R. WEIDMAN: Well, we would suggest two things: one is the primary thing of when I said several million dollars a year for at least that three-year period is that those go to the Medical Follow-up Agency and let MFUA, they do some — that's the only part of IOM that actually does research, direct research. They may ..

R. TREWYN: But there's a Congressional line for that or there's a budget line for that? Doesn't it have to go through something?

R. WEIDMAN: DOD, probably it'll go through and then go directly to MFUA. Dr. Butler can probably — the funding for MFUA, does that all come from VA?

D. BUTLER: The funding for the Medical Follow-up Agency comes from a variety of sources. There is a small amount of core funding that is provided by Department of Defense and Department of Veterans Affairs. Other monies depends on the particular mix of projects that come in. It's true that the vast majority of that funding is Department of Defense, Department of Veterans Affairs. In principle, there's no reason why other monies couldn't come from other institutions.

R. WEIDMAN: DOD is where the money is and quite bluntly. And whatever source, whatever pass-through you use, it has to be — and that's our job to make sure it's absolutely ironclad specified in report language as well as in the line item that it can only be

used for this and it must be transferred. And then the RFPs and RFAs could come forth from MFUA.

Plus, they can do some research themselves by convening scientists because they have a relatively small national staff. And Dr. Butler can correct me if I'm wrong. But on the studies that they do internally, they're not only to internal scientists. They convene a panel and then joins with them to review anything and everything that they do.

M. STOTO: Ron, I think your point about the enthusiasm is important, but the enthusiasm of the VA for the project would be more necessary if they were going to be the one that was actually the custodian, and trying to drum up business and so on. And it's less important if they were the pass-through of the money to MFUA.

R. TREWYN: And I agree, but I think we also want to look long-term. And my only thought is that maybe Labor HHS, in having it come through NIH or somewhere else, some other component, if you're trying to — if you're trying to move ultimately to have dollars available for universities and other entities that have research programs to really tap in, if you had this line going through whatever agency, it might start to build some ownership and some enthusiasm.

R. WEIDMAN: It's frankly a conundrum, Ron, you know, because we have keep coming up, and coming up and coming up against this. And unless the study is absolutely mandated and the monies are earmarked, they don't do it. They won't do it. I mean, it seems absolutely mind-boggling.

We're a nation at war and they're not doing some basic things. And it took a major effort on the part of the military service organizations and the veteran's organizations to prevent them from cutting the Traumatic Brain Injury Center at Walter Reed. If there is a signature wound that's coming out of Iraq, it is brain injuries, traumatic brain injuries.

I'm pleased to say and the Senate accepted the Durban Allen Amendment day before yesterday. But it took a significant effort on the part of the veteran's community to make it happen and it wasn't in the initial request. And this is to take care of the men and women who are serving today, never mind us fossils who served in Vietnam.

M. STOTO: But the challenge — coming back to the Ranch Hand Study — the challenge is, coming back to the Ranch Hand Study, is that the people who see the national interest in having those data available most clearly are the people, are the veteran's communities.

And they have their strongest influence with the veteran agency and the veteran's committees on the Hill. Even though that may not be ultimately what makes the most sense for the government to do, that's where you — those are the people you can influence most easily.

R. WEIDMAN: We've tried with HHS. We try with DOD and we work closely with some organizations that have a bit more clout with DOD than we do, like Military Officers Association and National Association of Uniformed Services to help increase the clout.

But it's still — it's still — it's still difficult because the commitment has not been there from the top to deal with the wounds of war in their completeness because the modern battlefield is not just gunshot wounds anymore and it hasn't been for a long time. And it's going to be increasingly a toxic battlefield.

M. STOTO: Okay. Okay. Thank you very much, Rick.

R. WEIDMAN: Again, thank you all very much.

M. STOTO: Now Mr. Brooks is here from a newspaper. I forgot which newspaper it is or he was here. Yeah, and I told him that this was not an opportunity for him to ask questions of the — of the Committee to be a reporter. But if anybody here would like to talk

to him, I'm sure he'll be here at lunchtime and that will be fine to do that. I thought I should give him that opportunity.

And then having said that, I think it's time to take lunch. So why don't we take, you know, 20 minutes to gather our lunch and come back. And then we'll get started again with the last couple of items from the — from the Air Force. David, do you want ...

D. JOHNSON: I thought at our last meeting we had designated you as our voice to the media ...

M. STOTO: Yeah, that — but you ...

D. JOHNSON: ... as the chair.

M. STOTO: In terms of what the Committee says, that's true. But you certainly, if you want, you can talk to him or you don't have to either.

D. JOHNSON: Okay.

M. STOTO: That's up — that's up to you. Okay. Let's take a 20-minute lunch break to get your lunch.

[LUNCH 12:01 P.M.-12:25 P.M.]

Update on the Air Force Health Study Closeout Activities [continued]

M. STOTO: Well, I think it's time to get started again. We have three more things on the agenda for today. One is — or the first two are presentations from the Air Force about — the first two are presentations from the Air Force about the transition activities and the compliance study. And then we have this last one: Committee discussion.

And what I propose is to say what I think the Committee is heading, and see whether you agree with me, and then have that be in the minutes. And so particular, I would like to say three things so people can think about it now. One is to compliment the Air Force

Ranch Hand staff, all the work they've done over so many years and the — and the good quality work that they have produced which is of tremendous value to not only veterans, but the nation.

Two is to, in general terms, endorse the findings of the Institute of Medicine study about the value of the data and materials that have been gathered over the course of the study and about the importance of finding a way to make that available to other researchers in the future.

And three, to recommend to the Air Force that all of the analyses that have been done and presented to this Committee that they find a way to make them available in the — in the — to the public and in the scientific literature. So we can think about that as we go forward and people even want — may want to add more as well. But that's my proposal, so think about that please as we hear from the Air Force about the closeout issues.

Program Management Activities

J. MINER: Good afternoon. I'm Judson Miner.

RECORDER: Microphone, please.

J. MINER: Good afternoon. I'm Judson Miner and I work with the Program Management people at Brooks Air Force Base. I have been with the study since 1985. I have been a principal investigator in the study. I held Colonel Robinson's spot at one time and Dr. Fox's spot at one time. But after I completed my active duty, I guess I went over to the dark side of the force onto Program Management.

So what I thought I'd like to do is just give you a brief glimpse of where we are in Program Management. And as you may well determine, that without having our Congressional direction passed into law yet, we have to kind of do a dual track activity.

One is if it doesn't pass and when if it does? So with that in mind, I think I'll tell you what's going on.

Our technical team as of 30 September, all permanent civilian slots and technical contractor slots will be gone. There will be one individual that stays as a term civil service employee. That will be Ms. Robinson for a transition administrative team that she will work with to hopefully transfer assets to a custodial agency. We will contract for about 6½ full-time equivalents: help with data sets, and shipping, and with records, and with getting permissions, and follow-up and completing all those things that the Institute of Medicine has asked us to do.

On the Program Management side, we will have a part-time, half-time civil service program manager and then he will be supported with about 1½ individuals for — one individual and one individual half-time, I guess is a better term. For contracting efforts, we hope to continue activities in the Relational Informational Warehouse, specifically as addressed by you to make these data more usable to the custodial agency. We've come a long way with that now and we asked SAIC to give us a best effort right up until the end of the study.

And so we were hoping by 30 September that we'd be well under way and indeed we are. But we are also hoping that we might be able to extend that a little bit into next year to do even more work for the custodial agency. We also want to complete, into a report, the Air Force Health Study and Project Ranch Hand II Program History: what we did, things that worked well and maybe pass on some of our experiences to other agencies or individuals. And we plan to contract with SpecPro for the transition team, and with Core6 and Operational Technologies for the Program Management activities.

As far as funding, as been almost talked a lot today, the Congressional language is identical for both the House and Senate FY'2007 Authorization Bill, which is really a good thing because then it doesn't have to go to committee and get resolved. But both of those entities have identical language.

M. STOTO: And that's the Defense Department Authorization Bill?

J. MINER: In the Defense Department Authorization Bill, yes, which has not been passed yet in answer to a question earlier. Now we have undertaken in Program Management some contingency funding. As you all know, that Congress doesn't necessarily pass the budget so it's effective 1 October.

And we have made some plans that if that does not happen and we don't have monies available from our 2007 budget, that we will have some funds carried over from 2006 to keep us viable until the — that budget is able to be used. So again, it's not going to be on 30 September that we're going to turn out the lights and that's all because we really want this data — these data transferred to a — to the Medical Follow-up Agency. And our headquarters, U.S. Air Force — question?

R. SILLS: No, finish up.

J. MINER: Program Element Monitor is aware of this funding disconnect and we are working closely with the Air Force as regard to that budget.

R. SILLS: So just for my clarification, so you have enough money in terms of your transition for a year, in terms of the freezers, in terms of, for example ...

J. MINER: Not for a year, about three months worth.

R. SILLS: So you just have enough for about three months worth?

J. MINER: Maybe a little more, yeah.

R. SILLS: And so in terms of the appropriations and, you know, in terms of hopefully that comes through within the three months, but if it doesn't, what are the contingency plans? I'm trying to get a feel for what's going to happen with the materials?

J. MINER: I think that's going to be specifically addressed by the next individual.

R. SILLS: Okay.

J. MINER: But there is a requirement that the Air Force keep those materials for one year after the end of the study ...

R. SILLS: So there's ...

J. MINER: ... no matter what.

R. SILLS: ... funding for the freezers being kept on for a year?

J. MINER: That will be — that will be taken out of Air Force hide probably ...

R. SILLS: Thank you.

J. MINER: ... is my guess because that is required.

M. STOTO: Is that a — is that a — is that a requirement in the pending legislation or in some ...

J. MINER: No.

M. STOTO: ... in the original authorizing ...

J. ROBINSON: In the authorization.

J. MINER: In the authorization, I think.

M. STOTO: In the original authorization going back to the 1970s?

J. MINER: No. No. No. No. No. No.

K. FOX: No.

J. MINER: In — I'm sorry. In the pending authorization is a requirement that Air Force keep those specimens and the data for one year after the closeout of the study.

M. STOTO: In the pending authorization?

J. MINER: In the pending.

M. STOTO: Okay.

J. MINER: And just a quick wrap-up, perhaps some personal observations, opinions on Program Management and the study. As you know, this has been a political "hot potato" for most of the study and great passions by individuals: both from this Committee, and the veteran's groups, the media, press, TV. It's really been something and hasn't stopped yet, I think.

We have managed, appropriated dollars of $139.6 million — 139.6, yeah. Okay. And indeed though, there's been probably lots of other costs associated with the study other than just the dollars appropriated. We've managed 50 separate contracts over the course of conducting the study and that includes writing statements of work, and evaluating, and monitoring, and putting dollars on, and contract mods.

We have monitored and provided logistics for about 12,000 person trips out to the physical exams and back. And even though we had a contractor doing most of that, when their bills came back to us, we had to make sure that all of the travel vouchers that had claims on them were, in fact, accurate, and represented the right per diem and all the government travel requirements.

And our integrated product team systems approach was, I feel, highly successful in completing the Air Force Health Study protocol as directed by the White House. And as a reminder, that what really kicked this off was General Dettinger was testifying in front of a Congressional subcommittee and was asked the question, "Are the Ranch Handers having any — or experiencing any ill health because of their occupational exposure in Vietnam?" And that was the basis of our protocol and I think we have accomplished that.

We'll talk a little bit and have some transition slides on activities in a little bit. But again, as far as the funding, we identified in 2001 to the House and Senate Veterans Affairs committee staff that the study was going to end and that there would need to be some dollars if they wanted to transfer the data.

And so indeed as you all know, this has been going on a long time. And hopefully, finally we will make that happen and make the data available to other researchers. And I think, again, as a — as a personal note, that the support of the Committee over all these years has been very beneficial to the study and I greatly appreciate it.

M. STOTO: Okay. Thank you very much.

Transition Activities

K. FOX: With all the medical records and other pertinent materials, 2,000 boxes full of it, have been packed up, palletized and being — going to be shipped to St. Louis because that's where we got — finally, somebody told us where it needed to go. It's going to stay in St. Louis.

Kind of thinking about that *Raiders of the Lost Ark*, the last picture. We're going into the warehouse, and it needs to be there for 30 years and then goes, hopefully, to the National Archives and that's for permanent archiving. The biological specimens, we completed the reorganization that the IOM asked us to do and ...

M. STOTO: Has all the — have all the hard — have all the hard copies been digitized and ...

K. FOX: Yes.

M. STOTO: ... stored electronically and so on?

K. FOX: Yes. We're continuing to construct electronic files for the IOM recommendations to try to make it so that it's easy for somebody, the new custodian to understand what each of the values mean and to make sure that it's — the dictionary is there. So we are — we are still following that and we expect that to be able to be done with the personnel that we are asking to be there for the next final year.

The Relationship Information Warehouse, that is a program that we're trying to develop to load all the data into one single program that can be searchable. And it will have the same definitions, and all across and we are trying to get that. And it goes along very well with as we're — the IOM's recommendations, that makes it easy then to load this database up.

Participant notification: we need — we — what needs to be done next is we need to get a — the — send out the consent form and letter notifying the participants of this new custodian. We've had it reviewed by our legal advisors. We are trying now to comb through, and try to locate all the "unlocatables," and get their addresses ready so that we can send this out to announce that the study's ending, and that the Institute of Medicine will be the new custodian, and to get their permission for it.

M. STOTO: Can I ask what you do about the people who have died? Is there — does next of kin get — does some of those get contacted or ...

K. FOX: No. I believe it gets transferred.

M. STOTO: It's assumed that that can be transferred?

K. FOX: Yes.

R. TREWYN: Can I ask, what if they say no?

K. FOX: Then what happens is part of the authorization bill says that we keep their data for a year so they can change their mind. You can't coerce them. And so if they don't

change their mind in a year, it has to be destroyed if not given their permission for it to be transferred.

M. STOTO: But their medical records that you sent to St. Louis will still ...

K. FOX: That's part of the study, yes.

M. STOTO: Yeah. Okay. Other questions or comments?

K. FOX: Well, that was ...

M. STOTO: Yeah.

K. FOX: ... that one that said that we had to keep it for a year. I think that's about — that's all we have at this time.

M. STOTO: Okay.

K. FOX: Again, I would like to thank you for the support and all.

M. STOTO: Other — I don't see any questions.

RHAC Business

M. STOTO: Okay. Well, then let's move to the last — I thank you very much — the last item, which is basically what we do as a Committee to wrap up and our ...

J. ROBINSON: Sir?

M. STOTO: Yes?

K. FOX: Julie.

M. STOTO: Oh.

J. ROBINSON: We do have one other item. I don't know if you want us to do it now or after you've completed? We have some recognition we need to ...

M. STOTO: Let's do that later.

J. ROBINSON: Okay. Thank you.

M. STOTO: Okay. So most of our work on this Committee, going back more years than I can remember, has been in the form of giving recommendations to the Air Force on draft materials that they've produced: plans, draft reports, so on and so forth. And I think that since I wasn't part of the Committee for most of those years, I can — I can say I think that we've done a good job of that and I'm glad to hear that it was helpful.

What I propose to do as kind of a wrap-up of these activities is to enter into the minutes three points that I hope that you all agree with and we can discuss them after I say what they are. One thing that came up this morning was whether we should send a letter to the Congressional committees.

But as Sandy pointed out, we are special government employees as a member of this and we can't do that; that's illegal, so we won't. Although once we're done being special employees, some of us may be able to communicate that as individuals what the Committee said in the minutes. So it'll be there in the minutes and it can be used by us or by others as they see fit.

So the three things I propose that we say are the following. First, I think it's important that we compliment the AFHS staff — current and all the previous people who have worked for it — for the tremendous amount of good quality, high quality, excellent work that they've done over all these years.

I mean, I think that this study has really turned out to be a national treasure. It has given us lots of good information that has helped the Veterans Administration, and the IOM, and veterans themselves and so on to understand what happened. And I think that it was — it really — it's really remarkable how well such a complicated undertaking was done. So I think the first part would be to — would be to extend our compliments to the staff that we worked with.

And I guess I'd also add that the professionalism with which they've dealt with us too. We've sometimes had contentious discussions like this morning, but I think everybody on our Committee and the staff especially has their heart in the right place about doing the right thing. And I think that we should recognize that.

Two, is I suggest that we endorse in general terms the finding of the Institute of Medicine study, which to my — well, maybe I can even quote back what I said about it in the letters. Well, we — there's something in here, but I think basically the finding of the — of the IOM study that I want to support is that there is value in the materials and the data that have been gathered over the cause of the — course of the study beyond what has already been published in the reports.

And that there — it's in the national interest to make those materials available to other researchers in the future and that the IOM committee lays out a way to do it. We're happy to see that the Air Force people are working to support that and so on. I don't know that we should support the Medical Follow-up Agency as opposed to any other group. But I think they're the only ones have really expressed interest in it anyway, so it doesn't make much of a difference whether we say it or not. Go ahead, Ron.

R. TREWYN: I would just add that, again, we — it isn't something we've analyzed and studied the issue. So I think, again, just going back to your point is very valid; that we endorse ...

M. STOTO: Right.

R. TREWYN: ... you know, the recommendations of this. And so rather than focusing on that, I think it is very appropriate. But we didn't analyze the various possibilities that were outlined in here, so I think this is the best approach.

M. STOTO: Okay. Thanks. David?

D. JOHNSON: We had made some recommendations to the IOM or what we thought should happen with this and from the information, materials. And I think they pretty much endorsed what we had suggested, did they not?

M. STOTO: Yeah.

D. JOHNSON: And I think that's what — that's what the key point is; that we would want, you know — we thank them for supporting our recommendations. I don't know if the Committee's gone through the entire report and is prepared. I — maybe the Committee's all looked at it very closely and is prepared to endorse everything that's in it. I don't know that we've done that?

M. STOTO: No, I ...

D. JOHNSON: But I think the key point is that they've supported our recommendations to them.

M. STOTO: Yeah. I would phrase it in terms of that their conclusions are consistent with what we have thought.

D. JOHNSON: Right.

M. STOTO: And, you know, that's in terms of the — how we've — what we've communicated to them in the past and are hearing from Dr. Tollerud and Dr. Butler about what they found.

D. JOHNSON: Right.

M. STOTO: And that we find that in general terms that we are — that our findings are consistent. There may be — there may be some specific items that one of us ...

D. JOHNSON: Right.

M. STOTO: ... might agree, but that's not the issue.

D. JOHNSON: Right.

M. STOTO: That their general findings are consistent ...

D. JOHNSON: In general.

M. STOTO: ... with what we — what we found.

D. JOHNSON: In general, yes.

M. STOTO: Yeah. And then the third point I would make is that there are — let me — let me — let me think carefully about how to phrase this; that it's very important that all of the analyses that have been done of the Air Force data to date are accessible to the public and particularly in the scientific literature.

By and large that is true. That has already happened with respect to the blue cycle reports; with respect to papers that have been published in the scientific literature; with respect to materials that have been — technical reports that we heard about that are — that are being prepared now; with respect to articles in the scientific literature that people have submitted in the last month, and so on and so forth.

But there are, in particular, this cancer report that we heard about that has a different perspective on things; that without endorsing the findings of that report or the methods, that we think is important that that be available, and to the public and other things that have been done. And that not doing that really undercuts the credibility of the study if there's a perception that some findings that may be at odds with other findings are being — are not seeing the light of day.

And so I think that it — I would just say that it's — that the Air Force should take every step that they possibly can to make sure that those — that material be made publicly available in an appropriate form. I'm not talking about making the data, the individual level data available. I'm talking about making the results of those analyses that have already been done in the — in the course of the study. Dr. Hassoun?

E. HASSOUN: If you go to other studies — I mean, of the cancer, I agree with you about, I mean, all that yet to be published. But with other studies, the Air Force contacted the collaborators.

M. STOTO: Yeah.

E. HASSOUN: And they submitted or they prepared manuscripts. We may recommend that there should be a kind of a follow-up on those also to make sure that they are — they'll be published. I mean, prepared for publication or in preparation doesn't mean that it is published; just kind of a follow-up, make sure that they'll be published, especially with the neurological disorder study because you previously published ...

K. FOX: That will be published. That is going to be published in a technical report.

E. HASSOUN: Is it accepted?

K. FOX: It's a technical report.

E. HASSOUN: Okay.

K. FOX: It will be published because it's a finite — it's finite. But what we — the report is going to be published in DTIC so that ...

E. HASSOUN: Yeah.

K. FOX: ... it can be accessible.

E. HASSOUN: I thought that was very important since you have previously published something different.

K. FOX: Yes, and it — that will be published.

E. HASSOUN: Thanks.

M. STOTO: Okay. Thank you. Ron?

R. TREWYN: And I'm really not going to try to throw kerosene back on the smoldering fire, but just one of the possibilities, and again, thinking in terms of very

generically on these materials. Some that have been submitted for publication that may not wind up being accepted for publication, that truly if a lot of those, even if it's over this next year when you're, you know, when this — the caretaker role is there, if those at least wound up then going out as technical reports so they could be accessed, assuming they don't get published, I think gets us to this issue.

And just my thought, and again, I don't want to throw kerosene on here. But might there be some way to — assuming this other 2005 data does not get published in any form — for the existing personnel to put that into something that's considered a technical report so it's at least out there? That, so I don't know if there — if that's doable, but I'm just throwing that out for thought process, so ...

M. STOTO: Yeah. I mean, I think that at this late date for both the Committee and the — and the Ranch Hand staff, there's not much that we can do except to express the interest, the national interest in having all the material available to the public and note that the problem that occurs if there's a perception that some of it is being withheld. Sandy?

S. LEFFINGWELL: Well, we've got 23 days. Would a letter to Dr. Michalek — perhaps get his sense of what's going on on the record, and why he has not sought collaboration and things like that?

M. STOTO: I guess I feel that I don't understand what's going on between him and the Air Force and that we don't have any chance as a Committee of straightening that out.

R. TREWYN: And I'm back to this point that, again, if the — if there's some way to at least have the data, the tabular material made available — and you're certainly making great efforts in some of these other areas where it isn't peer-reviewed publication — to at least assemble some of this stuff in technical reports. I don't know if it's doable on that. But it — if it is possible, I think that would accomplish what Mike's asking about, so ...

M. STOTO: Now the — I guess — is it true that the slides that were used for that presentation are available on our Committee's web site? Yeah. And now, of course, our Committee's web site will go out of business as a — as a web site when we do, I suppose.

But it doesn't — but that material might be preserved some other way; that's a — that's a possibility. I don't want to get in the business of making specific recommendations about that, but I just want to raise that as a — as a possibility. Okay. Does it — does — do you think that those three points sums up what the Committee — yes?

RECORDER: I just need clarification. Do you want this to reflect a consensus opinion where you're going to vote or you're just ...

M. STOTO: I'm not going to vote. I'm asking now whether the Committee ...

RECORDER: Yeah. You don't want a consensus? Just whether they agree?

M. STOTO: No. I'm going to — I'm going to ask for consensus without a vote.

RECORDER: Without a vote? Okay.

M. STOTO: Yeah. I'm going to — I'm going to ask do people generally agree with those — with those three points?

RHAC MEMBERS: Yes.

M. STOTO: Okay. Dave, you look perplexed. Is that — okay. Turn your mike on, please.

D. JOHNSON: I agree with the points.

M. STOTO: Okay. Thank you. I mean, this is, you know — we're not — we're not writing an official report so, but I would like the minutes to reflect those three things and as we've discussed them here.

RECORDER: And that you all agree?

M. STOTO: Yeah. Okay.

R. TREWYN: And they all agreed.

M. STOTO: Yeah. Is there anything else people would like to discuss?

S. LEFFINGWELL: Do we want to weigh in on the idea that studies of veteran's health issues in other parts of the government might be a good thing?

M. STOTO: That's a good question. Dave, do you have a ...

D. JOHNSON: What was the question?

S. LEFFINGWELL: Does the Committee want to weigh in on the idea that encouraging other government agencies — NIH, CDC, so on — to consider veteran's studies in part of their research protocols?

M. STOTO: This was Rick's second recommendation, but specifically with respect to NIH. And then he also made the — suggested that the DOD, or the DVA or both support research based on the Ranch Hands, not just the maintenance of the material.

R. TREWYN: And I guess I — and I don't know the right answer. I'm just going to throw in some points on this. I do think that going back to '95 when I first got on the Committee and through various, you know, time frames, that one of the things that has been discussed is that, you know, it's too bad that this — there isn't — are materials out there for analyses so you can go through the standard things that an NIH does, NSF, on external entities — whether it's university or whatever groups that do various studies — that there isn't some independent analysis of issues of importance to veteran's health.

And I think it has been something that has come up periodically, specifically with regard to this, the Agent Orange issues. There were other — one of the things that wasn't talked about, I remember in the '90s when this group evaluated the VA health effects on chemical core officers and made various recommendations. And that study, apparently

along the way, wound up being killed. That was again, chemical core — individuals in Vietnam.

So I mean, this group has dealt with a variety of these various topics and issues. And I think whether it's the purview of this Committee to make that recommendation, I know that a number of us have really believed that something like that, of having independent studies of veteran's health issues ongoing would be a good thing.

M. STOTO: I guess I personally feel that while that might be a good thing, I don't think it's in the business of our — it's in the purview of our Committee to make recommendations along those — about what — about what NIH should do.

You know, Rick picked up in his talk two things from the conversation I had with him a minute before. One is about the — one of my colleagues at Georgetown who's doing a study in Taiwan. She's there now with a lot of funding from NIH following a cohort with biochemical markers and so on and funded by the National Institute on Aging.

And I don't think there was ever a mandate saying, you know, "NIH should support studies of Taiwanese." What she did was that she made a very strong proposal about what could be learned from this population. And I think that people could make that same argument with respect to what could be learned from the Ranch Hand cohort. And they would get — they'd be more successful in getting funding that way than by the Congress trying to earmark money for veterans at NIH. That's my personal point of view. Go ahead, Dave.

D. JOHNSON: Can I go back to — are we finished with that point, I wonder?

R. TREWYN: I'll just say, I mean, I certainly have no problem with that; that, you know, from a Committee perspective, I don't — I don't know that it is in our purview. So I have no problem with us not coming out formally on that one.

M. STOTO: And, you know, I think that we address it.

RECORDER: Microphone.

M. STOTO: I think that we address it in the sense that we do endorse the IOM recommendations about making this available and that couldn't happen unless the data becomes available.

D. JOHNSON: I want to go back to the three points and the perplexed look that you saw on my face. I'm not — I'm not really — I'm not really clear what we're asking as a Committee or suggesting to the Air Force to do about this unfinished study. It's, I mean, if the author didn't finish the study, would you — would you ask the Air Force or any other agency — the agency you come from — to somehow put it into a report when it's — when it hasn't been peer-reviewed and hasn't been completed? Would you want — would you want your agency to do that?

I mean, the point — the point you make about making all the information available, absolutely. It should all be there, but it's there. But I'm not sure what else we're asking to be done of the Air Force. I mean, it seems like they did everything they could and it really falls back on the author to complete what he — what they started.

And so if you were to — if you were to put it in a publication, you'd have to qualify it and say, "Well, the author really didn't finish it." And that's not such a great idea either because maybe the author doesn't want that. I mean, really the author needs to come forth and tell us what they want to do with this.

M. STOTO: Right. Well, I mean, I ...

D. JOHNSON: And so ...

M. STOTO: ... agree with you that the author is important.

D. JOHNSON: ... I agree with the three points ...

M. STOTO: Yeah.

D. JOHNSON: ... and absolutely make everything available.

M. STOTO: Yeah.

D. JOHNSON: But I'm not really clear what you're asking further with this report. I'm not sure what the answer is.

M. STOTO: I don't — I'm — I tried to phrase in a non-specific way because I don't know what to do in this particular case. I do know that — what I do know is that there's a disagreement between the Air Force and Dr. Michalek about the publication of this. And he has told me that he wants it published.

R. TREWYN: And I would just add that I have not seen any of these publications, any of the peer-reviewed publications coming out of this study — any — that had a single author ...

M. STOTO: Yeah.

R. TREWYN: ... on any of them, meaning there has to, on this one, there have to be an — coauthors, I would certainly believe. And if that's the case ...

M. STOTO: They have — they have rights too.

R. TREWYN: There are — yeah.

M. STOTO: Yeah, so I don't know what the facts are here. I don't think there's any chance that our Committee can resolve them, but I think that what we can do is state the principle about the importance ...

D. JOHNSON: Of sharing it.

M. STOTO: ... of making that information available. Julie, you want ...

J. ROBINSON: We have gone above and beyond to try to get Joel engaged. I mean, I talked to him as late as the 14th of August. We've done all we can do. It's the onus

is on the author to engage. I mean, the mechanisms are there. We're open, but I don't know.

M. STOTO: I mean, you know, it may well be ...

J. ROBINSON: We've gone above and beyond.

M. STOTO: I mean, that may well be true. I don't want to say that's not true because I don't — I just don't know the facts. And, I mean ...

J. ROBINSON: I can provide you the ...

M. STOTO: I don't want to get involved. I don't want to know all that. I just — I think it's ...

J. ROBINSON: But I'm saying I have the ...

M. STOTO: Right.

J. ROBINSON: ... data to verify all the interactions.

M. STOTO: I don't think it's — I'm not — I'm not doubting you. I don't think it's the — but I don't think it's the Committee's business to get involved at that level. I think it's important that we state the principle and that's the way I tried to phrase it. And it may be that you have gone, done everything that's humanly possible to do, in which case you've done everything that we expect. Yeah.

D. JOHNSON: We certainly all agree.

M. STOTO: Right. Sandy?

S. LEFFINGWELL: In the working lunch period, I was listening to Dr. Hassoun's comments on "citability" of references. And there are ways these tables could be got out that still would not be of any use to another author seeking to cite them. They would just not be credible. So I don't know how this problem gets dealt with, but it'd be nice if we could.

M. STOTO: Okay. That's the end of our business. Yeah. That's the end of our scientific business, but I think that other people want to say something now to us.

Recognition and Appreciation

K. FOX: Well, we thanked each other ...

M. STOTO: Yeah.

K. FOX: ... for our support. And there's one group, one set of people that we have not thanked. And we would like to thank the FDA for their support and ...

M. STOTO: Yeah.

J. ROBINSON: Len, Kim, Nadine?

K. FOX: Could you please come up?

J. ROBINSON: You've got to leave your ...

RECORDER: I'm a contractor. I'm not with FDA.

K. FOX: It doesn't matter. You have been supporting the quality of what we've seen on the reports. Our — we want to say thank you and all. And this is one of our things. It's an "Official Member of Air Force Health Study Crew." And it's a certificate of appreciation given to Nadine Rivera in recognition of outstanding performance and we want to say thank you.

RECORDER: Thank you.

J. ROBINSON: Thank you.

K. FOX: And Kim, without your e-mails, we wouldn't have been keeping in touch and we really appreciate that.

K. CAMPBELL: Thank you.

K. FOX: Thank you. Len, thank you so much. We appreciate all the work you've done.

M. STOTO: And I probably should add that on behalf of the Committee, that's absolutely seconded as well. I mean, we couldn't have met. We couldn't have been productive. We couldn't have been effective without the excellent work of your team. So thank you too from us. Okay.

L. SCHECHTMAN: Well, thank you all. Thank you all very much on behalf of Kim and myself, Nadine. Thanks to the Air Force. And I also have some comments to address to the members of our Ranch Hands Advisory Committee.

So on behalf of the Department of Health and Human Services, the Food and Drug Administration and the National Center for Toxicological Research, I wanted to extend our sincere gratitude and appreciation for each and every one of you for your time and dedication in serving on the Ranch Hands Advisory Committee. The Ranch Hand Study has been going on now for some 25 years. And as we all have heard today and have experienced, it's now drawing to a close.

Some of you have been involved for a rather extensive period of time; others of you have been involved for less time. Some of you are still here with us today and others that have preceded you have since completed their terms. Nevertheless, taken together, all of the efforts of those who have served on this Committee have been most valuable in providing the advice and direction sought in the conduct and the evaluation of this study.

Although we've come to know one another and have worked together for some time, for the record of today's final meeting of the Ranch Hands Advisory Committee, I want to read the list of current Committee members.

First, we have Dr. Michael Stoto who has served as chair. He's now Professor of Health Services Administration and Population Health, Georgetown University School of Nursing and Health Studies. And his service began in February of 1999 and he served two terms: the first ending in 2003, the second in — from 2003 to the present.

Dr. Paul Camacho ...

M. STOTO: I wasn't the chair the first time around though.

L. SCHECHTMAN: Yeah, that's true.

M. STOTO: Yeah.

L. SCHECHTMAN: Okay. Dr. Paul Camacho, who is Director of Special Projects with the William Joyner Center, University of Massachusetts-Boston, also served two terms: one began in October of 2000 to January of 2004 and then again from February of 2004 to the present.

Ezdihar Hassoun: Dr. Hassoun is Vice Chair of the Department of Pharmacology, the University of Toledo College of Pharmacy. And her date of service began in February of 2004 to the present.

Dr. David Johnson, Executive Medical Director of the Division of Environmental Health, Florida Department of Health, whose service began in February of 2004 to the present.

Dr. Sanford Leffingwell, Occupational and Environmental Medicine Consultant, HLM Consultants, his dates of service ran from July 2003 to September of 2006.

Dr. Kwame Osei, Director of the Division of Endocrinology, Diabetes and Metabolism, the Ohio State University College of Medicine, served two terms: the first beginning in August of 2000 and running to January of 2004 and then again from February of 2004 to the present.

Dr. Robert Sills, head of the Molecular Pathology Laboratory of Experimental Pathology, National Institute of Environmental Health Sciences, also served two terms from August 2000 to January of 2004 and again from February 2004 to September 2006.

Finally, Dr. Ron Trewyn, Vice Provost for Research and Dean of the Graduate School of Kansas State University: two terms served from July 1995 to January of 1999, and then after a break in service, from November 2001 to the present.

There have, of course, been other individuals who've also served on the Ranch Hands Advisory Committee over the course of its history: two of whom are Dr. Michael Gough and Dr. Robert Harrison, former chairs of the Committee, and who are known by some of you and whose service began in the early 1990s.

My list, of course, is not exhaustive and my not listing all of the other persons for you at this time in no way diminishes the importance of their participation and service nor the gratitude that we want to express for them — to them today.

Also for the record, I wish to acknowledge three other individuals: one of whom you are all familiar with, and who has been communicating with you on a semi-regular basis, and who's with us today as you saw. And her name is Kim Campbell, NCTR's Management Specialist who administrated the logistics of our Ranch Hands Advisory Committee meetings.

And the other two persons are former FDA employees who have since retired: the first being Ronald Cooney. He's the former Executive Secretary of the Ranch Hands Advisory Committee and my predecessor, and Barbara Jewell, former NTCR Office Manager and Advisory Committee Specialist and predecessor to Kim Campbell.

So with that, I want to thank all of you sincerely — from myself especially as well as the agencies involved — those present today and all those who have preceded you. Let me

add that certificates and letters of appreciation for your service will be forthcoming from the Department, signed by Secretary Michael Leavitt, as a further testament of our gratitude to you for your participation and hard work on our Ranch Hands Advisory Committee. Thank you all very much.

R. TREWYN: Running for politics, Len?

Closing Session

M. STOTO: Well, let me — let me just end by, on behalf of myself, thanking the Committee, who we haven't thanked yet, for your work and, of course, all those that went past as well. And I think it's time that we adjourn.

S. LEFFINGWELL: Is there any chance we can get minutes for review some time before we cease to exist?

M. STOTO: Well, before the study ceases to exist. Yes. Maybe we — maybe we can focus on the — that last — this last little bit and get that out fast. That would be good. Yeah. I'm sure they'll make me sign it whether we exist or not. Okay. Yeah. Right, but that is true. So we'll try to focus on this last discussion and getting that out quickly. Okay. Thank you, everyone. Thank you, everyone.

[ADJOURN 1:14 P.M.]

CERTIFICATION

State of Georgia)
)
County of DeKalb)

I, Nadine Rivera, do hereby certify that the foregoing transcript, consisting of pages 1-127 in total, was personally typewritten by me and is a true, complete and accurate transcript of the proceedings recorded by me.

I further certify that I am not related to, employed by, or attorney of record for any parties or attorneys involved herein. I further certify that I have no financial interest in this matter.

WITNESS MY HAND AND OFFICIAL SEAL BELOW.

This 6th day of October, 2006.

_____
Nadine Rivera
My Commission Expires: August 1, 2010

[Seal]