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

Ranch Hand Advisory Committee

February 27, 2006
Rockville, Maryland

Certified Verbatim Transcript

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

RANCH HAND ADVISORY COMMITTEE MEETING
February 27, 2006
Rockville, Maryland

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1
2 **Opening Session**
3
4

5 **[CONVENE 8:46 A.M.]**

6 **M. STOTO:** Everyone ready to get started? Okay. Let me begin. I'm Mike
7 Stoto. I'm the Chairman of the Ranch Hand Committee. I work at the Rand
8 Corporation. And I think the first order of business is to just go around the room and
9 have the Committee and then the other guests introduce themselves. So Paul, would
10 you want to go next?

11 **P. CAMACHO:** I'm Paul Camacho from the William Joiner Center at the
12 University of Massachusetts.

13 **M. STOTO:** And don't forget to turn your microphone on.

14 **R. TREWYN:** Ron Trewyn, K State.

1 **E. HASSOUN:** Ezdihar Hassoun, Professor of Toxicology, the University of
2 Toledo.
3 **S. LEFFINGWELL:** Sanford Leffingwell, HLM Consultants.
4 **J. ROBINSON:** Julie Robinson, Branch Chief for the Air Force Health Study.
5 **K. FOX:** Colonel Karen Fox, Principle Investigator for the Ranch Hand.
6 **L. SCHECHTMAN:** Leonard Schechtman, FDA, National Center for
7 Toxicological Research, Executive Secretary.
8 **M. PAVUK:** Marian Pavuk, SpecPro, Ranch — Air Force Health Study.
9 **M. OWENS:** Maurice Owens with SAIC.
10 **M. BLANCAS:** Manny Blancas, contractor with the Air Force Health Study.
11 **D. BRUCE:** Denise Bruce, Program Manager for Ranch Hand.
12 **W. MURRAY:** Bill Murray with the Air Force Surgeon General's Office.
13 **M. YEAGER:** Meghan Yeager, SAIC.
14 **W. GRUBBS:** Bill Grubbs, SAIC.
15 **S. CHERUVILLIL:** Sonia Cheruvillil, IOM staff.
16 **J. PETROLLO:** Jackie Petrello with Exponent.
17 **D. BUTLER:** David Butler, National Academy of Sciences.
18 **D. TOLLERUD:** David Tollerud, University of Louisville. I chaired the Air Force
19 Health Study Disposition Committee.
20 **K. CAMPBELL:** Kim Campbell, FDA.

1 **M. STOTO:** Okay. Well, thank you, everyone. Thanks.

2 **D. JOHNSON:** Dave Johnson on the Committee, from Florida Department of
3 Health.

4 **M. STOTO:** Okay. Thank you, everyone. Len, do you want to lead us through
5 the housekeeping items and the conflict of interest?

6 **L. SCHECHTMAN:** Thank you, Mike. Before we begin, I'm going to read to us
7 the conflict of interest statement. The following announcement addresses the issue of
8 conflict of interest with respect to this meeting and is made a part of the record to
9 preclude even the appearance of such. Based on the agenda submitted for today's
10 meeting, all special government employees have been screened for their financial
11 interests related to the topics at hand. FDA has determined that all financial interests
12 and firms regulated by the Food and Drug Administration present no potential for a
13 conflict of interest at this meeting.

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

1 Okay. Next on our housekeeping list is the sign-in sheet. I will be sending that
2 around for everyone to indicate their name, affiliation, e-mail address and telephone
3 number so that we can have a record of the attendance for the meeting. And lastly ...
4 **M. STOTO:** So we can sign right here on the Committee?
5 **L. SCHECHTMAN:** Yeah, Committee. And lastly, we need to look at future
6 meetings or a meeting. As we know, the drop-dead date for this entire activity is
7 September 30th of this year. We have to consider the remaining activities that we will
8 need to cover before September 30th so that in our discussions regarding how many
9 meetings, whether it be one or two more before the end of this fiscal year, we're going
10 to have to consider what is left to be done.
11 So please be thinking about that and also be considering the time frame of
12 perhaps the late summer because September, we're rapidly approaching the end of the
13 fiscal year, which means the end of budgets and the end of our ability to expend any
14 remaining funds. So we're looking at the probability of say mid to late July and all of
15 August. So please be thinking about that and later on we can, perhaps by lunchtime,
16 poll the members and get some sense of what is comfortable.
17 We realize that that may be a difficult time because of everyone trying to
18 squeeze in their vacations before the end of the summer. But we also realize that
19 considering the business at hand, that we do have to bring the efforts of the Ranch
20 Hand Advisory Committee to closure by that time. So that being said, Mike?

1 **M. STOTO:** I — let me just make a little bit specific proposal to bear in mind.
2 Obviously, we'll have to discuss this later, but it seems to me that the report that we're
3 going to discuss in a few minutes makes a recommendation that there be continued
4 access to the data and the specimens from the — from the study and lays out a number
5 of options in terms of how that might be done. And I don't think that we really can
6 address those options right now.

7 But I think that I'd like to propose that what we ask is that the government come
8 back at our next meeting and lay out what the pros and cons of various options in a way
9 that we could then respond to that. And I say the "government" rather than just the "Air
10 Force" because most of the options involve another agency rather than the Air Force.

11 **P. CAMACHO:** Well, we need to look at this and make our own ...

12 **M. STOTO:** Turn your mike on, please.

13 **P. CAMACHO:** It might be good for us to look at — get the full report, and be
14 able to look at it and address it as a Committee. I think it's appropriate for us to do that
15 as a closing ...

16 **M. STOTO:** Yeah.

17 **P. CAMACHO:** ... piece of this Committee because that report is really the — a
18 legacy of the whole study and what's going to happen to that. I think we have an
19 obligation to do that. I don't know if others think so, but personally ...

1 **M. STOTO:** Well, let's come back to it after we actually hear the discussion of
2 the report. But I'm just sort of laying that out as something concrete to think about.
3 **L. SCHECHTMAN:** Okay.
4 **M. STOTO:** Okay.
5 **L. SCHECHTMAN:** I guess the question I would have would be — well, more of
6 a statement than a question — is it might even be appropriate should we get that far to
7 rather than leave it loose like the "government," we may want to ...
8 **M. STOTO:** Be specific.
9 **L. SCHECHTMAN:** ... ask specific agency or agencies as to what their
10 consideration of the report is and — because I'm afraid that if we don't target a specific
11 agency, then it's going to be out there and fall into some black hole.
12 **P. CAMACHO:** Yeah.
13 **M. STOTO:** Yes.
14 **P. CAMACHO:** The VA.
15 **M. STOTO:** Right. Okay. Okay. So the overview of the agenda is that we're
16 going to hear first about this IOM report. We will then spend some time on a number of
17 other — hearing updates about a number of other studies that were discussed last time
18 and in the past.
19 We'll have time at 11:30 for public comments. I don't know if anybody is here
20 who wants to make themselves known? They want to speak, please do so if there is.

We'll have a working lunch and a chance to talk about the *Nightline* TV show. And then we'll sort of wrap up with coming back to this question about the final meeting, I think, primarily.

Review of Previous Meeting Minutes

M. STOTO: The — so the other business item is to review the minutes from the last meeting, which are — the draft is in your blue folder. Are there any comments about those? And they were sent out a couple of weeks ago to the Committee as well. They reflect changes that I suggested. I think they reflect changes that the Air Force suggested as well. Is that right? Yes. But of course, it's the Committee's turn now. Paul?

P. CAMACHO: Yeah. The chapter — what's the final agreement? What are you — what is going to be done with Chapter 16, the psychological assessment? I e-mailed Jay Miner. Is that — is that the — I e-mailed Jay and said in my opinion — because I was asked to e-mail him.

And I said it's simple that you had all these — you had the breakout. The whole chapter as we reviewed it, you had a breakout of the subgroups and it was that pesky ground crew that showed up — showed all these high levels. But Simpson's paradox, when you aggregate, it disappears.

M. STOTO: But Paul, in terms of just ...

1 **P. CAMACHO:** So my bottom line is that you were going to rewrite that chapter
2 or Jay left the notion that that chapter was going to be rewritten. What's been done?
3 **M. STOTO:** Well, I ...
4 **K. FOX:** It's still being planned to be rewritten.
5 **P. CAMACHO:** It's still ...
6 **M. STOTO:** It's not appropriate to talk about the substance of this here. We're
7 approving the minutes at the moment. But what I would — what I would suggest is that
8 the minutes be amended to say that you brought up an issue.
9 **P. CAMACHO:** Okay.
10 **M. STOTO:** That you were asked to write a — some text. Maybe we can even
11 put in in a footnote the text that you prepared.
12 **P. CAMACHO:** Yeah. It's very short. The — what I wanted the minutes to say
13 was that the subgroup that they talked about, the effect of the subgroup disappeared
14 and that that should be expressed clearly because we both said that.
15 **M. STOTO:** Well, but can you just ...
16 **P. CAMACHO:** Go ahead.
17 **M. STOTO:** ... rephrase the text? No, I don't want to deal with the substance
18 now just in terms of procedure. This is the minutes we're talking about now.

1 **P. CAMACHO:** That the problems of Chapter 16 should be addressed and that
2 those problems involves the breakout of an effect that disappeared. They involved a
3 phenomenon known as Simpson's paradox.

4 **M. STOTO:** Okay.

5 **P. CAMACHO:** That's what it's called.

6 **M. STOTO:** So that Dr. Camacho raised an issue about essentially involving
7 Simpson's paradox.

8 **P. CAMACHO:** Yes.

9 **M. STOTO:** And he was asked to prepare some text to deal with this and ...

10 **P. CAMACHO:** I was asked to prepare some text. I sent Jay a small note
11 saying what the problem was and that they should just acknowledge the problem.

12 **M. STOTO:** Okay.

13 **P. CAMACHO:** And do what they — what they ...

14 **M. STOTO:** Okay. The issue isn't what that they're going to do with the report.
15 The issue is what we're going to say in our minutes. And the minutes should be
16 amended to say that Dr. Camacho raised an issue about Chapter 16, particularly about
17 Simpson's paradox. He subsequently prepared ...

18 **P. CAMACHO:** Not text. I e-mailed, I communicated with Jay Miner ...

19 **M. STOTO:** Right.

20 **P. CAMACHO:** ... on this issue and expressed the issue.

1 **M. STOTO:** Right, and maybe you can even give us a copy of that e-mail that
2 we could include as a footnote or something like that.
3 **P. CAMACHO:** It was very — he was on the phone. I'd have to — I'd have to
4 look to see if I even have it. Jay might have it.
5 **M. STOTO:** Okay.
6 **P. CAMACHO:** But it was simply saying that this issue was a Simpson's
7 paradox where the — where the — where the data and a subcategory, the effect
8 disappears.
9 **M. STOTO:** Paul ...
10 **P. CAMACHO:** That's what I said.
11 **M. STOTO:** Okay.
12 **P. CAMACHO:** That's all.
13 **M. STOTO:** Any other comments about the minutes? So would someone like to
14 move that they be accepted with the change that we just discussed? Okay. Dr.
15 Hassoun? Okay.
16 **P. CAMACHO:** Move that — I move that the minutes be accepted.
17 **M. STOTO:** And Dr. Hassoun seconded it. Okay. All in favor, say yes or no.
18 Yes?
19 **RHAC:** Yes.

M. STOTO: Anyone opposed? Okay. It was unanimous, I believe. Okay. Thank you very much. And again, let me give my compliments to the note taker and thank the Air Force for helping with the factual check in there. Okay.

Report of the Air Force Health Study Disposition Study

M. STOTO: It is now 9:00 and we're exactly on schedule for the — hearing from the Institute of Medicine. Would you guys like to come up? Well, let me welcome Dr. David Tollerud, who was the Chair of the IOM Air Force Health Study Disposition Committee. Is that what it's called? And Dr. Butler, who was the committee staff — head of the committee staff is joining us at the table too.

D. TOLLERUD: Great. Thank you very much. My name is David Tollerud. I'm Professor of Environmental and Occupational Health Sciences at the University of Louisville and chaired the committee that produced the — this — called the "Disposition of the Air Force Health Study." Pardon me if I stumble a little bit. This is the third or fourth presentation we've made on this and the slides are slightly different for each one.

So, but my intent is really to take you through the study point-by-point giving a little bit of background. Some of the — David has edited the slides, I think. Some of the background things will slip through pretty quickly as this group, unlike others, obviously knows all of the ins and outs of the study.

1 And try to get down to where the committee really wanted to be as helpful as
2 possible to the various stakeholders, which was to lay out the — what we felt as the
3 scientific strengths, some of the barriers, some of the hurdles, and then a range of
4 recommendations to — as to what could be done with the study.
5 Let's see. So just reminding everybody of the charge of the committee and I'll
6 take these through one-by-one. This was the specific mandate laid out in the
7 legislation. And we tried to organize our report both for ease of readability and also
8 from a logical sequence, the charge, more or less sequentially.
9 So the committee was asked to evaluate the scientific merit of retaining and
10 maintaining the medical records, other study data and laboratory specimens collected
11 as part of this study. You'll see these phrases "maintaining" — "retaining" and
12 "maintaining" because they really are two somewhat different functions. They have
13 different implications both from a scientific standpoint and certainly from a budgetary
14 standpoint. So we tried to make that point again and again as we go through the report.
15 The second, whether or not there are obstacles to retaining and maintaining the
16 records. Third, the advisability of providing independent oversight. And referring to the
17 paragraph above, and if oversight was recommended, the mechanism for providing that
18 oversight.
19 The advisability of extending the study, including the potential value and
20 relevance, the potential cost, and the federal or non-federal entity best suited to

1 continue the study. And finally, the advisability of making the lab specimens available
2 for independent research, including the potential value and relevance of the research
3 and the potential cost.

4 This was the members of the committee, really an outstanding committee and
5 one of those committees that from day one, took the charge, I think, very seriously.
6 Each of these people are obviously very busy as you are and you well recognize the
7 amount of effort it takes to put into an activity like this. But I think as you read through
8 the report, you'll see that they really took the whole matter very seriously.

9 And I'd to put in another sort of thank-you and acknowledgment because we
10 don't have a slide specifically stating that here; and that is to the Ranch Hand Study, the
11 Air Force Health Study staff themselves. Throughout this entire process, they were
12 extremely open, very transparent, extremely helpful and really got us the kind of
13 information that would've been impossible for us to obtain otherwise.

14 Answered reams of questions that came from the committee, some of them very
15 difficult. And hosted a very productive site visit with a subcommittee of the team who
16 actually went to San Antonio, spent a couple of days actually getting their arms around
17 the samples, asking for specific analyses to be done, including us as experts to see how
18 accessible the data from the various rounds of study were. So please carry that back to
19 the staff. That was just extremely helpful.

1 So the organization of the report, we began with some background, really
2 remarkable background of the — of the Air Force Health Study; some description of the
3 data holdings and their accessibility to outside researchers in Chapter 3; the collection
4 protocols, processing and storage; and some of the obstacles and limitations to the
5 collection's future use; the scientific merit of retaining and maintaining; and the options
6 and recommendations regarding further study.
7 Just to give you a quick overview of the — of the committee's schedule and
8 tasks, we had a committee meeting in Washington, DC in February where we were
9 given the charge by the Department of Veterans Affairs and a briefing from Joel
10 Michalek; an April 2nd committee meeting and workshop. In May, the subcommittee
11 went to visit the research facilities in San Antonio and then we had two further working
12 meetings to bring the report to a closure.
13 So quickly through the findings and recommendations, the committee — I'll just
14 take a step back for a minute. I pushed the committee at the very beginning knowing
15 that this was one of those bottom line reports that somebody was going to have to ask
16 — act on and it was a lot at stake. It was a lot at stake for all of the stakeholders. We
17 heard very early on a variety of opinions about what should be done with the study:
18 ranging from "it should've been killed long ago" to "this is the greatest thing that's ever
19 happened and we should continue as we're doing."

1 And at the very first meeting of the committee during the closed committee
2 portion, I asked members to consider what the range of options were — what is the pole
3 on this side where we plan to flag? What is the pole on this side where we plan to flag?
4 And what are some possible options that might occur in the middle? — before the
5 committee had heard anything about the Ranch Hand Study, before we really knew
6 what was involved, but just to frame that.
7 And I think that was — that was a helpful challenge. It took us probably a half a
8 day to actually frame that out. And again, the poles were similar. It was, on the one
9 extreme, was to shut it down completely with no access. And on the other extreme,
10 was to keep going the same way that it had been going. It think everyone felt from the
11 beginning that it was somewhere in between, but it was a healthy discussion and really
12 helped us as we went through the process to decide where those various options might
13 be.
14 So the bottom line, and this came out in the — some of this came out in an
15 interim report. Let me maybe explain that. Was the interim report presented to you all
16 in the past? Okay. So the point of that was we realized over the summer that looking at
17 the time-line of report release and some of the activities that might have to be done to
18 kind of get the samples and the database into a shape with which something could be
19 done with it, that the Air Force Health Study staff might run out of time if they weren't

1 given sort of a heads-up and some recommendation — interim recommendations from
2 the committee.
3 So we pushed out that interim report quickly. So the bottom line was we really
4 felt that the data collect — had been collected in a careful way; the samples had been
5 collected carefully and had been stored appropriately. But there were some
6 organizational issues that needed to be done. And I think perhaps you'll hear later
7 today about the success of doing that. We heard on Friday at our briefing — pardon?
8 **D. BUTLER:** Thursday.
9 **D. TOLLERUD:** Thursday at our briefing that virtually all of the
10 recommendations that the committee had made, both with respect to data and re-
11 inventorying the samples, would be accomplished by closeout of the — of the study.
12 And the conclusion is similarly, the recommendation was that a series of actions be
13 taken by the staff and those have largely been taken.
14 I think I'll skip over these. These just dig down into some of the detail of the
15 specific requests and with respect to the biological samples again. And we noted that
16 the re-inventory was already taking place and we agreed with those efforts. We put —
17 we were mindful of the issue of funding that underpins all activities here and going
18 forward. And so we made specific recommendations that sufficient funding be made
19 available to bring these recommendations to fruition.

1 So the value of the research assets — and this again was kind of our bottom line
2 — we spent a lot of time within the committee debating the scientific merit of the study
3 thus far and what the potential for the future was. We had numerous presentations by
4 different groups from the NIH, from other federal organizations, from VA and from
5 independent researchers who held similar, relatively small, but data-intense and
6 specimen-intense collection, and heard about the range of options that could be —
7 could be carried out on these.
8 And importantly, heard about the level of interest in the independent scientific
9 community, the NIH-funded, CDC-funded, EPA-funded scientific community about
10 accessing these samples. Because as we'll see with the various options, the committee
11 did not feel that a government subsidy into perpetuity was an appropriate option for the
12 — for these samples and that ultimately, the study should become self-sustaining from
13 a financial standpoint.
14 Yeah. Okay, so the conclusion was that there is scientific merit in retaining and
15 maintaining. And the question then is how and for what purpose? We identified some
16 weaknesses which you all are very familiar with, but I'll just reiterate them: the small
17 size; it's relatively unrepresentative of other in-theater veterans. Biomarkers, even from
18 the first round of the study, are really not available for any of the herbicide exposures or
19 other exposures except for TCDD.

1 And the possibility of herbicide exposures in comparison populations and in the
2 Ranch Hand themselves after coming back from duty since these are the particular
3 agents that were used in Agent Orange are widely — were widely available in the U.S.
4 and throughout the world, particularly early on. Database privacy and security and
5 other ethical, legal and LC — and social issues or "LC" issues. And I'll come back to
6 that again.
7 There's a sizeable writing in the report to deal with ethical, legal and social
8 issues. Those, I think, we believed were the biggest hurdles that had to be overcome.
9 But at the end of the day, they could be overcome and they had been overcome in other
10 similar kinds of studies. We had some very strong committee representation in the — in
11 the LC issues, so we believe that further study should be carried out.
12 The kinds of research that could potentially be done in the future — and there are
13 more specific examples in the text of the report, but just a couple of examples — is not
14 only further extending the study, looking at different outcomes, but actually a re-analysis
15 of outcomes that have already been examined.
16 As you all know, the computational ability and the develop of new analytical
17 approaches has boomed in the last decade. In particular and especially some of the
18 early analyses that were done and even some of the subsequent analyses, we think
19 could be — could be redone with more sophistication by outside researchers who
20 specialize in these areas.

1 New analyses of the medical records and other data that examine requests — questions that weren't examined in the original study and reexamination of the biological samples. Two primary considerations that the committee evaluated in terms of disposal or disposition of the records, one is there's something called the "Federal Records Act" which we heard a bit about. A little arcane, I guess, a little complicated, a little tough to figure out exactly what it means, but the — I'll come to it again later.

7 The bottom line is it needs to be presented to the National Archivist for some decision about what to be done from a — from a federal standpoint. But none of those decisions would — needed to seriously impact the availability of the records or the biological samples for external use by other investigators.

11 Most of the hard-copy records have been scanned and the images have been stored in pdf files. There are other hard-copy records, x-rays, ECGs, videotapes and whatnot that are not as easily converted to digital form. The recommendation, based on current — as I understand it — current state-of-the-art LC recommendations are that hard-copy assets, meaning paper records that can be written to electronic form and the originals then should be destroyed unless the National Archivist believes they should be kept otherwise.

18 We heard from numerous experts in the field that keeping papers, copies around once you have electronic formats is just not considered appropriate at this point. X-ray films, the technology is readily available for converting x-ray films to digital format. It's

1 done in many medical centers routinely. Those should be done and the originals
2 likewise should be destroyed.
3 EKGs or ECGs are not as readily — they can certainly be digitized, but the — as
4 we understood from experts, the ability to transform digitized data into readily
5 accessible or usable information from a cardiology standpoint is not quite to the point
6 where everyone felt comfortable having them destroyed, so we believe that they should
7 be maintained.
8 And we really didn't know what to do with these fascinating teeth videos, so
9 thought that they should be looked at, recommendation from the National Institute of
10 Dental and Craniofacial Research, to identify the value of them and whether or not they
11 should in fact be digitized.
12 The data assets, federal law requires that they be presented to the National
13 Archivist for evaluation and possible retention. I'll go through in another couple of slides
14 the nature of the entity that would maintain — retain and maintain these assets for
15 potential future use.
16 So this is the — this is the range of options, the "flags in the sand," if you will, that
17 we proposed early on. So the sort of the "don't do anything more" is "render the assets
18 to the National Archives" and at the other pole is "extend it as it's been previously
19 constituted." And the steps in between is to, one is just to establish a research entity to

1 manage and disseminate. The second, actually charge that entity with continuing
2 passive data collection on subjects, but not doing exams.

3 The next most invasive would be maintain contact with the subjects and conduct
4 or facilitate further active data collection. Talked about the National Archives; doesn't
5 really have to interfere with what is done with the data assets beyond that. So the
6 conclusion was that the both the database and the biospecimen collection — and I want
7 to emphasize we had — we had numerous discussions of the potential for splitting out
8 the biospecimens from the data.

9 The data are much more easily and much less expensively maintained, but we
10 heard — I think both of us on the committee believed and we certainly heard from
11 externally funded researchers that the real value here is the linkage between this very
12 rich data set and the biological samples that have spanned the entire length of the
13 study.

14 And so the committee had very little enthusiasm for supporting one or the other,
15 but really felt that the data and the repository assets should be maintained together and
16 linkage. Even though that poses all kinds of obstacles and expense, that's the real
17 value going forward. I'll come in a — in a few slides to some recommendations, a short
18 list of possible custodians.

19 We debated about the use of the word "custodian" because it implies to some
20 people sort of a passive holding of the data. That's really not what we meant, but we

1 also couldn't come up with a better term. So when we mean "custodian," it means
2 somebody who not only watches over, maintains and retains the assets, but as we'll talk
3 about, plays an active role, not necessarily in doing the research itself, although it could,
4 but making it — the assets available to external researchers, and in fact, in essence
5 marketing it to the scientific community.

6 This is — this is one where the word needs to get out. We actually have some
7 specific recommendations about how to facilitate that. But if these are simply parked
8 away in a — in a — in a dark corner, no matter how well they're kept and maintained,
9 they won't reach the potential that we think could possibly be used with these data
10 assets.

11 So the first is an ability to operationally manage the assets and that's no small
12 feat with both the data and the bio-repository. But there are many places out there that
13 can do this within government, outside of government, private institutions, academics, *et*
14 *cetera*. And the second is a commitment to address the extremely complex ethical,
15 legal, social and related issues when you're managing epidemiologic records and
16 assorted biospecimens. And I'll talk about some specific recommendations that the
17 committee had regarding consent issues going forward for this study.

18 The custodian needs to be able to demonstrate in advance its capacity to protect
19 the privacy and security of the research participants and their data. This is not one —
20 you would not want to consider transferring these assets to someone who's on a

1 learning curve. This really needs to be an organization that's already been doing this
2 for some time and has a demonstrated track record because the — frankly, the stakes
3 are very high.

4 When you're dealing with as small a population, relatively speaking, as the
5 Ranch Hand where it wouldn't take too many Google searches I suspect to come up
6 with an exhaustive list of all Ranch Hand veterans, dates of births, number of children,
7 you know, the — it would — it would take very little effort to triangulate these findings
8 and identify a single individual. So it's very — it's very important to maintain the security
9 and the privacy of these assets and there's some confidentiality issues.

10 Specific recommendations about informed consent, again, we heard from a
11 number of experts about state-of-the-art informed consent issues. This is clearly, as I'm
12 sure you know, a moving target. It's becoming more and more stringent all the time.
13 But as of 2000 — end of 2005, it was our understanding that there needed to be — for
14 these assets to leave the Air Force and be transferred to another custodian there
15 needed to be a — and then used further for other research — there needed to be a two-
16 step consent process.

17 The first was a consent of the veterans to have these assets, their assets
18 transferred to a new custodian. They signed on to do this study with the Air Force.
19 They gave the data with the understanding that they would be — it would be managed

under the umbrella of the Air Force. And if something else is to be done with them, the veterans need to have an opt-out option.

I view it as an opt-in option, but the legal — the legal recommendation was — or the legal writing in consent is that the — a participant has the right to withdraw from the study at any point when they desire. And with something as title changing as moving the assets to a new custodian, each and every veteran needs to have that option.

We recommended strongly that that needed to be carried out by current Air Force Health Study staff. They're the ones that have the relationship. They're the ones that can best counsel the veterans. If I was a veteran, I would say, "What do you think?" And we hope we've made a compelling case. And we — and we hope the staff will agree that the options that we've outlined will be useful and that they would give an affirmative response. But that — so that needs to be carried out and it needs to be done before the end of the study. So that's step one.

The second is that once the assets are transferred for all those continuing to want to participate in the study, there needs to be a second round of consent that defines for what uses the data and the biological samples might be used. It may be of interest to you — I discovered just last week actually — the National Cancer Institute has now posted its suggested recommendations for standards, procedures and protocols for all NCI-funded bio-repositories.

1 It's on their web site; 42 pages, very useful, a lot of appendices, example consent
2 forms, defining sort of the range of consent that you can ask for: biological samples all
3 the way from "do anything you want and I don't care" to very specific, "you can use it for
4 this. You can use it for cancer, but you can't use it for anything else."
5 NCI funds 120-some odd repositories around the country and it's their intent to
6 harmonize the way these things are all done. My guess in reading it, I think it's very
7 well done. It's been about a year in the process. NCI actually has a separate office
8 now to deal with biorepository issues, including ethical, legal and social issues.
9 My guess is that unless someone else steps up pretty quickly, that's going to
10 become the federal standard and I — and I think it's high time that that happened. So
11 that would be very useful. That was not — it's not in the report. It came out — at least
12 wasn't known to us at the time we wrote the report, but I think it speaks to the same
13 kinds of issues and will be a useful resource to anyone who's running a biorepository.
14 Okay. These are the kinds of things that we expect that the new custodian would
15 obtain informed consent for: new types of studies. One of the — of the real ongoing
16 issues for the future will be the extent to which individual veterans will permit
17 themselves to be re-contacted. Again, they've signed consent forms over the years to
18 be re-contacted by the Air Force. It's a different matter when this gets out.
19 We heard from a number of presenters who manage studies like this, different
20 models that could be proposed by a custodian. One that has worked well — I think for

1 one of the MAVERIC Studies as I recall or the — I think it was the MAVERIC Study, the
2 Normative Aging Study — where their deal with the veteran participants is if you allow
3 yourself to be re-contacted, we'll be the ones to re-contact you.

4 Say, "We've been approached by an independent investigator. Here's the deal.
5 Do you think you might be interested? Would you like to have them contact you?
6 Would you like us to give you their contact information?" There are a variety of ways to
7 protect the veteran participants so that they're not at risk of getting — of being
8 approached from outsiders without knowing whether or not in fact it's cleared the
9 clearance process of the custodian. But that's one of the considerations that really
10 needs to be done.

11 Children — there are no biological samples as we understand it related to
12 children, but there is information; there are data from children. And that poses particular
13 informed consent issues, so that we address that in the report as well. Independent
14 oversight — we believe that there needed to be independent oversight of the data
15 assets in — for a couple of different areas.

16 The — there needed to be an independent oversight board that would not only
17 sort of watch over how the assets are managed, but really look critically at proposed
18 additional research studies that have been done. This is a — these external advisory
19 boards are common for large complex epidemiological studies that have biological

samples. They — it really needs to be a clearinghouse which — and the — this — the oversight — I'm not sure if I've talked about who it might be.

The — so not only IRB, and HIPAA and other kinds of regulations, but to really look at the appropriateness of various kinds of research that might be done. The — this oversight board would, we think, would be comprised of scientists, of appropriate stakeholders and certainly folks in the military. Many of these oversight boards actually have study subjects themselves that sit on the boards who can — who can give a voice to the study participants. Obviously, experts in ethical, legal and social issues and potentially other organizations that have a stake in this.

The process from here on out once the assets are transferred, it really needs to be a transparent process where everyone understands exactly what's going on. Again, this isn't — this isn't different from what's done elsewhere. Most large groups that have large holdings have some sort of a — of a formal application process not unlike applying for a grant with the government. You go through a peer review process.

The expectation, again we — always keeping the budget in mind — the expectation for these studies and the way it's done with a number of groups that we talked to around the country is not only do you propose a study, but you explain how you're going to pay for it. So it's not sort of coming, "I have this great idea that you can fund for me." But these would be individuals who actually — often, it's a two-step application process.

1 The first is sort of a pre-proposal. “Do you all think this is a good enough idea
2 that I should spend my time trying to get a grant to do it?” And often, there’s a
3 partnership between the custodian and the researcher to actually help get that grant
4 support in exchange for having one of the internal investigators actually funded —
5 partially funded by the grant to help with the work to go forward.

6 Feedback to the veteran participants with study results; options for management
7 of the data assets, again, we talked about the National Archives. Other options would
8 be to use the existing Air Force Health Study infrastructure within the Air Force if the Air
9 Force was interested in continuing that. Department of Defense has some
10 epidemiological study management and distribution mechanisms. The VA or VA-
11 affiliated organizations have data management distribution mechanisms as well.

12 The NIH and CDC have a number of agencies or sub-agencies that manage
13 epidemiologic data and associated repositories and we considered those as well. The
14 Institute of Medicine actually has the Medical Follow-Up Agency, “MFUA” as it’s
15 affectionately known as internally, actually does this kind of work as well or there could
16 be an entirely new custodian through a competitive process.

17 There’s a — there’s a fair amount of discussion in the text about the pros and
18 cons of all of these various groups. And we pushed each other, I think, hard to get
19 beyond the laundry list and say, “Okay, you go find somebody,” and really tried to come
20 up with a — with a short list.

1 In particular, we walked a fine line, I would say, with MFUA because it's — we
2 felt the sort of the internal potential conflict of interest of one IOM committee
3 recommending that another IOM agency be on board. I think we walked that line fine
4 and the external peer review actually was fairly congratulatory in that we kept an arm's
5 length, tried to lay out the pros and cons of different organizations.

6 We didn't offer a single recommendation, but we did list a number of options and
7 came up with a short list of three. Now one of the considerations in these three was we
8 felt that it really should be an organization that had some experience with veteran's
9 research. The National Institute of Aging, for example, was posed as an organization
10 which might be very interested in these assets.

11 This is — these veterans have been followed through an age span which is
12 largely blank in the epidemiological literature, particularly the biology of aging. There
13 aren't very many funded studies out there who pick young men up in their 20s and
14 follow them through their 50s and 60s while they're perfectly healthy. We've tended to
15 focus on groups that are either ill, or ready to get ill, or at risk or whatever.

16 So many of the — of the aging specialists that we heard, and one on the
17 committee in particular, said this would be a very interesting data set and biological
18 repository for the study of aging. Our fear is that NIA might well view this as a veteran's
19 study and, "What are we going to do with a veteran's study?" So we really felt that it
20 needed to be an organization that had some experience with veteran's studies; that

1 understood how studies of veterans of various types could in fact be used to look at
2 broader health issues unrelated to their — to their military service and had some
3 experience.

4 So three — the short list includes three, two of which are VA-affiliated, not very
5 heavily funded as we understand it, currently by VA. They're largely externally funded.
6 The Massachusetts Veterans Epidemiology Research and Information Center; that's
7 where the Normative Agent — Aging Study is housed.

8 I actually — I had to smile because I'd completely forgotten, but something
9 pushing 25 years ago, one of the early papers that I wrote was an analysis of the — of
10 the Normative Aging Study. And I remember working on that paper for the better part of
11 a year, working on the study for the better part of a year. And it wasn't until I actually
12 wrote it up that I realized that these were veterans. And that's the — that's what needs
13 to get out to the community; is that this is a rich data set. It's not about veterans. It's
14 about aging.

15 The second was the Seattle ERIC and the third was MFUA as we talked about.
16 The characteristics of these three that were important, we thought they have experience
17 in conducting veteran's health studies. They know how to collect and store data, and
18 manage repository assets, and disseminate it to independent researchers. They
19 demonstrated years, and years and years of quality control. They've published results
20 in the peer-reviewed literature.

1 Some of the — both the Seattle ERIC and the — and the MAVERIC Studies
2 have literally hundreds of peer-reviewed publications. And we think that the veterans'
3 assets, the Air Force Health Study assets, if those are made available to the
4 independent research community, could provide over time a similar rich peer-reviewed
5 literature base well beyond what has been done so far.
6 The other important thing is that these are all studies now that are independently
7 funded, so the most of the work that's done at Seattle — or at Seattle ERIC and
8 MAVERIC are not VA-funded research. It's NIH-funded research. It's other externally
9 funded researchers. These folks are approached on, as we understood it, on a weekly
10 basis by outside researchers who say, "I would really like to collaborate with you. I'm
11 about to write a grant. Can you give me a letter of recommendation that I can go
12 forward and do this?
13 And if anything, it's accelerating because of the — with the breakthrough of the
14 human genome project and the ability to look at biologics in different ways, the ability to
15 do — actually do DNA studies on serum, which I had never heard of, is really made
16 these kinds of assets that go back in time extraordinarily valuable.
17 So none of them are perfect; that's why we didn't come up with a single
18 recommendation. It's — we didn't approach any of these organizations with whether or
19 not they would be interested. We felt it wasn't — that wasn't our job. Our job was to
20 look at the best possible custodial options and somebody else might approach them.

We simply don't know the degree to which the ERICs, for example, would have the interest or ability to take on additional work or whether how easily it would be for MFUA to manage the biospecimens because they don't currently have a biorepository. And they all would need funding.

We talk about funding issues. There were two kinds of — sort of two types of costs. And although we didn't come up with a — we wrestled with the idea of whether we should come up with a price tag or could we come up with a price tag. And we sent out feelers and inquiries to various organizations that do this kind of work. And frankly, the range of numbers we got back was so broad as to be not very useful.

There — a slide or two in the future here we'll talk about how you might bracket some of those, but we really didn't try to come up with a specific cost. But there's a — there are costs of maintaining and providing the access to the assets and then there's the cost of conducting research on the assets themselves. And we talk about the kinds of costs that it might be.

So roughly speaking, $150,000 to $300,000 a year to support the custodian's database management responsibilities; $200,000 a year or more to properly maintain the biosamples. Conducting new studies on top of that would be additional costs that we felt, over time, needed to be borne by the researchers who are doing it.

We did think that there should some money put into the pot right up front for pilot studies, basically to get the outside research community interested in this, to kind of get

1 the word out that these assets are available. Because marketing is going to be a big —
2 a big deal to help the research community understand the potential value and give them
3 the will to help overcome some of the obstacles which, again, are not insurmountable,
4 but are not trivial either.

5 We had a specific recommendation that a $250,000 a year for three years be
6 provided for seed money grants to investigators who might be interested in carrying out
7 the research. Again, this — these are not sort of big studies, but would allow people to
8 get their feet wet with the data, look at what possibly could be done. And those needed
9 obviously to be in addition to the other funds to retain, and maintain and allow access to
10 the — to the research.

11 The committee wanted to be very careful to not recommend a blank check. So
12 we didn't, you know, at the end of the day, we really didn't know what the ultimate value
13 of these — of these samples and associated database would be. We think that they
14 could be extremely valuable based on what's already out there and being done, but
15 we're not sure completely. And the other thing is we don't know — especially in the
16 current funding situation — we don't know what the level of interest will be in the
17 scientific community.

18 So rather than leaving this sort of open-ended, we have — we have specific
19 recommendations about kind of a five-year plan; that the assets need to be — need to
20 be moved to a new custodian. Seed money needs to be made available for pilot grants.

1 And then at the end of five years or so, someone — perhaps the oversight
2 committee, perhaps another organization — would take a step back and say, "Okay.
3 How successful has this been? Is this something that should — that we should keep
4 going?" Take a second look and sort of evaluate it at that point. And that's the end. I
5 think we've — the report is available?

6 **D. BUTLER:** Yes. The report became available online on Friday. Text can be
7 accessed in full through the National Academies Press web site and it's possible to
8 download the executive summary in pdf form, which I believe was printed. And it's
9 available for distribution at this meeting.

10 **M. STOTO:** Well, first of all, thank you, both Davids, for the presentation and for
11 all the work that you, and the committee and the staff did on this. This clearly was quite
12 a lot of good effort went into this and I think they're very sensible conclusions and
13 recommendations.

14 Personally, I want to — I want to just thank you for making clear the distinction
15 between what it's going to take to maintain, and the resources and make them available
16 on one hand and do research using those resources on the other hand. And really, it's
17 only the first of those things that we're asking the government to do new. NIH and other
18 agencies already can support the second.

19 **D. TOLLERUD:** Right.

20 **M. STOTO:** Is the Air Force going to respond to this?

K. FOX: No. We haven't had a chance to look at it and really it's not really directed to the Air Force.

M. STOTO: Okay.

K. FOX: It's directed to other government agencies and all, but we're looking at it to see what we can do to support it in the future, a portion that was supposed to be — what they recommend to do, but we are not ready to talk about it.

M. STOTO: I don't want to put you on the spot. I just wanted to know where this — where the second agenda item actually is?

K. FOX: The second agenda item is about the interim report to tell you what we were doing on that.

M. STOTO: Okay. So then let's have a discussion then from the Committee about this and — Ron?

R. TREWYN: Thank you. That really did clarify a number of issues. I did download the executive summary and looked through it. One of the things that wasn't clear to me, at least reading the executive summary and wasn't totally clear in what you presented, you stated that the MFUA does not have biorepository capabilities at this point, which implies that the other two, the Massachusetts and Seattle do. And that was not clear to me in looking at the executive summary that they — that they have that capability?

D. TOLLERUD: Yes, they do.

1 **R. TREWYN:** Okay.

2 **D. TOLLERUD:** David, I'm — that's correct, right? MFUA does not currently —
3 okay.

4 **D. BUTLER:** That's correct.

5 **P. CAMACHO:** Who's — where would you say that this goes from here? I
6 mean, how would you contact these people or how would you envision the
7 Massachusetts or the Seattle people being contacted? If you were sitting where we
8 were, what would you ...

9 **D. TOLLERUD:** That's a good question. I don't know. I mean, I guess this body
10 might be — might be the entity that would do that. The — it was interesting when we
11 briefed the VA, they talked about their sort of interesting position in all this; is that
12 they're not — while they were told to be the sponsor of the study, it really wasn't aimed
13 at them *per se*. It was — it was to look at a study for which they have no particular
14 responsibility. So it really is sort of out there, I guess, at this point to decide how the —
15 what the mechanism might be for going forward.

16 **M. STOTO:** This brings us back to when I earlier said the "government" and Len
17 said ...

18 **D. TOLLERUD:** Right.

1 **M. STOTO:** ... we have to figure out who in the government. And I think that
2 that's a relevant issue. Can you tell us who you briefed about the report and maybe
3 something about what the response has been? You mentioned the VA.
4 **D. TOLLERUD:** Sure. David, you know the players.
5 **D. BUTLER:** Okay. We've presented a few briefings on this report: one was to
6 Department of Veterans Affairs staff and Colonel Robinson also attended that briefing.
7 We also gave a briefing to staffers for the House and Senate Veterans Affairs
8 Committee, had nice attendance at that briefing; gave a separate briefing to Mr. Shays'
9 staff.
10 Mr. Shays also has involvement in veteran's affairs issues on the Hill and interest
11 in those. And we presented a briefing for some veteran's service organizations and
12 gave them some background on the content of the report.
13 **M. STOTO:** Okay, and presumably the Medical Follow-Up Agency knows about
14 it?
15 **D. BUTLER:** That's correct. What — the way we administered this internally
16 was to erect a curtain between this committee and the Medical Follow-Up Agency while
17 the study was being conducted. We used them as an information source as the same
18 way as we got information from other outside bodies, but did not discuss with them any
19 of the committee's thoughts or deliberations.

1 And after and only after the report, had finished the report review process and
2 had been cleared as an official report of the National Academies did we go down and
3 brief the Medical Follow-Up Agency just as we briefed Department of Veterans Affairs
4 on what the result of this report was.

5 **M. STOTO:** By the way, I should add for the record, listening to the — Len's bias
6 and conflict of interest statement earlier, that I used to work for the Institute of Medicine
7 and that my wife still works for the Institute of Medicine. And I never thought of that as
8 being a product, but in fact, it is a product that's at stake here. So I'm disclosing that for
9 the record. Paul?

10 **D. BUTLER:** And for the — for the record, the Committee should know that as a
11 Study Director for the Institute of Medicine, I have done and will do work in the future for
12 the Medical Follow-Up Agency.

13 **P. CAMACHO:** Is it possible for the — this Committee to get a list of all the —
14 really names, especially the VA or all these committees who are at these briefings? So
15 I mean, if the — if the Committee decides — my point is if the Committee decides to
16 make any recommendation, it, especially about the — who's going to maybe pay, take
17 care of these materials, then we ought to — so we're not starting from square one, it
18 would be good for this Committee to be able to know who you guys briefed. So I don't
19 know; is that possible?

1 **D. BUTLER:** I'll touch base with my leadership to check on that. And if it is
2 possible, I'd be happy to do so.
3 **M. STOTO:** Thank you.
4 **S. LEFFINGWELL:** Did either of the ERICs receive copies of this in the last few
5 days and has NIH and CDC been apprised that their names are about to appear in
6 print?
7 **D. TOLLERUD:** Go ahead.
8 **D. BUTLER:** When we briefed the Department of Veterans Affairs, we asked
9 them as sort of the parent body, even though we realize it's not a reporting relationship,
10 to take responsibility to contact the ERICs. The NIH has not been informed directly by
11 us of the content of the report.
12 **D. TOLLERUD:** These are all individuals who came, and gave presentations
13 during the committee's deliberation process and were fully aware of sort of what was
14 going on. So I don't think they'll be surprised to see that they're — they they're
15 mentioned in the text.
16 **M. STOTO:** Will you be sending copies of the report to the people who
17 participated in the workshops and so on?
18 **D. BUTLER:** Yes, we will.
19 **M. STOTO:** Thanks. Ron?

1 **R. TREWYN:** I don't believe we have copies of the presentation, so would we be
2 able to get those for one thing?
3 **D. BUTLER:** Dr. Schechtman, as I understand it, is having someone from his
4 staff print up the slides for you right now.
5 **R. TREWYN:** Okay, and the second thing is since you had indicated that the
6 NCI information on the biorepository, all their material came out and they obviously
7 have a lot of — lot of experience in dealing with biorepositories, I guess the question is
8 should NIH — I know they were on your list overall, but I'm curious if this might change
9 sort of the waterfront and ...
10 **D. TOLLERUD:** Yeah.
11 **R. TREWYN:** ... maybe suggesting that might be a better spot to look at?
12 **D. TOLLERUD:** Yeah, it's — I'll just — I'll give you a little personal perspective.
13 We're grappling with this at my home institution right now because we have — we're
14 trying to consolidate. I'm in the environmental health side of the — of the fence and
15 we're trying to look at consolidating a number of small biorepository pockets of samples
16 that are around campus.
17 And the Cancer Center is — similarly is consolidating all theirs and I — and I —
18 so I've been personally grappling with, you know, are they — are we partners? Are we
19 competitors or whatever? And it really comes down to what the — what your mission is.
20 I think NCI funds cancer research and they're not interested particularly in myocardial

1 infarctions, and in diabetes and all the other kinds of things that we might be interested
2 in.
3 So that's the one point and that gets to the National Institute of Aging as well and
4 the — and the sort of the lack of a — of a sense of understanding about the richness of
5 a veteran's study. You know, if I go out and talk to my colleagues about the Ranch
6 Hand Study or the Air Force Health Study, they cannot disconnect that from dioxin and
7 from spray missions over Vietnam.
8 I mean, you just — you could talk to them for an hour about the value of this as a
9 — as an aging, you know, study of aging, and they really just can't get away from it.
10 "No, no, this is a study about Vietnam veterans and pilots no less. And, you know,
11 that's — it's so ungeneralizable as to be not useful."
12 Right, so that — and that's really why we came back to the idea that it — the
13 custodian needed to have significant experience with doing veteran's studies and
14 expanding studies that had initially been set up to answer questions about veterans to
15 looking at broader health medical and public health issues.
16 **M. STOTO:** But if the NCI wanted to make a play for it, they certainly could.
17 **D. TOLLERUD:** We didn't — I mean, we didn't exclude anyone. We sort of laid
18 out the criteria for what we thought were necessary.
19 **M. STOTO:** Right.

1 **R. TREWYN:** And I guess my thought was clearly, the more — the broader
2 mission of NIH in general with all of the various branches, you really do get, except for
3 the veteran's component, you get to most of the topics so ...
4 **D. TOLLERUD:** Yeah. Yeah. No, and again, I think the — Mike, you had asked
5 about the response from the various constituencies as we were briefing them and I
6 would say it was "cautious enthusiasm." The enthusiasm was there for the scientific
7 value; the caution has to do with funding. So I think the — and that's really, you know,
8 "who's going to pay for this" sort of thing. Yes, it's a great idea, but who's going to pay
9 for it?
10 And I think if you — the point that I personally tried to make and I sort of — I
11 stepped away from the committee and spoke personally to the, particularly to the
12 Congressional aides, is say, "Look, you know, the committee didn't take a stand on
13 what they thought this would actually cost." But just to make two points: first of all, if
14 you — compared to the investment that's already been made in this, this is, as one of
15 the veteran's groups had said, that this is "decimal dust."
16 It's a really a fairly small investment and we tried to be very careful to say this is
17 a time-limited investment. And so, you know, I personally was hoping to sell this to
18 someone who says at least make an additional, you know, the $140-odd million is some
19 cost, right? That's not going to come back no matter what. So a relatively modest
20 additional investment to transition this over, to advertise it to the scientific community, to

1 try to make it available to researchers who could bring in external funding, you know, I
2 really tried to make that pitch to not let it sort of wither on the vine.
3 **M. STOTO:** But it seems to me that given that the VA was the sponsor of the
4 IOM study — and I guess that was Congressionally mandated that it be the VA?
5 **D. BUTLER:** That's correct.
6 **M. STOTO:** And that the ERICs are and to some extent MFUA is associated
7 with the VA in terms of funding, MFUA is not an agency of the — of the VA, but does
8 work with them on funding. I mean, I — it seems to me that we ought to regard the
9 veterans — Department of Veterans Affairs as the primary partner for this ...
10 **P. CAMACHO:** Yeah, the primary actor.
11 **M. STOTO:** ... for this report. Right, and that's probably a good thing. They'd
12 probably have more interest in this than other agencies that we could think about.
13 **P. CAMACHO:** They should.
14 **M. STOTO:** Right.
15 **P. CAMACHO:** Yes.
16 **M. STOTO:** So the question that I want to put to the Committee is, you know, do
17 we want to (a) endorse kind of the main findings of this report in principle — and I'll —
18 and I'll say what I think they are in a moment — and (b) offer to help with sorting out
19 some of the things as we go down the line?

1 So the main findings I think that I would consider endorsing, if you — if you turn
2 to page 4 of the executive summary, it's that box that has the main findings. And I
3 would — I would focus on the beginning of the first paragraph and the beginning of the
4 third paragraph. And that basically says there's scientific merit in retaining and
5 maintaining these records, and data and specimens after the scheduled termination
6 date of the study. That's the first half of the first paragraph.

7 And then the first half of the third paragraph says that further study of these
8 records, data, specimens essentially should be accomplished by taking — by making
9 these materials available for research via a custodian that takes an active role in
10 fostering the use of these assets. And I propose that we endorse those basically two
11 statements.

12 **P. CAMACHO:** Yeah.

13 **R. TREWYN:** Yeah.

14 **M. STOTO:** I see — I see people shaking their head; that doesn't show up on
15 the microphones. Other discussion about that, Ron?

16 **R. TREWYN:** Well, I think that what they have recommended is very consistent
17 to the stance we've been taking as a Committee, have been arguing or at least stating
18 rather forcefully for a long period of time; that this — and I think this very much supports
19 what was the consensus of the Committee. So I certainly would agree with that and
20 would be happy to make a motion if you are looking for that.

1 **M. STOTO:** Okay.

2 **P. CAMACHO:** We should also ...

3 **M. STOTO:** More discussion before we do that though.

4 **P. CAMACHO:** Yeah, but we should also — if we're going to do this, we should
5 also have the entire report available and at least be able to say that we had it in front of
6 us so that it could be looked at.

7 **D. BUTLER:** We have — we offered all Committee members a chance to get
8 FedEx copies of the reports on Saturday morning and have brought additional copies of
9 the report for the Committee that we can give them right now.

10 **P. CAMACHO:** I'll take one.

11 **M. STOTO:** Okay. Other discussion from — go ahead.

12 **D. JOHNSON:** So — it's Dave — are we talking about endorsing their findings?
13 Is that what we're talking about?

14 **P. CAMACHO:** No, these two sentences.

15 **M. STOTO:** I'm suggesting that we endorse those two things that I paraphrased.

16 **D. JOHNSON:** Okay.

17 **M. STOTO:** The first half of the first paragraph and the first half of the third
18 paragraph on page 4.

19 **D. JOHNSON:** I — I'm just not clear. What is our role? We didn't — we didn't
20 make this determination ourselves.

1 **M. STOTO:** Right.

2 **D. JOHNSON:** We had — whoever decided to have somebody else look at this
3 and make the recommendations. I'm just not — I'm not clear what our role is to
4 endorse their recommendations.

5 **M. STOTO:** Well ...

6 **D. JOHNSON:** I'm not — I'm not saying against it; I just don't understand it.

7 **M. STOTO:** It's complicated because we, you know, essentially are — exist to
8 advise the Air Force.

9 **D. JOHNSON:** On the study.

10 **M. STOTO:** On the study.

11 **D. JOHNSON:** Not necessarily on — they — somehow or another, we stopped
12 at this point and transferred responsibility on what to do with these records to NI ...

13 **M. STOTO:** Well, let me — let me — let me just lay it out. I mean, I think that,
14 you know, most of our activity has been involved in advising the Air Force on the
15 conduct of the study. But I think that it's also reasonable to interpret our mandate as
16 advising the nation on the study more broadly and then the issue here is whether or not
17 there's national value in maintaining the ...

18 **D. JOHNSON:** What do you mean "advising the nation?"

19 **M. STOTO:** Well, it's hard to say because there's no obvious target, but I'm —
20 but I'm — but I'm saying make a statement that is of use to the people making decisions

1 on behalf the government: that includes the Congress, as well as the VA and other
2 agencies that may be involved about the advisability of this — of these
3 recommendations. Go ahead, Paul.

4 **P. CAMACHO:** Part of this goes back to the whole political — am I on? Yeah.
5 Part of this goes all the way back to the whole political, social, very emotional
6 ramifications of all this that are anchored in a war that was 40 years ago and it is not
7 going away. And that's the whole process of politically, emotionally of, I guess, the
8 activism involved in how this — we ended up with this study and then all the whole
9 community of veterans from the — that's 7.6 million people or whatever the entire
10 population is that were involved in that war. That's what's really here.

11 And if you say do we owe a responsibility to them, well, I think we do, at least to
12 say we have a responsibility to look at these recommendations. We don't have a lot of
13 time, but we — but we should at least look at these recommendations and if nothing
14 else, make a formal recommendation about what we think to the, perhaps to the
15 Veterans Affairs Committee as the Congressional mandaters before we close our life
16 span.

17 **M. STOTO:** Well, I want to ...

18 **P. CAMACHO:** I think that that's very, very viable and it's — and I think it's our
19 responsibility.

20 **D. JOHNSON:** So we're making a recommendation to where and ...

1 **P. CAMACHO:** Somebody. I asked the question what are going to do? Where
2 does this go now? And the gentleman didn't have a great — didn't have an answer *per*
3 *se*. So whose responsibility is it to see follow-up?
4 Well, it seems to me that this Committee should step up the plate, at least to give
5 a letter of recommendation about what we think about this report to the Veterans Affairs
6 Committee. And if after that it doesn't go anywhere, we at least can say we've done our
7 job when we notify the veteran's community ...
8 **M. STOTO:** Right.
9 **P. CAMACHO:** ... *et cetera*. But to just walk or just to go to sleep, "nice study,"
10 and put it away and walk away from it, I don't — I don't think that's ...
11 **D. JOHNSON:** No, I'm just — I'm just trying to clarify ...
12 **P. CAMACHO:** Yeah.
13 **D. JOHNSON:** ... what our — what we've been mandated to do. What's our
14 official role here? I mean, it appears that we ...
15 **P. CAMACHO:** It's "mission creep."
16 **D. JOHNSON:** It appears they're reporting back to this Committee.
17 **M. STOTO:** Well ...
18 **D. JOHNSON:** So does that mean ...
19 **M. STOTO:** This is, you know, if you — if you go by the letter of the law in terms
20 of our mandate, we don't have to do anything and we have no responsibility to do

anything. On the other hand, the question of who's in charge here is a very complicated one. You know, the IOM has done what the Congress asked them to do and Dr. Tollerud's going to go back to Kentucky; that he — and the IOM doesn't have any more money to pay Dr. Butler to work on this. He'll go work on some other project now and so ...

D. JOHNSON: So the report will go back to Congress who asked them to do this and this is a courtesy that they're reporting to us here in this meeting today?

D. BUTLER: That's correct.

M. STOTO: Right.

D. BUTLER: We — this has, you're right, been a very complicated subject for us because we were given a mandate through a piece of legislation passed by the Congress. The Department of Veterans Affairs was mandated in that same piece of legislation to provide funding for us to do this study even though they have no direct involvement in it. That was Congress's decision and that's how it worked.

We briefed the Department of Veterans Affairs as the sponsor of the study of our results. We also briefed staffers for the House and Senate Veterans Affairs Committee because we believed that they were the natural audience for this report. We note in the body of the report that the legislation did not specify who had decision-making responsibility to act on the recommendations that this committee makes and that that was an issue.

1 Because it's difficult — it was difficult for the committee to address its questions
2 and to propose a plan of action in the absence of a body that was taking responsibility
3 for at least considering those actions and either acting on them or choosing not to act
4 on them. As a result, we've tried to cast sort of a wide net in informing various bodies of
5 these results in hopes that in disseminating the word, that someone will take
6 responsibility for this and will act on it.

7 **M. STOTO:** The IOM has often ...

8 **D. JOHNSON:** It's very interesting because there seems like there's a void here
9 and we're just kind of — we're kind of falling into that void, but we don't really have an
10 official mandate to make recommendations on their findings.

11 **M. STOTO:** Exactly. You know, this is often an issue with IOM reports because
12 the committee, once they're done, they're done. But it's even worse in this case for two
13 reasons: one is that there's no official obvious government sponsor. The other one is
14 that the IOM is also in a conflict of interest position because the MFUA is part of the
15 IOM, so they've got to be even more careful about this than normal. Sandy?

16 **S. LEFFINGWELL:** My understanding of our charter is we advise the Secretary
17 of Health and Human Services, not the Congress or any committee of Congress. So
18 what should come out of this Committee would be to request that the Secretary use his
19 good offices to try to see that these recommendations are implemented: be that by

1 twisting arms in Cabinet meetings, or calling in the Director of NIH and telling him how
2 he's going to make a play for it or whatever.
3 **M. STOTO:** Right.
4 **S. LEFFINGWELL:** Just we should ask the Secretary to exert his good offices to
5 see that these are implemented.
6 **M. STOTO:** Yeah, and we, of course, we can copy lots of other people on that
7 as well so they can understand what our position is.
8 **K. FOX:** And I think that's what this Committee did. They — you guys wrote a
9 letter to the Secretary of Human Health Services. You also did it to the — a copy to the
10 VA.
11 **M. STOTO:** Yeah.
12 **K. FOX:** You made this to ask people to look at the disposition of the Air Force
13 Health Study. And through various means, somehow it did get to Congress and
14 Congress then mandated this study. But actually, I think a lot of this happened out of
15 this Committee; that you made the — that this needed to be looked at as to what could
16 be done with the disposition of this study.
17 **D. JOHNSON:** So I don't mean to put you on the spot. I don't mean to put you
18 on the spot, but do you think this Committee then should make endorsements or
19 recommendations about these findings at this point?

1 **K. FOX:** I think you've already started on that road and I think that you're — you
2 have a vested interest. And I think — I think it would be appropriate that you at least
3 acknowledge that this is — this is from your request a long time ago. It started about
4 four or five years ago ...
5 **P. CAMACHO:** Yeah.
6 **K. FOX:** ... since I've been on this ...
7 **M. STOTO:** Right.
8 **K. FOX:** ... in this study that you started realizing the end was coming, and what
9 was going to be done with the data and all, and that it needed to be raised, that some
10 people needed to look at it. And this is what you guys did.
11 **M. STOTO:** Len?
12 **L. SCHECHTMAN:** And perhaps one thing the Committee might consider is a
13 follow-up letter to the Secretary of HHS with the endorsement of the recommendations
14 that are made ...
15 **M. STOTO:** Yeah.
16 **L. SCHECHTMAN:** ... by IOM. And in that way, the Committee can feel
17 empowered as having put forward an endorsement of this nature to the Secretary as a
18 follow-up to which initial contact with the Secretary regarding the need to conduct such
19 a study. And in that way, perhaps the endorsements will be followed under the HHS
20 umbrella. I mean, it's a continuing saga obviously.

1 **M. STOTO:** Yeah.

2 **L. SCHECHTMAN:** But, you know, there will be a point in time, and that's rapidly
3 approaching, when we're going to have to let go of the reins as a Committee and hope
4 that under HHS or some other department within the government that those reins are
5 picked up.

6 **M. STOTO:** Yeah. I think that's a good idea. I mean, one of the
7 recommendations in the report is that there be a scientific — some kind of advisory
8 committee be set up once this whole process gets set up. But in the interim, we're kind
9 of all there is in that — in that regard.

10 So I would — I would — I would propose, picking up on all these things, that we
11 write a letter to the Secretary that does, first of all, reminds him of our earlier statements
12 on the record. Secondly, says that we think that the — this study addressed those
13 concerns and that we endorse those two parts that I — that I — that I mentioned earlier.
14 And third, offers in our, you know, in our last meeting or maybe meetings that we help to
15 sort out some of the pros and cons ...

16 **P. CAMACHO:** Yeah.

17 **M. STOTO:** ... of the options that the IOM put on the table for doing this.

18 **P. CAMACHO:** But right now — right now this is — for all practical purposes,
19 there is no hand — you're recommending a hand-off, you know, hand this off. But
20 there's nobody there to catch it. They ...

1 **M. STOTO:** They're handing — they're handing off a hot potato.

2 **D. TOLLERUD:** The team is still — the team is still in the locker room.

3 **P. CAMACHO:** Yeah, so come 30 September if there's no hand-off prepared,
4 the refrigerators are pushed out into the sun and the data is zapped?

5 **K. FOX:** The data will go to the National Archives. The data will go to the
6 National Archives or we will at least offer that data to the National Archives. And yes,
7 the extreme of that list was that the electricity gets turned off.

8 At this, I mean, I can't say — there are no more people. Everybody's retiring or
9 riffed already and all and I'm retiring. So there's not too many — there's no more
10 funding, okay. So yes, at this time, that's what's going to happen. But again, we
11 haven't looked at everything and we haven't analyzed. And so I do not know what the
12 final ...

13 **P. CAMACHO:** Yeah.

14 **K. FOX:** But that's the worst and that's what's going to happen.

15 **M. STOTO:** Go ahead.

16 **D. JOHNSON:** I might — I'm going to say something that might take this
17 conversation someplace else. But the reason I'm kind of asking clarity is because I'm
18 wondering what this Committee — what we're supposed to do? And if I can say some
19 things that are in my packet here, I'm a little confused.

1 If we're developing a consensus as a Committee, and then you're saying we're
2 — we need to advise the nation, and then we have things going on in here where
3 people within the Committee are advising the nation and now it's confused whether —
4 so when we — when we come to a consensus in this Committee, can anybody in here
5 then go in front of the nation and give their opinion which then is not clear who's talking:
6 the Committee or that person? I mean, I'm kind of sliding into another issue that was in
7 our packet.

8 **M. STOTO:** Well ...

9 **D. JOHNSON:** And it's a little bit ...

10 **M. STOTO:** I mean, the Committee has to decide what it thinks before anybody
11 can say this is what the Committee thinks.

12 **D. JOHNSON:** So is that a consensus of the group and then can — but yet —
13 but yet ...

14 **M. STOTO:** And I'm seeking — I'm seeking a consensus.

15 **D. JOHNSON:** But that yet anybody, even once we've had this consensus, any
16 one of us can then go and say, give our opinion to the nation?

17 **M. STOTO:** As long as ...

18 **D. JOHNSON:** It might be different than our consensus. Is that what ...

19 **M. STOTO:** As long as that ...

20 **D. JOHNSON:** Is that how Committee works?

1 **M. STOTO:** This is a free country. I mean, people can say whatever they want
2 as long as they don't represent it as something that's — people can't represent their
3 views as the Committee's if they're not the Committee's. But the Committee or no one
4 else can stop you, or Ron or anybody else from saying anything they want.
5 **P. CAMACHO:** I think — I think it isn't that much more in a lot of ways. We're
6 simply saying let's send the Secretary a letter asking him to use his office to prompt
7 somebody to make a decision and we cc other people. What are they going to do with
8 this? All we have to do is one more piece that's really a follow-up and I'll be happy that
9 we at least as a Committee, we at least tried to do the right thing.
10 And the right thing is to alert people that everything's going to fall off a cliff
11 September 30th. Here's the recommendation that there should be a hand-off. Now
12 somebody's got to do something, but there isn't anybody to report to to do — there's
13 nobody charged with doing something, so it's ....
14 **D. TOLLERUD:** Part of the sense — the sense I got at Congress was they were
15 going to wait and — wait and listen for hoof beats.
16 **P. CAMACHO:** Right.
17 **D. TOLLERUD:** Right? I mean, I think someone needs to push this ...
18 **M. STOTO:** Yeah.
19 **D. TOLLERUD:** ... agenda and ...

1 **P. CAMACHO:** And the Committee, I think, has an obligation simply to write the
2 — at least to write the letter and suggest that the Secretary help start some hoof beats.
3 **M. STOTO:** Sandy was trying to say something earlier. Did you want to still?
4 **S. LEFFINGWELL:** No.
5 **M. STOTO:** Okay.
6 **S. LEFFINGWELL:** Well yeah.
7 **M. STOTO:** Go ahead.
8 **S. LEFFINGWELL:** I'm not sure this is the best time, but you mentioned two
9 sections in the box there. A caveat: the government is in general run by lawyers. In
10 law, if you enumerate things, anything that is not enumerated is not considered part of
11 the list. So if you list two things, they are likely to say, "Okay. We can ignore the rest of
12 it."
13 **M. STOTO:** Well, we'll have to be careful how we — how we phrase it. I mean, I
14 don't — I don't — there's no way that we can have only gotten this ...
15 **P. CAMACHO:** Right.
16 **M. STOTO:** ... at best 48 hours ago, at worse ten minutes ago that we can
17 endorse the specifics of the report. And I'm — I just offer that as a way to endorse the
18 general thrust of the — of parts of the report, and then offer to come back and spend
19 more time on the specifics later. And so we would obviously make that clear. Ron?

1 **R. TREWYN:** Yeah, and I would just — because of the issue of September 30th, we can't wait until our next meeting when we've had time to get through all of the specifics.

4 **M. STOTO:** Yeah.

5 **R. TREWYN:** So I think we have to respond. These two recommendations are essentially what we have been pushing for all along, so I think we're just that now that we have the analysis done, we see these two summary statements, we can clearly endorse those as consistent with ours and encourage folks that they're doing it to be hoof beats.

10 **M. STOTO:** Right.

11 **R. TREWYN:** We need to move this along, funding has to be there, so on September 30th, somebody doesn't pull the plug, that the electricity is maintained, that there is a way of doing a hand-off appropriately.

14 **P. CAMACHO:** Has that been studied?

15 **M. STOTO:** Paul, turn the mike on.

16 **P. CAMACHO:** Exactly procedure, is that another bag of wax we have to consider? Procedurally, how is this hand-off take place? I mean, actually, how does it go? Some — is that really a big problematic effort? Is that a big — is that a whole other issue nobody's thought about? How this hand-off physically, I guess ...

20 **M. STOTO:** I mean, I don't think that's a question within our authority.

1 **P. CAMACHO:** That's not a question? Okay.

2 **D. JOHNSON:** Yeah.

3 **K. FOX:** I'm sorry. We — the Air Force has not looked at this and analyzed this 4 enough to make a statement on that. But you imagine it might be a problem? Well, I 5 could imagine it too.

6 **P. CAMACHO:** Yeah.

7 **W. MURRAY:** Bill Murray of the Air Force Surgeon General's Office.

8 **AV TECHNICIAN:** You just need to flip the switch to turn it on.

9 **W. MURRAY:** I do have a concern.

10 **M. STOTO:** Hold on a second until he turns the mike on, please.

11 **W. MURRAY:** Okay. Bill Murray with the Air Force Surgeon General's Office, 12 representing the Surgeon General's Office. The Surgeon General does have a concern 13 about what is the next step for this process. The specific questions I got from his office 14 was who decides where the specimens go, when do they decide, how will this transfer 15 take place, and who pays for it?

16 That — those are very key questions that I think you as a Committee are 17 certainly grappling with as well. And I think both from the Air Force community and from 18 the Committee's perspective, we're grappling with the same issue. The reality is from a 19 funding perspective, we are operating with what '06 funding we had left. For Congress 20 to act, by the time they make an '07 appropriation, the program will be gone.

1 So unless the Air Force comes up with a unfunded request here in the next few
2 weeks, which is the time-line I have to submit any unfunded requests for fallout money
3 at the end of the year, there will be no money to help transition this. We're going to
4 operate just within the monies that we have today.

5 Where the report addresses additional funding requirements to maintain those
6 samples and all, if we don't clearly have an identification of an office to assume
7 responsibility probably within the next two months — the latest probably — a
8 reasonable time to say that we then had Congress appropriate them the appropriate
9 monies for that 300 to 500,000 to maintain the samples and allow us to work with them
10 to make that transition possible, we're going to be in — painted into a corner where we'll
11 have no options other than to disconnect the freezers at the end of 30 September.

12 **M. STOTO:** Yeah. Well, thanks. I mean, that's important that we get that on the
13 table. And we've heard that before, but it's really timely now to just be reminded of that.
14 And I think that is what is driving some of us to say it's important for us to say something
15 now.

16 And what we can say now is limited obviously by the amount of time we've had to
17 look at this report, and what our role is and so on. But I propose that what we can do
18 within our mandate is to — is to endorse these two statements and to offer to help to
19 sort out some of the pros and cons of the options laid in the report.

1 **D. TOLLERUD:** And if I could just offer to the Committee that the — somewhere
2 in there it should be the phrase “time is of the essence.”
3 **M. STOTO:** Right.
4 **D. TOLLERUD:** And there’s actually some sidebar discussion in the — in the —
5 when during the briefing about the potential need for a bridge, what they referred to as
6 “bridge funding.”
7 **M. STOTO:** Right.
8 **D. TOLLERUD:** So, and I think that’s what — that’s what you’re talking about as
9 well, not necessarily a commitment for the whole ball of wax, but you know, similar — I
10 mean, what I see your letter might be something like our interim report does — did,
11 which was to signal that something needs to be moving forward more quickly than the
12 September 30th deadline might look like, so ...
13 **M. STOTO:** Yeah. Okay.
14 **RECORDER:** Pardon me. Do you have a quorum without Dr. Camacho?
15 **M. STOTO:** What’s that?
16 **RECORDER:** If you’re going to make a motion, do you have a quorum without
17 Dr. Camacho because he just left the room.
18 **L. SCHECHTMAN:** I think he just walked out to make a copy of something.
19 **M. STOTO:** Yeah, we have a quorum without him.

1 **D. JOHNSON:** I had one question of clarification. If we vote, from what I
2 understand we're heading toward, the two sentences or the two start of the paragraphs
3 that you're recommending and we're saying that we endorse that, what are we saying
4 about the rest of the document? Nothing? We're making no comment at this point or
5 we're saying we don't agree with it? We do agree with it? We're just not — we just
6 don't want to — we're not commenting on that? Are we just saying ...

7 **M. STOTO:** But yeah, we're going to — we're going to say that we haven't had a
8 chance to review the rest of the document in detail. But since time is of the essence,
9 we want to make clear that we endorse the general thrust of it as represented in these
10 two statements.

11 **K. FOX:** Maybe a suggestion is that you get to go and read it and then maybe
12 do a tele-conference ...

13 **M. STOTO:** Well, what we ...

14 **K. FOX:** ... for at least one area ...

15 **M. STOTO:** What we could do ...

16 **K. FOX:** ... for the letter.

17 **M. STOTO:** That's a — that's a good idea. What we could do is I could draft a
18 letter. And then maybe we can have a tele-conference in about a week when people
19 have had a chance to look at the report and then people can then sign on to the — or

1 not — on to the letter. Would that be doable? Does that make sense? Does that make
2 you more comfortable, David?
3 **D. JOHNSON:** That's fine. I — so at that point then ...
4 **M. STOTO:** Yeah.
5 **D. JOHNSON:** ... we're going to make specific recommendations about their
6 findings throughout the entire document of whether or not we agree with it?
7 **M. STOTO:** No.
8 **D. JOHNSON:** Or endorse it or ...
9 **M. STOTO:** No. No, I'm not — that's not what — I'm suggesting that in a week
10 ...
11 **D. JOHNSON:** Right.
12 **M. STOTO:** ... that we ...
13 **D. JOHNSON:** We do that in a week?
14 **M. STOTO:** Yeah.
15 **D. JOHNSON:** That we ...
16 **M. STOTO:** No, we ...
17 **D. JOHNSON:** That this Committee makes ...
18 **M. STOTO:** What ...
19 **D. JOHNSON:** Critiques this very closely?
20 **M. STOTO:** No. No. No.

1 **D. JOHNSON:** All points of it?

2 **M. STOTO:** No. No. No.

3 **D. JOHNSON:** Okay.

4 **M. STOTO:** But that ...

5 **D. JOHNSON:** Okay.

6 **M. STOTO:** ... the — that we'll endorse these two statements ...

7 **D. JOHNSON:** In a week.

8 **M. STOTO:** ... in a week. And that'll give us time to see whether there's
9 something in the report that makes those things inappropriate or, I mean — yeah.
10 Okay, and I will draft, in the next couple of days, a potential statement. And I think in
11 the past what we've done is we've had a letter from the Chair to the Secretary.

12 **L. SCHECHTMAN:** Yes, from the Chair; that's right.

13 **M. STOTO:** Yeah.

14 **D. JOHNSON:** Could you — do we need that week? I mean, do we need a
15 week? Do we need — do we need a week just to say that we generally want to — want
16 to use this data to move forward? We want to keep it open is basically what we're
17 saying.

18 **M. STOTO:** How about the end of this week?

19 **D. JOHNSON:** Okay.

1 **M. STOTO:** I mean — I mean, I'm prepared on my own to say that now, but I —
2 but I think that, you know, people have appropriately said that, you know, for the — that
3 the Committee really needs to have a chance to look at it before it can endorse that. So
4 I think that a week is an appropriate amount of time. I'm open to making it longer or
5 shorter. Ron?

6 **R. TREWYN:** What you have recommended with you drafting a letter and having
7 us review it is very consistent with what I was going to make as a motion, again,
8 focusing on these two statements which I think we can do in principle already because
9 this is, like I say, I think this is very consistent with what we have been advocating all
10 along, but we need this sense of urgency.

11 My suggestion would be — let me think about this. We would be circulating the
12 draft letter anyhow regardless for people to make comments and recommendations for
13 it, which is going to take a few days. And I think if we — if we see by then we will have
14 the document, be able to review it.

15 And if we see any land mines, we can — we can raise those during that
16 exchange and determine then whether a conference call is necessary, which is going to
17 be a bear to schedule. And that's why I'd almost rather get the motion out of the way
18 and move forward now with the drafting.

1 **D. JOHNSON:** I don't know that we really need to review the document in detail
2 if to just make the statement that we think that the material is valuable and should be
3 not completely closed. I mean, that's ...
4 **M. STOTO:** Okay. No, I'm ...
5 **D. JOHNSON:** It's not necessary to ...
6 **M. STOTO:** That was — that's — was my original proposal.
7 **D. JOHNSON:** If that — if that's all we're going to be doing.
8 **M. STOTO:** Yeah.
9 **D. JOHNSON:** If that's all we're really saying is a general — a general
10 consensus of the Committee.
11 **M. STOTO:** Right.
12 **D. JOHNSON:** Because then it becomes something else if we review this in
13 detail and then make recommendations based upon the whole document, that's a
14 different — that's a different statement.
15 **M. STOTO:** That's not what I'm proposing.
16 **D. JOHNSON:** Okay.
17 **M. STOTO:** So I propose and hopefully someone will — I can't — no, I can't ...
18 **R. TREWYN:** Say what you're saying and I'll make the motion.
19 **M. STOTO:** "Move" is the word I'm looking for. I propose that Ron moves that
20 we — the Committee ask me to write a letter to the Secretary that (a) reminds him about

1 our previous statements and interest in this; (b) endorses those two statements from
2 box 1 that I — that I mentioned earlier, not the whole report, but those two statements
3 as consistent with what we have — our scientific opinion has been all along; and (3) or
4 (c) — whatever I'm, you know, I'm using — that we offer to advise the Air Force and
5 other government agencies on the pros and cons of the options laid out in this report in
6 the upcoming year.

7 **L. SCHECHTMAN:** And more.

8 **P. CAMACHO:** There's another — the urgency has to be expressed.

9 **M. STOTO:** Yes, and the urgency will also be a part of that.

10 **R. TREWYN:** The urgency issue because there has to be funding for this before,
11 so there's ...

12 **D. JOHNSON:** Can ...

13 **M. STOTO:** Right. Yeah.

14 **P. CAMACHO:** What was it that Murray said?

15 **M. STOTO:** No, I'll ...

16 **D. JOHNSON:** Right. Can you — can you include maybe what was just
17 reported to this Committee from the — from the ...

18 **P. CAMACHO:** Yeah. Yeah, the list.

19 **M. STOTO:** Yeah.

D. JOHNSON: If they can just let — include in that letter that those points were ...

M. STOTO: Okay.

D. JOHNSON: ... given to us in this Committee.

M. STOTO: So I'm going to modify the first point to say given our interest in this in the past and given the urgency at the — at the moment ...

P. CAMACHO: Yes.

M. STOTO: ... that's the reason we're writing. And then (b) is that we endorse these points and (c) is that we offer our help in the future.

L. SCHECHTMAN: And perhaps my notes also indicate possibly another point; that the Secretary of HHS initiate proactive steps to implement the recommendations ...

M. STOTO: Okay.

L. SCHECHTMAN: ... funding, hand-off transition activities.

M. STOTO: Okay. I'll make — I'll make that part of the second point; that we endorse it; we recommend that the Secretary take steps to see that it's carried out.

R. TREWYN: Brilliantly stated and so moved.

P. CAMACHO: Seconded.

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

RHAC: Yes. Aye.

1 **M. STOTO:** Any opposed, please say — indicate. Okay. I think it passes
2 unanimously. Thank you, Dr. Tollerud. Thank you, Dr. Butler. You're welcome to stay,
3 particularly for the next part where I think the Air Force is going to report on what their
4 response to the — to the interim report. Do you have anything else to add now?
5 **D. TOLLERUD:** No. I just — it's just an open question. I'm — I'll certainly stay
6 for the next part ...
7 **M. STOTO:** Yeah.
8 **D. TOLLERUD:** ... and stay for a break if anybody has any questions. It —
9 would it — do you have a point on the agenda that would be helpful for me to stay later
10 or not? I mean, it's your call. Otherwise, I'll take an earlier flight back to Kentucky.
11 **M. STOTO:** Yeah. Do you mean — do you have something else to add, you
12 mean, or ...
13 **D. TOLLERUD:** No. No. No, I'm just making myself available.
14 **M. STOTO:** I think — I think — well, basically the agenda is — the next part is
15 about their response to the — to the interim report and then the rest is about various
16 kinds of continuing activities, most of which relate to closure.
17 **D. TOLLERUD:** Well, certainly David — I mean, David Butler is the contact
18 person at IOM even though he'll be working on other things and I'm happy to provide
19 any perspective at whatever point for this Committee going forward. As you know, you
20 — as of — since this work was all volunteer for me, I don't get a cut in pay by continuing

to be active so I'll be happy to help you all over the next months. And if that means, you know, coming back to a meeting or whatever, just let me know.

M. STOTO: Okay. Thank you.

D. BUTLER: I will stay to the end of the meeting today if there are any further questions from the Committee.

P. CAMACHO: Do you want to have a break for 15 minutes, or ten minutes or ...

M. STOTO: We had — the break is not scheduled until later. Let's — can we do this part and then we'll take a break? I think it makes sense. Yeah. Okay. Thank you. Colonel Fox?

Updates on Air Force Health Study Activities

Response to the Institute of Medicine Interim Recommendations

K. FOX: Well, Colonel Fox can't figure out the computer because the mouse isn't working. I need to cut this on, don't I? Okay. All right. I was going to talk about the interim recommendations, what the Air Force is doing about those. The first one was "create a comprehensive inventory of master data files organized by cycle." And right now, we've got Cycle 1 through 5 completed and we're about 90 percent completed on Cycle 6.

Second one was "create a comprehensive inventory of the variables contained in the master data files." Five and 6 are completed; we're working on 2 and 4. And we're

working on all of it and we hope that this can be done by the end of the study. "Create a master data code book containing the name of every data variable represented anywhere in the Air Force Health Services database." I read the whole thing because there's just no way we can do that. Okay, so that will not be able to be done. And below, I — we kind of listed the complications of that, so this is one of those ones that we told them that we wouldn't be able to do.

"Create a document describing the contents, format and location of the Air Force Health Study collection of materials." And we expect — this is ongoing and we expect to be able to complete this. "Develop a plan to prepare electronic files for transmittal to the National Archives." We are doing that. I want to say that when we reviewed the National Archives, they asked for rich-text format. We will not be able to do that, but we plan to open discussions with the National Archives to turn over our data or see that they want it — if they want it or not.

"Re-inventory all the laboratory specimens and verify the location, the number, volume and type." This has been going on and we expect to be able to complete this. "Compile all information regarding specimen history." And we — *et cetera* — and we expect that we will be able to do this. "Document the status of all laboratory specimens sent to outside investigators." All the returned specimens were never disposed of, but were reintegrated into the — our specimen bank. And then we are also now sending out letters to external investigators trying to obtain those specimens.

1 “Perform currently planned re-assays to aid in the evaluation of specimen
2 stability and condition.” You will be hearing about that next; it’s been done. And that
3 concludes the part concerning the interim ...

4 **M. STOTO:** Okay.

5 **K. FOX:** ... from the IOM.

6 **M. STOTO:** Thank you. Questions or comments from the Committee? Ron?

7 **K. FOX:** Yes?

8 **R. TREWYN:** I presume the things where you’re talking about the time
9 constraints, this master data code book and whatnot, I presume you agree or maybe
10 you don’t that having that sort of a document is important for the future use? I guess ...

11 **K. FOX:** It would — it would make it easier, but you could still do without it. It’s
12 just that unfortunately, you don’t have enough ...

13 **R. TREWYN:** Right.

14 **K. FOX:** There’s people that know how to do — there’s people that are the
15 experts on it and they can only do so many things ...

16 **R. TREWYN:** Okay.

17 **K. FOX:** ... in the time limit that we have.

18 **M. STOTO:** Is it something that could be done by some group that would take
19 this over?

20 **K. FOX:** Probably; it would take a lot of work.

1 **M. STOTO:** But the information is there?

2 **K. FOX:** The information is there. It just would take — it would be a lot of work.

3 **M. STOTO:** Okay.

4 **K. FOX:** Okay, so we tried to — basically, we're trying to do all the steps that
5 would be needed to do that next step and all.

6 **M. STOTO:** Okay. Other comments? Let me ask a maybe a little broader
7 question. I mean — I mean, you basically have said that you're doing most of the things
8 that were asked for and there were a couple that you thought were not practical. Do
9 you think that what you're doing, if you're able to accomplish it as planned, will at the
10 end of September be enough so this organization that is envisioned in the — in the final
11 report can take over?

12 **K. FOX:** I think so.

13 **M. STOTO:** I mean, is there some particular thing that ...

14 **K. FOX:** I think that and I think it would help for the National Archives to have
15 this data done this way also. So I think they were good ideas and we would — we
16 supported them ...

17 **M. STOTO:** Yeah.

18 **K. FOX:** ... as much as we could.

1 **M. STOTO:** Is there — is there something that you think that would be important
2 that you don't have the resources to do? I mean, let me take — let me rephrase it. I
3 don't want to say "important," but critical; that somehow if it's not done that the data ...
4 **K. FOX:** I think the information is there. I think what the IOM was trying to do
5 was making easier for people to have access to it. So the data is there; the information
6 — I think what we're doing will have the data there. It's that next step that would've
7 made it all in one place.
8 **M. STOTO:** Yeah.
9 **K. FOX:** Now they're going to have to look at certain areas to get the data, but
10 the — with what we're doing, I think all the information will be there. They're just going
11 to have to work a little hard to get it, but it will be there is what — we've filled in the
12 spots that were empty.
13 **M. STOTO:** Are you in a position to comment on that, please?
14 **D. TOLLERUD:** Do you mind if I move up here?
15 **M. STOTO:** Yeah. No, that'd be great. Thank you.
16 **D. TOLLERUD:** Yeah. I think — I think I'm sympathetic to the fact that the
17 staffing level has fallen to the point where there are only so many hours in the week and
18 there are only so many months until the end of September. What I think from the
19 committee's perspective, and we tried to reflect that in the report, is exactly what you

1 said; is the data are there. And we outlined a series of steps that would make it more
2 readily accessible.
3 I think — I don't know if it's explicit in the report, but it's certainly — it's certainly, I
4 think, was understood by the committee that not everything that needs to be done to
5 make this available to the scientific community is — was likely to be accomplished by
6 September 30th, even in the best of all worlds because you can't anticipate whatever —
7 what anybody's going to want.
8 And I think that we anticipated that part of that maintenance — what we called
9 "maintenance costs of the data," for example, in the repository — part of that is not just
10 sitting on it because it doesn't cost $200,000 a year to have a computer plugged in, but
11 part of that was a continuing activity to continue what you would do.
12 So what I — my — it's not a recommendation, but I — but I think that what I
13 would see, and it's probably useful for this Committee if you're planning a facilitating
14 role in this, to have the understanding that the data will continue — these data will
15 continue to need to be put together in different ways as investigators rise for particular
16 kinds of uses and that will be a job of the custodian. So I think that next step could well
17 be the year 1 activity of the custodian; is to — is to finish off that job and put it all
18 together in ways ...
19 **M. STOTO:** Right.
20 **D. TOLLERUD:** ... that could be used.

1 **M. STOTO:** But is it — is it your sense that if they do everything they plan that
2 some other organization will be able to take that next step?
3 **D. TOLLERUD:** I mean, I'm speaking as an individual now because we ...
4 **M. STOTO:** Yeah.
5 **D. TOLLERUD:** ... obviously, the committee didn't have access to that
6 information.
7 **M. STOTO:** Yeah.
8 **D. TOLLERUD:** But from what — from my understanding of the data assets, I
9 would say yes. Because, you know, the committee basically felt that even without that,
10 it could be done. It mean, it would've been a real mountain to climb because you —
11 clearly, you need sort of inside information. I mean, there was — the field trip was
12 useful as I understand it because there were — there was a lot of documentation, a lot
13 of excellent documentation that hadn't made it into the files, into electronic files and was
14 at risk of sort of disappearing.
15 So I think the — if the — if what's been accomplished is that all the data have
16 been collected, made electronic and put into files that are understood, that the activity of
17 actually linking all of those together into a grand master file where you could actually
18 query a single time instead of perhaps querying multiple rounds of times, that's all, I
19 think, manageable with the documentation that we requested.
20 **M. STOTO:** Okay. Thank you. Other comments or questions? Well ...

1 **P. CAMACHO:** In short, you think that whoever gets this — let's assume
2 somebody takes on the project, that the code books could be developed in the first year.
3 They'd probably make it like real short.
4 **D. TOLLERUD:** Correct me if I'm wrong. It's the master file, right, that you're
5 talking about not being able to accomplish? I mean, the code books are there for all of
6 the — all of the parts, right?
7 **K. FOX:** The master.
8 **D. TOLLERUD:** I mean, but what we had — so, you know, you have six cycles
9 of it. If I'm interpreting what you're saying correctly, you have six cycles of exams. We
10 — step one is the make sure that each one of those cycles are completely documented,
11 all the data are electronic. They're all query-able and they're all put in.
12 And then really what you want for a longitudinal study is to roll all that up into a
13 master file where you could say, "Tell me about John Jones, Cycle 1 through Cycle 6"
14 — excuse me — without having to grapple with the variances that happen from cycle to
15 cycle. So we asked for not only the — each cycle to be well documented, but to
16 understand the difference because there were differences: lab tests changed and
17 various things over time.
18 **P. CAMACHO:** And data.
19 **D. TOLLERUD:** So that would be what I would be want to be assured that was
20 done; is that the pieces are there. The aggregation hasn't yet been accomplished.

1 **P. CAMACHO:** And field names. You said something; field names for some of
2 the — changed. Fields in the database, they changed the names.
3 **K. FOX:** Yes.
4 **P. CAMACHO:** Did they document all those so we can — you can get a ...
5 **K. FOX:** For each cycle will have that code book, but then you ...
6 **P. CAMACHO:** Somebody can put it together.
7 **K. FOX:** That — somebody will need to put it together.
8 **J. ROBINSON:** And we have documentation for what changed from cycle to
9 cycle and so all that's going to be made available.
10 **D. TOLLERUD:** And the other — the other thing, I think if I were the new
11 custodian, I would be looking for consulting help from folks who had been working with
12 this for a long time and ...
13 **K. FOX:** And they'll be retired.
14 **D. TOLLERUD:** And well, but on the other hand, I — anybody, I mean, I've been
15 part of projects that have gone on for a long time and I've been off doing something
16 else. And I can't, you know, I'm not willing to move. I'm not willing to give up, you
17 know, full-time. But on the other hand, there's — if you invest in something for a lot, I
18 would be surprised if it wouldn't be possible for the custodian to get sort of periodic help,
19 but electronically if not — if not otherwise to help through this.
20 **M. STOTO:** And might even rent some refrigerators for a while.

1 **D. TOLLERUD:** Well, one of — one of the — I mean, if we're just talking on the
2 table, one of the — of the questions that was raised I think by VA, someone that we
3 queried was, you know, is it really necessary to do anything on September 30th if the
4 funding were available to sort of keep things going? And as I understand, the Air Force
5 is actually leasing these facilities where the freezers and stuff are there because it's no
6 longer Air Force property, right? It belongs ...
7 **K. FOX:** That is correct.
8 **D. TOLLERUD:** ... to the city?
9 **K. FOX:** Belongs to Brooks City.
10 **D. TOLLERUD:** Right.
11 **K. FOX:** It's a Brooks City Base. And on top of that, the Air Force will be — we
12 — Brooks City Base was — the Air Force portion was bracked and we will be officially
13 out 30 September 2011.
14 **M. STOTO:** Okay. Thank you. I propose we take a 15-minute break now and
15 come back and do the rest. Thank you very much.
16 **K. FOX:** Thank you.
17 **[BREAK 10:40 A.M.-10:56 A.M.]**
18 **M. STOTO:** Well, let's get started again. Before Dr. Pavuk gets started, does
19 anyone on the Committee still need a copy of the IOM report? Did everybody get one?
20 David, do you have a copy?

1 **D. JOHNSON:** The IOM report? Not the full report in front of me.

2 **M. STOTO:** Okay. Well, they will give you one right now.

3 **D. JOHNSON:** Do you have the full report?

4 **M. STOTO:** Yeah.

5 **D. JOHNSON:** I'm not the only one that doesn't have one.

6 **M. STOTO:** Okay.

7 **E. HASSOUN:** I don't have a copy.

8 **D. JOHNSON:** Thank you, sir.

9 **M. STOTO:** Okay. So everybody has a copy now? Is there anybody on the
10 Committee who's not here today? Dr. Osai.

11 **E. HASSOUN:** Dr. Sills.

12 **M. STOTO:** Dr. Sills; that's right. Yeah. Did ...

13 **D. BUTLER:** We'll be happy to mail copies.

14 **M. STOTO:** Will you mail copies to them? Yeah. Thank you. Okay. Now
15 please go ahead, Dr. Pavuk.

16

17 **Viability Study**

18 **M. PAVUK:** Thank you. Thank you, Dr. Stoto. Good morning, everybody. I'm
19 pleased to present the results of the viability study. We were successful in getting the
20 results last week Wednesday, so this is the first look at what we got. The first

1 introductory slides, so I'll just briefly review what I told you last time. There are over
2 70,000 samples stored, some of them for more than 24 years.

3 We were interested to see whether the samples are viable for use in future
4 studies. And we have selected and analyzed 25 specimens for five veterans that
5 attended the first five examinations. And those were analyzed by high-density
6 quantitative immunoassays panels by Rules Based Medicine Company in Austin, Texas
7 that provides this multi-analyte profiles in humans and in some laboratory animals.

8 Each serum — each serum specimen was analyzed for 177 analytes, but
9 different kinds: 78 specific serum antigens, 43 autoimmune serologies and 56
10 infectious disease serologies. Before receiving the results, we have identified 16
11 analytes that were measured repeatedly in the Air Force Health Study in at least two
12 examination cycles and that were also included in the Rules Based Medicine human
13 panel for comparisons.

14 Eight of those analytes were continuous measured levels with normal laboratory
15 set ranges. These included alpha-1 antitrypsine, C3 complement, creatine kinase,
16 immunoglobulins A and M, prostate-specific antigen, aspartate aminotransferase, and
17 thyroid-stimulating hormone. Results for two enzymes, aspartate aminotransferase and
18 creatine kinase, not directly comparable in the measured levels. It's normal; usually
19 labs will use enzymatics and this is immunoassay that measures more of the mass of
20 the enzyme.

1 Also, the prostate-specific antigen as measured in Air Force Health Study was a
2 total PSA. It was a free PSA in RBM panel. Eight analytes had positive or negative
3 finding in Air Force Health Study that are including comparisons: those are hepatitis A
4 antibody, hepatitis B antigen — surface antigen antibody, a core antigen, and hepatitis
5 C and D antibodies. Also included were mitochrondial antibodies and thyroidal
6 microsomal antibodies.

7 Overall results: out of 177 analytes that were examined, we have received some
8 measurable results as a result of the standard curve in over — in 96 percent, in 170
9 analytes using the MAP technology. Seven analytes didn't provide results measurable
10 on the standard curve and most of these analytes are those that you would not really
11 expect to measure in serum in very high levels.

12 Or if they would be present in serum, they would be present in serious disease
13 conditions, like inflammation, cancer for interleukins and metalloproteinase, glutathion-
14 S-transferase. Again, it was not enzymatically measured, but immunologically. And
15 calcitonin would be present at higher levels and so would thyroid disease. Some other
16 interleukins were measured in — by MAP assay. Also, metalloproteinase 2 and 3 were
17 measured in our samples.

18 Maybe more importantly, 147 out of 177 analytes were totally complete, so they
19 provided results for every five cycles for each of the five veterans. And when we looked
20 at those analytes that did have some results below the standard curve, they appear to

1 be more subject-related that we had some missing results in more — in some persons

2 — in some veterans. It didn't seem that they were related to the time of storage so we

3 would have a missing levels in exam 1 or exam 2.

4 Now I present some slides, some figures with the results from both Air Force

5 Health Study and Rules Based Medicine: Air Force Health Study on top.

6 **RECORDER:** Could you come back to the mike, please?

7 **M. PAVUK:** Sorry. Air Force Health Study results on top; Rules Based Medicine

8 at the bottom; "N/A" means that the — not available results, that the measurements was

9 not done at the Air Force Health Study. At the bottom under the years of the exams are

10 the normal laboratory set ranges for both methods.

11 **M. STOTO:** Do you need a pointer? I've got one here.

12 **M. PAVUK:** Normal set ranges which, of course, are the same for all the exams

13 for Rules Based Medicine as the assays were conducted now. For Air Force Health

14 Study, for some assays, these are different for alpha-1 antitrypsin. The method they

15 didn't change, so the ranges are the same.

16 **M. STOTO:** What's the vertical axis on those graphs?

17 **M. PAVUK:** Vertical axis is in milligram per milliliter, which is the same for both

18 assays here.

19 **M. STOTO:** Okay, so it's the level of the ...

20 **M. PAVUK:** Yes, it's the level of the ...

1 **M. STOTO:** ... of the protein.

2 **M. PAVUK:** ... of the result ...

3 **M. STOTO:** Yeah.

4 **M. PAVUK:** ... which is indicated here on the top. If it's the same for both
5 assays, for two assays, as I said before, there were — there were differences. As you
6 can see here, the normal ranges are similar for both methods, are close enough. We
7 do not see really some very clear pattern, although veteran number five has got a lower
8 level. I'll go through several of those. Some of the patterns are clearer than the others.
9 Similar for complement, C3 complement, milligram per milliliters. Again, normal ranges
10 are about the same.

11 Results for both assays are within the normal ranges for both of the assays.
12 Here, much clearer pattern and we also have one veteran that is — has values much
13 higher than the other veterans. As you can see, this is immunoassay and the results
14 are very similar in both Air Force Health Study and Rules Based Medicine, including the
15 patterns for different veterans that are quite similar.

16 For immunoglobulin M, also very similar patterns, and correctly identified one
17 veteran with much higher level than the other veterans and similar normal ranges for
18 both methods. For prostate-specific antigen, as I mentioned, Air Force Health Study
19 measured the PSA total and PSA free here. That's why the difference on the scale of

the total measured levels. It's not the same thing, although some correlation for these two cycle can be seen in the results.

For thyroid-stimulating hormone, again, the results and normal ranges are quite similar. And one of the veterans is correctly identified as having the levels above the normal ranges. Creatine kinase, as I mentioned, these are different units. It's per liter, different assays, so we would not expect the results to agree. But the assays were performed successfully on all stored samples; the similar thing for AST. As you can see here, some of those were under the limit of detection for the particular assay.

For positive and negative results, there were no veterans that had present anti-mitochrondial and thyroid microsomal antibodies identified in Air Force Health Study data. Similarly, RBM didn't detect any positive reactions. Hepatitis A antibodies, there was the — here we found a discrepancy in the results. There were two veterans in Air Force Health Study and then a third one identified hepatitis A antibodies. RBM analysis did not detect those antibodies in the same veterans.

We talked with our colleagues at Rules Based Medicine what could be the reason for the discrepancy; could be the presence of different serotypes or some other issue. We will discuss this further, but don't know. For hepatitis B, one veteran had hepatitis B antibodies and the hepatitis B core antibody too. And the Rules Based Medicine confirmed those findings and correctly identified this veteran. No positive results were found for hepatitis C or hepatitis D by either assay.

1 So as I mentioned earlier, over 96 of the analytes provided measurable results
2 and a very high percentage of the assays were complete, provided complete results for
3 all five veterans across all five examinations. From looking at the data, we didn't see
4 any indication that older samples may be less preserved than the more recent ones.
5 And inter-person variability seemed to be more prevalent than the indication that older
6 samples could be less preserved.

7 And on the data that — in the 16 analytes that we could compare results
8 between Rules Based Medicine and Air Force Health Study, we saw quite a high
9 degree of consistency between assays in those frozen serum samples. So we believe
10 that biochemical integrity of the samples appears to be well preserved and sensitive
11 immunoassay-based analysis were successfully performed. And this result suggests
12 that the stored Air Force Health Study samples seemed to be a great source of scientific
13 data that is really well preserved and could be used in future studies.

14 **M. STOTO:** Okay. Thank you.

15 **M. PAVUK:** Thank you.

16 **M. STOTO:** Questions or comments from the Committee? So it seems to me
17 that what you're saying is that when you take these things out of the freezer and
18 analyze them using this MAP technology ...

19 **M. PAVUK:** It works really well.

20 **M. STOTO:** That technology works?

1 **M. PAVUK:** Yes.

2 **M. STOTO:** And I guess my question is how generalizable is that? I mean, if
3 you were to use some other technology, is that also likely to be true or we don't know?

4 **M. PAVUK:** I think these are — these are fairly, you know, sensitive assays that
5 — or if the samples are not well preserved, it would not run. You wouldn't get any
6 results. So in my opinion, it suggests that, you know, other technologies could be also
7 successful, but really becomes really generalized based on this.

8 **M. STOTO:** Yeah. David?

9 **D. TOLLERUD:** Just as somebody who's done some biomarker work also, first
10 of all, these are wonderful results, not just for their consistency of it all, but to have from
11 a — looking in from the outside, what you really want in a study like this is to have big
12 differences between individuals and small differences within an individual over time
13 because that's what you're trying to tease out is the difference between people.

14 In answer to your question, I think the committee discussed frequently that
15 investigators with new techniques or new technologies are going to have to do their own
16 QA/QC and validation with stored samples if they haven't already done it. But what this
17 speaks to is the — is, as the study was meant to do, as the viability of the samples
18 themselves and now we're taking a well standardized, well understood battery of tests.
19 There doesn't seem to be any deterioration over time, so I think they ...

20 **M. STOTO:** The proteins haven't deteriorated or ...

1 **D. TOLLERUD:** Right. Yeah.

2 **M. STOTO:** That we can tell, yeah.

3 **D. TOLLERUD:** Yeah. Yeah, which I think is terrific. From the standpoint of the
4 — of the future of the study, I would hope that these results would be put out in the
5 scientific literature pretty quickly because they are exciting. And it would — it would be,
6 again, it would be a visibility factor for outside researchers to say, "Wow, you know, 24-
7 year old samples that seem to be rock solid."

8 **M. PAVUK:** It seems that the consistency ...

9 **M. STOTO:** Speak in the microphone.

10 **K. FOX:** Mike.

11 **M. PAVUK:** It seems to me that some of those results are — they're very
12 impressive: the — how the ranges being so close, and the results, even on just five
13 veterans, the pattern is being repeated very closely. It seems very impressive for some
14 of the assays.

15 **M. STOTO:** Okay. Well, let's make sure that that's in the — in the minutes; this
16 recommendation that that be published quickly.

17 **M. PAVUK:** I asked researchers at Rules Based Medicine whether they publish
18 some of their, you know, validity study or some other things and they usually do not.
19 Just ask, I was wondering whether they would be interested to do something like that
20 and preliminary, they were interested in doing something like that.

1 **M. STOTO:** Good. That — I think that we would like to encourage that ...

2 **M. PAVUK:** I have seen ...

3 **M. STOTO:** ... because that's important.

4 **M. PAVUK:** I have seen reports like that on small number of samples.

5 **M. STOTO:** Right.

6 **M. PAVUK:** I've seen a report on samples that were irradiated. And people
7 were looking for the DNA that's well preserved or — but it was damaged and it was on
8 small number of samples.

9 **M. STOTO:** I just want to enforce the point that Dr. Tollerud made; is that a
10 publication of that sort can really make this database — make researchers aware of the
11 availability of this database.

12 **M. PAVUK:** As a source, yes.

13 **M. STOTO:** Okay. Thank you.

14 **RECORDER:** That's general agreement from the Committee?

15 **M. STOTO:** Yes. Okay, so now we're on to the mortality update.

16

17 **Mortality Study**

18 **M. PAVUK:** Yes. The last mortality update before this mortality update used the
19 data — the mortality data on this cohort through December 31st, 1999. This mortality
20 update contrasts cumulative Ranch Hand post-service mortality rates through

1 December 31st, 2003 and with the rates in comparison population of 19,080 veterans
2 with the whole group of veterans where the mortality information was available.
3 Twenty-two Ranch Hand and 109 comparison veterans that were killed in action
4 were not included in the analysis. We calculated the relative risks, a 95 percent
5 confidence intervals using proportional hazards methods. The analysis on the whole
6 group of over 20,000 veterans adjusted for analysis for year of birth and military
7 occupations. Analysis with veterans by dioxin category and those that participated at
8 physical examinations had some more detailed analysis and additional covariates were
9 adjusted in those analysis.
10 This is the descriptive table. There were only about 6 percent of non-black
11 veterans in the whole cohort. The military occupations distribution is also on this slide,
12 shown on this slide. Total was 1,263 for Ranch Hand and 19,080 for comparisons that
13 were used in the big analysis.
14 This table shows cause-specific mortality to December 31st, 2003 using all of
15 those veterans adjusted only for year of birth and military occupation. We see elevation
16 in the risk of that from all causes — 240 Ranch Hands, 2,734 comparisons — which is
17 statistically significant.
18 The other significant increases or well major increases in heart disease: 89
19 Ranch Hands, which is 1.4, is really significant; but also smaller increases, elevation in

digestive and ill-defined diseases, and a small number of endocrine diseases that was significant. This seven here was one thyrotoxic causes and six diabetes-related deaths.

M. STOTO: Can I just, by way of interpretation here, does diabetes show up in endocrine?

M. PAVUK: Yes.

M. STOTO: And presumably also in heart disease too? If diabetes puts people at a higher risk for heart disease and ...

M. PAVUK: This is as a — as a cause of death on death certificate.

M. STOTO: Right, so I mean, this — these three things that turned out to be significant all — can all ...

M. PAVUK: Right.

M. STOTO: ... reflect diabetes because the first one is total. Okay.

M. PAVUK: So here are — would you like to see that slide now?

M. STOTO: No, go ahead.

M. PAVUK: So here are the diseases here, small numbers. Analysis by military occupation, see that for all causes, there are significant increase for enlisted ground crew, smaller elevation or no elevation for officers or enlisted flyers. For cancer mortality, we do not see any major increases or decreases. For circulatory disease mortality, again, enlisted ground crew, 49 deaths is statistically significantly increased.

1 When we look at the distribution which diseases, those were — there's a majority
2 of atherosclerotic disease, but also cerebrovascular, hypertensive and other circulatory,
3 all those are elevated which makes the total elevated. So overall, but majority is
4 atherosclerotic disease, including heart attacks and the usual.

5 **D. JOHNSON:** But they're not all significant?

6 **M. PAVUK:** Pardon me? No, only the atherosclerotic disease. All these that
7 have small numbers, so they're elevated, but they're not significant. Second part of
8 analysis included all those veterans that participated in at least one physical
9 examinations and had the valid dioxin measurements. These are the total numbers:
10 about 1,500 comparisons; there is higher proportion of enlisted ground crew in the high
11 dioxin category. Also high dioxin category is quite younger than the comparison in the
12 other dioxin categories.

13 All cause mortality by December 31st, 2003, there are only slight elevations which
14 are not statistically significant, but they are getting — they are elevated a little bit.
15 Cancer mortality, we do not see any elevations here. There are a total of 40 cancer
16 deaths in that group. Small number, but we did attempt to look by — as our other
17 cancer analysis to look a year of service or days of spraying didn't seem to change
18 result of this analysis.

1 And circulatory disease mortality, we see elevation in the low and high category
2 with a significant type of trend. This result — we didn't see this result in association with
3 dioxin in previous mortality reports.
4 **M. STOTO:** And that could still reflect the connection through diabetes? Is that
5 true?
6 **K. FOX:** No.
7 **M. PAVUK:** When ...
8 **K. FOX:** We didn't control. I mean, we didn't ...
9 **M. STOTO:** Turn your mike on.
10 **K. FOX:** Because didn't you then — we looked at adjusting for diabetes, and
11 BMI, and those kind of things and that did not really change anything. In the previous
12 group ...
13 **M. PAVUK:** Well ...
14 **K. FOX:** ... we couldn't adjust for diabetes because we didn't have that kind of
15 information on the 1,900. All we have is death certificates and we just looked at the
16 primary cause of death.
17 **M. STOTO:** So diabetes was one of the factors that were adjusted here?
18 **K. FOX:** No. It was not adjusted for the first portion that he talked about
19 because it's consistent with the 19,000 comparisons so that we don't have any history
20 on them. All we have is their death certificate.

1 **M. PAVUK:** In this ...

2 **K. FOX:** And this here ...

3 **M. PAVUK:** In this analysis, we didn't — those numbers are not adjusted for
4 diabetes. But when we include diabetes in the middle and adjust for diabetes, those
5 risk estimates do not change. It doesn't affect the risk estimate or magnitude of the risk
6 when we adjust for diabetes.

7 **M. STOTO:** Well, then that's really surprising then. I mean, this is suggesting
8 that the doubling of the circulatory disease mortality rate in a good part of the sample for
9 reasons independent of diabetes and that's ...

10 **M. PAVUK:** It's ...

11 **M. STOTO:** That's what that says there, right?

12 **M. PAVUK:** Right. Partly what — why is that is that the distribution of diabetes
13 through — or the prevalence of diabetes through the dioxin categories is fairly similar in
14 these groups. So in — when you look at this particular mortality analysis, you look at
15 the proportion of diabetes in different categories: background, low, high. The
16 prevalence of diabetes is similar in these veterans in this mortality analysis by dioxin
17 category.

18 **M. STOTO:** Well, I'm just saying that if this really is not due to diabetes, that's a
19 — this is a stunning new result.

20 **K. FOX:** It's not — we've been saying this.

1 **M. STOTO:** Turn your mike on, please.

2 **K. FOX:** Believe we've said this before in 1999; that we're seeing circulatory
3 disease in the enlisted ground crew in the high dioxin. We've seen this before. This is
4 just a little bit stronger, but it's been — and they were still adjusted for the same things.
5 So this is not something new.

6 **M. STOTO:** It's new to me, I should've said. Okay. Go ahead.

7 **M. PAVUK:** I do not have those tables here to show you the distribution of
8 diabetes, but ...

9 **M. STOTO:** I trust you. I mean, I think that ...

10 **M. PAVUK:** We also look at, you know, hypertension, diabetes and some other
11 factors that could influence, you know, this. And this estimate is very stable and doesn't
12 change with the covariates that are included here.

13 **M. STOTO:** It's not that I mistrust you or that you're misrepresenting. I'm just
14 trying to understand what this — what this means here. I think this is an important
15 result, at least it's new to me.

16 **M. PAVUK:** You see, we didn't do the — analysis on diabetes before were rarely
17 done on diabetes and mortality. Those were, you know, analysis on incidence and
18 prevalence of diabetes, not diabetes related to mortality really when you think about the
19 previous results.

1 **K. FOX:** When we were reviewing this, your comment, I asked to have it looked
2 at for the diabetes and the other risk factors. And then when we looked at it, it really
3 didn't change anything. This is how it's been always presented, but then I agree with
4 you. I was curious about the diabetes and the other risk factors that we might have
5 information to adjust for. And when we found — when we did adjust, it didn't change
6 anything so ...
7 **M. STOTO:** It kind of makes you wonder why if mortality is really twice as high,
8 why this didn't show up in terms of heart disease in the morbidity studies?
9 **K. FOX:** Agreed. And we weren't seeing that and, but we are seeing it in the
10 mortality. And it seems to be getting — and it's been getting stronger as the years go
11 by. It was not as strong in the previous one. And now just the relative risk seems to be
12 getting bigger and I don't know the answer to that. It's further research that could be
13 done on this data.
14 **M. STOTO:** I guess it's another one of these things; that obesity is a risk factor
15 for circulatory disease and people will retain the dioxin longer, so there's that
16 complicated relationship that we talked about with respect to dioxin too.
17 **P. CAMACHO:** That comes from the pesky ground crew.
18 **D. JOHNSON:** It seems I have a question. You know, I have more questions
19 than answers. But is this part of the study then? This — these results here, is this part
20 of the final report?

1 **K. FOX:** No. Okay. Let's get some definitions. Okay. This is where I think
2 there's been a lot of misunderstanding. All right. We did a Cycle 6 report. We did the
3 physical exam on the Cycle 6. Then from that, we have all the data from Cycle 1, 2, 3,
4 4, 5 and 6 and we try to analyze it, not just giving the Cycle 6 data. That's what the
5 comprehensive report was looking at; was looking at all the published peer-reviewed
6 information that had been published. And the — what was published in the cycles, we
7 analyzed that.

8 We have been doing mortality reports like this for numerous years. And I wanted
9 to get the last one out for — that this study could do and we said we could get it through
10 31 December of 2003. These reports have been published throughout the years and
11 this is the final one that we have with this.

12 **M. STOTO:** Just one thing ...

13 **K. FOX:** We take the information and we look at the information in different
14 methods.

15 **M. STOTO:** Just to clarify what you said, these weren't the kind of things you
16 published in journal articles ...

17 **K. FOX:** Yes.

18 **M. STOTO:** ... as opposed to those big thick books that ...

19 **K. FOX:** That just analyze everything from the cycle.

20 **M. STOTO:** Right.

1 **K. FOX:** Yes. These are ...

2 **D. JOHNSON:** Is this just for one year or is this for the whole ...

3 **J. ROBINSON:** No, the whole ...

4 **K. FOX:** Whole year, all the way from post-Vietnam all the way to 2003.

5 **D. JOHNSON:** That's the data.

6 **K. FOX:** This is the data. We have been collecting — we look and get death
7 certificates on all the 1,900 comparison group that we had selected. We don't look at
8 them other than that death certificate and then all the Ranch Hands and all. Now what
9 we've done here is we're now analyzing the portion that went to the study — the
10 physical exams where we have additional information so we can adjust for risk factors.

11 **D. JOHNSON:** The thought I'm having right now is just the Chair of the
12 Committee is seeing some interesting data which is news to him. And I'm just — I'm
13 just kind of curious, do we have — would it be possible to have a synopsis written that's
14 — that lists all the significant findings?

15 I don't know how many significant there were and say, "Well, this is what we've
16 seen that we thought may be significant and these are the limitations of — and the
17 strengths and the limitations of that finding," so that there — would that be a huge
18 document or would that be a ...

1 **K. FOX:** It's as close as we've gotten is the comprehensive report that you
2 reviewed. And so yes, to do anything other than what we've done and what we're trying
3 to finish up, there is no way we could.
4 **D. JOHNSON:** But this isn't ...
5 **K. FOX:** But ...
6 **D. JOHNSON:** ... in the comprehensive document.
7 **K. FOX:** No. This is a — everything that can't be published in a peer-reviewed
8 journal, we are now making into technical reports so that at least it's not lost to
9 something. So this is going to be turned into a technical report and all. The previous,
10 the 1999 through the 1999 thing got published. I think we reported about it last meeting
11 and all.
12 So we're trying to turn everything into a technical report now because the time is
13 just not there for us to make it, get it published in a peer-reviewed journal. So we're
14 trying to make it so that it's not lost totally and it will be in the data set that gets sent to
15 the National Archives.
16 **M. PAVUK:** The technical report looks like your peer review article. It just, you
17 know, it has the same sections: the introduction, results, a discussion.
18 **D. JOHNSON:** It just seems it would be nice to have a concise short document
19 that everybody on the Committee has looked and says, "Well, these are some of the
20 things: diabetes was one, and there was one or — one or two other cancers, and these

1 were the things that we thought might've — that were found that might be significant.
2 These are the strengths and limitations of that data." Just, I would think that would only
3 be — that wouldn't be that many.

4 **K. FOX:** That's a comprehensive report.

5 **D. JOHNSON:** That's the comprehensive report.

6 **K. FOX:** Yes, but the comprehensive report had to end at some time because I
7 can't continue to modify it. So it ended at one — at one time and then I said, "Okay.
8 We needed to look at — finalize this, at least get this out, this data out that we looked at
9 it." And it's showing the same trends. It's just a little bit stronger.

10 **D. JOHNSON:** So has ...

11 **K. FOX:** But the comprehensive report was our attempt and it has not been
12 finalized yet, no.

13 **D. JOHNSON:** Does the comprehensive report, does it have this trend, lacking
14 this latest report? Does it have the mortality trend?

15 **K. FOX:** It probably won't. It will not have this trend in it because ...

16 **D. JOHNSON:** Not at all?

17 **K. FOX:** No, because I've got to stop the comprehensive report some time. So
18 it's going to cover ...

19 **D. JOHNSON:** No, but you said the trend's been going on for years.

20 **M. PAVUK:** Yeah, the trend was there before.

1 **K. FOX:** Yes. Yes. The previous trends have been shown, yes.

2 **D. JOHNSON:** And that's been shown in the comprehensive report?

3 **K. FOX:** Yes.

4 **M. STOTO:** The comprehensive report's on the agenda.

5 **J. ROBINSON:** Well, it's already reviewed.

6 **K. FOX:** Yeah.

7 **M. STOTO:** So we'll come back to this in the — in the context of the
8 comprehensive report. Okay. Why don't you go ahead and ...

9 **M. PAVUK:** Well, I have just concluding slides: that the analysis of all Air Force
10 Health Study participants, more than 20,000 of them, all causes mortality and mortality
11 due to circulatory diseases were statistically significantly increased; and that other
12 increases that we seen in digestive, ill defined and endocrine diseases had small
13 number of cases. We didn't see significant decreases risk of death. And these analysis
14 were adjusted for year of birth and military occupations as most of those comparison
15 veterans did not attend the physical examinations.

16 Enlisted ground crew had increased risk of all causes death and death from
17 circulatory diseases. And we didn't see a substantial or statistically significant increases
18 for the officers or enlisted flyers. In analysis by dioxin category, similarly we see the
19 increased risk of death due to circulatory death. It was found in the low and high
20 category and a significant test for trend. We didn't see increase in the risk for deaths

1 due to cancer. And all cause mortality was slightly elevated, but not significant. And
2 those analysis were adjusted for possible confounding factors.

3 As Colonel mentions, these results strengthened the trend of increased risk of
4 death in Ranch Hand participants that you observe in earlier mortality studies, and
5 circulatory diseases in all Ranch Hand, and in particular, the Ranch Hand enlisted
6 ground crew, the highest exposed group. Analysis by dioxin category this time
7 supported this finding and found increased risk of death due to circulatory disease in the
8 low and high dioxin category. And we see dose-response relationship and a significant
9 test for trend in that analysis.

10 **M. STOTO:** Okay. Thank you. I would just personally urge you to look again at
11 the role of diabetes in there because the groups exposed to dioxin, we know from other
12 studies, are the ones that had more diabetes and that just seems like an obvious
13 explanation. So I mean, we can't — obviously can't do the analysis here on the spot,
14 but I just urge you to take a look at it again.

15 **K. FOX:** I think they — that the numbers of diabetes wasn't — didn't really
16 increase. The prevalence is still the same, but what we're seeing is the severity or the
17 onset of it seemed to be faster in the ...

18 **M. PAVUK:** Ranch Hand.

19 **K. FOX:** ... in the Ranch Hand high dioxin levels.

20 **M. STOTO:** Okay.

1 **M. PAVUK:** Thank you.

2 **M. STOTO:** Thank you very much. Any other comments or questions from the

3 Committee?

4

5
6
Public Comment Period
7

8 **M. STOTO:** Now we're at the time now when we're scheduled to have public

9 comments. And is there anybody here who would like to make a comment? Okay. I

10 guess not. Well, let's go on to the next topic and I'll ask again by noon or so just to be

11 sure.

12

13
14
Updates on Air Force Health Study Activities [continued]
15

16 **Comprehensive Study**

17 **M. STOTO:** So the next topic is in fact the comprehensive study that we were

18 started to talk about a moment ago.

19 **K. FOX:** I was going to go over — you guys — they — the Committee gave us a

20 lot of recommendations and I'll start off with saying we took all the recommendations.

21 Here are the exceptions. But I'm already going to tell you that Chapter 5, we did take

22 your recommendation and we have put that into the — to the report, so was — we can

23 — I'll say that. One was ...

1 **M. STOTO:** Before you go into the specifics, a moment ago when we were
2 talking about this, I couldn't remember whether the comprehensive report, it primarily
3 focuses, if I'm — if I recall correctly, on the — summarizing the Cycle 1 through 6.
4 **K. FOX:** Cycle 1 through 6 and every peer-reviewed journal article that has been
5 published by the Air Force Health Study or in ...
6 **M. STOTO:** And they're in — but the peer review are incorporated in the — in
7 the discussion and the tables focus ...
8 **K. FOX:** Are summarized in the report and put into the discussion.
9 **M. STOTO:** But the tables in the report focus on the Cycle 1 through 6 if that's
10 — is that right?
11 **K. FOX:** Yes. The tables do the 1 through 6, but we do summarize everything
12 that was looked at.
13 **M. STOTO:** Okay.
14 **K. FOX:** Yes.
15 **M. STOTO:** Thank you.
16 **K. FOX:** So Chapter 5, "reproductive," we did that take one. Chapter 9 for
17 "endocrinology," "using a bar graph to show incremental increases across cycles" — we
18 could not do that. It would require re-analysis and the scales of measurement changed
19 from cycle to cycle. And relative risk and confidence interval was reported in Chapter 4
20 only.

1 “General health” — specific things we left as is. “Need to provide information on
2 peripheral neuropathy” — we didn’t provide information on every disease, but we did
3 state — we did add the statement concerning that the compensation is for — the VA
4 compensation is for acute or transient peripheral neuropathy and we did not have
5 anybody with that.
6 “Pulmonary,” they talked about non-malignant respiratory disorders. Malignant
7 disorders are discussed in the neoplasia chapter. We disagreed with bringing — one
8 suggestion was to “bring the VA list to the front of the report and use it as a framework.”
9 We decided against that because that does — that limits all the stuff that we were
10 reporting on. And we left it as is in its own chapter.
11 “Conclusions,” “don’t tie everything to dioxin” — we’ll say that it’s just hard
12 sometimes not to do it when there’s not very much difference between Ranch Hands
13 and comparisons and really when you start seeing the differences is in — actually when
14 you’re comparing the dioxin levels. And that is that on the comprehensive. We are still
15 working on it.
16 **M. STOTO:** Okay.
17 **K. FOX:** All right, so ...
18 **P. CAMACHO:** That’s it? Will there be a — is there any opportunity to look at
19 the draft of 16? I mean, you — did that get farmed out?

1 **K. FOX:** It's going to be farmed out, yes. We are going to try to get — we are
2 trying to get a psychologist to look at it so that we can put the ...
3 **P. CAMACHO:** Pesky ground crew.
4 **K. FOX:** That and the — one little here, one little there does not make a whole
5 person type of thing. And we took what you were saying and I understood. We
6 understood where you were coming from and so ...
7 **P. CAMACHO:** Okay. Thanks.
8 **K. FOX:** ... that is going to be looked at to try to ...
9 **P. CAMACHO:** As long as the cards are laid out on the table, I think you're safe.
10 **K. FOX:** Understood, but we need to put it into a clinical perspective.
11 **P. CAMACHO:** All right.
12 **K. FOX:** And I think we saw — we heard that.
13 **M. STOTO:** Okay. Thank you. Any other comments or questions?
14 **K. FOX:** Okay.
15 **M. STOTO:** You ready for the compliance study? Is that you again?
16 **K. FOX:** I guess it's me again.
17
18 **Compliance Study**
19 **K. FOX:** This is draft only. We just received the first draft report to us. We have
20 not even gotten a chance to look at the whole thing, so this is just a snapshot just to

give you an idea of what some of the trends that we were seeing. We didn't want to not talk about something.

Of all the Ranch Hands and original comparisons, 87.8 percent chose to participate in at least one examination. For the Ranch Hand, it was 91.2 percent and for the original comparisons, it was 84.5 percent. So pretty impressive for our group. Of all the Ranch Hand and original comparisons eligible to attend all six examinations, 61.4 percent chose to participate in all six examinations: 65.3 percent for Ranch Hands and there — comparisons, 57.6.

Associations between group, race, military occupation, age, dioxin level and military commitment on Air Force Health Study compliance were studied. The compliance rates: Ranch Hands had a higher compliance rate than original comparisons and original comparisons had a higher rate — compliance rate than replacement comparisons.

Enlisted flyers had a higher compliance rate than enlisted ground crew. And the compliance rate for officers was similar to the enlisted ground crew at the beginning, but was closer to the enlisted flyers. So it improved by the end of the Air Force Health Study. Older veterans had a higher compliance rate than younger. Retired veterans had a higher compliance rate than veterans who did not make the military their career. There was no association between the compliance in race and compliance in dioxin.

1 We looked at the reasons for refusal. We — health reasons, or logistics reasons,
2 and some other reasons were, as you can see, dissatisfaction with the U.S. Air Force
3 and government, with the Health Study, with previous Air Force Health Study
4 examinations, fear of a physical examination, confidentiality and other.
5 We considered a “passive” refusal was when they were scheduled for exam, but
6 twice canceled or failed to show. There was a gatekeeper present and 28.6 percent at
7 the 2002 physical examination were passive refusals. Yes?
8 **W. GRUBBS:** Karen, that’s — I was looking at that as Karen was preparing that.
9 It’s 28.6 percent of anybody that refused the physical exam. So contingent on you
10 refusing, 28.6 percent of them were passive refusals just to clarify that.
11 **M. STOTO:** What does “gatekeeper present” mean?
12 **K. FOX:** It’s where we — you couldn’t get to the person. The — somebody else
13 was answering the phone; somebody else was not allowing you to speak to somebody
14 — the participant.
15 **M. STOTO:** Like his wife?
16 **K. FOX:** Just the gatekeeper.
17 **R. TREWYN:** No accusation.
18 **K. FOX:** And we had an “adamant” refusal category. They didn’t want any
19 contact with the Air Force Health Study ever and these were first classified in 1992.

1 And of the refusal, 23.3 percent of the refusals were actually adamant refusals. And for
2 the Ranch Hand and for the comparison, it was 21.1 percent.
3 Increase — we looked at non-compliance between 1997 and the 2002 physical
4 due to refusals for health reasons. It showed no association between refusing for health
5 reasons and group or race. As expected, older veterans refused more often for health
6 reasons than younger veterans. After adjustment for age, the refusal rate for health
7 reasons was greater for enlisted ground crew — the youngest occupation on average —
8 than for enlisted flyers and officers. And ...
9 **M. STOTO:** What does — what does, in the first bullet in that one, what does
10 "group" mean? So it's not age group? It's ...
11 **W. GRUBBS:** Ranch Hand and comparison.
12 **K. FOX:** Ranch Hand and comparison.
13 **M. STOTO:** Okay.
14 **K. FOX:** And we're looking at reasons other than health; that's still ongoing.
15 Some other preliminary results: reason for refusal because of dissatisfaction with the
16 U.S. Air Force, the Health Study, the government or previous exams, the percentage of
17 total refusals and you can see. And it's been fairly — it's not — it's fairly consistent.
18 The best predictor of compliance at examination was compliance at the most
19 recent previous examination. So if you — and you could see that in 90 — that
20 correlated with 93 percent. If you looked at 1985 and then you could see how many

1 showed up in '87 — 93 percent — it predicted it. It was correlated with that and then
2 you could see that. And if you looked at '97 and then follow up in 2002, 88 percent.
3 And I think that was it. That's our preliminary report on the compliance.
4 **M. STOTO:** I wonder whether you or anyone else has a guess of how many of
5 the study participants would agree to comply with what's laid out in the IOM report about
6 ...
7 **K. FOX:** I think it's — you saw that — I think it was 94 percent said that they
8 would allow any other military thing. I think if we had asked the question a little even
9 broader, I think it would still get close to 94 percent saying that they would support it. I
10 think — I think the vast majority would allow their data to be used.
11 **M. STOTO:** And that obviously can only be a guess, but I mean, it's an informed
12 guess. Yeah.
13 **K. FOX:** But it — I really — talking to the guys at the — at the physicals ...
14 **M. STOTO:** Yeah.
15 **K. FOX:** ... that's the impression I got; was that they would allow this to — they
16 would allow their data to be used. I really do.
17 **M. STOTO:** Okay.
18 **P. CAMACHO:** I get that sense from California too.
19 **M. STOTO:** Yeah. I mean, right. Paul, turn your mike on and say that, please.

1 **P. CAMACHO:** As a Committee member, I got that sense from the guys in
2 California when we — when we had the tour there, so ...
3 **M. STOTO:** Right, and so did I. David, did you have ...
4 **D. BUTLER:** This is a topic that is addressed in the report on pages 126 through
5 127 where we're talking about consent. They note that the Cycle 6 consent had a very
6 general question about future use of the — of the materials.
7 And as Colonel Fox indicated, 94 percent of the Ranch Hand subjects, 97
8 percent of the comparison subjects elected the most permissive option. When at our
9 first workshop session, we spoke with Dr. Michalek on this topic. He offered a personal
10 opinion that he thought that a broader permission would've been given if that had been
11 asked at the time.
12 **M. STOTO:** Okay. Thank you. Okay. We have — another issue we have is
13 about external collaborations. I wonder if you're prepared to talk about that now before
14 lunch? Then we'll let you sit down and have lunch after.
15
16 **External Collaborations**
17 **K. FOX:** External collaborations, we have — I'm a little rumpled. Don't copy that
18 — "rumpled." There's three papers in submission to journals from Dr. Frame from
19 Texas Tech concerning sleep. I think we briefed those one or two times ago. Dr.

1 Gough, former member, has asked for data and we have sent his data — sent him data.
2 And he's looking at diabetes and dioxin in Ranch Hand.

3 And then Dr. Stephen Boyle is looking at — he's done some papers already on
4 psychological factors and incidence of coronary heart disease. And he is — we have
5 sent the data to him and we are working with him on that.

6 **M. STOTO:** One name that's obviously not there is Joel Michalek. And I wonder
7 if you can — and I know at one point that he was thinking, hoping to continue to work
8 with the project. And from a scientific standpoint, I mean, it seems reasonable. Can
9 you say something about that?

10 **K. FOX:** Could not agree to working with the outline with it. And he's no longer
11 — he needs to get outside sources to do that kind of work and he doesn't have that
12 access to that. I mean, we attempted at one time and it was unable to get agreement
13 with him. And he's fully employed at another facility at this time.

14 **M. STOTO:** Well, even from the point of view of, you know, papers that are —
15 that result from the, you know, analyses that were started?

16 **K. FOX:** He — it — we attempted and it did not happen.

17 **M. STOTO:** Okay.

18 **K. FOX:** I can't say anything else other than that.

19 **D. JOHNSON:** I'm going to backtrack to ask a question, but we had a discussion
20 a little bit about people agreeing to use the data and there was a general sense that

1 most of them would. But if that — if before the data is actually used, who's going to
2 make determinations?
3 If, I mean, there's — is there going to be individual consents given or is that
4 going to — how is that going to be handled? It might be too much of a detail to talk
5 about right today, but who's going to determine whether or not somebody consents to
6 having their data used for further studies?
7 **K. FOX:** Well, that's what the IOM made the suggestion; is that we send out
8 another informed consent type of paper from us outlining who we think is going to be —
9 who is going to take over this database and then gaining their consent from — to allow
10 that. If they don't allow that, then I would assume that we're going to have to remove
11 that data from ...
12 **D. JOHNSON:** Individually?
13 **K. FOX:** Yes. So we'd have — we're required — if we — this is personally how
14 I'm seeing this process having to happen is we first need to know who's going to take
15 over because you can't write, ask, telling them that somebody's ...
16 **D. JOHNSON:** Okay.
17 **K. FOX:** ... some entity is going to — we need to explain to them who's going to
18 take over and then ask their permission for that. Now that can get pretty difficult by the
19 simple fact that I think we got good access for all the Ranch Hand and the comparisons.

1 I think we have a good access, good addresses, but I think the wives and the children
2 are another entity and all.
3 **D. JOHNSON:** You're asking consent just that the — that it's ...
4 **K. FOX:** Just that it could be ...
5 **D. JOHNSON:** ... the data be shared, not — it's not a blanket consent to use it
6 for whatever study comes along?
7 **K. FOX:** No. Then ...
8 **D. JOHNSON:** It's each individual researcher would then have to get that
9 consent?
10 **K. FOX:** No. Then ...
11 **M. STOTO:** This is spelled out; it's on ...
12 **K. FOX:** Yeah.
13 **M. STOTO:** This is spelled out on page 128, the IOM's recommendations.
14 **D. JOHNSON:** Okay.
15 **K. FOX:** And then ...
16 **M. STOTO:** Yeah.
17 **K. FOX:** ... what would happen then is whoever takes over the database would
18 then have to get consent for — individually for that study.
19 **D. JOHNSON:** Thank you.
20 **M. STOTO:** Okay. Other questions or comments?

1 **K. FOX:** I have one more thing.

2 **M. STOTO:** Oh, okay. Go ahead.

3

4 **Technical Reports**

5 **K. FOX:** And that's just to — the time's limited and so for technical reports, we're
6 doing the report that we just briefed you on. Mortality — we're making a technical report
7 out of that. There was a hypertension paper that we reported about in 2003; unable to
8 get a journal to publish, therefore, we will turn it into a technical report so it's not lost.

9 The checkmark pattern was reported in 1998; again, unable to get a journal to
10 publish, therefore, we will — we've turned it into a technical report. And the same thing
11 goes for the matched analysis of diabetes and herbicide exposure. That was reported
12 to this Committee in 2001 and that will be turned into a technical report. And I believe
13 that's the end.

14 **M. STOTO:** Okay. Thank you. Any other comments or let me ask again
15 whether there's anybody in from the public would like to make a comment? Okay.
16 Going, going, gone, I think is the — so let's do this.

17

Update on the *Nightline* Interview

M. STOTO: We have left on our agenda to talk a little bit about the *Nightline* study and also just to sort of wrap up the Committee's business, further meetings and so on. Anything else going to be on it? So how about if we — if we grab lunch ...

P. CAMACHO: And then I'll throw rocks at Ron.

M. STOTO: ... and then come back to the table and then — and then discuss those two things over lunch, so it's a working lunch.

J. ROBINSON: I have the VHS presentation of *Nightline*. *Nightline* actually sent the original presentation to me.

M. STOTO: I'm inclined not to take the time to watch it to be honest with you.

P. CAMACHO: How long is it?

J. ROBINSON: It's maybe 20 minutes and it actually could be shortened to — you could just hear the experts — Dr. Trewyn and Dr. Schechter — that section.

M. STOTO: You know, but I mean, I'll let the Committee decide. But my sense of this — of the issue is that, you know, Ron made a comment as any citizen in this country is allowed to make on TV; that the TV station represented it the way they chose to represent it, which may not be the way that he intended it. But, you know, it doesn't matter at this stage.

As you see from the correspondence with General Watts, that he sent me a letter complaining about that. And I pointed out in my response that Ron is entitled to say

1 what he — what he — what he wants to say; that that's the way the scientific system
2 works in this country and we should be happy with that; and that I have no control over
3 who's on the Committee in any case or what — or what they do. The Secretary makes
4 the appointments, so I'm not inclined to spend any more time on it personally. Is there
5 anyone that would like to?

6 **P. CAMACHO:** It's his prerogative to say it.

7 **M. STOTO:** Yes.

8 **P. CAMACHO:** Yeah, it's passed. It's ...

9 **M. STOTO:** Okay.

10 **P. CAMACHO:** It's already occurred. I mean, the event's passed. I don't think
11 — it doesn't do that much good. I mean, I think it takes away from what we're trying to
12 do. That's — I don't — you know, 20 minutes, I suppose isn't a lot of time.

13 **M. STOTO:** Right.

14 **RECORDER:** Take it off the agenda?

15 **M. STOTO:** No, we just did it.

16 **RECORDER:** Right. Let the record show that.

17 **M. STOTO:** That was our discussion about it, I mean, unless there's more
18 discussion? And we do have the transcript. I think the transcript was sent out to us in
19 addition, so unless someone strongly wants to ...

20 **P. CAMACHO:** Do you strongly feel we should all watch it?

1 **J. ROBINSON:** I have some strong feelings. I have — I have some strong
2 feelings about the presentation. And I know that Dr. Schechter contacted me for
3 information, and I explicitly told him that we would not want the public to perceive him as
4 the representative for the Air Force, the spokesperson for the Air Force and ...
5 **P. CAMACHO:** He presented himself ...
6 **J. ROBINSON:** Dr. Schechter.
7 **P. CAMACHO:** And he presented himself that way?
8 **M. STOTO:** Turn your mike on, Paul.
9 **P. CAMACHO:** Did he, in your opinion, did he present himself that way?
10 **J. ROBINSON:** He was introduced as a "Air Force Health Study researcher."
11 **R. TREWYN:** That's nothing to do with him.
12 **J. ROBINSON:** Well, Dr. Trewyn was introduced as his title at the university and
13 as well as a member of the Ranch Hand Advisory Committee. So I mean, if you all
14 don't feel it's important to know, you know, in context what he said ...
15 **R. TREWYN:** No. No.
16 **J. ROBINSON:** ... then that's fine.
17 **M. STOTO:** Well, we read the — we read the transcript and he said what he's
18 been saying for 25 years. And if the TV station, you know, presented him as —
19 misrepresented his affiliation, that's their problem. There's no way in the world that

1 they're going to change it. If we got President Bush to send a letter to them, they
2 wouldn't. They're not going to go back and change that.
3 **D. JOHNSON:** I have a question. Does this Committee have a designated
4 spokesperson for the media who we would refer the Committee's position — the
5 Committee's position, not their individual position — but the Committee's position on
6 these issues? Is there a person designated for this Committee?
7 **M. STOTO:** I think that's part of my job as Chair.
8 **P. CAMACHO:** The buck stops there.
9 **M. STOTO:** But if they ever ask me, I would only speak for the Committee. I
10 mean, if — I take that back. I would make clear what — that I would — if I was
11 speaking for the Committee, I would make clear I was speaking for the Committee. In
12 fact, I would avoid speaking as an — as an individual to avoid confusion about whether I
13 — what hat I have on.
14 **D. JOHNSON:** And so preferentially, if somebody were to be approached on this
15 Committee by the media, the appropriate thing to do would be to say, "Our
16 spokesperson for the Committee is the Chair, Mike Stoto?"
17 **M. STOTO:** Right.
18 **D. JOHNSON:** Okay.
19 **M. STOTO:** Or on procedural matters, I would refer to Len as the government ...
20 **P. CAMACHO:** Yes.

1 **M. STOTO:** ... official in charge or whatever that title is.

2 **L. SCHECHTMAN:** And for the record, that's Dr. Schechter, not Schechtman
3 that's being referred to.

4 **R. TREWYN:** Let Dr. Schechtman do it.

5 **M. STOTO:** Okay. Well, then let's break, get lunch.

6 **P. CAMACHO:** How about we can show it while we're having lunch?

7 **M. STOTO:** If — do you want to watch it?

8 **P. CAMACHO:** Better than that she's going to be upset. I'm rather — how about
9 this, Ms., if we — if we show it while people are having lunch, Ms. Robinson? Show it
10 while people are having lunch? Is that good enough? I don't ...

11 **J. ROBINSON:** It's your decision.

12 **P. CAMACHO:** Well, we'll see it and while we're having lunch. How's that for a
13 compromise?

14 **M. STOTO:** Yeah. Does — is that — anybody would like to view it? Okay.
15 Let's have — let's have lunch. We'll come — we'll come back in about 15 minutes and
16 continue our meeting at that — at that point. And so we're not going to — we're not
17 going to view it. We've had an opportunity to review the transcript and we're not going
18 to view it.

19 **[LUNCH 11:58 A.M.-12:18 P.M.]**

RHAC Business

M. STOTO: Okay. Can we get started again while people are munching on their cookies? Oh, wait a minute. Wait until David comes back. Okay. What happened to Paul?

R. TREWYN: He heard you wanted to start so he ran.

M. STOTO: Well, let me — let me begin by — where we left off with respect to the letter to the Secretary. And let me just say again what I have in mind to put in that letter and let — give people a chance to say whether that should be changed based on what — anything we heard later in the — in the morning.

So first thing that I think that I'll do is — I mean, this'll be a letter from me, not from — not on FDA letterhead because that's not allowed and not on Rand letterhead because this is not something I'm doing as part of my job there. They've got lots of other connections there, so this is a personal letter from me. But I'll represent myself ...

R. TREWYN: As the Chair.

M. STOTO: ... as the Chair of the Committee and say that this — that the Committee agreed to this at its meeting on February 27th. So then the first point is to remind the Secretary about the communications we've had in the past, particularly the ones that urge that something be done about maintaining and — the information in the study.

R. TREWYN: And I assume that was done the same way?

1 **M. STOTO:** That — the other one, we think so.

2 **L. SCHECHTMAN:** Yeah.

3 **M. STOTO:** Right. Well, Bob Harrison actually wrote it on University of
4 Rochester ...

5 **R. TREWYN:** That's right.

6 **M. STOTO:** ... letterhead.

7 **R. TREWYN:** Okay.

8 **M. STOTO:** But I absolutely can't do that on Rand letterhead. So we're trying to
9 get a copy of — Kim has gone to get a copy of the previous letter I wrote and we'll be
10 consistent with that, so consistency is the right thing. Okay.

11 So the first substantive point is to remind the Secretary of the past
12 communications, particularly the ones that we've had supporting the idea of the need to
13 maintain access to the data and specimens at a minimum and the value of them; and
14 pointing out that because this study is scheduled to end on September 2006 with no
15 money for continuation that time is of the essence; and that we're responding nearly
16 immediately to the IOM's report.

17 **P. CAMACHO:** In fact, to copy the gentleman was sitting there — to copy what
18 he said, there was a very even shorter time frame.

19 **R. TREWYN:** Turn your mike on.

20 **M. STOTO:** Turn on your mike.

1 **P. CAMACHO:** The gentleman that spoke here earlier and provided an e-mail
2 from the Air Force. But it's about the Air Force considers that time of who decides
3 where to go, how do they decide, how will the transfer take place, who will pay — it's a
4 very short time period here. I believe ...
5 **K. FOX:** Two months.
6 **P. CAMACHO:** ... he said two months was the maximum. So that's kind of ...
7 **M. STOTO:** Okay.
8 **P. CAMACHO:** That has to be expressed, how fast. It's not even September.
9 **M. STOTO:** Okay. I'll add that. The second point is essentially to endorse the
10 parts of the — of the committee's — IOM committee's summary that I identified earlier,
11 which are — I mean, I'll just — I'll just read them out here again just for the — for the
12 record. And if you want to look, actually copy them down, they're on page 4 of the ...
13 **RECORDER:** In the box.
14 **M. STOTO:** ... in the box. "There is scientific merit in retaining and maintaining
15 the medical records, other study data and laboratory specimens collected in the course
16 of the Air Force Health Study after the study's currently scheduled termination date."
17 The sentence actually goes on, but I'm going to stop the quote at that point.
18 And the next one, I'm actually going to combine two studies — I think this point is
19 what the IOM had in mind — to say, "Further study of the AFHS medical records, other
20 study data and laboratory specimens should be accomplished by making these

1 materials available for research via a custodian that takes an active role in fostering use

2 of the assets." That sentence ends there and I'll end at that point, so I'll basically quote

3 the report.

4 **P. CAMACHO:** There has to be a custodian? We have to — some kind of

5 custodian has to come forward?

6 **M. STOTO:** Right.

7 **P. CAMACHO:** A custodian has to come forward in the time — again, I'm

8 concerned about the time here.

9 **M. STOTO:** Well, there's nothing we can do about the time. We can, you know,

10 just get this out quickly ...

11 **P. CAMACHO:** Yes.

12 **M. STOTO:** ... and point out that that's important. So we're basically saying

13 we're endorsing those two statements from the report as being consistent with what

14 we've been saying along and that's — and then refer back to these letters, and the

15 minutes of the meeting and so on.

16 And then the third point will be that — say that "the IOM lays out some criteria for

17 who that custodian should be and how they should operate. And we are not prepared

18 to make recommendations about that at this time, but we are willing to work with the Air

19 Force, Department of Veterans Affairs and other relevant government agencies to

1 review plans and options along those lines. And we'll do so in a timely way given the
2 urgency of the matter."
3 And then well, you know, actually there's another part of the second point that I
4 had marked down, but forgot to say here. The second point is that "we're endorsing
5 those two statements, and that the action there is that we urge the Secretary to do so as
6 well and to take steps to see that these recommendations are carried out."
7 **RECORDER:** Proactive steps.
8 **M. STOTO:** Proactive steps, very good. Okay. "Proactive," that means within
9 the next months or — okay. Is that reasonable?
10 **P. CAMACHO:** It is for me.
11 **M. STOTO:** You know, could you possibly — since you've drafted it all, just e-
12 mail me that and then I'll — and then I'll craft it into a letter form. Okay. Okay, and so
13 are there other unresolved issues that people want to bring up or new issues? Kind of
14 hard at — after 25 years to have new issues. And what about that comprehensive
15 report? We made recommendations on that: mostly accepted, some — are we going
16 to see that again before it's published or would that make sense for us to do that?
17 **K. FOX:** No, you will not see it before it gets published. We're — we've put it
18 back on contract to get those changes re-instituted and to get the changes put into the
19 — into the report. But there was no — there's no plan for you guys to look at it again.
20 **M. STOTO:** So could we at least see it before it gets published?

1 **K. FOX:** We'll send it to you. If you want it, we'll e-mail it to you.

2 **M. STOTO:** Yeah. I think that would be — that would be good.

3 **P. CAMACHO:** And when's the Chapter 16 going to be finished? I'm always

4 concerned about those ...

5 **M. STOTO:** Turn your mike on.

6 **P. CAMACHO:** I wanted Chapter 16 because it has my favorite issue.

7 **K. FOX:** I — yes.

8 **P. CAMACHO:** It just — of course ...

9 **M. STOTO:** I think — I think you raised this issue with your mike off last time.

10 That's why I've got to — it didn't get handled properly.

11 **P. CAMACHO:** All right, so we'll get it in some kind of time?

12 **K. FOX:** Some — when — I'm not sure we have any dates as to when we

13 expect it to be finalized, but yes. We will — once we're done with it, we'll let you guys

14 see it again.

15 **M. STOTO:** Chapter 16?

16 **K. FOX:** No. We'll give you the whole report.

17 **M. STOTO:** For the whole — the whole thing.

18 **P. CAMACHO:** Works for me.

19 **M. STOTO:** Okay. Okay.

1 **K. FOX:** Just with the realization that there's not going to be any changes; that
2 once you get it, there's not any — there's not going to be an opportunity to change
3 anything, but you will get it before it gets published.
4 **P. CAMACHO:** So we can complain.
5 **M. STOTO:** Well, so in case anybody asks us about it, we know what they're
6 talking about somewhat.
7 **K. FOX:** Did you have — yes.
8 **M. STOTO:** Yeah.
9 **K. FOX:** Did you have knowledge of it? Yes.
10 **M. STOTO:** Yeah. Okay. I mean, that seems reasonable. And so given all that,
11 I mean, it seems to me that the main thing that remains on our agenda for the rest of
12 our Committee's existence is to — is follow up to the IOM report. And that is something
13 that goes beyond our more typical role of advising the Air Force, but something that
14 where we think we may be able to make a contribution.
15 **P. CAMACHO:** Does this Committee sign off on the final report?
16 **M. STOTO:** Go ahead.
17 **P. CAMACHO:** Do I have to ask that?
18 **M. STOTO:** You have — you have to ask the question on the microphone.
19 **P. CAMACHO:** Does the Committee have an obligation to sign off on this ...
20 **M. STOTO:** No.

1 **P. CAMACHO:** ... report?

2 **K. FOX:** No.

3 **J. ROBINSON:** No.

4 **P. CAMACHO:** Okay.

5 **M. STOTO:** No. We don't sign off on anything. I mean, you know, we're an
6 advisory committee. We give our advice and they take it or leave it as they see fit.

7 **L. SCHECHTMAN:** And in this case, the advice is given to the Secretary of
8 HHS.

9 **M. STOTO:** I think he — I think Paul was asking about the comprehensive
10 report.

11 **K. FOX:** Yeah.

12 **L. SCHECHTMAN:** Right. I'm sorry; go ahead.

13 **M. STOTO:** Don't worry — don't worry about it.

14 **L. SCHECHTMAN:** Oh.

15 **M. STOTO:** Yeah. We — okay. So then it seems to me — again, let me open
16 this for discussion — that we have resources for one more meeting. It needs to be
17 before September for a couple of reasons: one is because the money runs out for us at
18 the end of September, but more importantly, the decisions have to be made before the
19 end of September as well. And then so the question is when would be the best time ...

20 **D. JOHNSON:** What decisions?

1 **M. STOTO:** What to do with the data and the specimens.

2 **D. JOHNSON:** The end of September is too late, isn't it?

3 **M. STOTO:** Oh yeah, right. I said for a number of reasons we have to do it
4 before September, maybe substantially before September. Do you have something to
5 add?

6 **W. MURRAY:** Well, I was just going to ask the question.

7 **M. STOTO:** Speak to the mike, please.

8 **W. MURRAY:** I'm not sure if this — it's on. Okay. I just wanted to ask the
9 question in terms of your Committee as to what you view as being your role in making a
10 recommendation on whether the disposition of these samples and all should go to and
11 how you — anyway, if that's the key decision that needs to be made?

12 In terms of us going forward, from my perspective, speaking on behalf of kind of
13 the Air Force Surgeon General's Office, I think to facilitate a transition, we need some
14 sort of guidance within the next two months probably so that we have at least six
15 months to reasonably work the transition, work with Congress to have a funding
16 strategy in mind so that they will make potentially recommendations in terms of an
17 appropriation for '07 to whatever gaining agency is going to obtain these samples.
18 None of that can be done if we wait until August, so ...

19 **M. STOTO:** Right. No, I — no, I understand that your question was what's our
20 role?

1 **W. MURRAY:** Yeah.

2 **M. STOTO:** And this is where we're on thin ice because, you know, our mandate
3 doesn't clearly give us a role here, and although I think that there are people who would
4 like to hear what we say about this. And of course, we can't get anybody to step up to
5 the plate and want to take this on and so on. We're just not in a position to do that.

6 What I would suggest is that we offer to review plans put forward by any agency
7 about what to do here. I mean, the IOM committee laid out some options, laid out some
8 strengths and weaknesses of those — of those various options and that we — I think
9 the way that we can be most helpful would be to review some version of that.

10 Maybe it would be the VA that — the Department of Veterans Affairs that does
11 something, but I think we have to have something to respond to is the bottom line. And
12 you're absolutely right, the sooner the better, but that's not our schedule. We can't ...

13 **P. CAMACHO:** Can we make a suggestion to the Secretary?

14 **M. STOTO:** You can't make any suggestion unless you speak on the
15 microphone.

16 **P. CAMACHO:** I don't know. Can you make a suggestion to the Secretary that
17 he urge the Committee on Veterans Affairs to have a hearing on this? Can we do that?
18 I mean, I don't know if that's in our province.

19 **M. STOTO:** Which Secretary?

20 **P. CAMACHO:** The Secretary who's getting that letter.

1 **M. STOTO:** Of Health and Human Services?

2 **P. CAMACHO:** Yes, that he pass on ...

3 **M. STOTO:** Yeah.

4 **P. CAMACHO:** ... pass the urgency on. He can pass the ball, but he should
5 send a letter to the House and Senate Veterans Affairs Committee and urge them to
6 have a hearing on this immediately, I mean, if — by March. Put it in his hearing
7 schedule because the hearing schedule's being formed now if it isn't already formed, so
8 it has to be ...

9 **M. STOTO:** I guess I would be reluctant to say something as specific as that
10 given that it's different agencies and different committees. And that really isn't our
11 business. That's a political issue. It's not a scientific issue. I think that the scientific
12 issue is that if this is to be accomplished, it needs to be accomplished quickly and that's
13 what — I mean, that's clearly a scientific point of view. And that's probably as far as we
14 can go. Ron?

15 **R. TREWYN:** And I would, again, since Jay isn't here and always carried the
16 original law with him, I know this Committee though came into existence by the
17 mechanism of HHS making the appointment so we would be advisory in this particular
18 study. And since I always advocate, you know, ask forgiveness after the fact and
19 permission up front, you're going to get farther, I think, for us to push the envelope as
20 far as we can, again, because of the time-line here.

1 I mean, we have to, I think, very carefully push as hard as we can that this needs
2 to be — we didn't — at least have this collective voice added to the others. I'm sure
3 IOM is going to make it very clear and has — or the urgency. But again, if it doesn't get
4 out and something doesn't happen quickly because two months, again, with Congress
5 not dealing with this year's money; they're looking at what to do next time around.
6 Well, the study's done this year. So how do you come up with enough money
7 now to transition this or to at least keep the plugs in and have the funding go to the folks
8 that currently have it until that transition can take place? There has to be some pretty
9 fast action, so I think we need to push as hard as we can.
10 **M. STOTO:** Yeah, I mean, I don't doubt anything about what you're saying about
11 the urgency. I just think there's a limit to what we can do as a scientific advisory
12 committee that advises the Secretary of Health and Human Services. Sandy?
13 **S. LEFFINGWELL:** One way you can sometimes pull this off is by backing into
14 the problem. Volunteer, for example, to schedule another meeting on the Ides of March
15 or pick a date, any date, to consider what he's come up with or what Congressional
16 action may be underfoot might determine the date we next meet. But put it in that
17 context, suggest, you know, this, that and the other: "We don't know it's your problem,
18 but we'd be glad to meet you on thus-and-such a date to have — help you work it out."
19 **M. STOTO:** Meet the Secretary of Health and Human Services?
20 **S. LEFFINGWELL:** Yeah. In the letter to the Health Secretary ...

1 **M. STOTO:** Yeah.

2 **S. LEFFINGWELL:** ... indicate the Committee would be willing to meet again on
3 such-and-such a date to consider what solutions have been worked out in Congress or
4 in Cabinet to make this happen.

5 **P. CAMACHO:** Well, he said ...

6 **M. STOTO:** Yeah. I guess — I guess I don't think that the Secretary of Health
7 and Human Services is going to do anything about this, but that the value of our letter is
8 the cc's to the Secretary of Veterans Affairs. I mean, that's a — that's a guess. And
9 that the Secretary is like Ron said; it's kind of like piling on to what other people do. By
10 ourselves, we're not going to get this. But having a letter from us would be something
11 that Secretary — what's his name now ...

12 **P. CAMACHO:** Nicholson.

13 **M. STOTO:** ... Nicholson can use to move it ahead or Congressional staff can
14 use.

15 **P. CAMACHO:** Can we cc Congressional staff?

16 **M. STOTO:** Sure, can use to move it ahead. But they've got to take the lead, I
17 think. I'm willing to be contradicted on that — a political person.

18 **P. CAMACHO:** Yeah, that's why I — cc to the staff.

19 **M. STOTO:** Right.

20 **P. CAMACHO:** And especially to somebody on Lane Evans's staff.

1 **M. STOTO:** Yeah. I mean, putting money in — putting — getting money up on
2 the table is a political issue. And, you know, we can just say from a scientific
3 standpoint, we think that there would be value in doing this and that it needs to be done
4 fast or it can't be done at all. But deciding who should do it is just clearly not in our ...
5 **P. CAMACHO:** That's right.
6 **M. STOTO:** ... in our — in our mandate.
7 **P. CAMACHO:** That's right.
8 **S. LEFFINGWELL:** Can you quantify it? I mean, how fast is "fast?"
9 **P. CAMACHO:** Yeah. We should use the two months ...
10 **D. JOHNSON:** Two months.
11 **P. CAMACHO:** ... window as he suggested.
12 **M. STOTO:** So we can — we can say that this — the Surgeon General of the Air
13 Force believes it needs to be done within two months.
14 **P. CAMACHO:** Yes.
15 **M. STOTO:** Yeah.
16 **P. CAMACHO:** Is that correct, sir? The Surgeon General of the ...
17 **W. MURRAY:** Well, on my behalf, will not speak for the Surgeon General, but
18 my belief is that it would have to be done very soon if no other reason from my
19 responsibility for funding the program. I need to go to the Air Force's corporate process
20 through the Research Development and Technology Panel within the next few weeks to

1 request unfunded requirement for additional ‘06 funding if we’re going to facilitate any
2 kind of transition, which means I have to quantify what those additional costs are
3 beyond what I already have programmed for this program.

4 And without additional funding — we don’t have the funding to facilitate the
5 transition of this program at this point. So I need to go in with no promise at all really
6 right now; to go to the corporate process now and say, “Here’s what I think realistically
7 we need — 250,000, 300,000 or so — to keep us alive until such time as we can make
8 this transition occur.” If that doesn’t happen, there will be no transition because there
9 will be no funding available.

10 **M. STOTO:** Well, we can — we can write in our letter that we were advised by a
11 representative of the Surgeon General of the Air Force at our meeting, which is now
12 done ...

13 **W. MURRAY:** Yes.

14 **M. STOTO:** ... is that time is of the essence.

15 **W. MURRAY:** Yes, that is a reasonable statement.

16 **M. STOTO:** And maybe even say weeks to months.

17 **W. MURRAY:** Right.

18 **P. CAMACHO:** And now I’m happy.

19 **M. STOTO:** Okay. It couldn’t hurt to say that. I don’t think — I’m not sure if it’s
20 going to make a difference, but that ...

1 **P. CAMACHO:** Understood. Understood.

2 **M. STOTO:** Yeah.

3 **P. CAMACHO:** But yeah, now I'm a happy camper because I'm — now I'm a
4 happy camper because I'm afraid if we leave it — any vagary about the time-line,
5 they're going to say, "We didn't know. You should've been more specific" — meaning
6 the Committee.

7 I just don't want the community out there, whether we want it or not, whether we
8 accept it or not, whether it's justified or not, the veteran's community out there, all those
9 thousands of veterans out there, millions of veterans out there and all those veterans'
10 associations are going to say, "You guys on the Committee had an obligation to let
11 everybody know."

12 Whether it's true or not true, doesn't make a difference. That's the reality and I'm
13 serious about that. I'm 100 percent convinced that that's the case. You can say, "But
14 that's not justified;" too bad. That's the same message I'm delivering to ourselves that I
15 told you.

16 **D. JOHNSON:** So I think it's important based on what you just said that we are
17 clear as to what we can do and can't do. And I think that's been made clear today that
18 we can — we can advise scientifically that it's valuable data that should be available for
19 research.

1 Is there anything else this Committee — anybody on this Committee know of
2 anything else that we are capable of doing to move this forward other than sending a
3 letter supporting basic findings of IOM as far as continuing — or having it available for
4 further research?

5 **M. STOTO:** And offering to help to vet the ...

6 **P. CAMACHO:** Yeah.

7 **M. STOTO:** ... options in the future.

8 **P. CAMACHO:** We're going to cc the veterans' organizations?

9 **M. STOTO:** Yeah. No, I just — Kim found a copy of the letters that Bob Harrison
10 and I have sent. The first one is on University of Rochester letterhead. The second one
11 says "University of Rochester," but it's not quite letterhead. Then there's one from me
12 that is on HHS letterhead.

13 **L. SCHECHTMAN:** Or FDA.

14 **M. STOTO:** Public Health Service, Food and Drug Administration, yes. So I
15 guess ...

16 **L. SCHECHTMAN:** We lied.

17 **M. STOTO:** Can it be done that way or does it — obviously, it can be. Maybe ...

18 **R. TREWYN:** It was once.

19 **M. STOTO:** Yeah.

20 **L. SCHECHTMAN:** We'll check into.

1 **M. STOTO:** So, I mean, if in fact it can come — actually, and this one was
2 written to Principe, not to ...
3 **R. TREWYN:** Not to HHS.
4 **M. STOTO:** Not to HHS.
5 **R. TREWYN:** Wow, proving you're willing to — you're just willing to push the
6 envelope, so good for you.
7 **M. STOTO:** Yeah. Okay. I mean, and so if we can — we — so we'll — maybe
8 we should send it to both of them.
9 **P. CAMACHO:** Yeah, good idea.
10 **M. STOTO:** Yeah, and members of the — ranking members of the ...
11 **P. CAMACHO:** Committees.
12 **M. STOTO:** ... House and Senate Committees or cc.
13 **P. CAMACHO:** Yeah, they may have changed since then.
14 **M. STOTO:** Sure, of course. Yeah.
15 **L. SCHECHTMAN:** Okay.
16 **M. STOTO:** Yeah.
17 **P. CAMACHO:** Yeah.
18 **M. STOTO:** Okay, so we'll push the envelope.
19 **L. SCHECHTMAN:** Just so we — we're all on the same page, the goal then is to
20 generate this letter between today and tomorrow literally. And I heard you say that you

1 will circulate the letter to the Committee and we would request that we receive your
2 feedback by Thursday the latest so that the letter can go out on Friday.
3 And we're really — we're trying to get this thing out and done quickly so that we
4 can't look like we've been dragging our feet when in fact we — and if we're dragging,
5 we don't — well, we don't want to be perceived as the "foot draggers."
6 **P. CAMACHO:** Right.
7 **W. MURRAY:** If I could just request that whatever letter is sent out that at least
8 we get a blind copy for the Air Force Surgeon General's Office?
9 **M. STOTO:** Oh sure.
10 **W. MURRAY:** That'll help us because General Taylor has expressed his interest
11 in going out to the committees as well and that will help us to — he wants the
12 affirmation that, yes, this Committee, I believe can give to him the assurance that, yes,
13 this is viable data and that it is worth proceeding with trying to keep these data. And
14 that will give me the basis then to recommend to him some next steps going forward to
15 also further back up what your Committee ...
16 **M. STOTO:** Well, maybe the — we should write the letter to General — what's
17 his name?
18 **W. MURRAY:** General Taylor.
19 **M. STOTO:** General Taylor.
20 **K. FOX:** No, I don't think so.

1 **W. MURRAY:** No, I don't think that's the right course.

2 **K. FOX:** I think who you're going for is the ...

3 **M. STOTO:** Okay.

4 **K. FOX:** It's the person that's — people that are going to get the — be the
5 custodian, not the current one.

6 **M. STOTO:** Okay. Well, we'll certainly cc General Taylor as long as you give his
7 address to somebody over here so they know how to — how to do it. Okay. Is General
8 Taylor Surgeon General?

9 **W. MURRAY:** Yes.

10 **M. STOTO:** Yeah.

11 **W. MURRAY:** He's the Air Force Surgeon General.

12 **M. STOTO:** Okay. The other issue is when should we meet again? And I guess
13 I'm not quite so clear about that. I mean, obviously, the sooner the better, but not so
14 soon that we don't have anything to discuss.

15 **P. CAMACHO:** In Hurley Burley's time.

16 **M. STOTO:** Right.

17 **P. CAMACHO:** Ides of March?

18 **M. STOTO:** No, if we — if we — if we — if we say any date, you know, that's
19 soon, there'll be nothing to talk about. It'll be like we will have a — had a chance to
20 read it in detail, but there won't be any specific proposal. I don't see that we could — I

1 don’t think we have anything to add to what the IOM has done in terms of substance.
2 What we can do is to say how does this apply to some proposal on the table.
3 **P. CAMACHO:** So what do you think or is this ...
4 **R. TREWYN:** We may just have to do this on an add-needed — as-needed
5 basis; that if something comes up, if there’s an issue that this group could bring its voice
6 to that would — might make a difference. So once this letter has gone out, if it — if it
7 hits a chord with some folks and they want follow-up, this would be a group that we
8 could offer to, you know, meet with them, whoever that might be.
9 And I think if the cc list is long enough because it really is going to — this is going
10 to be a political decision and it may just move along swimmingly without us. And in
11 which case, we wish them well.
12 **P. CAMACHO:** I don’t want to — I don’t want to be, you know — do we have —
13 do we have any kind of closing issues that we have or do we just fade away?
14 **L. SCHECHTMAN:** A closing ceremony?
15 **P. CAMACHO:** Closing ceremony, anything. I mean ...
16 **L. SCHECHTMAN:** Yes.
17 **P. CAMACHO:** ... is there some kind of a — is there some kind of an issue here
18 or do we just fade?
19 **L. SCHECHTMAN:** The corpses rot.

1 **M. STOTO:** Well, I think that maybe, you know, we should go down to San
2 Antonio and kind of look through the specimens.
3 **P. CAMACHO:** Well, I don't know.
4 **M. STOTO:** But I think that you're right.
5 **P. CAMACHO:** A closing letter?
6 **M. STOTO:** This will be our — the next meeting will be our last meeting, and we
7 should somehow recognize that that's the end and ...
8 **P. CAMACHO:** Yeah.
9 **M. STOTO:** ... I'm not sure what that ...
10 **P. CAMACHO:** Send a letter to — another final closing letter to the world.
11 **M. STOTO:** What you're saying is not being recorded.
12 **P. CAMACHO:** And have some final letter about — I don't know. Do we — do
13 we — do we, in a letter or a short letter, say all the — give a quick history of the
14 Committee in a sense, a thumbnail history of the Committee?
15 **M. STOTO:** No.
16 **P. CAMACHO:** Do all the things that ...
17 **M. STOTO:** No, there's no way to do that in a short letter.
18 **P. CAMACHO:** Yeah.
19 **M. STOTO:** Nor do I think there's much value from that. David?
20 **P. CAMACHO:** Fade away.

1 **S. LEFFINGWELL:** A tentative date in April might be something that we could
2 dodge if we decided we don't really have anything to talk about, and yet, might push the
3 agenda, indicate we could discuss this. We've tentatively scheduled a meeting.
4 **M. STOTO:** That sounds like a good idea to me; is to choose a date and that
5 may or may not, but it may push, move something along. And we could always move it
6 back. David?
7 **D. BUTLER:** If this factors into the Committee's decision-making, the National
8 Academies' contract for this study runs through 30 April of this year, which means I
9 have the ability to expend funds to bring committee members to talk to people and the
10 like through that date, but not after that — after 30 April, if it might factor into the
11 Committee's decision-making.
12 **M. STOTO:** Okay. So, yeah. If we — if we schedule something for —
13 tentatively schedule something for the last half of April, if the VA could sort of say,
14 "Here's what we think we might do," or somebody else, and then we could hear what
15 the folks from the IOM say about that, and then we could develop our own opinion about
16 that, I mean, that the end of April seems like a reasonable time to — for to push the
17 agenda. I think that's a — that's a good — that was helpful, David. Other — does that
18 make sense? I mean, I think that's consistent with what Sandy was saying. Okay.
19 **D. JOHNSON:** That's okay. I just wanted for NIH — so if it worked the way it
20 should play out is the Congress has asked NIH to do this study. And it's Institute — I'm

1 sorry — Institute of Medicine do this study on whether or not it should move forward,
2 your recommendations would go back to Congress and they would then make a
3 decision upon this as to what is going to happen? That's the way it's supposed to
4 happen, only the problem is timing; that it won't — that it won't happen quick enough for
5 the timing? Is this what we're dealing with here?

6 **M. STOTO:** Well, it's hard to say what's supposed to happen because ...

7 **P. CAMACHO:** That wasn't articulated.

8 **M. STOTO:** That's it; that it was — I'll say it since Paul didn't speak to the
9 microphone. Paul said that it was not articulated in the legislation and there's, I mean,
10 there's nothing in the original call for the study about what happens at the end nor in our
11 charge.

12 I mean, it seems to me that the most likely thing to — that will happen is that the
13 Department of Veterans Affairs will see the need to do something and will take the —
14 take the next steps, but that they're not required to do that and nor is Congress required
15 to do anything about it either.

16 **D. JOHNSON:** And it is, I mean, I think it's apparent to everybody here there's a
17 gap. There's a gap that we've done all we can as a Committee and IOM has done what
18 they're supposed to do, but there seems to be a lack of a place to move this forward.

19 **M. STOTO:** Right. Manny?

1 **M. BLANCAS:** I have a — I have an extract from the actual legislation if you'd
2 like to see it, sir?
3 **M. STOTO:** The — which legislation?
4 **M. BLANCAS:** The original Veteran's Benefit Act of 2003. It says the report will
5 be submitted ...
6 **RECORDER:** Sir, I have got to have you on mike. I've got to record every word.
7 **M. BLANCAS:** ... okay, to the Secretary and Congress, the report.
8 **M. STOTO:** Okay.
9 **P. CAMACHO:** The Secretary is on there.
10 **M. STOTO:** So, and I presume you've done this? You've submitted the report to
11 the Secretary and the Congress? Dr. Butler said yes. Okay, but that doesn't say that
12 they had to do anything about it.
13 **M. BLANCAS:** But it also said — you know, they said what they were going to
14 do two years ago.
15 **P. CAMACHO:** Right, the ball's in their court.
16 **M. STOTO:** Yeah. Okay. So I mean, I like the idea, you know, based on what
17 Sandy said and what David said; that we try to find a date in ...
18 **P. CAMACHO:** Third or fourth week ...
19 **M. STOTO:** ... the third or fourth week of April and that we try to use that to force
20 a decision. We're not going to hold our breath if it doesn't happen, but maybe it will.

1 And we could — we could add — we could add that to the — to the — to the letter as a
2 sign of urgency.
3 **P. CAMACHO:** Yeah.
4 **M. STOTO:** Okay. Should we look at dates now?
5 **L. SCHECHTMAN:** Yeah.
6 **M. STOTO:** So that would be ...
7 **L. SCHECHTMAN:** The end of April doesn't — there are conflicts there with
8 other meetings. May — the week of May 1st is as close to the end of April as possible.
9 **P. CAMACHO:** He's got to — he can only go to April 30th.
10 **M. STOTO:** Yeah.
11 **R. TREWYN:** If we're bringing anybody in or if we need to, for any members of
12 the IOM committee ...
13 **P. CAMACHO:** Right.
14 **R. TREWYN:** ... that has to be done before the end of April.
15 **L. SCHECHTMAN:** Well, okay. Then the latest in April that we don't have other
16 agency meeting conflicts that we're involved in is April 10th through 12th. And that's a
17 week earlier than the third week in April obviously.
18 **P. CAMACHO:** Really?
19 **M. STOTO:** How does that — how does that date look to people?
20 **L. SCHECHTMAN:** 10, 11, 12?

1 **P. CAMACHO:** That's bad; 9?

2 **L. SCHECHTMAN:** Nine?

3 **M. STOTO:** Nine is Sunday.

4 **L. SCHECHTMAN:** Nine is a Sunday.

5 **P. CAMACHO:** Or 10?

6 **L. SCHECHTMAN:** Ten is a Monday.

7 **M. STOTO:** Ten is a Monday.

8 **P. CAMACHO:** Ten — I could do 10; 11, 12 and 13, I'm at the Carlyle.

9 **D. JOHNSON:** Tenth of April?

10 **M. STOTO:** Yeah, Monday, April ...

11 **S. LEFFINGWELL:** Yeah, the 10th of April would be good.

12 **M. STOTO:** Okay.

13 **S. LEFFINGWELL:** And that's tentative if we ...

14 **M. STOTO:** Right.

15 **S. LEFFINGWELL:** ... have to go past the 1st. Understanding we won't have
16 some resources available, we can't.

17 **L. SCHECHTMAN:** Okay. Now just trying to think, if nothing moves forward
18 based upon our ...

19 **P. CAMACHO:** Initiative.

1 **L. SCHECHTMAN:** ... efforts, our initiative, then we're obviously at liberty to
2 cancel that meeting ...
3 **P. CAMACHO:** Yes.
4 **L. SCHECHTMAN:** ... or postpone it to some time in July or August prior to the
5 termination of the September 30 ...
6 **P. CAMACHO:** Yeah.
7 **L. SCHECHTMAN:** ... end date.
8 **P. CAMACHO:** What are we going to do then at the last meeting? That's what I
9 meant. Is there ...
10 **M. STOTO:** Well ...
11 **P. CAMACHO:** We have a closing ceremony?
12 **M. STOTO:** No, the ...
13 **P. CAMACHO:** A dinner party?
14 **M. STOTO:** The substantive topic that I have in mind would be to react to
15 proposals for what might be done. And that could be, you know, a proposal that the
16 group in Seattle take it on, that the group in Massachusetts take it on, that the MFUA
17 take it on and someone else take it on.
18 And, you know, we could look at it and, you know, in terms of what did the IOM
19 say about this, and what we think about this and so on. We can only be reactive. We
20 can't go out and, you know, scare somebody up to do it and so on.

1 **P. CAMACHO:** Are we going to get the copies of the letter ...

2 **L. SCHECHTMAN:** On the mike.

3 **P. CAMACHO:** ... in a week?

4 **L. SCHECHTMAN:** On the mike.

5 **P. CAMACHO:** Copies of — if we get copies of the letter and we think of people
6 to cc, can we do that?

7 **K. FOX:** It's not on the mike.

8 **M. STOTO:** You're not on the mike.

9 **P. CAMACHO:** Do I have to be on the mike?

10 **M. STOTO:** Yes.

11 **P. CAMACHO:** So when we get copies of the letter, can we also cc people we
12 think might be worthwhile to cc?

13 **M. STOTO:** Sure.

14 **P. CAMACHO:** Are we free to do that?

15 **M. STOTO:** Sure. You should; that's part of your job.

16 **P. CAMACHO:** Good.

17 **L. SCHECHTMAN:** Also, if in fact, Dr. Butler, for example, was not available
18 after April 30th because of restrictions that we've been made aware of, perhaps as a
19 Committee we could still invite him as a guest to a later meeting beyond April 30th. If
20 that has to happen, we would be interested in your ability to accept such an invitation.

1 **D. BUTLER:** I can't expend funds to bring committee members to a meeting
2 after the end of April. I can either obtain internal permission or use my own time to
3 attend a meeting thereafter.
4 **M. STOTO:** Or we can also, you know, invite Dr. Tollerud to come on his own
5 too. And we'd have to pay for him rather than the IOM pay for it, but we can do that or
6 other committee members.
7 **D. BUTLER:** Right.
8 **M. STOTO:** But we should try to do it — yeah. Okay. Does that — does that
9 seem reasonable?
10 **P. CAMACHO:** Yes, it does.
11 **M. STOTO:** You guys have anything to add?
12 **J. ROBINSON:** No sir.
13 **K. FOX:** No.
14 **M. STOTO:** Okay. Do we have any other business?
15 **L. SCHECHTMAN:** No.
16 **M. STOTO:** I don't — I don't — I don't think so.
17 **L. SCHECHTMAN:** I know we've covered it all.
18
19

Closing Session

M. STOTO: I think we were efficient. We got a lot done today. Want to thank the Committee members for their participation; the Air Force and — for the work they've done preparing too; especially the IOM staff and Dr. Tollerud; and of course, Len and Kim for organizing us. And we will get out a draft of the letter for the Committee tomorrow. Okay. So we're adjourned and I'll turn off my mike.

[ADJOURN 1:59 P.M.]

CERTIFICATION

State of Georgia)
)
County of DeKalb)

I, Nadine Rivera, do hereby certify that the foregoing transcript, consisting of pages 1–151 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 11th day of April, 2006.

____

Nadine Rivera
My Commission Expires: April 1, 2006

[Seal]