MEETING OF THE NATIONAL BIOETHICS ADVISORY COMMISSION
NBAC
GENETICS SUBCOMMITTEE

DAY 2

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EBERLIN REPORTING SERVICE
14208 Piccadilly Road
Silver Spring, Maryland 20906
(301) 460-8369

I N D E X

P R O C E E D I N G S

DR. MURRAY: Is Henrietta coming?

Jim, would you begin, begin first this morning?

And I should-- I would give you a lengthy introduction, but I wouldn't quite know what to say. Just I can say this much; that, to put it in context, we have felt as a subcommittee that it was very important to know something about how the American public thinks about and feels about their tissue samples.

And we decided to pursue the information in that realm by having a series of things which have alternately been described as "focus groups" and "mini-hearings." We are less interested in the label, but we are very interested in finding out though what people, how people regard their tissue samples and what happens to them and what is done with them.

And Dr. Wells, from the Center for Health Policy Studies, Henrietta Hyatt-Knorr and the Commission's staffer Sean Simon have been working on this. And the first mini-hearing was held I believe on the 16th?

DR. WELLS: Yes.

DR. MURRAY: And Jim Childress was kind enough to attend it on our behalf. So I don't know what order you want to continue discussion in, but I leave it to this group.

DR. WELLS: Okay. Do you want to say something, Henrietta?

Ms. Hyatt-Knorr: Well, I thought it would be best if Dr. Childress told us a little bit about his impressions since he was there and really got the feel for the environment.

DR. CHILDRESS: Well, I was actually most impressed. I guess I tend to approach such groups or mini-hearings with a degree of skepticism, but I thought this one worked really, really well.

I thought that the way you proceeded in raising the questions regarding the scenarios and involving all the members of the group in a non-threatening way, so that they really got involved in the discussion, I thought worked tremendously well.

I thought an interesting range of views came out. I think there were some points that might well even be viewed as close to consensus.

I thought it was a very reflective group, but not really reflective of the society. I mean, this was a pilot group. It was a very highly educated group; a lot of people who knew a lot about science, government regulation, law and so forth, so it was not the group we are going to find by and large.

But with just that one reservation, I was really tremendously impressed at the interest in hearing the views of others. I thought at least it suggested to me that this as a pilot project, though they may be making adjustments in it, it certainly should play very well in other settings and should produce information that would be very valuable to accept the mini-hearing.

Ms. Hyatt-Knorr: I would like to add to that. This was really primarily planned by Bette Kramer who could not be at the meeting herself, which was why Dr. Childress was there, and she had asked a neighbor of hers to set this up. And this happened to be a very dedicated neighbor.

(Laughter.)

Ms. Hyatt-Knorr: I really have to give her, you know, a lot of credit.

And we were forewarned that it was a relatively educated group, but they tried to pick people who didn't necessarily know anything or maybe--

It turned out one person really knew a lot because she had been ill and had had her sample taken and she had given it a lot of thought. And she was almost like a catalyst in the sense that she brought many of the issues to the table and then people really started thinking about it.

But we are aware of the issue of how representative-- But I think that we just have to approach this like you would any other focus group, even though we don't think this is a focus group, we like to make it mini-hearings, which is why Dr. Childress was there, but some of the methods-- It is a hybrid really between a hearing and a focus group.

And, with that, I would like to turn it over to Jim.

DR. WELLS: Okay.

DR. MIIKE: May I ask a question?

DR. WELLS: Sure.

DR. MIIKE: Ninety minutes seemed like an awfully short time for the list of questions and issues that were listed as being raised. Was that enough time? You had a very special group. When you come to my state it might be a very different situation for 90 minutes.

DR. WELLS: Well, it was in the evening. At the end of 90 minutes, they were all pretty tired. And actually I left off the very last question because I could tell that they had said everything they had to say and heads were nodding and people were beginning to clam up a bit, which was a pretty good sign that they are done talking.

(Laughter.)

DR. WELLS: So 90 minutes was their limit. Maybe it wasn't everything absolutely that they had to say, but I think it was all we could ask of them at the time. So, you know, we have to see. But my experience has been 90 minutes. It is kind of an outside limit.

DR. MIIKE: Talking in Hawaii, we normally have three to four hour meetings once a month and they don't want to end, so--

DR. WELLS: Well, I will be prepared.

(Laughter.)

Ms. Hyatt-Knorr: Actually, we had set another hour that we could have used.

DR. WELLS: Yes.

Ms. Hyatt-Knorr: So this was really played by ear, particularly since it was the first one. And I think-- It was my intent-- I think the Hawaiian mini-hearings are going to be set up the same way; that there is an additional hour for discussion, and we can make it two hours if you think more is needed.

DR. MIIKE: It just may be that the preparations in the beginning that take a lot longer. You say you had a very sophisticated group and someone who had intense personal experience and that would change it altogether.

DR. WELLS: Well, I wouldn't say "intense personal experience," but someone paid attention to bringing this group.

DR. RAUB: Well, Larry, I'll insist that my colleagues stay in Hawaii as long as it takes.

(Laughter.)

DR. JAMES WELLS
VICE PRESIDENT, CENTER FOR HEALTH POLICY STUDIES

DR. WELLS: Okay. Let me tell you what I am going to tell you; that is, first I will actually introduce myself and a couple of colleagues who have come along as well.

I brought some materials. I think everyone should have this packet. It has a brief report. It has the Moderator's Guide for the group discussion. It has a kind of a protocol, which was more just a set of notes to tell me what to do so I don't forget anything. It also has a self-assessment tool that we handed out to the participants, and I will tell you about that in a moment.

And the report, I am just going to briefly highlight some of the findings that we got together afterwards and had a briefing among the investigators and came up with a few conclusions and some suggested changes to the procedures and so forth. And those are also included in the report.

Let me start by doing the introductions. I am Dr. James Wells. I am the Vice President of the Center for Health Policy Studies. We are a health services research and consulting firm. Our main office is in Columbia, Maryland, which is just up the road from here. We have another office in Albany, New York.

I brought a couple of colleagues, Dana Carr and Bonnie Cassidy, over there in red. And they are going to be assisting me with the remainder of the focus groups. Miss Cassidy couldn't be at the one in Richmond, but Dana Carr was there, and some others of our staff, to assist.

The way we are approaching the hearings is to start with a group discussion--as we said, 90 minutes. I moderated the first. We will be changing duties on that among the staff. The others take notes, try to take notes as carefully as possible. We are also audio recording and preparing a transcript, although usually I like to rely on the notes more for doing reports than going back through the transcript, mostly because it is inefficient. We can usually get--

DR. EMANUEL: What about videotaping?

DR. WELLS: What about videotaping. I usually don't do that for this sort of thing. I mean, it can be done. We hadn't really discussed it. I don't know if Henrietta had thought about it.

Ms. Hyatt-Knorr: One of the things that we did in order to make people most comfortable, even though of course we cannot guarantee them their privacy because it is a public occurrence, we call everybody only by their first name and there is no record as to what their last name is. If you videotape them, you lose that.

And we really did not provide for the videotaping--

DR. WELLS: Right.

Ms. Hyatt-Knorr: --in the task order, so that is another issue.

DR. WELLS: Okay.

So the usual procedure then is that we-- Well, actually, in this, we have used this additional tool, the self-assessment tool, and what we did was just ask them four simple questions about having ever provided a tissue sample, if they had any concerns about potential uses, you know, for what purposes they would think it was okay to use their tissue, and whom they would trust with that information.

We asked them to fill that out, set it aside, we had the group discussion, and then we asked them to answer those questions again after the discussion.

Then I moderated the discussion. We had a series of scenarios. You can see those in

the Forum Moderator Guide. I believe there are four scenarios, or five scenarios, with a series of probative questions that followed those.

For the most-- I don't think I ever had to ask all of the probative questions after any of the scenarios because a lot of the issues spontaneously arose from peoples' comments or reactions to the scenario. When that didn't occur I led the discussion in that direction.

I tried to let people talk as much as they could, and I listened as much as possible because often they will continue to bring up new ideas or different twists or different looks that we might not get at otherwise, and that is actually the purpose of having this sort of discussion as opposed to a survey or something.

And then afterwards the team gets together, compares notes, and then ultimately we can look at the transcript to make sure that, if we are quoting and if we have jotted down quotes, that we make sure they are accurate and so forth.

So that is the procedure.

Findings. I think we were all very pleased that the participants, you know, were very involved and they were somewhat knowledgeable about tissue, although some issues came up as to whether there were cells and tiers and things like that. And maybe you experts can answer that for us.

Right from the outset, I think we got their attention by actually suggesting that tissue gets stored and saved. I don't think-- I think everyone was shocked to realize that that was the case.

Even people who came in, actually the first thing we asked them was just what are you feeling right now here attending this meeting and, you know, most said, well, you know, this is kind of interesting and we are excited to get going and doing it.

And there were two or three who said, well, you know, I really have some concerns in this area and have read about cloning or genetics or, you know, related topics, but even those people were shocked to realize that their tissues were saved.

DR. MURRAY: Dr. Wells, you missed yesterday afternoon and Elisa Eiseman's report in which we learned that it is probably only a few tens of millions, maybe 100 million or more samples out there.

DR. WELLS: Yes.

DR. COX: I think we should send that in-- If they were shocked that they were saved, when should they see those?

DR. WELLS: Conversely, I think that they were fairly uniform in agreeing that it was worthwhile to use tissue to do medical, you know, studies of genetic conditions and that that was a useful thing for the public good.

Conversely, they had concerns about who would protect the subjects of the research.

They weren't particularly-- We brought up the issue of the potential misuse of information in terms of discrimination or stigmatization. They found that a concern, but not a great one.

But they could suggest, for example, that their own physician they would trust to keep track of their information, although even that trust is eroding rapidly. They felt that with the changes in the health care system, managed care-- The word was used, the phrase was used often; that even that was a concern.

DR. LO: Can I interrupt to just ask a question?

DR. WELLS: Yes.

DR. LO: I am having trouble getting the feel for sort of how deep the conversation went. So, I mean, you say that people questioned, people discussed, on the one hand and on the other hand. But I am a little concerned.

I mean, do people realize that their personal physician is out of the picture here? I mean, I am just wondering are we really presenting the scenario where their DNA is going to be tested in a sample they didn't know was stored for a disease that is perhaps unrelated? I am just wondering, are we pushing hard enough to get the kind of policy points that we are going to have to deal with, or are they just sort of saying, well, I am talking about managed care and, you know, science out of hand. How precise were they getting to the questions that we are trying to grapple with here?

DR. WELLS: Well, we got as precise as talking about the kinds of people that comprise IRBs and who was on there. I think that was a concept that most people found alien. They weren't really aware of IRBs and the way that research efforts are discussed ahead of time and dealt with in that manner.

But I think in general the discussions went quite deeply. I think in particular this issue of trust, you really capture more generalities because people don't know the system very well. I mean, you could say, well, who should be on these boards? And they had some ideas, but I think it is just something that they don't relate to on a very personal level.

Ms. Hyatt-Knorr: It really wasn't my impression that we went as deep as we could considering the knowledge that they people had. If you don't know very much, you can only be pushed so far because it is just beyond your imagination.

One of the other issues that I think came through very strongly, particularly by-- Even though it was one person talking about it--the notes--there were others who echoed that, is the whole idea of consent.

If the tissue has been collected for some medical procedure and later it is used for research, whose is it and who should consent to future research? So many of these issues that people had really never thought about.

DR. WELLS: Right.

Ms. Hyatt-Knorr: It was just outside their realm of experience.

DR. WELLS: And, in particularly, consent, there is just-- I don't think we ever came to any consensus about that.

I mean, I think people agreed that anonymous research was perfectly fine, but then when you get to consent, under what circumstances, there were a whole variety of discussions about whether there should be consent for all perspective studies, whether there should be consent for all of them. You know, under what circumstances they would want to have people come back, and then they also brought up the practical issues, or the impractical issues of having to do that. I think they recognized that themselves immediately.

DISCUSSION

DR. LO: Was this-- I guess I would almost want to say, you know, there is a proposal under discussion to allow anonymized samples to be used without further consent, and perhaps even without oversight of an IRB board. I am just wondering, are we posing them the dilemmas we are going to have to grapple with? Sort of the ones that Jonathan laid out in the report.

DR. CHILDRESS: I thought at least some of the those came out pretty well in the way you raised the questions and would probe. For example, anonymous versus anonymized, and so forth. I thought--

I mean, I guess one way you could look at it, to go further, would be to look at the kinds of questions that are raised and see whether there are some things that need to be asked but were not listed here.

Now, I thought he did a very effective job in sort of taking where they would move at each point and then try to take them further.

And they did have some questions that were, for example, directed toward issues that--this can't be tied on at each hearing--but Bette's pathologist husband was there and a couple of questions were directed toward him, right?

Ms. Hyatt-Knorr: Yes, but he was not on the panel.

DR. CHILDRESS: He was not on the panel but he was in the audience. But--

Ms. Hyatt-Knorr: He was in the audience.

DR. CHILDRESS: --but with a pathologist there, then certain things did come out.

DR. COX: But, Bernie, can I say that I understand and I share your concerns, but I think that, in my own personal views, that is how we can help you because we can listen to what you said. We have got all these other really smart people that are coming in and giving us the papers, and then we can help you say, well, let us make sure that we focus on these issues. But it can be a process so that the--

And then I quite agree that we want the people at the hearings helping us on these hard issues. But I don't think we have defined, even for ourselves necessarily, exactly the area that we want to focus. I mean, we started yesterday, right?

DR. EMANUEL: Well, I want to ask one question about-- You said you had one person who had just recently had a surgical procedure or something--

DR. HYATT-KNORR: I didn't say "recently." I don't know how recently.

DR. WELLS: No. Not recently.

DR. EMANUEL: But none of the others had been in the hospital or had a relative recently?

MS. HYATT-KNORR: No.

DR. WELLS: No. That is not the case. I mean, I think several had, several had.

DR. EMANUEL: Because it just seems to me that--

DR. WELLS: But no one remembered signing anything about a consent form. I mean, if possible-- Possibly that they signed something. They signed a piece of paper. But they also said, well, what if we didn't sign? Then we wouldn't get the procedures we wanted. So, you know-- And they didn't remember any clauses or discussion about research or future uses of tissue or anything like that.

DR. EMANUEL: But I think you have got a highly educated group. I mean, we are not talking about the Hawaii sample.

(Laughter.)

DR. EMANUEL: And I think this is-- I mean, this is a serious issue because, despite taking an unrepresentatively high sample--educated, fairly well off I assume socioeconomically--the

whole thing we are talking about have absolutely no relevance to them and they don't understand the system at all.

Ms. Hyatt-Knorr: But that in itself is very interesting.

DR. EMANUEL: That is my point.

Ms. Hyatt-Knorr: That was part of what the intention was; to find out what people really know. And in a way you are caught in a dilemma because, on one hand, you want to find out what they know and that may be very little, and then you say but do you really want their input on these very complex issues?

So there is some balance in there and I think you certainly did the best job, from my perspective, that anybody could have done under those circumstances.

DR. WELLS: Actually, if you look at the very end of the report, where it says modifications to the Moderator's Guide, there are three particular issues that we felt, based on our experience, needed to be changed in the Moderator's Guide, and they are exactly the things that have been brought up.

One is that we didn't-- No one there could really tell them exactly what the standard kind of content for the surgical consent would be. We needed to, even ourselves, to beef up a little bit on that.

We needed more on questions regarding linking. I mean, we certainly talked about linking tissue samples with other information and that that would require identifiers. The conversation got around to the issue of anonymizing that, but not as explicitly as it probably could have been on the Moderator's Guide. The discussion got there I believe.

And then also a little more standard description of an IRB and who sits on an IRB.

DR. MIIKE: I have a couple of questions. Did you impart, or did they get any sense about the likelihood--given the average citizen going into a hospital and giving some tissue--the likelihood that it is actually going to be used for a research application?

DR. WELLS: No. No. I couldn't tell them the likelihood about it.

DR. MIIKE: Did they raise it?

DR. WELLS: No.

Ms. Hyatt-Knorr: No.

DR. WELLS: Not at all.

DR. MIIKE: Second of all, did ownership and commercialization and "I get a share of the profits"--those kinds of things--did those come up?

Ms. Hyatt-Knorr: Yes. That did come up.

DR. WELLS: That came up. Actually, one member knew about the Moore case. Not by name, but had read about it in the paper, you know, a while back.

But in general I think people didn't care about ownership. They didn't want their tissue bought and sold. Someone brought up that issue. They said that, you know, it would really be bad if my doctor were selling this stuff to drug companies for research or something like that.

On the other hand, the fact that an academic investigator gets, you know, career advancement on the basis of this, or a drug company makes profits, if that is what they do, we don't care. I think that was the general sense.

DR. MURRAY: Dr. Wells, a couple of observations. One of them I guess is in the

form of a question.

We had a choice early on, or thought we had a choice, although we probably didn't, between sort of this kind of way, this method of getting some picture of the public knowledge and concerns, and a survey. From what you have said so far about what how little people knew about the realities of this, I guess as a survey it would have been meaningless because you would have had to explain so much.

DR. WELLS: Yes. It would be very difficult to correct, that survey, especially if it were self-administered. If you were doing an interview, or something like that, it might be a bit different.

DR. MURRAY: So that is, in a way, that is good news.

DR. WELLS: Yes.

DR. MURRAY: I think this is probably, whether by wisdom or by a fault, we stumbled on the--

DR. WELLS: We do both. This would be my choice, at this stage anyway.

DR. MURRAY: The second thing is, I guess, currently there are three kinds of questions I hope that would be answered by these hearings:

One is, what do people know;

Second, what do they care about; and,

Thirdly, what would they have us do? That is, what would strike them as a fair, reasonable set of rules, protections, and so forth.

My-- I guess we are going to be getting the information about the first. I am really concerned about the second in that, to me, if nothing else comes out of this, I want to know what really matters to people. And the third, which would be issues like consent and some of the details about it, I am not sure how much we can learn from these. But perhaps you have a sense of that.

It is number two that I am particularly interested in. And do you feel like you are getting that?

DR. WELLS: That you feel strongly about?

DR. MURRAY: Yes.

DR. WELLS: Well, it sounds like this buying and selling of the tissue is something they feel strongly about.

DR. MURRAY: Very strongly about it.

DR. WELLS: Another one we haven't actually mentioned is notification of relatives. Everyone universally thought that that would just be like dropping a bomb in the middle of the family. Although maybe "universally" is too strong, but there were a couple of people who said in my family that would be the beginning of a bomb. Most of them felt that that was in general a bad idea.

DR. MURRAY: What sort of notification to the family was a bomb?

DR. WELLS: Well, suppose you go in and your tissue sample is tested, you have some condition that might be familial, and whether then, on the basis of that, the investigator should notify other family members or invite them in to be tested, or something like that.

DR. COX: It really--

Tom, I completely agree it is figuring out what the people--participants that this--feel is important because right now what is important is being molded. But it is by what certain people think

is important. And they come and they speak to us.

And I am not saying that they are right or wrong, but I am saying that, at least in this particular situation, this is one example I find really interesting because the way, you know, the wind is blowing is that you are going to give more stuff to all the family members. All right? And the-- So, again, you know, it is far too early to judge, but you would certainly like to know what people think is important.

And I have actually one question in that. Another thing with where the wind is blowing is that people are going to want to know about all sorts of different uses, different types of research that one anticipated in the beginning. And was that an issue that anyone cared about or was it discussed?

DR. WELLS: You mean what types of research?

DR. COX: Well, say that is--

DR. WELLS: Or whether they were concerned about--

DR. COX: Were they concerned about--

DR. WELLS: --utilization?

DR. COX: --actually having input, utilization, input into--

DR. WELLS: Yes. There were people who expressed the desire to consent to that, for example. Is that what you are asking?

DR. COX: Yes.

DR. WELLS: Yes. And, you know, I think that because a lot of them hadn't really thought of that before that, you know, their attitudes weren't all that well developed, but there were people who certainly said, yes, I think I would like to consent to that, and there were others who said I don't care as much.

Henrietta?

Ms. Hyatt-Knorr: I think one other issue that we haven't talked about yet that came up at the discussion is that there will very well be generational differences. And this group that we had here was roughly--I would say--from their late 40s to their 60s. I mean, I am guessing.

And one of the persons actually brought up the issue that his children would see this very different than he saw it. And I am-- Just simply because they may be more knowledgeable or they may have more concerns about privacy and consent than this parent, generation.

And I think that also relates to the relationship that generations have to their physician and the way they view their physicians, so I think that is something that we need to keep in mind as well.

DR. EMANUEL: It sounds as if this group is very pro science and pro research.

Ms. Hyatt-Knorr: I think that--

DR. WELLS: They seemed to be, yes.

Ms. Hyatt-Knorr: I think that is true.

DR. WELLS: Yes. I mean, I don't think they intrinsically mistrusted the process of science. They did seem to intrinsically mistrust--

DR. EMANUEL: The commercialization aspect?

Ms. Hyatt-Knorr: Right.

DR. WELLS: Not just commercialization, just bureaucracy in general. You know,

they were hard-pressed to come up with anyone that they really trusted to ensure that the enterprise operated in a way that would protect everyone.

Although often they said I think it would be okay for me, but I think other people would have concerns. I don't know if that means they really had concerns and were kind of expressing them indirectly, or they just, their own experience they feel good about but they are not sure about running a larger enterprise.

DR. MURRAY: Trish?

MS. BACKLAR: Well, to follow what David was saying, that it is moving in the way of disclosure to larger collective family situations, one of the questions that you may want to probe is to ask them how they would like that done.

In other words, should it be the researcher, should it be-- Should the person whose tissue-- How-- What are kinds of methods one would use to disclose?

DR. WELLS: Well, I think we got at that to a certain degree, and I think part of it is there just wasn't a real consensus in the group.

MS. BACKLAR: Right.

DR. WELLS: What is the right way and the wrong way?

DR. MURRAY: Bernie?

DR. LO: To follow up on sort of the line of thought that Tom and David put out, I think the extent that we, as a commissioner, are able to sort of define a list of issues where we would like to have some sense as to how concerned the members of the focus group are about it, we should try and state those pretty clearly, and David said a couple. I just would like to state a couple of additional ones.

First, disclosure of information back to the person from whom the sample is obtained. Is that something they care about and do they appreciate the dilemma of if you anonymize the samples you may not be able to do that?

And then secondly, to sort of push a little harder on the type of research, I would actually ask them are there types of research you would not want done on your tissue samples, and how would you feel if you had no control over it?

I mean, I think to say do you care about the research may not have any meaning unless they have a sense of what kinds of research are being talked about. And perhaps we should even prompt them with some examples of research that some people have found offensive or inappropriate and see if these are a wide-shared perception.

DR. CHILDRESS: Okay. On the first one, that was addressed.

DR. WELLS: Yes. I was going to say, the first definitely was addressed and they realized that and they kept coming up against that. I mean, someone would say, well, I would want to know but then, you know, but then somebody would say, well, how are you going to do that if it is anonymous and--

DR. LO: And so how did that get-- I mean, did they say--describe--as a Commission as thinking about this?

DR. WELLS: They did.

Ms. Hyatt-Knorr: Actually yes.

DR. WELLS: They precisely said that.

Ms. Hyatt-Knorr: Exactly.

DR. WELLS: That was almost a direct quote. They said we are really glad.

I mean, first of all, I should perhaps preface it by saying that, you know, one of the choices for who do you trust to take care of this was the government, and no one, you know, went along with that--

(Laughter.)

DR. WELLS: --although someone pointed out at the end that this Commission and its sponsorship of the group discussion was, in fact, the government trying to do something about it. And someone said we are glad someone is paying attention to this issue.

DR. CHILDRESS: We are here to help you. I just read-- I would be-- One thing on that if I could if we could just focus it. They were actually very interested in NBAC and glad to be part of the process.

DR. WELLS: Yes.

DR. CHILDRESS: Questions in public and afterwards directed that.

And one thing that did come up as a question that I think would be quite appropriate to think about is that, since they are involved in the process, one asked if it would be possible to get the report at the end. And it seems to me that we ought to be keeping a list of the participants and sending them a copy of the report as just a small token of appreciation for--

DR. MIIKE: That has already come up in my group.

DR. WELLS: Yes.

DR. MIIKE: They expect to see it.

Just to follow up on Bernie's question about what kinds of things we want to get from them since I think you are going to find this everywhere because it was probably--among us too--a surprise at the extent to which tissue is collected.

I am looking at your before and after discussion, the list of questions. It seems to me you should expand that because, if they go in not knowing much but at the end of the discussion having had an intense discussion around the issues, they are obviously are in a different frame of mind so it might be better to-- Maybe that is the place where the kinds of questions that we are most interested in should come in so we get to see whether the perceptions have changed from the beginning of the discussion to the end of the discussion.

DR. WELLS: Well, we did ask them about that because--

DR. MIIKE: But there is just about four of them.

DR. WELLS: Right. Right. There could be more questions added, but every single person said they had changed an answer on the form.

DR. MURRAY: In what direction?

DR. WELLS: Before and after. Well, I think that-- For the most being less certain about what their answers were.

Also, I mean, if there are specific research issues or research types that we ought to address or bring up, we would be happy to. And if you want to give them to Henrietta or one of the staff, they could get that to us for incorporation.

Ms. Hyatt-Knorr: Well, yes. I would like input. And some people have promised me input.

DR. LO: There was an e-mail exchange before my computer crashed a couple of days ago. I don't know if that--

Ms. Hyatt-Knorr: Yes. And we have already taken care of that. And anything, you know, anything that you have to say, I mean, please let us have it soon, like yesterday.

(Laughter.)

DR. MIIKE: Well, it seems to me that-- And my guess is, yes, this group is representative in that they don't really have a major objection to the use of these things.

I don't know whether we can get from them how we protect. I think it is-- You just need to--

The other thing we expect to get is their concerns. And it is a group like us that has got to come up with the specifics about how to put that in. You know? I mean, the appropriate way of addressing it. It is just unrealistic to ask groups like this at that level of detail.

DR. MURRAY: I was trying to review these very quickly and then I had a chance to see an earlier version and gave feedback to Sean. Yes. Okay. It is in here.

The issue-- One of the issues that has come up for us is what happens if my tissue is anonymous as to individual identity, but may still have group identity attached to it?

And the research may be regarded, by at least some members of that group, as negative, in terms of the group's welfare. It looks like we did have a question on that.

DR. WELLS; We did bring--

DR. MURRAY: Did you get a response to that?

DR. WELLS: We did bring that up. I don't think it was one of those that people felt real strongly about. They recognized that there was a possibility of that and somebody spontaneously brought up Tay-Sachs and said, you know, well, we don't think that that is a big problem, for example, as an example of genetic-- That that is the kind of thing that that question elicited. It would be thoughts about that.

But someone did come up and say, well, you know, AIDS created a lot of stigmatization so there is always the possibility of that. So that is kind of the direction the discussion went in.

I don't think, you know, there was great emotion surrounding it, but some thoughtfulness about, well, how big a problem is this and in what directions can it go? And that is kind of where it ended.

DR. MURRAY: I will be very interested to see if different groups have a different--

DR. WELLS: Well, I think that--

Ms. Hyatt-Knorr: Yes. I just wanted to point out that I think from this particular group that was not something that was of a concern to them. If you had had a different composition of the group, I am absolutely certain that you would have had different sensitivities.

DR. MURRAY: Am I correct in assuming that groups in different communities will, in fact, sort of be, in some cases, quite different?

Ms. Hyatt-Knorr: Absolutely. Absolutely.

As a matter of fact that is something that we really would like some input in but, I mean, we really need it now while we are still planning the remaining meetings. But, yes. We will identify it and solicit participation from a number of groups.

DR. MURRAY: Yes. Good.

Ms. Hyatt-Knorr: And I think both generationally, as well as class-wise, as well as ethnic background. I mean, this is something that we really need to consider very seriously.

DR. MIIKE: I don't know what to do with information like that though in the sense that let us suppose there is a very good predictor for a particular type of cancer in a particular group. I-- You know, it is sort of like research that leads you toward better medical care, better predictive value. But it is the application that I would be worried about, the application outside the medical arena, which is in insurance areas or those kinds of things.

Ms. Hyatt-Knorr: That was discussed.

DR. MIIKE: And it is sort of disjoint there. You know, you can't control the consequences of research in all aspects of society, so I don't know how you would address that.

DR. WELLS: Well, I think that their concerns, in response to a question about is it possible for there to be group or individual stigmatization based on this thing, were a little more abstract. But when we were talking about concrete cases, again and again they came up with employment and insurance discrimination as a great fear. So I think those are the two in particular that they were--

Ms. Hyatt-Knorr: Well, it--

DR. MIIKE: Well, I don't know what to do about it. That is my point. Which is that research that one would do in an area is-- You know, you can't just sort of-- Unless government or society steps in and says you cannot use that for rate-setting, et cetera, et cetera.

DR. MURRAY: There is also the possibility of use of tissue samples for behavioral genetics kinds of studies, and I think many of the concerns about stigmatization have been raised in that context.

DR. COX: Something that you said to me makes me feel very comfortable and that is that people walked out less sure than they walked in. And it follows something that you just said, Larry. Each of these things has, you know, a good and a bad.

And I think that if we present scenarios then that we can't ask too much from this. But if people feel really strongly on one side or another, that is kind of information that would be very meaningful to me.

I mean, we are not going to be able to choose, I mean, because there are pluses and minuses. But just to see when that is put out to people--the pluses and minuses--if they still remain polarized to one side then I think that is very useful information.

And another sort of very global piece of information, that I think the whole tissue sample thing hinges on, has to do with peoples' attitudes towards health care in general. And I think you really hit upon the generational thing. It is a very important, Henrietta.

Because if people in general don't want to be messed with; that is, they don't want to play the game of having people come back and they don't want to be partners in trying to have longitudinal ongoing assessment, I want to know the answer to that. And I think that is not a complex concept.

And I don't think we are going to get an easy answer to it, but that is one other issue that I think is really important because it impinges on all the different levels that we have to make decisions. If people say they basically, you know, don't want to be in longitudinal studies, then it has a

whole different caste in terms of linkage and everything else.

DR. WELLS: Right. Well, I think that issue came up as well, of longitudinal studies.

DR. COX: And what did they say?

DR. WELLS: They said if you are going to do that, you have to have linked records.

DR. COX: Yes.

DR. WELLS: And then you need some protections for that information.

You know, so I don't-- I didn't hear anyone being strongly opposed to that, or participating in that, although there were some people who were skeptical about--I guess maybe one or two people in particular in the group of 11--who were kind of skeptical about that.

Ms. Hyatt-Knorr: But that is in this group.

DR. WELLS: Yes.

Ms. Hyatt-Knorr: Actually.

DR. WELLS: But in general there were-- You know, I think they recognized the utility of those kinds of studies and recognized the conundrum that they involved.

DR. LO: There are a couple of things I would be interested in seeing if they were raised during the discussion.

First, did they make a distinction between DNA-based genetic testing versus other types of research that might be done on their sample?

And, secondly, earlier you said something that gave me the impression that these people thought that if they went to the hospital, in order to get the service, they must have to sort of sign on to this tissue banking, you know, program. Was there any sense that you could get your surgery done and refuse to allow the sample to be used for later testing, or do they think that, you know, that--

DR. WELLS: No. Because I don't think they were asked anything in first place.

DR. LO: They were never asked.

DR. WELLS: So they never thought they had a choice.

Ms. Hyatt-Knorr: And I assume--

DR. EMANUEL: That paragraph about samples could be used for educational research, no one ever--

Ms. Hyatt-Knorr: But I think the other point they made is when they went in for various medical purposes and medical procedures, they were so tense about what was going to go on--

DR. WELLS: Yes.

Ms. Hyatt-Knorr: --that they just wanted them to go do the surgery and get it over with without really being in a frame of mind to focus on this anyway.

DR. EMANUEL: Well that suggests to us-- I mean, it suggests to me, sitting here, that the process of including a consent form with check-off boxes at hospitalization or at surgery is ridiculous.

We might get lots of checks and lots of signatures, but the meaningfulness of that in terms of protection sounds like it is approaching zero if people can't even remember signing for their procedure.

DR. MURRAY: This is a very important point that Zeke is raising. I mean, I think our concern as a Commission ought to be not what paper trail is cleanest but what actually this means

to people, and how to do it, how to structure the process in such a way that it conforms to the best understandings of the American people.

And we also-- I mean, I think this Commission is generally, you know, supportive of science but, on the other hand, we want to know what people really care about and what would be a reasonable way of incorporating those concerns into the process. And it doesn't sound like it is going to be easy to do.

I mean, a family member just had occasion to sign one of these forms and I was present when this happened. And this family member, you know, just as Zeke said, didn't even notice this part of the form that required a separate signature or check-off or something. But, you know, he just didn't notice it.

But I think if I hadn't been there to point it out-- If I hadn't been alerted to it, through some of my own research as well as Commission duty, I am not sure I would have noticed it.

DR. MIIKE: A process question. At the end of all of these hearings, or whatever you want to call them, how are you going to tease out the information that you got?

DR. EMANUEL: Well, the usual focus group.

DR. WELLS: Right. The usual way is to sit down and go over the notes and-- I mean, the first thing we did was to just sort of share our first impressions on the ride home from Richmond. And then the next morning we got together and brought up the notebooks and--

DR. MIIKE: Well, I don't mean that. I mean, after you have done several--

DR. WELLS: After we have done several?

DR. MIIKE: --and how do you do it?

DR. WELLS: Well, I think it is the same way. I mean, the problem with this sort of research, as opposed to say a survey, is that making the distinction between--if I can be technical--central tendency and variation is very difficult to do.

So I have been trying to be careful about that where people, where there isn't, where there was consensus, that is fine, but where there is not, you know, it is hard to say what the average answer is. You can just say that some people said this and some people said that, so it is a little more difficult to characterize across a large group, or several groups like this.

But I think what we would do is, you know, in this one they seemed to have no problem with anonymous research. If there were another where people said even there we have a problem, well I think, you know, we have to bring that into the summary of the results. But that is basically how we do it.

DR. LO: Sort of a related process question. It seems there is going to be a learning process; that after each group we will realize some things that we hadn't realized before. How are you going to build that into the way that consecutive groups are--

DR. WELLS: Well, I think we will include it in particular because-- I mean, I think the point of this probably is not to make sure that, or to do several of these in order to kind of confirm or replicate the first one, but to learn something new.

So if we change the Moderator Guide, then I don't feel that that is a problem. I don't know that we were aiming to ask everything precisely the same way to every group. The discussion-- And that is typically what happens in a focus group type of research is that-- Actually, you can have a totally different conversation with a different group with the same questions.

DR. LO: Just to follow up. I mean, how will you sort of-- I found this discussion very valuable in sort of how will we try and do this back and forth between the Commission and your team when we are not going to be able to meet after each meeting.

Ms. Hyatt-Knorr: Well, e-mail.

DR. LO: E-mail. Okay. So will it-- I mean, will it be technically possible after each, after one meeting, to sort of give us some sense of what that group was like in time that we can respond before your next meeting?

Ms. Hyatt-Knorr: Except between the Hawaiian.

DR. WELLS: That is right. I was going to say--

Ms. Hyatt-Knorr: There just simply isn't time.

DR. WELLS: I mean, with the two Hawaiis and the San Francisco there will be a day in between.

DR. EMANUEL: I find the summary helpful personally in terms of--

DR. WELLS: And we can certainly do this.

DR. EMANUEL: I think we appreciate it.

DR. WELLS: For us to do that, too.

DR. GREIDER: How many of these are scheduled currently? I hear the Hawaii--

DR. WELLS: Three. Three more. Three more are definitely with time and place.

DR. GREIDER: Two Hawaiis and a San Francisco?

DR. WELLS: Right.

Ms. Hyatt-Knorr: But we have six plus--

DR. WELLS: And four others. Three others.

Ms. Hyatt-Knorr: --the other one. So that was the total that we contracted for at this time.

DR. GREIDER: And where are the other ones going to be?

DR. WELLS: Probably in New York, Cleveland and--

MR. SIMON: We are actually thinking of Boston, Cleveland--

DR. WELLS: Boston.

MR. SIMON: --New Orleans, Miami, and we already mentioned San Francisco. So we are trying to get the geographical dispersement.

DR. BRITO: One thing I don't see on here. Maybe it was discussed earlier; I missed the first few minutes. But about keeping track of the demographics of the people involved in the groups. Is there a process for doing that?

Ms. Hyatt-Knorr: Only in a descriptive way.

DR. BRITO: Okay.

Ms. Hyatt-Knorr: And that is inferred. I mean, we don't know anything about the people other than what we see.

DR. BRITO: Is there not a possibility of just at least getting the ages, the sex, the ethnic background groups--

Ms. Hyatt-Knorr: I don't think so. This is not a survey. This is the mini-hearing.

DR. CHILDRESS: It could be done easily on this form.

DR. BRITO: That is what I am wondering-- Just simply--

Ms. Hyatt-Knorr: No. But, but, but-- But you see then we request identical information from more than seven, eight or nine or 10 people and this is not-- That was not the idea with which we approached this particular study. This is a mini-hearing and it is a panel. It is not a survey. So we really can't do that.

DR. BRITO: Okay. Because I think--

Ms. Hyatt-Knorr: We can't.

DR. CHILDRESS: Even if you don't need it for statistical purposes, and it wouldn't be any help at all for that, it still might be useful to have.

For instance, if--

DR. WELLS: Well, it is just--

DR. CHILDRESS: Let me just say one thing, if I could. I said well, it could easily be put on this form, but then I was told these forms weren't collected, and yet--

Ms. Hyatt-Knorr: It is not collected.

DR. CHILDRESS: So the only report you have of the fact that they had changed their mind on some of these is just the way they raised their hand. It seems to me this would be useful to collect and we--

Ms. Hyatt-Knorr: We cannot do that because then it becomes a survey.

DR. CHILDRESS: Is that true?

Ms. Hyatt-Knorr: Yes. Absolutely. You cannot do that and it was not designed that way.

DR. CHILDRESS: So I was just--

DR. EMANUEL: Paperwork reduction.

(Simultaneous discussion.)

DR. CHILDRESS: I guess I didn't understand that legalistic limitation, but so be it.

Ms. Hyatt-Knorr: Yes.

DR. COX: But having accepted that, and I hear you, Henrietta, then this issue of generational or demographic support--

Ms. Hyatt-Knorr: Well, what we observed-- what we observed at the meeting certainly can be described.

DR. COX: Yes. I guess so. But who shows up isn't random and so now we are talking about how, you know, we beat the bushes for the people to show up I think becomes where we should focus our attentions.

Ms. Hyatt-Knorr: Absolutely. Absolutely. I agree.

DR. MURRAY: I think part of the design, as I understood it all along, David, has been to try to be sure to engage a sector of groups. I mean, we will find out what some of the other sort of communities that have participated in prior sessions, such as the one in Richmond and the ones in Hawaii, and in Cleveland we will try to find a different, perhaps a different ethnic group or we will try to positively engage some diversity.

DR. COX: Yes.

DR. BRITO: But you are still going to get--

DR. MURRAY: This is the problem with community dialogues. When we dialect with community dialogues, if all you do is say I am having a dialogue, people like us show up. Now,

that is not a bad thing. I like people like us. But I also like other people and we don't necessarily represent everybody.

DR. COX: But if the group comes--because I think Henrietta has really got my attention on this--the group that is going to take some cleverness is getting young people because I will assure you that if we, you know, head up and talk about, you know, the Breast Cancer Consortia and prostate cancer, I mean, you know, there is an awful lot of people that hang out at dance clubs in San Francisco that are going to show up.

(Simultaneous discussion.)

Ms. Hyatt-Knorr: We hope that Bernie will help us with that.

DR. LO: Well, I guess to follow along, I mean, the other thing I would be concerned about is are we going to have focus groups that are targeted at people who weren't represented in Richmond, so different ethnic groups as well as age groups? I mean, and I am not sure just adding one or two to, you know, sort of a group that is predominantly of a different background is going to be the answer either.

DR. MIIKE: We get that in my groups.

DR. LO: You have that in your groups?

DR. MIIKE: Yes.

DR. MURRAY: I think we will shoot for that in Cleveland.

DR. MIIKE: I think one of our mini-hearings is going to be held in a public housing project, so that group has Filipino and Chinese, Koreans, and they have an age range. These are from high 20s into their 60s.

MS. BACKLAR: Well, if you ended up going to the Northwest you could go to Seattle and the coffee houses.

DR. MURRAY: We could do the grung contingent.

(Laughter.)

Ms. Hyatt-Knorr: Well, I think what I really would appreciate is if you would send some feedback to Sean and me.

Now we will be, of course, on travel the next 12 days, but if we get the information early I will make sure that we get it in Hawaii and San Francisco because, you know, we need to plan these things now. We cannot plan them four to six weeks--

DR. COX: What are the dates?

MR. SIMON: We have the dates open from October 15th on.

DR. GREIDER: What are the dates of the planned meetings?

MR. SIMON: The dates of the planned meetings are Hawaii next week from--

DR. WELLS: The 25th.

MR. SIMON: --the 25th and the 29th.

DR. WELLS: The 29th. And then October 1st--

MR. SIMON: For San Francisco.

DR. WELLS: --for San Francisco.

MR. SIMON: We decided, since the 2nd was Rosh Hashana, which begins on the 1st.

DR. MURRAY: We may be reaching a natural end to this part of the program.

I have a couple of questions I would like to address not just to Dr. Wells, but to everybody who was there--Jim, Sean, Henrietta and Dr. Wells' associates. At least one of you was there, right?

DR. : Yes.

DR. MURRAY: Dr. Miike. My question.

If you had to say what you thought people cared about most in tissue and things that you explored in terms of what people didn't mind, didn't seem to care about but that we had built into questions because they thought they might, what would you put on those two lists?

Ms. Hyatt-Knorr: Well the question is, to me, what they cared most about in the beginning and what they cared most about at the end, and I think those were two different things.

I think at the end I think people cared about that they really hadn't known that much about it and that it might very well be a serious issue and they would like to learn more.

MR. SIMON: They were concerned throughout and in each question they found some way of coming back to discrimination in employment and insurance most probably.

DR. WELLS: I would have to agree with that, that the issue of potential--especially health insurance-- discrimination was the biggest one.

DR. SIMON: One has to presume this is a highly insured group to begin with?

DR. WELLS: Yes.

DR. CHILDRESS: I think the commercialization theme was also a prominent one.

DR. MURRAY: What?

DR. CHILDRESS: I think it came out in several different ways, but that particular concern that Dr. Wells mentioned earlier. It was one of those kinds of things that this is being used for the public welfare and somehow they felt that commercialization almost entered in; that that tainted things a bit. I may be overstating that, but that seemed to me to be a persistent concern.

Wouldn't you agree?

DR. WELLS: I think so although I think there were kind of different levels.

DR. CHILDRESS: Different levels.

DR. WELLS: I mean--

DR. CHILDRESS: You gave a complex--

DR. WELLS: They were especially concerned about sort of having a trade in tissue samples, not that they were really aware that there was one or wasn't one, but that was something that they speculated would be bad.

I think the other-- The thing that they didn't respond to as strongly as we expected was the stigmatization issue. You know, while they saw possible ways for that to go wrong, they didn't seem particularly worried that it would.

DR. MIIKE: In the commercialization area, are we being influenced by organ versus these types of tissues? Because I think those are really different issues altogether.

DR. WELLS: Well, I think these were things they probably hadn't thought about much before, so they were just thinking of some of these things for the very first time, mostly speculatively.

DR. MURRAY: I know we always process things through our preexisting categories, but having written about tissue and gifts, and we understand giving tissue as gifts, I am at

least hearing confirmation that that is, in fact, the way a lot of people seem to regard it in.

You can-- I won't go into that. (Inaudible.) Thank you.

DR. LEVINSON: A point of information. I guess we are back to Larry's question about process and how do you protect-- How would recommendations go forward from this group to protect confidentiality and other misuse of information?

There are two activities going on in the administration right now. One was having to do with genetic non-discrimination in the area only of health insurance, not life insurance, but that the administration is working with Congress on measures to prevent the use of genetic information for discrimination of health insurance and employment practices.

And the other one has to do with confidentiality of medical records and the Secretary released guidelines last week that would limit access to medical records. And the proposal is still in discussion. There are legislative proposals that do or do not track with the administration right now, but that information coming from these focus groups on peoples' concerns about the use of such information and materials would be useful coming from this group in support of how those initiatives develop.

DR. MURRAY: Thank you. One of you was nodding that you were present when this conversation took place?

MS. CARR: Yes. I was. I have a sense about that and have been going back to the fact that the group, the focus group, or whatever, the discussion really felt that research was important and felt that it was good for the public. (Inaudible.)

DR. MURRAY: Any other questions to this group or about the process?

DR. COX: One very fast question about the process. So that by looking at this I mean it raises some things for me and I will let you know, Henrietta, by e-mail, so that everybody knows. Is that--

Tom, how do you prefer this?

DR. MURRAY: What? I am sorry.

DR. COX: Because-- Well, let me--

DR. MURRAY: I am not sure what you are asking.

DR. COX: We have very tight timelines which I wasn't aware of that are coming up in terms of what these dates are, and so if we want to get feedback for Hawaii or for San Francisco then we can tell you individually-- separately, Henrietta--but then also put those things up on e-mail so that all the commissioners know what each of us is thinking?

Ms. Hyatt-Knorr: If you want to distribute it to everyone, then I suggest you put it on the NBAC list.

DR. COX: Okay.

Ms. Hyatt-Knorr: If you want us to know it so we incorporate it, I mean, it can be the same but it can be different--

DR. COX: Exactly.

Ms. Hyatt-Knorr: --depending on what your aim is.

DR. COX: But I am bringing it up, Tom, not just for--because I know what I will do personally--but just to see what the commissioners feel and if we have a process by which, you know, it would be good to share this information.

DR. LO: Absolutely. I would like to see what everybody thinks are the key issues that we want to know about.

MS. BACKLAR: Right.

DR. MURRAY: Could we ask then that, you know, understanding the constraints of travel and such, that after each individual or set of--and I know you have got those three pretty much strung together--if you could do your report the way you did this one, which has been very helpful, and post it for us on the NBAC list server. That seems to be the most efficient way of getting it to everyone.

Ms. Hyatt-Knorr: But, you know, I will attach deadlines to these things, and then when we get things two weeks after the deadline we really won't get to use them because the event will have come and gone. I just want to make that clear.

DR. COX: I understand that.

Ms. Hyatt-Knorr: And I really appreciate all your input, but that is the way it is.

(Laughter.)

DR. MIIKE: I know you asked me to answer by noon but when I looked at it, it was 5:00 o'clock.

Ms. Hyatt-Knorr: Well, no, no. I mean--

DR. CHILDRESS: That goes without saying, Henrietta.

Ms. Hyatt-Knorr: He was kidding.

(Simultaneous discussion.)

DR. MURRAY: Right. Any other questions?

(No response.)

DR. MURRAY: Thanks very much Dr. Wells.

DR. WELLS: Sure.

DR. MURRAY: I know that Sean has-- A lot of people-- There were a lot of hands in this and I think it has been-- It is very promising and very useful. Sean Simon, I know, has been running herd. Henrietta has been working very hard on this, as well as your group. So thank you all very much.

DR. WELLS: Right. Thank you all.

DR. MIIKE: And the beaches are very nice in Hawaii.

(Laughter.)

Ms. Hyatt-Knorr: I really want--

DR. RAUB: There won't be any time for that.

Ms. Hyatt-Knorr: I really want everybody to know we are only going there because Dr. Miike made us go there.

DR. MIIKE: Under protest.

Ms. Hyatt-Knorr: Absolutely.

DR. MURRAY: I can actually sort of attest to that. I think Larry was, at our urging, was terrific in being willing to host one of the early sessions for this. And it turns out two of them. And I think it was great. And the staff may just have to suffer the consequences of that.

We are at the-- We hadn't scheduled a break until 10:00 a.m. We have Courtney coming.

What do you want to do? Do you want to press on or do you want to have a brief break now? We can have two brief breaks this way. Should we do that? Yes. Let us get back in 10 minutes.

(Whereupon, at 9:38 a.m., there was a brief recess.)

DR. MURRAY: We are now going to invite Courtney Campbell to join us at the table.

Let me just make one request. The public testimony scheduled at 10:30 a.m., we will try to hold it on or about schedule. We have one person listed at this time--Mr. Cavanaugh-O'Keefe. If anyone else wishes to provide public testimony today, would you please contact Pat Norris and let her know. Good.

Courtney Campbell is helping us out by trying to review religious perspectives on the use of human tissue samples in research. Courtney has got a draft paper and he is here to tell us a bit about his work and to answer any of our questions.

Courtney?

RELIGIOUS TRADITIONS' VIEWS ON TISSUE SAMPLING

DR. CAMPBELL: Thank you.

Let me just give you the outline that-- Part of the review-- Some of the materials that you are to receive is in the e-mail version and part of it is some of my--(Inaudible.) I sent out that e-mail so it is a little bit different.

Dr. Murray requested or invited me to prepare a report that really had three kinds of questions. One had to do with the issues that might be raised for religious traditions and religious communities with respect to the use of human tissue samples, their banking, and so forth.

Second, would there be any distinctive religious objections to such use of samples and research on tissue samples?

And third what, if any, practical policy recommendations might be forthcoming from religious communities concerning these kinds of questions.

So that is the kind of focus I will take today.

Really there is not a whole lot of religious literature, or literature from theological discussions, on the kind of human tissue samples that you are concerned with. And I will talk a little bit about that in a few minutes. But I did review what literature there was and what was accessible to me.

I also had a chance to review the transcripts from your previous meetings in July and March.

And then there was just an element of casuistry in terms of my meeting, in terms of my approach here, trying to go from what is familiar, that is use of organs and blood and so forth within religious traditions, to what is really unfamiliar, and that is research questions.

I have tried to look at what kinds of religious arguments might be used to justify the use of human tissue samples in research as well as limit of that kind of use.

Okay. Well, I would just like to begin with a couple of broad themes.

One possible ground for objection might be that this just would focus on the general historical conflicts between religion and science. And I tend to think that that would be a misguided religious understanding that would object to research on human tissue because this happens to be in the

realm of scientific progress.

I wanted to reiterate that I think, within the religious traditions of the West, there is a deeply-held value that scientific inquiry in general can be a form of worship or a way of uncovering the secrets and mysteries of the created design. That is with respect to science in general.

With respect to specific scientific projects or inquiry, however, there is I think a requirement that those be justified and that there needs to be some kind of accountability beyond say normal peer review within the scientific community; that there needs to be a requirement of public justification for specific research projects such as research on human tissue.

It seems to me if there were to be a religious objection at this level, it would have to do with the notion that science has some kind of autonomous domain that is immune from moral scrutiny or public scrutiny, as well as theological scrutiny.

And there have, to be sure in the last couple of years, there have been religious communities and organizations--and I mention this, give an example of this in the larger extended paper--of very strong objection to the patenting of various gene sequences and cells and animal life forms and so forth.

I tend to think that the arguments that were offered though are not very good religious or theological arguments. But I think if one presses and looks beyond what was motivating the objections, I think there is a concern about the perceived autonomy of science from the public and theological realms and correlatively a need for public accountability of science, as well as an attentiveness of the scientific, the research and the policy-making communities to important kinds of religious values.

So the recommendation, the policy recommendation that really flows out of that, from my standpoint, and it is something that I know this Commission has been working with and the subcommittee is working with, is that you really do follow up very strongly on developing forums for public dialogue, developing forums for scientific literacy and ethical and social policy literacy.

That is; the kinds of recommendations this Commission gave in its report to the President on cloning human beings, with respect to recommendations four and five, need to be reiterated publicly but then also followed through and a mechanism set up to elicit public dialogue and values. And it sounds like, at least coming in just in the middle of this last discussion, there are steps being taken in that direction.

Anyway, so that would be one level at which conflicts I think are not--and issues for religious traditions--are not all that significant.

By the way, if you want to intervene with questions and so forth, please feel free to do so.

Well, there is this-- If we look at research on human tissue samples in particular, unlike any objections to that as opposed to any kind of general scientific project, I think there is a potential for conflict here because of the disparate meanings of the body to researchers and to religious communities and members of religious communities.

Someone, to borrow a phrase from Dr. Murray, who is interested in, or hopeful in getting lucky in the biotechnology lottery, is going to have a different view of the body than perhaps a member of the religious community. And I think there is a potential for conflict because there is different starting points.

That is; typically within the religious traditions, one begins with a sense of bodily integrity and totality and that is where the focus of theological attention begins.

Then one can move, if you will, a little bit more reductively, to body parts that are removed or dis-incorporated--that is; removed from the body or excised from the body--but the whole is much more important than the parts within the religious font.

Whereas in much of the scientific discourse, and I refer to an example of a lot of the talk that has come out of the Human Genome Project, one begins with the parts and maybe the bodily whole is just simply an aggregation of the parts, but it is not clear if there is anything more to the body than just an aggregation of these parts.

So a real question from the religious side to the scientific community would be a question about what are the relation of the bodily parts to the body as a whole? So that might lead to some kinds of objections that would emerge at that level.

When-- The question, in terms of ethical uses of human tissue samples, really I think ultimately turns-- the major religious issue is going to turn--on then the attitudes toward the body that are adopted by researchers, by the scientific community, by policy-making bodies, and how they comport or contradict certain profound religious values.

The tradition that I have vandalized the most, the most frequently--and that is broadly traditions within Judaism, Christianity and Islam--tend to share some common features about the understanding of human embodiment; that is, the body is a real phenomenon, not an epiphenomenon or a mental construct, that it has intrinsic value. It has instrumental value, but it also has intrinsic value.

And that it is central, critical, intrinsic to our sense of personal identity rather than instrumental or accidental to one's personal identify. There is a real strong relationship between one's bodily self and one's sense of personal identity.

And, given that, of the questions I raised, the few questions that seemed to come up within religious traditions are:

How may the body be used;

What is the status of tissues and organs and so forth that might be removed from the body; and then,

What are the appropriate modes of transferring dis-incorporated parts of the body?

So that is-- It is those areas that I really want to focus on in my remarks because I think they are the most--

On the one hand, I don't think that the religious traditions that I have worked with and through have really addressed the kind of detailed questions that are before this Commission. On the other hand, it is possible to make some inferences and some possible analogous proposals.

I want to suggest that as religious, at least as this main category of religious thought in the West--and my report in general will do more than just the Western religious traditions--that, within the Western religious faith communities, again one starts with the person as in their embodied integrity and totality. I mean, that is the starting point for theological reflection.

And the primary use of the body is for purposes of worship and service of other persons. It becomes the vehicle, the medium, by which service is carried on to, for other persons.

Then the question becomes, if that is sort of a starting point, how is it possible to justify uses of the human body, and particularly human tissue samples that are retrieved, for purposes of

research?

What you find in I guess on the outline there is a very classic example of thinking inside boxes.

(Laughter.)

DR. CAMPBELL: But I tried to sketch out, as best I can-- And here I am not going to spend any time really just reviewing what some of the specific denominational attitudes are, or religious traditions attitudes. I am just trying to think about in general three kinds of understandings of human body tissue.

And I did make a mistake on the middle one. It should be "resource" rather than "research." That came to me--as I said, this is a work in progress--and that came to me about 2:00 o'clock in the morning last night.

I wanted to suggest that in thinking about how body tissue can be used, and how that use can be justified within the context of religious traditions that consider the body sacred, or at best some sacrality in the body, that there might be three kinds of ways of thinking about this.

The first would think about this on the model of donations and really draw inferences from the way that the human body and its parts are used within the context of transplantation and transfusion.

There you get what has been-- Within that context, you get what has been referred to by Marcel Moss and others as sort of a gift exchange that could be applied to the context of retrieval of human body tissue. The primary intent of the donor in those situations is to give a gift, a gift of the body. So there is a sense of altruism embedded within a donation of the body.

The expectation, and this I think is very important in terms of understanding the religious take on this, is that the expectation is that this bodily gift is going to provide therapy for the recipient. And that is where the majority of the religious reflection is focused on; bodily gifts but for therapeutic purposes, not necessarily for research purposes.

I mentioned earlier that there is I think a deeply-held value within the religious traditions about bodily or totality or organic integrity. So if a body part is removed, one of its outcomes should, in ideal circumstances, should be reincorporated back within some bodily whole, whether it is, again, a transplantation or of use of blood for transfusion purposes and so forth.

And then part of this gift exchange model is that the recipient of the gift has certain kinds of responsibilities, responsibilities for gratitude that is expressed in the way the body is used, or the body part is used, and conduct, as well as reciprocity, which may not necessarily go back to the individual that has provided the organ or the transfusion, but can be more diffused towards other strangers in the community.

Okay. Well, that is one way of thinking about it that I think has pretty much dominated the religious reflection. It is a gift. We think about human body parts that are donated as gifts for purposes of therapeutic intent.

There is another way that I think is less difficult--I mean is more difficult--for the religious traditions to really accommodate and that is to think about bodily tissue and body parts as resources, communal or private resources, but nonetheless resources.

Here the intent--excuse me--the intent is not so much to provide therapeutic benefits to others, but really to discard surplus or to transfer some kind of property.

The expectation might be that there will be some information of use generated. And that the body part will be sort of dis-incorporated, or remain outside the bodily whole for a long period of time.

The main recipient responsibility of this resource is that of informed consent. You obtain an informed consent to use the bodily resource.

Thank you, Tom.

Now, in thinking about if the majority of the religious reflection has focused on use of organs and blood and other kinds of body tissues for therapy, then it is not clear that the kinds of research questions that you all are concerned with quite fit under that category. I mean, there is some resemblances, but there are also some dis-similarities.

On the other hand, I think that the resource model, which is prominent in some of the genetic discussions, I don't think really fits well with--or fits at all well, frankly--with some of the religious approaches.

So what I tried to work out over in the last week is what I would call, if you will, something that builds on the donation model but is somewhat different from it, and that is what I call the "offering" or "contribution approach."

And here one is involved in a sense of donating to--one might contribute to--scientific research and provide body tissue not because this is an altruistic gift necessarily, but because one is seeing one's self as participating in some larger cause or larger social endeavor, such as developing new scientific understandings, discovering new sources of scientific understanding and the like. There is a sense of cooperation in a much larger cause than therapy to a specific individual.

And I will-- Well, let me just work through this.

So the benefit here accrues to a larger whole; that is, the good of society as well as sub-communities, like the scientific community, and not simply a single individual.

And then the requirement that body tissue be reincorporated is, in some sense, satisfied symbolically because one reincorporates this within a body of knowledge, if you will, where the body becomes a symbolic body, a body of knowledge of the scientific knowledge. So there is this element of re-incorporation.

And then, within that context, one could make a case that there are recipient obligations of gratitude and reciprocity so long as this is used for the common good, the good of all and not, again, specific individuals. So the suggestion at the end of the last section there--Dr. Childress put forward about responding to those that are participating in the focus group meetings by providing them a copy of the report--is one way of respecting this notion of gratitude and proper use.

So that is a way of thinking about the notion of contribution as I think a very secular kind of language. And in thinking about this again last night-- Probably in Washington notions of contribution is probably really difficult language, but I hope you see the spirit in which I am trying to present it here.

I think the religious language here that is closest is a notion of offering-- You know, it is different than sacrifice, but there is something important to that.

There is another possible way that one can think about, you know, what is the status of human bodily tissue. And I tried this out on Dr. Murray and Dr. Childress, and I don't know if they were all taken with it, but I am going to try it out anyway just to try and illustrate the different ways that

one might come to think about these kinds of tissue samples.

At our house there are various ways we dispose of kind of household goods. If we-- One way is we will donate certain kinds of goods such as clothing and so forth to the community Good Will. And there is-- That is a reflection I think of a gift, a donation, a sense of generosity and so forth. It really does kind of fit the donation paradigm.

Then there is a second way we dispose of household goods and that is we view them as disposable trash that we are quite willing to pay someone to come and take away from us. They have no value to us. We just discard it, put it in the trash bin and so forth.

It may well be the case, in fact I am sure it is the case, that if someone were to go through our trash they could find something valuable.

I recall that my wife once found a game of Life in a trash Dumpster, which I always thought was an interesting metaphor that I haven't quite wanted to confront yet.

But you can indeed find things valuable in other people's refuse, either household refuse or body refuse. And that might apply again to some kinds of tissue samples that may be surgical specimens or pathological specimens if the person just simply wants to be rid of because they are causing them disease or they have a surplus or so forth.

Then there is a third kind of thing that we do and this is--I don't know how permanent this is back here but in Oregon it is very important--and that is you recycle things, whether it is plastics, newspapers, magazines, and so forth.

And there-- There is again my sense of there is not so much a donation of a gift to specific individuals in need and they are participating in a larger-- I am contributing something that tries to participate in a larger cause, mainly the cause of cleaning up the environment or environmental integrity and so forth.

And I guess it is my suggestion that within the religious context--and I haven't obviously fully worked this out yet--but in the religious context it may be possible to locate mainly human tissue samples, not all, within this context of sort of recyclable materials that I can't really do anything with myself but if I give those materials--contribute, not give--contribute those materials to those with the proper skills and knowledge they can indeed create something useful, very useful out of them.

DR. CASSELL: That is "Solent Green."

DR. CAMPBELL: What is that?

DR. CASSELL: That is "Solent Green." Remember the movie?

DR. CAMPBELL: No.

(Simultaneous discussion.)

DR. CAMPBELL: So if this kind of analysis is useful on what kind of recommendations for your purposes might fall from it?

And I list four at the bottom of the outline. I haven't developed these yet in the paper. I just haven't gotten quite there.

One is that I do want to say that, in terms of dispositional authority, that the patient, or the person who comes in with the tissue sample, really has authority as a trustee, not as an owner of property but as a trustee, to transfer body tissue not for private interest but for the good of the whole, for the common good.

So here human tissue is understood not as property but as a kind of trust that one has been given and can be-- One can intrust that to others for the use of the common good.

DR. MURRAY: Courtney, this is really interesting and I hate to interrupt your flow. You are on a roll here.

DR. CAMPBELL: In the interest of time...

DR. MURRAY: You were even funny, and that is great.

(Laughter.)

DR. MURRAY: When-- In this model of the contributor of tissue as trustee, what does that mean for the recipient? And not just for the first recipient but for the second, third, fourth recipient down the line? What-- Do they then also become trustees?

DR. CAMPBELL: Well, yes. I mean, I think the initial recipient is, say would be the physician or the scientist, there is some sense I think bound by the conditions of the trust, which is to use that tissue for the common good in that I think that sort of obligation extends, you know, down the line to all those who would be beneficiaries of the trust.

DR. MURRAY: One issue that is going to come up is, because commercialization is at times the outcome of some of these, not necessarily individual contributions but a collectivity of contributions, to take your recycling analogy, it is okay if this company down the line makes money in the recycling. In fact, that is how we sort of do things in a market-oriented culture, so--

DR. HANNA: Well, what if we have a yard sale?

DR. CAMPBELL: Yes. Well, that is another way that-- You know, our yard sales have never been successful but--

DR. HANNA: That is direct benefit.

DR. CAMPBELL: Yes. Yes.

DR. MURRAY: Well, I was just thinking--

DR. EMANUEL: Can I raise another issue?

DR. MURRAY: I was just thinking that a pharmaceutical company then two or three steps down the line makes use of a particular collection of contributions and makes money on it. Would that be offensive to the point of view you are making, or would that be sort of in keeping with your model of recycling?

DR. CAMPBELL: Yes. Yes. My sense is that so long as-- And I guess there is a little bit under number three, under "commerce in the body," that one should try and avoid, or at least the religious traditions want to avoid, kind of an organized institutionalized commercialized market in human body tissue.

That there may well be benefits to be made financially as well as medically for the use of human tissue but ultimately, since this is a contribution given in trust, that it should be, you know, the entire community or the entire society that should be the beneficiary. And so that does place limits I think on the extent to which there would be accommodations for an organized kind of market or use.

But it doesn't rule out, you know, potential biotechnological companies using these for--using the tissue samples--for research purposes gaining some profit so long as that profit is not used to line the pockets so much of CEOs or something like that, but is used to further the purpose for which the tissue was given in the first place.

DR. MURRAY: Sorry I jumped on you.

DR. CAMPBELL: No, no.

DR. EMANUEL: One of the problems I have with the contribution model is it doesn't--I find it doesn't-- exactly mesh with what we are looking at because we are not actually looking at something that I give with the intent that it is going to be used for this larger whole.

The original intent was to get rid of my bodily, was some therapy item for me and the consequence later on is that we found it had some-- It could be useful to the larger whole. So the original-- In the original giving there isn't the contribution element to it.

So-- And I am not sure how much that takes apart both of the analogies, including the recycling analogy, which I like a lot, but it seems to me it is not actually-- I mean, if I was asked to give, as part of a research project, say, you know, two test tubes of blood, that is one thing, but all the pathological specimens which we are talking about don't exactly fit this model it seems to me.

Now that doesn't mean that-- I think it takes away this issue of--somewhat--of the intent of the giving. It may not take away the larger thrust of it, that it has to be for a larger whole, that it has to have this re-incorporational item, that if it was just research for understanding without research ultimately for some therapeutic good it wouldn't work. That kind of stuff.

DR. CAMPBELL: Yes. I think that, as I said, I mean, it may be possible for particularly those kinds of tissues--surgical specimens, pathological specimens--maybe in the model there is discard of surplus tissue and that is at least the initial step.

And then, subsequent to that, find out that there is some perhaps beneficial knowledge that can be generated from that. It is that-- Whether it is your blood, whether it is my wife's placenta, whether it is John Moore's spleen, or something like that, you find out subsequent to that that you have got, you know, some possible either-- You have got some material that either will generate information or perhaps generate some cell lines for therapeutic purposes. Then I guess it moves from just the kind of--

Well, okay. I mean, I think your point is right. It is hard to see how it-- I mean, it might begin to start as a kind of resource model, and then the question is does it fit within one of these large ones?

Now--

DR. EMANUEL: Or the other question--

DR. CAMPBELL: I think it is-- Yes?

DR. EMANUEL: The other question is when we go in for surgery do we need to say people have to think about it differently? Maybe they don't now think about it differently but, you know, maybe one of the calls is that we really need to think about this differently.

That there are-- Every researcher really has two processes and people need to be much more aware of the second process which, up until now, frankly has been submerged and only us in the medical world really have thought about it as an inherent and secondary-- I mean, otherwise we would have never kept the specimens.

DR. CAMPBELL: Right.

DR. EMANUEL: I mean, the entire reason really to keep the specimens is the accrual of knowledge.

DR. CAMPBELL: Uh-huh. Uh-huh.

DR. COX: I mean, I think Zeke is onto something, but I don't see it as a deal-

breaker.

(Laughter.)

DR. COX: Because in the past, when--and, in fact, this has been an argument that has been put forward by the pathologists--is that, you know, this discarded tissue, any information that comes from any single person's discard wouldn't be useful, but it is the body, you know, the total body of knowledge issue.

So where the rub comes now is with some of this genetic information that does have personal interest to the individual and so that it is tying up this individual use with the confounding of it with the societal common good use.

But I think that, you know, that doesn't really destroy the products. We just have to keep it straight, you know, whether we are talking about the individual's use or not, and when. You can't sometimes have it both ways.

DR. CAMPBELL: Right.

DR. COX: So I really like the--

So my conclusion is exactly the opposite of yours. I mean, I think that the contribution model is really nice, but it is confounded by this personal use, but that can be sort of an addendum where we talk about it and that is sort of, you know, individual cases, but it doesn't have to be the driving force of what is prepared on this.

Because I think if we try to get one paradigm that is going to accommodate both of these--the personal use and the public good--it ain't going to happen. I mean, those are two different issues.

DR. CAMPBELL: Yes. I mean, at least some of the contribution model-- The original idea is to provide for the common good and then if, in searching--

I mean, you know, I was very struck, you know, three nights ago when I viewed this PBS, "The Question of Genes." I thought it was very well done. And people were using the language of contribution all the time. "I will contribute my genetic sample for the BRCA study for..." I mean, they were using the language of contribution. So I think it has got language that resonates with people.

But you are right. It is you say for the good of science, but then if it comes back and if you will have some implications for your personal identity, then you will end up with some real balancing questions about at what point does individual identity, personal identity, you know, really take precedence over whatever benefits to the common good can accrue from that?

DR. MURRAY: Just a procedural interruption here for a moment. It is 10:30 a.m. We had scheduled public testimony at 10:30 a.m. There is only one individual who has indicated an interest in doing that. That is Mr. Cavanaugh-O'Keefe. And he has graciously offered to wait a few minutes while we continue the conversation with Courtney. And if that suits everyone else, I think we are going to do that. So we can continue. Thank you.

Trish?

MS. BACKLAR: The issue in here that is still also problematic is that the common good may be all very well and good but it may be personal harm that may occur in many different ways which I don't need to illuminate that we are aware of. So we have a gain of societal issue which we may not have that much control over and you have to figure that into this.

DR. LO: I think this is a really useful way of trying to look at things. And it seems to

me, following up on sort of the contribution offering column, you may want to think about how we define this intention or outcome because we both have been talking about it as sort of the common good and the incorporation may be incorporation back into the community as a sort of a symbolic body.

And that may be very different than scientific knowledge or discovery for its own sake. And I think there would be some people who would really say that they are not doing it for further knowledge, they are doing it, in a sense, to help other people help the community.

DR. CAMPBELL: Yes.

DR. LO: And then to follow on what Trish just said, it seems to me that part of the recipient responsibilities of the community in a sense, as the recipient, is to acknowledge the contribution by making sure the contributor does not have harm befall him or her as a result of making that contribution.

DR. CAMPBELL: Yes. I mean, I think, you know, in some sense that there are ways-- Well, I know, at least in reviewing your transcripts, there are ways you have talked about anon, anon, anon--

MS. BACKLAR: Anonymizing.

DR. CAMPBELL: Right.

(Laughter.)

DR. CAMPBELL: And linkable samples. And I-- And I am not sure whether you have all come to that particular question; that there are ways that you can sort of block some of the samples I presume from having that, having a personal impact, or impact on personal identity.

In the same way that, you know, there is really not much direct contact between the donor of an organ and the recipient of the organ and the way that we sort of block that knowledge and that transaction from occurring directly. We have scientific and institutional intermediaries that deal with that.

DR. LO: If I could just follow up? I mean, in terms of the bottom right-hand, extreme right-hand lower box, I mean, another way to protect is to, you know, prevent discrimination and to not stigmatize people but to recognize that as being, you know, fellow human beings like us as opposed to people that we try and stigmatize.

DR. CAMPBELL: Thank you.

DR. CASSELL: I am struck as I listen to this that, in the cost between what you are saying and what we are discussing and the issue of confidentiality of records and the openness of medical records to law enforcement agencies, nobody has-- Nobody can get into my body just to see whether fraud has been committed without asking me. And yet what you want to make clear is the information is part of the body. It may be have been disembodied in the process of becoming information, but nonetheless it wouldn't be here if it hadn't arisen from the body and if I hadn't given my consent in some form or another to it being removed from my body.

So that when somebody is able to enter those records without my permission they are in essence entering my body without my permission. And I find the idea disturbing. I found it disturbing before, to tell you the truth, but I find it even more disturbing in this context because what I hear you saying really is that my own doctor views me as a piece of meat and that is the way it is and--

(Laughter.)

DR. CASSELL: Growing up and watching pathology specimens and so forth all my

life has-- When you keep that going out and out it is different. That is right. And it actually goes right back into whether-- It wasn't different in the beginning. You know, we were all in the beginning. But it didn't matter that much.

It was more a pathology laboratory, and it isn't a little pathology laboratory anymore. It is now something with world-wide consequences. And I think that that is a very valuable contribution. Certainly to my thinking.

DR. CAMPBELL: I guess one of the questions rightly posed to me have to do with how to sort of limit the abuses of human body tissue. And the reason-- What I am-- What I am really struggling with, in terms of the religious traditions, is how you justify the use in the first place?

I mean, I don't think that question has really been thought much about so that is where the donation-contribution paradigm comes out of this. It is to try to get an argument to justify use from within a religious perspective and then the issues that you raise. You know, how does-- Once the use is justified, how does one limit the potential for abuses?

Now, there are some--not very many--but there are some that would say the very use of the tissue would be a kind of abuse, but that is a fairly minor segment of the community I think.

DR. EMANUEL: One of the things I haven't heard is this sort of imperative for scientific advance, or imperative to-- Not scientific generally, but actually health care. To push health care as much as possible.

I mean, it is certainly a strong omen in the Jewish tradition. Whatever you can do to save lives is, you know, a very high obligation actually, high enough to violate all sorts of other rules. And that, it seems to me, at least to give you a very strong justification for some of this, from the Jewish tradition.

And I don't know the other traditions as well, and I am curious as to how that pans out in the Christian and Islam tradition.

DR. CAMPBELL: Yes. Well, I think that-- Yes. Within Judaism-- I mean, Judaism has the most extensive body of literature on uses of the human body of any that I have been able to uncover.

But I think the general imperative that, you know, science is, despite the, you know, the potential for conflict between religious world views and scientific world views on these well-known historical episodes, I think in general, you know, there is a religious imperative from certainly the Islamic tradition and certainly within very conservative Christianity, who looks upon Bacon, Baconian science and Newton and so forth, as really the heros of scientific revolution. And other traditions within Christianity, Roman Catholicism.

I mean, it is the way we deal with the mysteries of the divine creation, the divine order, and that is through the scientific process. And of-- So--

And that can itself lead to a kind of, when that is supplied in context of medicine, that can lead to a strong imperative for healing. I mean, I think that is pretty central to all of the, you know, all of the Western religious traditions.

I mean, there would be variations, and I don't think you would get quite as strong a view as the Jewish tradition where, as you rightly point out, all but three commandments can be violated in order to save a human life but, you know, it comes pretty close to that in most of the other traditions I think.

And so that provides at least a presumption I think in favor of this, but when you get to, you know, the status of specific body tissues or body parts, again there is, as it may be as you found with your focus groups, there is just not a lot of thought that has been given to this directly.

DR. LO: Can I ask--sort of a different tact--and ask whether from sort of a religious perspective there are differences between DNA-based genetic research and other kinds of research that might lead to improvements in health for specific individuals or for mankind as a whole? Can you help us there?

I mean, I want to take you away from the sort of tissue sample as the sort of research, the type of research being conducted.

DR. CAMPBELL: What is the theological status of DNA? Is that sort of the general question?

(Laughter.)

DR. CASSELL: For you as well as anybody else.

(Laughter.)

DR. LO: For research on DNA. When you talk about sort of revealing, you know, the work of God for understanding, is there a limit to that in terms of probing DNA?

DR. CAMPBELL: Yes. What can I say about that?

I guess the limit-- Well, I guess the first thing to say is, within the religious traditions I am most familiar with, I just don't think the question has really been addressed to that kind of specific level.

The second point I would make is that I think that it is certainly possible that-- I mean, justifiable. If you take this argument that the creation of God, or the will of God, or the purpose of divine creation is somehow revealed through the scientific process that would encompass DNA as well as one unlocks really the essential mysteries of life, and that can be indeed a source of--

That that process of unlocking can be a source of awe for both the researcher as well as the rest of us, which is a foundational religious sentiment. So I would argue that you can go ahead and do the kind of research on DNA from a religious standpoint.

The proviso would be that, since the body is integral to our sense of personal identity and personal integrity, if research on DNA comes back to, if you will, reveal some knowledge about personal identity, then it becomes theologically problematic; that is, even though the tissues and DNA cells might have been removed from the body, disembodied, that therefore severed somewhat from personal identity.

If you study them in such a way that they reveal aspects of personal identity then that would be I think the theological limit there. At least there would be the concern. Again, you need to work that out in terms of protections of confidentiality and privacy.

DR. MURRAY: I was getting a little confused there, Courtney. When you say "aspects," when it would "reveal aspects of personal identity," you don't mean in some cosmic sense; you mean that it is this individual?

DR. CAMPBELL: Right. Right. Uh-huh. Yes. Yes.

DR. CASSELL: (Inaudible.)

(Laughter.)

DR. CAMPBELL: That this individual with this genome type which might mean that

they have some predisposition to this which they didn't want to know about.

DR. MURRAY: Right. Okay.

DR. MIIKE: Let me ask a follow up question. Unlocks the secrets of life. But if we unlock the secrets of life, the next step is to modify what you have unlocked and what is the attitude there?

DR. CAMPBELL: Well, I think that-- I guess here I will kind of fall back on a denominational response. I think within Judaism there is a very strong imperative to engage in cultivation and mastery of creation and so certainly partaking of the knowledge of the tree of good and evil you run that risk. But there is that potential for good and Judaism, I think--

DR. MIIKE: So I could change the apple to a Golden Delicious?

DR. CAMPBELL: Yes.

(Laughter.)

DR. CAMPBELL: Within--

DR. MIIKE: No. I ask this seriously.

DR. CAMPBELL: Yes. Well, you know, if-- I think that-- Again, I go back to my notion of the common good. If that is going to be for the benefit of the common good, then yes, you can probably go ahead and do that.

Christianity has this notion of continuing creation; that creation just didn't sort of stop back whenever, so human beings can participate through the scientific process in ongoing creative processes. That can include potential modifications. Again, I think there are limits to that.

And Islam makes a very important distinction between what can't be created by human beings--that really belongs to the domain of God--and what human beings are allowed to really be co-participants with God in creating.

And science is again the major vehicle.

DR. MIIKE: So in different religious traditions there would be room for discussing what is a positive change or a common good change--

DR. CAMPBELL: Sure.

DR. MIIKE: --versus others that would say no, once you unlock the secrets, that is the end of it?

DR. CAMPBELL: Yes. I mean, I think-- Well, there is certainly room within the major traditions and sub-traditions, certainly room for discussing what is going to count as a benefit to the common good and what is going to count as contributing to the body of scientific or communal knowledge.

And there are some traditions that reflect what I refer to in my paper as sort of dualistic traditions that would be opposed to that.

DR. MIIKE: And is there a framework within those religious traditions to decide what is the common good?

DR. CAMPBELL: I think, you know, within-- I can't say for sure about Islam, but within Judaism and Christianity there is certainly deliberative bodies that are looking at genetic issues.

Again, I don't-- I don't know that they have looked at the specific tissue sample issue per se, but in terms of genetic modifications, you know, there are Protestant, Roman Catholic and Jewish bodies that are looking at those questions.

So at least it is an open question about the meaning of, you know, what does it mean to be created in the image of God, part of which is to be creative and imaginative, and how far one can take that. So I don't think it is necessarily in violation of some of those religious stipulations.

DR. MURRAY: Jim, and then Kathi.

DR. CHILDRESS: I also, if I might, will just add a point or two; that some that essentially have been drawn have to do with ones that have been discussed elsewhere too, between somatic cell gene therapy for instance--wide acceptance in the religious communities. But when you move beyond that to germ line interventions--great suspicion and so forth.

So there are ways in which the discussion has occurred, but I think Courtney is right in the kinds of directions he is telling about; that some of these haven't been developed very far.

DR. HANNA: Related to what Jim just said, I am just curious if there are different religious perspectives in the tissue, the donated tissues, in gametes, in sperm?

With the cloning issue you kind of addressed it; that it was going to be used for appropriated purposes, but in terms of donating for research, are there different religious perspectives if the tissue is enabling sperm versus a skin cell or a muscle cell?

DR. CAMPBELL: Yes. I think that within some kinds of-- Well, I think that, you know, within the Roman Catholic, that can violate sort of the natural law or the natural purposes of those cells.

I am trying to think within the other religious traditions. I need some help here.

I mean, again, within Judaism you get the sense that any sort of imperative can be overridden by the presumption of saving human lives, so if somehow you can make out that reproductive cells can be used in the creation, generation or preservation of human life, I think that, you know, there is not necessarily an intrinsic religious objection there.

And, you know, I guess I don't know the Islamic traditions well enough to really speculate on that.

DR. MURRAY: Bill Freeman had a question.

DR. FREEMAN: It seems, from my experience with hearing that the American Indian people were concerned about the use of specimens, and also other native groups like the Maori in New Zealand, that there is, in addition to the system that you have about these three ways of looking at what happens or how we consider tissue, there is something that you said earlier that is much more important to them; that the body is sacred. That the body has an intrinsic power, value, sacredness, whatever, and that that continues, the chain continues as you take out, you know, amputate a limb for disease. Lots of people, including some of my Jewish ancestors, would say that that needs to-- We need to do something special about that. That is not discarded--the resource kind of thing--it is part of me. And I guess it is related to a phrase that is current now about human dignity.

How does that play out?

Because I think that additional way of thinking of it, I think is separate. And is not just native peoples. I think it is a lot of people in the U.S., and that there is something inherent and therefore-- And that limits what you can do with it and how you can-- And the procedures you can do with the part of the body.

DR. CAMPBELL: Yes. Well, I have looked at a lot of native materials and I think that, you know, your general description is quite accurate; that the kinds of distinctions that tend to be

worked with in Western religion and Western philosophy and Western medicine between body and self, between nature and culture, I mean, those just really are not present in the world view of the Native American cultures.

And there is this sense of a unity with all-- I mean, my body is part and united with the rest of the natural order, so insofar as there may be a need for a medical intervention, you know, of course, in many cases Native traditions would rely on their own indigenous, you know, healing approaches and so forth and not make use of more scientific medical approaches.

But insofar as those were used, then I think there are very profound limits on what might be done with discarded body tissue.

In most cases, I mean, at least among the tribal customs that I am familiar with in the Northwest, one would need to return those bodily tissues to the person. Usually they request that because, again, you have-- There is a sense-- There is a sense of harmony and unity with all created life that doesn't end just because you happen to have amputated or removed some tissue.

That still is, in some sense, part of the entire cosmic body I guess in some respects and needs to be given appropriate respect and dignity which, in most cases, might mean some kind of burial or at least some kind of ritual, religious ritual. That would be important.

So I think you are right to suggest there are different-- I mean, that is a different way of thinking about the body and body tissues that, you know, by and large, is not part of at least the Western faith discussion.

And it would also be part of some of the Eastern faith traditions as well because of their different views.

DR. FREEMAN: Except just to say--coincidentally my mother was a nurse, now long retired--it was said that back in the '40s and '50s it was routine at surgery, or before surgery or after surgery, to ask everyone what do you want done with, you know, with your amputated limb? It is not asked anymore. But this is in, you know, mainstream U.S.

And it seems like there is a moving; that things are moving, which is also to say that there is a spread of beliefs and sets of values in the U.S. population, not just in Native Americans, and not just in non-- It is also in Western religious people.

There is, I assume, still a significant proportion that say that there is something special about the body and it would have to do something with the tissues and, you know, you cannot do other things. There is a limit to what you can do and it has nothing to do with science; it is just you can't go beyond that.

DR. CAMPBELL: Well, I think that I go back to the first recommendation that I made, even though I never got to three, four and five.

(Laughter.)

DR. CAMPBELL: I think that if there is a sense that, you know, science is interested in body tissue, just simply for the purposes of a kind of a scientific scavenger hunt, then I think you are going to have some real kinds of objections, and so the point that needs to be made is some clear public justification and clear statement of what are the scientific purposes and values at stake and research at stake.

And I am not sure that the-- I mean, I am not entirely clear on some of this. And I take it from the focus group discussion that was reported on earlier there isn't a sense of real clarity

about that either.

And I think that is where, as I say, following up on the recommendations you all made for the cloning, in terms of forums for increasing scientific public literacy about genetic issues and genetics, in that context, but uses of the human body that science can find important, is a way to at least meet those kind of incipient objections.

DR. MURRAY: Bernie, and then David.

DR. LO: I am going to make one of these double-barreled comments.

The first is try and tie this discussion we have just been having back to what we found in the focus group discussion before the break.

I mean, people have no clue when they go into a hospital for surgery what is going to happen to a part removed. And what I am hearing convinces me that some people, many people, have very strong religious views about what the proper disposition and outcome of that removed issue is.

And then if we asked them in a context which virtually guarantees they won't notice that we are asking, or not know to think about it or make a thoughtful response, we can actually inadvertently be violating some people's very strong religious beliefs.

And then my second point is really sort of an open question. Would it be useful--I find this sort of religious context, you know, very helpful--would it be useful to do what we did for cloning; is to ask some people who actually represent, or are more sort of familiar with certain specific faith traditions, to come and address some of these issues as well?

DR. MURRAY: We can take that up later this morning.

David?

DR. COX: So I would like to continue on what Bill said because--maybe I am not getting this right--but I see it very much as a continuation of what Eric said. Eric made a really strong statement and it had a big effect on me basically.

That from the point of view of the medical community-- I guess because I personally did this too. Well, it is just me. Give me a break. It is not. And so we were wrong. At least I was wrong. That is my personal view.

And so I am not sure that in Western culture, I mean, that it is so different. It is just that what has happened is that some of the people in Western culture have said, well, it is just me. All right? And now we are saying wait a minute. You know? Is it really?

And so that that is why, if it were really true that we had this long-standing, you know, Western tradition, that it is just a body part, and it wasn't part of the whole and we could sort of do with it what we wanted, then I think we have a real problem if we are sitting and trying to redefine it now.

But I guess what you are doing for me, and what Bill did and what Eric did, is saying, you know, that maybe we have been looking at it sort of not, you know, very critically in recent time and we need to look at it more critically in this religious perspective.

So what is the net result of what I am saying? The net result is to keep it in this context of benefit for the whole and the context that, you know, you have to ask people what they want to do with their body parts. And the only deal-breaker to me in that is that that hasn't been part of the Western tradition because, for better or worse, I mean, you know, we live in a Western culture. So if that hasn't-- If that really is very different from what, you know, the Western tradition has been, then I

think we have got ourselves a problem.

And I thought I heard you sort of say that, but maybe not.

DR. CAMPBELL: Well, I--

DR. COX: You know, if what Bill said-- You see, what I heard you say is, well, that is very different from the way most Western people think about it. Because if that is true, then, then--

DR. CAMPBELL: Well, I think that there is-- I think the native cultures have, you know, a deep sense of reverence and sacrality for all of what is considered in the realm of nature and that includes the human body. And there isn't much distinction made between the body in its organic totality and body tissue that is removed. Okay? I mean, it still has that same sense of sacredness or sacrality.

Within the-- And so you want to treat it with a great deal of reverence, respect and engage in rituals, which I think are important so that you try and restore that sense of wholeness or sense of balance within the native culture.

It seems to me that, within the Western faiths, there is this shared premise that the body in its organic totality is very, very unique, special, sacred, the image of God, and so forth, but that the specific tissues that might be removed don't have the--

Again, it is the bodily whole is greater than the sum of the parts here, and so it doesn't have that kind of deep sacrality within the Western faith traditions that it does within the native cultures.

And so it seems to me that the monotheistic Western traditions would be much more accommodating to, you know, research on tissue samples. If you can make a case for it having some kind of contribution to the body of communal, the scientific body, or whatever, then perhaps the native cultures might be--

DR. COX: So I did hear you right?

DR. CAMPBELL: Right.

DR. COX: And, in fact, that then is going to lead to a really interesting, you know, push and pull because we are, as I see it, pushing it more back towards the native culture with this idea that it is not just a piece of meat.

DR. CAMPBELL: Uh-huh.

DR. COX: But that we are only going to be able to push that so far because basically the whole idea that--

And, in fact, I was surprised by this, to tell you the truth, by the religious testimony on cloning, because I wasn't sure I got it right because it didn't seem like the whole, you know, and the body parts were equated to the same thing at all in that religious testimony. And that is exactly what you are confirming.

And so with these stored tissue samples it becomes complicated because we would like to get it back more, you know, or at least-- I mean, I don't know what we want to do. But there is this push and pull.

DR. CAMPBELL: Right. I mean, the question for the Western traditions is what is the status of these tissue samples? I mean, do they fall into the category of gifts, like organs and blood? Are the resources to be mined or used as meat? I don't think that quite works. Are they something that falls into the category of offering and contribution? And that is where I was trying to go.

DR. MURRAY: I am having this emerging sense that we have been laboring with a

dysfunctional ritual that has been described as this little consent form, that you check off the box, and then that is a part of-- I mean, it is a secular ritual, but it is a kind of ritual that signifies that it is okay to now use this for other purposes. I don't know what I am supposed to do with that particular image.

But I don't know who you are, sir, but would you identify yourself?

MR. SOLON: Jerry Solon. May I make a comment and perhaps trigger some additional discussion and relatedness?

I am puzzled that in this whole exposition and discussion there has been no relating of the disposition of tissue samples to the disposition of end-of-life corpse as a whole, which opens up a whole arena.

For example, cremation as one form of disposition; those who make that choice for the end-of-life corpse and disposition or cremation of tissue samples during life.

DR. MURRAY: Well, one thing to say is that we do have--and maybe Courtney will and Jim will correct me--we do have, in American culture, notions of what is respectful treatment of even the dead human body. And we don't exhibit it, we don't sell it, we don't-- There are a lot of things we don't do with it.

DR. EMANUEL: It is not trash. We know that.

DR. MURRAY: It is not trash. It has to be-- Even in death, it has to undergo some sort of respectful treatment. What constitutes respectful treatment differs among cultures, but the commonality is that there must be some sort of ritual or limitations on what we may do to bodies, even upon death.

(Simultaneous discussion.)

MS. BACKLAR: It was interesting yesterday, the discussion--

DR. MURRAY: He is still alive.

MS. BACKLAR: It was interesting yesterday to hear that decisions for that, for what will happen, for the disposal of the corpse, goes back to the family.

DR. MURRAY: But within limits.

MS. BACKLAR: Right. But that is part of the process that we accept.

DR. MURRAY: Yes. Yes.

DR. CASSELL: I was bothered by David's comment before. I think, as he points out, the whole idea that the thing is meat went down the line too far. We are here because we can't quite accept that the tissue specimen is just-- Do whatever you please with it, right? And yet the idea, well, what is it? Well, what are our obligations to it and its owner?

And the Commission represents our culture's step toward redefining that, bringing it back from, bringing it back from the too far that it went. I mean, we struggle.

I mean, I find this discussion very, very interesting. And bringing it back from that and yet trying to figure out, well, what else? Because we are sitting here with the balance between the needs of science and so forth and so on. And it is a really interesting subject. Not, fortunately, not easily disposed of.

(Laughter.)

DR. MURRAY: Thank you, Eric.

DR. CAMPBELL: Could I just--

DR. MURRAY: Yes. I will-- Actually I am going to invite you, Courtney, to go

ahead and finish your outline.

But if you wish to begin with another comment, go right ahead.

DR. CAMPBELL: Well, I just wanted to respond to his comment because it illustrates how complex and difficult this can get within a specific religious tradition.

I mean, the most sustained discussion of donation of one's body to science, for example, for research purposes, is within Jewish literature, and there you get, again, some-- I think you get some Orthodox rabbis arguing that really that is inappropriate in terms of respect, the respect that should be owed to the corpse. You get some more conservative rabbis that have argued, and I do believe I cited one of these in the paper--I can't recall--saying, well, you know, in principle, that is permissible to let the body be used for even purposes of anatomical dissection. In practice, medical schools don't need bodies from Jewish patients so in practice there is no obligation for Jews to contribute their body to scientific research.

But if it is done then the body tissues and parts that are removed for anatomical purposes need to be returned to the family for burial. So that is a pretty powerful kind of ritual that goes on and it just illustrates that, you know, the status of the body parts are important, but they don't have the same kind of respect, or they don't have quite the same kind of status as the human body as a whole I think.

It is-- I mean, it is a point well taken I think.

DR. MURRAY: Okay. Finish up.

DR. CAMPBELL: Okay. I am not sure how to take this up now.

I guess I was down to "E-2," which was sort of issues about informed consent. You had discussed, in one of your previous meetings, about, as I trace it out on the transcripts, about nine different possibilities of consent.

I think by and large the religious traditions would--I am not representing as much as interpreting--would argue for what some of you have referred to as "thick" informed consent, which means that, rather than just sort of a general waiver of sign-off that, again, the purposes of the research be outlined, be anticipated--the purposes of the research--be outlined to the patient if those are known. Sometimes obviously things change in advance.

But I think that reflects what one of the leading ethicists, early on in the days of biomedical ethics, Paul Ramsey(?) referred to as a cardinal canon of loyalty between the patient and his or her physician, or the patient and his or her researcher.

So one of the recipient obligations of gratitude--you have already touched on this--is protections of privacy, confidentiality and anonymity, prevention of discrimination and harm that needs to be more fully fleshed out on my part, I know.

And then the third kind of implication had to do with commerce in the body. There is some real strong--I think there are strong--religious concerns from some, emanating from some traditions about treating the body merely as a form of property and merely as a kind of economic asset. The body as a whole or body tissues.

And so contributions or donations are really the ethically preferable and ideal.

The Roman Catholic tradition, at least Pope Pius, did not rule out compensation for individuals who might contribute blood, or potentially organs, but that is different from saying that we should have some regulized institutionalized market in tissues and organs. So there might be some

compensation but really on a very individual level and not an entire system set up for it.

That is pretty much all I wanted to add.

DR. MURRAY: Well, I think judging by-- You can tell by the quality of the conversation and the questions that you have done an excellent job for us. Thanks. I know you are going to continue to work with us.

DR. CAMPBELL: Thank you very much.

DR. MURRAY: It is-- I have about 11:10 a.m. We have still one person to do. Testimony should-- Should we take a break or have the testimony?

MS. BACKLAR: Do the testimony.

DR. MURRAY: Mr. Cavanaugh-O'Keefe, would you be willing to do your testimony now?

Thank you for your patience in waiting. I want to remind you that we ask that these be--that your remarks be--no longer than five minutes. Thank you.

STATEMENTS BY THE PUBLIC

MR. JOHN CAVANAUGH-O'KEEFE

MR. CAVANAUGH-O'KEEFE: My name is John Cavanaugh-O'Keefe. I am the Director of the American and Bioethics Advisory Commission.

Thank you very much for this opportunity, unprecedented opportunity, to speak.

And thank you also Dr. Murray for your response in the letter after the last meeting.

After the last meeting I wrote to Dr. Murray suggesting that the paper on human tissue include some look at the history of the abuse of genetic records, specifically the Eugenics Record Office in New York, because the horror at the Eugenics Record Office was so immense, including two of the great evils of American History.

The Eugenics Record Office helped to push through the Johnson Act, which kept out specifically Jews up to 1940. It was a substantial contribution to the Holocaust. The ERO also-- The ERO helped to push through that act.

The ERO also helped to push through laws permitting coercive sterilization in 30 American states. And I think that the question of what has been done in the past with genetic records is something that probably is worth looking at carefully.

And I didn't want to add anything more to that recommendation, that you look at ERO, but I did want to break past one possible objection to it.

There is-- Many people have never heard of the Eugenics Record Office. And so the question can come up, is it worthwhile looking at what happened 70 years ago, or 50 years ago, at one research institution, which has since been dispersed?

And I want, in response to it--I have only got 10 copies of it--but in response I did want to just take one-- I wanted to just run through an article from 1964 and just flag some concerns about it.

The central point that I want to make is that I really do think it is worthwhile looking at this piece of American history. I don't think that it is part of the deep and distant and forgotten past, and I think it is relevant to your current work.

The article is written by a member of, by Howard Newcomb, a member of the American Eugenics Society. For some people that is a flag already. The article is subject to a benign

interpretation, but it can also raise a whole series of red flags.

This particular article is written in 1964. That is 20 years after the Eugenics Record Office was closed down. But still 20 years later at a meeting at that same site, at Cold Spring Harbor Laboratory, there was a member of the American Eugenics Society speaking at a symposium where at least a dozen other members of the American Eugenics Society were presenting papers on genetics and population.

In this particular paper, what Newcomb was describing was a tool for developing pedigrees of handicapped people, disabled persons, without their knowledge or consent.

Now, he was doing other things as well, but that is one aspect of the paper. Twenty years after the ERO was closed down, there was still somebody who identified himself as an eugenicist talking to other eugenicists about how to develop the records.

He talked specifically about Canada, where he was working with at the time on a project, a pilot project with 1.5 million records in British Columbia. That is a large pilot.

The-- The-- He mentions in the paper that the Canadian vital statistics were altered slightly, whoever maintained them--if I understood it, altered in 1946 or soon thereafter--to include the mother's name carefully so that it would be easy, through vital statistics, vital records, to build the pedigree. That was an alteration which--

I mean, today every credit card company maintains-- For the confidentiality records, they ask you, you know, can you give your correct social security number and your mother's maiden name. People think of that as being a way of protecting the confidentiality of their credit cards but in fact we have also put into a database a way of building their pedigree, if someone else has access to those records.

And that--I assume that came out of this article in '64--I thought was just fascinating.

The-- Newcomb was still, in 1992 at least, talking about how to build pedigrees, and so this is not ancient history. It is not even 30 years old.

The last point that I want to make about it is that Newcomb does mention that the records in Canada that he was using are protected. There are security requirements surrounding them.

However, other people looking at his work with a jaundiced eye might think that if the records are protected, but Newcomb can get them, then they are protected by the wrong people and from the wrong people.

And if members of the American Eugenics Society are scrutinizing vital statistics in order to build pedigrees of the handicapped, the records may be protected from most public access but substantial questions about protection of those records remain.

I think I am just going to urge that I think it is worthwhile looking at the history--the history--of the abuse of genetic records.

DR. MURRAY: Are there any questions? David?

DR. COX: I have a comment. And I think that I agree with you, but that I would like to see it done right.

And that I think if that were done solely by focusing on the Eugenics Record Office, that this Commission and everybody else would get the very wrong idea because to look at it correctly in my view is to look at the context of genetics and society from 1910 through 1964. And the scientists were one component of that so that the I think--

I am really quite familiar with this literature, and I think that it is much more complicated than a few scientists sitting up at Cold Spring Harbor talking about putting pedigrees together. So that I would just encourage--I would agree with you--but I would encourage that if this is looked into to that it is looked into in the broad context of society.

MR. CAVANAUGH-O'KEEFE: That would be wonderful. It is clearly-- I think that could stall forever. I think that--

DR. MURRAY: Bernie?

DR. LO: I think it is important to understand history because it is a very unsavory history in many ways. And there is an easy way to do it. There is a professor at Cal Tech named Daniel Kimisis(?) who has written a very good book called *In the Name of Eugenics,* which goes into both the specifics of Charles Davenport and the Eugenics Record Office, who also puts it in a much broader and-- It is frightening because, you know, some of the people, you know--

Carl Pearson(?), who, you know, developed the statistical test we use, was very active in the eugenics movement in Britain. And he also puts in this context that social Darwinism made a mysterious-- And, you know, it is nice book and there is an airport near Cal Tech. We could fly him out here.

MR. CAVANAUGH-O'KEEFE: Kimisis' work is excellent up to about 1948 or so, or shortly after the war.

I think that working with his material it is extremely to understand that he accepted the history of the eugenics movement written within the eugenics movement; that much of the history of the eugenics movement was shaped by Frederick Osborne, who wrote the Encyclopedia Britannica article on eugenics in the '70s, but was a member of the American Eugenics Society, and who encourages people to believe that eugenics is a thing of the past and that it disappeared with Hitler.

And part of the reason for bringing forward this is just really to say, listen, it didn't die with Hitler. It is still there.

DR. MURRAY: Thank you.

DR. COX: I have a comment.

DR. MURRAY: Yes. One more comment. And then we are going to have to stop.

DR. COX: And that is that I would-- Again, I just want to emphasize, Mr. Cavanaugh-O'Keefe, that I endorse the spirit of what you are saying, but I find, on this that you passed out to us, that associating specific names with a specific society like the American Eugenics Society and then sort of classifying those people in one camp or another is probably not a good way of getting a good public dialogue of this kind of issue because it is very analogous to what Joe McCarthy did with respect to Communists, and so I just wanted to say that I am not very much in favor of that approach of figuring out who are the good guys and who are the bad guys.

DR. MURRAY: I want to thank you for contributing your testimony today and note that I think, without committing to any particular use of history, I want to agree with other members of the Commission and with you; that it is important to understand this in historical context.

It is also important to understand that the use of tissue samples in genetic research is-- That this is probably a very small piece of the puzzle in terms of what uses those tissue samples, to which they might be put. Developing pedigrees, et cetera, is, I suspect, a very tiny segment of the larger research uses of such tissue and I just want to place that in context.

Let us take a break until 11:30 a.m., and then we can talk about what to do next on this project.

(Whereupon, at 11:23 a.m., there was a brief recess.)

DISCUSSION OF THE FUTURE OF THE REPORT

DR. MURRAY: We will thank you for sitting down. It is our intent to adjourn our schedule at 12:30 p.m., which gives us 50 minutes or so, and I want to do two things in this order.

First of all, I think we need to talk about the structure and process of getting this report finished. And if we have any time left--we may or may not--we would like to get into some substantive discussion about what we want in there, particular issues in the report.

But let us construct how we are going to get this report finished.

The goal has been to issue the report in the middle of January roughly. If you work backwards from that, that means we really have to put the finishing touches on the report sometime by the middle of December, which means we have to do most of the substantive decisions and have most of the draft ready sometime in November, which means we have to have a lot of the report already relatively well in hand in the next meeting in October.

So in October, we can have some further substantiations of various background papers. We can get into some very substantive discussions. You know, we have to make some difficult choices. We can do some of that in October. We have to have much of that done in October.

And in November we can come back and clear up most of the residual hard questions.

December would be available then--we are talking about potentially meeting in mid-December--to come back and take, you know, any last pieces that haven't been completed yet. And we will have a sense of what the full report will look like, you know, with minor modifications still a possibility.

That is roughly the schedule. Is that a schedule we are willing to live with?

DR. COX: And what is the October piece going to be?

DR. MURRAY: October is going to be heavy substance. We really have to work through some of the most difficult issues in October.

DR. EMANUEL: No hearings or testimonies or any of that?

DR. MURRAY: Well, I mean, I think I would like to have the paper--background paper writers with us. Like Robert Weir has agreed to write an ethics piece, so Robert should be here and maybe we will be in conversation with Robert, so he will tell us something about what he wants to write, but he should be here also listening to our deliberations. But, yes.

Well, what do you want to do?

DR. MIIKE: One process thing. You haven't included the full committee in this, just the next sequencing. That is--

DR. MURRAY: What parts of this are subcommittee and what parts of this are full committee are open. I would expect that the full Commission would be together for certainly portions of these deliberations. I am not sure what-- What do you think about this?

DR. COX: For the 19th?

MS. BACKLAR: Yes.

DR. NORRIS: Jim, what I heard yesterday was half and half from Dr. Shapiro; a half-day for each subcommittee.

DR. CHILDRESS: We have a pretty full day.

DR. NORRIS: Yes. It sounds like Tom does, too.

(Simultaneous discussion.)

DR. NORRIS: But Sunday was the best day according to the collective schedule on October 19th.

DR. CASSELL: Tom, are we going to have recommendations for legislation?

DR. MURRAY: We will certainly have recommendations. Whether they will be for specific legislation, I honestly don't know. I mean, anything is open to us, but I don't know whether--

DR. EMANUEL: I think it is more regulatory than legislative.

DR. MURRAY: Yes.

DR. LO: Let me go back to this process with regarding the full committee. I think it would be extremely helpful to have the full committee in on what would be our next set of discussions, partly because I think I feel uncomfortable having the two committees start to diverge at the point of making the first cut at resolving tough issues without having the benefit of the full committee.

I mean, if one of the subcommittees starts to go off in a certain direction and the other half of the committee hasn't been in on that discussion, and then two drafts down the road says, "Wait a minute. What is going on there?" it is going to be a bigger mess in the long run.

DR. CHILDRESS: And it ends up taking more time in some ways.

DR. LO: Absolutely.

(Simultaneous discussion.)

DR. COX: Then perhaps a solution to that, because we haven't make the cut yet, is to make the cut on the 19th, but basically at least it is laid out as the tentative cut and then people can come back from the full Commission and make comments on it.

The problem is that if you are having-- And then you could say why. I mean, that is why you have subcommittees. So the subcommittee evaluates this and then we say to the whole Commission why we made these decisions. But then it allows--

And the same thing. I mean, that is really what you are doing, Jim, because we don't listen to everything that your group says, but I am hoping that you do that on the other thing.

DR. EMANUEL: I would second David's view. I mean, my own assessment is that we need probably the better part of the whole day discussing between ourselves, first of all, what we think the key issues are and then our sort of intuitive sense as to which direction we should go with it, and to get some organized framework for our recommendations.

And then maybe, at the end of the day for a couple of hours, sit down with the whole committee, or at the next-- I don't--

I mean, the problem is, after October 19th, we have a long gap and we can't let that long gap go before everyone is at least pretty much on board, otherwise we won't get any, have any time to write it. So it seems to me, maybe at the end of the day, a couple of hours to hash out.

And part of the sort of deliberative process, I would urge, is that we come with some concrete cases and examples of where, that we are going to resolve, to help focus the kinds of recommendations we have.

Now Steve was really good with this, partially I guess because his company is out there doing it, but I think, you know, maybe all of us could scrounge around, or maybe get more

information on some of the big research projects going on--that that might be helpful--or at least examples that we know about where this has been a key element.

DR. MURRAY: Using stored tissue.

DR. CASSELL: Could I pick up on what Zeke said? Because I think it is very important. If we are going to do this, some of us are going to have to come up with written materials. And I have a plea. I mean, it was wonderful to get all that material this week. It was just really one of the more thrilling things that has happened because it made everybody know how important I was.

(Laughter.)

DR. CASSELL: But I would like to get-- We have a topic in front of us, in this particular, whatever particular week it is. I would like to get one piece of material and know, or at least one piece of material labeled "This is what we are talking about," so that I can spend the time doing that and not trying to figure out what I am supposed to read for this next meeting and then doing what everybody else did, read almost none of it.

I think that is really important so I can really read and reflect; that I actually would like to get-- My machine is working now and I can get my e-mail. I would really like to reflect on a hard copy that can be read in places easier than the other.

But I think it is really important to reflect on this before we come into a meeting and after it because there are some real issues in this.

DR. MURRAY: For non-commissioners, this pile represents a small fraction of the material received for this meeting.

DR. GREIDER: So can I follow up on that with one question? Do we have a written outline of what is going to be in the report that we are talking about? I know we discussed it at the last meeting.

DR. MURRAY: No. Not per se. No.

DR. GREIDER: Because that would--

DR. MURRAY: That is something we need to discuss.

DR. GREIDER: --be nice, just to have the overall outline, a hard--

DR. : We had a proposed table of contents, but the chapters--we didn't.

DR. MURRAY: Right. I had sort of sketched out what I thought the components would be.

DR. GREIDER: And that is in here?

DR. MURRAY: No. No, no. It is not in there.

DR. GREIDER: I don't know--

DR. MURRAY: I think at the last meeting--

DR. CHILDRESS: I think it would be useful to lay that in front of us all and--

DR. GREIDER: Yes. If we could go through the different components, because I don't remember what all--

DR. MURRAY: Kathi Hanna is going to be working with us on the actual summary of the report and everything.

DR. : Is she smiling?

DR. MURRAY: Kathi?

(Laughter.)

DR. MURRAY: She and I will shortly make sure that you get something like a tentative outline of the report.

DR. NORRIS: May I ask for a point of clarification since both of our subcommittee chairmen are here? I think what I am hearing is that there may be a change in plans and what you are considering is a full day subcommittee meeting for each one of you simultaneously on Sunday, October 19th?

DR. CHILDRESS: I think I am hearing essentially that both subcommittees need a fairly large portion of a day. The question that Patricia and I were just talking about is we said that Sunday is best, but is Saturday out? That is, say is there a reason we couldn't do a day and a half?

DR. NORRIS: What do you recall of the calendar?

DR. CHILDRESS: Well, Monday is-- I am cancelling for a lot of these things. I can't cancel anymore.

(Simultaneous discussion.)

DR. CASSELL: I don't know what time of day it is, but it would make it hard to--

DR. CHILDRESS: Well, it is like 2:00 o'clock, I thought.

DR. NORRIS: Is Saturday fine?

(Simultaneous discussion.)

DR. MIIKE: Jim, do either of you report as the Federal Agency Report? Is that what--

DR. CHILDRESS: Right. That, plus moving as far as we can on getting stuff ready on the decisionally impaired. Those are the two major tasks.

But given our discussion this time, I would hesitate to-- We might be able to squeeze it in to half a day. I thought the feeling was that we really needed more time for reflection and discussion. Is that-- Arturo and Harry?

DR. BRITO: Absolutely.

DR. NORRIS: That is what it sounds like.

DR. BRITO: Even a full day may not be enough. Yes.

DR. CHILDRESS: Especially with a long gap.

DR. BRITO: Can I make a suggestion, because it sounds like it is going to end up being just Sunday. Would it be too much to have each subcommittee present to the full Commission just for, you know, half an hour, just basically where, at least to know the progress?

DR. MURRAY: At the end?

DR. BRITO: At the end. Or not at the very end, because what is going to happen-- I know a lot of people have to take flights and it becomes very difficult. I am worried about people leaving. But maybe like at 1:00 o'clock, and that would leave a little time afterward for each subcommittee to further discuss.

DR. CASSELL: Zeke has got a point. We can work over lunch.

DR. BRITO: Over lunch, too.

DR. CASSELL: (Inaudible.)

DR. BRITO: That is a good idea. Yes.

DR. COX: What is going to happen? I mean, what I see is people will just figure this out. It will be sort of done, but not quite done. So it is really after than Sunday that you would like to

have this presented, and like in between then and December.

Now, we have already said it is difficult to have another meeting in between, but I think that at least even if we had that up on e-mail, which is two different things, so that there is time for people to reflect. Because I think that the discussion will happen that day, but to expect it to come out in a real coherent way at the end I think--

DR. MURRAY: Oh, that is right I think.

DR. COX: So what we really need is another meeting, but if we can't have another meeting at least we could have it posted in November because there is a large part in between, and then people could discuss it.

DR. MURRAY: Trish?

MS. BACKLAR: I also would like to suggest that we meet very, very early on Sunday morning. I mean, really much earlier so that--

(Simultaneous discussion.)

MS. BACKLAR: --for those of us who are hoping to get a flight back to the West Coast, we can spend a day, a real day. If we are flying here, the least you could do is meet earlier.

DR. CASSELL: Well, what do you mean by "earlier?"

DR. : We have been meeting at 7:30 a.m. in the past, right?

DR. EMANUEL: Well, 7:30 a.m. is no problem.

MS. BACKLAR: We could meet at 6:30 a.m.

DR. CASSELL: 6:30 a.m.?

MS. BACKLAR: Sure.

(Simultaneous discussion.)

(Laughter.)

DR. MURRAY: There are many proposals floating around at the moment. Let us just--

DR. CHILDRESS: 7:00 a.m. seems reasonable.

DR. MURRAY: It is fine with me to start early on whatever day we meet. I am just thinking now about the dates we have available, and the needs of the two subcommittees.

My sense is that we need almost all--if we are going to have just one day in October--virtually all the day for our own conversations. We just are going to need that.

At some point-- I don't have a sense-- Actually, I think maybe mid-day is the right time to do it because, David is correct, we are not going to have a fully fleshed out, carefully articulated report to make to the other members of the Commission. So perhaps sort of in mid-course on that day, we can sit together, the two subcommittees, and sort of tell each other where we are in process and then go back and finish our own deliberations, taking into account whatever we hear from the other subcommittee members.

Sometime after that we should begin circulating something like some tentative recommendations, or at least a good paper that explains the major points that we seem to be reaching as a-- Major decision points that we are making, major decisions that we have made. Some tentative conclusions and recommendations. And that, obviously, goes to the full Commission.

MS. BACKLAR: And we could use that. We could eat our lunch together.

DR. MURRAY: That is what I am saying.

MS. BACKLAR: So that we don't--

DR. MURRAY: We will do that at mid-day.

MS. BACKLAR: --waste anytime during that day.

DR. MURRAY: Yes. There is a cost to be paid in ability to concentrate through the remainder of the day when you don't allow a break, but maybe that is a cross that we should bear.

MS. BACKLAR: Coffee.

(Laughter.)

(Simultaneous discussion.)

DR. MURRAY: We will start at 7:00 a.m. in the morning, have a working lunch. Okay.

MS. BACKLAR: Then I can get home that night.

DR. MURRAY: I am hesitant to even offer you this possibility, but I have to.

DR. MIIKE: Would you take two disembodied voices? Because he and I are not going to be here.

DR. COX: I have to be in Taiwan on that Sunday, but I just physically have to-- I don't have any work to do there, but I have to be there for Sunday night. But what that would mean is that I can basically call in. But I really--

Ms. Hyatt-Knorr: We may need to look at the cost of that.

DR. COX: Yes.

Ms. Hyatt-Knorr: Of a full day of--

DR. COX: No. It wouldn't be the full day, but it would be for parts of this, Henrietta.

Ms. Hyatt-Knorr: Well, it depends how big a part it is.

DR. COX: I understand.

(Simultaneous discussion.)

DR. MURRAY: Yes. I think-- Yes. Okay. We can go. We will deal with the realities including who can make it and who can't make it.

Ms. Hyatt-Knorr: Did you already talk about October, or do you need to talk about that?

DR. MURRAY: Well, we recognize the different things--

Here is the possibility that I am reluctant to mention. All right.

DR. GREIDER: Do it. Yes.

(Simultaneous discussion.)

DR. MURRAY: No, no, no. That is another one. And that would be to--and I hate to do this--but it would be to put the report off by a month or so because, instead of having a mid-January report date--

DR. GREIDER: There is no possibility of meeting in November?

DR. : Yes. That is what I thought you were going to say.

DR. : That is what I thought you were going to say, too.

DR. MURRAY: Oh. Well, we have a meeting in November.

Ms. Hyatt-Knorr: We have November 23 mentioned as a date and December 1.

DR. MURRAY: But I want to propose this--

Ms. Hyatt-Knorr: November 23rd-- Wait a minute. Wait a minute.

DR. MURRAY: Yes.

Ms. Hyatt-Knorr: Can I just say one thing? Dr. Shapiro wants to have-- On the schedule thought that December 1 should be an all-NBAC meeting so you have to decide about October and November. And since the November and the December meeting are so close, he wasn't certain that you wanted to have both meetings, so that was something that I was supposed to have--

DR. MURRAY: We need to meet in November. We need to do substance in November. I gather you need December 1st? That is a critical day for you?

DR. CHILDRESS: Well, one reason for discussion is that, because of that planned meeting we worked out with the National Institute of Mental Health and scheduled when people might be available, they were going to do a conference in early December, and they are going to do it on Tuesday and Wednesday following that meetings. And since it is on decision-impaired subjects in research, the conference is very important. This was passed out yesterday, this schedule for that. But exactly what we do on the 1st, that is still open.

Ms. Hyatt-Knorr: Well, Dr. Shapiro did want to have an all-NBAC meeting. I am sure he would want at least half a day.

DR. CHILDRESS: I think what he wants to do at the all-NBAC meeting depends on what these two subcommittees do.

Ms. Hyatt-Knorr: Absolutely.

DR. CHILDRESS: So I think it is contingent on that.

DR. MURRAY: That is a useful clarification. I thought that your subcommittee needed the full day, but I take it--

DR. CHILDRESS: We-- I just don't know where we will be until after the 19th.

DR. MURRAY: I think we need a meeting in mid-December, or this subcommittee will need a meeting in mid-December.

DR. EMANUEL: Or mid-November.

DR. MURRAY: Mid-December. We have a November 23rd meeting scheduled which is-- But I am open to that. I mean, I think we are going to need, you know, between mid-, between December. November 23rd, December 1st, which falls in the Thanksgiving weekend, we are not going to get much done.

Ms. Hyatt-Knorr: Exactly.

DR. EMANUEL: That is all Thanksgiving, right?

DR. MURRAY: Right.

DR. LO: If the next meeting--October--is where we meet and develop a sort of a preliminary set of conclusions or findings or resolutions, it seems to me the next big step, or the next step is try to refine that, and then to bring that before the whole committee.

And my intuition is that that is going to be a full day for each of the subcommittees. Each of the subcommittees is going to need a full day to present to the full committee just because it will be new material for others, there is going to be a lot of sort of bringing people up to speed, catching them all up. It is hard for me to imagine that a one-day meeting in November will allow us to reach closure on major points of both reports.

DR. MURRAY: Your schedule on reports is a little different though, isn't it, Jim?

DR. CHILDRESS: The one we are pushing for first is the Federal Agency Report, and then the decision-impaired. Obviously we wouldn't want to put anything in final form until after the conference the 1st of December, 2nd or 3rd of December. We would want to have a lot in draft, but we want to wait until we get input from that before--

DR. MURRAY: Am I correct in thinking then that, as we currently envision the tissue sample report, it would actually be in a final form somewhat after your Federal Agency Report but before your subjects' report?

DR. CHILDRESS: Yes. Or very close in time. Maybe we will do it after the first of the year. It will probably be close to that or a little later.

DR. MURRAY: What is your pleasure?

DR. EMANUEL: Well, here is-- We have more than a month between the October 19th and the November 23rd. Now there is a good reason for that. The mega-bioethics meeting and lots of other stuff in November. There is a question as to whether there is another date in there that we are going to need.

I mean, one of the things we are banking on is that in essentially six to eight hours we are going to be able to iron ourselves out.

DR. LO: That is very optimistic.

The other thing is we have a deadline that we imposed, or was imposed, some time ago and what we are not finding easy to do is let the natural flow of discussion run its course.

And I am just a little concerned that we-- I mean, I understand, you know, needing to keep promises and commitments, but to me this is very different than a dollar report where we really needed to get that out by a certain time. And I am just a little concerned that it is a rush to meet a January publication date when we don't have the meeting scheduled that is going to allow us to do that in an optimal way. I am not trying to put this off six months--

DR. CASSELL: I mean, if Microsoft can put off Windows '98, what the hell.

(Laughter.)

DR. EMANUEL: Here is a virtual deadline.

(Laughter.)

DR. EMANUEL: As all of us know.

DR. MIIKE: Well, either prior to or right after the October meeting, I would want--actually, right after this meeting--an outline.

Somebody's comment--I think maybe Kathi--saying what are the issues we have to reach resolution on it, and then let us do it like the cloning one. Anybody who wants to start drafting conclusions or recommendations do them and pass them around on the Internet. That is how we got it done the last time around, and it seemed to work. It starts focusing people on specifics.

DR. COX: That is what I-- I agree with that. I think after the October meeting, the Internet can be really good. If we could get in another November meeting, great, but it sounds like it is going to be tough, but at least that time--after the October meeting and before the December meeting--the Internet should be fine.

DR. LO: Let me say, as a great enthusiast of the Internet, I thought, as I looked back on the cloning report, we had too few face-to-face discussions and too much lines on the Internet, and we ended up at the very end having to sort of very, very hurriedly redo sections; that we hadn't had

things emerge.

I think one of the reasons was we tried to do too much over the Internet without meeting face to face and really talking.

The problem with the Internet is you only get one person's response at a time. You don't get sort of a group sense that, "Hey, this just isn't working. We have got to kind of go back and reconsider."

DR. CASSELL: Well, then there is another possibility and that is that we set up conference calls for shorter periods of time. You know? And then you get an hour on a conference call and if you have got nothing to say, you don't have to sign on, on the conference, but if you do that allows us to--

(Simultaneous discussion.)

DR. CASSELL: Because what you said, and what ended up happening, is so you know this draft and then somebody else responds, they write a draft, and then there are eight drafts out there. And that just drove everybody crazy.

DR. MURRAY: Eric, I am reminded that we should do as much of our work in public as possible, so conference calls can be used sort of for very specifics for a small working group task, but we should rely on--

DR. CASSELL: They can be recorded and they can be transcribed.

Ms. Hyatt-Knorr: No.

DR. CASSELL: No? Well--

Ms. Hyatt-Knorr: That is not public.

DR. EMANUEL: I mean, there is this practical problem. If we exclude the week of November 3rd to 8th because of the mega-meeting in Baltimore for bioethicists, that more or less limits us to something like the week of December 27th, or the week after that meeting, which is only one week before our 23rd meeting.

DR. MURRAY: Yes.

DR. EMANUEL: That is why we have this big gap.

DR. MURRAY: Well, let me--

DR. EMANUEL: It does--

DR. GREIDER: What is--

DR. EMANUEL: I mean-- Sorry.

DR. GREIDER: Go ahead.

DR. EMANUEL: I mean, one question is whether, at the end of the 19th, we are going to think we need another period of time to hash out something focused or not, and that is hard to say.

But I do think-- I agree with Bernie. I do not find exchanges on the Internet as fruitful as, you know--and germinative of ideas--as getting together.

DR. GREIDER: What is the mega-meeting in Baltimore and how many people are going to be there from this group?

DR. EMANUEL: It is a bioethics meeting.

DR. GREIDER: Right.

DR. EMANUEL: A big, bioethics meetings.

DR. GREIDER: But when?

DR. EMANUEL: The 5th through the 8th, right?

DR. GREIDER: Of?

DR. EMANUEL: November. And Bernie and I are also engaged--

DR. GREIDER: And are there other people? I mean, maybe you could tack on at least a partial meeting.

(Simultaneous discussion.)

DR. LO: --schedule in San Francisco because I wasn't going to be in Baltimore.

DR. MIIKE: Well, I am not saying the Internet is a substitute for the meetings, but it certainly can act to get rid of some of the chaff that we are going to have to deal with anyway. Rather than waiting for a meeting and then having to discuss absolutely everything around that, certainly the interchange on the Internet can get rid of a whole lot of stuff.

DR. MURRAY: Let me make a proposal.

Zeke is right in pointing out that some of this is contingent. I mean, how much agreement are we going to be able to reach quickly? And we don't know that until we actually do it.

Let us move with the October meeting with the focus as we-- Do the October meeting as we have been planning it right now; that is, start early, really focus on the hard questions on the substance, have a lunch of the full Commission, sort of trading, making them aware of where we are, we will let them know where they are, we will take some feedback, continue our discussions to the point of when people begin leaving for home and/or exhaustion, whichever comes first. See how far we get.

We may, at the end of that day, decide we can do this. We can clean up what is left in November and maybe we need another meeting in December, later in December than December 1st.

I would ask Henrietta and the staff to sort of see whether that is a possibility from our perspective calendars.

Maybe we decide at the end of that day, it becomes apparent to us, that we really need more time. And then we will put off the due date, our self-imposed due date of the report. I really do think there are virtues in deadlines and I think we should-- I would like us to try to reach this deadline. If it is not possible, I would rather have a good report come out a little bit later.

So is that-- Are we--

DR. LO: It sounds reasonable.

DR. MURRAY: Is that acceptable?

Now, there are some things we can set in motion very rapidly. You are going to get feedback to the people doing the mini-hearings, right?

Kathi and I will work together to draft both a kind of outline of the report--that is going to be very brief; it is going to be sorted by chapters--but also try to come up with some ideas about what crucial issues there are that we have to decide. And that will-- We will distribute that and get your feedback on that.

Any other specific things we are going to do immediately?

(No response.)

DR. MURRAY: And I have got notes and I will go back and look at them. That seems to me to be--

DR. LO: The other thing that would be useful is to, as Zeke suggested, try and think of illustrative cases that we will use to sort of hammer out things.

And I think we should adopt, try and come up with a list of issues that we want to try and resolve at that October meeting, and try and prioritize them so the most important ones and the most difficult ones are--

DR. EMANUEL: Well, Tom, that framework that I had came under a lot of attack and had some defense to it. Now, one possibility is to just use that framework and use the revised version suggested by others, come with-- I have written down three kind of examples that have been published in *The New England Journal*. It seems to me we can test against that kind of framework. I am sure Steve and many others could come up with a few. We might even get the papers that they are based on just to help us out.

DR. MURRAY: That would be good. Can we ask staff if they would please do that? Will you help them locate the appropriate references?

DR. EMANUEL: Yes. No. I will get the papers and fax it to them.

And then I think, you know, maybe if we got that circulated in the next couple of weeks, we could all react to it and we might have a more developed framework by the time we even sit down and talk.

DR. MURRAY: Okay.

DR. EMANUEL: Does that seem reasonable?

DR. MURRAY: It certainly does to me.

DR. EMANUEL: And that way we could also get reaction from the other subcommittee so that they are not excluded with a list of, you know, the top seven things we have to resolve yeah or nay, one way or another.

DR. COX: At the risk--because I know we are talking process now--I would just like to make a plea of an important distinction between prospective and retrospective. We all know that at the table, but at the end of the day dealing with those two things is going to be important.

And the prospective is so much a bigger issue than the retrospective. There are lots of people working on the prospective, but just so that we don't forget to deal with this retrospective issue because I think that that is something that we can deal with, but I just don't want to forget it.

DR. CASSELL: Would you-- I might be sleeping. Which is-- What are you talking about?

(Laughter.)

DR. COX: The tissue samples that have been stored and the tissue samples which will be stored.

DR. CASSELL: Thank you very much. (Inaudible.)

(Laughter.)

DR. MURRAY: Most of the discussions will not need to make the distinction. I mean, Courtney's discussion about the status of tissues and all, but when we get to making recommendations about what happens, absolutely we have to make the distinction clear. I agree.

Jim, in terms of-- This has immediate impact on the meeting in October. Are you comfortable with a proposal to sort of join at lunch time?

DR. CHILDRESS: I think so. The only hesitation I have, let me just mention--I will

do it in a couple of different ways--is that if we want to move forward with the Federal Agency Report unfortunately we were split yesterday. We lost you folks at the point of our talking about the Federal Agency Report. So we may need a little more time with the whole Commission just to talk about that.

Now, we will have a much fuller draft before the next one with some recommendations, at least for purposes of discussion, but maybe-- I-- That is my only hesitation. We just might need a little more time with the whole Commission than the lunch will provide.

DR. MURRAY: What if we took two hours in the middle of the day, with an hour to us and an hour to you where we met together? Would that be-- Would an hour do you feel be sufficient?

DR. CHILDRESS: I think so if-- Let me put it this way. If people-- And this body of material we had to deal with was just overwhelming. But if people could go back and look at the draft and offer any suggestions. But the one problem is that the draft is very compressed. It is going to be hard through discussion to pick up a lot of it.

But if people could give us any reactions to that, Bill, would that be one way? That would be helpful.

DR. FREEMAN: And that can also be if people want to call us, you know, just to talk about it. It might even be more helpful than e-mail. At the stage where it is, if you haven't participated in the discussion, it may well be that--

(Simultaneous discussion.)

DR. CHILDRESS: It makes no sense.

DR. FREEMAN: --less important and helpful both to you and to us.

DR. MURRAY: What is the subcommittee--(Inaudible.)--is it a vote on the report?

DR. CHILDRESS: I don't think it will be so much a vote on the report. I mean, we were hoping to get it in, in November, but given the, you know, given what this schedule is, we probably couldn't.

I think what we would like people to do is really be brought up to full speed on it and to see where we are going and to give suggestions on the recommendations and perhaps then be able to vote finally in December.

Bill, I think it looks like we are sort of being pushed to that, do you think, in terms of the scheduling?

DR. FREEMAN: Yes.

DR. MURRAY: So it is really kind of update and feedback opportunity?

DR. CHILDRESS: Right. But moving closer to what would then be between-- What would then be put into final shape and vote on it the next time we meet. If we are going to get it out in this calendar year.

DR. MURRAY: Is an hour, if we all have the materials to review in advance, do you feel an hour is sufficient time?

DR. CHILDRESS: It is hard to say, but--

DR. EMANUEL: The problem with that--

DR. CHILDRESS: In some ways it is descriptive, a lot of tables and so forth so, I mean, it is hard to say. It depends in part on the recommendations. We could try it and see.

DR. FREEMAN: I would think that for our report pay less attention to the tables--

we can explain them very quickly in the hour--and it is the substance of the written report, things that need to be in there or not, and then I think it is going to be very tight with an hour because I am assuming that the draft that we sent out to staff, before the 19th, will be--

There is going to be a recommendation section. That is really developed by the Commission. We can draft up a few ideas, but the substance is going to be those recommendations. And so to try to both bring up the subcommittee and then talk about the recommendations in that one hour is going to be tight as possible.

DR. EMANUEL: Just look at it this way. From 7:00 a.m. to 4:00 p.m.--maximum time allotment, right?--gives you nine hours, two hours in the middle of the day plus an hour's worth of breaks because we are not even taking a break for lunch. It reduces our conversation time to five hours, maximum six. And it is a zero sum game the more we--

DR. CHILDRESS: I am trying to think through from the other subcommittee's standpoint. I think if we could work on-- We could work on the Federal Agency Report in the morning and we could give you a very quick summary of sort of what we have reached at that point, given the draft you would have already seen, so we could, you know, we could try to move it forward by proceeding that way, I think.

DR. MURRAY: All right. So let us--

DR. CHILDRESS: Shoot for it.

DR. MURRAY: --shoot for it. That would give us maybe five productive hours of conversation, which isn't bad.

DR. EMANUEL: As long as we don't schedule anything else.

DR. MURRAY: Yes. Yes. Is that-- Are we willing to live with that as our final schedule? I mean, it would be nice if we could have two days.

DR. LO: Can we get food on Sunday?

DR. MURRAY: No, no.

Ms. Hyatt-Knorr: No.

DR. MURRAY: We can just order something in.

Ms. Hyatt-Knorr: We will arrange something.

DR. CHILDRESS: And we will be staying close by so we can start early with Trish?

Ms. Hyatt-Knorr: We will try to get you as close as possible, particularly if you don't criticize the facilities where you will be staying.

(Simultaneous discussion.)

Ms. Hyatt-Knorr: No. No. I am going to try to get the Crystal Marriott.

DR. CHILDRESS: That is fine.

Ms. Hyatt-Knorr: Well, some people have objected to this considerably, so we will find out.

DR. MURRAY: It is better than the Holiday Inn.

Ms. Hyatt-Knorr: I would say so, but there have been a couple of people who have really not liked it, okay?

DR. MURRAY: On the Commission? Yes. Oh, well. Live with it.

Ms. Hyatt-Knorr: That is what we are going to try.

DR. CHILDRESS: And it is close.

DR. MURRAY: It is close. Right.

ADJOURNMENT

DR. MURRAY: It is 12:15 p.m. It is hard to do much substance in 15 minutes. All right. It has been a good day. Thanks everybody. The meeting is adjourned.

(Whereupon, at 12:17 p.m., the meeting adjourned.)