NATIONAL BIOETHICS ADVISORY COMMISSION

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P R O C E E D I N G S

JOINT SESSION OF THE SUBCOMMITTEES

DR. SHAPIRO: Thank you all very much and thank you all once again for agreeing to be here on a Sunday which, I know, represents a considerable inconvenience for many of you and your families. I thank you very much for coming.

I have just a few small things to say by way of remarks, call to order and so on. One, probably the most important one, is to focus a bit on our next meeting. I just want to go over those with you and go over our plans. The Genetics Subcommittee will meet on December 9th. Okay. I do not know, Tom, if you have decided on a specific time or location. That is here in Washington I take it.

DR. MURRAY: I defer to staff here. It is in D.C., right?

DR. NORRIS: Yes.

DR. MURRAY: Then it will be at NIH?

DR. NORRIS: No, it is going to be at Crystal City.

DR. MURRAY: Oh, wonderful.

DR. SHAPIRO: Lucky you.

DR. NORRIS: Back by popular demand.

DR. SHAPIRO: In any case, would you send a

note around to all the subcommittee members because I did not have any information on that.

DR. HYATT-KNORR: We are just putting it together. We could not send it out any earlier.

DR. SHAPIRO: But that is relatively obviously near term. That is only another couple of weeks.

DR. HYATT-KNORR: Right.

DR. SHAPIRO: The full --

DR. NORRIS: As a matter of fact, I would like to circulate a form in a little while and if you want us to make the reservations for you because of the short notice if you will give us your credit card, exact name on it, number and expiration date, we will make the reservation for you on Monday. I am not suggesting that you do it but if you are willing to do it because of the short -- very short time line.

DR. DUMAS: Now that is the Genetics Subcommittee.

DR. SHAPIRO: Right.

DR. NORRIS: Or anybody else who happens to want to come.

DR. SHAPIRO: And, of course, any member of the commission is welcome to attend. Have you selected a time for that meeting?

DR. NORRIS: No, we have not yet. Dr. Murray,

what time would you like to start?

DR. MURRAY: Would our West Coast contingent like it to be an early morning start again?

DR. _____: As early as possible.

DR. MURRAY: As early as possible. We are awfully nice to the people who come in from the West Coast. Barring other sentiment I guess we will have an early start.

DR. NORRIS: 7:30?

DR. MURRAY: I mean as early as 7:30. Steve Holtzman is --

DR. HOLTZMAN: I cannot come early in the morning coming from the Midwest.

DR. MURRAY: Well, I would not want to say that not only would we be happy but we would be positively delighted if members of the Human Subjects Subcommittee wanted to come to this. It would help establish this kind of cross talk that is not possible when we meet simultaneously but in separate rooms. I think it will make the transition to being a subcommittee work group -- full commission work easier if you come. So as many of you as can come I would be thrilled.

DR. SHAPIRO: I just want to point out, Tom, that meeting simultaneously in different rooms might be better than meeting simultaneously in the same room.

(Laughter.)

(Simultaneous discussion.)

DR. SHAPIRO: In any case that is the next scheduled meeting of our committees or subcommittees. The full commission is currently scheduled to meet on Wednesday, January 7th. That will be here in Washington. More details will be forthcoming. We will also have a scheduled meeting on February the 6th. On Friday, February 6th, we expect to be in Los Angeles. So that again will be coming forward with more details but we will have a full day meeting in Los Angeles, Friday, February 6th.

The next meeting will be here on March 4th. Here meaning in Washington on March 4th. Also followed by -- I am afraid to say it -- a Sunday meeting on April 19th, also here in Washington.

We will send everybody here details of all these. We will meet here in Washington in April and in May we are hoping to meet in Cleveland on the 20th of May and back here in Washington in June, on June the 8th. We are currently planning the following two meetings, that is the one in July and then one in September away from Washington. In Portland, Oregon on July 7th.

MS. BACKLAR: Whoopee.

DR. SHAPIRO: Hear it for Portland, Oregon.

In Madison on September 16th and 17th. And then we will be back in Washington for our October meeting the 13th and 14th. Then in Miami on November 17th and 18th. And then back in Washington in December.

So as you can see we are going to move the meetings around this year. There will be quite a number of different locations and we look forward to that, and staff will be -- for those of you who happen to reside in one or the other of these locations staff will be in touch with you. We are not going to ask you to run out and do all the logistics but just to see what help and suggestions you might be able to give us that would make the meetings as productive as possible and as pleasant as possible.

DR. DUMAS: Now this is the schedule that was sent to us earlier.

DR. SHAPIRO: By e-mail.

DR. DUMAS: By e-mail.

MR. CAPRON: Mr. Chairman?

DR. SHAPIRO: Yes.

MR. CAPRON: There was some discussion of our meeting in Tuskegee at the time that we would be issuing a release of the report on our federal oversight. I gather that has not made the agenda.

DR. SHAPIRO: It has not made the agenda for

two reasons. One, we really could not predict with very much accuracy exactly when we would be ready with the report. Also, it is logistically difficult. It is not an easy spot to meet and we thought unless we really had some very direct reason that really was very much connected to something we were recommended that it really did not make sense. So we thought we could not plan for that right now. If we decide at some future time we would like to try to do that either as a full commission or as part of the commission we can still do it. But it was difficult to plan on that not knowing, one, when we would be ready and, two, what it is we have to say and what way would it be relevant to that for the symbolism.

MR. CAPRON: I mean, it does seem to me that our report as it is shaping up on the federal agency work is I think in many ways a very relevant follow-up to the type of Tuskegee situation and there is nothing like the prospect of hanging and there is nothing like the prospect of a deadline that says the meeting is going to be there, we better have a report that we can affirm, but I leave it to you and Dr. Childress to see whether that date could be predicted.

DR. SHAPIRO: Thank you.

There are -- I want to -- I think all of you received quite a lot of mail about conferences here and

there on issues of direct relevant or direct relation to the committee's own work. There is a major conference in Japan next year. Somebody might have the date. I do not have the date in front of me.

Do you have the date, Alex?

MR. CAPRON: November 4th through 7th, I believe.

DR. SHAPIRO: It is November --

MR. CAPRON: I think that is correct.

DR. SHAPIRO: Early November is my recollection.

Alta, you and I talked about it also. I do not know whether you have the date.

MR. CAPRON: I sent it in the e-mail to you. It is November 4th through 7th.

DR. SHAPIRO: Yes.

They are very anxious to have members -- any members of the commission here to attend. They think it will, in part, not only as a sort of a general conference but a kind of second attempt at the summit that we arranged in San Francisco about a year ago, now just about exactly a year ago now. And so I think some of you may or may not have received additional -- your own requests.

I am trying to put together some resources from nonfederal sources that might make it a lot easier

for people from the commission who wish to go. I will know more about that the next time we meet. I think it would be very valuable to have at least some representation there. Of course, it is certainly not necessary to do it. That is a long ways away.

DR. HOLTZMAN: Where and when did you say?

DR. SHAPIRO: Japan. That is always a bit of a barrier. It is a long trip. It takes time and the flight, of course -- flights are very --

DR. MIIKE: It is a short trip.

DR. SHAPIRO: A short trip.

(Laughter.)

DR. SHAPIRO: I forgot how geographically advantaged you are in Hawaii in this respect.

(Laughter.)

DR. SHAPIRO: So that is just information. I will let you know more either by communicating directly with you or certainly by the next meeting. The next meeting I will certainly -- I expect to know a good deal more regarding resources. The conference is taking place independent of that and I think we will arrange at the very least to have one or two -- at the very least -- people from the commission go. And so if any of you are especially interested please let me know.

DR. SCOTT-JONES: What are the dates?

DR. SHAPIRO: I do not know precisely. It is around the 4th of November.

MR. CAPRON: It is the 4th through the 7th. But the international summit as I understood it from a recent -- a discussion with a couple of the organizers, they were thinking of doing -- saying like we did which was to have that on a day before or after but probably before.

DR. SHAPIRO: So we will let you -- I will let you know by the time we meet again. All right.

Is there anything further on our meeting schedule?

All right. Thank you very much.

Also, as you all know, I think you all know, we of course have identified a key person to fill in the position of director. I do not know what the exact title is. Executive director. Whatever the formal title is. That is very good news to us. There are still some final issues that have to be resolved before a formal appointment can be made but I expect those to be resolved easily from one respect. That is it is a matter of straight forward going through the steps but who knows how long those take. So I am not able to say anymore about that right now. But that is going to be a very big help to us as we tend to try to organize our staff for the next

stage of our work.

Okay. With that let's just go on to see -- turn to the chairs of the two principle subcommittees that we have right now to report to the entire commission on the nature of the progress of their work in particular areas.

Let me turn to Jim first of all to report on the subcommittee's activities regarding human subjects. Jim?

DR. CHILDRESS: Thanks, Harold.

Let me make a few observations about the two main reports we are working on and make a few comments about some long-term aspirations -- though it turns out these reports are now becoming long-term aspirations -- and then see if subcommittee members would like to add anything.

We will not have either report ready for NBAC's full consideration until early in 1998. First, on the Federal Agency Report, which you will recall is a mandated task for us, we are close on the basic data with Bill Freeman and other members of the staff doing an excellent job in obtaining the information we need for the report and in getting that information before us. But we are still some distance from a final report in a couple of ways.

One is we need now in response to expressed concerns at the last meeting to get a clear picture about findings and move forward recommendations that are both important and feasible. Second, we need to take the material that -- very helpful material that has been provided and now recast and redraft that in a report form. Kathy Hanna has agreed to join us for that purpose and will be helping us in that task.

In connection with that we are also looking at issues surrounding location of a possible OPRR-like mechanism within the federal government. We will be spending some time this afternoon on that discussion based on two important papers by Charles McCarthy and John Fletcher and discussion with Joan Porter about the history between the proposal and the adoption of the Common Rule. All in an effort to fill out what we can learn about both development and possibilities and limitations within the current structure for implementing the Common Rule.

Of course, one of the things that we have in mind over time is thinking about ways in which to revise it. Questions have come up along the way, comments and criticisms, particularly from those within the federal government, about difficulties in the Common Rule itself and we are not ignoring those but we are not able really to address those at this point.

That is the direction we are going and I would hope that we would have a draft with flushed out recommendations that we could put before NBAC as a whole and perhaps it can be at the February meeting. We will need to talk about sort of when to do all this and when each subcommittee might submit something to NBAC as a whole since at that point we will -- we will be getting together and having to reach some common decisions.

The second report, we spent all this morning discussing that. Jonathan Moreno building on the work of Rebecca Dresser and testimony from research and the public has produced an excellent second draft. The second draft is very responsive to the discussion we had last time at the meeting and also individual questions and criticisms or suggestions following the meeting.

We are going to -- that will not be revised immediately. We will be working on it again, the members of the subcommittee, on December the 3rd following a day-and-a-half meeting at the National Institute of Mental Health, devoted to the whole area of research involving decisionally impaired subjects. We want to learn what we can from that meeting and incorporate that information and those insights into the draft. And then Jonathan based on that work and on the discussion this morning will proceed to come up with another draft.

At that point we need another meeting to talk about not only the draft but about the recommendations and see if we can come to some rough consensus and then go before NBAC as a whole. Then beyond that there will be some time after the first of the year -- we are thinking about how to proceed in an evaluation and analysis and evaluation of IRB's as a protective mechanism but we need there to get at least preliminary results of Charles MacKay's study and the Office of Inspector General's study, and when we get that information in hand we will proceed to talk further about how to proceed.

And then also to look at international research ethics. Thinking of working out a way to address the large questions of framework for international research.

All the while we are getting contract papers on broad concepts in research ethics. I just received a draft by Charles Frazier on community. We have Celia Fisher's on vulnerability. We expect another one on vulnerability. Another one is being developed for justice. And this morning we talked about the need for one on risk and one on changing conceptions of autonomy in relation to informed consent. So we are accumulating those and at some point in our history we hope to be able to address these broad concepts as well.

MS. CHARO: Just a question and clarification. The Charles Mackay study, when we had him before us he said the results would be in, in March of '97, and I was wondering are the preliminary results available now in November?

DR. CHILDRESS: If we had time today we could have gotten an updated report. I think it will be better actually to have that in January. I think he will be a lot further along and be able to tell us more.

DR. EMANUEL: I do not think they have all the results in yet.

DR. CHILDRESS: But they are beginning their analysis at this point as I understood it of at least the basic information. Okay. I may have misunderstood what he said.

DR. EMANUEL: The last I had heard is that they were not quite ready to do that because they had not had everything.

DR. CHILDRESS: Okay.

DR. EMANUEL: But that may be out of date.

MS. CHARO: Thank you.

DR. CHILDRESS: At any rate I talked to him. He was available to come along with a member of the contracting team that had done the basic work but given what we had to do today I thought it was prudent not to

have him come today. We will expect to have him, though, in January.

DR. SHAPIRO: Could I just -- Jim, I hope I am not interrupting.

DR. CHILDRESS: No.

DR. SHAPIRO: I did want to say before in relation in part to the question you got regarding the issue of when a recommendation would come to NBAC as a whole. I did want to inform the group that I have put together, I guess, another informal bucket, or whatever name we are going to use this time, of some of your colleagues to help us think through our longer term agenda, that is where do we go once February and March and April pass us by.

I did the natural thing. I chose all the committee members whose names begin with "C" to form those. And at least Eric -- Eric Cassell has agreed to kind of be an informal chair of that group and I have asked Alta and Alex and David to serve on that group. They will present, I hope, some initial ideas to us at our next meeting or two and help us just all think through to get at the staff just what our agenda ought to be as we go ahead past the reports that are currently contemplated.

As Jim said, these reports tend to generate their own sequelae, so to speak, of additional things. I

want us to not only look at that but look at other possibilities all together rather than just be drawn on by yet one more implication of the topic that we had to take on. That may or may not be desirable. Those will only be some of the things this group will consider, I hope. And then hopefully that group can report back to us initially at least in January and probably at every meeting until we kind of resolve this over the months that go through the rest of this fiscal year.

Now I am hoping that both in January and our February meeting we will have some time to hear at least initial recommendations on some of these issues from the subcommittees. That is the main purpose for having the commission meet as a whole and some of these will be very preliminary, I am sure, but I think there is really no substitute for beginning to sort of argue them out. So I would hope that both in our January and especially our February meeting of NBAC we will have from each of the subcommittees, at least part of their work or aspects that they are working, some particular preliminary recommendations.

We will have to treat those, I think, in the spirit of really conversations and we should not think of these as final or the position of the commission or anything else like that, but a way to get us all thinking

very focused -- in a very focused way on exactly what actions that we might take.

I am sorry to interrupt.

DR. CHILDRESS: No, I actually was at the end. Thank you.

DR. SHAPIRO: All right.

MR. CAPRON: I should note on behalf of my colleague, James Childress, that if your method of appointment is logical. How do you think he spells his name?

(Laughter?

DR. CHILDRESS: With a "J".

MR. CAPRON: I know how you should spell it.

DR. SHAPIRO: The current subcommittee chair is exempt from this procedure.

DR. CHILDRESS: Thank you.

(Laughter.)

DR. CHILDRESS: And I would hope, though, that other subcommittee members might want to add something to what I said.

DR. SHAPIRO: Any comments from any of the members of the Human Subjects or questions that other commission members might have as a result of the materials that were distributed? You have the new draft of the paper by Jonathan and you have other materials that were

distributed, some of which have not yet been discussed. It is something we will get to later on in the afternoon.

Okay. Let me turn to Tom. Excuse me, I am sorry. I apologize.

DR. EMANUEL: I am sorry. I just have -- I was not exactly sure what the -- you have a number of contract papers out and I am not sure where they fit into the scheme of things. Where -- and this may be just because I do not fully have a picture for how all the pieces evolve at the moment. But where does the say autonomy or risk paper fit into the kind of report, I guess, we are contemplating?

DR. CHILDRESS: Well, that is what I said. That is not a report. Broad concepts and ethics in the research involving human subjects. I mean, we are stumbling at every turn on the question of how one thinks about risk, minimal risk, more than minimal risk, et cetera. And we, at least in our discussion this morning, felt that might be a useful paper for us to get for our own exploration that we can then talk about the broad concepts relating to research involving human subjects but also to inform the work we are doing along the way.

A similar point about autonomy. So these are broad concepts that can inform particular discussions but at some point we would like to think again about Belmont

and related matters.

MR. CAPRON: That was something that the whole commission discussed a year ago at the meeting in, whenever that was, December or January. The notion of revisiting the Belmont concept. So in other words not so much those three principal principles but rather the whole question of an intellectual structure for analyzing research, human subjects research, and some of the issues that probably had not been as fully flushed out there like the vulnerability issue and so forth, the community issue and things like that.

DR. EMANUEL: I guess I understood that but I did not hear among the four things that Jim had outlined in terms of reports sort of a revisiting of the Belmont framework.

DR. CHILDRESS: Your question very usefully provoked --

DR. EMANUEL: So I guess I was just trying to see how A connected to B.

DR. CHILDRESS: Maybe the one on justice but clearly autonomy and vulnerability are getting at some of the issues surrounding respect for persons and the risk one is one of the most difficult areas under it and that is the one that seems to me to be the hardest to get clear on and to use.

MR. CAPRON: Well, I would certainly think that the Belmont revisiting is a shorthand for something which as final issued by the commission as a report might not look like a revisiting of Belmont. In other words, it might be a report on substantive important issues in human subjects research, some of which might cause a reconsideration across the board and others would be explorations of particularly important topics. So that is one report that our committee thinks we are working on and we are sort of adding pieces to it and it does not yet have a conceptual framework.

DR. CHILDRESS: And we are adding them in part as we hit problems in trying to address other areas. That is a more concrete --

MR. CAPRON: Yes.

DR. SHAPIRO: I think this comment is also quite important. I mean, an example -- if you do not mind, Jim -- that came up this morning when we were struggling and the committee was struggling with the issue of autonomy and what it meant, either your vulnerable -- so-called vulnerable population or in this so-called nonvulnerable population, how one would think of autonomy. And that has very practical impacts on what you might recommend regarding appropriate human subject protection let's say for vulnerable populations.

And Eric had made the point this morning that the concept of autonomy has just simply changed since the 1960's and then we have revisited, we, that is the broader community has revisited it, and so I think that would be very helpful. So it is in that context. It might be of some help to this report but also, as Alex and others have said, we can use it as part of a broader effort to just improve our understanding of this area.

DR. CHILDRESS: Could I just add one other point? Even in terms of sort of Belmont revisited there are two different ways to revisit. One is to go back and now look at the principles over again and see whether one can modify them, reject them, et cetera, or supplement them. But the other is also to deal with the patterns of interpretation that have developed and that are really often specifications of those broad principles. That is sort of where we get into the risk issue, for example, or into the autonomy issue.

So it is not so much that you have to necessarily go back and take those broad ones apart again, maybe we should and maybe we will, but at least interpreted patterns have developed that need to be addressed and that certainly is part of what we are trying to get at.

DR. SHAPIRO: Other questions on this related

subject before turning to Tom?

Tom, I will try once again.

DR. MURRAY: I am ready.

DR. SHAPIRO: Dr. Murray.

DR. MURRAY: I will go the reverse of the usual order. I will talk about our sort of longer range aims and then tell you where we are on the report we are working on.

I am not sure if the descriptions that were just given change our goal but our goal had been to have a report on tissue sample research by February and to roll out the report in February. I still hope we can achieve that. I think it is a possibility. Beyond that we want to do a report on genetic privacy and discrimination followed by a report on gene patenting.

MS. CHARO: I am sorry. I could not hear you.

DR. SHAPIRO: Followed by a report on?

DR. MURRAY: Gene patenting.

MS. CHARO: Thank you.

DR. MURRAY: Which we were -- again part of the terms of the Executive -- the one that established us -- is to look particularly at gene patenting and also at genetic information.

We should begin thinking about what papers we

want to commission for certainly the first of those two reports and begin commissioning them in the fairly near future so that we have materials to work from as soon as we finish the tissue sample report. We will talk about that, I hope, today before we leave.

The report we are currently working on is the same one that we have been laboring at and that is on tissue samples. Today we heard from, among others, Lisa Eiseman who has been trying to find out what kinds of tissues, how many are held by whom.

And has the handout been distributed to the --

DR. NORRIS: Yes.

DR. MURRAY: Good. We are up over the 100 million mark. In fact, if you count the number of specimens we are up well over 200 million and we should note that at every step Elisa has taken very conservative numbers, that is she has used low end estimates for many of these subcollections. There is a lot of tissue out there. Virtually all of it seems to be identified, that is to have some personal information, identifiable information with it.

I do not know if any --

MS. CHARO: Does this include the Publisher's Clearing House sample?

DR. MURRAY: No, this does not include the

Publisher's Clearing House sample. I have got a patent on that and --

(Laughter.)

DR. MURRAY: We also had some very interesting comments, things that I had not anticipated. What is not in here are the pathology specimens held, for example, by community hospitals in their pathology labs. And the question was raised, "Well, will those samples ever be used for research?"

And the answer that was given is increasingly probably yes, at least they may be now -- researchers may be interested in them and those collections might be more accessible as health systems tend to aggregate and community hospitals now become affiliated with academic medical centers. So it looks like much of these -- many of these materials might, in fact, at least be possible subjects of research.

Now, I am going to proceed to just talk briefly about the people who spoke today. So why don't I invite other members of the Genetics Subcommittee to add anything they want about Elisa's presentation.

DR. COX: Tom, I will just add one thing and that is that there is in addition to a ton of samples, the vast majority of those samples are the ones held in sort of university based pathology departments.

DR. MURRAY: Right.

As you know, we -- excuse me. As you know, we commissioned a series of mini-hearings. We chose the mini-hearing format rather than say a standard opinion poll for a number of reasons but I think the most compelling of which is that asking people questions say over the telephone is not very useful if people do not know what you are talking about. So the mini-hearing format provides an opportunity to educate people a bit about what it means to have tissue samples out there and how they are gathered, et cetera.

I, at least speaking personally, have been very pleased with what we have ascertained through the mini-hearing procedure. We had a report, I think essentially the final report today, from Dr. James Wells and associates, including Henrietta Hyatt-Knorr and Sean Simon, who have attended the mini-hearings.

And just very briefly, among the things that the mini-hearings disclosed were that most people have not the foggiest idea that they consented to having their tissue samples used in research. The great majority of them did this through clinical procedures, surgery or biopsy or some such thing.

If people are asked what happened to it they say it was thrown away or otherwise disposed of. People

seem to want to be asked for consent although they are fairly willing to have the tissue used for legitimate purposes once they have been asked for and given their consent, which arguably they have but they do not remember doing so.

Also, to the extent that they have expressed sentiment, people at the mini-hearings indicated that they wanted to have the tissue used in research. In fact, we found a generally favorable attitude towards scientific research and a desire to see the tissue if it is going to be kept to be used for science.

The public perceives a benefit from research. On the whole it did not matter whether the research was sponsored by the government or by some private source. The Cleveland group, which I attended, may have been an exception there. Nor did it appear to make a great deal of difference whether the research took place in an university setting or in another setting, including an industry setting.

The key seemed to be what useful things come out of it like new drugs.

On the issue of privacy discrimination there was a general mistrustfulness in the sense that by and large people could not name one profession, group, agency, whatever, that they would trust completely to guard their

privacy and protect them against discrimination. You might call this the X Files factor.

They did not have a problem with linking the tissues to data so long as their personal identity could then be protected in the research. There was a general -- there seemed to be a general sentiment that if the researchers learned something that might be significant to the individual they would like to have an opportunity to know about that. Now there is a question there obviously between protecting individuals' privacy, which you can do better if you sever the link, and retaining the ability to walk back and say that this sample with this particular characteristic came from this individual.

There is no question the villains in the piece in the public's eye are insurers and employers. They definitely do not want them to have access to whatever genetic information or other information might be created by virtue of being a research subject.

We asked about stigmatization of ethnic groups. We found that less concern than I think the scholarly literature would have suggested would exist. Including groups that were very cognizant of things like the Tuskegee study, the radiation study in Cincinnati. The attitude seemed to be as much we could learn something that might help us as it was that we need to guard against

victimization in research. So again the favorable view of research seemed to overcome most of the fear that the information generated by research would be used to then stigmatize the disadvantaged.

We asked about third party concerns. There was a pretty clear consensus among our participants in the mini-hearings you tell me, not my family. That is you leave it up to the person whose tissue was studied whether they want to disclose whatever was learned to other family members.

If the person were incompetent that was not a problem for most people. You ask the appropriate guardian of the individual. If you ask them about safeguards they have the concern about privacy. They were not sure who they could really trust to protect their privacy entirely.

Although people were, with rare exceptions, not familiar with the concept of the IRB. They knew the idea of a research ethics committee and they thought it was a very good idea. When we asked them who they should put on the research ethics committee it was very clear ethical people ought to be on the research ethics committee, which they could distinguish from ethicists. It is not the same thing necessarily. Present company excluded, of course.

They are very astute about the possibility of

conflict of interest and they said they definitely wanted members of the ethics committee not from the organization doing the research. My guess is the sort of single public representative, which the IRB regs seem to require, is not adequate.

Lastly, there was some spontaneous sentiment that we ought to at times have a representative of the group actually on the study. Just some kind of community or group involved in at least the consideration of the protocol.

The methodology of the mini-hearing is not perfect. We do not have a random sample of the American population here or anything closely -- anything remotely resembling that. But we got a good sense of what different groups of Americans of different ages, male and female, different backgrounds from different parts of the country felt.

Many commonalities, not universal agreement, but we felt it was -- I will speak for myself. I thought it was very helpful to hear these reports in some cases firsthand but in other cases through the group doing the research for us about what people really cared about. How they understood what went on, what they did not know about it, and what they wanted to see happen. I feel like it was a very helpful process. And it may be that for future

commission reports the mini-hearing format is something we would like to modify perhaps but put in play.

I will just very quickly mention the three other parties who spoke with us were Sherry Alpert who is here, I believe, still. Sherry continued her work on privacy and the analysis of stored tissue. Sherry is a privacy expert and policy analyst and has provided us a very useful background paper. Sherry has particularly -- I think one of the most original parts of her paper was trying to sort of flush out the notion of group privacy interests and group interests.

Robert Weir returned to give us his paper again on ethical issues. He came with rather short notice to the prior meeting of this commission. He has had a chance to complete his paper. It is also very useful.

And Marc -- when we broke for this luncheon meeting Marc Sobel and Fran Pitlick, both representing -- both pathologists and representing professional organizations of pathologists, were responding to a request we made of them as to whether the idea that Zeke had proposed and that the subcommittee has been, I think, embracing of a kind of one way permeable law through which you would have the tissues which are themselves good identifiers as virtually all tissues are we discovered. If someone wants to use them for research you have some

process and some barrier so that what goes forward to the researcher is not the identified tissue but is a sample with the other information that is needed but without specific identifiable information.

We asked Marc and Fran if this were practicable and how one might do it and we were in the process of talking with them and hearing their ideas when we had to break for this.

That is where we are. I invite other members of the subcommittee to add to that and members of the commission in general to say anything they want.

Rhetaugh?

DR. DUMAS: Well, I have a question. I am somewhat embarrassed because I feel I should know it coming from a large medical enterprise. How are decisions made about what tissues to store and which ones to discard? Do you know?

DR. MURRAY: Well, probably Marc or Fran could give you a more precise rendition but I will give you the quick one. If it is for -- if the tissue was taken as a part of a clinical procedure it may well be a matter of law in your state that you have to keep certain parts of that, certain samples of the tissue.

DR. DUMAS: For a certain period of time.

DR. MURRAY: So quality control -- yes. It

might be for a specific period of time but they tend to hang on to these samples for long periods of time. The samples, I guess, range from --

DR. SOBEL: Two to twenty years.

DR. MURRAY: Two to twenty --

MR. CAPRON: That is what the law --

DR. SOBEL: Depending on the state laws.

DR. MURRAY: Yes. But some of the collections are 100 years old.

MR. CAPRON: This would be the pathology specimens.

DR. DUMAS: Pathology. They have to send that -- I know they have to send specimens to pathology. I did not know how long they keep them, where they keep them, what determines whether they keep them two years or ten years.

DR. MURRAY: Yes. I think what determines it is they have a minimum number of years that would be specified by statute. But as far as I know there are no laws that require them to dispose of the tissues after that time.

DR. DUMAS: I see.

DR. MURRAY: And I suppose they are generally kept. Is that true, Marc?

DR. SOBEL: They are generally kept if there

is potential future use for the samples and it is limited by the amount of storage space that is available so there are many places that are not able to keep these samples beyond the required limits because of storage.

DR. DUMAS: And right now do the patients from whom the samples come sign releases routinely that their tissues can be stored and kept and used?

DR. MURRAY: Yes, I will invite Elisa if she wishes to add to this but my understanding is certainly within the recent years or decades people have signed things. But typically it works this way, you get a page, sign the consent for the procedure --

DR. DUMAS: Yes.

DR. MURRAY: -- and then underneath it is another sentence that says can we use your tissue for research or education, and people sign that, too. You ask them afterwards do they remember signing this and I think the --

DR. DUMAS: No, they do not.

DR. MURRAY: -- answer is no.

DR. DUMAS: I have had surgery. I do not ever remember seeing that statement.

DR. MURRAY: Well, a family member of mine went through --

DR. DUMAS: I hope I will not have to look for

it.

DR. MURRAY: Yes. A family member of mine went through a biopsy and I was present with this individual and this individual had no recollection having just signed it of even seeing it.

DR. DUMAS: Right, but it was there. It was on the form. Okay.

DR. MURRAY: Yes.

DR. DUMAS: Thank you.

DR. MURRAY: Alex?

MR. CAPRON: From your description of people's response at the mini-hearings I had the impression which may be totally erroneous that these were people selected because they had some experience in having tissues stored or was this just a random sample of people in Cincinnati and wherever else you were?

DR. MURRAY: Right, not a random sample.

DR. EMANUEL: Either of those were the universe of possibilities.

MR. CAPRON: Okay. What was the group that was --

DR. EMANUEL: We have had six of them, seven of them, seven hearings, and there have been all sorts of different groups but some people who have had surgery, some older people. I mean, more convenient samples if the

way they are being described. They are not random. That is for sure.

DR. MURRAY: Right.

DR. EMANUEL: And they are not only people who have had biopsy samples.

MR. CAPRON: Because Tom's description that the participants, which I guess means some subgroup, who said, "Yes, I have been through this," a la what Rhetaugh was just saying, "But I do not remember it."

DR. EMANUEL: Right.

MR. CAPRON: Okay. And will we get a report?

DR. HYATT-KNORR: Yes, you will.

MR. CAPRON: Giving us the details.

DR. EMANUEL: Actually in the notebook --

MR. CAPRON: I did not read through all the materials for your subcommittee because there are a lot to read for our's.

(Simultaneous discussion.)

MR. CAPRON: I have not read through all the transcripts of your subcommittee either but I would like to do that in some other life.

DR. EMANUEL: I think it is --

(Simultaneous discussion.)

DR. MURRAY: I am proud of Alex's candor. I think that is a good example.

(Simultaneous discussion.)

DR. MIIKE: Alex, the way they were picked were very different but in any group like that there are always people who have been to the hospital and had surgery. So they are recounting if they had specific knowledge and recounting from their own specific experience.

DR. EMANUEL: Tab C, sorry.

MR. CAPRON: Tab C.

DR. MURRAY: They were not quite a convenient sample of the -- they were not just randomly chosen as people. In different areas in different cities we went after different kind of groups, whether it be in terms of age or ethnicity or some other thing. But we wanted to try to get a variety of people and not have, you know, just go to seven cities and basically ask the same people at seven different places. That was less interesting to us than trying to get different groups.

MR. CAPRON: And they were -- because they were asked a standardized set of questions that is how you get comparable information.

DR. MURRAY: There were scenarios that --

DR. HYATT-KNORR: We did not ask the specific questions per se. I mean, this was not a survey. But there were scenarios and they discussed the scenarios

amongst each other and not everybody necessarily responded to the same issue. But they were very comparable from one set to the other.

MR. CAPRON: So the things that are said -- are called issues are an abstraction of what the issue would be from one of these scenarios in effect.

DR. MURRAY: What we had, Alex, was we started out with a set of issues that we thought ought to be addressed in any of these and then scenarios were developed in an effort to make sure that each of the issues would be at least raised. They were then -- I only attended one mini-hearing so I can tell you how that one went. We did not need to use all of the scenarios to get at all the issues because people would spontaneously start talking about something that we thought was going to be raised say in scenario five but they were already there by scenario three.

So in every grouping each of the issues I take it came up for that area but often the participants raised it without our having to.

DR. EMANUEL: You have a transcript outline and they try to go through it all but they do not necessarily have to ask it all.

DR. HYATT-KNORR: If there is anything else that you want to know, assuming that it is in the

information, this is a draft and, you know, if there is anything that you think ought to be addressed in addition please let me know soon.

MR. CAPRON: Okay.

DR. MURRAY: Diane?

DR. SCOTT-JONES: I had some questions about the mini-hearings also but Alex has already asked most of them and you have already answered them. What I will go ahead and ask is how easy was it to get this accomplished? How easy was it to get the group and to get the whole thing done?

DR. MURRAY: It was very easy. I just told Henrietta to --

(Laughter.)

DR. SCOTT-JONES: Well, I am recommending that we might want to do it so just on a scale from one to five.

DR. HYATT-KNORR: I think finding the participants was relatively easy even though we had an extremely tight time frame. We might have wanted to have done things a little differently if we had had more lead time. But getting people from the public to participate in addition, which is what we had hoped, even through advertising did not yield very many responses. Does that answer your question?

DR. SCOTT-JONES: Yes.

DR. MIIKE: Just to expand on that, these were mini-hearings but the public was invited. The problem is how do you tell the public what this thing is about. I mean, that was very hard to try to grasp that. That is all.

DR. HYATT-KNORR: But I think even -- no matter how you tell, I think the general interest of the public to contribute three or four hours in the evening, you know, getting there, being there and going back home, is probably limited and it would not surprise me at all.

DR. MURRAY: Developing the scenario work, the scenarios took some work and I have to credit members of the commission and also Sean Simon who did a lot of work, as well as the contracting group who actually executed the scenarios. So there is a lot of effort that goes into making it appear effortless.

DR. SCOTT-JONES: And then will you then give some information back to the participants?

DR. HYATT-KNORR: They asked for it as a matter of fact and when we have a final report then we will go back to them and also when the recommendations in the report from the commission as a whole eventually is published we will send it as well. Specifically they were very interested in it.

DR. CHILDRESS: I participated in the one in Richmond and I was struck with this that they felt they were participating in an important process and they actually wanted to get feedback from it. Very strong interest on their part.

MR. CAPRON: Just looking at this quickly, it would be helpful, I think, since the issues and so forth are set out in tabular form to have as an initial part of that table a statement of the numbers of people participating and the basic demographics, male, female, broad age groupings. I mean seven people at the Mt. Zion Congregation Church in Cleveland, ten people in Miami, fourteen people in Boston and so forth, just so we get some sense of what we are talking about here. As you look down a column and it says "most people" or whatever if you are talking about sample size, what is the make up.

DR. MURRAY: Some things we can tell you. Things like age we did not ask people.

MR. CAPRON: But you represented that this was broadly representative as to --

DR. MURRAY: Yes. But I do not know the precise age of the people there.

DR. HYATT-KNORR: But we observed and we should know some other demographics, but to the extent that we have it and they match from one observer to the

other we will be happy to add those.

DR. CHILDRESS: Am I wrong in remembering a discussion though that we could not actually go the route of getting all this information without converting this into a kind of survey that would take a very different direction. Am I wrong in remembering that?

DR. NORRIS: Yes, you have to get special OMB clearance.

(Simultaneous discussion.)

DR. HYATT-KNORR: These are not questions that we asked and certainly we are not going back and asking them but at the same time the observers did write down some general characteristics.

DR. CHILDRESS: But I think it goes to the larger issue that Alex is raising, sort of how one uses it. I understand that the use of the focus group and we are limited than to be able to say X number of people said the following. Is that --

DR. HYATT-KNORR: Oh, that is a different issue.

(Simultaneous discussion.)

MR. CAPRON: I am not asking for the breakdown on the answers. I just want to know --

DR. CHILDRESS: But your interest in part and where the answers that came out relative to age and gender

and so forth, I think, is the question you are asking.

MR. CAPRON: Well, it was represented to us that the group was broadly representative of the population although not randomly chosen. The groups are small enough that I would be very worried about putting much of any weight on this. Clearly if there had been a very harsh reaction uniformly across all these groups on some point, that they had been very upset or extremely supportive, I do not mean harsh, I mean pronounced reaction in one way or another, that gives you a little -- some indication. But beyond that when a self-selected group of seven people are at the Mt. Zion Congregational Church in Cleveland I do not know what I want to do with that information.

DR. EMANUEL: Well, but in all fairness, first of all, there is some sense and I think I did do a reasonable job, you know. In the San Francisco group there was an effort to get young people. In the Miami group we heard that most of them were retirees even though they were quite active retirees. So in some sense we have some assessment of that range of ages as well as ethnic groups and socioeconomic groups.

Second -- I mean, part of what we have heard from Jim Wells and from Henrietta and from Sean is the fact that there are consistent themes which seem to go in

the sort of 80, 90 percent response categories and that is helpful, I think. That is a pronounced kind of understanding. And that has been, I think, helpful. And as was noted in our hearings today some of those go against the biases we went in with. We, the commissioners, as well as the survey people.

For example, how concerned people are about confidentiality versus medical practice. Now one of the suggestions we have made is that maybe we could formulate some questions that at some future date if we are ever going to do a survey or someone else could do a survey we could add on to a survey, or we might get some data.

MR. CAPRON: Yes, I take the point. I always remember the kinds of studies like the one the March of Dimes did a few years ago on genetics where they got 75, 85 percent of people saying they were in favor of genetic engineering and a comparable number saying they did not know what it was.

Now when you get those kinds of results you are obviously trying to have some salience in what you were doing and make it a little bit real to people. That is why I wondered when you are describing were these all people who had at least had some biopsy specimens stored so that they would immediately say, "This is not a general issue. You took something from me. Oh, it turns out you

kept it. I did not know that. Now how do I feel about your doing things with it? Well, what are the kinds of things you can do? What can you find out?"

And then the question is how clear what you can do to it and what implications that has to people as they focus on it because if we are going to say 80 to 90 percent of them said, "Let's go research. It is great and we are not really worried about it," how much they know to be worried to start off with affects my sense of whether or not I should take that as a result that is very reassuring that as you say maybe I go into it, you went into it with greater concerns than the public has. Or do I simply say, well, it is sort of interesting but it does not tell me much because it says people who -- again like the other survey -- 85 percent will say yes to it because 85 percent of them do not know what it is.

So, I mean, I do not know what -- and maybe if I have been hearing from Dr. Wells and others who have spent more time on this, and I will read over these materials more carefully, I would have more reassurance that I should conclude anything from this process other than it --

(Simultaneous discussion.)

DR. MURRAY: Okay. A lot of people want to speak. Let's start in a more organized way.

Arturo?

DR. BRITO: Having attended the Miami forum I think that there is a little bit of clarification. Had I not attended I would be -- I think I would be in the same ball park as Alex is in right now.

But the March of Dime survey is just that. It is a survey. It is very leading questions. The way Dr. Wells did this hearing and the other hearings I assume is they were very open ended and these were forums. So I do not think we are trying to get statistical numbers. Even 80 to 90 percent, whatever numbers like that. So I think we just have to keep in mind these are forums and I was very impressed with the way these were held and the open ended question type of format even though there was a script scenario that was not always attended to. A lot of these responses were very spontaneous. I think what I am hearing is that across the country regardless of the group a lot of those spontaneous responses were very similar.

Is that right?

DR. MURRAY: Yes. On quite a number of questions they were similar and sometimes, as Zeke has mentioned, in ways that might have surprised you or me before we --

DR. BRITO: Right. So it was very informative to me to hear some of those responses. So I think it is

more just general information.

DR. MURRAY: We recognize this is not a random population sample from which one can generalize. But it gives us some notion of how people are constructing the situation and what meanings are taken out of it and what they care about. We will use it as that.

DR. COX: They were not just self-selected either. So it was a fix. But not people that just had raised their hand and said that they had something they wanted to talk about.

DR. MURRAY: Bette?

DR. KRAMER: Tom just covered the point I wanted to make.

DR. MURRAY: Alta?

MS. CHARO: Generally, not facetiously, but to set up things as a piece of performance art for the Human Subjects Group, who among you decided whether or not this was human subjects research and, if so, whether or not it was exempt, and who among you knew which IRB you should go to if it was not exempt since you were recruiting people for a seemingly systematic investigation of their attitudes?

DR. EMANUEL: Well, it was precisely not a seemingly systematic investigation of their attitudes.

MS. CHARO: So you are the one who made the

determination it was not research?

DR. EMANUEL: No, I did not.

MS. CHARO: Who did?

DR. EMANUEL: As a matter of fact, Alta, I believe I raised that question, too.

MS. CHARO: Just because -- I mean, we are talking to agencies about their ability to know what to do when and I was curious how you all knew what to do when.

DR. EMANUEL: Well, I do not remember the details, Alta. We did have some discussion of that when we consulted people about it, whether it was exempt or not. We just did not make the decision. But we could check exactly who we went and spoke to about it.

DR. _____:

I think part of the issue was we are prohibited from doing -- not prohibited, but the process of doing a survey. That is why, for example, the sociodemographics could not be asked. It was decided that could not be asked. That was to make it -- also, it was decided to make it open so that members of the public could come. So it was more hearings. That is why we are calling it mini-hearing or focus groups. And, you know, on the other hand there was an effort to make a sort of systematic use but it is not generalizable knowledge. It is certainly not publishable.

So, you know, I am just telling you I thought the same question was -- I raised the same question with Henrietta and I think, you know, part of the -- I am just giving you part of the rationale that goes into it.

DR. SHAPIRO: Diane?

DR. SCOTT-JONES: It is a little bit concerning, though, because even though you are saying that you did not assess the demographics of the persons who attended you are still making statements about it and saying that it varied in age and ethnicity and so forth and you still sometimes are using language of quantitative research like saying 80 to 90 percent said or did X. So you are kind of converting nonresearch into research. Well, I will stop there.

DR. SHAPIRO: Any other questions?

DR. HOLTZMAN: So when we systematically ask each other our opinions around this table then we engage in human subjects research?

(Simultaneous discussion.)

MS. CHARO: You might be.

(Simultaneous discussion.)

DR. MURRAY: I agree that the perfectly clear and bright line might be difficult to draw between hearings and research but we did it in the spirit of good and the idea was to see how do people feel about this and

we did not want -- since we did not want to go to basically hear the same voices every time, we thought that added less insight into how a broad variety of Americans might feel, we purposely set out to go to different communities and talk with different groups. But apparently it is not counted as research, however these things are counted. But, yes, did we try to learn something about how the American people felt, sure. But one can do that by a hearing process.

Zeke is right. There is no way on this earth that this would ever pass peer review as a piece of research. That is one criteria. So I guess it could be really lousy research --

(Laughter.)

DR. MURRAY: That is the principle I want to articulate here. It was done in the spirit of hearings.

Eric?

DR. CASSELL: Well, this is just anecdotal. This was my introduction to ethics in January 1971 when the Hastings Center had this research group on death and dying and I was presenting some material. That was my first appearance there. And Henry Beecher said to me, "Do you have permission for this?" I never even heard that word before. I did not know what he was talking about. So in point of fact we finally decided I did not need to

but on the way there I got shook up by the process.

DR. MURRAY: Larry?

DR. MIIKE: Yes. I hope we do not use a double standard about what we use collectively and individually in making our decision. If we applied a rigorousness and most -- I would say 90 to 95 percent of the kinds of things we are considering, including the contracting papers, would not meet the test. So I would say that all of you read what happened at our mini-hearings, take what you want out of it, put that into your decision making process. We are not asking you that we as a group must consider this or reject it. It is just another bit of information that is floating around.

DR. KRAMER: And let me add to that that we never intended that it be anything that was scientifically drawn or systematic. It was an ad hoc. It was very ad hoc. And perhaps when Tom put those numbers on it, 80 to 90 percent, I mean that is just Tom's interpretation of that because, in fact, the same question was not necessarily asked at the same time of each group so there really is no way of putting a number on it.

DR. MURRAY: I tried systematically to avoid assigning --

DR. EMANUEL: He is a philosopher. I put the 80 to 90 percent on it.

(Simultaneous discussion.)

DR. MURRAY: Okay.

MR. EMANUEL: I would add, though, we are -- I mean -- you know, the point of full disclosure, I mean we are calling, for example, pathology departments and asking them about their store -- you know, what kind of samples they have. Now I do not think that is going into another report. I do not -- we did not get IRB approval for that either. It is not a systematic survey. It is an attempt to get a ball park story. But I think, you know, if one has concerns that this is going to qualify as research that also is -- any time you ask doctors questions about --

MS. CHARO: Zeke, my goal was not to challenge as to whether it is or not. It was to have us notice that we are a government agency or a government entity and that we are engaged in things that one could wonder are research or not and to ask ourselves how are we dealing with that question specifically because the human subjects people are about to talk about how agencies deal with that question. My only point was to be self-reflected and to have some understanding of what is going on throughout the government.

DR. SHAPIRO: We did not think --

(Simultaneous discussion.)

DR. SHAPIRO: -- we did not discuss our intention. We did not pass --

(Simultaneous discussion.)

DR. COX: But, Harold, for me I think that this is a very timely discussion, particularly for those of us in the Genetics Subcommittee, whether it is possible to draw sharp lines between what is research and what is not research because clearly there is an academic standard of what is research, but there is human activity too. So that if you draw too sharp a line as we found in the past couple of minutes it becomes an interesting dilemma.

DR. SHAPIRO: Thank you.

Other comments or questions?

Tom, anything else?

DR. MURRAY: Thanks very much.

DR. SHAPIRO: Thank you. Regarding -- just returning for a moment before we break to go back in the subcommittee sessions -- the January meeting, as I said before, is open to either of the subcommittees to present material to NBAC as a whole. In February, of course, we really must have material really quite while perhaps still not final. So depending, Tom, on how quickly you and your subcommittee move we are certainly prepared in January to hear from your group if you are -- at whatever stage you are at. So we -- the schedule remains pretty much as we

indicated before.

DR. MURRAY: Will there be any time for subcommittee meeting in January?

DR. SHAPIRO: I think we could have some time for subcommittee. We will keep in touch with the subcommittee chairs and see if we need to make -- have notices and so on.

DR. HYATT-KNORR: But the problem is that we really need to decide these things now and that those will be for much of next year because we will have a support contract and we need to make arrangements for rooms and other such things way ahead of time. It is very difficult for us to continue to do it as late as we have.

DR. MURRAY: Well, I think we should get a very flexible support contract.

DR. CHILDRESS: I agree. It has to be at least for when we come back in January. We will not know for a while yet, I think that Tom will not either, exactly whether it will be mainly a subcommittee or --

DR. SHAPIRO: We can always have an extra room or two set aside even if we do not use it.

MR. CAPRON: Is not the discussion that we have just had, however, in which several of the questions to your committee came from the people who are not on it and the questions to Jim came from the people who are not

on his indicative of the value of having more of our time together as a whole group and that the very way you expressed it, both of you expressed it about these -- when we get to them there are going to be preliminary thoughts and questions and some tentative conclusions and so forth.

The more time we have to digest and think about that and have a discussion and then come back to it in another month, instead of saying, well, we are going to do it in February so we do not need to do it in January, in other words -- or the faster we can have something ready, even however preliminary it is, and then know that we are not going to dispose of it at that meeting, that it is worth having more than one time as a whole group to chew it over so that we who have not been through the process can be better educated.

DR. EMANUEL: Can I second that?

DR. SHAPIRO: I think you are going to have more than one time. Nothing I have said --

MR. CAPRON: No, no, I was just encouraging -- I was agreeing with the notion that rather than giving up time in January for more subcommittee process that we plan to have a good deal of time for discussions of wherever the subcommittees are even though we could on some efficiency level say, well, we get more done if we were meeting in subcommittees.

DR. CHILDRESS: That is what is planned. Even if we are still fairly tentative let's say on the recommendations.

MR. CAPRON: Yes, exactly. Even if we are very tentative our direction might be changed as a subcommittee and it was only that Tom was now saying could we have some time in subcommittee and I was encouraging the plan that you originally endorsed that was going to resist that, that inevitable pull to say, well, we have more work to do as a subcommittee.

DR. EMANUEL: Can I -- if we think -- if we come back at least on the Genetics Subcommittee, if we want to release a report in February and we want to have the whole commission on board, that means that the -- I mean, January is very late in that process and that means we have to get our recommendations done by this December meeting, not done but at least in some vague format so they can be debated and argued about.

MS. CHARO: And, indeed, one of the things that we risk as we go on too long is that you will get conclusions that some committee gets totally invested in. You want to bring them to everybody at a time when everybody, including those who worked on it, are willing to step back and say, "Well, maybe we will change it."

DR. DUMAS: A good point.

DR. MURRAY: Our process is itself a kind of experiment. Meeting as we have largely in subcommittees has enabled efficient work within the subcommittees but it has had this problem of the other members of the commission do not know necessarily what the subcommittees are up to. I do not know what would work best.

What I was hoping for is we might need an hour either at the beginning or at the end say of the January meeting to reflect on either what is about to happen, make some last decisions or to sort of try to incorporate the whole committee. I was not planning -- I was not proposing that we do it like we did today but I think it would be useful to have the option at least, I do not know how Jim feels, of at least a little time as a subcommittee.

DR. CHILDRESS: And perhaps I could imagine a scenario in which it would best at the end for the subcommittee to think about how to revise in light of the discussion that obviously will be helpful but will not be as complete whereas you will not be able to get everything done in that context.

DR. SHAPIRO: The key issue here is to be sure that -- is to be sure that the subcommittees have a discussable a set of propositions for us no later than our January meeting and at our February meeting. Just when

the reports are actually issued will depend somewhat on just what happens at those meetings and we may feel just delighted with it all or you might feel that you really have to do something further. And so I am trying -- I was trying to struggle for a balance between, you know, let's get this done but not doing something that you would not feel good about. So, you know, we need a certain balance.

Okay. Other questions?

MS. CHARO: Just a general question?

DR. SHAPIRO: Yes.

MS. CHARO: Our web site, I had occasion to revisit it after it came up on e-mail lately and was -- are we going to put the transcripts of the meetings up and the meeting dates and the agendas for the meetings, and all the other public material, or has that web site been abandoned basically because it turned out not to have a lot of our stuff that is I know available electronically posted on it?

DR. SHAPIRO: I think the web site has not been maintained appropriately in my view and I think we ought to either do that or not have it. One of the two.

MS. CHARO: I personally would like to do it. I think it is a great concept and I would love to see it really do --

DR. SHAPIRO: Yes.

DR. HYATT-KNORR: We did switch it and we just recently got a new address and it is in draft and it is by no means finished nor did we think it was and we do intend to put these things on. But only very recently did we get the new address which is very easy for the public to remember.

MS. CHARO: Right, but I think the crucial thing is the transcripts which have been available electronically for months and months that are not posted could be posted in a flash because they exist already and clearly meeting dates and sites and agendas --

DR. HYATT-KNORR: We want to do that.

MS. CHARO: Great. Okay.

DR. DUMAS: And I thought that the statement that went from Harold and the two subcommittee chairs would be a good one. Alex has trouble with a statement in there but I would think that if that could be added that would be a very good piece for the public who would want to -- it is a very succinct statement of what this committee is -- this commission is all about. He heard different things about what we decided about. I thought it was accurate in relation to that statement at issue. But it seems to me that is something that can be --

DR. SHAPIRO: We can discuss that in another moment. That is another issue.

DR. CHILDRESS: Just to add one point in relation to what Alta just said, e-mail exchange and looking at the report, and I think there are -- you know, there are two plausible ways to interpret what we agreed on.

MS. CHARO: Yes.

DR. CHILDRESS: At least.

(Laughter.)

DR. DUMAS: But the public needs to have something -- a statement that they can look at when they want to know what is this commission about so they do not have to read the whole report.

DR. SHAPIRO: Well, let's -- that stuff we are still discussing and I do not think we want to post anything right but we can discuss that at some time if people are interested.

Okay. Other issues?

If there are no other issues right now I would propose if the subcommittee chairs agree that we just get back to your agendas. So if it is necessary you could take more time or finish early. Either one would be appreciated. So let's take a -- we only have seven minutes -- take a break.

(Whereupon, the committee meeting adjourned at 1:21 p.m. to resume subcommittee meetings.)

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