

## MEETING OF THE NATIONAL BIOETHICS ADVISORY COMMISSION

Friday May 2, 1997  
7:30 a.m.

Crystal Ballrooms 1 and 2  
Sheraton Crystal City Hotel  
1800 Jefferson Davis Highway  
Arlington, VA

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P R O C E E D I N G SWELCOME AND INTRODUCTIONS

DR. SHAPIRO: -- call today's meeting to order. I want to begin by thanking my fellow commissioners for their continued dedication to our effort to complete this report in the time frame that the President has asked for it, requiring many members of the Commission to go to heroic efforts to participate, not only in our meetings, but to talk with us as we talk to each other on dealing with some of these issues that are really quite challenging.

So I want to thank all the members of the Commission. Of course, I want to thank our staff as well for the work that they have to do that is above and beyond what is normally expected in order to meet this particular deadline.

Let me say a word about where we are. We are, of course, beginning to write parts of the report, which we will be sending around to each of the commissioners for their views and for their suggestions.

We are at that moment where every time you get something from us, you ought to be taking out your pens, because we do, if we are going to make this deadline, need to have responses in writing and as thoughtfully as you can. So that we can put them together in an effect way and generate a report which will garner your support and will achieve its objectives.

Now, you have, in your packets, initial working drafts of both the introduction and the science chapter. Neither are complete, let alone adequate. We will have to hear from you as to what you think.

Speaking for myself and I think it is probably true for others -- certainly, for Kathi and others who have written -- we have no particular pride in authorship here. You oughtn't hesitate to say -- tell us what seems silly to you and what seems tangential and not straight to the point and so on. We really need very thoughtful criticism.

I have often said what these reports need to these drafting stages is kind of loving critics; that is, we want the criticism, but you all know what our objective is, and so if you can, any of you, help us reach them, that is very helpful.

Now, many members of the Commission before today is over will have particular writing assignments. We have to, roughly within the next week or 10 days at least, have initial working drafts of all parts of the report in order that we can then hone in on our recommendations and get through on time. So we have a period of very intensive work ahead of us, and I thank you in advance for the help in putting this together.

So to just give you an idea of the kind of schedule we are going to have to keep, you have drafts of -- drafts -- initial ideas and drafts of two chapters of the report,

as I have already said. We really want your feedback no later than Monday on those. So that we can then move to something which really is a draft of that section. It is not quite at that stage yet.

And so we are going to need turn-around like that in order for us both to have a quality report and to make it within the time frame that we have.

So thank you very much, once again in advance, and of course, a good deal will depend on today's discussions and discussions that will take place after today. Are there any questions simply about -- Steve.

MR. HOLTZMAN: Yes. If comments -- presumably, they will be useful as mark-ups, where should we fax the mark-ups?

DR. SHAPIRO: I think it is easiest if we fax them to Kathi, just so we have one place where they go. Kathi and I are burning up the fax machines in our offices, but if you fax them to Kathi, I think that is the most useful. Kathi, what do you think?

DR. HANNA: Let me give you my fax number. It is 410-414-2618.

DR. LO: And what is your phone number in case we have TROUBLE ---

DR. HANNA: My phone number is 301-494-0900.

DR. SCOTT-JONES: 09 what?

DR. HANNA: 0900. And my phone and fax are on the same line. They just have different area codes.

DR. LO: That is quite a trick. How do you do that, Kathi?

DR. HANNA: The fax is 410-414-2618. Phone is 401-494-0900.

DR. SHAPIRO: Yes, Alex.

PROF. CAPRON: I notice that there is a draft cover for our report in here. I think we are missing just a terrific opportunity at the moment. We really ought to have a cover that has one picture of Chelsea enrolling in Stanford and her clone enrolling in Princeton.

DR. SHAPIRO: Well, we will give that some consideration. Incidentally, talking about covers, I did get -- I received a fax.

If anybody has any good ideas regarding title for the report and so on, we are also very open to suggestions. People have different views as to whether one ought to spend a millisecond or a long time thinking about that. So if any of you who are in the latter category and have any ideas, please let me know. Because I, myself, haven't thought about that much yet.

Any other questions? Okay. Just let me review the agenda today. We will begin in a few moments with some of the scientific issues and responses that we have had on certain issues. Then we will move on to discuss the ethics issues discussion. The scientific issues, led by Carol. Bernie will take over doing the ethics issues. We will have a coffee break. We will then

go to the legal and policy issues discussion and so on. By that time, I think we will have learnt just how we are going to spend the rest of the day.

I think that there is a certain amount of reiteration here. It is not clear just what issues we will focus on today, depending on which ones give us the most controversy and the most challenges to figure out and get ourselves focused on.

So let's begin then. Carol, we will turn to you, and we will deal with some of the scientific issues.

#### SCIENTIFIC ISSUES

DR. GREIDER: Okay. There is really just one thing on the agenda that I have for scientific issues, unless anybody else has any other suggestions, and that is, that as you all saw at the last meeting, we had circulated a letter to a large number of scientific societies to try and get some of their views on specific issues in cloning.

And we did this for a couple of reasons: one was us in the science bucket felt that we needed more broad input from a larger cross-section of science to sort of see if there were any issues that we were missing that we hadn't thought about dealing with the science.

And also for the Commission as a whole, I was hoping to get a sort of overview of where scientists come down in a lot of these areas. So we have had what I would say is a pretty good

response from these scientific societies, and you got some of those letters the last time, and some were in the packet of things that you should have gotten from NBAC.

And what we have done is to ask Elisa Eiseman to summarize some of these for us and to put them together in a sort of a coherent fashion. Elisa has done an absolutely outstanding job at summarizing that. So you should have in front of you this draft report on the view of the scientific societies.

And, again, this is a draft. You will get a final report next week. Because a lot of these responses from the scientific societies were still coming in at the end of the week -- the end of the week, which is today.

A lot of interesting things have emerged from the letters. So reading the letters themselves -- a number of societies responded to our questions, but had a lot of other ways in which they describe the views on cloning that had a lot of interesting input into it.

So Elisa has tried to capture some of that in this report, but you might also want to take a look at the individual letters themselves. So in order to give an overview as to sort of where -- what the summary of this is, I have actually asked Elisa to give a short presentation.

And I think she is ready to do that now this morning, sort of summarizing what she found, and then we can open it up for

questions when she has done that.

DR. SHAPIRO: Are you using these overheads here? Okay.

(Slide.)

DR. EISEMAN: [Not at microphone.] Okay. As Carol mentioned, the Science Working Group decided to send a letter to approximately different scientific societies and associations to ask for their views on the cloning issues.

They actually asked them to give views on six specific areas and then also asked for their general comments on the issue of human nuclear transfer cloning. Listed here are the six areas of research that the different societies and associations were asked to comment on, and they basically fall into three categories. And then it is whether they were going to use adult human nuclei for transfer or embryonic nuclei.

Okay. So the first two questions here deal with using either donor embryonic -- [reporter asking speaker to use microphone]  
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So the first two questions deal with using either adult or embryonic donor nuclei or doing basic developmental biology research. The second two questions, number 3 and 4, deal with using either adult or embryonic donor nuclei to generate specific human cell types for potential cell-based therapies.

And the last two sections -- two questions -- deal with either using embryonic or adult nuclei for research towards

generating cloned offspring in the treatment of infertility or otherwise reproductive problems.

We got 31 responses to the survey. Five of those responses did not directly address questions 1 through 6, but did give us a lot of comments, and those are captured in the report you have in front of you.

Seven of the respondents only said they had no position on any of the questions, and a lot of those reasons were because they were educational associations and did not routinely give positions on issues like this.

So that left us with 19 respondents, who answered -- or gave comments on the research areas 1 through 6. And these are the responses.

There are a lot of numbers, but I think it is pretty clear that the majority -- the way they were supposed to respond -- I am sorry -- was either whether these areas of research should be prohibited entirely, allowed in some limited circumstances, or allowed freely. And then the last column, of course, is people who said they had no position.

What you can see is for the first four questions, which again deal with basic research issues, that the vast majority of respondents out of 19, for both questions 1 and 2, and 11 and 12 for questions 3 and 4, responded that that type of research should be allowed freely with no restriction.

But when you get down to questions 5 and 6, when you are dealing with the issue of generating cloned offspring for the treatment of infertility, again, the vast majority this time said that that should be prohibited entirely.

So there were a few respondents that said that there should be -- these types of different research should be allowed with limitations, and I will discuss some of those limitations in the following slide.

(Slide.)

Okay. One of the main issues that a lot of the societies wanted to get across is: What is the definition of cloning? Because a lot of societies and associations were worried that if we don't have a very distinct definition of what we are talking about, we may inhibit research that we don't want to inhibit.

So, basically, the consensus was that cloning is used for a lot -- the word cloning is used for a lot of different things. The basic definition is that it is the copying of biologic material to produce identical genetic copies from a single entity. That entity could be genes. It could be cells, or it could be whole organisms.

Some of the examples that were give of what the term human cloning is used for are shown on the slide. Clones of human genes can be placed in various cells to study their function.

Human genes are cloned in bacteria to produce proteins for therapeutic purposes, and I have given two examples that were

given by some of the societies: the use of Factor VIII for hemophilia or interferon gamma for the treatment of cancer. And cloning of human cells is a routine technique to study cancer, genetic diseases, or a lot of other types o diseases.

So the bottom line, like I said, is that we need to have a clear definition of cloning to avoid prohibiting important genetic research.

(Slide.)

One of the general areas that the societies and associations were asked to comment on was: Why should this technique of human nuclear transfer cloning be allowed or prohibited? And so one of the general areas that some of their comments could be grouped into was that it should be allowed because of the knowledge gained and the potential uses of this technology.

And it kind of fell into two areas, research and then technology. The main feeling was that this type of research could revolutionize and advance the understanding of basic developmental biology by addressing certain areas that may not be addressable by other techniques.

One is addressing how cells become different from each other during the development of an organism from an egg to an adult.

Another is confirming that genetic material of adult cells is intact and potentially totipotent.

And the last one that I have listed on the slide, but you

will see more in the report, is advancing the knowledge of the fundamental processes such as how genes control human development and how oocytes can reprogram adult nuclei.

As you can see, this research area very much fits in with the question of the basic developmental biology.

The second area of technology, it was stated that this technology is fundamental to developing new, more effective cell-based therapies for human genetic and degenerative diseases.

The examples given here are: It could be used to figure out new ways for repair and regeneration of human tissues, and it may be a great way to eliminate graft rejections for people who need organs or also the problem of the scarcity of donor material.

And an example of the regeneration that was given was interesting, an idea of regenerating nerve cells or brain cells for the treatment of Alzheimer's.

(Slide.)

I also wanted to share with you some of the reasons that people had objections to this type of research, and a lot of that focused -- or some of that focused on the potential risks and scientific constraints. A lot of it also focused on ethical issues, which I will show you in a minute.

The first point deals with the cloning of entire beings, and that is, that the efficiency of nuclear transfer is so low and the chance of abnormal offspring so high, that this type of

experimentation in humans is not currently a good thing to do.

The second two deal with both research, basic research, and the cloning of entire human beings, and that is, that at this point, it may be inappropriate to waste human tissue, cells, and embryos before perfecting these techniques in animal models.

So there was a call by a lot of the societies to do a lot of this research, or at much of this research as possible, first in animal models before it was applied to human cells and tissues.

And one of the respondents did point out that even if this technology is perfected in animals, it will eventually need to be performed in human experiments, because there are going to be differences between animal models and human research.

(Slide.)

What I have done here is to put up the exact quotes that were given, which I have grouped under the category of ethical issues, and the reason I left them as quotes is because they are too nice to change. And I thought that the quote really said a lot, and I thought it would be better for you guys to see exactly what was said.

So these are just a few of the more poignant statements that were made, and you will see the rest in the report. But I thought that these were pretty representative.

So the first one is: "These new prospects of cloning human beings from the genetic material of an adult cell challenges

some of the most fundamental concepts we hold about ourselves as social and spiritual beings. These concepts include what it means to be a parent, a brother or sister, a family."

The second one is: "While our everyday lives may include identical twins of the same age, we have never experienced identical twins substantially different in age, indeed, perhaps alive during entirely different periods of history."

And the last one: "In our everyday lives, we may decide to procreate a child and wait in wonder and awe to see the unique individual he or she will turn out to be. We do not, on the other hand, have experience creating a child where part of that decision may include an evaluation of the life, health, character, and accomplishments of an adult from whom we will take the genetic material that will become the child's genetic makeup."

PROF. CAPRON: Elisa. Are all of these statements individual expressions of the writers? Or were any of them statements, in some sense, officially on behalf of their organizations?

DR. EISEMAN: All three of these statements were made officially on behalf of the organizations.

PROF. CAPRON: And the third one comes ---

DR. EISEMAN: From BIO.

Okay. The last area that the societies and associations made comments about was the issue of restrictions, regulations, or

possible legislation for prohibiting this type of research.

And so what I have shown here are the different ideas that the societies and associations came up with. The first one is no restrictions. The second one would be some type of oversight by the scientific community, something like an Institutional Review Board.

Another idea was for federal oversight, some kind of national bioethics authority, and also within the federal oversight, what I have included in the report was the idea of federally funding would also allow federal oversight.

The next would be a voluntary moratorium, and the last is federal or state legislation. So let me show you, when they called for these different types of policy options, what they wanted it applied to.

(Slide.)

So the no restrictions category was mainly applied to the cloning research, to study developmental biology or to develop cell-based therapies. Three of the respondents did say that they wanted - - they thought that all types of research with human nuclear transfers -- that includes basic research, as well as cloning of entire human beings -- should be allowed freely without restrictions.

The next set of policy options, the oversight by either scientific community or by federal oversight, as well as the voluntary moratorium, were suggested for both cloning of an entire

human being, as well as cloning research.

And I just wanted to point out, because I thought it was very interesting -- oh, I am sorry -- one thing I want to point out first is that two of the respondents did say that they wanted a voluntary moratorium on all research, both cloning of human beings and basic research.

And then, finally, the last category -- I am sorry for the typo on the slide -- is that of federal or state legislation. And there was no support from any of the societies or associations for federal or state legislation.

As a matter of fact, a lot of the associations and societies specifically said there should not be state or federal legislation to regulate this type of activity. So those are the responses we have gotten so far. As Carol said, they are still rolling in the door. I got one as late as Wednesday that is not incorporated in your report fully, but hopefully, by next week, I will be able to incorporate all of the responses. I would be happy to answer any questions.

DR. SHAPIRO: Just -- well, thank you very much, and indeed, I want to second what Carol said. It is really a very impression job you have done in collating this and bringing to us in such a coherent fashion.

Just from the point of view of information to the commissioners, and then we will just open it for questions, if that

is all right with you, Carol, the issue of definition is, in my view, more and more critical. Indeed, we discovered last night, the legal policies, three or four of us were meeting and talking, we were talking past each other for a while until we got our definitions straight.

And if you will look at the draft later on today or tomorrow of the science chapter, it goes into quite some care to get those definitions straight. If any of you have any reactions to those, of course, you think we haven't gotten them straight for one reason or another, you ought to let us know.

But that part is taken care of. At least, we tried to take care of it in the science chapter. Carol, do you have anything you want to say now before we -- why don't you go ahead? Why we don't ---

DR. GREIDER: Go ahead.

DR. SHAPIRO: Bernie.

DR. LO: Could I ask to put your last slide back up? I want to ask you a question about that.

DR. LO: I am not clear how the questionnaire was worded. Am I to understand that these scientific organizations believe that it was appropriate to carry out research that would involve taking cell samples from human beings and doing cloning research *in vivo* could proceed without oversight by an Institutional Review Board? Or was that an ambiguity in the way the question was phrased?

And when they said, no restrictions, did they mean no oversight by an IRB?

DR. EISEMAN: In those responses, they did not say that there should be any oversight. They did not specify. They didn't say, no, we don't need the IRB review. They just had not specified whether or not it was needed.

DR. LO: Okay. So these are not -- I guess I am not clear whether these are your interpretation of free text responses they made or that we gave them categories and they checked things off. I would be very concerned if people thought they could do research that involved taking samples of people ---

DR. GREIDER: I wouldn't interpret it that way. We had very broad, open-ended questions and then just asked for any other comments. Most of these, I think, came from the "Any Other Comments" area, and I think they were thinking in terms of new kinds of restrictions, not changing the way things currently are.

I didn't get any sense that anybody wanted to change the way things currently are in terms of Institutional Review Boards and that kind of stuff.

DR. EISEMAN: As a matter of fact, certain people did even say that. That there should be no restrictions beyond those that are already in place.

MR. HOLTZMAN: To second Carol's point, Bernie, if you look at the questions we asked, basically, we tried to get at two

different categories of basic research. What we found is that people said it is all basic research, and second off, did it make a difference with respect to basic research in 1 through 4 whether the source of the DNA was somatic cell or embryonic cell, and the answer was no.

So the conclusion was that the bright line divided is between baby-making and non-baby-making, and with respect to non-baby-making, no restrictions equals no new restrictions beyond that which is applicable to basic research, and if you want basic research, involving embryo research.

DR. LO: I just want to say that I think ---

DR. SHAPIRO: Bernie, you want to talk really pretty close to the microphone. Otherwise, it is very difficult to hear.

DR. LO: I think it would be really important to sort of be clear in our discussions of drafts, because I think if the public were to think that scientists think that no oversight by a community or an IRB was permissible, it would be a really unfortunate inference to draw.

DR. SHAPIRO: I agree. Diane.

DR. SCOTT-JONES: I just want to point out that it should be clear that we didn't actually ask a question about oversight. The questions, as Carol said, were very broad, and there were six specific questions at the beginning that didn't ask the societies to respond to the issue of oversight.

What Elisa is presenting now really comes mainly from very, very open-ended questions, where we just asked them to comment on anything they wanted to comment on about this issue. So we really shouldn't interpret these in that manner at all.

And I think also we should continue to emphasize that the persons contacted responded typically without the benefit of polling their societies or even polling an executive committee. I think, in a few instances, they did poll people who were on executive committees, but they were basically responding as best they could to help us. They weren't really -- even when they were responding in an official capacity, we would need to put quotes around official, because they really had not polled their societies asking explicit questions for their society members to respond to.

DR. GREIDER: I just want to further clarify that. We weren't able to actually do some sort of a questionnaire, as you know. On purpose, this was open-ended kind of questions, just to get some feedback to help us.

DR. SHAPIRO: David.

DR. COX: I have three points that I would like to make. The first is that the science bucket hasn't had a chance, okay, to sit down together, okay, and deal with some of these points that you are bringing up, Bernie, and that is very important that this discussion that we have overall is going to be helpful when we get together at noon to sort of make a list of these.

Point number 2 is that, and this is a personal opinion, not one for -- of the whole bucket -- based on what I just said -- is that I was struck by the overwhelming, in my view, statements from the scientific community that they didn't see that this was any rush, okay, and that they felt that there was plenty of time, okay, or hoped there was plenty of time, for ongoing discussion about this issue.

So rather than setting firm policies one way or another, it was a statement of don't rush, okay, to make, okay, firm cuts, okay, before we can have an extended discussion. Because my reading of a lot of this was that it wasn't clear, okay. And that that was the overwhelming plea. It is reflected really by that oversight of the scientific community, which could allow continued discussion.

My final point is that I was pleasantly surprised, in my own view, by some insights offered in terms of specific language, as well as specific scientific considerations, and okay, that I think in the issue of definition, the response from the American Medical Association was extremely useful.

Not that it changes the definition that the science bucket had, but it is written in extremely clear language, and I think that that is one place where -- not just this one -- but others where we could, as a commission, lift some language directly, because it really formulates what we have been talking around, as you said, Harold, with some very good language.

And the second component of that was something I hadn't considered, and I want to raise for the whole Commission. The logic goes as follows: Is that, yes, we need more animal work before we can assess what the risks are in human beings, and then, as was stated here, we have to go and look at the clinical research. Okay.

But one of the things that was posed: Is clinical research in this area ever going to be ethically acceptable? And if you look at that right now, and some of the respondents carried that analysis further, and in their view, they didn't see how one would ever be in a situation to carry out those kinds of clinical trials, okay, to determine this.

And we know that there is a variety of types of human experimentation where, okay, it is not possible to scientifically collect the data, because it is not ethically, you know, thoughtful.

And I would like to raise that for the Commission, because if it is true -- if we look at this from the scientific point of view and we conclude, okay, that if we can't envision, irrespective of what the science is, an ethical way that would allow those kinds of experiments to go on to assess the safety of baby-making, I think that is a very important statement, because -- in terms of how we deal with the issue of baby-making and cloning.

DR. SHAPIRO: I have got two people on my list, Carol,

Eric and Alex.

PROF. CAPRON: I had a question about whether any of the people in responding differentiated the cloning work at a cellular level between that which was Dolly-like and that was what -- I mean, in other words, were any of them talking about the fact that all the attention publicly has been on this field, because of Dolly?

But that the work that they were concerned about really used technologies that were not dependent upon the findings from the Roslyn Institute. And then I have a question ---

DR. GREIDER: I think most of the questions -- I mean, they did specifically ask about nuclear transfer cloning, which I think is your Dolly-like.

PROF. CAPRON: Right.

DR. GREIDER: And we were hoping to get responses in that area, since that was I felt like we had agreed we were dealing with here on the Commission.

There probably were a couple of responses in other areas, and other people might help me remember this. but I think that most of them that I read really came down on the nuclear transfer cloning issue.

MR. HOLTZMAN: But I think the broad concern that was expressed about don't throw the baby out with the bath water or the bath water out with the baby was specifically the ambiguity of what is cloning.

And therefore, they did address, in a generic sense, we want to make the distinction between baby-making versus research, whether it is with embryonic nuclear material, whether it is with somatic nuclear material, or other kinds of embryo research.

PROF. CAPRON: The observation, to follow up on what David was saying, I am not comfortable -- we may end up needing -- we do need a science chapter, and some of the material that we have gathered from this process of questioning may end up there.

But in terms of policy and views on cloning, I am not really very comfortable separating out people who come to us as theologians or scientists or whatever. It would seem to me that our policy is not going to be determined by these results in any way. I mean, we are not asking the scientists to set policy here.

Mostly, our reason for doing this, as far as I could tell, was the same reason of asking people to come and testify from different religious views and so forth. Are there ideas out there that would not immediately occur to someone that we want to become aware of?

So we are not going to end up saying that the reason for any policy we adopt is by a vote of 4 to 14. The respondents to this questionnaire said one thing or another.

I also was struck, and the reason I asked Elisa about the statements that she put up there, was I think it would be of value, if we are using any statements of any of the people who have come

before us as witnesses or otherwise gathered, to note where there is a comment from a scientist who has been asked to address this, qua scientist, that reflects on concerns which are more than scientific.

To the extent that we can knit the communities together here, I think that would be very valuable, and I hope that we, with the help of Elisa and others, extract from the materials such opportunities to cross lines of science and non-science.

MR. HOLTZMAN: You know, to the specific quotes which were put up there which came from BIO's letter, but I think that were indicative of others from other letters, what we found -- others should jump in -- is that the line that was emerging between embryo research versus baby-making.

People were trying to articulate the concern they had about baby-making, and that they found themselves talking in that kind of language, and in that sense, what was being engaged were their sensibilities not as scientists, but as citizens.

DR. SHAPIRO: Thank you. Any other questions for Carol, Elisa, regarding -- Bernie?

DR. LO: I have a couple questions that pertain to discussions that come up in the ethics bucket. Let me state them as kind of hypotheses.

One is that scientifically it would be inappropriate to attempt to clone a human being, baby production, at this time, because we just don't know what the risks are, and the information we

have from the Dolly experiments suggest the risks may be quite high.

And I just want to sort of be sure we understand -- my understanding is that that is virtually a unanimous opinion in the scientific community. Is that a correct sort of ---

DR. GREIDER: I would say an overwhelming opinion. I wouldn't say unanimous.

DR. LO: Overwhelming. Okay.

DR. : Unanimous is a bad choice of words.

DR. LO: Okay. Okay. Overwhelming. Good. And then a second issue has to do with cloning in the sense of using adults somatic cells for nuclear transfer -- well, doing really pre-implantation embryo research with no intent to transfer.

Is there agreement among the scientific community that that work could proceed without use of human cells. Using animal cells, and sort of reap, for the foreseeable future, the sort of the basic science insights into cell biology and development?

Is there any compelling reason now, if one's ultimate goal were either basic science or sort of cellular level therapeutics and not baby-making, to do research with human cloning in a sense of non-implantation embryo research? That is a very long way of trying ---

DR. GREIDER: Some of the societies did come up with that sort of thing on their own, to say that -- so we just said, should we do this kind of research or not? What is your view?

And rather than addressing that directly, they said, well, first, it had to proceed in animals, and then we have to learn all that we can learn, and then maybe consider doing it in humans. Not all of the societies, of course, said it in that way, because, you know, we didn't structure the questions in any way to get that information.

DR. LO: Let me try and ask the question slightly differently? Based, not on this survey, but on your sort of knowledge of your scientific colleagues, is there anyone who has a compelling reason to say, to answer this vital scientific question, we have to now turn to human ---

DR. GREIDER: That was striking in that the answer was no. I mean, that was -- nobody came forward and said that we really need to do this now. That was my reading of this. I mean, I think that is a pretty -- interesting.

DR. LO: But also -- not so much that no one has come forward, but your opinion as scientists is that there are no compelling such reasons that ---

DR. COX: But, in the same sense -- what Carol said is no one came forward, but everyone came forward loud and clear, saying, but don't put restrictions on it, because we haven't thought about this very much.

Now, I think that -- I quite agree with what Alex said.

We don't take what people are saying here as our sort of mandate of what our policy should be. But I think that there are a number of people who really, as scientists, don't see a difference between using, you know, human cells versus animal cells.

So it would be not fair, even though we around the table may agree with what you said, Bernie, I don't think it adequately reflects the entire scientific community to say that everyone believes that, you know, you should not just do everything with human cells to start with. Some people really believe that.

In terms of whether there is a scientific justification for it or not, okay, I think that their argument under scientific justification is that different species are different, and if you don't work with humans, you won't know what works with humans. That has been articulated by a variety of people.

Whether that is adequate justification for doing human stuff beyond animal stuff is not a scientific reason. That is more a philosophical and an ethical one.

MR. HOLTZMAN: Bernie, I had a somewhat different read on it maybe than Carol, because of the way we structured the question, and I will take your question to mean:

Within the sphere of embryo research, lacking the goal of baby-making, all right, is there something special about that species of research which involves somatic nuclear transfer, all right, wherein we should say, with respect to that class of research, that

it ought not proceed with human somatic nuclei at this time but should only go forward with animal cells?

And I didn't hear anyone say that. What I heard -- it is just another form of embryo research, okay, and that you would really have to look case-by-case at the particular experiment, all right, and ask the question whether this is justifiable at this time to move forward with human material -- and not drawing a distinction between different sources of the material, of embryonic nuclei versus adult nuclei.

DR. SHAPIRO: Tom has had his hand up. If you will just excuse me for a moment, I want to ask a question, or make a statement, see what is wrong with it. That issue, the precise question that Bernie asked, I guess all of us have asked a lot of people that question. This is sort of what scientists I happen to meet I ask this question, people I meet and respect, and I find it really to be a contested issue.

DR. GREIDER: Can you tell what question it is? I am not sure what question we are talking about.

DR. SHAPIRO: The question is whether at this time there are important scientific reasons to proceed using human material rather than just animal, material from animals, in embryo-type research.

DR. GREIDER: For research. Non-baby-making?

DR. SHAPIRO: Yeah. Non-baby -- that is right

-- nobody -- and I just find it a contested issue. I can't decide it right now myself. But, I mean, is that unfair, David?

DR. COX: No, it is fair. Whether it is contest on scientific grounds or political, social, or philosophical grounds, okay, I think, is not clear to me. Some people may justify on scientific grounds. I am not sure that that is really the basis on which it is being contested, but I quite agree with you that it is contested.

I also really think what Steve said is true. That almost all of these groups aren't making any distinction about whether you are doing nuclear transplantation or whether you are doing other sort of embryo cell work. It is like one and the same. There is nothing special about the fact it is nuclear transplantation. That is what I hear you saying, Steve, and I quite agree with that.

MR. HOLTZMAN: Well, I guess I would want to ask Bernie: Was your question about embryo research *per se* or the specific species of embryo research, which the Dolly experiment makes one think of?

DR. LO: No, I am sort of putting aside the baby-making part of it. I was concerned about the transplantation, human embryo research that involved nuclear transfer as opposed to, you know, *in vitro* --

(inaudible) -- or something like that.

And I guess I would find it very helpful to have the

scientists who believe that there are important scientific questions that would need to be done with human cells now to try and articulate what the research questions are and why, so we could get a feeling for how compelling their cases are.

Then I guess my other concern was I thought I hear somebody say that many scientists don't distinguish between doing embryo research using human cells as opposed to non-human cells.

And if that is, in fact, an accurate statement, then I think we have an educational job to do with scientists to make them understand that there are many people who believe there are significant moral/ethical differences even if they don't think there are, you know, sort of scientific differences in some sense.

It seems to me we have talked a lot -- I mean, Eric, in particular, has reminded us about the importance of education in this Commission. It seems to me this may be an area where the scientists ---

DR. SHAPIRO: Tom, does your question deal with exactly what we are discussing?

DR. MURRAY: No, it doesn't.

DR. SHAPIRO: All right. So I know Elisa wanted to say something and then David.

DR. EISEMAN: I don't know if this helps answer your question, but a few of the respondents did point to the recommendations of the Human Embryo Research Panel and indicated that

their recommendations were appropriate for this type of research.

So that does address the issue of: Is this type of research acceptable and is there good reason for it to be performed and using human embryos?

DR. SHAPIRO: David.

DR. COX: Yeah. Bernie, I think that this is coming back to something that we have said before, and it is something that I have observed happens in the scientific community a lot, and that scientists will say, just on the basis of the science. Right? Not considering the ethical issues.

What does that mean? We don't live just on the basis of the science, and so we start ourselves breaking it apart that way in terms of what are the scientific reasons as opposed to other reasons. We have to keep them together.

Many of the people who are scientists that aren't making a distinction between human tissue versus others, okay, are doing it on -- just saying, well, just looking at it from the science, you know, I am not in a position to deal with the ethics, okay. And I think that that is not a useful way of couching of or even, you know, separating the stuff out.

DR. SHAPIRO: Something you said, David, caused a lot of people to want to say something. I am going to turn to Tom first. He has been waiting longest.

DR. MURRAY: I think much of the conversation of the past

few minutes, at least in the way I would frame it, is: What out of this sort of -- it is not a survey -- but this sort of rough sampling of scientific opinion by professional organizations ought to appropriately be incorporated into and/or influence our conclusions in the report?

Alex made a very pertinent comment earlier on, part of which I take to be that the moral views of scientific associations should not be privileged. I mean, they are counted like any other organizations or individual's views, but no more.

And, David, I reinforce that particularly poetically sensible manner. And I agree with that. I want to second that. So let's ask what positively ought to come out of this sampling of scientific views?

And the question I haven't heard thoroughly addressed, and I think Elisa mentioned it, but not completely is, and I am not putting you on the spot. It might be one of the other members of the science bucket. Were there any surprises in the views of the scientific associations in terms of lines of research that they thought might fruitfully be conducted by means of the nuclear transfer technology? And, if so, and if they would be interesting, I just want to affirm that I think they ought to be mentioned in our actual report.

DR. GREIDER: That is exactly what I was trying to get out of this sort of non-scientific survey, just to see if there is

anything out there that we are missing. That was the whole point of doing this.

And from my reading of this, the answer was no. I didn't find anything that surprised me, that was new, that we hadn't dealt with to some degree here. Maybe other people in the science bucket would like to comment on that. That was my reading of it.

DR. COX: I agree.

MR. HOLTZMAN: I agree. That is also because what we got from Janet and from Stuart was so complete and so generic. When one says generation of stem cell populations, generation of stem cell growth factors, generation of basic knowledge of development, there is not a lot left.

DR. GREIDER: But what I wanted to be sure was we had two people come in and two individual scientists gave us very good reports, but I didn't know how completely that was going to represent all of the ideas that are out there.

And since I am not an expert in this area, I wanted to be sure that we weren't missing something, and that was the point of it. And so I didn't feel there was anything totally new that came forward.

DR. SHAPIRO: Jim. Excuse me, Jim.

DR. CHILDRESS: In some ways, I would like to build on very strong comments that Alex and David and others have offered.

If someone says, speaking as a scientist, or speaking

scientifically, or something like that, I think it is important for us not to put that in a kind of separate category, but to recognize that even though the person may be thinking and operating in that particular capacity, I mean, that person offers judgments about, a particular society offers judgments about, say, the benefits, the risks, the appropriate kinds of constraints, those are not purely scientific matters.

And they involve important value questions that we want scientists, theologians, philosophers, lay citizens, and others to address, and it is important to have the kind of perspective that has been offered. I have found the discussion this morning very valuable.

But as Alex suggested, we take it on its own terms as a contribution to the discussion.

DR. SHAPIRO: Thank you. Alex, yes. Then Steve.

PROF. CAPRON: I am going to sound rather schizophrenic now, but I think there is a flip side to this. If we are concerned about restraining certain areas of activities, one restraint is the judgment of the relevant community that such an activity would be unacceptable at the moment.

And I would like either the science bucket or Elisa or somebody to give some thought -- I have roughly looked at this -- I tried to look at those respondents who represent clinical bodies, American -- Society for Assisted Reproductive Technology and the

other clinical groups, the genetic groups, and so forth with the question in mind:

Does the study -- does this tell us whether their judgment is, in fact, based on Bernie's assumption, which we all assume it is, that it would be irresponsible, given the physical, in which I include damage to developmental -- development of any child, mental development, as well as physical malformation -- to proceed with baby-making?

Because if we end up saying that this is an area in which we are dependent upon the operation of private law to provide some of the restraint, and you put doctor so-and-so on the stand to testify that the defendant went ahead and did this, behaved in a way which departed from the accepted standards of medical practice, it will not, at that point, do for doctor so-and-so, the witness, to say, I believe that a child created in this way is disrespected or something like this. Or even I, my society, has decided that on moral grounds, it would be inadvisable.

So that, as I say, I am somewhat schizophrenic. I want the scientists' views, as Jim just put it, on the moral issues to be treated like others, and we want to encourage, as Bernie said, scientists to think in these terms in their own work.

But in judging whether it would amount to malpractice and violate the standards of due care that a physician should be using, my guess is that an objection from the defense will be heard if the

witness is invited to talk about these non-medical harms as it were.

So it would be very useful to know whether the societies are -- when they are listed on the draft -- the table at the back of this report -- prohibit, prohibit, prohibit under questions 5 and 6, whether that is solidly based on the notion that this would be dangerous. It would be an irresponsible way in terms of the risks to the human beings involved rather than the social/ethical/moral question.

And I don't know whether the question will tell -- any questionnaires -- or the answers and the way they explain them -- fill that out.

DR. GREIDER: I mean, some of the societies that said prohibit specifically said because it is not even clear that physically you can do this with humans and get -- you know, based on purely scientific grounds.

So this is to answer the question that it is. Mainly of them did address it on purely scientific grounds that they would fear that there would be something grossly abnormal with some sort of a developmental pathway.

PROF. CAPRON: Obviously, this is not -- we haven't nailed them down on this -- but to the extent that you have that material, I think that is important material for us when we start talking about the policy options, to be able to say that this opinion -- if we have any good quotes ---

If we have anything in there that would indicate that we have reason to believe that there would be professional self-restraint and that anyone going ahead would expect the strong view of his or her colleagues to be that this was conduct that departs from the standard that applies to reasonable physicians behaving according to the standard of the community.

DR. COX: The AMA response was very clear on this.

DR. SHAPIRO: Steve.

MR. HOLTZMAN: Specifically, Alex, I think it is very clear that the first line rationale for a moratorium, a ban, a prohibition on baby-making at this time is it would not be safe. So then the residual question is: Suppose, like that, the technology was perfectly safe.

PROF. CAPRON: Yes.

MR. HOLTZMAN: Okay. Is there still a discomfort in this community?

PROF. CAPRON: Yes.

MR. HOLTZMAN: All right. Then you have to go to the individual responses. A number of them, such as the quotes that were put up there, there are remaining discomforts. They are not scientific or safety based.

PROF. CAPRON: And those are important in the evaluating what is likely to happen and the reasons it should or shouldn't happen, but they don't have the same constraining effect --

(inaudible) -- on the private law side of the view of colleagues that this is simply irresponsible.

What you have provided is exactly the sort of thing we need to be able to recite at that point in the report.

MR. HOLTZMAN: And I think, clearly, in the ethics section of our report, I think we do have to address that. Whatever we think about the ethics of experimentation towards baby-making, given the current state-of-the-art, that is one issue.

PROF. CAPRON: Yes.

MR. HOLTZMAN: But envisage a different state-of-the-art, where it is perfectly safe, there is still a bunch of ethical issues that need to be engaged.

PROF. CAPRON: I totally agree.

MR. HOLTZMAN: And if I could make one quick other comment. It is still coming back to Bernie's earlier question and David's comments about some scientists don't distinguish between human material versus animal material.

I don't think one, for a moment, should take the comments about no restrictions on basic science as having implied that. Certainly, there are scientists, people, if you will, who don't make distinctions between human cells versus animal cells, and within human cells, reproductive cells versus other kinds of cells.

But many do, most do, arguable, and would make distinctions about what is okay in the way of research and when you

should progress to a certain stage. I think all we were addressing was: Was there something special about a particular kind of research or class of research, and the answer was no.

Okay? And that, therefore, whatever you believe are the appropriate restraints, in terms of orderly scientific progress moving from animal cells to different kinds of human cells, would be in play for that kind of research.

DR. SHAPIRO: Thank you. Bernie.

DR. LO: I want to think for a minute about the implications of what scientists would believe would be sort of appropriate to proceed with in terms of research and how that might affect our thinking about a voluntary moratorium in the private sector.

To sort of pick up on some of the conversation here. If, in the policy section, one of our options is going to be a voluntary moratorium, which would need to be enforced by individual scientists and research centers going along with it, it seems to me then that the views of the scientific community would be very important to know in terms of how likely is it the moratorium would hold in the sense that the country as a whole, to the extent that you can say what the country as a whole thing, believes that the moratorium should be appropriate.

Or a scientist or a lab may disagree and use their own judgment to say it is appropriate to sort of proceed, because the

moratorium now is no longer appropriate.

So I just think that when we come to the policy options that somehow we need to factor that in. I don't know if any of the data we have gives us a sense of how likely it is that certain scientists will not observe a moratorium that is generally held in the wider community, as well as in the scientific community, and what the implications would be.

DR. SHAPIRO: I think it -- Larry wants to make a comment here -- I think however we use these comments and information we are gathering, we know, for certain, that we don't have the view. Okay? We don't have the time to go and get the view and really answer in the definitive way a number of the questions that have been raised.

We have kind of indicators, responses, which we can refine on and consider. But there will be a certain conditionality on what we say, I believe in this response, because of just the limits of the 90-day effort. But, Larry.

DR. MIIKE: Yeah. Just a comment. This discussion has been totally dominated by this "survey," and I don't put much credence to this survey in the sense that it was just trying to get a flavor of what was out there.

There are no surprises to me in this survey, and I just want to remind people that I would rather base our decisions in this area about what we know about the science rather than what scientists' opinions are about we are supposed to be reaching.

DR. SHAPIRO: Any other questions on this issue? Okay. Thank you very much. Carol, thank you for getting this done. It has been very helpful. Elisa, thank you very much. We enjoyed your presentation very much.

Depending on how the Commission feels, we were -- we are running a little bit behind time. We got started late. We had a scheduled coffee break at 9:00, but we could either postpone that or -- I think we probably ought to -- and just go on with the next agenda item. We will try to pick up a coffee break -- later on.

Bernie -- in a discussion of some of the ethics issues.

#### ETHICS ISSUES

DR. LO: Okay. The ethics bucket had a very interesting meeting both in San Francisco and in Boston and New York via telephone technology about a week ago, and it was again a very interesting and wide-ranging discussion. I think it is fair to say that there are disagreements among members of the Commission on a lot of the ethical issues that have been raised.

What I tried to do was to push towards a draft preliminary version of what we might be saying in the ethics chapter, so to speak, and I circulated that on e-mail in keeping with the spirit of Harold's remarks to try and move the process along.

I would really appreciate your comments as specific as possible. Some of you have already done so by e-mail, and I would

just encourage all of you to take that text and, you know, just intersperse your comments, suggestions, you know, where we are missing things, where we are wrong, where we off-track, and so forth.

It could certainly help us.

Let me talk a little bit about sort of the big picture strategy and then some questions I think we need to discuss further.

One is that I think -- I don't -- except for making a point that at this time, there is unknown and presumably very large physical risks both to the women who would undergo hormonal manipulation and to any child that might be born as a result of human cloning, that it would be inappropriate to think of proceeding with cloning in the sense of baby-making.

As Steve pointed out, that is sort of the easier sort of version of the dilemma. It is harder if somehow safety were not an issue, and the evidence was such that the technology would be effective and safe in human species. What would be the moral objections there?

And I think there is a divergence of opinion on this Commission, I think, and as there probably is in the country as a whole.

So what I tried to do -- and I just want to sort of ask your thoughts on whether this is the strategy we should taking the ethics committee, ethics bucket report, chapter -- is to just try and

lay out arguments for those residual moral concerns that don't have to do simply with

-- both pro and con -- and sort of the strongest, clearest way possible and not try and sort of force the discussion toward an agreement, where I don't think we are going to reach agreement.

But really to sort of have our contribution be the sort of lay out the arguments as clearly as possible. Obviously, there are situations where arguments have been advanced that when you look at them more closely, there are a lot of rebuttals, there is a lot of misunderstand-

ing. I think we can clarify, correct, and educate. So that is sort of my conception of sort of how the pro and con section works out.

Again, in terms of structure, I did want to focus primarily on what we have been calling the baby-making, because I think that is the hot issue, the controversial issue.

I think it would be important to say a little bit, but not very much, about ethical issues involved with cloning in the other sense of cloning DNA, cloning cell lines, that have nothing to do with reproduction, cloning in animals. But not to focus a lot of our attention at this point on those issues, because I don't think those are the key issues.

I think we have a decision we need to reach on whether we want to reopen in our report the human embryo research debate. That, clearly, if you are going to do research not for baby-making, but

using human cloning in the research sense -- (inaudible) -- that you are creating human embryos for research in the NIH report language.

That report is done, and it was not enacted in policy on both the executive level and legislative level. I don't know whether we want to try and readdress those questions. I think the arguments are there in the report, the arguments.

Why it wasn't reported, I think, are clear, and I am not sure we need to reopen that discussion in this context of this current report. But, again, I think that is an issue we need to sort of think through as a Commission.

Then, finally, there are some issues that have been through the discussion, and which I am not sure we have any set answers to, but I would like to push toward answers and start to identify people for writing assignments.

One is a theme that has been sort of weaving through our discussions on this is just the question of presumptions and starting points. And should the burden of persuasion on those who would start to clone, or should the presumption of persuasion be on those who would oppose it?

And do we have enough evidence at this point to say that the burden should start with those who -- being placed on those who would be proponents of cloning and what is the reasoning behind that?

Second is the role of cases in our chapter. We found it very interesting toward the end of our meeting last week to think of

cases which are put forth as the allegedly most compelling reasons for cloning in a baby-making sense, and a couple of them we managed to sort of look at and say, well gee, the arguments really don't look so compelling.

There were one or two where we said, gee, even if we were deeply, strongly morally opposed to cloning in any shape or form in the baby-making sense, this would be a bothersome case.

A number of people sort of brought up the difference between individual actions and social policies and sort of, in a sense, the dangers of building public policy on exceptional cases. I think we need to think that through a little more.

On many sort of bioethical issues, we have a general policy and sort of an understanding that there will be exceptions, as there are to any sort of ethical guideline or precept, but they will be rare, and we will tolerate those exceptions, but not sanction a general policy allowing such cases.

You know, the analogy has been raised to assisted suicide debate, where some one position is that we should not legally sanction it, but in exceptional cases, it may be ethical for a physician and patient to agree that it may be, for very exceptional reasons, as an exception to that policy.

But I just want to raise the question here as to whether we can really have it both ways, so to speak, have both the general rule and the exception in that if cloning in the sense of baby-making

were not permitted as a general policy, but we said there may be these very exceptional cases where we really couldn't say it was wrong in that individual case -- we couldn't fault that parent or parents, but that we certainly wouldn't allow a policy to be erected on those individual cases -- I am not sure that would work, because of the third party involved, the child who is born as a result of cloning.

If cloning ever happens, I think you will see all the bizarre cases we have seen in other assisted reproductive technologies, where the original family structure into which that child is going to be reared falls apart, and you have issues of who is the parent or record, who has visiting rights, so forth and so on.

It seems to me that we get dragged in, in some sense. I want to sort of direct your attention to that issue and sort of -- I think that these -- this is, again, another issue, I think. We have talked about it. We know it is something we have to deal with. We haven't really kind of try to come to closure on it.

So with that, I would like to sort of just stop, throw it open for discussion, not sort of go through some slides I have, which basically go through the material I sent it, which is very preliminary, but ask you to comment.

But try and get some discussion on what I take to be the big picture issues, as I have outlined, and any other issues that you think are important that we have missed. I guess the only -- in the

spirit of informed consent, you are also being auditioned as writers of different parts of the report. So what you say will be used ---

MS. : Against you.

DR. LO: Not against you, but for the benefit of the country.

DR. SHAPIRO: Well, whatever it was you said, it stimulated a lot of desire to respond to particular aspects of it. Let me say a few words, and then since I am suffering from laryngitis, I will just listen carefully to what everyone else has to say.

I am going to say a few things about some of the issues Bernie raised in the spirit of just trying to get our discussion as lively as possible, not that I have a final view on this. But I have some views on some of the issues that you raised, at least tentative views.

First of all, I, in general, feel that exceptional cases make bad law. Now I can say that. I am not a lawyer. I don't know what Alex would say. But as I think about it, I am inclined towards that. It is very hard to make public policy on exceptional cases.

Society has a way to adapt and adjust to rules if they are persuasive enough and so on. That is just my general view of that, and I don't know how others will feel.

Now, regarding the presumptions and perspectives we ought to take, I think we ought to take advantage of the fact that this

report is not settling this issue both for now and for later. It is too early to settle thing for now and for later.

For now, there are some really quite straightforward things which we seem to be honing in on, and they are reflecting in much that everyone has said. And I think we ought to be very clear as to what that situation looks like now.

As for later, when, as Steve said, you know, when it is all safe and straightforward, what would we think then when we really have to face the harder decision, that is a very, and will be a very, hard decision, set of decisions, it is not absolutely necessary that we solve that problem right now.

But it is necessary, in my view, that we give a framework for thinking about it and some ideas, such as they may be that we have that might help others thinks about it.

So that when that time comes, should it ever come, and should we have to face that issue, then, of course, hopefully, we can look back and say, you know, what we said, what we started, what we laid out, was really helpful to people.

That is a significant responsibility in its own right, quite aside from what we might think later when all these other conditions start changing. Because later, not only might those conditions change, but a whole host of other unknown conditions may be in front of us.

So, to me, that helps simplify, in a way, and it helps me

see a path through some of these very difficult arguments, at least as it respects -- with respect to our report.

Now the last item that I will take on now, and I am very glad you raised it directly, and of course, I am not part of the discussions of the so-called ethics bucket that took place by these inter-continental or trans-continental -- excuse me -- telephone calls and so on, and that is, the issue of embryo research.

I think you asked a direct question. I am going to try to give a direct answer to that. It is my judgment that this is not the time to revisit that.

I think that the report, as the draft science chapter always does, raises the issues of what could develop down this, why that might be important some day, why we might want to continue to rethink this issue over time, (?) by implication, but I think it is the wrong time to re-engage that issue.

Because I see, one, no pressing reason to do so, and I see public policy by the President and Congress, having been thought about after a very careful and thoughtful report, and decided whether I agree or not is a secondary matter to me right now.

So my view is that it is, you know, not the time to do that, but you know, you never want to be in a position to say you can't change your mind. So I could have my mind changed by other perspectives.

Now, I have a long list of people. Start with Zeke.

DR. EMANUEL: I just wanted to add a couple of comments to what Bernie's nice summary of our meeting. I would want to re-emphasize the fact that I think we have probably three distinct views in the ethics bucket that probably, I would venture to guess, mirror the Commission, which is, one, of those people who think they haven't heard a persuasive argument against it, but they are, as it were, willing to wait, maybe even pro-cloning as baby-making.

The view, I think, may be more cautious than you outlined, Dr. Shapiro, which is we have some arguments now, based on science and risks, etc, and we have to leave open and more discussion, and then some people who are against it, or fail to see good reasons for and see reasons against.

So I think that is important in and of itself to say, and in that sense, we probably do mirror something in the country pretty accurately.

The other thing I thought that came out of our meeting that I think is valuable to say is something about the non-neutrality of any position we adopt. And I think this is important. If we permit it, it is not like we are being neutral with regard to people's views, and if we prohibit it, it is not -- there isn't a neutral position here.

And I think the idea somehow we can have a neutral position and leave it to private views is not right -- or not tenable

-- especially if we are going to think about this in terms of the social practices and not each isolated case, and the more extreme the case, the more persuasive it being.

Finally, the other thing, I think, that became clear as a result of our discussions, and this relates to the issue of how cloning fits into the whole notion of right to reproductive freedom, is the sense we had of all of the moral judgments being interconnected.

And by that, I mean the following: Whether you think cloning falls under the right to reproductive freedom depends upon whether you think cloning is distinct from other forms of reproduction. But that notion of whether it is qualitatively, essentially distinct already presupposes other moral considerations.

So they sort of travel in a package. Whether you think the right to reproductive freedom is dispositive, whether you think, therefore, cloning is like or not like other technologies, and whether you are for or against cloning.

And I think it is important to lay that out, because there is no independent judgments, as it were, here. They are all part of one view, one way or another. And I think that is relevant to how we consider it.

So if we were to ask, for example, John Robertson or Leon Kass, give us your criteria by which you distinguish as essentially different or essentially the same and, therefore, covered by rights

or not covered by a certain moral right, it is impossible, I think.

And I think that was the conclusion -- I don't want to speak for the whole bucket -- I think that was more or less our conclusion. There is no independent criteria here.

DR. SHAPIRO: I just want to make sure I understood the very last thing you said. What is it that is impossible in your judgment?

DR. EMANUEL: If you -- to ask them for some independent criteria for us to distinguish one way or another and, therefore, to determine whether this is covered by a right or not covered by a right.

Because if it is covered by a right, our arguments would look different, it seems to me, or at least we would weigh them differently.

DR. SHAPIRO: Thank you. Let me just add another comment here. That, of course, that if there are importantly different views on the Commission about some important aspects of the report, those should be reflected.

That is, there is no reason to hide it, no reason just to get ourselves a situation where you have to agree on everything, because these are very difficult issues. So that is an open possibility as far as I am concerned. Jim.

DR. CHILDRESS: I think it was a very fruitful discussion. I participated by telephone, but I -- so I wasn't -- I

would have liked to have seen the faces as arguments were made. That is one of the difficulties of being at a distance. But it was, I thought, a very fruitful discussion, and Bernie and Zeke have summarized it well.

Just a few observations. One is I agree that there remains considerable disagreement on ethical issues, and yet there is, I think, sufficient agreement for continuing a moratorium. And I think it is important to keep in mind that we will probably make a recommendation, and there may be a variety of arguments for making that recommendation.

It is important -- I think Eric has emphasized all along that we contribute to, and recognize the importance of, education of the public and even professionals regarding scientific matters. But I would also emphasize the way in which this report can make perhaps some modest contribution to moral discourse in this society.

And, thus, I think it is important to lay out the arguments as well as we can and attending the counter-arguments at the same time. It seems to me that process of analysis and assessment is something that we should take very seriously.

Now, regarding -- two other observations, regarding the draft that Bernie has circulated, I think a lot does depend on how we raise the questions we are trying to address. Let me just note two different ways of thinking about the arguments for and against.

For and against what? The draft document looks at

ethical arguments in favor of cloning human beings and ethical arguments against cloning of human beings. But it might look a little different if we instead asked about the ethical arguments in favor of allowing the cloning of human beings or ethical arguments against allowing the cloning of human beings.

That they are sort of different questions, and the second set of questions really will force us to look more at the policy issues. Should we allow or not allow, which is a little different again from looking at what the arguments in favor of cloning, actual cloning.

DR. : Good point.

DR. CHILDRESS: That pushes me to the act/social practice distinction, which has been discussed. I wasn't -- when I was trying to focus on it, I wasn't thinking so much about the parallel with physician-assisted suicide and whether there may be some exceptional cases that would draw us, out of compassion, to say that we ought to have some exceptional mechanism for those in a policy that perhaps should remain prohibitive, because of other kinds of social considerations.

It is really rather more how we think about the arguments here and whether we are concerned with particular acts of cloning that we think would necessarily or intrinsically violate or infringe some fundamental values versus the infringement of those values by a social practice.

I think of a couple of examples from our discussion. When we say, for instance, that an argument against cloning would be that cloning would undermine human dignity.

Now, undermine human dignity suggests to me that we are talking about a value in the society that would be seriously subverted. But I don't think it would be subverted by 5, 10, perhaps even 100 acts of human cloning. But it might well be subverted by a social practice of cloning with all that is associated with that.

So that is really what I had in mind is how we think about the arguments and not so much again the parallel with physician-assisted suicide.

Similarly, when we say that human cloning would alter our view of what it means to be a human being in ways that would undermine important moral values. Again, it seems to me that that is plausible if we are thinking about a social practice. I am not convinced it is plausible if we are thinking about a few isolated acts of human cloning.

DR. CASSELL: Well, I thought it was an excellent discussion, too. Also, participating by telephone leaves something to be desired, especially for one's ear.

But like most clinicians, I hate to make a decision you don't have to make, and I think that in terms of the business of moratorium, we have a very solid basis on which to make a decision, and that is, the risk at this time. We don't have to go to another

single criterion.

On the other hand, the dispute in our section, or bucket, about -- centers on what Charles Taylor has called hyper-goods.

There are different representations of what people consider the good.

For some people, what comes out again and again is the sort of thing called the natural in human behavior, and we hear it all the time. It is in our society, and it was in our meeting. And for others, myself one of the, the hyper-good is of human nature and plasticity.

Those are very different views of the human condition. I think that they are not resolvable. Certainly, not by this Commission they are not resolvable. But they may deserve some mention.

That, in fact, the view that people take about this is really secondary to their larger view of what it means and how people adapt and so forth, if you wish, what it means to be a human and words like dignity, which are just unsolvable words like beauty and justice and health and stuff like that.

But I think on the hard issue, we don't have to go one step beyond saying, this is not permissible because of risk and also that what Jim just brought up, which I think is just excellent, about the difference between a social policy and an act and the difference between permitting also is very important.

And they don't take up a lot of space, but they make a low of room for thought in the people who read this report.

DR. SHAPIRO: I like the image. It doesn't take up space, but it allows space. I like that image. That is terrific. Carol.

DR. GREIDER: I just had one minor comment at the beginning of what you said, Bernie. This is something that I want to take out rather than put in. So I am not asking to be asked to write anything.

(Laughter.)

DR. : Turn off your microphone.

DR. GREIDER: You just mentioned the issue that there should be something in the ethics section on the issue of cloning DNA and cell lines and that sort of thing.

As I understand the report, we are going to have something like that in the introduction and then say that we are going to focus human cloning issues regarding nuclear transplantation.

So I don't know that every single section needs to go into the details of DNA cloning and cell cloning, etc. So you might not even need to address that.

DR. SHAPIRO: I took -- just to intervene -- I took Bernie's comment to mean -- I just want to clarify it with asking questions -- that you felt that it was important that we might draw attention to the fact that cells are not just cells.

They are human cells or other cells, and that has got

some kind of important -- there is an important difference here, which we ought to focus on. I thought you were saying that.

DR. LO: Yeah. I guess it seems to me that some of those issues -- there are ethical concerns -- but it seems to me they have been worked out and resolved on a level of public policy, and I thought maybe we should just say ---

DR. CASSELL: That is it.

DR. LO: Just that.

DR. SHAPIRO: Larry.

DR. MIIKE: I take a different tack on this. If you look at the issue about embryo implantation, embryo research, I don't think even those who oppose on it on moral grounds would dispute the fact that there are public goods in here, public benefits.

It is just a means to an end kind of an argument that says, yeah, I agree that there are all these wonderful things in cancer research, but I believe that that one or two or four cells is a person, and I object on that basis.

When you get into the cloning of a human being, I don't really see a public good here. I see individual benefits. I see, you know, whether they are malevolent benefits or ones that we might be sympathetic to, malevolent benefits being having another Saddam Hussein, a beneficial benefit being trying to at least replicate a child that is dear to parents and who will die.

But my dilemma is that we are in a society that values

individual rights and benefits, and I don't think we would be having this discussion -- it would be cut and dried -- if we were in some other society. So, obviously, we are working within the context of American individualism.

So I don't have much problems with a moratorium, and maybe I would think twice about a ban forever in terms of cloning of human beings. But that doesn't cause me much problem. So that is the easy part of where we are.

And I agree now, even though I have taken a different position before, is that this is not the forum to reopen any kind of issue on the embryo side. I think the arguments have been made.

Public policy for the time being has been set, and it may be reopened again some other time. But it just seems to me that in this current situation, we can only describe what has happened and what the current situation is.

But, again, I say my main point on my rambling here is that I don't find it useful to talk about pros and cons about cloning of human beings, and I would rather make the distinction about where is the benefit in terms of societal benefits in the cloning of human beings?

And I only see individual benefits, maybe heart-wrenching benefits, but I don't really see the kind of public goods that we would have in terms of the fruits of research on the front end of these kinds of activities.

DR. SHAPIRO: Thank you. Alex.

PROF. CAPRON: To the extent that you are asking us to express our views on each of these points, I would agree with what you and Larry have said about the embryo research and what we should do about that.

I do think it is useful to follow the model that Jim so nicely described as contributing to moral discourse in talking about the reasons for and against cloning in the report.

We then face the problem: Are we talking about the report that will be available by Memorial Day, or are we talking about some further opportunity to refine what becomes the report?

Because doing that well is quite difficult, I think, and it would be not a contribution to moral discourse to put out a poorly phrased, poorly described set of considerations even if our ambition is simply to give people, thoughtful people who want to make their own judgments, something to chew on, which is what the idea would be.

That you would illuminate the issues for parents, of physicians, for scientists, and you would also indicate to the public that what we have spent a lot of our time on doing, which is thinking about those issues.

I am not sure that I fully understood Zeke's point about the question: Is cloning like other forms of reproduction? It seemed to me that several of the comments after that assumed that it

was.

If we begin from a premise of saying that what we are really going to talk about is the arguments for and against allowing this practice, then what we are saying is these arguments that might influence individuals, but which ones are strong enough to come into the policy arena?

And in that policy arena, we begin with an assumption of liberty to make decisions about one's own family formation. But to say that cloning fits within that, and I wasn't saying -- I wasn't clear, Zeke, whether you were saying we should address this or other people have addressed it or they didn't address it, we need to know their answers, or what.

If someone were talking about a technology that is some way is dramatically different, I mean, making babies literally in test tubes out of the raw chemicals themselves, one might say, wait a second, that doesn't come within the reproductive liberty that we have had before.

So that when you say that it is the argument about whether or not to allow, I agree that that is the way to frame it. I agree with Jim that that is the way to frame it. But it only makes sense to me to say that if you are making some assumption that this form of creating a child comes within that initial allowance.

DR. EMANUEL: Maybe ---

DR. SHAPIRO: Go ahead -- (inaudible).

DR. EMANUEL: Maybe if I am not being clear, other people who were at the meeting could help elaborate. But I think the conclusion we had come to at the meeting is that, you know, you have said it falls within the rubric of other reproductive technologies.

It goes from sperm donation to IVF to surrogacy to cloning, and they are all within the same thing, same kinds of reproductive -- they fall within what we consider reproduction and therefore are covered to a right to reproductive liberty.

But, certainly, part of what we have heard from other people is that they do view this as qualitatively different. It doesn't involve contributions from two independent people, half of the genome coming from each side, etc.

And so the question of whether you view it as part of that spectrum or as a significant qualitative, essential, whatever you phrase, is different from prior forms of reproduction is the issue, it seems to me.

And all I wanted to say, or I thought all we came to agreement with, was that making that decision, whether it is, you know, just one form on the same line or qualitatively different, and therefore not covered by the right to reproductive liberty, depends already on certain ethical judgments and isn't -- you can't enunciate standards for what would be qualitatively different and essentially the same without the other moral judgments about whether this is the right or wrong thing.

That is all I was saying. Now, you may ---

PROF. CAPRON: It doesn't -- can I -- can we discuss this instead of just -- it seems to me that to say that something is wrong because it has wrong consequences -- is that what the suggestion -- doesn't seem to me to get to the essentialist argument at all.

DR. EMANUEL: No, wrong not necessarily in the consequential phrase. I mean, here is the ---

PROF. CAPRON: What are the ---

DR. EMANUEL: Well, here is the other thing. Think of what answer John Robertson would give to the question of: What are your criteria for it being essentially the same? And think of the answer that Leon Kass would give for: What are your criteria for it being essentially different? Okay? Or qualitative different, just not on that spectrum.

And it seems to me the answers that those two people can give already presuppose something about whether this is intrinsically right or intrinsically wrong. They are not consequential arguments.

I mean, fundamentally, it doesn't seem to me Kass's arguments are consequentialist and neither -- I think Robertson's arguments might be a different kind. So I don't think they are purely consequentialist.

You know, Kass would point out if naturally you need contributions from two people, 50 percent of the genome coming from

each, this breaks it. It is only from one. You don't need another partner. Robertson would say it is just another form of making a, you know, creating babies, and any form of creating babies is all within reproductive liberty. I think ---

PROF. CAPRON: I mean, I agree that it is a fulcrum on which a lot turns. It can still be seen, I suppose, as part of the allowance issue, and it may be seen on where the burden is.

It is just enough different that it makes sense to say that before you could go forward with it, you would have to overcome a burden of showing that it is important in a way, it is essential in a way, to your achieving your liberty in a way that you don't have to if you are using artificial insemination by donor.

If we say there is reproductive liberty, and you say, I want to get the sperm this way rather than by sexual intercourse from my husband, does the woman there have to overcome some burden, or does society have to, in effect, say, why it is so bad to allow this to happen that we would restrain your liberty to achieve reproduction in this fashion.

DR. EMANUEL: Right.

PROF. CAPRON: But it seems to me that it isn't the inherent rightness or wrongness of it that Kass would be arguing. It is the different-ness. I mean, that that is an important issue, but he doesn't have to -- he is what?

DR. MURRAY: Never mind. I will have my turn.

PROF. CAPRON: Okay. Well, I mean, it ---

DR. EMANUEL: All I am saying, Alex, is that different-ness, the criteria you would use for different-ness, is value-laden in precisely the way that it traces marks (?) to your judgments already about whether it is the right thing to do or the wrong thing to do. There is no independent criteria different-ness.

That, I think, is an important point, which means that it is all of one -- as Eric was saying -- and I think quite correctly -- it is all of one world view or all of one view about rightness and wrongness of these kind of things.

So no -- and the importance here is that no independent criteria with an independent moral foundation means you can't decide whether it is a right or not a right in some independent way prior to some other set of moral judgments, which is why there is not a neutral standpoint.

PROF. CAPRON: Well, okay. I have to see this worked out. On the final comment about this cases and practices issue. As I fumbled around on that on the e-mail trying to see -- my instinct is to agree with you that this is somewhat different from other ways in which this is used.

But, in a way, the whole Kantian perspective of universalizability seems to me to be operating with any of these things. The real question is: Would this act, as an act, be acceptable if it became a practice? The same is really true, in many

ways, of the euthanasia and assisted-suicide issue.

I mean, we live in a society in which there is a small tolerance for the exceptional cases, even though we have a principle against it. But what is frightening and an argument against openly tolerating by changing policy and allowing is that it would become a practice, and a practice that would sweep in a great many cases which would be totally indefensible.

I am not sure -- as I said a long time ago, in response to a hypothetical that Harold was putting forward, I put another hypothetical. Suppose a child were born, and no one knew it was a cloned child. No one knew it at all.

It would be unlikely there would be any harm -- and there was no physical harm to the child in the process -- it would be unlikely there would be any harm to society, to the child, to anybody from that child being genetically the duplicate of another born, much older person. I mean, what would there be?

But there are potential social harms in terms of genetics and so forth, and certainly, social harms if it became known and this became the dominant way of practice. In this *Wall Street Journal* thing that has just been distributed to us, there is language, for example, from David Baltimore, the first one, in which David ends up sort of being against it.

But in the meanwhile, well, but if it were possible to have -- take an adult who has lived a healthy life and clone that

person, you can give the child freedom from genetic disease. There is the eugenics argument, right there in the first paragraph of this article, stated, and that then becomes the social practice that isn't just a practice. It becomes almost the preferred practice.

That the responsible parent will not throw the lottery, but will take the Fletcher -- Joseph Fletcher -- view that the right thing to do is to design your child's genes by picking out -- from the well-known sample list here those that work well.

So it does seem to me that in many ways, the cases/practice argument works very much the same way here. I mean, I was originally thinking it didn't, and it didn't quite fit, and I felt uncomfortable with it. But the more I hear about it, the more I come out the other way, Jim, in saying, this is really another instance of the same kind of argument.

DR. SHAPIRO: Okay. Thank you. Tom.

DR. MURRAY: Well, I was in San Francisco, watching the expressions as Jim and Eric spoke by telephone, and all I can say is we are very glad you participated by phone, because you wouldn't have wanted to be there and seen the various expressions people were pulling as you spoke.

(Laughter.)

And you will get no more out of me about this. I also want to agree with both of you and with some of the comments that have been made already this morning.

If I can try to read -- I will frame my own way what I think is consistent with what Zeke is saying. It strikes me that the strong moral arguments, certainly, the ones really on both sides, are not sort of -- are not simple kind of compositions expressible in sentences, but they really are more like different conceptions of what are good lives for women and for children and for men.

They really are fairly well fleshed out and embodied conceptions of the human good, what philosophers call different views about human flourishing. Those are not easy to state simply, and in fact, they entail a fairly complex web of different beliefs and commitments and values.

It is -- these are the values, the values embodied in those kinds of conceptions, are the things that Jim said were, you know, unlikely to be undermined by the occasional, isolated act of human -- making a baby by cloning. But if it became a widespread practice, it might be the sort of thing that would change in a way that we would want to reject and try to anticipate and not embrace.

Now, those kinds of ideas do help us get through the ethics of cloning and why people would either find it permissible or tolerable versus find it repugnant or threatening.

Alex was getting to the point, well, what does that mean for public policy? I mean, do you take -- how much leeway, how much power, do we give to sort of the protection of a particular conceptions of human flourishing and public policy? That can be

tricky, and I guess I just want to acknowledge that right now.

There are libertarians who say, well, you shouldn't have any -- that it should be nothing. But then they have a conception of human flourishing which says it is maximized by complete individual liberty, which is already -- it is like Zeke said -- it is not neutral.

It makes certain commitments, and I think those of us who don't embrace that conception can, you know, forcefully put forward our own commitment and say that what we want, if anything, is a policy that seems to respect those different conceptions of human flourishing. And it won't necessarily be a libertarian perspective.

DR. SHAPIRO: Thank you. Alta.

PROF. CHARO: I would like to continue this, and I would like to try to ask the Commission perhaps for some responses to some specific questions on the case and practice issues that will feed into the policy discussions.

Because given a backdrop in the United States of basically everything being allowed unless it is specifically forbidden for any act, the strength of that presumption depending, in some cases, on how we characterize the act, but that is the same presumption for almost every act, versus a slippery slope argument, where even if a specific act is not horrendous in and off itself, the fear of the practice is so strong that one chooses to forbid even the single act as the only way to guard against the development of the

practice.

That being a kind of a classic, simplistic set of concerns. I wonder if I could try out the following kind of four categories of moral objections, or ethical objections, that are captured in the discussions and see, for each one, how strongly people feel about them and how they fit in then with the notion of it being sufficient to prohibit an act and sufficient to even prohibit - - or sufficiently -- never mind. I am no making any sense.

But, anyway, let me go through them. It strikes me that they come out as concerns about physical safety, which strikes me as concerns about a single act, as well as about a practice.

Concerns about psychological safety for the child, and here is where I very grossly encompass the concerns about identity, self, being viewed as an object or a commodity by one's parents as opposed to a serendipitous gift. A whole lot of things that are amorphous, but I put under the psychological rubric, which is something that would go to even a single act, as well as to a practice.

And then two other large categories that strike me, Jim, as being more in the kind of concern if it is a widespread practice.

The kind of overall rubric of defiance of the natural order, the defiance of the death to the extent that people see this as a form of physical immortality, the defiance of natural constraints, of natural family forms.

And, second, the whole set of concerns about the prospects for mass production and control of people, particularly when done in conjunction with genetic engineering, the kind of sci-fi scenarios that people absolutely have expressed concerns about.

And those two latter conceptual concerns, defiance of nature, or however you want to view that one, and prospects for control, struck me, reflecting on the discussion as being things that really go the practice.

And from the policy point of view, because the options of voluntary moratorium versus legislation really, in some ways, go at how desperately hard you want to try to ban something so that not even a single act is ever committed. Right?

But that the stronger your measures, the more disadvantages you have to face. So that the strongest, let's say, legislative measures with criminal penalties, will face the strongest legal challenges -- which might not succeed, but are hassle factors -- would pose the most difficult problems in terms of building in sunset provisions if you wanted such a thing.

To the extent that these strong measures then have disadvantages, it is helpful to know how desperately you want to the strong measures.

So, therefore, I would wonder if people could give feedback on how strong they think these objections are for the two that focus on the act, physical and psychological. Do you think

these are so terribly frightening that for that reason alone, we should be trying to forbid every single act as effectively as we can.

And if that is not the case, if you think, well, we can work around that -- we have got other means -- do the two practice concerns come up to a level of concern so strong that for slippery slope reasons, you would want to prohibit every single act in order to avoid the practice. Am I making any sense?

PROF. CAPRON: No. Because as a practice, the physical concerns or the psychological concerns would be there. I mean, you would just have more ---

PROF. CHARO: Yes. No, no, of course. Of course.

PROF. CAPRON: And the notion that violating nature, the natural order one, doesn't apply to the case. Certainly, someone like Kass would look at an individual case and say, if you were doing it in a way that violates nature, that is your attempt to have immortality and screws up your family, who is this child going to be?

PROF. CHARO: Yeah, I ---

PROF. CAPRON: -- comes up with a ---

PROF. CHARO: Right. Alex ---

PROF. CAPRON: So I think the mass production doesn't come in ---

PROF. CHARO: Alex, I am trying to take what Jim said seriously, which is that those kinds of concerns are really at their

most dramatic when you have a widespread social practice, because the concerns are raised in the context of undermining human values, the human experience, etc.

So it is not that the single act defies nature that is necessarily the big issue. It is the widespread practice of this is viewed by some people as undermining something fundamentally important about human relations.

I guess what would be helpful for feedback on the policy direction would be whether or not any of these concerns seem strong enough that every single act needs to be prohibited at whatever cost, in terms of disadvantages of your policy option.

And if that is not the case, whether any of these things, if a widespread practice are of such concern, that we should try to prohibit even a single act to avoid the slippery slope.

DR. CASSELL: Is that a question?

PROF. CHARO: Yes.

DR. CASSELL: Well, I don't want to speak for everybody else, but I can't -- I don't know anybody who would feel that -- the possible reasons against it are so strong that we should have -- you know, make it into a criminal act and so forth. I don't know how everybody else feels about that, but I don't think that that surfaced at all.

That their are objections that are so deep and so strong that we would require that kind of prohibition. Did we? Does

anybody think that?

DR. MURRAY: I think there are people in this country who think that.

DR. CASSELL: No, but in our group? Oh, there are people in the country who think anything.

PROF. CAPRON: I don't know what a moratorium means if there isn't some prohibition with it. The difference -- a moratorium says for the moment, don't do this. And when we say don't do this, we usually mean, if you do, there are problems for you.

DR. CASSELL: Well, but there is a level of the problem, isn't there?

PROF. CAPRON: Well, there is capital punishment and then -- (inaudible) -- I mean, torture and capital punishment are not, I suppose, options for people who go forward with this. But the question is, are we just sort of making this a hortatory statement? If we are talking about a moratorium, it means this will not go forward.

DR. CASSELL: Yes, but there is a difference. Then we agree ---

PROF. CAPRON: You lose your license. You go to jail.

DR. CASSELL: But we generally agree that there is a time limit on it ---

PROF. CAPRON: Yeah. But while -- until the time limit is reached, is there some ---

DR. CASSELL: Well, nobody thinks there is a moratorium on car theft, you know. It is not a moratorium. It is against the law, period, and it has got penalties, and they are big penalties.

A moratorium implies that, certainly, with federal funding, you don't get any federal funding, and if you break it, you liable never to get any federal funding. That doesn't close off all avenues of funding, obviously, but it does have censure in your community.

PROF. CAPRON: That is a moratorium on federal funding, but if we talk about a moratorium on the practice, on the doing of this, we mean that -- a moratorium simply means that you are putting it to rest for a certain time.

DR. CASSELL: Yes.

PROF. CAPRON: But while you are putting it to rest, you have to say what does that mean?

DR. EMANUEL: Can I interject for a second? Straighten me out, Alta. Was the question whether it should extend beyond the public to the private? Is that the goal of any act question? Because if that is the goal, and here I plead ignorant.

I mean, it seemed to me that the agreement we had, if I heard it right, was that on the physical harms, everyone agreed that now, and for the foreseeable future, the physical harms are enough that we think that any act, public or private, would be wrong.

And now whether that means, you know, as Alex was just

saying, you do it, we shoot you on sight at the press conference, is a different story. How we design the penalties is a different story.

PROF. CHARO: Yes.

DR. EMANUEL: I think I heard, and again, you know, reading the tea leaves here can be difficult, but I heard that everyone agreed that at least on one, physical harms, now, if done, whether it is done at the NIH with public funds or privately in some clinic, solely with private funds, it is wrong, period, end of discussion.

PROF. CHARO: Right.

DR. EMANUEL: Now, whether it is wrong means it is criminal or not, that is another story.

PROF. CHARO: Right.

DR. EMANUEL: Let me ask ---

DR. CASSELL: --- it is just that thing.

When we say no, and then the next is a level of how strong. I mean, is it a criminal act? I think Alta is, in fact, addressing that, aren't you?

PROF. CHARO: Yes. To clarify, I am, in fact, asking about how strong a prohibitory recommendation you want to make. I am asking now, because since we are talking about the list of ethical objections, it seems pertinent to get a handle on the strength of those objections. Because that then plays into the level of prohibition you are trying to achieve.

In addition, because some of the objections are being made to the widespread subtle effects on human society if this were to become a practice, right, it seems to me that it is appropriate to anticipate slightly essentially Steve's scenario of a moment at which the safety concerns have been sufficiently resolved that it is not immediately unethical on a safety basis to imagine proceeding with this and ask, do you still want something prohibitory in place?

And I am just -- everybody was listing all their objections, and I am just trying to get them to be maybe more specific about the strength of their objections on these various grounds to feed into the policy recommendations that go to things like voluntary moratoria versus legislative bans, which do have differing degrees of likelihood of extending indefinitely into the future.

DR. SHAPIRO: Can I -- let me try to respond to your question, Alta, if I understand it. My own view is that on B, C, and D or 2, 3, and 4, whatever, on the grounds that we may not understand enough about any of them to consider just what level of prohibition or what level of legislative intent and so on we ought to recommend right now.

I just don't think we understand enough about those. I understand the arguments that have been made, and there were some very strong arguments on all sides of the issue. But I am not sure that we have to decide that now.

I think on the A or 1, I think we do have to decide, whatever, and what I took Alex to be saying, namely, that a moratorium means something more than a slap on the hand. That, it is just my own view, it is serious enough and sobering enough, given that 2, 3, and 4 remain to be developed in a national discussion and understanding of where we are heading as a society.

That the moratorium -- I have no way of knowing -- criminal -- as to what level and what other kinds of restrictions we ought to have and penalties. It is an interesting question. I don't know how to quite answer it. I don't have a good feel for it.

But I think it would be difficult, if not impossible, to answer the questions on B, C, and D right now from the point of view of public policy. We can all pick very thoughtful people who have addressed themselves to B, C, and D and have very strong feelings about it, and I respect those and want to think about them more.

But I, just speaking for myself, don't understand the interactions of all this well enough to answer your very thoughtful question.

Does anyone else want to try answering Alta's question, and then I have to go -- we still have a lot of people on this list.

DR. CHILDRESS: I guess, in one way, Harold, we can say that your response is an answer.

PROF. CHARO: It is a response.

DR. CHILDRESS: It is an answer to it. To say,

basically, that the strength of the objection, as you, and I would share that view, that it is strong enough on the first to lead us to some pretty vigorous action. But discussion is required on a wide societal basis on the others.

DR. SHAPIRO: Okay. Bernie has been waiting a long time and is really mobilized. You are on the list, Diane. It is a long list. Bernie. Excuse me, I know you have to leave early. Is that -- are you still going to be here a while?

DR. SCOTT-JONES: I will be here a while. I will wait my turn.

DR. SHAPIRO: Okay.

DR. LO: I think this is a very helpful discussion. I think I would like to come back to Alta's points, but maybe do it under policy bucket time, because I think they are important issues.

A purely selfish point of view, to help with the ethics chapter, I have heard some very good ideas. There needs to be a section that Jim Childress is heading, "Arguments in Favor of Allowing the Practice of Cloning in Human Beings as Babies and Arguments Against Allowing the Practice of..." blank, blank.

A couple questions again to sort of help -- rough outline. Do we want this to be in addition to the sections on for and against cloning as an action, or do we want to throw out the sort of section and replace it?

My own personal view is I would like to add this in,

because I think it is helpful to lay out the arguments why you would do it in an individual case for and against and the arguments why you would allow or not allow as a social practice.

But in this new section, as I am envisaging Roman numeral whatever it is, it seems to me there has been a line of argument that has been proposed, and I just wanted to sort of get the big parts of the argument out and see if there is disagreement.

There seems to be a sentiment that I have heard today very well that in the public policy area, the question of whether we allow it as a practice, to clone humans, we start with the presumption that the burden of proof rests on those who would forbid the practice based on our conception of individual liberty in this society.

Let me first sort of put out -- is that how we feel the presumption should lie as the starting point? Second, once we have put ---

DR. MURRAY: That is for the policy bucket?

(Simultaneous discussion.)

DR. MURRAY: Not as a moral presumption. I would not ---

DR. LO: Okay. Well then I want to have that discussion

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DR. MURRAY: (Inaudible.)

DR. LO: No, no. As a policy for -- I am sort of saying as a general capital bold heading is: Ethical Issues Concerning

Whether We Should Allow or Not Allow the Practice of Cloning Human Beings as Babies.

Next capital A: Starting point is -- starting question:

Where should the presumption lie? One, on those who would forbid to -- what I have heard so far is the argument that the presumption should lie on those who say, no, we don't want that practice to be, because --

(inaudible) -- so Tom is saying, he takes a different -- so I want that -- I want to try and articulate it. I mean, just lay it out ---

DR. MURRAY: That is not a neutral starting point.

DR. LO: Absolutely, it is not a neutral starting point.

And then I guess -- I am just sort of trying to reconstruct what I heard, and I want to make sure that we are not missing other approaches that we either need to articulate or actually believe in strongly.

Then following that next same line -- (?) --presumption is liberty. Then goes -- there is a particular kind of liberty that has to do with reproductive liberty, and we believe -- or another argument that we believe, another argument, is that this cloning for babies is essentially the same, not so much different that we would form different policies than other forms of ART, and it seems to me that is another --

(inaudible).

And we had some discussion of that already, which was

tending, you know, to be -- some people say, well, you know, I don't really see how this is a whole lot different. Since we have others disagree that this really is different, and it was pointing to the one differences as factual differences. That you don't have two equal genetic parents. Is that a morally relevant difference as well?

I mean, these seem to me the kinds of issues that only ethics of public policy sort of section need to be thought out, and I would like to kind of stoke the fires of discussion, so to speak. So far, I have heard sort of one line argument, and it is going to end up saying there are no compelling public policy reasons to not -- to ban this practice.

I am saying we need to look at each step in that argument to see if we really agree and what the alternatives are. Let me stop there.

DR SHAPIRO: Okay.

DR. MURRAY: Just a clarification. The last thing, Bernie, actually confused me. You said, there was no compelling public policy reasons. Are we talking -- this is the ethics chapter. Are we talking there are no compelling moral reasons that would lead to a public policy? Is that what ---

DR. LO: I guess, if you follow the language -- if you follow the reasoning that the ethics of public policy runs

as follows, one, the presumption has to be that we are going to allow it as a policy. We are not going to forbid unless we have really compelling reasons to forbid, but ---

DR. MURRAY: Because of the presumption in favor.

DR. LO: Right. So if you accept that, and if you then accept cloning of human beings is not, in essence, or qualitatively different from other things we have included under reproductive freedom, then I can see where the conclusion is going to come out.

I just want to make sure that we look at each of those steps. Because if we don't, we are going to end up with a conclusion that we may not ---

DR. SHAPIRO: Diane, then Tom.

DR. SCOTT-JONES: I have a couple of comments that I would like to make, and they are two different kinds of comments. And I haven't been able to participate in any of the discussions, but I have read everything you have circulated over e-mail real carefully.

And my first comment is that I looked for something in the ethics section that isn't here at all; that is, when I first read it, I expected it to have more to do with research ethics and maybe medical ethics. It seems to me that a lot of the discussion becomes policy issues that I thought would be in the policy and law section rather than the ethics section.

For example, the mundane research ethics issues, such as

confidentiality, consent, they are not dealt with at all here, and when I look at overall what is here, I guess it would fall under the rubric of beneficence, non-maleficence, justice, those kinds of issues that come up in research ethics. But it seems to me that the ethics chapter isn't focusing a lot on the basic issues of ethics of research or ethics of medical practice.

For example, I can look at the AMA statement that they send us where they do talk about the issues of consent, confidentiality. They also add the issue of discrimination, that is, a person may not be allowed to use cloning if it were allowed if they had a genetic defect.

So it seems to me that they are addressing the ethical issues that I thought would be addressed in this chapter, and I wondered if there is a way to focus more specifically on the various elements of research ethics or medical ethics instead of just these broad discussions that I think somehow end up being counter-productive or they end up pre-empting what would then be in the policy section.

And then I have a second and very different kind of comment. And it seems to me that in reading the various drafts, two or three drafts, that circulated, even though I think they make very interesting points, I think there is, underlying in them, a theme that I think we should avoid in the writing of this.

And that is the idea of whether you are for or against

cloning, that cloning allows a parent to exert control over such items as music lessons -- I don't remember all the specific examples ---

But I think we need to be very careful to avoid language that suggests that in controlling genes, somehow we are controlling not only medical outcomes, but we are somehow controlling psychological outcomes or outcomes of complex characteristics.

I think it would be, given our role to be educational, to have in there this subtext that there is somehow extraordinary control that would be exerted over child outcomes.

But my main point is that I thought the ethics chapter would focus more specifically on research ethics and medical ethics in the more traditional sense.

DR. SHAPIRO: Okay. Tom, then Trish.

DR. MURRAY: Bernie might -- looked like he wanted to respond.

DR. LO: Let me just respond to the second point, because I think I would like to hear more discussion of the first.

On the second point, we did not mean to suggest that cloning is going to determine your phenotype. In fact, we are trying to sort of kill that misconception. What we were trying to say is that many people felt that we allow and, in fact, encourage parents to shape their children in all kinds of ways, and that is where the music lessons and whatever comes in.

To the extent that we want parents to educate and rear their child in ways that tries to shape them in certain ways, there is the argument that has been made, and Alex has made it quite forcefully, that cloning is along that same line of things people do to try and give their kids as good a head start as possible, knowing full well that -- you know, my son just quit flute lessons last week. He is not going to be a musician.

So I just -- I mean -- I totally agree with you. If it is coming out as we think that, you know, that cloning is the same as -- cloning is going to determine the phenotypic expression of the child's traits and characteristics, we need to really correct that. Your suggestions on where that comes through ---

But I would like to say we would like to, I think -- but, again, as I say, I am open to discussion -- address the issue that has been raised that parents try and shape their children in a whole lot of ways, and I actually think that is good and part of being a responsible parent.

So, yeah, I just want to say I think I am agreeing with you and want to try and ask everyone's help to try and correct those points.

DR. SHAPIRO: Diane.

DR. SCOTT-JONES: If I could just respond real quickly, I think some of the language that you just used might usefully be in the report. Just to say directly that you know that parents cannot

exert this kind of control rather than allow statements that sort of are: Well, what if we could do this? Then parents could do more to control.

I think a clear statement like the one you just made would be appropriate, and again, I refer to the AMA's letter that they sent us. They make clear statements against those notions. They make clear statements that promoting reproduction of favored groups over less favored groups are widely discredited.

I mean, they make these clear statements, and I think our report should, as well, clearly state that we, by no means, expect that cloning would allow us to exert that kind of control or should be used for that purpose, if it did.

DR. LO: Again, help me with the -- please help me with the writing, because I tried to put that in the -- but it clearly didn't come through. So red pencil it as you have done on e-mail ---

DR. SHAPIRO: Okay.

DR. LO: That is the kind of interaction I think we need to sort of make sure -- (inaudible).

DR. SHAPIRO: Okay. Tom.

DR. MURRAY: Thanks, Diane, for both of those points. I think in reaching for the larger ethical issues, we probably -- and I accept full responsibility -- I am willing to share it with other members of the ethics group -- for not having done more to specifically make those points. I think

if we can get your help even in trying to give language to some of that, we would be very grateful.

PROF. CAPRON: It is all your fault.

DR. MURRAY: Thanks, Alex. Okay. It is the same in my department and my family. Then why should it be any different here?

About Bernie's point, I think it is going to be important in the report not to fall into that kind of quasi-syllogistic trap that Bernie just outlined.

If we are going to talk about the ethical issues, we shouldn't -- we should say, look, liberties, individual liberty, is an important value in America.

It is not the only important value in American culture, and in fact, it is part of a larger network, web, whatever, of values and different ideas of what makes for good families, what makes for a good society, what makes for good lives.

I think we should put it that way and not start off by just saying, let's start with -- you know, what we have to do is rebut individual liberty in this case. Now, when we get to the policy pieces and the ethical considerations that rightly ought to be considered when one formulates policy, then it may look more like that.

Then we start with, you know, individual liberty as a very important thing. It has a kind of privacy in the sphere of policy that does not have *per se* in the larger sphere of discussions

about ethics.

DR. SHAPIRO: Thank you. Trish.

PROF. BACKLAR: Yes. Diane, thank you for bringing this up. In fact, I think that one should take a sentence that Courtney Campbell wrote that might start the whole ethics discussion, which was "Human cloning will inevitably involve non-therapeutic research on the unborn without valid consent." And that I do think this has to be a centerpiece of our ethics report.

I wished, in a way, that we had talked about this in the same way that when I sit on my ethics committee at Oregon State Hospital, we talk about a situation going through all the issues of consent and confidentiality, and then we would be able to bring in the issue of who is the parent.

Lori Andrews, I thought, wrote about this very effectively in her paper, and there is much that we could draw from that on the issues of the provenance of consent and who are the parents are. And it is a very different way of approaching those and yet bringing in some of the same issues that we discussed at our meeting.

The other thing I did want to say is that -- I think Jim may have suggested this or Harold -- that we may need more time to write this section of the report, and it is a kind of Belmont Report on cloning.

And that we also might take a clue from Al Johnson said

this week on a (?) that I am involved with on bioethics in which he talked about, when they wrote the cloning report, the Belmont Report

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DR. : (Inaudible) -- the cloning report.

DR. SHAPIRO: No, that is right.

PROF. BACKLAR: That they tried to use language which was easily accessible and understood by everybody, and I think that is very important.

DR. SHAPIRO: Can I just ask a question about the issue that has come up here now, which is -- I think it is described as research ethics and how this deals with this issues.

Here is what has been suggested. That we point out that if one were ever to enter this area, there would be a whole series of issues to consider, namely, consent and whatever else, the traditional -- maybe other non-traditional ones. Is that the point? I just want to make sure I understand. I am asking.

PROF. BACKLAR: Yes.

DR. SHAPIRO: Okay. Thank you. I just wanted to understand.

DR. LO: If I can ask another clarification? I think there are clearly problems with obtaining consent from the sort of parents and -- (inaudible) -- are you suggesting cloning of humans *per se* would be unethical, because you could never get consent from

the child who was born as clone?

PROF. CHARO: Bernie, will you speak in the mic. I can't hear you.

DR. SHAPIRO: You have to almost speak directly into the microphone.

DR. LO: When you raise the question of consent, I think there are clear issues with obtaining consent from the parents who donate the genetic material, the surrogate mother, and the oocyte donor, and perhaps even genetic parents of the person to be cloned.

Did I hear a suggestion that there should have been consent from the child who was to be born by the baby-making cloning, and since you can't do that, it is unethical *per se*? Because that is an argument that has been raised in the discussion, and is that something that we feel is a meritorious argument?

DR. MURRAY: I just want to point out that that sentence that you read from Courtney, that that would apply to all novel reproductive technologies and, you know, probably would be assimilated within the way we generally think about so-called clinical research, research designed to provide a benefit to a child, where we regard the consent of the well-intended adult ---

PROF. CAPRON: Well, now I really think it is an example of the kind of issue we can either brush aside or go into. There is a fundamental question. It is an ontological question. Are you providing therapy when you create a child who does not now exist and

doesn't have any problems to therapize?

I mean, yes, if you have a fetus *in utero*, and Michael Harrison at UC-SF wants to do some novel pre-birth technique on that to fix polycystic kidney disease or something, you are allowing the parents to say -- this child can't consent -- it is not even a child yet. It is a fetus. But we are going to allow the parents to consent to do therapy.

This is an oocyte sitting here, and a nucleus sitting over here. It is not a child yet. If you create it, and in the process expose it to risk without its consent, it is hard to say that that is therapy.

DR. MURRAY: It is no therapy. It is a procedure to benefit what will be a child. Now, I am not trying to skip over the complexities. There are complexities.

PROF. CAPRON: There are complexities. I am just sort of pointing out they apply equally to ---

DR. : IVF.

PROF. CAPRON: They apply equally to IVF. This is a new technique, and therefore, with IVF, you would now said that is not a research technique. The phrase from Courtney's thing was non-therapeutic research without consent. It is an issue that has to be at least acknowledged if we can't resolve it.

DR. SHAPIRO: Jim and Steve.

DR. CHILDRESS: I think some of this has become a lot

clearer for me in the discussion, something I was pushing toward, but hadn't fully grasped.

Bernie said, we will make an ethics of policy -- deal with that in the second section, and Tom said when we get to policy.

See, my question is: What question should control our discussion?

What were we set up to do? It seems to me what we are set up to do is to basically deal with the ethics of policy. And so the discussion of individual acts of cloning and so forth should be subordinate to that.

So when I am asking a question -- and why I was concerned about Bernie raising it -- are you in favor of cloning or opposed to cloning, no, I think from the policy standpoint, the question is whether we are in favor of allowing or prohibiting cloning?

MS. : Right.

DR. CHILDRESS: Now, see, if you take that as the central issue, then you bring in all the other discussion as subordinate to that. So I wouldn't think about the ethics of policy as the second section, or with Tom, when we get to the policy questions.

I would see that as the central issue. I am sorry Alta is not here. I would see that as the controlling question for our whole report. So that would then put the discussion of the other issues in relation to that, and I think that -- I think we really have to think very carefully about this, as to what our task is, what our mandate is.

If we go the direction I am proposing now, the issues about research ethics will become much clearer. They will play a much more central role in what we do, because we are trying to address the issue in a different way than simply looking at individual acts of cloning and thinking, well, is this right or wrong? What are the particular cases and so forth?

Is this neutral or non-neutral? No, it is not neutral. We are working within a particular social context, a liberal democracy, where whatever you think about reproductive liberty, to ban something requires a certain kind of justification.

Now, you can talk about that as presumption, burden of proof, whatever. If you are going to ban something, then that requires certain burden of proof. Now how you characterize what you are banning, whether it is reproduction -- it is going to play a major role in that.

But it seems to me that when we think in those terms that we have a kind of direction for the report that would probably tie the parts together in a different way than if we are thinking about sections, science, ethics, religion, etc.

So that is a fairly perhaps radical proposal. But I hope we will take it seriously.

PROF. CAPRON: Could you entertain a direct response to this, please?

DR. SHAPIRO: Sure.

PROF. CAPRON: Jim, I agree with your approach, but it doesn't seem to me that that is a distinction between cases and policy.

DR. CHILDRESS: No. I am -- it would effectually handle the cases, though. That is all I am raising. Not that we don't use the cases.

PROF. CAPRON: Right ---

DR. CHILDRESS: The best way to handle them.

PROF. CAPRON: -- the ethics of allowing is discussing the reasons that would be relevant to society taking a stand on cases or on policy.

DR. CHILDRESS: Right. But it puts the cases in a very different way than simply starting with them, arguments in favor of cloning or against cloning.

PROF. CAPRON: Right. But you can have arguments in favor of cloning on cases or as a policy.

DR. CHILDRESS: That is what I am saying, but you treat them in a different way when you put them in this context.

DR. SHAPIRO: Tom.

DR. MURRAY: I am not sure I understand. I am responding to Jim's proposal. I am not sure I understand it fully. Because on my current understanding, I think I disagree with Jim, and I rarely disagree with Jim. So maybe I misunderstand him, or maybe I disagree with him. We will find out, I suppose.

I think it is possible to construct the ethics, even the ethics portion, the ethics discussion, or the report in a term that would say, look, in the end, what we want to find out is: Is there strong enough reasons to not permit cloning for the making of babies right now? That is the focus on that.

DR. LO: As a practice.

DR. MURRAY: As a practice. And you have research ethics questions or issues. You would have issues about different ideas about significance of family, etc. That would be okay with me to do it that way.

What I don't want to do is a sort of framework that Bernie was proposing and say, look, let's start off by saying the real policy question is what can we -- we have got to start with individual liberty and everything else can we rebut, and we rebut individual liberty.

I don't think that would be the way to go, because I think it would fail to capture what most -- what is sort of deep -- what most people feel most deeply about baby-making. I think we need -- in the report, we need to be able to state as clearly as we can, or capture as well as we can, what I think are some of the deep moral reservations people have about cloning.

So long as we can do that, I am less concerned about just, you know, what comes first. But I want to be sure that is in the report.

DR. SHAPIRO: Steve, I have your name down here. It is at the end of a long -- not the end of -- but part of a long list. Trish, I have your name as well. Has times passed you by or do you have ---

MR. HOLTZMAN: Just a thought, and it sort of tacks onto, I think, Zeke and Tom's. I personally find it useful not to think about arguments for and against something, because there is no arguments about facts here, which goes to your point about no independent criteria.

I view the Kasses of the world and the Robertsons of the world and the moralists in general, if you will, as giving us invitations to think about a social practice in a different kind of light, to entertain them under different kinds of descriptions, and ask ourselves what are the consequences of thinking about that way and not only thinking about that way, but acting in certain ways?

And that leads naturally to asking questions about what about when a society embraces it in its social practices with such an understanding?

So I can't help but wondering from an educational perspective, instead of a framework of arguments for and against, one rather took on the perspective of we have been asked to think about cloning as just another species of reproduction. We have been asked to think about cloning as replication and, therefore, fundamentally different.

What does it mean to conceive of it in those ways? And what would be the practices that would be embodied? And what would be the consequences potentially of those practices?

DR. SHAPIRO: Okay. Trish, then Larry.

PROF. BACKLAR: Well, I am just concerned that we keep talking only about the liberty issue, because I think there is another way of looking at this, and that is, in terms of the justice issue in future generations and how this will affect future generations. It was just another point of view that I wanted us to take in considering the ethical issues.

DR. SHAPIRO: Larry, then Rhetaugh.

DR. MIIKE: I just wanted to remind people that in terms of our specific charge, our decision is going to be made on the certainty of the science and not on the ethics here.

To me, this discussion is a perfect reflection of what is going on in society, because even among the ethicists, we are not clear about to present the argument and which way to go, one way or the other.

But I think that is a valuable lesson, and I think it is something I think we should state clearly in our report.

DR. SHAPIRO: Rhetaugh and then David.

DR. DUMAS: I think Jim really stimulated some thoughts for me about the overarching focus of our report and whether it should be on issues related to cloning or issues related to allowing

or not allowing cloning at this time.

It seems to me that in the area of ethics, the question that comes to my mind is whether the critical question has to do with ethical considerations as determinants of policy decisions rather than ethical considerations in relation to cases specific to cloning, if that makes any sense?

I think that it is worthwhile to give some attention to these competing areas of focus, because we get into ideas about the value, the pros and cons of cloning, which, to me, seems now to be secondary to the pros and cons of making a decision at this time as to whether or not cloning should go forward.

DR. SHAPIRO: David.

DR. COX: That is exactly what I would like to continue on. I completely agree with what Rhetaugh just said. I think Jim has really helped focus this for me.

DR. DUMAS: It helped me.

DR. COX: And we have listened to the discussion, okay, of the ethical and philosophical points, okay, which to me, okay, illustrates how this needs to go on for quite some time.

DR. DUMAS: Yes.

DR. COX: I find it extremely interesting, extremely thought-provoking, but, okay, I don't really see that by having that discussion, it is going to decide for me, okay, whether, okay, we should have cloning or not. Right? It contributes to it, okay, but

it is not the main focus. I would really like to see us discuss that issue and have that be the main focus.

DR. SHAPIRO: Well, let me make just a couple of suggestions. I think we are going to break. We have been sitting here for quite a while.

This discussion will naturally come up again, at least many issues of this discussion will come up again, as we begin discussing the, so to speak, law and policy area.

I do want to state, or restate, the obvious. That dividing these areas was just a way of getting some material before us. It is not a statement that these are separate, and we finally get the report -- that they are not going to relate to each other and so on and so forth.

So we ought not to worry a lot about the fact that we happen to use these temporary buckets to mobilize ourselves. Obviously, these are going to interact in an organic way, or they had better interact in an organic way.

DR. CAPRON: Can you define finally?

DR. SHAPIRO: So that will certainly happen. Maybe I could ask Jim one question. I am trying to think carefully, Jim, about the distinction you make between what I understand is the difference between the odd act and the social practice of it. I can certainly understand that, and they suggest different images.

But it is hard for me to completely separate those two.

It is hard for me to understand just what moral/ethical arguments would apply that would totally treat these as independent kind of approaches. But maybe you can help me with that. I am not sure that I fully understood the point you were making.

DR. CHILDRESS: The act/practice point?

DR. SHAPIRO: Yeah.

DR. CHILDRESS: Well, some of the discussion, and this came up in the ethics bucket as well, and we had Professor Faden there, and I thought her contributions were very important.

But one of the arguments sometimes offered against human cloning is justification, and another is commodification. Well, it seems to me, commodification becomes an issue, and I think her comments suggested this, only when you are at the practice level. You are really talking about a social practice.

Objectification, however, may well be present in both, and that would just be one way in which I think one would just need to attend to what comes up where.

And I didn't want to push it too far, and Alex is right to press me on the case issue. I am not sure I was sufficiently clear on that. It was really -- and probably muddied the waters by even bringing it in at that point.

DR. SHAPIRO: Thank you. We could go on a long time, but I think it is time for a break. Let's take a break for about 20 minutes, certainly, no more than a half an hour, and reassemble -- we

will start looking at the legal/policy issues. But I am sure we are going to get back to the issues that are still on your mind. Thank you.

(Whereupon, at 10:28 a.m., a brief recess was taken.)

DR. SHAPIRO: Okay. If we could call the meeting to order, please.

Just a small issue regarding some of the draft materials that are being distributed. If you recall, back to the outline of the report we distributed sometime ago, the report will include an executive summary. Indeed, the executive summary will be right up front in the report. That is not the intention of the introduction. If you look over the outline, you will see that. The executive summary, obviously, is going to have quite a different flavor than that, whatever happens with the existing introduction.

Finally, I want to, before we begin our discussion, I do want to remind the Commission that at 1:15 today we have our public comments section.

That means that whenever we break, we really have to be sure to be back here for 1:15 not to inconvenience those who want to speak to us, and it is important that as many members of the Commission be here for that as schedules allow. So that will be at 1:15 today.

That means we are going to break in no more than an hour from now so that we have -- I suppose we are in an area of the world

where you can get lunch in an hour. I don't know, but I am hoping that is the case, and so we will try to be back at 1:15.

Obviously, our discussions today, as, of course, the report, as it evolves, have a good deal of overlap in these various kind of artificial sections we have developed for purposes of mobilizing our efforts. Certainly, a lot of the issues that were discussed this morning already deal with legal/policy issues and so on.

I am sure, as we discuss these issues, where Alta and Alex have been providing us the leadership, we will go back -- find ourselves back into some of the ethical and other issues as well. So, Alex, Alta, I don't know which one of you wants to begin this.

#### LEGAL AND POLICY ISSUES

PROF. CHARO: Oh, well. Thank you. We have distributed around here an outline that Alex wrote up for us of one approach that we could consider. It is titled, "Baby-Making Draft, May 1, 1997."

DR. SHAPIRO: Just to be formal and sober about it.

PROF. CHARO: You will notice, first of all, it does continue the distinction we are making between uses of cloning that aim to initiate pregnancies and uses of cloning that do not. It starts with the ones that are contemplated with regard to pregnancies.

So it puts out on the table the following proposition that might well have gained enough support now that there is a

consensus with some meat on how you would implement it.

The proposition is that it would be wrong to permit for the indefinite future any attempt to transfer to the uterus an embryo created from human oocyte and the nucleus of a somatic cell of an existing human being.

The reasons for this are the ones that the people who were discussing ethics this morning have outlined. They have been briefly summarized here on three lines: safety; deep concerns, which I think is everything except for physical safety; as well as the need for more time for public education and discussion.

And then puts forth the following series of steps that could be taken to implement this particular policy recommendation, assuming that this is what we want to adopt.

First, that we recommend a continuation of the moratorium announced by the President on March 4, that is, that no federal funding would be used to use cloning to make babies.

Second, to ensure that any research going on anywhere in the United States, or subject to U.S. jurisdiction, any research going on, that involves the transfer of a cloned embryo to a uterus would be subject to human subjects protections, as outlined in the Code of Federal Regulations.

That means IRB review and because it would involve pregnancy, and therefore, fetuses, would invoke the special provisions, if this were HHS funded -- we would like to see that

these provisions be invoked more generally -- that require minimal risk only.

To call, however -- even given that that would exist -- to call, nonetheless, for a voluntary moratorium on this practice throughout the United States, to be implemented by the relevant societies of both researchers and clinicians, in other words, to cover the waterfront of all the people who might be involved in using the technology, whether it is pure scientist, scientist/clinician, or regular old doc.

And we have strong indication from the reports that came back to Carol that there would be compliance with this.

And then, subsequently, down the road, if it appears that a voluntary moratorium is ineffective, that considering be given to carefully drafted legislative prohibitions.

And if there were to become necessary, to go down a legislative route, and I should point out to you that some of the states will pre-empt this by going ahead and passing some state legislation on this -- that is their purview ---

But thinking now at the federal level, as well as guidance for the states, that if that legislation ever were to be drafted, that it ought to include some sort of sunset provision that allow for re-examination of the issue as both information about the safety and as discussion about the ethics of it continues over time and experience with it continues over time.

And that that legislation should include -- if it doesn't include a sunset provision, some kind of ongoing review by an appropriate body. So you would want sunset provisions or a body to do review, or both.

And, finally, that -- this is not on the paper. This was added. If, under any circumstances, there ever was to be clinical application of this permitted, that we need to emphasize the existing protections in the context of research regulation, which should be extended to all persons, as well as in the rules of clinical medical ethics.

And this goes back to what Diane was saying earlier today about informed consent, etc. that are part of a larger set of protections we have for people in these settings.

But also to emphasize the gaps that exist now concerning things like the ownership and control of human tissues, over the definition of kinship relationships, gaps are problematic if this ever were to become a practice and need to be identified here.

So that, in a sense, this is a proposal for a multi-staged kind of moratorium that takes advantage, as fully as possible, of all the existing protections we now have; extends them wherever possible; calls on voluntary compliance from the scientific and medical communities; and contemplates over time, with more experience with both the moratorium and the technology, the possibility of legislative interventions that are carefully drafted.

It then, on the issue on research that is not leading to pregnancy, proposes that we describe the benefits that have been identified from working with this technology, both in human and non-humans, at the level of cells and embryos; describe the current constraints because of federal funding constraints, state law constraints on the actual practice of research that involves embryos; try to observe and identify as much as possible the research of value that will be allowed to go on with public funding that does not use human tissue; and therefore, leave the audience with a clear understanding of exactly what is or is not at stake in the remaining areas of research that can't be done. But it is limited to this descriptive function. That is it.

DISCUSSION

DR. SHAPIRO: Thank you very much. Oops, a few hands. Bernie and then ---

DR. LO: Zeke actually was first.

DR. EMANUEL: I just want a point of clarification, if you don't mind. I am trying to figure out, if anyone were to go to do baby-making, they would have to be a clinician.

PROF. CHARO: Right.

DR. EMANUEL: Right? And their medical license would be at stake, it seems to me. One of the enforcements you could have on the private sphere ---

PROF. CHARO: Right.

DR. EMANUEL: -- is that we could say, this would violate medical practices and standards, and their license should be automatically pulled. Now, that doesn't require state law in terms of legislation.

PROF. CHARO: Right.

DR. EMANUEL: -- additional legislation, and yet it is not exactly voluntary. It seems to me if there could be a sort of very important middle ground that I would like to see.

PROF. CHARO: Yeah. The role of the professional societies is very important here, and I think the clear statement by the AMA that we got back was very instructive.

Because the AMA continues to stick to the position that it is medically inappropriate to do this. That exercises strong discipline, both on the state bodies that interpret their own rules as to what constitutes inappropriate medical practice, as well as on private enforcement through litigation, as well as on just the exhortatory function of what doctors will do.

In a sense, it is still "voluntary," because it is up to the AMA to make that position known, which is why we are saying it this way.

The problem with going down this kind of multi-stage moratorium route is that we don't get the cooperation we are expecting, it won't work. But that is why the legislative stuff is put on at the end as a back-up if the collaborative approach with the

professional societies is not enough.

DR. EMANUEL: I guess my question to you, Alta, is: Can't we go a little further than saying, we are relying on the AMA to say, in our judgment at this point, right, this would be grounds enough? We don't obviously have authority except that the medical boards in various states would be able to appeal to us as the justification for that action.

PROF. CAPRON: Well, yes and no. To respond as the other co-chair. It seemed to me we were talking about something where you are correct to say voluntary simply meant non-legislative moratorium. It could be understood to mean each individual would restrain herself, himself, from going forward. It meant more than that.

It meant through the force of existing malpractice laws, licensure laws, and so forth. We can say that we believe that those should be used in this way. We have no authority to force them to be used, and frankly, the licensure laws on that kind of issue, I don't believe, are an enormously effective mechanism. We certainly haven't seen that exercised in related areas, it seems to be, very effectively.

DR. EMANUEL: -- I am sorry ---

DR. CAPRON: I don't want to name names, but there are a lot of people who have been involved in some very unsavory behavior, and as far as I know, the state has not yanked their medical license.

DR. EMANUEL: Well, let me just observe two things. One is it does seem to me valuable to distinguish the voluntary from the regulatory from the legislative.

PROF. CAPRON: Yeah.

DR. EMANUEL: Which we don't do here.

PROF. CAPRON: Yes, I agree with you.

DR. EMANUEL: Second ---

PROF. CAPRON: I just wrote it down here.

DR. EMANUEL: There is a recent case in California, I think, where two guys just did a liposuction of 20 pounds.

PROF. CHARO: What is their name?

(Laughter.)

DR. EMANUEL: The lady died.

PROF. CHARO: Details, details.

(Laughter.)

PROF. CHARO: But she died thin.

DR. EMANUEL: And their license is being pulled. This is California.

DR. SHAPIRO: All right. Now that we have ---

PROF. CAPRON: A homicide doesn't upset me.

(Laughter.)

PROF. CHARO: They are still licensed in Wisconsin.

DR. SHAPIRO: Let me go to Bernie and then Bette.

DR. LO: That is the last time I cede my place in line.

I want to make a comment and then a question. My comment follows up on Zeke's point, and I also would like to encourage us, under this sort of voluntary non-legislative list, to, fairly high up, encourage the state licensing boards to adapt as their own guidelines the rule that if you violate this voluntary moratorium, that would be grounds for professional discipline.

I think that is really important. Although I agree with Alex -- the licensing boards are weak, and they do funny things -- a lot is at stake. It is a lot easier if they adopted proactively as a warning than have someone do it, and then someone raise the complaint, and then you have expert witnesses, and what the standard of care is. It is a mess.

But I think my real concern is that I don't trust people who are in a position to attempt to clone someone.

I think the history of reproductive innovations is that the people are very eager to try innovative things at a point when a lot of sort of scientists don't think the procedure is ripe. There are financial pressures, prestige pressures, to do so.

There are some really unsavory examples of ART physicians doing things that they thought was no problem, and everyone else thought it was grossly immoral. And there wasn't any hook to get them on. So that people looked around and said, well, what can we do?

You couldn't do anything, because, you know, it wasn't a

crime, but it wasn't even unprofessional conduct to take some woman's oocytes and give them away to someone else without her consent or knowledge.

So I think that with that background, I would like to put whatever we can, knowing that it may not be very effective.

I actually really wanted to ask a question, which was -- I, unfortunately, couldn't attend your discussion last night -- I think this was a very compelling and clear position, which I personally agree with ---

PROF. CAPRON: This isn't a position. This is the chapter. This is the whole ---

(Laughter.)

DR. LO: But I was wondering -- someone earlier on alluded to the discussion, and I am sure it was a very rich and kind of thoughtful discussion. Could you give us a flavor or it and particularly -- I think Harold said that for a while, people were talking past each other, because they were using terms in very different ways. Could you kind of give us a sense of that for those of us who weren't there?

DR. SHAPIRO: Well, just before Alta answers, I would say that the most heated discussion last night occurred over the order in which the food arrived, for those of us who were eating dinner.

(Laughter.)

PROF. CAPRON: And we plan to put that in the final

report.

DR. SHAPIRO: That is right.

PROF. CHARO: By the way, Trish, I have to tell you that I went ahead and ordered something else when I got back to my room, and the bread came right away. It was probably Trish's bread from back then.

DR. SHAPIRO: And just to report on one of the issues, and then I let Alta and Alex -- the broader issue. On the particular issue I was referring to had to do with what I think of as cellular cloning and not the same thing as dealing with embryos, dealing with cell lines that are created from whatever, and it was important that we not talk about it in those terms and we use embryo when we mean embryo.

PROF. CAPRON: A misunderstanding. We thought he was talking about cellular phoning.

PROF. CHARO: Bernie, I am going to start by giving a summary of two areas of discussion that took a while for people to clarify. Alex, I am sure, will remember some others clearly that I have lost.

One had to do with whether to go for broke and start with a legislative response and what the advantages and disadvantages are of a legislative response as opposed to this multi-stage response that takes into account existing protections.

And legislative responses, in some ways, would be better,

because they send a stronger message. They are clearer. In a single swoop, you can take care of a fair number of problems.

On the other hand, they suffer from the following disadvantages: First, if you are of the opinion that it is possible to imagine a time in the future when it would be appropriate to revisit this moratorium, legislative bans are much more difficult to overturn until you have got a substantially -- a pretty strong interest group lobbying for it.

And the option of using a legislative sunset provision to ensure such an opportunity in the future is a good mechanism, except that it is not likely to survive the legislative process upon the initial enactment of the legislative ban.

So if you are strongly of the opinion that you want to be able to revisit this, then legislation runs a risk you will never be allowed to revisit it.

The other thing that, personally, but I don't think this was widely shared, but I will tell you anyway, that I think of a disadvantage to legislation is that it invites a judicial, a court-based, challenge, coming out of the area of Constitutional law, which Alex and I and a number of law professors that I have talked to, and I gather he as well, and Lori Andrews, all have as our best guess is a challenge that probably wouldn't survive.

That is, that the legislation would probably be upheld, but it is a challenge that would be a hassle factor. It is a

distraction. On occasion, injunctions are issued to prevent the implementation of a legislative enactment, pending resolution, depending on how strong the harm is that is alleged. You can't forward, etc.

So simply the fact that you can challenge it raises some questions, and ironically, a moratorium, because it is not legislative, is more resistant to challenge. It is a real irony, in some ways. If it isn't broken, it can be actually far more -- far stronger.

On the other hand, the bottom line is that with legislation, you have a much stronger deterrent effect against single acts. Because with a moratorium, there are few penalties for breaking the moratorium that have strong, strong teeth that will help you to be sure that not a single person will break it.

Now, we have got a very good history of moratoria in the research community. Not such a clear history one way or the other in the clinical community and some concerns in the IVF community, although that experience is driven by a large body of people who wanted those technologies, a body of people that haven't yet emerged in this context. So we don't know what the pressures would be for a clinician to go forward.

But, you know, with legislation, you can have strong penalties, although that won't necessarily do it. You know, you have a death penalty for murder, people will still murder. But you can

have the strongest possible deterrent.

So this was this discussion of a legislative approach as the first bite versus as the back-up. Maybe I should stop there, you know, because the second one had to do with the relative emphasis on baby-making and non-baby-making applications. Maybe I should stop there, though.

DR. SHAPIRO: Okay. Let me just say something. Then I want to turn to Bette and then Alex.

Just to complete what Alta was saying, it is also true that drafting appropriate legislation is a serious challenge in the time we have available.

PROF. CHARO: Thank you.

DR. SHAPIRO: As a drafter -- I have never drafted legislation -- but I think that is also an issue that was in the mix of the discussion, just to give you a flavor of that. Bette.

MS. KRAMER: Well, I came in late last night, and I missed this discussion. So mine was a question, and that is, was there a discussion about including a sunset provision and/or an ongoing review by an appropriate body within a moratorium? Or is that technically not feasible?

PROF. CHARO: As a matter of fact, you remind me that there was, and I may turn it over to Alex here, because he was very much a part of that session.

PROF. CAPRON: Dr. Freud was at work here. Alta was not

very enchanted by the notion of some review body.

PROF. CHARO: And I completely forgot we talked about it.

(Laughter.)

PROF. CAPRON: There is a paragraph she didn't read in this outline, but it is missing on her copy, I think. And on that point, the thought was that, again, in the limited time we have, we are not in the position to really design a review body, but we can talk -- let me talk about the review body for a second, and then we can go back to the sunset.

We could, however, as this paragraph says, talk about what the goals of such a process would be, and one thing that was brought out, which I thought had a good deal of support -- I know Harold resonated to this, and I think Larry may have as well -- was all this educational issue that Diane and Eric and others have been pushing.

That is going to require some impetus. That if you have a body that has concern in this area besides sitting passively back and waiting for developments that are worth reviewing, it could be a generative, proactive group. So that was linked in there. And that we could describe different kinds of groups that could fill that function.

And Harold said, well, NBAC might be able to do this, particularly if the amount of materials necessary to review are, for the foreseeable future, quite slight. Of course, our charter does

say that we can't get into case review of individual applications, but we could talk about different alternatives there and then sort of put that out to the policymakers to say, here are things that you might choose among.

On the sunset side, the major difficulty, and I think Larry had raised the sunset idea, the major difficulty that we all talked about is there are certain ways of phrasing a sunset that aim toward describing the conditions precedent before changing things, and Rhetaugh suggested that as an alternative.

The idea of a sunset with a certain number of years kind of arbitrarily says, we don't think that this issue will be ripe for reconsideration for five years or two years or ten years, when you pick a number, and say, as Alta said, at that point, by having it sunset, you force the process to look at this.

The question that I have is about our word moratorium, and I think we need to be clear that I think the word is being used - - if you are talking about confusion in terms -- in two different ways.

One is to emphasize the notion that whatever it is we are talking about only lasts for a period of time. We are not saying -- the prohibition on murder is not a moratorium on murder. It is a prohibition on murder, because we cannot understand circumstances where it would become justified to engage in what is called murder. There is war, but there is murder.

But in this case, there are some people who take that view. That the ban ought to be a ban forever. There is no question. It is not a good thing to do. You should outlaw it, prohibit it.

There are others who say, well, right now, mostly the safety issue, and then there are some other lingering things we should be talking about. Maybe we will work those through once the safety issue has come up.

So that is the time aspect to the moratorium.

The other is this notion that it isn't legislative. That is not clear at all. If we are talking about federal funding, that could be achieved by an Executive Order.

The President says, you can't spend federal money on it, or to be achieved by the kind of legislation that is in the appropriations language, where you say, none of the money for this year shall be spent.

But if you are talking anything broader than that, you are then talking about some enforcement mechanism. For the moment, the staging idea says, the initial enforcement probably ought to come out of the private system, malpractice limitations, professional standards, professional licensure. Those are all things which are not criminal, but they are a strong impetus.

But it might get to legislation on the state or federal level. It could still be, at that point, a moratorium, however, even though it is legislated. So when Alta was saying, the advantage of a

moratorium over legislative, those two are not -- those are not ---

PROF. CHARO: I was using the word differently. Yes.

DR. SHAPIRO: Okay. Jim.

DR. CHILDRESS: I actually wanted to follow up -- my question, I think, though, builds nicely on what Alex was saying. There is a political context question, given the interest that emerged in Congress about some prohibitive legislation.

Is what we consider a back-up possibility likely to emerge earlier, given concerns about the limitations or inadequacies of moratorium? I don't have an answer to that. And if it is the case that there would be a lot of pressure to go that direction, should we say more about what a prohibition ought to look like? Not in any detail, but should we offer some kind of guidance?

PROF. CAPRON: I think that was where Harold's comment about cloning cells and cloning DNA and so forth comes in. That any moratoria, any legislation of the type that was introduced, has got to be exquisitely careful in describing what it is that is the problem, lest it squelch other things that are appropriate and don't raise the same kinds of problem.

We could talk about the disadvantages of legislation that doesn't have a sunset clause in it, but we would then be faced with people who would say, I am sorry, Alta, you know, the fact that someone overturned this through lobbying doesn't bother me. Because if there is ever a group that is affected enough to make this a real

problem, they will come forward and persuade us to lift it.

I think there all we can do is probably describe that that is an issue. That if you don't sunset it, you then require that force to come forward. That might not bother some people, people who are more on the really ban-it side will say, fine.

DR. SHAPIRO: Okay. Steve.

MR. HOLTZMAN: A couple of points. I think it is important that we be very clear, as we have been stressing throughout this, and I think it is a great idea, that if there is legislation, here are the key distinctions that need to be made.

I think we ought to point out one of the benefits, potentially, of federal legislation is the potential pre-emption of a bunch of diverse state laws. Though that is an open question, whether it would pre-empt.

Clarity about moratoria. There is a difference between federal -- in some of the things I have read -- there is a big difference between moratorium on federal funding versus the kind of moratorium we are asking for, where we say, people don't do this *per se*.

I have two questions about your second document, or the second step of, "Ensure that any research involving transfer of cloned embryos is subject to human subjects protection."

First off, are we saying any procedure involving transfer should be subject? So, therefore, we are saying that the research

versus clinical distinction is not an operative distinction here.

PROF. CHARO: This is very tough stuff.

MR. HOLTZMAN: Okay. That is a question I think we need to declare about. And the second is, and I don't know what the answer is, what does it mean to ensure? How does one ensure?

PROF. CHARO: Right.

MR. HOLTZMAN: Does that mean passing legislation that says that these things, which currently only apply to federally funded or undertaken by federally funded institutes, now has to be extended beyond?

PROF. CAPRON: Very good question.

PROF. CHARO: One thing that we can do that is consistent with a developing theme in the Subcommittee on Human Subjects is to recommend that there be legislation that extended human subjects protections to all persons, not just those that are in the settings that are currently covered.

That would mean that if anybody were to proceed in a research setting to try to use this technology to initiate a pregnancy, they would be covered by those regulations that currently exist, to which the legislation would be referring. That still does not cover the clinical context.

Can we also recommend that legislation identify this technology as not only experimental, but demand that it always be treated whenever it is done as a form of research? That is a

trickier thing.

There is an attorney in New York working with their state legislature on exactly that notion. That in New York State, this would be defined as research and, therefore, would come under their state research regs, and he is not yet sure that it is going to be doable.

And there are, of course, reasons why sometimes you wouldn't want to legislate that something is research, because then the realities can outstrip the legislation very rapidly. But it is something to work with, to see if that is usable.

Notice that this is all against, however, a backdrop of expectation that none of this is going on. So these are background protections. Should it happen despite the expectation that it won't, here are the protections that would still be in place.

So that something that falls through the cracks of a legislative prohibition, or a legislative moratorium, or a voluntary prohibition, or a voluntary moratorium, would, nonetheless, not fall through the cracks into a scenario of no controls, but at least fall into a scenario of some controls.

PROF. CAPRON: I am not sure that is an answer, however. It says you recognize the problem, but it doesn't yet say -- is there a basis for saying, to ask of this area -- there are two reasons we have a set of human subjects protection.

One is the notion that a person is being used for the

general good. You are participating in something in which the desire to produce generalized knowledge might override the normal protections that adhere in a physician/patient relationship, and in order to keep that from happening in a way that is bad, we set up these protections.

The other is, we have these protections because the level of risk in activities that are novel is much greater, and we need the protections for that reason.

The latter reason would certainly apply to something that a clinician is saying, well, I am not doing research. I am just doing a clinical innovation called, creating the first cloned baby. But I am not doing research on that. I don't belong to a research institute.

But the latter would certainly apply as a reason. We can talk about that, and that is really, I suppose, where the New York lawyer that you describe is trying to see, can you define it and put all the emphasis on that. The problem, of course, is that the federal regulations define research in terms of the production of generalized knowledge.

PROF. CHARO: Exactly. That is the stumbling block, and so you would have to freshly and independently legislate on just this point. And that is the stumbling block. So, really, it is an implementation problem, not a conceptual problem, necessarily.

PROF. CAPRON: But the question is: Do you address

cloning alone, or would this be a statement that recognizing these two channels, these two reasons that lead into the human subjects protections, as a general matter, we want to regard human subjects protections as applying to forms of clinical innovation, even though a person says, well, I don't have a control group, or I am not planning to publish this. And I don't ---

PROF. CHARO: And this is a big topic. It is a particularly big topic in the surgical area, far greater in terms of numbers of people affected than by cloning, even if cloning got popular, is the phenomenon of surgical innovation and its falling through these cracks of definitions of research.

And so you have identified something that actually plays into a huge area. I am being cautious in my responses, because not having really thought through what people want to do in that area, I don't want to say anything.

DR. SHAPIRO: I think the -- I have Zeke and Larry want to speak in a minute -- but I think this issue of trying to figure what kind of federal intervention is appropriate into medical practice, which is what physicians and patients believe is going on, is a very difficult issue. I don't know if we can quite get our hands around that in the time we have. Zeke.

DR. EMANUEL: I just want to go to this issue of a moratorium and a sunset provision. I mean, it seems to me that there are generally two kinds of -- we can either have a time-limited

moratorium, or we can have a condition-limited moratorium.

PROF. CHARO: Right.

DR. EMANUEL: You don't address it here, and I guess it is somewhat hidden. But if you have a time-limited moratorium, then the sort of impetus for a review body is less. If you have a condition-limited moratorium, it has to -- I think the reason for a body to review the conditions and whether they are met is very high.

I personally find the justification for a time-limited moratorium quite weak. It is completely arbitrary. It is based upon our prediction here in 1997, etc.

Therefore, I think -- and I think, similarly, flowing from the ethics considerations, the condition-limited moratorium seems much more justifiable, which does push us, I would say, to the idea of thinking about a body, at least suggesting some bodies.

PROF. CAPRON: Could you state the conditions?

DR. EMANUEL: Well, I would think you would need -- advancement in animal research would be one of them.

PROF. CAPRON: To what point?

DR. EMANUEL: Ah ---

PROF. CAPRON: I am not trying to be difficult.

DR. EMANUEL: No, no, no, I understand. I understand.

PROF. CAPRON: When you start talking about those conditions, you have to be able to state them.

DR. EMANUEL: I am standing on one toe, but it does seem

to me that when it is -- you know, we are going to use some weasel words -- reliable to grow up, where we are sure that they have normal longevity and not a premature death.

I don't know what else. That the, I guess, the fetal wastage, the number of ones, because of the increased problems from manipulation, would be sufficiently low to other procedures. Wait one second.

But there also seems to me to be a second, besides just the scientific advancement, a sort of moral condition. I mean, what we have been talking about in the ethics group is the sort of deliberative process that we are encouraging, because the arguments aren't completely resolved.

It seems to me that part of the condition has to be that we think there is some, you know -- closure might be a little strong -- but we are developing or seeing some consensus.

The arguments have been developed. People are either strongly for objectivication or strongly against objectivication. It doesn't have that much weight. That seems to me also to be important for these considerations about the conditions that we might put on it.

And let me just tag on this one footnote to that. If we do believe in this deliberative process, I think we would have to -- while I completely agree with everything Eric has said about education -- it seems to me deliberation involves more than education

and maybe would require us to spur or to suggest that the government or this body or whatever actually do some -- encourage, maybe even financially, people to think about this in a process. I mean, it is not just going to happen again out there. People actually have to focus their attention. It seems to me we might go beyond just the normal request for education, but talk about, you know, maybe ELSI should put aside some money, or whatever mechanisms.

PROF. CAPRON: Even if you had a sunset provision, the notion was that the legislature is going to have to return to -- or the NIH directorate -- or somebody is going to have to return to this issue, you could still have a reason for a body to be doing some ongoing thinking, deliberation, education, about this.

Because the notion would be that the usual legislative process deals with these kinds of issues extraordinarily badly. Because they are long-term, and they require a thought process that doesn't fit with legislative committees.

And if you have that ongoing, then when the legislature sees the clock ticking and says, we are going to have to make a decision again in six months, that is when the body comes forward and begins to educate them and the world again. Here is what has happened in the thinking on the safety side, on the ethics side, on the public consensus side, and so forth.

DR. SHAPIRO: I agree with you, Alex. In both cases, it is desirable to have an independent body, but in the condition-

limited one, it is almost necessary.

PROF. CAPRON: Well, you have to have somebody to make the judgment of have the conditions been fulfilled.

DR. SHAPIRO: Larry.

DR. MIIKE: I don't make a distinction between a condition- and a time-limited moratorium. Clearly, if you are going to have a time-limited moratorium, you cannot do anything until the time expires, and then you have a flurry of activities.

So one must have -- the purpose of a time-limited moratorium is to force the relook and not an automatic extension. So that all of those conditions are being discussed in the meantime. So it is a merger of both. But that was just in reaction to what you were saying.

But I want to comment in terms of what specifically we are recommending and also to respond a bit to Jim Childress's concern about losing control of legislation or putting it first.

I don't think we necessarily have to say which we prefer. That we prefer a gradualism approach, or we prefer a radical legislative approach. We can lay that out. Whatever we recommend, we are not going to control what happens to what we recommend.

I know there was some discussion in the past, I guess, last night, about we don't want to go into -- and it was Alta, I think -- we don't want to get into a legislative moratorium with a sunset clause, because they will have a legislative moratorium with

no sunset clause.

Well, whatever we recommend is thrown out, and then it hits the real world and not our little circumscribed world over here.

So I think, for my preference, would be to say, here is the range of activities. If someone out there decides -- I mean, if the end decision is that I am going to leap toward the end, that is something out of our control.

But what we can say is that if you leap toward the end, here are the kinds of things that you have got to worry about, and that is, I think, what we should be doing.

DR. SHAPIRO: Yes?

PROF. CHARO: May I just -- I would just like to interject a question in this. If we did not, as a body, strongly recommend that there be some kind of sunseting, if we were comfortable, as a body, with the idea of an indefinite prohibition, you could have a much simpler approach here, which is a simple recommendation for legislation that clearly prohibits this, period, end of story.

Here are the things the legislation has to do. It has to be very carefully drafted to make these distinctions, and it has to be done with enough attention to findings that you can hope to withstand a challenge Constitutionally.

I don't know. Maybe there is enough support around the table for that. There has been an assumption here that a sunset

provision is required if people want to be able to revisit the issue.

But I just want to double-check.

MS. FLYNN: Could I just speak to that one? I am glad you raised that, because I have been sitting here wondering why we don't do that. But then I believe that the legislative process is quite dynamic.

That there is huge set of growing interests that will be very much focused on these issues and that there, you know, there is no need to build into this potential legislative effort a sunset provision.

There are no end of ways in which pieces of legislation, both state and federal, get relooked at on a regular basis. This will be a high-profile, very actively engaged-in area.

So I have been having sort of a disconnect here, knowing what the conversation has been about how concerned we are; knowing that we see some tremendous risks, both in the technology and in the readiness of our society to deal effectively with these issues; seeing that we are comfortable with a federal moratorium continuing.

And you asked my question, thank you, about how we would ensure in the second set. I haven't really understood why we would want to, in my view, kind of fail the common man test. We say a lot of reasons why we need something, and then we say but we really are not sure we want it.

We really want to make sure that there is a lot of stepping back from it, and even in terms of any legislation, should there be any, which we are not currently on this paper recommending. We want to make sure it is really not too long and too strong.

You know, we have to decide where we are on it. If we really think it is a bad problem, we really think we aren't ready, we really think the education isn't there, we are really worried about not the federal stuff, but the stuff outside that scope, and we know that legislative initiatives are coming, you know, we need to get clear where are we on that.

And, again, I would urge you to realize, as you said, this little group is so not representative of the people outside looking at this issue that I think we risk making ourselves look like we are not in touch with the real issues as they play out for real people in their lives.

PROF. CAPRON: Can we get more responses to Alta's questions?

DR. SHAPIRO: David ---

DR. CAPRON: Yeah. It is a response to Alta's question, and it is my own personal conflict of the two things that Lori brought up, okay. The personal conflict I have is the stick and, at the same time, having ongoing discussion.

I think what we are doing is we are saying it has to be one or the other, and I don't think it has to be. I think it is

possible to have a strong stick, what Lori is advocating, but I think even -- not more importantly -- but equally importantly is that we have a mechanism for ongoing discussion.

Because I, for one, am extremely uncomfortable having that ongoing discussion be the stake-holders with the most to gain or lose for the discussion. I think that is the real problem. That is why we have a NBAC right now, because we need mechanisms in this country to have ongoing discussions that aren't determined by NBAC, but are framed by NBAC.

So I think this cloning is one great example where we can have that ongoing discussion, not because -- and I really like this idea of NBAC being the group that can do that. It goes on for a long time. I don't think it has to be tied to sunseting or not, just so that we have a forum for that.

But this is what I have been conflicted about, and I must say, when you said it, Lori, it sort of clicked in for me, is that you could have both. One doesn't preclude the other.

DR. SHAPIRO: To respond to Alta.

PROF. CAPRON: My sense is, I think, related to what David just said, although I come to a slightly different conclusion.

But the reason to have a moratorium, that is to say, to have a sunset or other provisions that would say it will end, is because our report has to be done in two weeks.

And the kinds of arguments that you would have to marshal

and the clarity and strength with which you would have to marshal them to say that it should be decided now -- not for all time, because any legislation can be reversed by -- but presumptively decided in this way unless there is enough social force to overturn that in the future, and to put this -- in other words, put this issue behind us ---

And say, we have decided that question -- there are a lot of other pressing issues -- we have decided cloning, can't do it -- it is against the law -- requires more work than we can produce between now and whatever.

So I had thought that part of the appeal, maybe being a psychologist about this for a moment to people around the table of moratorium, was it is easier to say, don't do it now, and it requires more thought and public discussion than it is to say, don't do it, and it is over and done.

And then maybe that discussion will happen, David. If we have it as a topic, fine. We can have it as a topic, but we ourselves will have more pressing things. The reason that a moratorium says to you, you have got to keep discussing this, because it is going to be back on the table in a year, two years, five years.

It is going to be back on the table. You had better be in a better position to have a coherent, well-thought-out things to say about it than we have now.

This is largely uncharted territory, Francis Pizzuli (?)

notwithstanding and so forth. I mean, it has been talked about, but it has largely been off the shelf, or off the table, for a long time.

That is the reason that, Lori, that I just think that if we were to be recommending legislation and facing a skeptical committee, what is the basis and where are the legislative findings that this legislation is necessary? What exactly are you preventing and why? Why do it? I just don't think that those arguments. That we haven't developed them.

MS. FLYNN: Can I just respond? I agree. If we are dealing with a two-week time frame, we can't do all that. But that doesn't mean it doesn't need to be done, and that doesn't mean we don't need to be the people to take the leadership in trying to do it.

And I would much rather see that happen in a thoughtful process even over a larger period of time. I don't believe it is impossible to imagine that we could develop a paper that says, we think this needs to be done. We realize that these are issues that require more developed discussion and thought, and we are committed to being a resource in that process, not necessarily delivering the entire package and having everything all refined at this point.

Just parenthetically, I happened to be having a discussion about a whole set of other issues -- we deal with the

human subjects issues -- with Harold Varmus about two weeks ago, and his reaction was, he had no expectation that we would be able to define in great detail any of these things in the time frame that this Commission was given by the President.

The best we are going to be able to do, at least in his view, and I think I represent it fairly, was to articulate some of the parameters that will then need to have continuing work. Because this is a subject that we are not going to put behind us when we turn in the report. I mean, this is going to continue to be out there in a variety of ways.

So I understand your self of we don't have enough time to do the whole job. I don't think we need to do the whole job. I think we need to own the whole job.

PROF. CAPRON: Right. I guess the answer then -- the way I see that connecting to the question that Alta poses is: What should you think should happen now, if you say ---

MS. FLYNN: I think Zeke described it.

PROF. CAPRON: -- this isn't the time to go forward, and all these other things, and our responsibility for continuing the discussion are all there.

If you answered Alta's question by yes, we can put this all aside. We can say, recommend a legislative ban. Then that really takes it off the table. At that point, you say -- then we would have to come forward with a report that really would say, these

are the reasons why it should be allowed. I mean, these are the reasons in favor of cloning.

That really changes things around. That puts us in the odd position, or any other group with the responsibility, in the odd position of making out the affirmative case in favor of cloning rather than saying, well, it is still disallowed. Now, what further thought can we contribute to whether this disallowance should continue or should not continue?

DR. SHAPIRO: Okay. There are other people who want to speak. Carol and Bernie.

DR. GREIDER: I would also like to respond to Alta's question. As I understood the question is, should we ban or should we have a moratorium or something with a sunset clause?

And I agree with Alex for completely different reasons. I don't think us having a short time frame is a reason to choose one direction or the other. I think we should decide what we are going to do, regardless of the time frame.

I, however, am not comfortable with the just ban position. I would prefer the moratorium with the sunset clause or legislation with the sunset clause. That comes more from my scientific background. I just don't have enough information.

Things change over time. I don't feel comfortable saying, no, period. I like the idea of having some sort of a review process. That is the reasoning.

DR. SHAPIRO: Bernie.

DR. LO: Let me pass.

DR. SHAPIRO: Let's see who else we have got here.

David. David, do you want to ---

DR. COX: Well, I have already said -- and I won't say -- I keep going back and forth on this, but because as a scientist, I really like it being open.

But I have got to tell you, okay, that right now, when I think about ways that I am ever going to be able to check the safety of this with respect to human beings -- this may not be a very ethical point -- but it is one that I am looking at a lot, okay, I can't see how to do it.

And I am so worried about the stick in terms of being able to make sure, okay, that right now, people don't go and do this that I must say that legislation is appealing to me. My mind is open about it. I don't feel strong. I am on the edge. But Lori has put me over to the edge to the legislation ---

DR. SHAPIRO: Bette.

MS. KRAMER: Well, I would agree with Lori that we need to take ownership of it, but I would be against legislation. Because even though legislation can be overturned, I think that is a far more difficult process than -- I would like to see us continue the moratorium.

Ideally, I would like to see us be a reviewing body. I

am not sure that we need to really spell out all the conditions under which we would recommend a lifting of the ban. Because it seems to me that a part of the reviewing commission's obligation should be to have scientific people on board continuing to report, to survey the science as it develops.

And I think it is very hard even -- it is even hard to put a sunset clause on, because we don't know how quickly or how slowly the science is going to develop. So I would be in favor of a reviewing body and opposed to legislation.

DR. SHAPIRO: Let me make a comment about this issue from just my own particular perspective. One of the things that characterizes this area, at least as I have come to understand it, is there is a heck of a lot we don't know. We don't even know for sure what the Wilmot experiment teaches us. We don't even know that for sure.

We don't know for sure at all what is going to happen six months from now, and we probably can't even define, in my view, easily a piece of legislation. The history of this area is this is very tough territory in which to legislate in a way that doesn't get you into more trouble than you would bargain for.

My suggestion is, however -- without having to resolve that immediately -- my suggestion is that we ask Alta and her colleagues to draft something here along these lines. Let's see what it really looks like. Because there have been a lot of very useful

suggestions regarding malpractice and licensure and so on and so forth that have come up, which we can incorporate in.

And then we will take a look at that. We have the legislative possibility as a back-up. If we are not convinced, if it doesn't look good enough for us, if it doesn't make too many of us feel uneasy, then, of course, we can always -- we still have some time to reconsider.

It seems to me that that is a useful way at least to get there into our first drafting phase here, and then we will see how it looks. David.

DR. EMANUEL: I like that, and I wholeheartedly agree. The one thing that I keep in the back of my mind is I get worried of having the deliberative process short-circuited by some guy out in California -- where else would he be -- who does this in his own lab without -- privately.

I mean, it seems to me that is a serious danger. That the process we are looking at could be short-circuited, usurped, as it were, by one person doing it or trying it with the outcome being positive or negative.

I mean, then you are just going to get a huge amount of emotion without any reasonable deliberation like, you know, happened in Scotland. I mean, the advantage of Scotland is it forced some deliberation. I think if someone does it on human beings, it is

going to short-circuit the process.

That is why I think a -- ban may be too strong a word -- but throwing all we can to keep even the private sector at abeyance is very important.

DR. SHAPIRO: Bernie. Then we are going to break after this remark ---

DR. LO: A couple -- it seems to me as if we are really getting to the core of what we are being asked to do, and it is very useful. A couple of observations.

First, Lori's basic question of what is the reaction going to be from the country as a whole. I think the other issue is what is the reaction going to be from the world. If we have a voluntary moratorium, and people in other countries are enacting legislative bans, there is going to be a lot more pressure to do it here as opposed to, you know, the Bahamas or something.

Secondly, I guess I share everybody's concern about how to draft legislation, but maybe we can sort of try to compromise, where we say, we are going to put in place the strongest things that we know how to do on a temporary basis. And one of the things we are going to do in that time period is not just continue to deliberate and educate, we are going to think about trying to get somebody to help us think of drafting legislation. Because some people -- I mean, there are different kinds of arguments I am hearing about

legislation. Some have to do with the difficult drafting legislation on this topic and how if you say the wrong thing, it is going to have effects you never intended. That is an addressable problem if we get skilled people who, you know, are experienced at this. There are others who may feel that it doesn't matter how good the law is, there are problems with putting -- freezing things in time, putting things on the shelf, and stifling discussion -- (inaudible). But I guess I am uncomfortable sort of not thinking through what all the options are. It seems to me this is the dilemma any time you make public policy. You never get the chance to think it all through in as great a depth as you would like. Just like in medicine, you never get all the information in time. So you make the best decision you can. I think our question here is: Given everything we know in sum, are we going to do better by recommending legislation now, albeit imperfect, in order to forestall the rogue physician who is going to do it and, you know, leapfrog over everything? Or are we going to try and be more deliberative, but accept what I think is a very real risk that there is going to be a lot of prestige or notoriety -- there are going to be people who are going to want to try this -- (inaudible).

DR. SHAPIRO: Let me see -- I am sorry. Bernie. I apologize for interrupting. These are very helpful and thoughtful comments, and we really have to, I think, not make any final decision now, because these things still need to be considered.

I think the way to consider them is to try to draft

something, and we will work our way through that as quickly as we can and see how we feel.

I have to say on this kind of rogue character out there we imagine, it is a terribly difficult issue. I am sure there are people, and we have seen them in other cases.

What is equally surprising, however, is even when you have legislation, it is not always implemented, and as a matter of fact, people refuse to implement it. Anybody who tries to implement it gets thrown out of office. This is a very complicated set of issues, and that won't stop it, but it may be worth it. I mean, it is just ---

DR. LO: I would like to say, what is striking to me having been dragged into some of these scandals after they happen is that IVF physicians say, no one ever told me that was wrong. Show me where it says that is wrong. I didn't think that was any problem.

PROF. CAPRON: I was just borrowing the eggs.

DR. : I am going to have to tell the woman it was my sperm.

DR. SHAPIRO: Could I just ask one ---

PROF. CAPRON: He was convicted. Cecil Jacobson -- I mean, when you get to defrauding patients. Cecil Jacobson was convicted right here in northern Virginia. So, I mean, there are some limits. The lines were crossed, and I don't have the sense that prosecutors if you had a -- well, I don't have any sense that

prosecutors would have trouble going after people.

DR. SHAPIRO: But look at the case in Michigan right now in these assisted suicides.

PROF. CAPRON: That is because society is dramatically of two minds about this.

DR. SHAPIRO: That is exactly right. Okay. Let's -- I just want -- a logistical question here. Let me know what people's schedules are this afternoon. What deadlines we are up against in that respect. Let's just go around. Steve, do you have any deadline?

MR. HOLTZMAN: I have a 4:30 flight.

DR. SHAPIRO: 4:30. David?

DR. COX: Leaving here at 3:30.

DR. SHAPIRO: Okay.

DR. : Yes, leaving here at 3:30.

DR. : I am here all night.

DR. : Here till 3:30.

DR. : (Inaudible) -- flexible.

DR. SHAPIRO: You are not anxious to spend too long.

DR. : There is a thunderstorm in Chicago. I can't get out.

DR. DUMAS: I'm here overnight.

DR. GREIDER: I have a 4 o'clock train.

DR. : Six o'clock.

DR. SHAPIRO: Okay. We should try -- first of all, try to all be back here for 1:15 pretty promptly, and we will try to finish in the 3:15 area, if we can, to accommodate as many as possible -- thank you very much. We are recessed ---

(Whereupon, at 12:13 p.m., a luncheon recess was taken.)

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

DR. SHAPIRO: All right. Let me call this part of our meeting to order, please. There are four people who have told us they would like to address the Commission. I hope they are here. At the end of that time, if there are others in the audience who would like to address the Commission, they are certainly welcome to do so.

The rules are -- that is five minutes for each speaker. When the time approaches, I will ask the speaker to wind up their remarks. So let's begin.

The first one who called in was Mary Lyman Jackson, president of the Exodus Youth Services, Inc. Ms. Jackson.

STATEMENTS BY THE PUBLIC

MS. JACKSON: Thank you, Mr. Chairman, and members of the Commission. My name is Mary Lyman Jackson. I am the co-founder and president of Exodus Youth Services, Inc., an ecumenical Catholic ministry to thousands of at-risk children and families on the streets of our nation's capital.

Exodus reaches out to homeless, run-away, latchkey, and refugee children who have slipped through the cracks of the social service network of Washington, D.C. Exodus's mission is based on developing the principles of human dignity, personal responsibility, morality, and love of neighbor with the poorest of the poor.

I have come before your Commission today, Mr. Chairman, as a concerned citizen. I am not a biochemist or a research

scientist, but I do have some ideas about cloning that I would like to share with you.

I live in Gaithersburg, Maryland, in a nice suburban community, but spend a lot of time on the streets in Washington. I am very conscious of the way the differences between these two communities are developing, and it worries me.

I hear people talking about life in the suburbs in ways that are very different than from life in the streets. And it is the differences that concern me.

I do not know of anyone in the suburbs who has birth control pushed on them, but my girls in the inner-city do. They tell me a different story. And I do not know of anyone in the city who expects to get any benefit from genetic engineering.

For 11 years, I have walked the streets of the nation's capital, risking my life for the lives of many suffering children. I have been at shoot-outs, and I have had every weapon from kitchen knives to Uzis pulled on me. I have held dying children and cried with young mothers who lost their little boys in drive-by shootings.

But I have also witnessed many children giving up drugs and turning to God. I have rejoiced with teen-agers who have left their gangs and gone to college. I have cheered with disabled kids who receive their high school diplomas despite all odds. I have buried the dead and encouraged the living.

These wonderful people deserve to know that God loves

them, and that we will all stand with them during their many trials.

The gap between the rich and the poor is growing. The poor feel that they are not wanted. This is the message that we are giving them.

Human cloning makes this worst. Cloning removes human dignity and the mystery of life by allowing us to play God. Human life cannot be disposable.

It is not just that the best reproductive technology means better babies in the suburbs and dead babies in the city. Cloning also makes everyone think about people as products that you can buy with new and improved models coming out every year. Being treated like a thing does not help anyone.

You and I watch America become more and more commercialized. It is just heartbreaking to see the same thing happen with birth. Cloning is just one more way to treat people like property, to focus on the material things in our lives, and miss the deeper spiritual realities.

I tell you one thing my street kids know. They know they have dignity. They know when you treat them with respect, and they appreciate it. But they see a lot of disrespect. I think they can see some things that great scientists might miss. Cloning is not a very respectful way to treat human life.

A researcher can get lost in charts and graphs and test tubes and petri dishes and might forget that human life is very

precious. These kids get treated as specimens and research objects enough that they have a different attitude towards all this science.

These children know that scientists can treat people like things. They know it, because they have seen how much work goes into persuading them to get on birth control or have an abortion.

Mr. Chairman, and distinguished members of the Commission, please consider the sacredness of life. Please do not recommend human cloning as an acceptable path for science. If we persist in this genetic engineering, we will be limiting human identity, human sexuality, life, and parenting to a test tube.

We cannot lose sight of the fact that God is our creator, and that He made us in His image. We dare not alter that reality. We need to learn to respect all human life, to take personal responsibility for our actions, to teach morality to our children, and to protect the dignity of human life.

Thank you, Mr. Chairman.

DR. SHAPIRO: Thank you very much. Are there any questions from members of the Commission? Well, let me thank you very much for -- to be here today, and also express just personally my admiration for what you have done in your own personal work. Thank you very much for coming.

MS. JACKSON: Thank you.

DR. SHAPIRO: The next speaker is Miss Paulette Roseboro, executive director, African-American Life Alliance.

MS. ROSEBORO: Thank you for the opportunity to present my -- what I have to say today. the African-American Life Alliance is an African-American biblically based and pro-life and pro-family organization located here in the Washington, D.C., area.

I have come before this committee as a concerned citizen, requesting that we debate and answer all the logical physical and moral issues involved in this process before there is any sanction, continuation of research into human cloning.

I fully support the idea that says just because we have a technological capability to do it, that does not give us the authority to interfere with the natural course of things.

Although many in the human genetic research field are saying that there is a vast difference between animal and human cloning, we are a cross-roads where we must stop and determine whether it is in the best interest of mankind to pursue technology that has the potential of manufacturing sentient beings.

First, there must be a responsible answer to the question: Why do we need to duplicate ourselves through cloning when there is a perfectly natural and effective method of population replenishment already in use by a vast majority of the world's inhabitants.

Conception has been extremely successful, since all of us here today are here as the result of that process, and for couples or individuals who cannot conceive, adoption has been proven also to be

very effective.

Considering this, why do we desire to duplicate ourselves? We should take a lesson from our Creator. In His wisdom, he doesn't seek to duplicate His creation. He causes each person to be conceived in a unique body, spirit, and soul.

He knows that it is from our individuality and uniqueness that we are able to work together and prosper and survive. Human duplication is solely for the sake of human vanity, and no vanity is ever productive.

However, vanity is expensive. Is it prudent or wise fiscal management to spend millions of dollars, and perhaps billions of tax dollars, in cloning research and the subsequent manufacture of individuals, if a process is developed, when there is already a successful process in use, conception.

In pondering this subject from another layperson's vantage point, I see a distinct difference between the material composition of the sperm, ovum, embryo, and mature cell. I see a distinct difference between conception of a new life and the manufacturing of sentient beings.

Conception has been understood to involve sperm and an ovum or a male of the species and the female of the species. The human experience starts with the union of seed material from a man and a woman, since sperm can only be produced from male and the ovum from the female.

The biological/chemical reaction that causes the generation of a new and unique DNA pattern from the act of conception must, by sheer material foundation, be different from the results produced from the joining of two cells in the cloning process.

Are cloned individuals covered by the laws of this country? Do the individuals manufactured from cloning and genetic engineering have an equality of rights as those conceived? If the answer to these questions are unanimous among the conceived population, are the cloned individuals to be covered by the various anti-discrimination laws?

Taking this further, as the African-American community becomes better informed about cloning technology, a growing concern has surfaced regarding the desirability of cloning material maintaining African-American DNA traits.

Since our country has not healed itself of bigotry and racism, is it not unreasonable to conclude that social biases within the scientific community, dominated by whites, will influence research to duplicate individuals representing itself.

By selective genetic engineering during the cloning process, Afro-influenced traits will be replaced with the more desirable Anglo-Saxon traits. Or will there be a desire to manufacture cloned individuals for domestic, athletic, and entertainment tasks, maintaining the Afro-influenced traits, enabling easy identification of the service class cloned or manufactured

individuals?

Has our lust for the authority to control life and death for our unborn children, our sick, and our seniors expanded to seeking authority over our genetic make-up also?

What is our responsibility to individuals given life in the cloning process? After generation of experimental purposes and service in their part of the research project, can we consider embryos conceived or cloned as guinea pigs, whose lives can easily be considered trash and tossed in a research lab's defective can for waste disposal? Does the shortness of their lives take away their humanity?

It is my desire that my appearance before this committee will encourage active debate on the matter of human cloning and its potential to unnecessarily bring suffering to individuals, whose humanity will be in question.

I will conclude by saying that other than for the vanity of the conceived human species, cloning has no use in a society which cherishes the natural reproductive process of conception. Thank you very much.

DR. SHAPIRO: Thank you very much. Thank you for being here. Just before you leave, let me see if there are any questions from members of the Commission. Again, thank you for taking the time to appear before us.

Is Ms. Sheena Talbot here? Ms. Sheena Talbot from the

American Life League would like to address the Commission.

MS. TALBOT: Thank you very much, Dr. Shapiro and members of the Commission.

I come to you today to speak on behalf of 300,000 Americans across the nation who are supporters of American Life League. Human cloning is a grave evil, and if allowed to go forward, it would be one more step down the slippery slope towards human tragedy.

Human cloning is wrong and an evil that should never be given even the slightest consideration. I want to present to you today that human cloning is wrong, because it is inherently discriminatory, because it usurps God's authority and replaces it with human control over human life, because it cheapens and totally disregards any respect for human embryos, and because it mandates a involuntary human experimentation, which violates the Nuremberg code.

First, human cloning is inherently discriminatory. Cloning is, by its very nature, discriminatory, because the genetic make-up of a human clone is deliberately chosen. The race, sex, height, build, etc. are all predetermined characteristics of the clone even before he or she exists.

German scientists, who are still haunted by the memories of the Nazi Holocaust, where scientists sought to engineer a master race of superior humans, warned against this extremely hazardous outcome just two days ago.

German scientists, mainly those of the German Research Association, and other experts are called for a worldwide ban on human cloning. Germany, as you know, as well as several other European countries, has already outlawed human cloning altogether.

The German Research Association and other experts calling for a worldwide ban recognize no moral distinction between human cloning research and the attempt by some German scientists to breed a superior Aryan race by exterminating people and groups whom they considered to be inferior and unfit to reproduce.

The end result of improving the human race is the ultimate goal of the eugenic movement, which is very much alive and well today. They want the ability, as did Hitler, to decide which lives are worthy of living.

Those who are free of disease or handicap or free of any undesirable characteristics are clearly the wanted ones. Those who are perfect will be deemed worthy of life. Those who are now, according to arbitrary man-made standards, will be tossed out with the day's trash.

Second, human cloning usurps God's authority and replaces it with human control over life. Whether by cloning method or another artificial process, humans manufactured in science labs would then be looked upon as the property of another.

But humans are not disposable biological material. Humans are not property. Human beings are not products to be used

and destroyed.

This country used to practice the belief that certain human beings were property and could be owned, bought, and sold by other humans for their own use. Although the slavery of black people will always be a scar on America's history, thankfully, they are now free and able to exercise the same rights as the rest of us.

The equal protection clause of the 14th Amendment states that we are all created equal. It does not say that we are born equal. It does not say that once we are adults, we are equal.

From the time you and I were created, we possessed certain inalienable rights endowed by our Creator, not by the National Institutes of Health, not by our federal government. And among those is the right to live, the right to be born.

If you endorse the idea that human embryos and human clones are simply biological property that you are free to tamper with as you wish, please keep in mind that some day, perhaps in your old age, or in my old age, someone may take your place here and may make the same decision about the elderly.

That they are simply biological property and no longer valuable to society. What if someone sits in your place some day and takes it upon themselves to determine that you no longer have value other than that to be used for experimental research and thrown away when done?

The power over human beings belongs alone to our Creator

God. Humans have no right to exert such extreme authority over the life and well-being of other humans simply because they are too small to be seen. Such an attempt to elevate oneself to the level of God is certain to bring with it inherent disaster.

Third, human cloning cheapens life and disregards any respect due to humans at their earliest and most vulnerable stages of development. Cloning violates the dignity of all mankind.

If cloning of humans is allowed, what happens if a clone is made that doesn't quite measure up to the standard? When it comes time for the quality checkpoint and the cloned human doesn't quite make it, what happens then?

In the Scottish cloning experiment, which resulted in Dolly, 276 out of 277 didn't make it. How many cloned human beings will have to be sacrificed on the altar of science in order to gain more God-like knowledge?

The research necessary to develop human cloning would certainly cause the death of countless human embryos. Human beings cannot be considered as a means to an end.

Human cloning involves involuntary experimentation. Again, as the Nazi scientists conducted ghoulis, inhuman experiments on persons against their will, so, too, human cloning dictates that humans will be created simply for experimentation research and eventually exterminated.

One of the most valued principles of medical ethics is

that of informed consent. The Nuremberg code states that the voluntary consent of the human subject is absolutely essential, and that no experiment should be conducted where there is *a priori* reason to believe that death or disabling injury will occur.

The International Covenant of Civil and Political Rights, which was adopted in 1966, and took effect in 1976, states in Article VII, and I quote: "No one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."

Also, French physiologist Claude Bernard once said: "The principle of medical and surgical morality consists of never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science."

The World Medical Association Declaration of Helsinki, adopted in 1964, states that, and I quote: "It is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out."

It also declares that "The interest of science and society should never take precedence over considerations related to the well-being of the subject."

In conclusion, I hope you will seriously take these arguments, as well as that of the previous testimonies you have heard

today, into consideration, and that you will decide right here today that this vile human experimentation, human cloning research, must be universally condemned.

As the German scientists, who were reported in Wednesday's *USA Today* said it -- they said it very well, and I quote them: "Human cloning should be banned worldwide and forever." Thank you very much.

DR. SHAPIRO: Thank you very much for your remarks. Any questions anybody has for -- thank you very much for taking time to be here today. Is there anyone else here today who would like to address the Commission. Yes, please come forward.

MS. TENNANT: Good afternoon.

DR. SHAPIRO: Please give us your name, please.

MS. TENNANT: Yes. Good afternoon. My name is Lisa Tennant, and I thank you for letting me talk today.

DR. SHAPIRO: Excuse me. We had your name on the list, and I thought you weren't here. I apologize.

MS. TENNANT: Oh, I am out in the hallway with my children.

DR. SHAPIRO: Yes. I understand. I apologize.

MS. TENNANT: That is fine. I live in Bethesda, Maryland. I am a homemaker by profession. I find it somewhat frightening that it is even necessary for our nation to discuss the morality of human cloning.

The very fact that we have asked the question, is it ethical, suggests that perhaps it could be. But, as humans, we must follow nature's law or else ultimately pay a high price. Nature's law in this regard is clear. Human beings come into existence, and are meant to come into human existence, through the covenanted passionate of a human father and a human mother. Human beings are not meant to come into existence through cloning. Nature never intended that.

Human cloning assaults the dignity of the human person. Human beings are not animals, and to treat them as such by manipulating them in their earliest stages of development is clearly a transgression against their personhood.

We do not have the right to experiment on a future possible person. Every individual and potential individual has a right to be respected and protected from such treatment.

Human cloning, if it were successful, is also a transgression against the person cloned. No one should come into the world in such an unnatural fashion. Human beings have a right to a normal biological beginning, namely, a human father and a human mother. Should a cloned person come into existence, the individual would be at a distinct disadvantage throughout their life.

To legitimize human cloning would send a message to the world that human life is of particular moral worth, but rather in the same power as, say, sheep. Is this

the message we want for our youth? And if it is the message that we send them, how can we fault them for killing one another in the streets of our nation?

Why is a laboratory, where life can be manipulated and terminated, a more hallowed place than the street corner? Human cloning should be banned. A moratorium is not good enough. A moratorium tells our nation that perhaps some day, human cloning will be ethical and accepted. A moratorium says that we may not be ready for human cloning now, but in our deep descent down the path of immoral permissiveness, some day it might be tolerated.

A moratorium, in essence, opens the door for the possibility of human cloning. We need a ban. Human cloning should be put to rest once and for all with an emphatic no, never. Thank you very much.

DR. SHAPIRO: Thank you very much for coming here today. Let me just see if there are any questions any member of the Commission have. Again, thank you very much, and appreciate your comments. Others that would like to address the Commission? Yes.

MS. WILLIAMS: Good afternoon. My name is Audria Williams, and I am the house mom for the Northwest Pregnancy Center for Young Teens and Young Women. I would like to address you today on the cloning. And I am also a mother. I raised a family, and I am proud of it.

I don't speak for anybody but myself. Sometimes, when

people speak for themselves, they turn out that there are a lot of other people who think the same way they do. Thank you for the opportunity to speak to you about the cloning.

I urge you to recommend to the President, we, as a nation, should ban cloning completely. Cloning is a way to treat human beings as things, as property. This national already has a shameful history of treating people as property, and I do not believe we should go back to that way in any way, shape, or form.

I am not property, and I am not for sale. I do not have to let anyone size me up and set a price on me or set a price on my person or set a price on my body. And I don't want to see anybody treat any human being as property.

I have children and grandchildren, and I even have a great-grandchild. So I know some things about where babies come from. But nobody in my family ever commissioned a baby. You can commission works of art or buildings or expert research papers on cloning, but if you can sit still while someone talks about commissioning a baby, something terrible has happened in this country.

But we don't want to -- I am sorry -- maybe slave traders and commissions to deliver people -- but we don't want to revisit that sad and immoral chapter of history. Because we know that that was wrong.

If the President's advisers sit around talking about

commissioning babies, I have to wonder if we have forgotten what the Civil War was all about. People are not property. When the war was over, slavery was over, and we all agreed that people are not property. People are different from animals, and we have dignity.

I am a Christian. I believe that God, who made the whole universe, knows me as Audria and loves me. I believe God loves me so much, he sent his only begotten Son to set me free. I believe God loves human beings with a very special and eternal love.

If God loves us that much, it is wrong to treat a human being like a guinea pig. It is wrong to discriminate against people because of color or religion or no religion at all, young or tiny. I don't think we become human beings when we get big enough to have arms and legs or smart enough to argue about cloning.

As soon as we are alive, as soon as we are growing, we are human beings with all the dignity of God's children. We aren't slaves. We aren't guinea pigs. We are somebody special. God loves us.

I want to say one more thing. When God told us that he loves us and he sent his Son to die for us, he told us very clearly that we are supposed to love each other as He loves us. If I have the dignity that God gave me, then I have a duty before God to protect other people who have the same dignity.

Don't treat people like things. I urge you, please, to ban cloning. Thank you very much.

DR. SHAPIRO: Thank you very much for being here today. Are there any questions from members of the Commission? Thank you very much. Anyone else in today's audience who would like to address the Commission? Okay. Thank you very much.

THE DRAFT REPORT: DISCUSSION

DR. SHAPIRO: Let's return to our agenda. Let me say something about how we are going about constructing the report. It is somewhat repetitive to what I said this morning, but just to bring our attention to that.

We have identified all the particular areas of the report. We haven't identified just how they are going to relate to each other yet. But we have just -- to remind you, in addition to the material that will be in front of the report, letters of transmittal, executive summary, so on and so forth, we have an introductory chapter dealing with background issues.

We have a chapter on the scientific issues, and then we have, following that, I don't know if it will be in these orders, is the chapter regarding ethical concerns and issues, religious perspectives. Then legal, regulatory, policy issues follow that, and of course, then our recommendations.

Now, we really -- my objective, perhaps will not be achieved 100 percent, is to have draft materials for all of these by a week to 10 days from now. Some materials have already -- are already in the process of being distributed to you.

To repeat what I said this morning, it is extremely important that each Commission member read those materials, take out their word processor or take out scissors and paste or whatever way you do to deal with this and let us know -- give us your suggestions.

Tell us what you like, tell us what you don't like, so we can deal with that as effectively as possible.

I hope we will hear from all those -- every Commissioner really, and those who have something they want to tell us about the draft materials that are in the process of being distributed, hopefully, early next week. That is Monday, Tuesday.

In addition to that, of course, we are drafting early this week the chapter on religious perspectives. Jim is going to give us some help with that, and we have, as you know, a very interesting paper that was commissioner in that area, which will be very helpful.

We feel pretty confident that we will have draft materials in people's hands sometime this coming week, hopefully, in the Thursday, Friday area, perhaps as early as Thursday, perhaps it will be at the end of the week.

Again, on that issue, we would like to hear back from you in two-three days. We just -- I apologize for what seems like extraordinarily demanding requests for people who, I know, are very busy with a portfolio of activities. But it is the only way we can get your input and meet our deadline at the same time.

I have asked Bernie to take the leadership in drafting the ethics -- the chapter or section on ethical concerns, and he has already made a start with that.

We had some very useful suggestions this morning, which I am sure will lead us to reorientate at least parts of it, and I hope that Bernie will be able to get that, at least to myself, towards the end of the week and to his other members of the bucket. And we will work from there.

Alta has also agreed to take the initiative in drafting material for the legal/policy regulation chapter, and again, presumptuous as it sounds, I am expecting that sometime later this week.

It is a tough, tough time schedule to keep to. But I think we have to do it in order to meet our objectives. If all that works out, really 10 days from now or so, you should have draft material for really the bulk of this report -- have to turn to articulating our recommendations and so on and so forth, which we will certainly do as quickly and effectively as we can.

So that is where we are. There is a lot of hectic work going on here in Washington by the staff, and of course, each of us in our own offices and places where we do our own writing.

So that is the next week, 10 days, which will probably be the busiest time we have as a group. I heard Bernie say before, and I just want to second that, he feels he has some degrees of freedom

to pounce on one of his members of his bucket to help out in areas where he does need help.

I ask you all to be as responsive as possible, because it is very difficult to put it all on the shoulders of a single person.

And I know you will be responsive if you get a call from Dr. Lo as you will be if you get a call from Alta. We will be helpful, both I and Kathi Hanna, who are working continuously in this area. We will be as helpful as we can.

On the science chapter is, I think -- it is my judgment -- but you will read it yourself over the weekend -- I think it is really in pretty good shape. There are things that Carol and David and others want to add to it, and that will be done also -- I suggested to Carol -- by Monday. And I hope that that is the case.

So this is -- you know, I am repeating myself by way of feeling just a little guilty to be so demanding. But I know of no other way to meet our 90-day objective. Now, our next meeting, which will be, in all likelihood, our last meeting, where we will be trying to tie this up and make our final decisions, at least get as close as we can, is May 17.

The report, we hope to have available -- I mean, available, meaning ready to send to the President -- it is not up to us to decide just when -- how the President will deal with -- roughly the Memorial Day weekend, perhaps the first day after the weekend, which is the 27th of May.

That give us 10 days between our last meeting and ongoing communications we may have to have over unresolved issues or issues on which you may disagree, issues deciding where we want to display our disagreement in the report, and indicate where we agree and where we don't agree.

Any member who feels very strongly about any particular issue may want to consider adding a note and so on. I am hoping there will be a minimum of that, because could be on in that area forever, but I don't eliminate it. Because you may feel very strongly on particular issues.

Consensus is wonderful in those areas where we can agree, but that is not everything. And we want to give as much information as possible to the President about how we feel on these issues.

So that is how I see the work going on before us. I will turn in a moment to see if there are any issues from this morning's discussion that people would like to revisit before we go on to at least hearing a brief report, status report really, from Drs. Childress and Murray on the ---

What we might think of as the other subcommittees, or at least the ones that we initially established -- themselves are carrying very important work. And there is very important work going on in that area. I think there really will be very interesting issues for us to contend with once we get this particular assignment behind us. Alta.

PROF. CHARO: Just by way of information, for people who are staying overnight, this evening, we have -- Randy, it is Conference Room I? Conference Room I is available for anybody who is staying overnight who wants to torment Kathi with the fleshing out of the outline that we have from this morning on policy.

I know some people who have already planned to stay overnight to help her do that. So feel free. We discovered last night it is difficult to get room service in that room. So you might consider bringing something in with you if you come. But we have the room for three hours while Kathi will be expanding the outline and drafting it.

DR. SHAPIRO: Thank you. Are there issues that came out of this morning's discussion that people would like to revisit at this time? Okay. Let's me turn then to Jim, first of all, to get a brief update on the Human Subjects Protections Committee.

UPDATES FROM THE SUBCOMMITTEES

DR. CHILDRESS: I will make this brief. We have continued to work a bit during this post-Dolly period, sometimes wishing we were able to clone ourselves, and be able to continue fully.

One important part has continued in this significant way, and that is the federal agency reports, the examination, the interviews, and am really very grateful to Bill Freeman, Emily

Feinstein, and Joel Mangel for the fine work they have done.

I had an opportunity, as I mentioned last time to participate in one of the interviews. Other subcommittee members, but also other NBAC members, may want to do so as well. Emily Feinstein will circulate to all of NBAC on e-mail on Monday the schedule over the next several weeks.

I know it is hard for people to work this into a schedule, given the other commitments, but it may happen that you will be in D.C. at a time one of the interviews is occurring, and you might be able to spare a couple of hours to participate in that.

This is going to be a very important report, I think, and I am glad of the progress the staff has made on it and appreciate the suggestions from members of NBAC and the subcommittee.

Second, we have three papers underway: one on cognitive impaired research subjects; another one on relationality and vulnerability, with vulnerability being one of the categories we have attended to several times in thinking about the ethics of research involving human subjects; and third, the changing nature of research and research paradigms, with particular attention to the implications for informed consent.

We are in the process of defining other papers and seeking other contributors on topics such as community, something Zeke introduced in our very first NBAC meeting; re-examination of the Belmont principles, to which attention has been directed at different

times today; and one of those especially, the principle of justice and how changing perceptions of justice play a role in the way we think about research involving human subjects; and, finally, compensation for research-related injuries.

So, as I mentioned, we are in the process of further defining those and seeking contributors.

In addition, at the meeting planned for June, we expect to have testimony from a variety of parties relating to issues that we want to develop further. One of those that we have worked on now for each of the subcommittee meetings has to do with research involving cognitively impaired subjects. And we hope to be pretty far along in thinking about pretty concrete recommendations in that area.

Finally, we have something Alta has proposed that has been considered in a faltering way, an ideal or principle of universal protection, that is, protection of research subjects in non-federally funded research as well as federally funded.

Questions have arisen about that. Whether we should develop the implementation strategies and consider those along with the articulation of the ideal or principle, and we will pay more attention to that the next time the subcommittee has a meeting, and Alta, after drafting the chapter and so forth, will get back to that as well.

That very succinctly, I think, covers the major topics,

but perhaps subcommittee members would like to add something.

DR. SHAPIRO: Thank you. Any of the subcommittee members like to add to Jim's report. I want to express my gratitude to Jim and all the members of the committee and also to the staff, who have done a really -- continue to work very carefully on this and turned in a good report.

(Applause.)

DR. SHAPIRO: Thank you, everyone. We are really making some good progress. Tom?

DR. MURRAY: You can say, now, in contrast, the Genetics Subcommittee has done a bit, that is, we have -- I am going to ask Trish if she is willing to, in a minute, to say something about the concept of the mini-hearing.

We have been working on ways of getting a non-scientific, but we hope, useful sampling of community opinion about human tissue samples and why they are important and what sort of concerns people have about them.

We have been working with this idea of having sort of local mini-hearings, not intended as a research project, but intended as a chance to get information from some concerned members of the public. Trish, did you want to add anything about that?

PROF. BACKLAR: No, actually, we are in the midst of putting this together, but our plan is to have focus groups with consumers, people who have been involved tissue research, whose

tissue has been donated. And that is our plan, to go around the country and have these focus groups of people who have had some experience themselves as subjects in genetic research.

DR. MURRAY: We are hoping -- I think it was four or five of these in different regions, five in different regions, five different regions of the country, essentially places where members of the genetic subcommittee are located.

I have spoken with a potential author of a paper on international perspectives on human tissue samples, informed consent, privacy, and similar concerns, and we are sort of in discussion about other authors of other papers.

But, really, it is a very brief report. We had, quite frankly, this has taken a back seat to the cloning problem.

DR. SHAPIRO: I certainly understand, but I again want to thank the committee members for their continued sustaining of this activity. It is an important activity, and as you will recall, it is a study that we were asked to do when the Executive Order established NBAC.

We have interpreted it in a particular way, and certainly, as soon as this is done, perhaps more of us will have to turn our attention and help Tom and his colleagues out in completing this aspect of our work. Any questions for Tom? Or Jim? David.

DR. COX: I just have a comment about this, and people are probably going to get tired of hearing this comment. It in the

context of tissue samples, but also in general, different vehicles by which NBAC can really go out and make sure that we are getting some kind of a sampling of the opinion in this country.

I don't really think that there is one opinion. We live in a very diverse country. But there is one thing that really sticks in my mind, and every time I think about NBAC, it sticks in my mind, is our meeting, international meeting, in San Francisco, where all of those other commission members from around the world said.

if there is one thing for a successful commission, it is to figure out ways to do that, to hear from a diverse group of people.

And I would just like to reiterate that I have been doing a lot of thinking about that, and I don't have a lot of solutions. But I would like to always keep that on our table, and particularly with respect -- I think that we have some good ideas for the stored tissue samples, but in talking with this with people around the country, I have had responses that, well, that is not going to be very representative. And how are you really sure?

Again, I like to come up with solutions, not problems, but I just wanted to put this on the table.

DR. SHAPIRO: All right. If you will make a standard exchange, for every problem you put on the table, we will ask you for a solution to some other problem that we have. Thank you very much.

I think that is right. I think we do have to think about

that, and perhaps once this kind of intense job here is done, we can really turn our attention to some of those issues and the issues that arise out of the report. Tom.

DR. MURRAY: Harold, this is, in part, in response to David's concern. It is the intention of the Genetics Subcommittee to do an actual opinion survey, a genuine national opinion survey, or at least to be added on to some larger survey. But it won't happen in time for the tissue sample report, but we will try to build it into next year's budget. It depends on there being a Commission, I am reminded.

DR. SHAPIRO: Any other comments, questions, business to come before the Commission.

DR. CHILDRESS: Could I just make one observation? Building on David's comment, I was very impressed, David, with the views we heard in our public testimony regarding human cloning, and perhaps when we get back to some of the other topics, we will be able to get more public testimony on those.

And I think if there is a mechanism for encouraging that, then perhaps we could do so. Because I found the positions presented today very stimulating, and the language in which they were stated challenging in terms of some of the categories we may not have used before.

DR. SHAPIRO: Thank you. Any other comments, questions? Thank you very much. Now, you can do an hour-and-a-half of extra

writing that we have just released. Thank you. We are adjourned.

(Whereupon, at 2:08 p.m., the meeting was adjourned.)