NATIONAL BIOETHICS ADVISORY COMMISSION

Thursday, March 13, 1997
8:07 a.m.

Watergate Hotel
Continental Chesapeake Extender Room
2650 Virginia Avenue, N.W.
Washington, D.C.

EBERLIN REPORTING SERVICE

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

ATTENDANCE

NBAC MEMBERS
HAROLD T. SHAPIRO, Ph.D.
PATRICIA BACKLAR
ARTURO BRITO, M.D.
ERIC J. CASSELL, M.D.
R. ALTA CHARO, J.D.
JAMES CHILDRESS, Ph.D.
DAVID R. COX, M.D., Ph.D.
RHETAUGH GRAVES DUMAS, Ph.D., R.N.
EZEKIEL J. EMANUEL, M.D., Ph.D.
LAURIE M. FLYNN
CAROL WIDNEY GREIDER, Ph.D.
STEVEN H. HOLTZMAN
BETTE O. KRAMER
BERNARD LO, M.D.
LAWRENCE H. MIIKE, M.D., J.D.
THOMAS H. MURRAY, Ph.D.
DIANE SCOTT-JONES, Ph.D.

PRESENTERS
DR. SHIRLEY TILGHMAN
DR. GILBERT MEILAENDER
DR. NANCY DUFF
DR. LISA CAHILL
REV. DR. ALBERT MORACZEWSKI

PUBLIC COMMENTS
NANCY REAME, Ph.D., MSN
JUDITH LAMB-LION
ROBERT W. WEISE, Ph.D.
MICHELLE THEIMAN

STAFF
HENRIETTA HYATT-KNORR
RACHEL LEVINSON
PATRICIA NORRIS
WILLIAM F. RAUB
WILLIAM FREEMAN
EMILY FEINSTEIN
JOEL MANGEL
KATHI HANNA, Ph.D

I N D E X

P R O C E E D I N G S

WELCOME AND INTRODUCTION

DR. SHAPIRO: Good morning. I would like to ask those commissioners who are here to please take their seats so we can begin this morning's session.

My name is Harold Shapiro, President of Princeton University, and I am here today obviously in my capacity as Chairman of the National Bioethics Advisory Commission. If I could have the attention of all of the commissioners I want to call the meeting to order and turn to Mr. Raub to open our meeting.

DR. RAUB: Thank you, Dr. Shapiro. I need add only that the commission operates under the authority and the terms of Federal Advisory Committee Act. Therefore, this proceeding will be public. There is a well structured and rather full agenda. I call your attention to the fact that on both days of the meeting there is a designated period for public comment. Several members of the public have already requested and registered for the opportunity to speak. There is still some space available. So those of you who would wish to address the commission either today or tomorrow, please contact my colleague, Henrietta Hyatt-Knorr.

Thank you.

DR. SHAPIRO: Thank you very much. Just to help both remind myself and other commission members, if you are speaking I think if you just press this button in front of you it works through the loud speaker system and the light goes on. I hope that all works very well.

Well, I wold like to welcome everyone. Once again this is our fourth meeting of the commission since we were appointed last summer. As you know, we have already had two regular meetings plus a meeting in San Francisco which was what we called the International Summit to consulted on the various issues of concern to the commission with our colleagues from around the world who are addressing similar issues in their own national context. Today, of course, will be the fourth meeting of the commission.

In addition, the commission has two main subcommittees that we have appointed so far. One on Human Subject Protection which is chaired by Professor Childress. One on Genetic Information, particularly looking at the particular issue of stored tissue samples, that is headed by Professor Tom Murray. We will hear more from both of those subcommittees later on this morning.

Those two particular subcommittees were appointed pursuant to the request that was outlined in the Executive Order establishing this commission that as our first priority we look at issues of human subjects protection and the handling of genetic information. So those two subcommittees were put together and have been working since last fall on those two issues which the President asked us to take on as a first priority.

Now, of course, as everyone here understands in addition to those tasks we received a new request in the last number of weeks from President Clinton to look at the legal and ethical issues to review those issues as it impacts and surrounds the issue of cloning, human cloning in particular, as a result of the rather stunning scientific

information and result that appears to have taken place in a research institute on the other side of the ocean.

So we are now in the process of mobilizing ourselves to respond to the President's request and we will certainly intend to do so under the time frame that the President outlined. I came across -- and I will have more to say later on this morning of just how we are mobilizing ourselves to deal with the President's request. I will deal with that in some detail after we have heard from our two subcommittees regarding our ongoing work of the commission.

But I did come across a rather interesting quote which came from Nature magazine. Now Nature of course is the publication which reported the results from the Roslin Institute and I have the following quote from an editorial in Nature which might impact how our commissioners proceed or how they think about what they are doing. The quote is as follows: "If ethical committees wish to brood about something tangible they should worry about cloning, still some way off but no longer out of sight."

That is not an unusual statement except that this comes from a February 1982 editorial in Nature magazine, which eventually, of course -- Nature also reported, of course, the recent scientific results. So it is -- while this is a stunning scientific achievement it has led to our new assignment which we will hear more about later as I said.

I have also, just speaking for myself, been -- I think stunned is the wrong word, that is too strong, but I have been at least some taken aback by kind of the unrestricted imagination that has been demonstrated by many commentators on this issue and, indeed, I find

that in terms of the national rhetoric on something which is really very important really quite troubling.

And in this sense I really want to take a moment to express my great gratitude to the members of the commission who have spoken to the press and/or appeared on television and other media channels who have, I thought, not only been extremely thoughtful and measured in their tone but have had, I think, a very salutary effect on the national discussion. I am very grateful to all those commissioners who have taken the time and to respond so thoughtfully to very understandable public interest in this area.

We, ourselves, as the commission takes on this task, again as I said a moment ago which we will discuss in some detail later on this morning, are going to be focused on trying to respond to the President's letter in a way that will ask ourselves what is often not asked out there today and that is why we believe certain things and why we will make certain recommendations.

So understanding why one has these opinions is going to be critical in my view in order to be able to speak effectively on both legal and ethical issues. So once again my thanks to all those commissioners who have played such an important part in the public discussion.

With that by way of review let me just say a few words about the agenda and then I want to say a word about the commission's staff. We will, of course, begin in just a few moments with a report of the Human Subjects Subcommittee. I will turn to Dr. Childress and his colleagues for that. We will allow approximately an hour for that

discussion. We will then turn to the report of the Genetics Subcommittee. We will turn to Professor Murray for a report on that and his colleagues.

Approximately 10:00 or 10:15 we will have our break for half an hour and then proceed to discuss the response to the President's most recent request. Really all the rest of today and tomorrow will be focused on that issue.

We will be hearing from a number of distinguished people who have asked to address the commission on various aspects of the issues that surround human cloning. We will hear from Dr. Shirley Tilghman on the science and technology issues.

We will then have a series of speakers this afternoon on various religious based perspectives on cloning and that will go over until tomorrow where that will continue through the morning, and then we will, ourselves, have time -- both a session with deal with the pros and cons from various philosophical or moral viewpoints, and of course our own discussion. And as Dr. Raub has said, we will have time for public comments on both sessions.

So we will it will be a very packed agenda from our point of view, very central to the issues that we, the commission, will have to make our own judgments about and we look forward on the commission to a very busy next -- I do not know how many days are left but somebody must be counting. It is very few dealing with such a difficult, complex issue but we certainly look forward to doing this with considerable enthusiasm.

Are there any questions from members of the commission regarding our agenda for today or how we are proceeding?

Thank you very much. Let's go then to the first item on our agenda which is a report of the Human Subjects Subcommittee. Jim?

REPORT OF THE HUMAN SUBJECTS SUBCOMMITTEE

DR. CHILDRESS: Thank you very much, Dr. Shapiro.

I will briefly report and be joined by members of the Human Subjects Subcommittee on our work since we last met. Our committee itself, our subcommittee itself, last met on February the 24th, which as you will recall is the day after the news about "Dolly" broke. And "Dolly" as you have heard altered NBAC's immediate agenda and shifted our immediate priorities.

As a result we have not advanced or greatly advanced the work of the subcommittee over the last two weeks but on the basis of my conversations with subcommittee members I would say that we really do not want to lose our momentum during this 90 day period. We have an ambitious undertaking and we want to continue working on that during this period even as we work on issues surrounding human cloning. So we hope to continue our subcommittee work, including having meetings as appropriate during this 90 day period.

Furthermore, we will need your help, particularly over the next few weeks, you will hear in our discussion today some matters that we want some feedback from you all over the next ten days to two weeks. For example, drafts of descriptions of papers that we hope to have people prepare under contract and also a response to the proposed

methods for studying federal agency compliance with the "Common Rule." I will come to those matters later.

Basically I hope to cover the following themes during this hour, and we will cover these very quickly: I would note that these are discussed in more detail in the transcript of the meeting for February the 24th. Of course, you have received a lot of material over the last several weeks and not only that transcript.

Someone has proposed in our subcommittee that we actually consider, and I mentioned this, and I am mentioning it now to our chair and to the staff, that we consider some way to have brief minutes accompanying the transcript serving as a kind of guide to the transcript when it arrives so that people can get a quick overview of what is there, know where they can dig into it in more detail particularly if they get on this disk they will be able to find very quickly the passages they want and study it in more detail. I think that may make our process more efficient.

Today I would like to deal first of all with methods and procedures for accommodating our mandated task of studying federal agency compliance with the "Common Rule."

Second, a request from the Human Subjects Subcommittee that NBAC endorse a recommendation to the President for a public apology to Tuskegee survivors and to the country on behalf of the Federal Government for the Tuskegee experiment.

Third, Alta Charo will introduce a proposal that we will take up in greater detail at the Human Subjects Subcommittee meeting

and at the next NBAC meeting regarding an ethical, principle or ideal of a universal protection for potential and actual subjects of research.

Then very briefly at the end I will say a word about what we are doing in relation to two IRB studies that are underway and the progress we are making on our general and specific topics for the subcommittee's work, and the topics that we want to get papers prepared on over the next few months.

So that is the direction we will go in this discussion. So the first is to consider methods and procedures for following through on our mandated task of determining what is happening in federal agencies in human subjects protection.

Now we have written reports from the agencies, and again you have probably received that batch of materials and have those materials somewhere in your office. If you do not have a complete file of those reports and would like to have one, please check with the staff.

It is important, obviously, that the subcommittee and then NBAC as a whole go beyond the written reports. So what we want to do this morning is discuss briefly with staff working on this particular area how we can go beyond the written reports.

You have met before Emily Feinstein and Joel Mangel but I think NBAC as a whole has met William Freeman who was with the Indian Health Service and has joined the staff to work specifically on this project.

So what I would like to do is have Bill or Emily, or Joel, or all three briefly indicate the plan for getting more information about the extent of agency compliance with the "Common Rule." And what you will

receive -- you have already received one draft. This is a draft to replace the one you received on methods. Bill and Emily will indicate that they will need feedback on this, not today because you have not had a chance to read it but by midweek, by Wednesday of next week. We would like to have you give them feedback on how this might be revised.

So let me turn to Bill and Emily. I guess Joel is not here today, is that right?

DR. FREEMAN: Yes.

DR. CHILDRESS: Okay.

DR. FREEMAN: Thank you very much. Since the subcommittee met two weeks ago, first of all we developed objectives that the subcommittee had not seen. We reread the responses to NBAC of the Federal Government organizations about how they protect human subjects. We then redrafted the questions based on those objectives that we developed and the responses that have been in NBAC for a while. We had everything re-reviewed by -- that is to say the questions and the objectives -- by several knowledgeable people.

Then yesterday afternoon we developed or drafted the protocol. It was a first draft done in an afternoon so I apologize for it not being polished but we wanted to get it to you today, this morning. That is why you have this revision and you can throw out the one that is in your packet that you received last night or in the book. We have revised the protocol a little bit and added three pages at the end which I will talk about.

The idea is to do the survey in two phases. The first phase is to interview appointed representatives that each organization

has appointed to work with NBAC that typically the secretary of the department has appointed. These are usually people in most organizations fairly high in the organization.

The second phase will be to interview people who are actually implementing the "Common Rule" and other protections for research subjects.

In the first phase we ask for information that the government does provide to the public on request. So it is not something special although it is more than they are probably used to.

In the second phase we do the same with more details but in addition we are asking, as you will see in the questions, a knowledge, attitude, belief, behavior survey to try to get at what are the incentives and disincentives and the knowledge base of the people who are actually implementing the protocol -- excuse me, implementing the "Common Rule" because we feel that if there is a problem with implementing the "Common Rule" it may well be in those organizational incentives and disincentives that people feel and experience.

We have an information sheet, that is what was added early this morning, for Phase I. It would be a very similar one for Phase II. I did not have time to do that. And then a -- what I call a "consent" for that KABB.

So one of the questions that this commission needs to look at and if possible feed back to us is, in fact, do you consider that as we propose, it is only a proposal or a draft, that aspect of Phase II, the KABB survey of Phase II, would be considered research and it has to go through an IRB.

The way we have done it, it is anonymous. There is no reason to keep the identifiers of the organization or the people responding about their own knowledge, attitudes and how they actually implement the rule if we are trying to find out what are common issues throughout the Federal Government and because it is anonymous it would be exempt from further IRB review but that is not a determination that the researcher does, that is a determination that the IRB does.

We would also, as Jim said, would very much like your feedback by Wednesday of especially the questions, especially Phase I but we would appreciate feedback from the entire protocol.

DR. CHILDRESS: Emily, do you want to add anything?

DR. FEINSTEIN: No.

DR. CHILDRESS: All right. Let's open it for discussion and response from NBAC members.

Bernie?

DR. LO: I was just going to say we have not read it so it is hard to respond.

DR. SHAPIRO: Jim, I have a question. Could you just say something about the time frame that you have laid out for this? It may be in here and I have not spotted it yet so I apologize for that.

DR. FREEMAN: It is not there. The time frame is -- we expect to have the report by October. We expect to have good results by the end of June or July. I suspect as you will look at the questions that we are asking much amplified from what they were for the subcommittee that we will not be able to do every federal organization certainly by June in certainly both phases.

So we are going to concentrate, we the staff, including Dr. Raub, have talked about whom should we -- what organizations should we target and we have a list of the ones that we want to do first. There are many federal organizations that responded that either are doing very little research in terms of amount or relatively low risk research like mainly surveys and they would be later in the process. So we will expect to have a product or information for the committee to consider at the end of June or early July.

DR. SHAPIRO: Thank you very much.

Jim, the only reason I asked this question is we, ourselves, are looking forward to a report in October which means that we have to have something to think about early enough on that is comprehensive enough, and it sounds to me that will be satisfactorily handled with your June-July for really pretty solid information. Am I correct?

DR. FREEMAN: That is correct.

DR. SHAPIRO: Thank you.

DR. CHILDRESS: And I agree that is important if we could plan on spending a fair amount of time at the July NBAC meeting discussing the results you have at that point. That would be most helpful.

Are there other questions?

Yes, Bernie?

DR. LO: I note that a lot of these questions are open ended questions and I think that is good because they will give us a lot of rich information. Do you have a plan sketched out for how you are

going to analyze this information and again to follow up on the questions about timing could we have sort of a timetable as to whether the analysis can feasibly be done on the schedule we are talking about?

DR. FREEMAN: Again the two aspects of the more typical information of forms and what are the processes and procedures that the organization does to implement the "Common Rule," we will try to collate it and put it into groups. The KABB, I have not thought about that. It depends -- I mean, actually I have thought about it and I do not know precisely yet.

It may be that we will be getting -- as you see, I mentioned this is really a qualitative interview. We may get some -- enough good qualitative information to use the standard qualitative software and methods to analyze qualitative information or we may do it in our heads. I would prefer to have it more rigorous and we will have to see what our resources are so that is as much as I can say at this time.

DR. CHILDRESS: Are there other questions at this point?

DR. FREEMAN: We would be glad to have recommendations about how we should analyze it as well from the commissioners.

DR. CHILDRESS: Yes. It is important to emphasize again that this is in process and this is the first time people have seen this. They saw some earlier versions of the questions in less developed form and it is important to get the feedback by next Wednesday particularly on the first part, on Phase I, because this is the part they would like to start. Phase II obviously will be longer in developing and there will be an

IRB review, et cetera, so they will give you more time on that but they would love to have your feedback on everything if possible.

Are there other questions?

DR. SHAPIRO: Jim, just a comment on the very last point that you made, that is the question of whether we will have resources to do the kind of analysis of the information you would like to do or what you think is most appropriate to do. I would just like to request from you, not now but after you have had a chance to think about, let me know what you would need to do it right because I am really quite determined we are going to do this right so we can meet the challenge of getting and pulling the resources together that you require. So if you could just let me know about that as soon as possible I would appreciate it.

DR. CHILDRESS: Yes, Laurie?

DR. FLYNN: Again I apologize for not having had a chance to review it and it may well be in here but one area I am interested in and wonder if it might be possible to consider as you phase out these interviews is whether or not these officials have any mechanism or have any information as they look at the implementation of the informed consent process, particularly with vulnerable populations as to identifying when individuals withdraw from research, to what extent their lack of understanding or their confusion may be a part of that, as well as any follow-up they may be doing over time with individuals who have participated as to their feedback or thoughts about whether or not the process was one that they found informative throughout and whether or not they were satisfied with the amount of information they received

not only at the signing of informed consent but throughout the procedures they were involved in.

I am interested in knowing if we can reach through some of this research to the individuals who are actually participating, most particularly those who may fall into the category of vulnerable populations.

DR. FREEMAN: We do have a section in both phases or both the higher level and the IRB level people on vulnerable populations. It does not include that. We will add that. I think that is very appropriate. I have done that personally in the Indian Health Service to ensure that the researchers did it. We did not ask for information back to the IRB. We just -- but it was part of the protocol that we asked the researchers to do and they did.

The -- let me add something that I did not say. We are not looking just at what the IRBs in the organizations are doing. We are also, as you will read it, very interested in what are they doing, the organizations, to assure that the grants and contracts, people who receive them, are doing. What is their oversight of those organizations' IRBS with the same kinds of questions? So we will add your comments but I wanted to make clear that we are not just talking about internal IRBs. We are talking about extramural research and oversight by the funding agency.

DR. FLYNN: Thank you.

DR. CHILDRESS: Any last question or comment?

(No response.)

DR. CHILDRESS: Bill and Emily, thank you very much, and Joel in absentia.

We would like to have your responses by e-mail and I guess we have your -- do we have your e-mail address, Bill? If not, would you make sure that we have that.

DR. FREEMAN: We will have it ready for tomorrow.

DR. CHILDRESS: Okay. All right. Thanks. Okay.

Any other comments on this?

(No response.)

DR. CHILDRESS: Again, thank you very much.

Well, let's turn to the second item on our agenda and that is the agenda of the Human Subjects Subcommittee's report to NBAC, and several mailings ago you received a copy of the report of the Tuskegee Syphilis Study Legacy Committee, co-chaired by Vanessa Northington-Gamble and John Fletcher.

This particular report was considered by the Human Subjects Subcommittee at its last meeting. It is a report that has also gone at least in modified form to the Clinton Administration. The Human Subjects Subcommittee recommended or recommends that NBAC recommend the following:

First that there be a presidential apology for the Tuskegee Syphilis Experiment, and in making this first recommendation we are joining a number of other voices that have also called for such action on the part of the Federal Government. We heard at our last meeting, for example, from Dick Schneider of the Centers for Disease Control, as well as other sources, about the discussion that has gone on in the

administration about an apology with several of the questions that remain having to do to a great extent with when, where, how to carry out such an action.

So we -- if we accept this recommendation, if NBAC accepts this recommendation from the Human Subjects Subcommittee we would be, in effect, joining a number of others who are also making such a recommendation and participating in a process that is underway already in the administration.

The second recommendation is that the administration also seriously consider other recommendations from the report that have been forwarded to the administration, not all the recommendations in the report I understand from Vanessa Gamble have actually been forwarded. For example, the one that has to do with setting up a Tuskegee Research Center. Apparently it was felt in further discussions that it would be better to have this proposal come from the community itself. So the second recommendation is that the administration seriously consider the other proposals contained in the report.

And third, and this is really directed to NBAC itself, that as a group -- as a commission we take to heart the lessons of Tuskegee and incorporate those into our discussions and deliberations, not only in the human subjects area but also in all the areas we addressed, that there be something from this experiment that, in effect, we keep in mind as we conduct our activities together.

There was a fourth that we invited Vanessa Gamble to join us for this discussion but we decided not to pursue that given the shortness of time today as a result of "Dolly's" appearance.

So let me ask Rhetaugh Dumas to comment on this and then Alta Charo, both very briefly, and then we will make this recommendation to NBAC.

DR. DUMAS: Thank you.

The Tuskegee Syphilis Study was conducted over 60 years ago but the details of that study became public in 1972, I believe, with an article that was published in the New York Times. The Legacy Committee intends to keep alive the memory of this study and its problems, and its impact, but at the same time to foster opportunities to move beyond that study to achieve more positive outcomes.

The study has become a metaphor which symbolizes, according to that committee, racism in medicine and ethical misconduct in human research, and the exploitation of vulnerable population groups in our country. It has affected adversely attitudes in general about human experimentation in research. So the study continues to cast a dark shadow on research, biomedical research on human subjects, and it is important that the impact of this study is addressed appropriately, and also that the lessons that can be learned are fully exploited and will guide people in research in the future.

Now the committee is asking the President to make a public apology and there is a precedent for this in the Human Radiation Experiments where the President made a public apology and indicated the importance of the American people recognizing the truth and the importance of the government admitting when it has made mistakes.

They would like to have the President make this apology at Tuskegee and preferably at a meeting of NBAC. So our proposal is

that this commission supports the recommendations that have been read to you and then we need to also take up the issue of the meeting at Tuskegee if the President should decide to follow this recommendation.

Is there something else I need to say about this?

DR. CHILDRESS: I think that is probably --

DR. DUMAS: That is okay.

DR. CHILDRESS: I think so.

DR. DUMAS: Any questions or comments?

(No response.)

DR. CHILDRESS: Alta, do you want to add anything?

PROF. CHARO: I am not sure whether or not it is needed now but briefly, Jim asked me just to mention something about the role of apology so far in the area of biomedical ethics.

As Rhetaugh has alluded to the survivors of the radiation experiments did receive an apology from the U.S. Government on behalf of the government and of the people of the United States for acts that took place years in the past. And this follows on a pattern now of looking to apologies as a form of statements of empathy, regret and beginnings of healing processes that include things like the apology to Americans of Japanese descent who were interned in camps during World War II.

In anticipation of some of the things that may be in your minds by way of questions I wanted to just mention that the members of the Human Radiation Committee debated the role of apologies and debated whether it was appropriate for apologies to be issued by people

today who were not personally involved in particular activities that took place in the past.

They had concluded in that context that apologies are not necessarily statements of personal culpability and pertinent to that particular set of concerns about the radiation experiments and less pertinent in the context of the syphilis studies they are not necessarily findings that the actions at the time that they were taken necessarily violated then prevailing ethical norms. That had been a debate on the Radiation Committee. In the end they did conclude those people had violated prevailing norms at the time but it was a subject of great debate.

Those are not necessarily concerns here. So that the request really is for a statement at the presidential level or requests for us to endorse a request for a statement at the presidential level of empathy and regret on the part of the entire government for activities that took place 60 years ago and are still having their effects reverberating today throughout the survivors and their friends and families, and the people who read about them.

DR. CHILDRESS: Rachel, would you like to add anything about the discussion that is currently taking place in the administration?

DR. LEVINSON: I can just say that it is true that the request has been received and the report itself, and it is also being discussed within the Department of Health and Human Services, and I appreciate the discussion over here this morning.

DR. CHILDRESS: Okay. Are there any questions or responses from commissioners?

DR. SHAPIRO: Jim, just on a tiny logistical issue, would you like the commission to consider really both trees -- both branches of this recommendation, both that we support the request for the apology and that the administration consider the other requests that are forwarded -- that have been forwarded by the commission? Do you want to take both together?

DR. CHILDRESS: We can take them together or separately. We have emphasized the apology. The apology request is made by the Tuskegee Syphilis Experiment Legacy Committee. The ones that come in by some other proposals, we are not sure about all the ones that have been forwarded, I thought Rhetaugh indicated one that was not, so we were saying in somewhat an indefinite way that at least there be a serious consideration.

DR. SHAPIRO: Well, if it is all right with the commission I would prefer to take those as two different proposals since one, I think, we are quite clear about what it is we might approve, the other is a less focused one and we are not sure even exactly what recommendation has been forwarded. I understand that you are just asking that we encourage consideration of these and we are not endorsing any of these but just careful consideration of those.

So if there is no objection on the commission we will consider a motion in front of us to support and back, and endorse, I guess is the word that is used, a request to the President that an apology be issued in this case.

Is there any comments, questions, concerns from members of the commission regarding this proposal?

(No response.)

DR. SHAPIRO: If not, all those in favor please say aye.

(A chorus of ayes was heard.)

DR. SHAPIRO: Opposed? That passes unanimously.

We also have a request from the subcommittee that we consider -- that we ask the administration to at least carefully consider other proposals that either have been or may be forwarded from that group to the administration. That is also a motion that is before us since it comes from a standing committee.

Any comments, questions, concerns about that?

DR. DUMAS: It might be useful for me to point out in general what the nature of some of the other proposals are. I understand that there have been some added but there was the concern about the necessity to somehow have tangible preservation of the memory of the Tuskegee Syphilis Study by having a museum where records would be kept and other information provided to keep the memory of this alive.

The other was to in some way recognize the impact of this, the adverse impact on the Institution of Tuskegee, the university itself, and to have some way of compensating Tuskegee for the consequences of this study. Those are examples.

There was another one, I think, that -- which I cannot remember. Oh, the third one was to have this public apology presented at an NBAC meeting at Tuskegee.

DR. SHAPIRO: Thank you. Larry?

DR. MIIKE: Is there any rush on this since we are meeting again in April? I am unclear about what we are endorsing so I would rather just sort of -- if there is no precipitous reason for addressing this motion I would rather wait until the next meeting.

DR. CHILDRESS: I am not sure there is on the second one. I think the first one is the one we gave priority to in discussion.

DR. SHAPIRO: Just to clarify, I also do not think that there is a particular rush or any precipitating cause that would cause us to move this. That is really why I separated these two motions. And the second one is much weaker in my judgment. I mean, it might be just as good ideas but all we are saying is to consider it as I understand the committee's recommendation.

DR. DUMAS: Yes.

DR. SHAPIRO: But, Jim, how do you feel about that? Would you rather wait until we know exactly what has been forwarded?

DR. CHILDRESS: I have no objection to that and perhaps Rachel could help us by helping us find out exactly what was forwarded from the report that everyone in the group had seen but we have not -- we do not know what was filtered through to the administration on that.

DR. LEVINSON: I would be happy to do that.

DR. CHILDRESS: Thank you.

DR. SHAPIRO: I think perhaps that is a useful suggestion but if there is -- that is if there is no objection from the commissioners then we could bring together a little more information by our next meeting and see exactly what has been forwarded since I, myself, am not

sure which of these recommendations have gone forward and which have not.

All right. Thank you.

DR. CHILDRESS: Then the third part, I am not sure we need to act on it formally, was that we take the lessons to heart of the Tuskegee Syphilis Experiment in our deliberations as a commission and that was an advisory one. I do not know that there needs to be any particular action on it.

DR. SHAPIRO: Thank you very much. We certainly -- we have, of course, distributed all the materials to all members of the commission and just relating my own reaction to the reading that all together in one place really presents a very powerful document, which certainly has personal impact just speaking for myself and I am sure the same is true of all the other commissioners, and we certainly appreciate the committee bringing this to our attention. It is certainly to impact how we proceed.

Thank you very much, Jim.

DR. CHILDRESS: Thank you. The next item on our agenda is to briefly consider a proposal that Alta Charo is making. Today all we intend to do is just discuss it briefly and then there will be a sharp precise proposal considered at the next Human Subjects Subcommittee meeting and at the next NBAC meeting.

Alta?

PROF. CHARO: You have had distributed to you a copy of the first draft of the memorandum that unfortunately was taken up too

late at the last subcommittee meeting to be appropriately redrafted so I welcome your input.

The thrust of it as follows: We have heard since our very first meeting that under current law at the federal and state levels there are people who are enrolled in medical research experiments, in theory, in the United States without any form of formal protection against being enrolled without their knowledge, without their consent, and without the protections of some third party review over the ethics of the experiment itself, its risk/benefit analysis and other aspects of its construction.

And the phenomenon of unregulated or unsupervised experimentation is one that just as a matter of principle is disturbing.

Following on from the Tuskegee Legacy report I think it is appropriate because it was in the context of those hearings in Congress back in the early '70s that a report was issued that said among other things that, "Congress should establish a permanent body with the authority to regulate at least all federally supported research involving human subjects...", and then it continued, "...ideally the authority of this body should extend to all research activities even those not federally supported." That is April 28th, 1973. Next month will be the 23rd -- 24th anniversary of that report with a failure to actually implement that most basic of recommendations.

So what I had distributed to you does not propose to adopt any particular piece of legislation as its model, nor does it require that action be taken at either the federal or state level.

In other words, it tries to eschew any particular legislative approach because this is not a committee of legislative drafters, but

simply to identify as a matter of principle that the "Belmont Report" and the "Tuskegee Legacy Report" have clearly stated that justice requires a fair distribution of benefits and burdens of research throughout the United States, and that a fair distribution of burdens of research also will always include a fair effort to minimize those burdens, and that the only way to accomplish those goals is, in part, to assure the kind of basic protections that are represented by things like informed consent and third party review of experimental protocols.

So it asks NBAC to endorse the policy first recommended in 1973 by the Tuskegee panel and called for appropriate federal or state action to ensure that no person in the U.S. is the subject of research without the protections of informed consent and IRB style review as exemplified in the "Federal Common Rule."

Because we are unable to ascertain precisely how many people currently are enrolled in medical experiments without their knowledge and the precise degree of injury that they have incurred it has been suggested that this kind of statement be adopted without reference to specific findings or perhaps with reference to the fact that such findings are impossible to make in the absence of some kind of body that accumulates that date.

It is to that that I would like to turn your attention. Whether or not this is a good idea? If so, what is necessary in order to state it properly? And then have it brought back in April for final action.

DR. CHILDRESS: So we are clear now that we are just getting your feedback on the way in which -- first of all, if it is a good

idea to go in this direction? The second, how it might be formulated more precisely for purposes of our subsequent discussion?

DR. SHAPIRO: Thank you.

Any comments or questions?

Bernie?

DR. LO: Well, I think we would all support the idea that it is not a good thing to have research in this country that is not subject to third party IRB review or where the consent of subjects is not obtained.

I am a little concerned about what we hope to accomplish by this broad a statement which I think I and I think most of us would agree with or would there be some benefit to doing a little more detailed analysis of at least the policy options as opposed to specific legislation.

I am not clear how one would as a matter of practicality extend the requirements of informed consent and IRB type review to nonfederally sponsored research outside of institutions that require it for all research. So would it be helpful coming from this commission to have some discussion of sort of how we can -- what are the options for extending these types of oversight and guidelines? Otherwise I am just afraid that people will say, "Yes, we agree with it," but nothing will happen.

DR. CHILDRESS: As I understand our discussion basically it is one thing to affirm the ideal or principle. The question of implementation, whether it is done through some particular governmental action, through voluntary action of the various groups, that is something that we obviously will have to talk about over time and presumably will make some recommendation about.

But I guess the thought that Alta has had and others who have affirmed it as something else, you know, motherhood, apple pie and so forth, sure we can all agree with that but it is important to have that on the table.

Is it so important for us to affirm something like that knowing that we still have to face the hard implementation questions?

PROF. CHARO: I would also like to try to give a more concrete answer to the question of, "Why bother?", Bernie. Yesterday in the testimony before Congress concerning cloning in the context of humans, I found myself talking about the degree to which any child who begins with a cloning experiment would be necessarily the subject of medical experimentation.

So that if it turned out that cloning does work in other mammals and if it turned out that it then works in adult cells of humans, a child who is subjected to this kind of medical experimentation might, therefore, feel entitled -- we might, therefore, feel entitled that such a child is deserving of protection against dangerous experiments, experiments that are unreviewed, experiments that are taking place without the fully informed consent of his or her progenitors. I loathe to say parents now that they are genetic siblings.

And yet I could not say the National Bioethics Advisory Commission has already determined that as a matter of ethical ideal no person in the United States should be subjected to experimentation without appropriate review to ensure the experiment is scientifically important enough to merit the danger it poses to the subject.

As a result I had to work all around that because I could not say it and I thought, gee, wouldn't it be nice to be able to say that and then base some of the concerns about cloning on that instead of couching it all on the subjunctive.

DR. SHAPIRO: Other questions about this? Reactions?

DR. FLYNN: I just -- thank you. I just want to endorse the notion that a general statement of principle is always valuable and may in this climate be especially useful. But I think I share Bernie's concern that we not fail as part of our work to take seriously the need for policy options, the need to recognize that if we want to see the extension of the "Common Rule," particularly with regard to vulnerable populations in a rapidly changing climate that it is important that we allocate some time and resources to at least looking at policy options, at the realities and practicalities of implementation, and where within the various scientific and regulatory structures such action might be recommended?

With that understanding I feel comfortable moving forward but I do think it is important that we not lose sight of that very important follow on task. It is a very large agenda item but it is I think in my judgment very critical.

DR. SHAPIRO: There are a number of commissioners who want to speak. Let me just go down around this way and then back up.

Steve?

DR. HOLTZMAN: I have a -- let me get to my remarks by asking Alta a question. In your testimony or what you just said is that you wanted to conclude or you did conclude that there was a subject

who was a subject of experimentation. Who was the subject? Who or what was the subject?

PROF. CHARO: There are several. The person whose cells are taken for the adult cells. The person whose egg is used and the child who results if a child ever could result from this kind of technology.

DR. HOLTZMAN: So the question that it raises for me is I broadly support the principle and then the question is but in your last point there you are claiming implicitly that the subject -- you have got a subject which is not a subject yet who is the subject.

PROF. CHARO: No, not -- it is not metaphysical. I was speculating in the writing that any attempt at cloning technology in humans would necessarily require follow-up on the developmental integrity of the fetus and the child over time because of the questions surrounding the use of adult DNA to begin embryonic life. As a result that kind of continuing surveillance, testing, monitoring, evaluation would necessarily make the child a subject of experimentation at the time the experimentation is taking place with no metaphysical problems about the person who is not yet a person to be.

DR. HOLTZMAN: Because while broadly supporting what you want to do here the question that arises is what is the interpretation of it? I could reasonably have interpreted what you were saying as suggesting that there was a need for the informed consent, the person who does not yet exist, all right.

PROF. CHARO: At a certain point I think we have to trust that people will interpret things sensibly and realistically but I take your point.

DR. HOLTZMAN: But, therefore, could be used by some to be interpreted that certain kinds of experimentation can be done.

DR. SHAPIRO: Thank you. Any other questions here before going to the other side of the table?

Larry?

DR. MIIKE: Alta, in your proposed statement you refer to the Animal Welfare Act. Do we know anything about -- and that is broadly applicable. It seems to me that that has been around for about 20 years. What has been the practical effect of that? It seems to be directly on point about enlarging the human side to any type of experimental protocols.

PROF. CHARO: The most concrete expression of this idea is embodied in a bill that is pending in Congress right now. Many other bills could be written with slightly different bases that would extend the existing system basically to nonfederally supported, nonfederally multiply insured in non-FDA regulated institutions.

It is certainly possible that in the context of that bill information has been accumulated about the Animal Welfare Act. OPRR administers a program to oversee the Animal Welfare Act as well as human research. So we have avenues to get some feedback on how well that has worked.

DR. SHAPIRO: Again information on that would be helpful.

Other comments or questions on this particular issue because I believe Jim intends the subcommittee to meet sometime prior to our April meeting and to have a specific proposal for us to deal with at

that time. Any other comments, questions, suggestions would certainly be welcome right now but at any time between now and when the subcommittee meets.

DR. DUMAS: I have a --

DR. SHAPIRO: Yes, Rhetaugh, I am sorry.

DR. DUMAS: I have a comment. I think it is crucial that we have a statement of principle in line with the idea that Alta has presented. It is also conceivable that in trying to formulate policy options that we may not be able to figure out at this particular junction in history exactly how that might be implemented more specifically. But I do not think that that should in any way defer us or deter us in making the clearest statement of policy -- I mean, of principle that we can formulate.

DR. SHAPIRO: Eric?

DR. CASSELL: Well, I take it that the statement of principle is that no one should have research done on them without their consent but don't we want to go further and say that we are looking for it not merely as a matter of principle but as a matter of regulation for people not presently covered by the "Common Rule?"

DR. DUMAS: Yes, yes, I do.

DR. CASSELL: So we have two parts to it that we think that it should be -- I mean that the basic principle we all agree on and the second is that it should be extended to other groups.

DR. SHAPIRO: If I could just ask people to turn off their microphones when they are finished that would help the sound system I think.

DR. CHILDRESS: But, Eric, exactly how that would be done is a matter that would be further discussed.

DR. CASSELL: Yes.

DR. DUMAS: Yes. My feeling is it may not -- we may not know exactly how it can be done at this particular moment but I think that there should be some statement that would urge all diligent efforts to find ways to ensure that that is implemented.

DR. SHAPIRO: Jim?

Any further question on this subject? I know Jim has two other subjects he wants to get around to, the IRB studies and some paper topics. But is there anything on this since this will probably come to us for some action the next time we meet? No, when I say this, some proposal that has yet to be fully articulated. We will give as much notice as possible.

Okay. Thank you.

Jim?

DR. CHILDRESS: And thank you, Alta, and thank you commissioners for the discussion.

Please, if you have further thoughts about this, why don't you send them to Alta or to me and we will make those a part of our discussion at the Human Subjects Subcommittee meeting.

The last two items I think I can move through fairly quickly and we will be mercifully on time. How about that?

One area of concern for NBAC from the very beginning has been what can we learn about what goes on in IRBs. Obviously one concern has been that we may not have enough resources or time

without at this point knowing whether we will be extended past October to be able to get the kind of information that would be useful to us in our discussion and deliberations.

So we have been particularly interested in one study that is already underway and another study that is being proposed. Let me just briefly mention those to you. Again these are discussed in more detail in your transcript from our meeting on February the 24th.

One is a study that was mentioned at the very first NBAC meeting. Charles McKay's study. And we spent some time talking with him at the last Human Subjects Subcommittee meeting. We had copies of the first three instruments, the first three of five instruments. And if you are on the committee's -- the commission as a whole but not on the subcommittee and would like to see those, please indicate that to the staff.

He provided information about the other two instruments and he also provided in a mailing that you received over the last several days a copy of the protocol itself. So I would urge you to look over those very carefully to see exactly what is being done.

He hopes to have the key questions, information about the key questions, available by June though perhaps will not have the data fully analyzed. The schedule depends in part on how complete a response he hopes to get from those being surveyed.

At any rate on the basis of what we saw this will provide some very helpful information to us and we are glad that we had an opportunity to talk with him about this and also to urge him to move this along in a way that could benefit us if we can get the information in time.

The second study we have had an opportunity to provide some feedback in its development. Dana Miller, a project leader in the Department of Health and Human Services, Office of Inspector General, Office of Evaluation and Inspections, talked with several of us informally and then communicated with me prior to the last meeting about a project they are planning to undertake and complete by August of '97 in time to get some results to us.

This particular study will focus on hospital IRBs and examine the challenges they face in their efforts effectively to ensure human subjects protection in the research they oversee. The challenges this study will look at will include changes in the health care market, for example hospital mergers and managed care, increases in private and commercial funding of research; shifts in the nature of the research, for example genetics research and new technologies, and newly defined diseases; and the increase in multisite trials. This study will ask which of these changes present the most significant challenges to IRBs and their effective of functioning and what strategies IRBs have designed to meet these challenges.

The method will be primarily interview, interview method focusing on number of IRB chairs and administrators with three or four IRBs studied in-depth and then others, experts who are knowledgeable in the area, commercial sponsors, et cetera, would all be included.

Now this particular study again is one that is just being set up and we had an opportunity to give some feedback and again we expect to have results available to us in August for our consideration. These go some distance towards filling the gap that we have in our

knowledge. They will obviously not answer all the questions we might have about IRB functioning but they will be of some help.

For further information again you can look at the transcript of the last meeting or I would be glad to try to address any questions you might have. I will continue to report on those as they develop. I would urge you to look at the instruments that Charles McKay has provided as well as his protocol which again appeared in recent materials.

DR. SHAPIRO: Thank you.

Any questions?

Yes, Laurie?

DR. FLYNN: I regret I was not at the subcommittee meeting. Just one question. Can you talk a little bit about the scope of Charles McKay's study? Is he attempting to survey all IRB's? Some percentage of IRB's, large ones, small ones? What do we know about the scope and range of the IRBs he hopes to capture information from?

DR. CHILDRESS: Does anyone want to comment on that? It is very extensive. I do not -- it is not totally comprehensive but it is very extensive and I am sorry I do not remember the numbers now but they would appear in the transcript.

DR. FLYNN: Just one follow-up. I presume this is a voluntary participation by the IRBs. Do we have -- does he have any concern which I would have just at the outset that the larger well staffed tend to be better functioning IRBs and are likely to respond? Some of the IRBs that we may have some greater concern about may be less

likely to respond. Does he have a strategy to deal with getting that range?

DR. CHILDRESS: Alta, did you --

PROF. CHARO: That is a very good point on response bias and I do not recall if that was addressed but it certainly will be remembered now.

DR. CHILDRESS: We will make a note of that and check with him.

DR. SHAPIRO: Jim, could I --

DR. EMANUEL: I am sorry.

DR. SHAPIRO: Yes, Zeke?

DR. EMANUEL: I did not -- just two points. One was in your list of new concerns that the IG was going to look at I did not hear the mention and I apologize because I have not looked at the materials, the issue of health services research which in the current era is, I think, going to be much bigger than we ever experienced. The second is the shading between research and quality improvement. Again quality improvement does not have to go before IRBs. Often those protocols look exactly like research another name and I have seen several where I am greatly concerned about the fact that these things never went through IRB approval because there is the quality loophole. I do not know if the IG is looking at those two areas.

DR. CHILDRESS: At least Donna Miller did not specifically mention those. However, one reason for presenting this today is to get feedback because that study is still being developed and I will pass that information on to her. So I would also welcome -- Charles

McKay's is already set. The instrument is already set so there is really no input we can have there other than urging early completion.

This particular one, though, is still being developed and I would pass that information on and I will also ask her to get in contact with you. She is Boston based and I will ask her to get in contact with you as well for further follow-up.

Thank you.

DR. SHAPIRO: Jim, I think the issue that Zeke raised is an extremely important one and is exactly the question I had in mind. So I really do want to second his suggestion. I think it is important if we can have an impact that way. That area as far as I know is unexamined and it is a big and growing area. So I hope we can look at it.

Bernie?

DR. LO: I would just along those same lines encourage the OIG people to look at the issue we just talked about in terms of studies done at their institutions that do not come under their purview because they are privately funded and to the extent that we can get information on how big a problem they think this is, what efforts do they try to make to sort of voluntarily get those protocols submitted, what do they do if there are allegations of unethical conduct of research that they have not reviewed, and what measures do they -- what policy options do they think might be feasible in bringing those types of research under their purview, and how much extra work would it take, and do they have the resources to do that? I mean, these sorts of very practical questions. I think they are going to be crucial for us to try and implement this statement of principle that Alta presented to us.

DR. CHILDRESS: Good things. And one of the changes that -- or one of the challenges already presented in their discussion as a result of the changes or increases in private-commercial funding of research is -- that is already present. So I think this would be a good way to expand that and make sure that in the subquestions that are being raised here that the concerns you just mentioned are addressed.

DR. SHAPIRO: Bernie, anything further?

(No response.)

DR. CHILDRESS: Okay. Well, again, if you have any further feedback on this let me know and I will pass it on to Donna Miller. I will be talking to her again at the first of next week. So if you do have something please let me know very quickly on that.

Now, quickly, the last items. I would simply update you on our discussion of general and specific topics. We spent a fair amount of time at the last meeting talking about cognitively impaired subjects. You will recall at the previous meeting we had Rebecca Dressler and Bob Levine present an overview of the issues that are raised by cognitively impaired research subjects who may not be adequately protected by the -- as a result of gaps in the guidelines. And then Dr. Shamoo presented in the public session so we had three presentations at that meeting.

We followed that discussion up at the last Human Subjects Subcommittee meeting by looking at more concrete proposals. In particular, we spent some time with Jack Schwartz of the Maryland Attorney General's Research Working Group that has drafted a proposal for protection, for guidelines to protect cognitively impaired research subjects. And with Jonathan Moreno who has been participating in the

University of Pennsylvania, Center for Bioethics, Working Group in Research Ethics, with particular attention in one of their draft reports to cognitively impaired subjects.

So we tried to make our discussion more concrete. We are at the point now where either if a professional staff person is added they would be working in this area that could help us bring this to some sort of resolution, that is some proposal for our consideration and then for the recommendation to NBAC, or failing that we are going to need to get a contract person to prepare the kind of report that will sort out the options so that we can come to some recommendations.

In addition to working at this very specific level at these meetings we have also continued to explore general topics, concepts and norms that relate especially to a revisiting of the Belmont Report and we are continuing our exploration of vulnerability which have been proposed as a possible key to thinking about research involving human subjects across various categories and not simply in relation to populations that have usually been considered to be vulnerable.

At the last meeting we had a very helpful discussion led by Cecelia Fisher of Fordham University thinking about vulnerability in relation to a relational model, one that focused on researchers and subjects and relation, and seeing vulnerability as one way to talk -- to -- seeing vulnerability and relation as terms that we need to think about together. I think that was a very helpful discussion.

Some have raised questions about whether vulnerability could really be the key recognizing that even if it is not the key to research as a whole, at least to certain populations, thinking about the

way in which they might be protected, what kinds of protections they might need.

Some have proposed instead of vulnerability we consider a justice as a category so we spent some time with three former staff members of the Advisory Committee on Human Radiation Experiments talking about the way in which justice might be understood more broadly than it was in the Belmont Report as a possible key for thinking about research involving human subjects. You will notice that Alta had an expanded vision of justice in the statement that she presented.

We also spent some time talking about the changing research involving human subjects and the changing paradigm of research and research protections, and Eric Cassell has agreed to prepare a paper in that area.

And then the last topic we considered was community and its importance.

Now these topics you will be receiving over the next ten days to two weeks draft proposals from the subcommittee and we would like your feedback on those because we would like to get papers out for contract. We would also like to get suggestions from you about possible writers of such papers. So we will be asking for your feedback over the next couple of weeks on that. Something we want to continue and obviously it is important to do even while we continue to work on human cloning.

That concludes my report unless the subcommittee members would like to add something to it.

DR. SHAPIRO: Thank you.

Any comments from -- first of all, from any of the subcommittee members?

Any comments from other commissioners?

Well, let me just say, Jim, to thank you very much for your own leadership of this committee. You have a full and comprehensive agenda in front of you. I very much appreciate the -- both the skill and the determination with which you have all faced this topic and very much appreciated by us I assure you.

Thank you very much.

Before we move on to our next agenda item I really have one logistical item and then one item I had meant to address in my opening remarks and simply have forgotten, which I will apologize for in a moment.

The logistical item is that we do need you to fill out those calendar forms we passed around and get them to Henrietta some time today so we can figure out when we will meet in April and May.

DR. HYATT-KNORR: Would you please be sure to mark those days on which you definitely cannot make it? I just wanted to be sure that that was clear. Thank you.

DR. SHAPIRO: We do -- as you know, we do need extra meeting days because of our new assignment and we are currently thinking of having one in April and another one in May. We would just like to pick dates that are most convenient for most members. It is difficult and I doubt we will be able to find days in which we can get 100 percent of the commission here. I just ask you to do your best and we

will try to pick the most convenient date for the most members. So get that in, please, to staff today.

DR. LO: (Not at microphone.)

DR. HYATT-KNORR: We have since faxed out some replacement pages but I have a couple extras that include April and May so we will give you one at the break.

DR. SHAPIRO: We have metaphysical issues ourselves on these issues but if anybody needs any forms please speak to Henrietta or other members of the staff. Thank you very much.

What I had neglected to say at the beginning and which I feel very badly about is I wanted to express on behalf of the entire commission our enormous debt to the staff that has worked so incredibly hard the last -- well, since we have been appointed but especially in the last month or six weeks.

There has just been incredible demands on the staff for materials, for logistical planning and many, many other things, and I just want to take this moment to thank them all and to appreciate really all the extra effort that they have gone to, to make sure that we are staffed as well as we can be for our meeting.

So, Henrietta, I hope you will relay this to other members of the staff.

Bill, I hope you will do the same.

All right. Let's go on to the next item on our agenda which is a report of the Genetics Subcommittee. Let me turn to Professor Murray.

Tom?

REPORT OF THE GENETICS SUBCOMMITTEE

DR. MURRAY: Thanks, Harold. You have just actually took my first item which was to thank the staff. Some of you may know, certainly those of you who showed up at 7:00 a.m. on March 5th, know that we ended up meeting very early. For the uninitiated it might strike you as a curiosity that we do that in part at the request of the members of the -- of our subcommittee who live on the West Coast. They actually like starting meetings at 7:00 a.m. Eastern time. We had planned to start it at 8:00 a.m. but because of the Congressional request for testimony we wanted to wrap the meeting up before 1:00 in order to be able to move down to Capitol Hill and, indeed, the staff arranged all the logistics that we were able to do this even gracefully or to make a close approximation of that.

The meeting was, in fact, on the 5th of March. The strategy of the Genetics Subcommittee was to spend the bulk of the meeting looking at the first and most urgent item on our agenda and that is a report on the use of human tissue samples in research, primarily genetic research but of course such tissue samples are used for many research purposes and anything we say about their use in genetics is probably going to be relevant to other uses.

We had tentatively identified a set of tasks or topics that must be covered for our report to be adequate. We chose three of those tasks to be the subject of the March 5th meeting and they were ethical issues, public beliefs and values, and religious perspectives. I would like to talk about each of them briefly. I am going to seek the formal and informal help of the other members of the Genetics Subcommittee.

Formal in the sense that occasionally I am going to ask people to say something starting with Zeke Emanuel in a moment.

Informal in the sense that if anything I say is incomplete please jump in and give your perspective on what happened that day and what was decided that day.

As I said, the meeting began with a discussion of some of the ethical and normative issues in tissue sample research and Zeke Emanuel was kind enough to agree to take us through our initial effort to look at the various position statements that had been issued, we had -- I have heard different counts -- five or so, and try to pull out the normative claims and principles that seemed to be embedded in those statements.

And I would ask Zeke to give us just a brief description of how he saw that part of the meeting.

DR. EMANUEL: Thanks, Tom.

Basically what I tried to do is to outline the four statements that we had from the different societies, including the ELSI working group and then I just indicated that most of them rely on the 45 CFR 46 and not much on the ethics trying to outline both intrinsic and instrumental values.

I think at the end of the discussion through a lot of input from the subcommittee we came to the idea that what we should try to do is to divide samples into anonymous or anonymizable on one hand and linkable or identifiable on the other hand.

And then to distinguish the kinds of research that could be done on these and we did not make a formal or final categorization

but with the help of some examples that Steve Holtzman identified we sort of crudely broke them down into nonstigmatizing research such as research on colon cancer that might be done on these kinds of samples, individually stigmatizing research, communally stigmatizing research, and as we say we were not -- these were not done hard and fast.

The idea was to try to create regulations that might apply across these kinds of research to try to create a two by three table as it were with indicating how we would evaluate that kind of research, the kind of protections both in terms of IRB and going back and obtaining informed consent would be necessary.

That is where we had left it but I think at the conclusion there was a sense that this did fit our intuitions and that we could work with this crude division and try to refine it but that many of the subcommittee members felt that it really did begin to look like we could develop a consensus around that kind of conceptualization.

DR. MURRAY: Thanks, Zeke.

At any point I invite other members of the subcommittee to add their perspectives or any member of the commission who might have a question or a comment so this is very open.

Steve?

DR. HOLTZMAN: Just to expand a little bit on what Zeke said. I think the conceptual breakthrough on the issue of anonymous we had was that all of the statements think of anonymity or anonymizable in terms of with respect to the individual subject. And that since there are clearly kinds of research which while anonymous or anonymized with respect to the individual subject nevertheless is not anonymous with

respect to a community we need to reconceptualize anonymous as having that other vector.

And then on the other axis that whereas traditionally people have distinguished the kinds of research vis-a-vis genetic research versus other kinds of research that the real issue is what is the harm that can come from the research? And that is why we have this notion of stigmatizing versus nonstigmatizing.

So colon cancer research could be stigmatizing. The specific example we were talking about is that the way the samples are collected it is truly anonymous. It does not -- an example I was using in that case did not involve the ability to pinpoint a community.

DR. MURRAY: Thanks, Steve.

I think it is fair to say that one of the concepts we began to entertain very seriously was the potential for some sort of community consultation for the acceptability of tissue use for certain purposes where perhaps although specific individuals' identities might not be revealed, information about membership in certain community or communities might be go along with the data and might have been sensitive within that particular community.

It was, I thought, a very fruitful session as was the entire meeting. I should also note that Dr. Mark Sobel of the National Cancer Institute took advantage of the public testimony period to offer his perspective on how pathologists understood the concepts of anonymous and anonymized, and Dr. Sobel has promised to give us a written statement which will sort of lay out that position.

Anything else on the ethical side?

Larry?

DR. MIIKE: Yes. Since I was not able to be there, am I to conclude then that any of the formal analysis and presentations by the various groups are insufficient for our purposes?

DR. EMANUEL: What I think is present in -- and I sent out a chart which tried to summarize the various positions. The first thing to say is that almost none of them really talk about ethics. They almost all talk -- rely on the regulatory language to inform and in that sense we do have to go one step back because the regulatory language, of course, needs its own justification. It may not have gotten it right.

There are -- I also have tried to indicate there were some levels of disagreement among the statements.

Third, it seems to me that the kind of distinction that we have drawn or that we seem to be heading in the direction of drawing seem more fruitful to most of the commission members than the distinctions drawn by most of the statements. The statements are helpful for areas of overlap and areas of disagreement but I do not think they go far enough. I think that would be a fair assessment and we think by rethinking the different kinds of research we can actually be more helpful and more ethically settled in our recommendations.

DR. MURRAY: I take it that is a no or rather a yes to your question which is are any of them -- are they all somewhat inadequate? Yes, they all seem somewhat inadequate.

Alta?

PROF. CHARO: Zeke, Steve, the others, can you help me understand better the difference between stigmatizing and

nonstigmatizing as you are using it here? What kinds of research or tissue samples would you consider stigmatizing and which ones not?

DR. EMANUEL: I am not sure we can give you a full elaboration. Again, I mean part of this happened at sort of the tail end of the discussion but one of the things we wanted to suggest is that the nonstigmatizing -- for example, in an anonymous sample is collected in a way that you cannot identify the individuals, you cannot -- it is not connected to a community where the results would be not specific or pointing to anyone.

So they would not lead to a personal self doubt, to a social stigmatization or to an overt discrimination for the groups on which the research is done. Whereas the individually stigmatizing, either because you know from whence the sample came identifiably or you can trace it back by descriptions.

For example, we took samples from people who were tested for Tay-Sachs. That created a different level of concern even for the anonymous as Steve was pointing out. Now we happen -- I mean, I think -- again this was a crude attempt to try to articulate and we have not refined it.

PROF. CHARO: Okay. So to make sure I am just getting it now, it is not the word "stigmatizing" in the sense of some things are embarrassing and other things are not because of the topic area, like colon versus sexual? That is -- I got misled by the example of the colon cancer. It is really about a kind of different way of cutting what has usually been referred to as anonymous and nonanonymous, and identifiable, and looking at it slightly differently but with the same

concerns in mind about privacy violations. It is really about degrees of privacy violations?

DR. EMANUEL: No, not only privacy. I mean, what we -- what I tried to do was to distinguish the fact that there are some benefits and harms and under the harms ones that arise out of certain elements of self-doubt, both for individuals and communities, certain elements of stigmatization...that are short of overt discrimination, and then elements of discrimination. So we were trying to identify ways in which you would balance these various goods, the goods of progress in research, advances in medical therapeutics, again certain harms. This outlines where places, I think, where the harms would be very preponderant although maybe not overwhelming.

PROF. CHARO: Thanks for the clarification.

DR. BRITO: Yes, Zeke, I just want a clarification because we get all these materials and if they are not labeled with the author's name it is very difficult to -- your outline is titled, "Analysis of positions on genetic tests using stored samples," right?

DR. EMANUEL: Right.

DR. BRITO: Okay.

DR. EMANUEL: And the comments I have just made do not appear in that outline in part because they came as a result of the conversation and they were -- you know, if I had been smarter they would have been included but I was not smart enough and more brains are better than one brain working alone. So we actually did -- I mean, I thought in that sense it was a very fruitful meeting because various

people pointed out how we might synthesize the various harms and concerns.

DR. BRITO: Okay. So my --

DR. EMANUEL: Totally appropriate.

DR. BRITO: -- search for those comments is --

DR. MURRAY: Well, the good news is that despite beginning a discussion about serious ethical issues at 7:00 a.m. it was actually a very fruitful discussion. The bad news is it was the easiest of the three major topics, I think, of the day. So let's move into the other two.

The second major topic was how to ascertain good information about public beliefs and values that would be relevant to the use of such tissue samples in research and we had two guests to help us begin that conversation, Dr. Dorothy Wertz and Dr. Chuck Denk. It has occurred to me you can sort of divide the questions and structure our discussion about facts and values, and there were at least two kinds of fact questions that we tackled.

One is could we design a high quality empirical study to get at such public attitudes and beliefs and secondly if we could design such an empirical study could we get it through the various approvals, whether they be IRB approvals or Office of Management and Budget approvals rapidly enough to be able to integrate it into a report which we still hope to deliver some time next fall or at the earliest by the end of this year. I mean, at the latest by the end of this year.

The value question began to look like what might we learn of value from the various -- by from the various means of ascertaining

public views. It turned out to be a trickier question than perhaps many of us had initially thought.

We learned from Dr. Wertz and Denk a number of things that I thought were helpful. If we had any delusions, which I do not think we did, but if we had any delusions about getting public permission for various kinds of research uses of human tissue we should not presume to get that by opinion polls.

The polls are not morally authoritative and polls are very, very different from informed consent. Polls do help map public attitudes. They identify problematic issues and help to distinguish those from issues that are relatively unproblematic in the public's mind and they may also be helpful in discerning group differences in responses to particular questions.

We received a lot of advice about what sort of questions to ask, advice about potential researchers with whom to collaborate, and a range of cost estimates if we were to ask a number of questions in a national opinion poll. We were also told that it would take a minimum of four to six months to get anything through the Office of Management and Budget, and since that took us beyond our reporting date that seemed problematic.

We were told there may be an exception if you surveyed patients. We were also told by Dr. Raub that, well, he has on occasion had success in getting things through more rapidly and we were told by a number of people including Dr. Emanuel that it is hard to construct a really good opinion survey, do it and analyze the results in less than a

couple of years. We were pretty sure that that was beyond the report date so we -- that caused some concern.

In the end we settled on what I recall as three possible tracks. One that I believed achieved a consensus on the subcommittee was to -- rather than -- this first track is not a formal study but it is a set of local hearings, local in the sense that we would ask as many of the members of the subcommittee as is willing to do this to have a hearing in their local area.

We are aware of some of the limitations of kind of community dialogue efforts and some of us have participated actively in such efforts in our communities. One of the principle limitations of these community dialogues is that you just announce it and issue an invitation. The people who tend to come are people who look a great deal like the members of this commission anyway.

So it seemed important if we were to try to get a little bit broader view of public opinion and attitudes about tissue sample use for research we had to make some affirmative effort to try to draw in to give testimony and to participate a more representative group of people in the community, and some strategies were discussed as to how that might happen.

We might, for example, contact local researchers and say would you talk to some of the people whose tissue you may be using in research and see if they would be willing to come forward and talk to one or more commissioners at a local hearing. I believe we are going forward with that although we have made no concrete plans to put it in place but I believe that was the consensus of the subcommittee.

Now let me stop there for a moment and say is that correct or did anyone wish to add to that?

PROF. BACKLAR: It is important to note that we -- that in our informal discussion about this we would contact our IRBs first before we contacted researchers. We would contact the IRBs to see who was doing -- if they would give us information about who was doing research on this kind of research and go from there. So it would -- we were going to move cautiously.

DR. MURRAY: Thank you, Trish.

Anyone else?

So as I understand it then we will proceed with the help of the NBAC staff to plan these series of local -- the mini-hearings and that will at a minimum give us a sampling of public opinion. It will not in any way be a representative sample in the way the statisticians think about representative but we hope what will come out will be if there are particular fears out there, for example, that the commission might not otherwise have thought of and that we will learn about those. If there is particular hunger and support of research of this kind we would also like to know about that. We are not just looking for the negative. We are looking for those considerations that are out there in the public that we should be aware of.

Trish?

PROF. BACKLAR: And the discussions would be case based. We would use the same cases throughout the country as we did this so that it would be qualitative research in the sense it could be

analyzed in that sense. We would keep some control about what the kinds of questions were.

Bernie, right?

DR. MURRAY: Thank you. That was -- so that was one track.

Track two was to, in fact, pick up on this idea of a really well constructed public opinion survey. Not try to get it done in a hasty fashion but rather to do it right and to have it ask questions that are pertinent not just to the tissue sample report, it would be too late to incorporate in the report in any event, but with the subcommittee's larger agenda in ethical issues in genetics, genetic information and gene patenting. We thought this was a very good idea and we would like to begin working with the staff in an effort to construct and execute such a survey.

Any comments from other members of the subcommittee about that? All right.

The third possible track was discussed. Namely a small scale study. As I recall it and my recollection may not be entirely correct, it was to have been a small scale interview study, perhaps exit interview studies of patients leaving hospitals that might be asked -- ask them do they know what they have just consented to, what uses would they regard as quite acceptable, were there any uses they would -- to which they might object and other such questions.

Now this -- if it were to be done it would be a real study. It would have to go through appropriate IRB review. We would have to find an investigator to take it on. We would have to get the money for it.

If we are to do that we probably need to begin that virtually immediately. I do not recall that there was a complete consensus that this would be done. I think it was regarded as desirable and I would very much appreciate anybody's comments about this third and, I think, less decisively treated track.

Zeke?

DR. EMANUEL: I thought there was a fourth track which you have not mentioned, which was the idea of doing the following things: One was to talk to one of -- to someone out there who may be one of the two people who we brought in, Chuck Denk or Dorothy Wertz, to do a survey of what actually exists for us. There was a feeling by us -- I think especially by Chuck if I am not mistaken -- that there actually was some useful literature already that we might -- or polls that had a few questions that we might draw on, and that could be assembled relatively easily and cheaply.

And second that we might try to contact investigators who were about to send polls out into the field and that Alan Weston at Columbia was a man mentioned who is about to send a survey out into the field on genetics, some of which is related to confidentiality, and to see whether they might include some questions for us. He is working with Lou Harris and that was another possibility. That would be costless theoretically if he could be persuaded to do it. And since he is already through the IRB process, et cetera, might avoid many of the delays that we might face if we did it ourselves.

DR. SHAPIRO: Laurie and then Diane.

MS. FLYNN: I would love to hear just a little bit more about the apparent less than full endorsement or support for the third track which was of interest to me in terms of interviewing individuals who may have directly participated to understand what they find acceptable and what may be their concerns. Can you describe a little bit what those cautions were?

DR. MURRAY: I think only to -- the only questions were could we do it in time. No one doubted the desirability of doing it. It was a matter of could we get the researcher, could we get the approvals, could we get the funds, could we get the study designed, executed and reported back to us really by this summer?

DR. SHAPIRO: Diane?

DR. SCOTT-JONES: I wanted to mention briefly some information that was circulated to you either last night or this morning. This is from a group in Michigan that some of you may already know about that is, in fact, already trying to assess the opinion of communities, seven communities in Michigan regarding genetics technology, and it might be useful to the subcommittee or to the commission more broadly as we try to assess public opinion on cloning or on any issue related to genetics technology.

This group has already done a series of what they call dialogue groups throughout the State of Michigan. They have seven communities already identified and they have overcome some of the problems that we have already mentioned that would happen if you attempted to assess the public. One is that many members of the public

will not be well informed already and will not have a well formed opinion about genetics technology.

But what this group does is a series of six evenings of informing the groups. They talk to the groups about the technology so that the groups before they form an opinion have information on which to base the opinion. They also overcome the people like us problem that you mentioned, Tom, in that they do have representative samples, samples that range in socioeconomic status and in ethnic group membership, and other variables.

So they have made a start at what it seems we need to do both in the subcommittee and in the commission as a whole and it might be useful either to link with this group because we could do that at a very low cost. They are already funded for this project and they are actually funded through the Center for Human Genome Research.

DR. SHAPIRO: Thank you. Tom?

DR. MURRAY: Thanks, Diane.

Bette?

MS. KRAMER: Tom, I have not had an opportunity to report to you but I did contact Alan Weston at Columbia just, I guess, Tuesday afternoon and it appears that we would not be able to attach to his survey. For one thing it is pretty much set to go and it is going to go on April 1st. In talking with him it seemed as though it would not be possible for us to put together questions to be added on at this time and there also was a substantial cost factor.

I did talk with him a little further about some of our other interests and he reported to me that he has an inventory of 100 pages of

questions that have been asked in surveys relating to Human Genome Project initiatives that he would be very happy to share with us and I told him that we -- somebody from the staff or somebody from the commission would be back in touch with him and he was very generous in offering to appear before us and give us some guidance on these issues.

DR. MURRAY: That is a gem. Thank you, Bette. That actually helps to satisfy Zeke's point about how useful it would be to gather already collected public opinion data. So that partly at least accomplishes that job as it relates specifically to genetics so that is good.

Diane, thanks also for the identification of the Michigan group. I think that is something that -- speaking for myself -- I would very much like to see us pursue.

I do not see that as -- it is not an either/or between that and say these mini-local hearings that we talked about having. I think they could both be very valuable sources of information.

DR. SCOTT-JONES: I would also like to add that the Michigan group is willing to insert questions from us if we choose to go that route and they are willing to do it very quickly. They have another series of their groups that will meet at the end of this month and the first of April and they could conceivably give us information with a week's turn around time from the analysis of these groups.

They also have their groups meeting with policy makers within the State of Michigan, too, so representatives from these communities are being oriented to thinking about policy, about

legislation that might result from the opinions that they form in the community groups. So it seems like a great model for both assessing public opinion and trying to inform the public as well.

DR. MURRAY: Thank you.

I know some of the people at least involved in that Michigan effort and they are very dedicated and very serious, and they are good listeners. So those are all characteristics I value. I think it would be useful.

Let me try to recap since I think we should move on to the next major topic in our report.

Number one that we will do these mini-hearings. Is that -- is there any dissent from that? Does everyone agree that that is something we should pursue?

Number two, we will begin the development of a well crafted public opinion survey, at least begin the explorations of how we might do that and how we might pay for it and such.

Number three that do I -- and on this I actually would appreciate some very direct feedback. Should we move aggressively to try to create -- to try to initiate such an exit interview, patient study? We should try to -- I am not -- I cannot promise that we can pull it off but should we -- I am certainly willing to work together with staff and perhaps other members of the subcommittee could work with me to see what we can -- just how quickly we could move to get that if we can, in fact, get it approved and funded, and completed in time.

DR. SHAPIRO: I have some at least initial responses to these. I do not want you to take them too seriously because I have not

fully thought out what is possible but it seems to me there really are five. You started off with three but there are now five on this list.

As I understand it there is the set of local hearings. There is the long-term survey which may come at some stage further on down the road. Then there is the exit interview study, the survey of what exists, which I guess Zeke encouraged us to do, and the Michigan group.

I am just concerned with the amount of time that the subcommittee members have to devote and it seems like a very, very large agenda. It is the latter three that seem to be most that will pay the early dividends and are most do-able. That is just my reaction.

It is not to say the others are not important and to go ahead but I am just -- given the time interval we have that might just be the best three to focus on in the immediate future. The long-term one I think is very interesting and we are behaving as if we are going to go beyond October even though as I understand in some legal sense that is not fully determined yet but we are certainly behaving that way.

And the local hearings, which are always an attractive idea, to do properly so that you can really infer some information itself is really quite a -- it has to be structured in some way. I am a little bit concerned about whether we can really mobilize that in time but that is just an initial reaction. I leave that to you and the committee to decide.

DR. MURRAY: It is an important point and why don't we pick up on that for a minute. Should we do these mini-local hearings? Would it be sufficient to use the already collected opinion data? Some of the work on that has already been done by Alan Weston I gather who is willing to share it with us. Should we pursue the work of -- the

collaborative work with the group in Michigan, which is part of the United States but, you know, we represent more regions than just Michigan? Should we try to do these mini-hearings? I think those are the ones that at this point are up for serious discussion.

Bernie?

DR. LO: Yes. I think obviously we have a real problem with needing to set priorities in terms of our time and resources. I would certainly support trying to work with the Michigan group because they have done a lot of the infrastructure work, I think. I guess, let me put a plug in for local hearings in a sense that is more akin to informal conversations that we have just to make sure we are not totally divorced from people in the community.

In point of fact, at these meetings and at our home institutions a lot of colleagues come up and say can I talk to you about X, Y or Z. And a number of these conversations are frankly about research or DNA testing of stored tissues.

I would just like to get the same kind -- some kind of feedback from people who are not scientists but who will be involved as the donors or the progenitors of this tissue. So even if it is not generalizable in the sense that it is research I just think it is good for us to talk to and especially to listen to people who might be affected as potential subjects.

To do it in as rigorous a way as possible so that we have sort of, you know, a common set of themes we are trying to test out but that I think that we need to do something given the constraints we have and be realistic about what we can accomplish. I think it is going to be

very, very different from publishable research but I think something that might just help us keep our feet on the ground.

DR. MURRAY: Trish, and Eric, and Larry.

PROF. BACKLAR: I concur with what Bernie says particularly because I am very concerned that we do not get our information from just one part of the country and that this is an opportunity for us to do it in different places. And as we well know from research if you do research in South Carolina it may come out very differently, your responses may be very different from that in San Francisco. So I urge that we make the effort even though we do not have much time personally.

DR. MURRAY: One of my all time favorite cartoons shows a car on a road with a billboard that says, "Leaving California, resume normal behavior." Presumably they do not have the same thing in Michigan but I think your point about potential regional differences is a good one.

I also say that if we did the local hearings I would not see this as an obligation for every member of the subcommittee. This is for those members of the subcommittee who want to do it and believe they can do it in their communities. So if even half of the members or roughly half did it I think that would -- and there was a spread geographically that would accomplish our goal.

Trish?

PROF. BACKLAR: And I think Bernie's point, and we had discussed this with David Cox, too, of making the cases very, very clearly

being as rigorous as one can be in going through this so that we really have something to compare.

DR. MURRAY: Thanks.

Eric?

DR. CASSELL: Because there is ongoing surveys and because of the Michigan group process I make a plea for finding out what they are finding out and then going on to a second level of it because I think assuming that we go beyond October you need some information about what people really do feel before you go in deeper into it so you do not get a relatively superficial stage in this process. I think you ought to let them do your groundwork for you, the people who are doing it now, and then go in the next level.

DR. MURRAY: Eric, would you clarify for me, when you -- are you saying with respect to the Michigan -- relation of the Michigan work to other work, do you mean to say that before we say do the big public opinion survey we should have the results of the Michigan work or do --

DR. CASSELL: Yes.

DR. MURRAY: -- you mean that to apply even to the hearings or to the small study?

DR. CASSELL: Well, I think you ought to get as much data at this level as you can about what people's concerns are so that your survey is done at a cut deeper than that.

DR. MURRAY: Thank you.

Larry wanted to speak.

DR. MIIKE: You started off the discussion by distinguishing between public opinion and public values. What are we getting at in these? Now I am a little confused about what we are going to end up with when we do all of these activities? By the way, to the extent that I would try to do one in Hawaii because Hawaii is very much like Michigan but I thought you would be interested in it.

(Laughter.)

DR. MURRAY: Would other members of the commission be invited to come to this hearing?

(Laughter.)

DR. MURRAY: Purely on an intellectual interest of course.

DR. MIIKE: If you have enough frequent flyer miles.

DR. MURRAY: That is a very good question and it was a question that we pressed our two expert consultants on, Drs. Wertz and Denk, what can you get out of such surveys. They said one thing you can -- or out of various efforts to find out what people think you can get some information about what people believe, even about what particular facts they believe. You can get some information that will help you sort of map their areas of concern and those things about which they are worried and those things about which they just do not think are, you know, worth a great deal of their concern and effort.

You can get some sense, I suspect, of what kinds of judgments they would make or how they would balance certain values, perhaps the importance of pursuing research versus the importance of assuring, you know, privacy. So we would hope to get at least some information about each of those things. My own primary hope is, as I

said, I think we are, you know, this is a very imaginative and very broad group but I do not think we are going to think of everything that might occur to, you know, numbers of Americans. I would really like to give people a chance to come in and say, "Well, have you thought about this? This is something that worries me."

Now it might be though that the worry is extremely well taken. It might be that the worry is based on a complete misunderstanding of what the whole issue is about but we need to hear that in any event. Even if it is a misunderstanding we need to be able to say in the report, you know, we have heard about this but this is not really relevant to this for these reasons. So those are my goals.

Others? Bernie?

DR. LO: Just to pick up on what Tom said. I think the concern -- my concern would be that we just miss issues that the public or at least some members of the public feels very strongly about or is put together in a way that is a little different than what we have put together.

So I would not want us to have a lot of deliberations that afterwards people could come back and say, "Well, what about this point or did you think of this, or you do not seem to realize that we care very strongly, much more strongly about this issue than your report seems to indicate."

What we do with that information I think is the next level. Just because people mention it does not necessarily mean that we adopt it or agree with it. I think it is important that we not miss values,

feelings and new ways of looking at things just for not having heard them.

DR. MURRAY: Bette?

MS. KRAMER: I think I need to clarify for the committee that with all of the work that has been done according to both Dr. Wertz and Dr. Denk who were there and then also when speaking with Alan Weston, nobody has polled or surveyed specifically on the issue of public attitudes towards the use of stored tissue. So we are going to get information back on what has been done around other types of attitudes towards genetic research but not with -- not to that issue specifically.

DR. MURRAY: Because we have about 15 minutes left before the break and I think it very important that we not intrude into the next part of the meeting when we take up cloning, if it is with your permission I will close this part of the conversation. We can continue it via all sorts of means of communication to reach a final decision but I think that this has been a very helpful airing of possibilities.

The third --

DR. SHAPIRO: Could I just ask a point of information on the proposed local hearings? I got two different feelings. One is a kind of more informal kind of process which would take place and each hearing have its own characteristic depending on the locale, the persons, people it attracted, so on and so forth, vis-a-vis what I thought I heard Trish saying, which is, in fact, what you have in mind is a series of cases to structure each of these meetings. I am just asking for information which of those do you have in mind?

PROF. BACKLAR: The second.

DR. SHAPIRO: Thank you.

DR. MURRAY: I would hope that we would have both that but we would also have an opportunity for people to come in and just simply state what they feel but the structure would be good.

PROF. BACKLAR: The reason for the structure is that we would like to have some ability to compare from region to region. It would help us.

DR. MURRAY: All right.

There still are questions to be addressed about the precise design and implementation of this but you are right in picking up on the ambiguity there.

The third major topic that we discussed at the 5 March meeting were religious perspectives. Many members of the commission have been well aware that there are on the record expressions of a variety of religious views on a range of issues concerning genetic research and biotechnology. We were utterly convinced that it would be wise to hear and consider the views of faith traditions on the issue of human tissue samples.

To help us in our initial cut at those set of views we asked Dr. Ronald Cole-Turner who has done work trying to understand religious views about the Human Genome Project, the Rev. Dr. Ronald Cole-Turner, to come in and help us begin.

Dr. Turner was both -- well, it was an interesting talk in that he identified a rather large and ambitious potential agenda and I will just try to summarize it very briefly here. He identified at least six

major themes through which religious traditions might have something to say about even an issue such as human tissue samples.

The first theme was the tradition's view of the body and at least in certain Protestant traditions the body is regarded as sacred but gifts of the body are regarded as good and that would certainly cover -- that covers organ donation but it might also cover the use of tissue for research. That is just an example.

The second broad issue had to do with families. How the tradition understood families and how the tradition might deal with the question of the family's participation in this kind of research and also the potential problems that might arise when you have one family with members of different religions in the same family, different traditions.

A third major theme was health. There has been renewed interest and spiritual connections to health and renewed religious concerns about physical health.

A fourth issue had to do with stigmatization. We have already had a preliminary discussion of that.

A fifth major theme had to do with the faith tradition's attitudes towards scientific research. There is a range of views among theologians and among faith traditions about the relative significance of scientific research and about the religious significance and value of scientific breakthroughs.

The sixth and last major theme Dr. Cole-Turner mentioned was the trust in public institutions. Within at least some faith traditions there is less trust of public institutions than in others and, in fact, in certain faith traditions the fallenist or sinfulness of humankind

means that they can expect everyone to disappoint us, even public officials, and we should bear such general beliefs and things in mind as we move forward.

That session was to me a bit awesome because I thought there was no possible way we can begin to do justice to such massive themes given the wide variety of religious traditions that exist in the United States. It would take several lifetimes of scholarship and even that would probably fail to exhaust what could be said insightfully about these things.

Nevertheless, there might be some specific considerations that particular religious communities might offer that we ought to hear that bear more directly and immediately on the issue of what should public policy be with respect to tissue samples. I think we will -- we reached a decision I believe to have the somewhat more narrow view, that is to make inquiries within religious traditions about what beliefs they might have that would specifically touch on our more narrowly constructed charge.

And then the question arose what is the best method to do that? I mean, initially I at least had thought, well, we would commission one or two papers. That did not seem to be the method of choice. Instead my notes indicate that we decided and agreed that what we would try to do is convene a meeting of a variety of religious thinkers from a variety of faith traditions and pose to them some fairly specific questions that would pertain to the use of human tissue samples for research. I think that is the method we are going to pursue.

Does anyone have a different recollection of our deliberations or decisions?

DR. COX: Tom, I do not have a different recollection but I just have sort of a coda to put on that, a person coda, and that is that based on the presentation which I thought was very thorough and accurately represented by you that it seems clear to me that presentations that we have are not going to be uniformly representative of one or another faith but one or another belief within a particular faith because the description as I heard it was that there is a greater diversity of opinion within faiths on this -- perhaps on these kinds of issues than between them.

DR. MURRAY: Thank you for that, David.

Yes, faith -- by faith traditions we do not just mean say Protestantism, all things considered, there are many. There is a wide variety of positions within each of the specific denominations in Protestantism just for example. There may be -- there are similar spreads in other faith traditions so we wanted to take all that into account.

MS. _____: Excuse me. Since there are no representatives from animal welfare groups we would like to make a quick statement here.

I would first like to ask you a question. Have you all considered that it might not be ethical to treat animals like test tubes with tails? Apart from the fantasy of what cloning might mean for people we need to look at what cloning experiments will mean for animals. Sheep after all are not commodities to be produced like tomatoes. They

are feeling sensitive beings. We must learn to respect them rather than use them for every fool thing.

Do we have the right to mutate and mutilate animals for dangerous experimental gains? Well, health officials in England just banned animal to human transplants because of the very real possibility of unleashing a new deadly virus on the human population. You all know how dangerous this game is.

Grant hungry scientists are already talking about "cures" from everything from lung disease to hemophilia but before we swallow the claim that babies might be saved it is important to realize just how unlikely and dangerous this might be.

We are urging you, the commission, to include animals in the proposed ban on cloning for the health of ourselves, for our children and for the animals.

Thank you.

DR. SHAPIRO: Thank you. Let me just say for -- do you mind turning off your microphone there, please? I appreciate your statement. Let me just say that we appreciate what you say. We have a public comment session later. If you would like to appear you are more than welcome to appear. We will all give very careful attention to your thoughts. We would like, however, at this time to return to the agenda that we are currently pursuing.

Thank you very much for your statement.

MS. _____: Well, I would just like you to at least spend some time here talking about the effects that these dangerous experiments have on animals. I know that this is a meeting to talk about

the dangers of human cloning. I know that we are all worried about what lunatics might do who want to, you know, recreate themselves. But we really need to start talking about whether we have the right to use animals and abuse animals the way that people have been doing it and trying to -- I mean, this is absurd. It is absurd. Okay. And not one word has been said about how this will affect animals and even how it will affect people in the long run.

I demand that you start talking about the animals now.

DR. SHAPIRO: We are not talking about human cloning or animals right now. I really appreciate your statement but we are going to return to our regular agenda. Thank you very much for your comment. We are not talking either about human cloning or issues of animals at this moment. Thank you very much.

MS. _____: That is what you are here to do, however, is to talk about the ethics of human cloning. Let's talk about the ethics of cloning animals. Let's talk about the ethics of mutilating animals for profit because that is what is all about. It is about curiosity and notoriety. He is hoping to make money off of us and make a killing. He is probably going to do that because you guys all support the use of animals.

DR. SHAPIRO: If you are unwilling to let us return to our agenda we will just adjourn the meeting. We really have an agenda. My understanding is you were going to come in to observe the meeting. This is not the time for public comment. We really do need to return. We published our agenda in the Federal Register and we need to return to that.

MS. _____: Right, I understand but, however, you know, it would be really nice if animal welfare advocates were included in discussions that affects millions of animals but unfortunately they are not. Why is that?

DR. SHAPIRO: Our discussion will take place over a long period of time and we will consider everything you have had to say but we really must return to our agenda now. I am sorry.

MS. _____: There has not been one word said about the ethics of using animals. Not one. I understand you are trying to change the subject and that is fine but why don't we have a dialogue about this now?

DR. SHAPIRO: Ma'am --

MS. _____: Since you have got some animal advocates in here let's talk about it.

DR. SHAPIRO: We are not going to talk about that now. We want to return to our agenda. I do not want to have to ask security to come in to allow us to return to our business but I will do so if necessary. We really must return to our agenda. Thank you very much.

MS. _____: Well, we would like to engage in a debate with you about the use of animals and the ethics of using animals. Animals are not test tubes with tails.

DR. SHAPIRO: I will just repeat once again we are not going to do that now.

MS. _____: Well, we are not leaving until you do.

DR. SHAPIRO: All right. Thank you.

We will take a temporary recess in our meeting. Thank you very much.

(Whereupon, a brief recess was taken from 10:13 a.m. until 10:37 p.m.)

DR. SHAPIRO: I would like to call our meeting to order.

I hope -- let me see how many of our commissioners do we have reassembled? I presume the others will be here shortly.

I would like to just with respect to our agenda we can, in fact, get ourselves pretty much back on time by assuming that we just had our coffee break which I will assume and we can get ourselves at least close to back on time.

I just want to apologize again to Professor Murray for having -- for the interruption of his report. Tom, I will just turn to you to see if you have any -- a few words just to wind up the report of your subcommittee.

DR. MURRAY: Thanks, Harold.

We really, I think, have finished sufficiently the discussion of that third major theme which is how to get in religious perspectives and how to begin to consider religious perspectives for our report on the ethics of the use of human tissue samples in research. We will try to assemble a panel at a future subcommittee meeting, a panel of religious thinkers representing a variety of faith traditions present in the United States.

So just in summary we have a rough -- very tentative sort of outline of what our report would look like. I will end just by presenting that. If there is anything urgent that anyone wishes to say, say so now,

but I think in order to be able to turn back to the -- turn to the discussion of cloning I would like to keep that discussion of our report brief.

Here is the rough organization: First would be a descriptive chapter. This is something we would presumably commission and we want it to say what kinds of tissue samples are there, under what circumstances are they gathered, by what -- from what kinds of people, and what kinds of science are they used for. This is a part of the debate that I think has -- part of the picture that has not been fully articulated. So we would very much like to know what it is that -- what scientific value these tissue samples and tissue collections have.

We might also want to include in that descriptive chapter the kinds of cases that Zeke Emanuel introduced for our deliberations at the 5 March meeting that help us to think through in more concrete terms just what kind of ethical challenges, as well as what sorts of scientific value these tissue samples might have.

Now the order of the remaining chapters is open for discussion. Maybe we should not have the discussion this morning. Perhaps another -- we can do it at another event so long as each of these pieces belongs in. That is what matters right now.

A chapter would have to address the normative or ethical -- and/or ethical issues that have been appropriately raised in regard to tissue samples.

A third piece of the report would be some effort to lay out in an honest and clear way what we have learned about public views from whatever sources we ultimately rely upon.

A fourth part of the report would be a discussion of the views from the different religious perspectives and the considerations and concerns brought forth from those perspectives.

A fifth piece would be a review of what has been said and done internationally with respect to tissue samples and related issues. We will probably do that as a contract report or contract draft.

A sixth piece would be an articulation of the framework that we propose ought to be employed to think through the tissue samples and as a kind of prelude for the seventh and last piece which will be our recommendations for policy.

Now I hope that was an accurate report of what the other members of the subcommittee think we decided upon. I invite you to add anything if you would like to at this time.

DR. SHAPIRO: Thank you. Are there any comments, further comments or questions? We really are back on time so we do have a few minutes for comments or questions if anyone from the subcommittee or other members of the commission would like to comment.

(No response.)

DR. SHAPIRO: Well, Tom, I want to again express my gratitude to you and to all members of your subcommittee. You also, as the other subcommittee, are working very quickly and you have very ambitious and I think an appropriate set of objectives. I really appreciate very much the work that you are doing. So thank you very much.

DISCUSSION: APPROACH TO THE PRESIDENT'S REQUEST

DR. SHAPIRO: We will now go directly on for the next half hour or so to discuss the commission's initial response or approach to the President's request.

By the President's request in this context of course I mean the request from President Clinton for this commission in addition to its ongoing work which you have just heard about address the legal and ethical issues that surround the scientific achievement in relations to cloning or the possibilities of human cloning, and so on. And I want to report to the commission what initial tasks I have already decided to undertake on behalf of the commission.

Now I do want to apologize to all the commission members, we were not able to call a meeting of the commission instantaneously upon receiving this request, and 90 days is a short time to deal with this very complex and important issue and so I decided it really was necessary to begin doing some work on behalf of the commission.

I did consult with individual members of the commission regarding some of the things which I am about to talk about to talk about and, of course, some of this was described in congressional testimony yesterday at Senator Frist's hearing where we were represented by Alta Charo and Tom also had -- Tom Murray had some very important things to say, also at the House hearing last week a subcommittee from the Science and Technology Committee.

But let me go back now and summarize some of the things that we have already begun doing, some of the things that we are about to do, and I would also ask if we have time this morning, if not we

will do it this afternoon or tomorrow, I want -- I would like Alta's and Tom's report back on their perceptions of the congressional hearings in which they participated last week and then just yesterday. So let me begin that way.

First of all, if you look at our agenda for today you can see that I took a number of steps with the advice of others to try to bring before the commission a series of really very distinguished scholars and thinkers who have thought about various aspects of these issues.

Professor Shirley Tilghman will be addressing us this afternoon on the science issues, the science issues that are involved in this issue. We will then have, as I said before earlier this morning, a really fairly long list of really very important thinkers addressing us from the point of view of various faiths.

Now we should not interpret the people we have invited as the representatives of these particular points of view nor should the commission think that these are the only points of view that we are concerned with and interested in. These are just a group of very thoughtful people capable of addressing us in this area who we have an enormous amount of respect for. There are many other people we have an enormous amount of respect for who are not on this list and we hope that those with an interest in that will take advantage of submitting their views to the commission.

But we will hear this afternoon from some interesting thinkers who will try to convey to us the views that the Protestant denominations have, at least some of them have, and discuss those

matters with us. The same is true from the Roman Catholic church. Tomorrow we will hear from representatives of Islam and Judaism.

Tomorrow, of course, we will also hear from four really very distinguished thinkers dealing with particular genes on cloning with one set dealing with the possible benefits, Dr. John Robertson and Dr. Ruth Macklin, and another with the possible risks, Dr. Leon Kass and Dr. Jim Nelson, all of whom are really very thoughtful observers in this area and I am sure we will gain a great deal not only from what they have to say but from our own interaction and discussion with them.

I will be trying to structure those parts of the session not only to hear from those people but to have them talk relatively briefly and enable the commission to interact with them so that we can probe and understand in our own terms just what the issues are in these particular areas.

So the first thing that we did in response to the request was to reorganize this meeting. This meeting had long been scheduled. Obviously its agenda is quite different from what we had anticipated and that in some sense was the first response.

The second response, we have already initiated or I have already initiated I should say, is to try to reach out into the community to have various experts prepare materials for us so that we could consider papers that would be available to us very early in April so that we could have -- take advantage of that information by the time we, ourselves, meet in April. I would just like to describe at least in very brief terms very succinctly to you what some of those initiatives are.

We have -- we will be commissioning and have commissioned a study already under way a survey of the relevant legal landscape, both federal and state legal landscape, here in the U.S. That is a study that is already underway. It directly responds to the request of the President that we deal with the legal issues here in ways that seem appropriate to us and so we thought it was absolutely critical that we get an updated survey of the status of federal and state legislation in this area of particular rules, regulations and so on, and we will do so. That is already underway and we expect to have that back to us April 2nd. That is Lori Andrews who is doing that from Chicago, Kent --

DR. _____: Chicago Kent law school.

DR. SHAPIRO: -- Chicago Kent law school, Lori Andrews.

We also thought it was very important to have a survey of the relevant legal landscape abroad, that is internationally, with countries who have thought about this and care about this issue, and also with current stance if you like or the current positions of various, what I call, NBAC-like commissions or are standing commissions -- they may not -- that sounds a little imperialistic to call them that way actually. Maybe we are something else like commission from -- that is why we are a world-like commission here really.

As you know there are many countries, including the Council of Europe and others, that have standing commissions in this area and we met with many of them in our meeting in San Francisco in November. We want to have some sense of not only what their views are but why they hold certain views.

I said earlier on today we are particularly concerned not only with someone who is in favor of something or against it but why they are so that we can evaluate its ethical, moral and legal content a little bit more effectively.

We have been very fortunate to get Bartha Knoppers from the University of Montreal to really do that for us. Bartha attended our meeting in November and was really a very, very effective participant, extremely articulate, very knowledgeable person and we are very grateful to her for willing to take on assignments like this which are in very, very short deadlines.

We also want, of course, to commission a review of the moral and ethical concerns that have been raised in this area. We will now think about these even more carefully but, of course, others have thought about this over really quite a long period of time.

Professor Childress was generous enough to give me a bibliography on cloning -- which I think you got off the Internet somewhere, Jim, and maybe put out by the Georgetown Center, I am not quite sure.

DR. CHILDRESS: That is right.

DR. SHAPIRO: Anyway this is very -- it is a really very good bibliography. Jim can probably give you the book mark if any of you want to get it off the Internet but it is very helpful. As Jim pointed out to me, there are three waves of interest in this area, both -- one that began really in the late '60s and early '70s largely carried on by some scientists and philosophers who were just thinking about the issue.

No one thinking this was anywhere close at hand but very interesting discussions took place.

There was then another wave of interest more or less around the end of the '70s and beginning of the '80s as near as I can tell stimulated largely by novels and science fiction, and movies, and plays, and so on, and things of that nature but also a very interesting set of discussions revived.

Of course, in the early '90s this issue was revived again as we began to think more carefully about embryo research and embryonic development and so on. And then, of course, what we are currently involved in right now.

So as a result there is a literature, an important literature out there, and Professor Brock at Brown University has agreed to survey that for us and provide that as input for our own discussions and I am certainly very grateful to him and my colleagues on the commission were able to convince Professor Brock who is already busy and has a full-time job doing something else to really help us out in this regard.

We have also commissioned a paper on the review of religious perspectives on this issue very much analogous I guess to what Professor Murray described in the genetic -- in the tissue sample study which he described just a few moments ago. Courtney Campbell has agreed to do that and we look forward to that. Also someone who is well-known to many of you and a very careful thinker in this area and I think will do very well.

We have a -- we also wanted to turn, of course, to the science side of this in which my own discussions with Carol Greider have

been really very, very helpful. Carol's leadership in this area to try to both define what it is that we would ask people to do and both -- and had interesting suggestions regarding who might do this.

What we are after here, of course, is a review of the current scientific issues in this area. Possible beneficial applications in the area of animal husbandry, other areas like that, nonhuman areas, that is not directly dealing with human cloning or anything like that, just so we can understand where the science is going and what it might achieve in that area.

But, secondly, and most directly -- also directly relevant for our ongoing considerations is what will the research agenda look like? If one were to proceed on a research program to move towards the possibility, desirable or undesirable, for human cloning what would that research agenda look like, what issues would it raise, what would be the potential agenda, benefits and risks as we move down that path?

I have not had a chance to speak to Carol recently but I think we have someone who has by e-mail signed up for the first of those yesterday. I am trying to -- it is -- I am trying to recall. Janet --

DR. GREIDER: I have not received confirmation of anybody. People have been contacted.

DR. HYATT-KNORR: I have received confirmation.

DR. GREIDER: I have just received confirmation. I was going from my e-mail after last night.

DR. SHAPIRO: I am just trying to think of -- I forgot her first name.

DR. GREIDER: Janet Rosanna.

DR. SHAPIRO: Janet, excuse me, Janet Rosanna who will do that but that issue has to be resolved and fully understood in the next day or so, so I do not think that is done yet in some sense but we hope to complete that very shortly. And then we have another area which we are going to focus on obviously and have someone to repair some issues for us and that is in the area of the policy options/recommendations that might be available in principle if we were to address those issues.

So those are all in the way we would hope to have these papers for the commission's review early in April which is a time schedule that we have to meet in order that they have any kind of an effective input for us at our April meeting and thereafter.

So those are underway and I have been extremely pleased with the willingness of some extremely distinguished scholars to help us out in this respect and I am sure we will all be very well served by their work.

Also, just sitting at the end of the table on my right is Kathi Hanna who may be well known to many of you and has worked on a lot of projects here in Washington and elsewhere. Kathi will be helping us mobilize our report, our final report, which I am going to talk about in a moment, working with some working groups which I am also going to discuss in a moment, and just helping me, Henrietta and the rest of the staff, Dr. Raub, to just oversee the whole process and try to guide us through to successful completion.

Now in trying to get this report done in an effective and helpful way in 90 days is no simple task and it can only be done with what you might call in the modern cliche "parallel processing." That is

we have to do things together which in some better world we might want to do them serially. That will mean we have to interact back and forth and go back and correct ourselves and shift positions and so on. So we are going to be in a position which is a little unusual for us and we will not be able to proceed in a simple linear fashion.

In that connection I want to talk about two further things that I would like to recommend to the commission. First I would propose that we establish three or four working groups composed of commission members who will take primary responsibility for particular aspects of the report.

Of course, when one tries to devise what I will call buckets, that is which knowledge categories into which we should put our work it is always somewhat arbitrary and I think of these as leaky buckets, that is that they will have -- these groups will have to interact with each other. We may find as we move ahead that we want to redefine their role and objective, and so on. But I felt it was very important that we had internal groups who were focused and mobilized on particular aspects of this both to receive the information we were to get from outsiders and to help us focus on particular parts of the report.

The groups that I would propose that be established are first of all a group in the science area in which we will -- which will be focused and take responsibility for all of those kind of science related issues and how they may impact various parts of the report. I do not mean to say that that will be off in the report in one kind of water tight section. It will influence lots of parts of the report and we will need an

internal group both to advise us and to look at our material to make sure that we have all the facts right.

I saw Tom quoted the other day, I do not know where the quote came from, Tom, but you said, "Something like philosophy starts off well if you start with the facts." I know that is something that has been around for a while but it reminded me of that and we want to make sure we have the facts right and we have the agenda correct.

I have already spoken to Carol Greider about this. She is willing to take the leadership of that group if we approve -- if the commission thinks it is all right to proceed in this fashion.

I will assign with your permission two or three additional people in addition to the chairs to each of these groups and try to achieve some mixture amongst us. You will not all be assigned to groups which are necessarily your either first choice because we probably cannot accommodate everybody's first choice or not even necessarily your direct specialty because I think it is very important to get into these groups people -- I would like in the science group to take an example, some of you who are of course tremendously expert in that area but others who just have an interest and to whom this report is going to be addressed, people like myself for example, so that we have right in the group some mixture of background opinion and so on.

So we are going to appoint one group to deal with the science issues and concerns. We will appoint another dealing with the philosophical and ethical concerns and I have also in this connection already talked to Dr. Lo who has agreed to take leadership of that group.

And then there are two other buckets, and our discussions have not gotten far enough to know whether we ought to combine them into a single category or a single bucket or to deal with them separately, or to be combined at some later stage of our discussions but the two areas are law/regulation dealing with the legal regulatory sets of issues that may come up here both to know what the current status is and how these avenues might be employed given our recommendation -- whatever recommendations we come up with. The final bucket or category dealing with policy options that are available and what the benefits might be and particular avenues to pursue in that area.

Now in the latter two areas I have asked Alta Charo to head one of those groups. I had in mind to ask Alex Capron to head the other. Alex is not with us today so I have been unable to -- I do not know if he is willing to do this but I will try to make an offer he cannot afford to refuse but the -- there is an open issue which I have asked Alta to talk to Alex about and that is whether these two groups should really be combined in the first place. They obviously are very intimately related.

The survey of the legal landscape is well underway and will be, I think, finished quite early on and it may be that it really is most effective for this group to work together right from the very first. I have asked Alta to speak and I will also, of course, speak to Alex and we will have some discussions to see whether that group ought to be merged right away in which case we would only have three groups with one group a little bit larger than the other two.

So let me stop there. First of all, to ask commission members if, one, they have some serious objection to proceeding this

way. More importantly maybe I ought to put some costs on whether you have a serious objection or not. The cost is you have to have a better idea.

(Laughter.)

DR. SHAPIRO: And I am sure there are better ideas. This is not something that I have had a long time to think about. I am sure there are better ideas. That is the only thing I am sure about but I would like to proceed in this way so each of us will be part of a small group and take some ownership to this particular set of responsibilities. I think that will drive us on.

Larry?

DR. MIIKE: I would prefer we start with these four groups. Clearly a policy group will have to relate to all three areas and it may be that the law or regulation group just moves quicker to move together with the policy group but eventually the policy group cannot go anywhere without input from the other three so I would prefer we start off with the four and then we will see how they emerge.

DR. SHAPIRO: Any other comments or questions?

All right. Then I will presume that what we will do is simply proceed along those lines. This is going to generate a lot of information. We are going to generate an awful lot of information in the next, it sounds almost ridiculous to say so but in the next two to three weeks and I do not know when in April we will be able to schedule our meetings since we have not had a look at the calendars but hopefully we will try to do that before we break up tomorrow. So I encourage you all to get your calendars in if you have not done so.

If I could also make another point, even though as, I guess, Tom or someone else pointed out this morning that we have yet to have the life of this commission extended, officially extended, my understanding is that that will certainly happen very shortly and we are certainly planning meetings for next year.

So we would like to get calendars not only for what is immediately required, that is up through June and July but also through next year, indeed the next two years, so we can try to schedule meetings where that is possible for you. So for those of you who have these calendars do not stop in May and June, if you can tell us longer in the future when you are available that would be a very great help to us.

Any questions about that? If there are none -- I mean, I encourage questions but I really want to be sure that you feel comfortable with proceeding in this way. I will speak to each of the commissioners some time before we leave regarding the assignment to particular groups here. I will try to accommodate everybody's preferences to the extent that I can. I mean, I really do want to try to put you into areas you would care about and want to work on but I cannot absolutely guarantee it because depending on how the preferences break down.

Okay. All right. We will proceed in that fashion. We will establish these working groups and I will, as I said, speak to each of you some time before we adjourn tomorrow regarding the assignments.

Let me ask another question. We are thinking about our April meeting and we have, of course, in today's agenda a list of organizations/individuals who we are hearing from. I would be very

interested in any advice the commission has regarding persons and/or groups that you think would be very important for us to hear from sometime during our deliberation in the April meeting might be a chance to provide -- we would not want to take up the whole meeting because we will need our own discussions to take up the bulk of the meeting by the time we get to April but we might provide some time to hear from groups who the commissioner members feel are particularly important for us to reach out to.

We are going to, of course, to a long mailing list as long as we can certainly make it to organizations we think might be interested and ask them to provide us with written input and they may wish to appear and make public comments but in any case to provide us with written input if appearing here is not convenient because we do want to spread our net as broadly as possible. So we will be sending a lot of genuine requests out of that nature.

The question is whether there is any particular groups and/or individuals which members of the commission would really want to hear directly from so we could have one on one interaction with. Just to give you an example of some of a group that one could think of, whether you think -- you could think of FASEB, for example, this organization of, you know, biomedical investigators who are obviously critically involved in -- would be critically involved and might have some views of long experience and so on but that is just an example and you may or not feel that is the right example.

I have the feeling that we should also reach out to and request some appropriate presentation from someone who is working --

people who are working in this area in what we would call loosely the private sector, people who have -- you know, we have had a lot of comments about that here but we have not really heard directly from those groups. There was testimony on Congress the last couple of days from one or two of them but that is another example.

So what I would ask you to do, if you have any suggestions right now that is fine, more importantly as you think about this during the day you might pass on to Henrietta and/or myself, or Bill suggestions you might have in that regard.

Does anything occur to you right at the moment?

Excuse me, Bernie?

DR. LO: To follow along with this line of thinking I wanted to tie this in with a comment we had before our break about how to sort of gather public viewpoints on the issue of DNA testing of stored tissue samples. I am just wondering if it is the same dilemma here. It would be nice to sort of have a way of finding out whether there are concerns in the public which may be not very well articulated at this point that we are just not aware of. So that is one thought. I do not have a clear idea how to do it.

And a second idea to consider is sort of a high tech idea. I know there are a lot of discussion groups. There is a bioethics discussion group and one thing we might think of doing is asking -- putting something out saying we are interested if you have something you want to send us I would be willing to sort of do it for the ethics sub-bucket to sort of gather input if people wanted to send us something.

DR. SHAPIRO: I would just like to point out you are not yet a sub-bucket, you are just a bucket. If you appoint another subcommittee that would be a sub-bucket.

Thank you. That is very helpful. I think you make a good point. There are a lot of discussion groups out there. Most of them are really quite serious and helpful. Any of the working groups, in fact for us as a whole, we might want to access that as a way of getting information easily for people to tell us something that is on their mind.

Yes, David?

DR. COX: I really like the idea of inviting FASEB particularly since, you know, there has been some concerns raised about whether this commission has the adequate scientific expertise to represent their case. So I think that it is particularly in those situations and very broad organizations like that when they voice such concerns it is very important that we hear from some.

DR. SHAPIRO: Thank you. Yes, Eric?

DR. CASSELL: One of the things that interests me and that might help us on our work, the time constraint pushes us badly, is this is an area where public policy impinges on science and the behavior of people with regard to science. I am interested in what has happened, what we know has happened in the past in relationship to -- for example, in vitro fertilization. I mean, what did actually happen. The fears that were raised and what was going to happen and what actually happened. What has been the history of this kind of endeavor in the past and the response of the public to it? So that we do not act as though there is no

-- there is no history. There is a history and I think it would be very helpful if we knew more about it.

DR. SHAPIRO: Thank you very much. I appreciate that remark. I have the same feeling and in that context let me turn to a single page that you have here. I will give it to all the commission. The page is headed "Draft Proposal, Preliminary Outline of the Report to the President." Now I have tried to think of ways to put more drafts and more preliminaries into there so that nobody gets -- assumes too much by looking at this. It just occurred to me as I was thinking through our time schedule earlier this week that we really had to get started and provide -- begin to try to get a brief kind of hazy -- at least hazy outline of the report that we were going to generate.

I do not want to -- so this is what I wrote down as I thought about this. Here is how the report could have been laid out I thought at least at my first pass at it. The question is not to take this so seriously. What I really need from the commission members is to look at this as thoughtfully as you can, scratch out things, do whatever you want and present some alternatives. That would be extremely helpful to us because given our time frame we do not know, of course, at this stage what we are going to recommend. That is entirely premature. But if we could just work out an intellectual apparatus, a kind of intellectual plan as to how we might structure the report, that will be enormously helpful to all those who ware writing parts of it and so on.

So this is simply a first stab. I hardly -- I did not even know whether I should sign it frankly it was so preliminary but I did just for purposes of keeping records so we would know who we interact with.

But I really ask each commissioner some time in the next four, five or six days, the time that is convenient for you, to take your pen, pencil, scissors, whatever you do to react to this, to give us some better idea. That would be extremely helpful.

So again this is part of our parallel process and we are not ready to write the report yet. We already have to at least begin thinking about the outline just as the working groups are going to have to begin before we receive all the information from the papers we have commissioned. So that would really be an enormous help to us so please get this back to me, to Bill, to Henrietta, whatever is convenient for you, that would be quite helpful.

Finally before we take our scheduled break I really would like to turn to Tom and Alta to report to the commission on their participation in congressional hearings.

Tom, yours was first so let me turn to you first.

DR. MURRAY: Certainly, Harold. The reason we began meeting at 7:00 a.m. on the 5th of March was so that we could be down to Capitol Hill in time for a hearing that was scheduled to begin at 2:00 p.m. Initially I had been asked to testify and had declined because it would have interfered with our subcommittee meeting but on consultation with NBAC staff and with Dr. Shapiro it was decided to compress the subcommittee meeting, begin earlier, take fewer breaks and eat on the run so that we could -- all of us who were able to could go down to Capitol Hill and be present for the House Subcommittee on Technology of the House Committee on Science Hearing.

There is not much I can say about the hearing itself except I would hope and I believe that the testimonies have been or are being distributed to all NBAC members. The people who testified were Dr. Harold Varmus, the Director of NIH, Dr. -- is it Kaird Rexroad? -- Kaird Rexroad, Dr. M. Susan Smith, who I believe it was in her laboratory that the rhesus monkeys where -- the embryo cloning of rhesus monkeys took place, and Dr. Jim -- or Jim Geraghty, who is head of -- is it Gen --

DR. _____: Genzyme.

DR. MURRAY: -- Genzyme Transgenics and myself. It was -- I did not know what to expect. It was actually, I thought, a pretty good interchange. The questions asked by the members of the subcommittee were by and large very much on point and, indeed, a number of them I thought raised very good issues. Otherwise I am not sure what to say except that it was a very good interchange. I was told it would last an hour, at most an hour-and-a-half, I think we were there -- still there two-and-a-half hours later. So they apparently found the conversation interesting enough to continue for a while.

DR. SHAPIRO: Thank you very much.

I know we have distributed Tom's testimony as well as the testimony of some others that appeared at that hearing.

All right. Let me turn to Alta just to reflect on yesterday's meeting at Senator Frist's committee.

PROF. CHARO: The agenda for this particular hearing was changed rather late in the game to permit Senator Kit Bond and Senator Pete Domenici to testify first. Senator Bond spoke to the bill

that he introduced, a copy of which was e-mailed to you, that proposes to place restrictions on human applications in cloning.

Pete Domenici wanted to speak to a bill he is introducing having to do with genetic privacy which is not specific to cloning but is in the area of genetics and so he thought it was appropriate, and to some extent that was the news event.

The public relations event was clearly the fact that Dr. Ian Wilmut was there from Scotland and so people had a chance to hear from him personally for the first time in the United States about his research.

Dr. Varmus, using the charts that, in fact, he had developed first for the Morella hearings, continued in what he called "Bio-101" and was working hard to help draw clear distinctions in the area human applications among cloning experiments that involve nonreproductive cells with no reproductive capability. Those areas of research that involve manipulation of embryos and those that involve babies and to make extremely clear the need to keep them separate because we do cloning all the time with human genes, for example, and that anything having to do with "Dolly" type cloning is still for the moment in the realm of science fiction.

And the testimony continued on -- I was asked to specifically represent the commission rather than speak for myself. So on the record is a preliminary listing of what it is that we were planning to do and some analyses of the effect of the embryo research regulations and discussions to date on this area of research, and also rules governing medical experimentation on children.

Other issues covered were ethics, George Annis, Karen Rothenberg, and a panel of three people who specialized in organ transplantation, pharmaceuticals and biotechnology with applications in that area.

And at the conclusion of the hearing it was not clear to me exactly what further action, if any, would be taken by Senator Frist's committee on this topic.

DR. SHAPIRO: Thank you very much.

Does anyone have any questions for Tom or Alta on this? Steve?

DR. HOLTZMAN: It is actually --

DR. SHAPIRO: Comments of your own.

DR. HOLTZMAN: No, it is a question to the commission. It has struck me that there are a number of bills that are being introduced both in Congress as well as in the states. Alta is very good about e-mailing us the --

PROF. CHARO: I have been e-mailing all --

(Laughter.)

DR. HOLTZMAN: Could we put -- would people think it would be useful that we could quickly put together a conceptual grid into which we could throw these bills? For example, what is being regulated? Some are addressing transfers of some nuclei from somatic cells. Some of them do not make that distinction and would include embryo cells, et cetera, et cetera. Some of them are making it a felony and some are not. Is there -- could we quickly get a framework in which to be able to start to put these?

DR. SHAPIRO: Alta?

PROF. CHARO: Yes. I apologize for those of you who have got limited kilobyte space in your e-mail boxes when I keep sending you drafts of these things but I run an automated search every morning on my computer for new stuff coming down the pike including things like state bills. So you are getting them as fast as I am getting them.

DR. CASSELL: I would not mind getting them slower than you get them.

(Laughter.)

PROF. CHARO: I would be happy to try and put them into buckets since that seems to be the phrase of the day and to deliver them to you in buckets so that it is easier to keep track of them. But you are right. For the moment basically the phrase that is being thrown around in most of these is human cloning and the definitional sections are usually omitted or abbreviated so that there is ambiguity about the extent of coverage which is one of the points that Dr. Varmus was, in fact, trying to bring out at yesterday's hearings.

DR. SHAPIRO: Tom?

DR. MURRAY: With respect to the March 5th hearing it is probably worth noting that Congressman Ayler, who has submitted two bills to the House of Representatives, was present at the hearings and the question was raised whether the panel, the five members of the panel, thought it was important to pass laws immediately.

I took there to be no dissent among the five panel members that it would be -- none of them welcomed the idea of laws passed immediately and that, in fact, it was certainly worth deliberating

clearly until the time, such time as this commission could issue its own report, and there were two lines of questioning that helped illuminate why it is probably not necessary to have a law passed instantaneously.

One line of questioning had to do with what capital investment was required to assemble the equipment to do this kind of research and the answer to that was not so much. The second question was what was the rate limiting feature here and as Dr. Smith, Susan Smith, I think this was the best line of the hearing.

She said something to the effect that cloning is very, very hard and, in fact, there are only a very small number of scientists around the world who are probably capable of this research even in animals let alone humans, and it is a relatively -- it is a community of scientists well known to each other, none of whom according to the testimony of the scientists there were likely to even attempt human cloning in the foreseeable future.

So given that there seemed to be no one with the ability to even try it now it was unlikely to be attempted immediately. So we have some time to reflect, pause and offer advice about what might be a well measured response.

DR. SHAPIRO: Zeke?

DR. EMANUEL: I just wanted to make two points. I sat in on Tom's hearings as they occurred after the Subcommittee on Genetics and I was actually struck by the somewhat inability to formulate the exact concerns and I think that that suggested to me that a primary obligation of our commission is both to formulate the benefits and the concerns clearly and intelligently. Congressmen were repeatedly trying

to go around and formulate the right question and even the right question was hard, I think, to get out.

The second thing I would ask you, Dr. Shapiro, as a chair, is 90 days is a very short time line and the question of whether we issue a report but continue to deliberate and maybe rethink even some of what we are doing, it may be a little awkward but I think there may be some virtue in it and I would -- you did not address whether we would keep this on the agenda as it were and maybe issue a follow-up report as we think more over a year or two years.

I do not always do my best thinking fast and I sometimes change my opinion when I rethink. So I just wonder how that is ruminating in your mind and also how the commission would react?

DR. SHAPIRO: Two things. The first comment do not take too seriously. The most frequent comment I get from students who do not like their grades is exactly that one, they do not think well fast.

(Laughter.)

DR. SHAPIRO: But more seriously I have two kinds of reactions to the very important point you have raised. Namely we do have to keep focused on our 90 day responsibility and really do something we are proud of in 90 days. And so I do not want us to kind of fall victim to the things -- as every time we get to a hard problem we will put it off to the post-90 days.

On the other hand I think I -- it is hard for me to imagine that we will not continue to do some thinking on some of these issues after that. So I expect that while we must and will meet the report deadline and have something to say, I believe, I also believe that this will

not leave our agenda after that because inevitably there will be issues which we want to do some further work on.

Yes, Professor Cox?

DR. COX: I would just like to say that I think that this result of Dr. Wilmut's gives this commission a golden opportunity or it could be looked at as a real sort of bad opportunity and that if we do not come forward in 90 days with a very clear statement then for us to adjudicate on some of the other issues which I personally feel are as or perhaps more important than this cloning issue it is not clear to me we will have that opportunity. So I would hope that the commission could be crystal clear in 90 days on how we feel on this issue.

The second point, and it is really something that both Eric said and Zeke brought up, it is not clear to me that we have all the facts. So for us to collect facts is very important. There is a particular type of fact that I am interested in which is not sort of the history of the reproductive technologies but what the cost benefits of them have truly been.

And that to -- for the patients, for the economic benefits of the people that are delivering them and for, you know, our country as a whole, I think that since this is really a technology issue about cloning to address at that level what the cost benefits have been I think for me will be extremely important in terms of adjudicating other types of technologies.

DR. SHAPIRO: Thank you.

Diane, did you want to say something?

DR. SCOTT-JONES: I was able to attend the hearings yesterday and so I just have a couple of comments. One thing that Senator Frist mentioned when he was talking was that he, himself, is a surgeon and he talked about how heart transplants were perceived when they were first started and he reminded everyone that we need to think about this in some context and I think a historical context is really important to think about how people have responded in the past in new developments.

And another of the speakers, Karen Rothenberg, mentioned the importance of considering this issue of cloning on a continuum along with other reproductive technologies and I think that is important, too, that we do not just look at cloning in isolation of other kinds of developments that are going on and that we place it in some sort of context, scientific context, and maybe look a little bit more broadly than cloning per se.

DR. SHAPIRO: Thank you for those comments.

It is, of course, true that this occurs not only in a particular scientific context as you have pointed out but in a social context in which behaviors and ideas regarding families and other things have changed in very important ways as Tom has written about much more carefully than I could articulate right now. We will try to reflect that in the report that we write.

Larry?

DR. MIIKE: Just a comment from a policy side is that this is no different from other complex issues where we argue about whether we should narrow the scope or whether we should enlarge and what can

we say with the current knowledge, what do we reserve for revisiting, and I think this is just sort of part of the process we are going to go through.

DR. SHAPIRO: I agree.

Any final comments before we break for lunch?

I want to thank you all very much. We are only running about 13 minutes late or something like that. We will try to get back on our agenda. We are supposed to reassemble here at 12:15. Thank you all very much.

(Whereupon, a luncheon recess was taken from 11:28 a.m. until 12:35 p.m.)

* * * * *

AFTERNOON SESSION

(12:35 p.m.)

DR. SHAPIRO: Those members of the commission and staff who have their backs to the screen may wish to change their seats for the next little while. Just either turn around or carry a chair over there because Professor Tilghman will be using multimedia here.

Thank you all very much. I would like to begin this afternoon's session. At the moment we also have, I see, some empty seats at least for the moment along the side to my left people could use that.

Well, it is a great pleasure for me as chairman of the commission to welcome our next speaker here this afternoon. It is Professor Shirley Tilghman from Princeton University, a colleague of mine at Princeton, a very distinguished colleague, a very distinguished scientist, and to tell Professor Tilghman that we are enormously in her debt for taking time off to help this commission address some of the background issues, some of the science issues that surround the focus of our concern, namely human cloning.

I think Professor Tilghman plans to address us for 20 minutes to half hour or something of that nature, then allowing the commission to enter into a discussion with Dr. Tilghman.

I do want to say that not only is Professor Tilghman a very distinguished scientist, she is also a very distinguished teacher and she heads our Council for Science and Technology which is aimed at teaching science to nonscience majors at Princeton. So I really cannot

think of anyone better suited to help the commission address some of these issues.

Shirley, welcome and thank you very much for coming.

SCIENCE AND TECHNOLOGY IN CLONING

DR. TILGHMAN: Can everybody hear me while I am standing here? Good.

Well, I will try and be as brief as possible. One reason is obviously you have a great deal to do in your deliberations. The other is that as I speak there is the tip off of the Princeton-Cal basketball game in the NCAA tournament known as "March Madness." If I was at North Carolina I could probably miss the first game and that would not be so bad.

(Laughter.)

DR. LO: Just so you know I live in Berkeley.

DR. TILGHMAN: So I only have a short time here.

(Slide.)

So I am going to try and review what I consider the real scientific issues that surround the recent publication of Dr. Wilmut's report which I sort of in this title have called "The Cloning Experiment."

One of the things that I think is unfortunate in this business is that the word "cloning" has, in fact, been used in different context in different times to mean distinctly different things. So until two weeks ago the word "cloning" as used most commonly in the scientific community was a strategy for essentially taking a single copy of a gene and this gene could come from literally anywhere in the biological kingdom, and to be able, in fact, to reproduce this gene

manyfold, usually in a host cell that was relatively simple like a bacteria or a yeast cell.

Cloning as we are going to talk about it today is a very different process where the common feature, and the reason these two very different things ended up having the same name, is that it involves replicating from a single copy many individuals. So I am going to try in the beginning to talk about three issues that I think are relevant to the science of cloning as meant by Dr. Wilmut's experiment.

The first is why, in fact, were scientists so surprised with his publication because there was, in fact, considerable surprise on the part of the scientific community, including highly knowledgeable people in the field that Dr. Wilmut, in fact, was able to do his experiment?

The second issue I want to address is why was the experiment so inefficient? I am going to go through what I mean by inefficient, but what does it really mean to be inefficient and what does that tell us about the scientific issues?

The final thing that I am going to address is what are the scientific risks and what are the scientific unknowns associated with the experiment under question.

(Slide.)

Now to answer -- oh, thank you. All right. So that will allow me to back up and get away from the screen so more people can see it.

So to begin to understand the first question which is why were scientists so surprised, in fact, that it was possible to do what Dr.

Wilmut did I have to back up a little bit and tell you about normal mammalian reproduction.

How far away can I move from this and still people can hear?

So this is a very simple depiction of early mammalian development.

You need me to move away? It is not showing up. It is too bright. All right. Well, I think I can point.

So, of course, mammalian development begins with an egg and a sperm, each of which contains half of the genetic information that is ultimately going to be directing the development of that embryo. The sperm injects its DNA into the egg and at this point one has the two male and female nuclei separate but very quickly these two merge together and we now have a single celled embryo.

Now the important thing and the reason why scientists were so surprised that this experiment worked is that during this early process the genes that are in these two pieces of collections of DNA called the pronuclei are largely silent. During oogenesis and during spermatogenesis this DNA has been packaged in such a way as to really have it quiescent. And as a consequence a very critical thing must happen immediately after fertilization which is those genes have to be reactivated because otherwise development cannot occur.

Now there are species specific differences in the rate of that reactivation. In the mouse where the vast majority of embryo manipulation experiments have been done in the past the reactivation is very fast. It occurs essentially by the time that one cell has divided to

make two cells. So mice have to be able to essentially strip the silencing mechanism off those genes and get them active very fast, literally within about 18 hours.

Now sheep and humans are different in this regard. So this is a species difference. There is no sign of gene activation in either sheep or humans until the age of 16 cell stage. So these organisms have a longer period of time, two or three days essentially, in which to do this reactivation of their genes. And that may be relevant to the issue I am going to come back to which is why were we surprised it worked in sheep.

Now at this point most of the genome, in fact, has reactivated which means that the genes are in states that are competent to be expressed. But now what happens is that we have to resilience them but now we are going to resilience them in ways that are specific for the different kinds of cells that must ultimately arise from these simple cells.

So if you look at a red cell or a kidney cell, or a liver cell, or a neuron, what you see is that only about ten percent of the genes that are capable of being expressed are actually expressed. So there is this really critical process during early development where the genes that you do not need to become those cells are silenced again.

Now scientists had, in fact, for really over a period of about 20 years been asking the question can we take genes that are packaged in this form in these cell types in which the genes have been silenced again, can we, in fact, reactivate them? Can we get them to be active again? And there was a sense that after about this stage of

development the answer was no, that you could not reactivate these genes.

So the surprise in terms of Dr. Wilmut's experiment was that one of the conclusions you have to draw from his experiment is that at least in one case, in one cell type, which was a mammary cell which he used, it is possible to reverse this gene silencing.

So what is the experiment within this context?

(Slide.)

So this is the experiment that Dr. Wilmut performed. So he took a cell that was in this state where 90 percent of the genes in that cell had been silenced, only about ten percent of the genes were active, and he fused the cell with, in fact, an unfertilized egg and the unfertilized egg had had its genetic information removed physically by microinjection.

So a needle had actually gone into that unfertilized egg, which is called an oocyte, the DNA had been removed so now it was only -- it had none of its own genetic information left and the -- the now completely enucleated egg was fused with a mammary gland cell. So I am only going to talk about one of his experiments, the one that I think is the most relevant one.

Now think about what must happen if, in fact, that nucleus that is obtained from a mammary gland cell is going to, in fact, be able to go on and generate all of the cell types that are in an adult sheep. Well, the first thing that absolutely has to happen is this gene reactivation has to happen. So the question of was this even feasible, if, in fact, this experiment is reproducible, the answer has to be yes, that

there is something, in fact, in an oocyte that is capable of reactivating those 90 percent of genes that are in a silent state.

Now why were other experiments very similar to this that had been done over the past 20 years, why did they fail? In other words another way of asking this question is what is different about what Dr. Wilmut did from what other people had done largely in mice but not exclusively in mice, experiments of this kind have been done in other mammals as well, as well as a very early experiment that had been done in frog.

So there are a number of possibilities. We do not know the answer to this but there are a number of possibilities worth considering. The first is that many of the mouse experiments had not been done with unfertilized eggs but had been done, in fact, with fertilized eggs. So there may be a difference in the ability of an unfertilized egg to reactivate genes versus a fertilized egg. So that is one difference.

The second difference is the difference I have alluded to and that is in organisms like the mouse where this reactivation has to happen very quickly, perhaps it is never going to be feasible, in fact, to have this reactivation occur fast enough for this to work. So that is a second possibility.

A third possibility is, in fact, an observation that had existed for some time but Dr. Wilmut took advantage of this observation and that is that we now know actually as a result of about the last ten years of experimentation that the decision of whether a cell is going to divide or not divide ends up being the result of a very intimate

connection and conversation that occurs between the cytoplasm of the cell which is all this stuff and the nucleus. And, in fact, if the cytoplasm and the nucleus cannot have that sort of conversation with each other in a meaningful way then, in fact, a lot of miscues get sent and development undoubtedly would not be able to proceed.

So one of the things that Dr. Wilmut did that was different than what many other people had done with this experiment is the source of cells that he used which were from the mammary gland of the ewe had, in fact, been taken out and allowed to essentially go into a very quiescent state, meaning the cells had not divided for three or four days. It was those cells that he used for the fusion to the oocyte.

So it is entirely possible that by using these nuclei that were essentially resting, they were in a silent state perhaps mimicking the silent state of the egg and the sperm nucleus that potentially this intimate sort of conversation between the cytoplasm and the nucleus was facilitated and, therefore, they were not out of sync with one another and, therefore, development could proceed.

So all of these are potential explanations for why in the past when scientists largely took dividing cells, in other words cells that were sort of in an activated state that once put into this environment in the unfertilized egg there was a failure of development as opposed to what Dr. Wilmut did. But clearly this is a case where a lot of experimentation needs to be done if we, in fact, are going to understand whether, in fact, this one successful experiment was -- which of these many possibilities explain this one successful experiment.

So now on to the question of why this process is so inefficient. That is once you have, in fact, introduced this nucleus into this unfertilized egg, why, in fact, are so few successful animals born?

(Slide.)

Just to give you a sense of how inefficient this really is, this is the data from the paper. So they generated 277 egg cell fusions where they could really show that the nucleus from the mammary gland cell had been incorporated into the oocyte. They cultured these for six days and then looked to see how many of them had begun to undergo development and you could tell this just by looking at these embryos. Actually in terms of the ones that survived a fairly substantial number of them survived, 247. So that is quite good.

But here is where you begin to take losses and that is when you looked at whether they had developed appropriately, only ten percent roughly had developed appropriately to the right stage for six days of development, and then these were implanted into foster mothers and of those 29 that were implanted only one survived. So this is going from 277 possible successes to one success.

So why isn't this more efficient? What is wrong?

(Slide.)

Dr. Wilmut, I think, emphasized this in his testimony yesterday. So again this is a question we do not have any idea but here are some possibilities.

So one possibility is that in the process of going into the egg and removing the genetic information of the unfertilized egg you actually disrupted the egg. This would not be surprising because, in

fact, it is a very large needle that goes into that egg and pulls out the genetic information. So you might have essentially destroyed the egg from the very outset.

The second possibility is that this gene reactivation, which is absolutely essential for development to proceed, was inefficient. And that is that the reactivation that normally works very well when you have an egg and a sperm does not work so well when you have a mammary gland cell. So that is a possibility.

There is a third possibility which I do not think is being considered as seriously as it should and that is remember that mammary gland nucleus is not inert. It, in fact, is making gene products that are appropriate for mammary gland cells. Some of those products could easily be quite toxic to an egg. So it is entirely possible that the inefficiency is because the mammary gland is producing products that essentially disrupt normal development.

Now this is actually from a scientific point of view a critical issue because it may suggest that the success of this experiment is going to be very tissue specific, that is where you get this nucleus may really matter in the end.

Finally, something which is almost certainly at least part of this story is that implantation is inefficient.

Now two of these possible explanations for the inefficiency are things which characterize all embryo manipulations that are done in animals and that is the first one and the fourth one. Those are inherent to embryo manipulation. If you manipulate an egg you do

take a chance of doing something damaging to it. Implantation is fundamentally an inefficient process.

The two that are unique to this experiment are the second and the third. These we know very little about. A great deal more experimentation will have to be done before we have any understanding of how much those two biologically specific issues contribute to the overall inefficiency of the process.

Now as a scientist what do I worry about in this experiment?

(Slide.)

I think that there are probably two major risks associated with this experiment that we do not know anything about and that will require a lot of experimentation in model systems, in animal models, before we can say anything about either one of these issues.

The first is that the donor nucleus has existed in this case in a sheep for six years. One of the things we know is that individual cells accumulate mutations. They are called somatic mutations because these are not mutations you can pass on to your children but they are mutations that are unique to a cell. We have very little idea of what the rate of somatic mutation is. We do not know how quickly these mutations accumulate in us. We know they occur and we know that because cancer is largely the consequence of somatic mutation. So there is no question it occurs.

Now there is a fundamental issue here and that is a somatic mutation in one mammary gland cell, assuming it does not, in fact, lead that cell to grow out of control and become a cancer, may be

completely innocuous to the mammary gland cell. The mammary gland cell may be able to continue functioning completely normally without somatic mutation. But when that somatic mutation now becomes permanent in every single cell of the new organism which it would do in this case then there is no predicting, in fact, what the effect of that mutation will be. So we need to understand what is the rate of somatic mutation. We have to appreciate that this will be an inherent risk of any experiment of this kind.

The other thing which I think is a general worry about this kind of an experiment, whether done -- no matter what kind of animal system it is done in -- is that we know almost nothing about this reactivation of genes. We really know almost nothing about it. And as a consequence we do not know efficient it is but remember in order for this experiment to work to produce a fully viable healthy offspring it has to be complete.

What I think would be most troublesome is the inefficient reactivation of genes that does not affect early development, for instance preimplantation, but affects in some later developmental stage. That I think is something that is very worrisome. There is, in fact, a precedent for this kind of problem in experiments that were done 20 years ago by John Gerdon (?) who was an investigator in England asking very similar questions in frogs.

What he found is that he could take a skin cell and he could, in fact, reintroduce its genetic information into an egg but he could never get progeny that developed past the tadpole stage. What

this suggests is that there was some reactivation, enough to get through part of development but not to get through all of development.

There is a third thing which actually came up at lunch today which I would add to this list and that is that this experiment absolutely requires that the DNA, for example, in the mammary gland cell has not been rearranged during development in any way relative to the DNA of a fertilized egg. We know in mammals that is not true for every cell type.

For example, our immune cells, both B cells and T cells rearrange at least a subset, a small subset of their genes in order to make antibodies in order to make surface molecules. The fact that one kind of cell can do this suggests that other cells have at least the potential to be able to do this and so it may again raise issues about which kind of cells would be donors and which kinds of cells would be very poor donors for this kind of research.

So I hope any of the commissioners will stop me at any point if something is not clear. I have teenagers so I am used to being interrupted all the time. I will not be offended. So, please, stop me if there is some point where I am not making sense any more.

Yes?

DR. EMANUEL: You did not mention as one of the risks early senescence of the cell, the fact that the nucleus does age and we do not know what that -- it has been reprogrammed to start at zero as opposed to 25 --

DR. TILGHMAN: That is correct.

DR. EMANUEL: -- you did not put it on your list and I was just a little surprised to see it --

DR. TILGHMAN: Surprised that it was not --

DR. EMANUEL: -- and maybe you could tell us about it.

DR. TILGHMAN: Well, part of the reason is I assumed that Dr. Greider is going to -- who, in fact, demonstrated this experimentally will be able to talk about that very knowledgeably to you. I suspect that we could spend the next hour and have that list be significantly longer. These are the ones that I think are areas where I think there is a great deal of concern and a lot of lack of knowledge.

All right.

(Slide.)

Now what I want to go on to do just for a few minutes is to compare the experiment I just told you about with the kind of experimental manipulations of mammalian embryos that are going on in many laboratories throughout the world as part of basic science and in some cases applied science projects to understand basic biology.

I emphasize that none of these procedures that I am now going to talk about a little bit just to put Dr. Wilmut's experiment into some context, none of them are currently going on in humans that I know about. So these are strictly experimental systems and they fall into two general classes.

The first which really began about 15 years ago was the ability to add extra genes to an animal's genome and the example that we now read about in the newspaper, for example that would be a very practical use of this technology, would be to make a sheep that can

produce a pharmacologically active protein in the milk. So this would essentially have an animal become a factory for the production of some pharmaceutical molecule. This we, indeed, have been able to do for about 15 years.

The second technology is slightly newer, about six or seven years old, and it has almost exclusively been restricted to mice. This has not been a technology that is expanded to other mammals. That is to remove a piece of DNA or to disrupt it or to change it in some way from an animal's genome. In some cases this is done so that one could begin to understand what is the function of that gene within the context of the organism and in some cases there is actually a very practical purpose.

For example, very recently there was an animal model generated for Huntington's disease. So Huntington's disease is a neurological disorder where there had been literally no advances made in understanding it over the past 25 years partly because there was no good model for it. Now that there is there is a lot of hope, for example, that we will be able to understand what the neurodegeneration in Huntington's is all about.

So let me just very quickly take you through these two other procedures and to contrast them and to show how they might be able to be integrated into what Dr. Wilmut has done.

(Slide.)

So the first is the introduction of the new DNA and this is done essentially by taking a gene in the form of naked DNA and injecting it into the nucleus of a fertilized egg.

Now this procedure is inherently inefficient just like Dr. Wilmut's procedure is inefficient. I just -- to contrast with what I showed you earlier, this is done in a lab that does this very well. These are good numbers. If you take 100 fertilized eggs and you inject them and implant them back into a host mother you would be lucky if 20 of these animals are born. So there is a lot of loss probably because the egg is disrupted and implantation is inefficient.

If you are lucky five of them, about a quarter of them will actually carry that extra piece of DNA. So the ability to get the DNA to stay is inefficient. Then if your goal is to express that piece of DNA then the real hooker comes and that is that anywhere from none of them to 100 percent of them will express the gene of interest. So from the perspective of someone trying to use this kind of technique in animal breeding experiments, for example, this is inherently inefficient.

Now how would Dr. Wilmut's experiment have any impact on this?

(Slide.)

Well, this is really taken almost directly from what Dr. Wilmut has, in fact, proposed he is interested in doing and that is to take these same mammary gland cells that are in tissue culture and to now introduce a gene instead of by injecting it into an egg, introduce it into this tissue culture.

This is something we know how to do. We have been doing this for about 20 years. And then he would be in a position to measure which one of these cells was making the most of the product, whether it is human insulin or whether it is Factor 8, whatever it is.

Unless he has found the cell line that is producing the biggest amount of this protein. That is the cell line he then fuses with the enucleated oocyte and the goal, of course, is to have 100 percent of the live born progeny producing the protein of interest in the milk.

The reason I put all those question marks there is that we do not know if this is going to work. Neither does Dr. Wilmut. In other words, if -- can we predict based on what happens in a tissue culture cell, can you, in fact, what is going to happen once you have that cell back in a mammary gland? This is going to have to be experimentally tested.

(Slide.)

But again just to compare these two techniques in terms of efficiency and strategy for someone who is interested in making a herd of these animals, here on the left I have put sort of the path again that I showed you a few minutes ago for using the transgenesis approach. At the very end you have got uncertainty, complete uncertainty about whether the gene is going to work. And on the right you have the way in which this same experiment could be using this new technology. That is -- and I will show you where the question marks are.

You, in fact, could transfer a 100 eggs. Of course, we do not know how many are going to be born, right? That is a complete unknown. However, we would know that 100 percent of them would carry the DNA. So that is different than the transgenic approach.

We have eliminated one uncertainty and then we still are left with this question mark. Would, in fact, this be a good strategy for

producing an animal that is making a lot of the gene product in the milk? And we do not know the answer to that.

So this, in fact, I really did take directly out of Dr. Wilmut's paper. I think this is interest in this technology. He is interested, in fact, in asking whether this technology is going to be significantly better than what is already existing technology which works inefficiently but works.

Now those of you on the committee who have already started thinking about reproductive technologies will appreciate that this is a form of gene therapy in the sense that one is introducing new genetic information. The difference, and it is critical, the difference is that the kind of gene therapy that one is, in fact -- that is going on already in human beings is not affecting every single cell of the organism that is potentially the recipient of gene therapy. In fact, most gene therapies targeting a small number of cells for the expression of the gene is going to be really critical.

This kind of technology is absolutely to my knowledge not going on in humans and the reason is extremely clear, and that is that when you introduce a piece of DNA through either this method or this method currently you have no idea where that piece of DNA is going to end up in your genome.

It could end up in a place where it is totally innocuous to the organism. It could end up right in the middle of an essential gene. And at the moment -- by this kind of basic strategy we have no way to control that. So for very obvious reasons then this kind of procedure is not going o in human beings.

So I think given the length of time I think I am going to stop there and entertain questions.

Yes?

PROF. CHARO: I wonder if you could go back to the overhead that you had concerning Dr. Wilmut's data in which he starts with 277 and moves to 259?

DR. TILGHMAN: Yes.

PROF. CHARO: If you could throw that up just for a second.

DR. TILGHMAN: Yes.

PROF. CHARO: Great. Thank you. Looking at the drop off from 247 to 29 in developmentally -- in developing appropriately, I do not remember from the paper if there was any discussion about the breakdown of observed kinds of development, each one differently inappropriate. Was that kind of thing taken into -- was that kind of thing recorded?

DR. TILGHMAN: No. No. So there was not sort of a breakdown that these had gotten to the two cell stage, these had gotten to the four cell stage, which he probably could have presented in the paper. But to put that 10 percent success rate into perspective I am not sure that this is very different than what we would see without a great deal of manipulation of the egg to begin with.

PROF. CHARO: Right.

DR. TILGHMAN: This is an inherently inefficient process that is just -- that -- on top of which we have added new degrees of inefficiency essentially.

PROF. CHARO: But would this coupled with an examination of the miscarries and stillbirths be the research agenda for identifying how it is that things go wrong to look for clues to understanding what is not working in terms of reactivation or -- I am trying to understand how it is that one is going to begin to get at what was on your list before of unknowns, which has to do with the kind of sequential activation of genes that are needed later --

DR. TILGHMAN: Right.

PROF. CHARO: -- later in the developmental process.

DR. TILGHMAN: I think that there are sort of two levels to your question and it really does have to do with the fact that the inefficiency fall into two different classes. The first inefficiencies come in the inefficiencies that are inherent every time you take an embryo out of its normal context. That introduces some level. Whether it is 90 percent or whether it is 50 percent can be experimentally determined. That can be really experimentally determined. And then on top of that we have the inefficiency that will come from the manipulation that you had specifically done. And in animals the relative contributions of those two to this can, in fact, be experimentally determined.

Yes, we could do that.

Yes?

DR. BRITO: I have several questions for clarification.

DR. TILGHMAN: Yes.

DR. BRITO: Since you are talking about the efficiency versus inefficiency right now. I understand the inefficiency based on a -- just scientifically there. What about financially because I think it is

important to understand that. What -- when we are talking about this inefficiency, what are the economic implications of trying to fuse 277 and ending up with one live birth? What is that? That is the first question.

And then the second question is the definition of "cloning" you started off with in the beginning. If you could clarify the public definition or understanding of what cloning is and the scientific definition of cloning. In other words, I have seen transgenic cloning. Does the public understand that to be included in a general definition of cloning? What does science define exactly to be cloning? Is it more inclusive than we seem to understand just duplicating human beings or animals, et cetera?

And a third -- you implied -- I want to make sure that this -- that the oocyte contains a substance that reactivates genetic duplication, et cetera. Did you imply that it is not known what that substance is and is anyone working on that right now?

DR. TILGHMAN: So it is not known what are the components in the oocyte that are capable of reactivating a genome. People are studying that intensively within the normal developmental context because it is very important to understand that from a normal developmental context. So that is an active field of investigation in experimental animals. It is not going on at all, of course, in humans.

The financial issue, I think, really comes back to -- it might be easier to talk about this in the context of this:

(Slide.)

The financial issues are a highly complex one, a subset of issues, and that is if you are an animal breeder and if your goal is to produce a herd of animals that have a particular characteristic, whether it be, you know, sort of a pharmacologically relevant characteristic like producing, you know, clotting factor in your milk or whether it is simply producing the most milk, or whether it is producing the most lean beef, you know, whatever your goal is.

And if this is a strategy that can ultimately lead to you being successful in that, I do not think we know what the answer is to your question about which of these two kinds of basic strategies. This then is ongoing and this which is now a potential alternative. We do not know what the financial outcome is going to be here in terms of which of these is ultimately going to be more efficient. I do not even know how to calculate -- I would not even know how to begin to calculate that.

Part of the reason we do not know is all these question marks. Right? These question marks are going to determine to a large extent whether ultimately animal breeders are going to go down this path or they are going to stay on this path which is tried and true.

DR. HOLTZMAN: Dr. Tilghman?

DR. TILGHMAN: Yes?

DR. HOLTZMAN: Maybe I can explain a little bit about why your motivations would be for going this -- and filling in some of those numbers, and it is actually species specific. Because, for example, first off the numbers in livestock are worse than you have shown in mice. The transgenesis that requires injecting the egg preferably at the stage soon after fertilization when the pronuclei are distinct, if you are dealing

in pigs, for example, that actually requires that the male and female mate and you go in and recover those eggs at the exact right moment so you get a whole bunch of eggs that are not at the right moment which -- and those donor animals that you have super ovulated you have to destroy. It is very expensive. Okay.

In other species such as bovine you can actually do in vitro fertilization which means you can go to the slaughter house and you can get ovaries and super ovulate out of the ovaries so you do not have the cost of the donors. Okay. That gets into some of the complexities.

In the other technique you do not have this timing issue since you can just deal with oocytes where you do not have to worry about the fertilization rates. So there is economics that are greatly at your advantage if you can do that. Again you get into species specific difference.

You saw Shirley's slide about culturing in the oviduct. Probably what you are trying to do there is see whether or not you have got good development to a certain point. It is a culling process. Again in swine, and I know many people have heard about the notion of organs for transplantation coming from swine, that is probably not do-able. It is more successful in sheep.

The last place where you would be looking for economic advantage of this method is actually after the slide where actually --

DR. TILGHMAN: Right.

DR. HOLTZMAN: -- there is another point is -- you did mention choose the better producer and then after you have got the animal that you want being able to replicate that animal. Okay.

The real advantage is what Shirley did not get to and that is targeted gene addition. All right. Which is currently possible in the mouse. It requires a kind of cell line called an embryonal stem cell line. All right. Which while there are reports in the literature, there were even patents issued on, for example, porcine embryonal stem cells, to my knowledge no one has made it work in the livestock animal. When you have targeted gene addition you can ensure that you put your transgene into a place where it will work.

DR. TILGHMAN: Right.

DR. HOLTZMAN: And that it will not disrupt other things. You can do targeted gene addition in a cell culture which means you could then achieve that using this methodology in the absence of embryonal stem cells from these livestock species and that is the critical advance that would be -- and that is not just a -- so now you have moved from the economic advantage of this to considerations of being able to do things you are otherwise not able to do other than in the mouse.

DR. TILGHMAN: David?

DR. COX: Shirley, so far we have had this discussion, okay, that this is a fact. So science works in a process. So what is the process that science works through to say, in fact, okay, a sheep has been cloned? And is there sufficient data from a scientific process point of view, okay, to say this event has even occurred? We are talking -- you are talking quantitatively. I am talking qualitatively. Has it happened?

DR. TILGHMAN: So what David is referring to is the fact that at the bottom of this we have the number one.

(Slide.)

And, in general, the number one in science is usually not good enough as a formal proof that something has occurred, that part of the scientific process that all of us belief fervently in is the importance of replicability, the ability of not only you to be able to reproduce your experiment but probably more importantly that you be able to describe your work clearly enough that someone else could reproduce it as well.

So what David is expressing is skepticism that with the report of a single live birth one should, in fact, view this as a tentative result until, in fact, it has been replicated and most importantly by someone other than Dr. Wilmut. Then I think -- then the requirement of scientific proof in that case has been met.

DR. COX: I mean, I want to make it clear that that casts no aspersions on Dr. Wilmut or on this work.

DR. TILGHMAN: Right.

DR. COX: Okay. But this is the scientific process and since we are talking about science here that should come into this analysis.

DR. TILGHMAN: Yes?

DR. MIIKE: Well, first my question will be sort of opposite of David's. One of the rate limiting factors in here they say the number of ewes that must be used in order to plant, what is the state of artificial uteri and what will this do for -- in terms of driving science toward the development of that because it seems like if I were out there as an entrepreneur I would see this as an opportunity or a field for long term investment.

DR. TILGHMAN: So I can only really speak for what I know about what is going on in experimental animals and not in farm animals, and maybe someone who knows more about what is going on in farm animals can comment. In experimental animals I know of really no credible work right now that is going on trying to create an extra uterine environment that would allow full development to proceed, for example in mice.

We, in fact, can culture mouse embryos to a certain point in development and at that point the embryos literally do not make it any further and the reason is I think relatively clear and that is that we have arisen as organism to develop as a parasite of our mother. Those of us again with teenagers would say this does not end.

(Laughter.)

DR. TILGHMAN: But reasonably there is throughout most of embryogenesis and fetal development this incredibly intimate conversation that goes on between the uterus and the mother and the embryo. And that is providing all kinds of cues, all kinds of signals, growth factors, growth directors that we know almost nothing about. So there is so much basic knowledge that must be acquired before we can begin to think about certainly in the case of the experimental animals that I know about and maybe you know more about what is going on other --

DR. MIIKE: Let me ask you a follow up question.

DR. TILGHMAN: Yes.

DR. MIIKE: If there is the ability of extrauterine to go into partial development --

DR. TILGHMAN: Yes.

DR. MIIKE: -- that still raises for me the question about the "utility of half baked products" in terms of one can think of uses of these embryos not to the full development stage but as the -- do you see what I am trying to get at? There is utility --

DR. TILGHMAN: Right.

DR. MIIKE: -- in the different stages as you go through them without having to get to the full development stage.

DR. TILGHMAN: That is correct. That is correct. And I think that there is -- in fact, one of the things that I did not show just because I was running out of time is that these embryonic stem cells that were being referred to are derived from early embryos. And there is I think a hypothetical, and I emphasize that this is really a hypothetical, ability to taking these cells, which are these early, early progenitor cells and learning how to direct them in one way or another in a tissue culture environment.

We can do it with inefficiency at the moment to get embryonic stem cells to make blood cells. This is being done experimentally. But could we, in fact, and there really should be question marks here, could we now take embryonic stem cells and could we learn enough about what are the requirements to get them to head in the direction of liver or into the direction of pancreas, for example.

There are people who are working on these kinds of issues in the mouse primarily directed towards trying to figure out what those signals are from a basic biology point of view. So you are correct in the sense that we cannot get this blastocyst to go much further in

development but as a tissue culture line we might be able to figure out how to get it to go in one direction or another.

Yes?

DR. EMANUEL: On your efficiency slide from Dr. Wilmut's study, it seems to me that there are two qualitative aspects to the inefficiency. One is that you start out with 277 and you get a 90 percent fall off. But then once you have the 29 that you can identify in the lab you then get to a three or four percent efficiency rate in terms of --

DR. TILGHMAN: Right.

DR. EMANUEL: -- getting one live birth.

DR. TILGHMAN: Right.

DR. EMANUEL: And that is a lot different than 99 percent or 99.9 percent inefficiency it seems to me. You are beginning to talk about real numbers of success. Can you say anything about improving that from three to four percent up to say 15 or 17 percent? 15 or 17 percent is the IVF success rate round about. And that is only sort of four -- you know, improving efficiency fourfold.

DR. TILGHMAN: Right.

DR. EMANUEL: Not a whole lot.

DR. TILGHMAN: I mean I think that you can begin to do that once you understand the basis for the difference, right? Why isn't it at IVF levels? I think that that will only come from experimentation.

Carol?

DR. GREIDER: I would just like to comment on that. With the number one live birth since there is no standard deviation there we cannot say that that is three percent.

(Laughter.)

DR. TILGHMAN: Right.

DR. GREIDER: There is no percent and we do not have any way to evaluate it.

DR. EMANUEL: Fair enough.

DR. TILGHMAN: Yes?

DR. SHAPIRO: You have got to the zero -- it is somewhere between zero and 100. You are sure of that.

(Laughter.)

DR. SHAPIRO: I am sorry. There is another question down here.

Bernie?

DR. LO: First I wanted to thank you for a very lucid and very helpful presentation. I would like to ask you to sort of help us understand sort of the long-term implications not for sort of making more efficient sort of processes whose goal is to produce a desired protein in, for instance, breast milk but in terms of basic science understanding of what controls cell differentiation and expression of genes.

DR. TILGHMAN: Yes.

DR. LO: Can you help us understand what sort of basic science knowledge is likely to be gleaned from this technology that was not going to gleaned very easily from preexisting technologies that would ultimately help us not to necessarily produce commercial products more efficiently nor even necessarily to increase IVF efficiency but to help us understand things about the basic cell biology that might lead to

advances in whatever, understanding why cancers grow, why organs get rejected and ultimately to therapies and vaccines.

It seems to me in some ways those kinds of potential benefits if they are there are a very different sort of benefit than saying the benefit is to produce pharmacological products more efficiently than we now can do or to have a more efficient treatment for infertility.

DR. TILGHMAN: I think there is going to be a small contribution of this technology to those kinds of basic questions. The most basic question and one that actually I have spent almost all my professional life trying to understand is how, in fact, do specific pathways choose those ten percent of the genes that should be expressed in this lineage in order for you to be a liver cell, not you personally but for a stem cell to become a liver cell.

And that is an enormous field of biology right now. There is a -- you know, I do not know what Carol would think what the numbers would be but, you know, literally tens of thousands of biologists who one way or another ultimately are trying to understand that question. Do I think this new result is going to contribute dramatically to that understanding? Personally no, I do not think it is going to.

I think that we already have all the tools that we need to ask the question what causes gene reactivation after fertilization. I mean, we can study that process in its most natural context which is in natural fertilization so I see little contribution there.

Will it allow us to ask the question whether when we silence genes later on do we do it in a way that is permanent versus

impermanent? That is a question that perhaps could exploit this kind of technology.

So I do not think that there is -- that -- as a developmental biologist I do not see this technology having the same impact on the field of developmental biology as some other things that I will mention. It will have a role but I would predict in the end a modest role.

Yes?

PROF. CHARO: I think I am going to be asking you now for a Bio-101 on something and it is the DNA contained in the mitochondrion.

DR. TILGHMAN: Yes.

PROF. CHARO: I wonder if you could help me understand because I have not done genetics since I was in college, which is a long time ago now, what we now know about the role of mitochondrial DNA and speculation on the effects of fusing mitochondrial DNA from the donor of the nucleus with the donor of the egg cell, speculation on the phenotypic consistency between the clone and the adult because of this difference in the mitochondrial DNA as well as among clones since presumably if you had multiple clones from a single adult they each have started with eggs from different adults unless the eggs are coming from, you know, a series of second generation clones.

DR. TILGHMAN: This sounds like Bio-301 to me.

(Laughter.)

PROF. CHARO: It starts with what is mitochondrial DNA.

(Laughter.)

DR. TILGHMAN: It got very sophisticated very quickly it seems to me. So what you are referring to is that all of our genetic information does not come in the nucleus itself but a very small percentage, and I think I saw the number the other day, is something like .01 percent of our DNA is actually encoded outside the nucleus in these very small but extremely organelles that exist in the cytoplasm. In other words, the rest of the cell that is left behind when you take out the nucleus.

Mitochondria are essentially there are for energy metabolism and so they are, in fact, the energy work horse of the cell. They are the part of the cell that allows you to use energy and to create energy, to create new energy, so they are critical. You do not survive without them.

Now if you think about what is going to happen in that fusion event where you take this now egg that is going to be chock full of mitochondria all of which are derived from the mother, right, there is no paternal contribution at this point, and you essentially electrically introduce the contents of that mammary gland cell into this now enucleated oocyte.

One of the questions I do not think that has been answered, at least I have not seen anybody really talking about it, is do mitochondria get transferred at the same time from the mammary gland cell. So will that individual now be a mosaic in terms of mitochondria. Some of the mitochondria coming from the original oocyte and some of the mitochondria are coming from the donor cell, you know, if it is a mammary gland cell, if it is a whatever, right.

Now there are individuals here who are -- who have different kinds of mitochondria, different genetic, they are called heteroplastic -- what is it, David? A heteroplastic?

DR. COX: Heteroplasmid.

DR. TILGHMAN: Heteroplasmid for mitochondria. So that is tolerated just fine. I mean, you could have mitochondria that are genetically slightly different in an individual.

So I am not sure there is going to be -- this is going to be a major -- have a major impact on this experiment. However, what it will ensure is that the individual animal that grows up from that fusion will not be 100 percent genetically identical to the animal from which the cell was obtained because the mitochondria are largely going to be different. And there are -- you know, there are clearly important functions that are carried out by those genes in the mitochondria that are going to have an impact on the physiology of the animal. So they will not be true clones the way identical twins are true clones -- you know, true genetical identical individuals.

Harold?

DR. SHAPIRO: Shirley, I am going to have to make this last question since I am conscious of both your time and our time so before the question let me thank you very much for being here with us. You have been extremely helpful. I just want to ask a question, I am not sure I can formulate it correctly, but you did have an overhead up there called "Scientific risks or unknowns," I have forgotten, "Risks and unknowns," and you had two major items there, a few more were

suggested here, and as you said the list could get longer if we spent a little longer at it.

DR. TILGHMAN: Yes.

DR. SHAPIRO: If you would speculate for a moment only with trying to get a better handle on these risks and unknowns in animals, is that a short-term research project, an extremely long-term research project, how would you assess that strictly now dealing with the issue in terms of animals?

DR. TILGHMAN: I think it is long-term. I do not think that there are going to be quick and easy answers to some of these unknowns. I think that all of the issues that were on that slide and some of the ones that came afterwards are experimentally testable so it is not long-term because we do not even know how to ask the question.

We do not know how to design the experiment. Until really this publication there was not an opportunity to ask these questions but now that there is the potential at least in some animals to ask the question, you know, I could think of designing experiments that could get at some of these issues.

The hardest one is going to be somatic mutation because somatic mutation is not a common event. You are going to be capturing rare events and that always means long-term.

DR. SHAPIRO: Once again thank you very, very much for a very thoughtful presentation.

(Applause.)

DR. SHAPIRO: If we restrict ourselves to a fifteen minute break we will only be five minutes behind. So please because we have

visitors here who may have their own schedule I would like all the commission members to be back in fifteen minutes.

(A brief break was taken from 1:37 p.m. until 2:03 p.m.)

DR. SHAPIRO: We had scheduled this part of our session to begin at 2:15 but we have got so much material on our agenda that I thought we would take advantage and get started a few minutes early.

Dr. Gilbert Meilaender I believe is not here yet. Is Dr. Meilaender here from Valparaiso University? I presume he will be here at approximately 2:15 and he will join us at that time but I think we could certainly use the extra time this afternoon and so I would like to get started at this time.

First of all, let me extend a very warm welcome to our guests who will be speaking to us today from different perspectives, perspectives of different faiths, more directly of course from their own thoughts and scholarship over the years, and thank them for responding to our invitation which gave them very short notice as well and very much appreciate the efforts they all must have gone to, to rearrange their schedules and be with us here this afternoon. We are really very grateful to them.

I will repeat what I have already said this morning. Namely that we are interested in having access to a broad set of views on these issues and we will certainly encourage others from other perspectives to -- if they wish to, to address us in the public comment section, if not to provide us with written materials which we will distribute to everyone on the commission so that we can think carefully about their particular perspectives.

If our guests do not object I will slightly reverse the agenda here this afternoon. The agenda for -- I do not know, perhaps if this was done in alphabetical order or whatever, I do not know how it was scheduled quite in this way, but we had thought we would hear from Dr. Duff and Dr. Meilaender first followed by Dr. Cahill and Rev. Dr. Albert Moraczewski. If there is no objection I will just reverse that order and begin with Dr. Cahill and then go to Rev. Dr. Albert Moraczewski.

Dr. Duff, is that all right with you?

DR. DUFF: Yes.

DR. SHAPIRO: So let's begin then by welcoming them again and turn first to Dr. Cahill.

DR. CAHILL: Thanks.

DR. SHAPIRO: That is right. The scheme is you press the button, the red light goes on, and then you are on microphone.

RELIGION-BASED PERSPECTIVES ON CLONING OF HUMANS I

ROMAN CATHOLICISM

DR. LISA CAHILL

DR. CAHILL: Okay. And then you can talk. All right. Thank you.

Thanks for giving me the opportunity to be with you. I will try and make my comments relatively brief and leave a short paper behind also in case you would like to take a look at them later.

I really have three comments or there topic areas that I would like to introduce as part of this discussion as moral issues related to cloning and they are basically the issue of individuality, the issue of co-modification, and the issue of family. But before I get into that I

would like to make just two preliminary statements about the possibility of religious communities participating in the dialogue about policy on cloning.

The first comment is that while religious language and religious symbols can bring a prophetic voice to the public's fear they can also be obfuscating and alienating when we use what I think of as kind of magical phrases like the "miracle of life" or "playing God" without relating those very carefully to the human and scientific realities that are on the table. So one of the things that I would like to try to do today is advance consideration of some of those realities.

The real questions to my way of thinking are not so much whether humans have any God given or natural right or even responsibility to intervene in the processes of life but rather what constitutes appropriate intervention and where appropriate limits can be drawn. I think those questions of appropriate limits are questions not just for religious communities obviously but for all of us in our society.

My second point is related to that. My second general point about religion and the public dialogue. Here I am going to revert to my Roman Catholic standpoint and roots. A particular contribution of the Roman Catholic tradition is to speak to the question of religion and public discourse by affirming that, indeed, there are some basic human experiences, basic human values, basic human obligations and limits that we can talk about in common.

In fact, our 100 year old tradition of Papal Social Encyclicals which talks primarily about economic issues, government issues and political issues is testimony to that commitment to talk about

the common good together across moral, political and religious traditions. So it is in that spirit that I come to you today and that I hope to talk in human terms as well as religious terms about cloning.

Now I would like to move to my three substantive points about the cloning of humans and as I mentioned they have to do with human individuality, with the co-modification of medical techniques and technologies in general, and finally with the issue of family.

So, first of all, individuality. The popular press has provided us with some great visual aids on this issue. We have Newsweek's three identical babies. We have Times two ewes and inside even more frighteningly or promisingly depending on your point of view we have five Dennis Rodmans. Okay.

(Laughter.)

The amount of play in the popular press and popular conversation that has been given to the issue of individuality is quite striking to me. It causes me to ask what is it that people are actually afraid of? Okay. Where is the terror in cloning? I think for many people it lies in a perceived threat to individuality because absolute individuality is the ground of our political tradition's prized equality, liberty, autonomy and privacy. And to many Americans individuality and autonomy seem like the moral sine qua non without which there can be no real moral content to our social life.

But as I am sure everyone else here is well aware, especially because I know that this morning you heard scientists, but even on a little bit of practical reflection it is pretty obvious that a cloned

individual could never grow up to be the exact copy of the individual who was the origin of the DNA.

As the mother of identical twins myself I can tell you that a shared genetic code is not enough to create true identity even between same sex children raised in the same household, never mind individuals raised at different times and in different environments.

But I think it would be a mistake to assume that once we have rebutted the individuality argument against cloning we have rebutted the major real arguments or even that we have gotten rid of the fundamental issue under the argument about individual uniqueness.

One of the things that I would like to point out and emphasize quite strongly is that our cultural tradition, including its moral traditions, tends to assume that autonomy should hold the most privileged and central place in moral thinking. That is why the popular mind and the mind of most of us go immediately to that issue of individuality and want to debate that back and forth.

But while autonomy is certainly a keen moral value as well as political value in our tradition I think that an excessive focus on that can prevent us from seeing why other values as well are socially important and protectable and why certain freely chosen practices can still be wrong even if they do not result in immediate or quantifiable harm or direct infringement on the options of other free agents.

A narrow focus on autonomy to freely choose personally preferred goals undermines our ability to talk together about what would go to make up a good society and what we can do concretely to move towards one. In addition to autonomy and individuality we need to place

on the table other human goods like the interdependence of all in the society we create for ourselves and for our children, or concern for the well-being of people with less decision making power than all of us sitting here in this room with fewer options.

Certainly we need to keep on the table a sense of restraint in the face of the profit motive. So I would say that we need more than autonomy in order to morally and socially consider the scientific imperative as it is sometimes phrased or free enterprise. We need to put those agendas in a broad and humanistic context which includes but extends beyond self interest and self determination of very talented scientists and very shrewd entrepreneurs. That leads me to my second area of focus here and that is co-modification. That is closely related to what I have been talking about.

Treating others as means to the ends of those with more status, more privilege and more power is represented in a particularly clear way by the dominance of the market in issues of human health and human life. Some bioethicists that have been quoted in the press over the last few days such as Daniel Callahan and Lori Andrews have even gone on record as predicting that economic incentives will control when human individuals will be cloned and not any supposed ban.

There was a very compelling, a very frightening but also impressive editorial by Kirkpatrick Sayle in last Friday's New York Times and its title was "Ban Cloning, Not a Chance." To illustrate the cult of progress which ensures that science will proceed with little conscious and few restraints Sayle quoted the makers of the atomic bomb. He quoted them as saying, "When you see something that is technically

sweet you go ahead and do it." And "Technological possibilities are irresistible to man." Those were quotations from Oppenheimer and Van Neumann respectively.

History teaches us, I think, that every instance of human progress creates an equal and opposite opportunity for moral and social regress. Let us not be naive, neither nuclear power nor new genetic technologies like are cloning are intrinsically beneficent instruments for the improvement of the human lot.

The Catholic social tradition has always exhibited confidence that human decisions and policies can be influenced by reasonable public discourse about values but my level of pessimism about self interest and profits as the key motivators of human behavior is rising quickly. The Doctrine of Original Sin is a religious symbol which springs all too readily to mind for the theologian.

Where people can make a buck they will and a variant on the same theme is the irresistible attraction of research prestige via landmark discoveries or even on the part of bioethicists, myself, a desire to protect our place close to the centers of economic and political power by refraining from damning commentary.

Certainly cutting off federal money will not be a deterrent to the cloning of humans. Stronger measures and more profound attention to our social values and the way we express and promote and change them will be required. Now just to add a footnote here, cloning a human being can be and should be distinguished from other kinds of genetic research which helps us in the pursuit of disease therapies. Profits are not completely out of line and immoral when we are talking

about development and marketing even of disease therapies. Or at least that is certainly part of our current tradition.

So I am not trying to suggest that the entry of economic incentives at any point in this process is immoral or should be prohibited by policy nor should all research having to do with the behavior of human genes and control of human genes, that does not need to be, you know, banned or legislated away either but the tricky part, the task is to distinguish carefully and prudently between categories of research and not let sort of the profit incentive in one area have a big spill over effect into the other so that the whole thing is either accepted or banned as one big category. So there are distinctions to be made. It is difficult. I realize there will always be ambiguities but in my view that is not enough to deter the process.

Finally the issue of family which I am using as a broad category here. Up until now every human child has had two parents. The biological relation between parents and children is a symbol of reproductive, social and domestic partnership with great personal and social significance. Historically and cross culturally families in all their variety of cultural form have been key institutions for the structuring of societies. A cloned individual will have a biogenetic link to one lineage only.

In the first relatively innocuous cloning cases we might imagine like an infertile couple using genetic material from one spouse only to create a child without having to resort to donor gametes the child will have a genetic relation at only one step removed after all to both of

the lineages of the cloned parent. But it would, of course, be possible in time to develop all male or all female genetic lineages.

It would be possible for female lineages to proceed without any male contribution at all and it would be possible for one woman to create her own child using her own ovum and DNA. My feminist instincts are at one level attracted to this possibility at least in a kind of iconoclastic move but the bottom line is that I am far from sure that separating male and female procreation or making men unnecessary to the procreative process at all would work to the ultimate advantage of women. I am pretty sure it would not work to the advantage of human responsibility for the next generation.

So the child who is truly the child of a single parent would be a genuine revolution in human history and her or his advent should be viewed with immense caution. In my view it is not too strong to say that cloning is a violation of the essential reality of human family and of the nature of the social related individual within it. Of course, I am talking about cloning an individual not other kinds of experiments with genetic material.

In conclusion, I hope the National Bioethics Advisory Committee will take up questions of the common good, will resist the technological imperative and market forces, will engage in moral reflections that go beyond autonomy, informed consent and even immediate identifiable harms to specifiable individuals.

Please provide our nation with a forum in which to set our sights on the big long range social picture that can be so difficult to

envision, to assess, and even to regard as a meaningful context of ethical responsibility and action.

It can and should be possible to discuss prudent nuance policies that resist pressures from either advocates or detractors of cloning to place the cloning of individual humans in the same policy category as research on disease therapies.

In the debate about human cloning the NBAC may have an opportunity to begin to create a more reflective, more cautious, more farsighted, less entrepreneurial and pragmatic social ethos in this country.

Thank you.

DR. SHAPIRO: Thank you very much for your remarks.

In order to make sure that we give each of our speakers here this afternoon adequate time the way we will do this is I will ask Dr. Moraczewski to speak to us next and the new will go to a period of discussion and questions and then we will do the same thing for the other two speakers.

I am afraid that if we get into discussion after every speaker we will just leave our last speaker with very little time and I really do not want to do that.

Dr. Moraczewski?

REV. DR. ALBERT MORACZEWSKI

DR. MORACZEWSKI: Thank you, Dr. Shapiro.

Now we are going to have a change of pace and a change of face. I am sure that Dr. Cahill is much more attractive to look at than I.

I also want to emphasize by way of a preamble a very important point. Being both a scientist and a theologian, though I am speaking here primarily as a theologian but as a member of the religious body, the Catholic Church, I am approaching this from a different angle than I would if I were approaching it as a scientist or approaching it as an academic theologian. So when I am saying I am approaching this from what I believe is would be the church's, the Catholic church's position, the best I can understand it from its documents and its tradition. So it is from that perspective that is important to understand the way I am approaching the topic.

Because it belongs in the Catholic church and generally in many churches the source of their beliefs and their actions, and their policies are at least for Christians and Jews the Scriptures, and then not only the naked Scriptures but the Scriptures have been interpreted and understood over many centuries, and then for the Catholics particularly there is the understanding that the living Catholic church of each generation has the position of authority in interpreting that tradition, that Scripture and whatever facts we can get from it. So I will be alluding then to authoritative statements from the Pope.

Now ordinarily it is the Pope who speaks to that subject for the whole church and it is each Bishop in his respective diocese that speaks to his faithful regarding the topic at hand whatever it may be.

With these few words by way of introduction I have the paper that I have given to each member of the commission, it has a brief biography and then I will begin the paper, the rest of it, I will read it.

"To be or not to be cloned, that is the question." Is it ethically appropriate to clone a human being? Just because the technology to do so is available does not mean ipso facto that the application of cloning technology to human beings is morally acceptable. Neither Sacred Scripture nor the Catholic Church's moral tradition have explicitly and fully treated this issue.

In contemporary times, the Church has noted that "attempts or hypotheses for obtaining a human being without any connection with sexuality through 'twin fusion', cloning or parthenogenesis are to be considered contrary to the moral law since they are in opposition to the dignity both of human procreation and of the conjugal union." That was stated by the Congregation for the Doctrine of the Faith in its paper "Instruction on Respect for Human Life in its Origin and the Dignity of Procreation, February 22nd, 1987."

More recently, Joseph Cardinal Ratzinger in an interview published in the Italian daily, La Republica, March 5, 1997, stated relative to cloning that "The sanctity of human life is untouchable."

Over many centuries the Church has treated in depth the human dignity of each and every individual human being from the beginning of life to natural death. It is that human dignity which is violated, we assert, by the cloning of human beings. The foundation for this dignity, as the Church sees it, is the fact that each human being is called into existence and maintained in existence by a unique creative act of God.

Furthermore, each and every human being is created in the image of God. As the Book of Genesis tells us, the "image of God"

consists in the dominion, delegated and limited to be sure but also very real, a dominion given to the human race over the creatures that swim in the sea, that fly in the air, or walk on the earth. That dominion is a delegated one with the consequences that humans have a limited dominion for which an accounting must be rendered to God, "The Lord God gave man this order: 'You are free to eat from any of the trees of the garden except the tree of knowledge of good and bad.'" That is in Genesis 2:16-17.

Adam and Eve were given freedom in the garden but with one limitation, which if transgressed would lead to death. Accordingly, human beings have been granted intelligence and free will so that human beings can search for, and recognize, the truth and freely pursue the good. In the cloning of humans there is an affront to human dignity for the ones who actively participate in the process as well as for the one who results from the cloning. Yet, it should be noted that in no way is the human dignity of that person diminished.

There are two other bases for human dignity which the Church recognizes: (1) every human being has been redeemed by Jesus Christ; and (2) every human being is called to share in the Divine Life and be united to God for a joy-filled eternity. Each and every human being, regardless of race, color, religion, socioeconomic status, nationality, age, or health status, possesses this inherent and incomparable dignity which must be mutually respected by all.

Does the cloning of human beings violate this inherent dignity? Yes.

And how? It does so by exceeding the limits of the delegated dominion given to the human race. There is no evidence that humans were given the power to alter their nature or the manner in which they come into existence. Cloning involves the deliberate duplication of the genome of an existing person. This would jeopardize the personal and unique identity of the clone or clones as well as the person whose genome was thus duplicated. Would that adult tend to see in the developing clone his or her own biological, psychological, and social development?

Identical twins are identical to be sure; but neither one is the source or maker of the other. Cloning also radically alters the manner in which a new human person is brought into this world. By sexual intercourse a husband and wife are united in body and soul to procreate another human being. At the same time, that physical and spiritual act both expresses and strengthens their mutual love and the strength and life and stability of that family.

In contrast, cloning introduces a technological substitution which eliminates the need for a male in the procreation of another human being; the clone-child would have no biological father, but obviously it would have at least in some cases a biological grandfather or great-grandfather depending on what the relationship is of the cloning sequence.

All that is needed is a woman's unfertilized oocyte, egg cell, and the nucleus taken from a cell of almost any human tissue. A woman could even choose to use both her own oocyte and a nucleus from one of her own body cells so that her offspring would be genetically

an identical copy of herself except for differences of age and the influence of environmental factors. In effect, such cloning would be to fashion a human being in the image of the woman.

Furthermore, couples who would utilize this technology would be asserting implicitly a right to and over another person. The child is treated as an object of manipulation when the marital act is eliminated and the couple attempts to design and control the very identity of the child. Cloning would offer the opportunity for genetic manipulation of the nuclear genome, perhaps with eugenic intent, before transference to the enucleated oocyte.

"The biological nature of every person..." as John Paul II has written "...is untouchable in the sense that it is constituent of the personal identity of the individual throughout the course of his or her history. Each human person in his or her absolute unique singularity is not constituted only by the spirit but also by the body. Thus in the body and through the body one touches the person itself in its concrete reality."

While this technology may be a helpful contribution to animal husbandry and the production of medicinal substances it is entirely unsuitable for human procreation even under exceptional circumstances. One may not use, even for a single instance, a means for achieving a good purpose which is intrinsically morally flawed. One can grant that this technology presents an opportunity for increasing our understanding of animal reproduction and indirectly of our own reproduction.

For example, is there an intrinsic barrier to interspecies reproduction? One could implant the nuclei from various species into the unfertilized oocytes of other species to determine whether one would obtain a viable and fertile offspring, say, a cat-dog or a lion-goat. But what if this were tried between a human and a chimpanzee? What sort of creature would we have produced if it were technically feasible which had the nuclear genes of a human but the mitochondrial genes of a chimp or vice versa?

Cloning may be a way of saving endangered species. It may be a way of improving the quality of sheep's wool, boost the quality of cattle whether for meat or milk, and the quality of horses for strength or speed, but certainly is not a way to improve human beings.

Any legislation or regulation should be crafted to promote and protect research and development in animal husbandry while at the same time it should prevent and block absolutely any and all such research involving human subjects.

We of the Pope John Center thank you, the National Bioethics Advisory Commission, for giving us the opportunity to make this presentation. It will take the wisdom of Solomon, and more, to recommend suitable actions to prevent abuses of this new cloning technology and meet the abiding concerns of the citizens of the United States.

May God grant you the grace of that wisdom which is from above.

Thank you.

DISCUSSION

DR. SHAPIRO: Thank you very much.

We will now go to questions from the commission. I hope there will be some interaction between us and both of the speakers who have just spoken.

Eric?

DR. CASSELL: Father Moraczewski, I understand where you would have us go and that is quite clear but, Dr. Cahill, I hear ambiguity at every paragraph. On the one hand we are a nation like Gary Larson's cartoon of the penguins all on a rock and one of them saying, "I want to be me."

(Laughter.)

DR. CASSELL: On the one hand we are a nation which is driven by individuality and autonomy and so that is a current theme where it goes back to the 17th Century. So we are both individual, in which case we would not want to be cloned except for the narcissistic desire it raises in us and anyway cloning does not make another person just like us because they are not going to be exactly like us. They either are or they are not.

On the other hand the profit motive is terribly important and it is going to drive it. On the other hand the profit motive has its limitations. On the other hand nothing is going to be done and will be done if technology is sweet. There is no question about it. If technology is sweet it gets done.

Now I understand the ambiguity because, in fact, that is the problem. What I am trying to understand is what would you have us do?

DR. CAHILL: I do not -- well, first of all, I do not have, you know, a completely developed policy proposal that I am bringing in for you to sign off on. But I -- the point -- I was, I guess, trying to make a couple of points. One about autonomy. I think that the public concern about individuality is like the tip of an iceberg. The individuality issue is not really my basic concern because I do not think it is threatened by cloning.

I think that the bigger issue is that we tend to use autonomy and individuality and individual freedom to drive and resolve most of our social problems and that is the one principle that you can get most people in a diverse group to agree on, that autonomy should be respected. Absolutizing or excessively focusing on autonomy, although it certainly is of value, then short circuits our ability to look at other values, other issues, ways in which autonomy perhaps should be eliminated. So I was suggesting that this group could provide a forum for trying to put additional issues on the table.

When I mentioned I was quoting from that New York Times editorial where the author mentioned the developers of the atomic bomb and they were the ones that said, you know, "If technology exists then the human drive is to follow it." And where I see a problem or a difficulty, and this includes my approach to this as a theologian, is that indeed there is a very strong human tendency to act on the basis of self-interest and that often plays itself out through economic interest and through the market. It can also play itself out in the so-called scientific drive to take research as far as it will go.

So on the one hand I do not want to be overly sanguine about our ability to stop so-called progress by trying to develop a number of bans and caveats and so on, and yet at the same time my more optimistic side wants me to at least place on the table or I do place on the table the prospect that there are human values and moral values, including autonomy but extending beyond that, that we can discuss here together or that our society as a whole can discuss even though we come from different moral and political subtraditions, even though we are members of different religious communities, I still think we can talk sensibly and prudently about the meaning of this research, about types of research that are on the table. It is not just cloning individuals but other researches having to do with disease therapies.

So I am pleading for, and urging you to, expressing some hope in, if not absolute confidence in our ability to think carefully about policies or bans and legislation, not to put everything in one basket, not to use autonomy as the only moral principle but to try to look at what is possible, what is not, and what are some of the long-range goods that might be at stake.

DR. SHAPIRO: Thank you.

We have a number of commissioners who want to speak. I will try to recognize them in some order.

Jim?

DR. CHILDRESS: I want to begin by thanking both speakers very much.

The official Roman Catholic moral thought over recent years has been clearly opposed to a number of reproductive technologies

and one could imagine sort of an argument from the positions already taken regarding reproductive technologies to human cloning. But I take it in both your comments there are some distinctive features about what you would take to be suspicion of and recognize again that there are differences between the two positions you have presented at least in tone.

What would be distinctive from your standpoint the way you would view the Roman Catholic tradition in relation to human cloning that would be different from the way the arguments might go in relation to artificial technologies generally? I mean, one way to think about this again would be to put it on that kind of continuum and just see how the arguments fit.

But would either of you or both of you like to comment on what is distinctive in the opposition to human cloning?

DR. CAHILL: Well, we could probably both say something but I will just start by saying and you can amplify it.

Of course the thing that is the same is that you do not have procreation through a sex act between committed partners. The thing that is different is that you are creating a child that does not represent the combination of the two intergenerational families that each genetic parent would ordinarily bring. That is the one thing that I can think of that is distinctive about cloning that does not exist in any other kind of reproductive technology or other technologies in general.

DR. MORACZEWSKI: I would say also that it represents a greater attempt to control the output, the product, by already specifying the genome. Whereas when you have a man and woman sharing the

sperm and the egg you do not ever know quite the outcome. I have a brother with seven daughters and they are all different. The same father, same mother, but each one is different. So I think that is another way.

The idea is in our culture of course control is so important. We have sort of an engineering mind where we want to control and be able to say I do not care how you get the product but get it done. And I think this is what we are saying. It does make a difference how you get the product, the human being. I think what cloning introduces is again a greater control over what comes out at the end.

DR. SHAPIRO: Thank you.

Steve?

DR. HOLTZMAN: Just as a follow up question to elicit what is special about this. In the context of, I think, the embryo study commission, they contemplated the following kinds of cases where you twin an embryo, you take one, you freeze it down, the other one grows up, says I like myself, all right, and then unfreezes the embryo. All right. Is that really distinctively different?

DR. CAHILL: I do not think that is --

DR. HOLTZMAN: The same -- both the elements are there --

DR. CAHILL: Right.

DR. HOLTZMAN: -- and being able to examine its own life and make that decision.

DR. CAHILL: I mean, yes, but the thing is either of those could be carried out in a number of different circumstances representing

greater or less degrees to say replicate one's self or another human being or to exert control.

There is -- in the Kennedy Institute of Ethics a year or so ago there was a report on human cloning that was done by the National Advisory Board on Ethics and Reproduction of which I am a member, and Gladys White, our executive director, I saw here before, but it spoke to that earlier type of cloning and tried to draw some parallels. Although cloning from -- the kind of cloning that has recently been developed was not actually on the table at that point.

DR. HOLTZMAN: The reason I am asking the question is already there is legislation or potential regulations or whatever being introduced that are making much of the fact that the DNA is from an adult somatic cell. I am wondering if that is where the rubber hits the road in consideration of the subject.

DR. CAHILL: That it is from an adult?

DR. HOLTZMAN: It is from a somatic cell.

DR. CAHILL: Yes, yes, yes, I see what you are saying.

DR. HOLTZMAN: And I am not sure that that is where the --

DR. CAHILL: Yes. I am not sure to be perfectly honest whether I could get distinctive moral content out of the difference between cloning from an embryo and cloning from an adult cell. Although maybe with more thought that would become evident.

DR. SHAPIRO: Thank you.

David?

DR. COX: So I --

DR. MORACZEWSKI: I would like to make a comment.

DR. SHAPIRO: Were you addressing it to both or just --

DR. MORACZEWSKI: Well, when you began your question I thought it would end something like this, I was once faced with having to baptize twins, identical twins, so I thought, ah, here is an opportunity, I will just baptize one and then have them both raised and see what -- if baptism made a difference in their behavior.

(Laughter.)

DR. CAHILL: You know, to go back to your point, I think it will make a difference whether you viewed the embryo that was cloned as the parent or as the twin. I mean, it is a philosophical or a logical distinction and I am not sure which is the appropriate way to regard it. But would it be better or more accurate to regard the cell taken from the embryo as derived from an already existing individual which is then in effect the parent although at a very early stage as with an adult in a somatic cell?

I think the difference is that with the embryo the cell would not be as developed. That would be the whole point. That is why that was -- it was possible to do that earlier. And it has not been able -- we have not been able to do cloning with somatic cells until now because the technology or the science was not in place.

So if it -- if it -- if the embryo was viewed more in the construct of identical twinship then both of those individuals could be regarded as having the two genetic parents, which is not the case with a child created from the somatic cell of an adult which only has one genetic parent.

DR. SHAPIRO: Thank you.

I want to turn to Professor Cox in a moment but I just want to observe that your story about the baptism shows -- is a marvelous illustration of not being able to straighten out your role as scientist from priest.

(Laughter.)

DR. SHAPIRO: We all have that difficulty.

Professor Cox?

DR. COX: Yes. I would like to follow up on Eric's question and put it a slightly different way and actually to both of the speakers the question he asked Dr. Cahill, which is this ambiguity. I actually appreciate the comments from both speakers very much because the ambiguity is obvious and what you have done is you have just stated both points. Okay. What faces this commission is figuring out a way of how to balance that and I think Solomon is quite appropriate.

We do not have Solomon though so what we have to do is figure out how we are going to do it and I would be very interested in hearing from you what kind of process that you think that would be a good one to be able to balance these kinds of issues because that is what we are really faced with. We are not faced -- we have to identify them and I think that you have both done a good job of doing that. But how do we balance them? And that is not so clear to me and it is not so clear to me that that kind of process exists in our society in any kind of clear way.

So I realize I am a scientist and I do not want to make this, you know, more reductionist than it is but we have to proceed down that path. So how do we do it?

DR. CAHILL: Balance the what?

DR. COX: So let me make it really clear, okay.

DR. CAHILL: Yes.

DR. COX: Is the balance the concepts of individuality and autonomy you were talking about versus the other social goods. Balance, okay, the commercialism versus an individual self-interest versus society's interest in commercialism, balance the issues in terms of destroying, you know, the standard family structure, okay, by cloning versus the ability of people. On the other hand they would argue that, you know, it gives us an opportunity to have kids that we would not otherwise would not.

So it is both of these sides that Eric was, you know, I detected frustrated by the equivocation, but it is the reality. And then we have to have a way of adjudicating between, you know, what is the balance because we come down with a final answer, right, is that maybe it is not the same answer in all three of those but do we clone or don't we clone, okay, or is that how simple it is.

But you have to look at these different things and weigh them. So how do we weigh them?

DR. CAHILL: I think both of us were saying, and this does not give you the process, but I think both of us were suggesting that we should not at this point give support to the cloning of human individuals,

which does not mean that there should be any support for any of the research that is related to the science that goes into that.

DR. COX: Good. So you just weighed them for me which is great. All right. And I think that, Dr. Moraczewski, I did not have any problems hearing him weigh them. I heard how you weighed them.

But in terms of -- do you have comments, doctor, in terms of the process of how the panel would go about doing this?

DR. MORACZEWSKI: Well, I would commend you or the panel, this is exactly what needs to be done, is to hear the various voices in society and not try to homogenize everything. This is one of the great difficulties. If one speaks from that perspective and the perspectives are different and yet now we have to be able to transcend the differences. And, you know, a dictionary of translation does not help very much. But it does bringing people together and working with them for a while. It cannot be settled in 90 days. I do not know. But it is a problem of communication.

I have worked with interdisciplinary fields many times and we find we use the same words but they mean different things because the context of our use and previous experience is different. So what I am saying here is one step towards what you are trying to achieve. You need a lot of discussion among yourselves. You represent many different groups and many different disciplines. You will be hearing from us and a variety of input from the public. You need to weigh this and eventually you have got to take a step.

Now there is no easy way to do it. You have got to bite the bullet and go on. But it is -- roughly I think possibly that the

question of individuals and society, individual rights and societal rights, how do you balance the two because sometimes they are in conflict. And we started off with we realize there is no easy answer but with good will and a clarification of what we hold in common. This is the important thing, what do we hold in common? Upon what platform can we speak together because if we do not then we speak at cross purposes. But establish what is the common note and then argue with trust about the differences.

DR. SHAPIRO: Thank you very much.

I have quite a few members of the commission who want to speak. No double questions allowed, you have to leave your colleagues -- and you cannot even ask two people the same question. So if you could direct your questions and find your most important one.

Let me turn to Tom first.

DR. MURRAY: I notice that Dr. Shapiro chooses me on which to begin the limitation but I will --

(Laughter.)

DR. MURRAY: -- take that up later.

DR. SHAPIRO: Actually I meant something very deep by that.

(Laughter.)

DR. MURRAY: I am sure he did. I cannot resist. This is not a question but I cannot resist thanking Dr. -- Father Moraczewski for his wonderful experiment and pointing out that one of my colleagues mentioned you had -- there was a potential moral problem, namely how would you get IRB approval for that study, also scientific difficulty, that

is the dependent variable of real interest would only happen -- it would be very difficult to assess at least in this earthly existence. But a good example.

Then let me just praise both of you and thank both of you for what I think is a very rich -- two very rich contributions to our conversation. If I have to choose and I hate to choose I will ask Father Moraczewski my question.

As Dr. Cahill, I think, rightly reminded us as you have just so eloquently expressed, we need to have a really intense conversation listening carefully to each other and I think that means we need to put our arguments in the most forceful but accessible manner possible. Now it is clear to me how for an American who is committed to the Catholic faith tradition, I think you have eloquently described the basis of the beliefs you would expect them to have, and the concept of human dignity of course has resonance much more broadly than any particular faith tradition in the United States.

Could you help us to frame, again as forcefully as possible, what the argument is that human cloning would, in fact, be an affront to human dignity and frame it in a way that would be understandable and accessible from people -- for people from say disparate faith traditions?

DR. MORACZEWSKI: I wish I was Solomon but I will try to -- you know, he used -- he was about to use a sword and I think that the only sword I have is to make distinctions. You know, there is a famous philosophical principle that seldom affirm, never deny, and always distinguish.

DR. MURRAY: I like that.

DR. MORACZEWSKI: So I have to make some distinctions you see. Obviously the question asked does not emit a quick answer at least for myself, my mind does not work as quickly as it used to when I was younger, but we begin with -- as I said before, we need a commonality. What do we agree on, see? Well, we can agree on a certain number of things. We can agree that life is important. We agree that individuality, autonomy, all these values are important.

We need perhaps for one thing to do a hierarchy, a priority among these values. Are they one and the same plane or does one supersede the other? And that is the one thing to clarify and come to an agreement. We say that would be one of the steps after deciding what is the common ground.

But to be able to then decide which of the values is going to be relevant here now, from the Christian point of view and generally from many other points of view as well, individual life and individual integrity is important. We try to protect that in a number of ways and yet we see in public life that integrity of many individuals has been shall we say twisted and distorted by greed perhaps or some other factor.

So we need to identify what it is that is really important in human life that we share in our society and that will take a process to do that as I see it, discussion. And then to be able to say a question properly formulated is half of the answer. So that means we have to formulate the question properly and that takes time, too. Time that we do not have here in these few minutes for me to do.

But I would at least encourage you to continue as you are doing not only listening but you need some time among yourselves privately. I do not want to drag this out but I think that is the thing I would emphasize. The need for the commission by itself after you have heard everything to really discuss this on their own.

DR. MURRAY: Thank you. I know it was a very difficult question and I appreciate your effort to help us.

DR. MORACZEWSKI: Thank you.

DR. CASSELL: Father, the context makes a difference with King Solomon's sword and cutting the baby in half, doesn't it, in this context?

DR. MORACZEWSKI: Maybe that it --

DR. CASSELL: He would not have cut the baby in half, he would have cloned the baby and satisfied both mothers.

DR. SHAPIRO: We could rewrite that incident in modern terms. Let me -- If I could ask my fellow commissioners to restrain their natural enthusiasm and let me go down this list and turn to Dr. Lo next.

Bernie?

DR. LO: First, I also want to thank both our speakers for not only their presentations but their very thoughtful answers to our questions. One of the things that is very difficult as we think about this is that it is not always difficult to identify the main themes that are concerning people but it is sometimes harder to articulate why exactly that theme is of such great concern for cloning compared to other technologies or actions.

Dr. Cahill, I thought what you did with individuality, saying that, you know, this is a real concern but when you look at it more closely maybe it is not as big as concern as it first appears. Could you help me understand concerns about family? I mean, I think there are on some very intuitive level grave problems with sort of confounding the roles of parent and twin and so forth.

But in a society where a lot of children have one parent doing the child rearing, although they have two genetic parents, can you articulate for us exactly what is the nature of the ethical problem with having the genetic sort of linkage to only one parent that would happen in cloning? Can you help us sort of --

DR. CAHILL: Yes.

DR. LO: -- can you give us more detail about what you mean by that?

DR. CAHILL: Well, I am not sure I can give a satisfying answer but the first thing I will do is distinguish as Father Moraczewski suggested. I am not sure that it would really be accurate to say that my concerns are the general public concerns and that is one of the things that bothers me. It goes back to my sort of focusing on autonomy as the on moral principle that everybody at a gut level thinks should be absolute.

And I think that in much of the way we regard families that autonomy principle, that people have a right to choose the kind of family they want to have, that they have a right to have children if they choose and how they choose, that if they want to use cloning or any

other method then that should be a free and informed decision of that couple or that individual.

I think that that is a very common popular approach to these issues. My own view is that that is not adequate although autonomy is important. I do not want to be read as saying that individual autonomy is meaningless but to me it is not a full enough understanding of the human reality of parenthood, being a child and family.

So I am trying to raise consciousness a little bit more about the historical and cross cultural importance of intergenerational family networks that we do not capture adequately if we only look at couples and their children, and the nuclear family, or an individual or two individuals making a free choice to create a family however they choose and, you know, using the means that they choose.

Well, in my own thinking about what I would write and what I would say here, I realize that one of the great liabilities of the so-called natural law tradition in general or just appealing to common human values and experiences in general is that those experiences and values are always read differently in different cultures by different people in different ways.

So I realize that while I might be able to point to the historical universality of the two lineage intergenerational family I do not have a final logical or empirical argument that will convince everyone beyond a shadow of a doubt that that can and must be preserved for all future generations.

So it is a matter of trying to work more consensually and inductively to raise up human experiences and at least to present the question whether given the real revolution in human family and reproduction that cloning of individuals would represent, we should not approach that with a great deal of caution and not assume too quickly that free choice should determine the decision that we may make that may have immense implications for our society and for other societies for that matter in the future.

DR. SHAPIRO: Thank you.

Larry?

DR. MIIKE: I am going to ask a simple question but my guess is the answer would be complex. In your minds, and I am asking both of you, do you distinguish between cloning itself and the consequences of cloning?

I know from the Catholic Church's position that probably there is no distinction because of once one has the potential for a full life that is considered a human being. But is it -- would it be as simple as that then? There is no distinction between the science of cloning as we have been talking about it today? Is there no room for discussion in that debate and the balancing of interests if that is, indeed, my correct interpretation?

DR. MORACZEWSKI: Well, there are several questions you have asked, one was folded in the other, but maybe first address one point. You said the difference between cloning and its consequences. The way I approached the issue initially was to address cloning in itself,

that is to say the very nature of cloning, and not -- in other words, the use of cloning rather than the abuse of cloning.

There are many things that can be done with cloning which one would be found reprehensible and that is a secondary interest in the way I approached it. I wanted to get at cloning itself. Now -- so I would say that there is a difference there between looking at cloning in itself as a use versus an abuse of cloning.

But now with regards to is there room for discussion, that is what you are asking I gather relative to the first, and I would say there is room for discussion and I would not want to say off-hand that the discussion was already predetermined in terms of a conclusion.

I think to my mind at least that the church would be concerned about discussion in case there be something that it is possible that has been overlooked. But I would dare say for the most part that it would have to be a most unusual element that was not considered.

So if you want to conclude that this is a dead end -- well, I say it probably is in terms of -- since the church -- what I tried to present was the essence of it so that it does not depend on the circumstances or the consequences or the need, but the very essence. It has to do with the very essence of human nature, human procreation and human marriage and family. I think that is why there is no room because if we understand correctly the nature of these items then cloning is really inimical to those standards.

DR. SHAPIRO: I just want to comment that Larry tried not only to ask two questions but two questions to two people.

(Laughter.)

DR. SHAPIRO: That is four times as bad and so I am going to go on to our next commissioner.

Alta?

PROF. CHARO: Dr. Cahill, by way of clarification, you talk about concerns about cloning of what you call a human individual. I wonder if you can help me understand what you precisely mean by that term. Do you mean a live born baby? Do you mean an embryo? Do you mean a fertilized egg? Do you mean sometimes one or another of the above?

DR. CAHILL: I meant a person -- an individual after birth because that is what has been really -- which does not prejudice any position I would take on, you know, zygotes or embryos. But I think that -- or my assumption just from the publicity and the nature of the recent discussion that has been in the press and that was stimulated by the scientific work that has been done in the last few weeks, focus the moral and policy debate on taking the somatic cell of the developed individual presumably after birth when the -- you know, end or desire to clone that individual would arise and then stimulating that or, you know, using its DNA so that it could grow. So that was where my comments also intended to focus.

DR. SHAPIRO: Thank you.

Arturo?

DR. BRITO: This question is for Father Moraczewski. A little clarification, on page four, the address by John Paul II to the World Medical Association where it stated that "Each human person in his or

her absolute unique singularity is not constituted only by the spirit but also by the body." It would help me in thinking through this process if you could clarify this and it is a question with a couple parts to it but it is very short.

(Laughter.)

DR. BRITO: I just want to ask you would you agree that the -- with that statement I have just read or that the individuality of a human being is more of a spiritual -- of a spirituality which we cannot assume is determined scientifically or any other way, and therefore if you agree with that am I to understand that, therefore, a major concern with human cloning is more of a biological concern than one that is theological?

DR. MORACZEWSKI: Well, from the church's point of view the individual is constituted, the Pope says, by their soul or spirit and the body. The two constitute the person. When church speaks about the human person it is speaking about the soul-body union. It is not the union of two things but of two principles to constitute one thing, namely the human person. And so that is why we treat the zygote -- in order to have the new organism, the new living organism, that is totality I suppose, is you have a human individual, a human person, that is, I say -- or the church has been with some distinction.

Anyway the point was that the human person is constituted by both the soul and the body and that both are equally important but from different points of view. Say that the body individuates in a certain way certainly and we have genetically -- we see that as a very important element in it. So that it is truly an individual. It

is different even as identical twins are different not only by virtue of the minor differences in their body and their experiences in utero or outside utero, but also by their spirit which we feel is also uniquely and separately created by God. So it is both are involved but from different aspects.

DR. BRITO: Okay. So, therefore, the body is also involved. So how would you distinguish this from let's say a cell biologist manipulating human cells versus a heart transplant surgeon transplanting an organ into a human being, therefore you are affecting the body. So is the Catholic Church also against this kind of interference of the human body as individuals?

DR. MORACZEWSKI: No. Because you see we are talking about parts of the body. An individual cell or an individual organ is a part of a total -- of a larger organism, the human being, the human person. So in the case of heart transplant, for example, or any transplantation, understanding of consent, it is ultimately for the good of the recipient that the heart be replaced or kidney be replaced, or liver, or what have you. And there has been no problem because you are not dealing with moving persons about, you are moving parts of the person into another.

So that the -- a cell while in one sense a unicellular organism is an organism whereas a one cell from a multicellular organism is only part of an organism. Itself is not freestanding.

Now the totipotential cell from the very beginning as long as it is totipotential is able, and given the right environment, is able to

develop into a full adult. But after differentiation has set in it loses its totipotentiality and no longer able to develop into an adult.

DR. SHAPIRO: Thank you very much. I, myself, have a long series of questions but you have had three half questions and one follow-up questions in case you think I am not keeping track.

(Laughter.)

DR. SHAPIRO: But I think we really do have to move on. There is a lot of further questions. I want to express my thanks again but I really would like to move on to our next speakers who have been kind enough to join us this afternoon, and that is Dr. Duff and Dr. Meilaender.

I do not know which of you would like to proceed first. Dr. Duff, do you want to begin, or Dr. Meilaender?

All right.

Dr. Meilaender, thank you very much for coming and we will turn to you first.

PROTESTANTISM

DR. GILBERT MEILAENDER

DR. MEILAENDER: Well, thank you very much for this opportunity. I am sorry that I forced you to revise your schedule by not being here. I did not realize you were going to start a little early. I actually was here but I was trying to catch the end of the Princeton-Cal game.

(Laughter.)

So I apologize for that.

DR. SHAPIRO: Who won?

DR. MEILAENDER: Well, I was -- I came at what I thought was the starting time and, therefore, I did not see who won but Cal was winning very close to the end. That is the best I can tell you.

Although my time is brief I want to take a moment at the outset to make a few introductory qualifications to everything that I will say. I have been invited, as I understand it, to speak specifically as a Prostestant theologian. I have tried to take that charge seriously and I have chosen my concerns accordingly.

I do not suppose, therefore, that the issues I address are the only issues to which you are to give your attention. Thus, for example, I will not address the question of whether we could rightly conduct the first experiments in human cloning given the likelihood that such experiments might not at first fully succeed. I assume that is an important moral question but I will not take it up. Nor do I suppose that I can represent Protestants generally. There is no such beast.

Indeed, Protestants are specialists in the art of fragmentation. In my own tradition, which is Lutheran, we commonly understand ourselves as quite content to be Catholic except when on certain questions we have been compelled to disagree. Other Protestants might think of themselves differently.

More important, however, is this point. Attempting to take my charge seriously I will speak theologically, not just in the standard language of bioethics or public policy. I do not think of this, however, simply as an opportunity for something like the Protestant interest group to weigh in at your deliberations.

On the contrary, this theological language has sought to uncover what is universal and human. It begins epistomologically from a particular place but it opens up ontologically a vision of the human. The unease about human cloning that I would express is widely shared. I aim to get at some of the theological underpinnings of that unease in language that may seem unfamiliar or even unwelcome but it is language that is grounded in important Christian affirmations that attempt to understand the child as always our equal, a gift and not a product.

In any case I will do you the honor of assuming that you are interested in hearing what those who speak such a language have to say and I will also suppose that a faith which seeks understanding may sometimes actually find it.

Lacking an accepted teaching office within the church Protestants had to find some way to provide authoritative moral guidance. They turned from the authority of the church as interpreter of scripture to the Biblical texts themselves. That characteristic Protestant move is not likely, of course, to provide any very immediate guidance on a subject such as human cloning. But it does teach something about the connection of marriage and parenthood.

The creation story in Genesis chapter 1 depicts the creation of human kind as male and female, sexually differentiated and enjoined by God's grace to sustain human life through procreation. Hence there is given in creation a connection between on the one hand the differentiation of the sexes and on the other the begetting of a child.

We have to come at the question of cloning indirectly then starting from that point. It is from the vantage point of this connection

that our theological tradition has addressed a question that is profound but mysterious in its simplicity. What is the meaning of a child and what is good for a child? That question is, as you know, at the heart of many problems in our society today and it is against the background of such a question that I want to reflect upon the significance of human cloning.

What Protestants thought they found in the Bible was a normative view, namely that the sexual differentiation is ordered toward the creation of offspring and the children should be conceived within that marital union. By God's grace the child is a gift who springs from the giving and receiving of love. Marriage and parenthood are connected held together in a basic form of humanity.

To this depiction of the connection between sexual differentiation and childbearing as normative it is, of course, possible to respond in different ways. We may welcome the connection and find in it humane wisdom to guide our conduct as I hope you will. We may also resent it as a limit to our freedom and seek to transcend it. We did not need modern scientific breakthroughs to know that it is possible and sometimes seemingly desirable to sever the connection between marriage and begetting children.

The possibility of human cloning is striking in one sense only because it breaks the connection so emphatically. It aims directly at the heart of the mystery that is the child. Part of the mystery here is that we will always be hard pressed to explain why the connection of sexual differentiation and procreation should not be broken. Precisely to the degree that it is a basic form of humanity it will be hard to give more fundamental reasons why the connection should be welcomed and

honored when in our freedom we need not but moral argument must begin somewhere. "To see through everything is..." as C.S. Lewis once put it, "...the same as not to see at all."

If we cannot argue to this starting point, however, we can argue from it. If we cannot entirely explain the mystery we can explicate it and the explication comes from two angles. Maintaining the connection between procreation and the sexual relationship of a man and woman is good both for that relationship and for children. It is good first for the relation of the man and woman. No doubt the motives of those who beget children coitally are often mixed and they may be uncertain about the full significance of what they do.

But if they are willing to shape their intentions in accord with the norm I have outlined they may be freed from self-absorption. The act of love is not simply a personal project undertaken to satisfy one's own needs and procreation is the fruit of coitus reminds us of that. Even when the relation of a man and woman doe not or cannot give rise to offspring they can understand their embrace as more than their personal project in the world as their participation in a form of life that carries its own inner meaning and it has its talis established in the creation.

The meaning of what we do then is not determined simply by our desire or will. As Oliver O'Donovan, a well-known contemporary Anglican theologian, has noted, "Some understanding like this is needed if the sexual relation of a man and woman is to be more than simply a profound form of play."

When the sexual act becomes only a personal project so does the child. No longer then is the bearing and rearing of children thought of as a task we should take up or as a return we make for the gift of life. Instead it is a project we undertake if it promises to meet our needs and desires.

Those people, both learned commentators and ordinary folk, in recent days have described cloning as narcissistic or as replication of one's self sees something important. Even if we grant that a clone reared in different circumstances than its immediate ancestor might turn out to be quite a different person in some respects, the point of that person's existence would be grounded in our will and desire.

Hence retaining the tie that unites procreation with the sexual relation of a man and woman is also good for children. Even when a man and woman deeply desire a child the act of love itself cannot take the child as its primary object. They must give themselves to each other setting aside their projects and the child becomes the natural fruition of their shared love. Something quite different from a chosen project.

The child is, therefore, always a gift. One like them who springs from their embrace, not a being whom they have made and whose destiny they should determine. This is light years away from the notion that we all have a right to have children in whatever we see fit whenever it serves our purposes.

Our children begin with a kind of genetic independence of us, their parents. They replicate neither their father nor their mother. That is a reminder of the independence that we must eventually grant to

them and for which it is our duty to prepare them. To lose even in principle this sense of the child as gift will not be good for children.

I will press this point still further by making one more theological move in very theological language. When Christians tried to tell the story of Jesus as they found it in their scriptures they were driven to some rather complex formulations. You probably did not think you were coming to this meeting to talk about these formulations but for a moment I want to.

Christians wanted to say that Jesus was truly one with that God whom he called Father lest it should seem that what he had accomplished did not really overcome the gulf that separates us from God. Thus while distinguishing the persons of Father and Son they wanted to say that Jesus is truly God, of One being with the Father was the language. And the language in which they did this, language from the 4th Century, Nicene Creed, one of the two most important creeds that antedates the division of the church in the west at the reformation, is language which describes the Son of the Father as begotten not made.

Oliver O'Donovan has noted that this distinction between making and begetting crucial for Christians understanding of God carries considerable moral significance. What the language of the Nicene Creed wanted to say was that the Son is God just as the Father is God. It was intended to assert an equality of being. For that what was needed was a language other than the language of making. What we beget is like ourselves. What we make is not. It is the product of our free decision and its destiny is our's to determine.

Of course, on this Christian understanding human beings are not begotten in the absolute sense the Son is said to be begotten of the Father. They are made but made by God through him in begetting. Hence, although we are not God's equal we are of equal dignity with each other and we are not at each other's disposal. If it is, in fact, human begetting that expresses our equal dignity we should not lightly set it aside in a manner as decisive as cloning.

I am well aware, of course, that other advances in what we are pleased to call reproductive technology have already strained the connection between the sexual relationship of a man and woman and the birth of a child. Clearly procreation has to some extent become reproduction making rather than doing.

I am far from thinking that all of this has been done well or wisely and sometimes we may only come to understand the nature of the road we are on when we have already traveled fairly far along it. But whatever we say of that surely human cloning would be a new and decisive turn on this road. Far more emphatically a kind of production. Far less a surrender to the mystery of the genetic lottery which is the mystery of the child who replicates neither Father nor Mother but incarnates their union. Far more an understanding of the child as a product of human will.

I am also aware that we can all imagine circumstances in which we, ourselves, might were the technology available be quite tempted to turn to cloning. Parents who lose a young child in an accident and want to do something that they might call replacer. The seriously ill person in need of embryonic cells to repair damaged tissue.

A person in need of organs for transplant. A person who is infertile and wants in some sense to reproduce.

Once the child becomes a project or product such temptations become almost irresistible. There is no end of good causes in the world and they would surely tempt us even if we did not live in a society for which the pursuit of health has become a god justifying almost anything.

As William F. May has often noted, "We are preoccupied with death and the destructive powers of our world." But without in any way glorifying suffering or pretending that it is not evil, Christians worship a god who wills to be with us in our dependence, teaching us in May's words, "Attentiveness before a good and nurturant god." We learn, therefore, that what matters is how we live, not only how long, that we are responsible to do as much good as we can but that means as much as we can within the limits morality sets for us.

I am also aware finally that we might for a time approve human cloning but only in restricted circumstances. As, for example, the cloning of preimplantation embryos up to 14 days for experimental use. That would, of course, mean the creation solely for purposes of research of human embryos. Human embryos who are not really best described, I think, as preimplantation embryos. They are unimplanted embryos. Elocution which makes clear the extent to which their being and destiny are the product of human will alone.

If we are genuinely baffled about how best to describe the moral status of that human subject who is the unimplanted embryo we should not go forward in a way that peculiarly combines metaphysical

bewilderment with practical certitude by approving even such limited cloning for experimental purposes.

Protestants are often pictured actually erroneously in many respects as stout defenders of human freedom. But whatever the accuracy of that depiction they have not had in mind a freedom without limit, without even the limit that is God. They have not located the dignity of human beings in a self-modifying freedom that knows no limit and that need never respect a limit which it can in principle transgress.

The meaning of the child, offspring of a man and woman but replication of neither, their offspring but not their product whose meaning and destiny they might determine, that I think constitutes such a limit to our freedom to make and remake ourselves. In the face of that mystery I hope that your commission in its deliberations will remember that progress is always an optional goal in which nothing of the sacred inheres.

Thank you.

DR. SHAPIRO: Thank you very much. I appreciate all your remarks.

Now we will turn to Dr. Duff and then we will go to our discussion period.

Dr. Duff, thank you for being here.

DR. NANCY DUFF

DR. DUFF: I appreciate very much the opportunity to be here not only to speak but to listen to all that has gone before and to have the opportunity to stay tomorrow and listen to the other presentations.

In the 16th Century John Calvin wrote this about childbirth: "Although it is by the operation of natural causes that infants come into the world yet therein the wonderful providence of God brightly shines forth. This miracle because of its ordinary occurrence is made less accounted by us. But if in gratitude did not put upon our hearts the veil of stupidity we would be ravished with admiration at every childbirth in the world."

Now in the 20th Century we find that infants do not always come into the world through the operation of natural causes. The miracle childbirth has moved beyond ordinary meaning through such procedures as in vitro fertilization. Now that we face the possibility of human lives springing not from a fertilized egg whether fertilized artificially or in the old-fashioned way but from a clone, we are making great account, some people would say too much account, of this possible new form of bringing an infant into the world.

Many people wonder whether this is, indeed, a miracle for which we can thank God or an ominous new way to attempt to play God. At the very least it represents the tension that often exists between the church and science.

On the one hand the church has sometimes taken an overly antagonistic opposition to scientific advances. So that Galileo was charged with heresy for supporting the unbiblical notion, Copernican notion, that the earth revolves around the sun. Darwin's theory of evolution, which apparently scared him a bit in the beginning too, is still opposed by some church groups who want to promote what they believe

to be the biblical view of creationism so that it would be given equal time in schools.

Such examples remind us that the church must guard against the assumption that faith requires protection by being shrouded in ignorance. We should be able to celebrate human accomplishments including accomplishments in genetic research as a result of the divinely bestowed gifts of knowledge and technical skill.

On the other hand the church widely understands that human sin can lead us to new scientific advances for extremely evil purposes. We can never support the pursuit of knowledge for its own sake apart from asking serious moral questions about the implications of that which we seek to know.

To date we have not been able to deal with the moral implications, the moral and legal implications of adoption, much less artificial reproduction. We certainly are not yet morally, legally or spiritually prepared to tend to the difficult issues that would arise if human cloning became a reality.

So my position that I recommend to you: While I do not rule out completely the morality of research into human cloning, I support a moratorium on such research which would be removed only in light of strong evidence for the positive benefits of such research. I offer eight guidelines with some supporting theological rationale for the commission to consider:

(1) We should proceed with research into human cloning only if compelling arguments can be made for its potential benefits. While the medical benefits of animal cloning and other kinds of genetic

research on human beings are readily discussed in the material that I have read, though there is not a consensus about those they are certainly discussed and proposed, I have not found equally compelling accounts of the potential benefits of human cloning.

The reasons that I have heard so far are inadequate. An infertile couple's desire to have a child through cloning does not provide a reason to proceed. There are other existing means of artificial reproduction. Furthermore, I agree that we should not make reproduction or in this case the replication of children no matter what the cost or what the reasons a constitutional right.

At the same time whenever I have proposed that to my students or different groups they say that I have not experienced the tragedy of infertility and my saying that I want to diminish that freedom to reproduce artificially. We need to be careful about that. There is a real sorrow for people who face that that some of us do not know but I still cannot so far as to say that it needs to be all right no matter what the cost.

A grieving parent's wish to replicate a dying child does not justify research into human cloning. In fact, it misunderstands the distinctiveness of each human being called into being by God.

We need to question any motivation to replicate a human being in order to replace another. I would even question having a child to replace another through birth if that is our only reason for wanting to give birth to the next child.

Of course, any overt suggestion that children can be cloned for directly instrumental purposes such as providing the military

with more soldiers or a basketball team with more talented players is ruled out of hand.

I do not dismiss the possibility that benefits from research into human cloning exist but I have not yet heard what they are.

(2) Guard against self-deception and, of course, public deception when presenting the pros and cons of human cloning. As Dan Horowitz (?) has pointed out, one test for truth, Christians would say one test for gospel truth, is that it destroys avenues for self-deception and forces us to recognize the limits of our own identity.

Debate over abortion provides an excellent and tragic example of our inability to avoid self-deception in search of truth. The debate over abortion recently focusing on late term or partial birth abortions depending on your position indicates a reluctance to look at the facts surrounding both sides of a very serious issue for fear that one might discover or publicize a fact that does not support one's stance.

Representatives from pro-life and pro-choice groups are equally guilty in this regard. Rarely able to state each other's positions fairly and hiding facts, sometimes from themselves as well as from others which do not support their particular position and exaggerating facts which do.

We need to avoid repeating this error in the debate over human cloning. We should understand as clearly as possible the benefits to humanity and the potential threats. The public needs to hear in language that nonscientists can understand the potential benefits and -- what the potential benefits and ills of human cloning are.

(3) Research -- I think while this moratorium or ban is in place we need to research all pertinent related topics. For instance, what is the effect that twins have on one another positively and negatively. What does it mean to their identity that they are twins? It is not exactly the same thing as being a clone but it is the closest parallel we have. So might we study the effects of twins' close identity as a way to try to speculate what it would be like to be a clone.

What is the impact of artificial insemination with an anonymous donor on a child in the family that it produces? Does that child have a strong desire to know who the anonymous biological father is? It is not the same as having no biological father but it still might bring us insight into what human cloning would mean for the child who came into the world that way.

During the moratorium we need to continue to gather information and anticipate policy decisions for that day when human cloning may occur whether banned or not. Also during that ban or moratorium on human cloning or research on human cloning we need to make a clear distinction, as Dr. Cahill said, between human cloning and other forms of genetic research.

(4) We must consider the status of the human embryo in research. Given the divisiveness of this question in relation to the abortion debate is the hardest issue that must be considered and one that cannot be fully resolved to everyone's satisfaction.

The Doctrine of Vocation claims that God calls each of us into the world for a purpose. Each human life has divinely bestowed value and purpose. Although we may never agree on the point at which

that developing life becomes a person, that is the popular way to pose the question, I believe we are compelled to take that life seriously and ask after what point is it no longer morally acceptable to experiment.

If it took 277 tries to get this one sheep, if we had a similar research experiment for human cloning, what is the status of all those developing embryos that did not make it? Are we only losing genetic material? I am open to there being an affirmative answer to that. Or would we actually be losing human lives? I am not proposing an answer to that one but I think that we cannot get around asking it.

(5) No human being can ever be cloned to serve a predetermined purpose in the world. Hence we cannot clone human beings as I said earlier to provide soldiers for the military or with the expectation they will be great athletes or an attempt to create a great musician or scientist. God alone calls a person into being no matter how that person was conceived, reproduced or replicated.

No matter how well we learn to manipulate genetic matter or replicate human life we do not create life in the way that God does. We do not, as God does, call human beings into existence nor do we, as God does, call human beings into different identities and tasks. Identical roles cannot be assigned to members of any one race, class, culture or gender.

We cannot provide -- I am sorry I cannot read my writing so I will leave that last statement for -- I will just leave it.

(5) We can proceed with research into human cloning only after considering the larger issues of elocution. I think this is very significant. From a Christian perspective we are concerned about the

least of the brothers and sisters around us. "For such as you have done to the least of these so you have done it to me." A well known passage from Matthew.

While many of us, certainly myself can included, can thank God that our children are not likely to die from flu, diphtheria or polio, or even suffer from the mumps, measles or rubella because of advances in medicine, we must remain mindful of the enormous number of children and adults in this country and abroad who are forced to live as if these advances had never occurred. Simple diarrhea kills thousands of children every year.

When considering research into human cloning we must look at the responsible use of limited resources. Though I am not a utilitarian ethicist I do believe that it is mandatory to ask whether other research projects will serve a greater number of people than research on human cloning and take the answer to that seriously.

(6) If we proceed with research into human cloning we must be mindful of those who are most likely to be exploited. Given the past history of medical experimentation and lack of access for certain groups to medical facilities we must be especially concerned that women, racial and ethnic minorities, prisoners and the poor are not exploited as a result of research into human cloning.

Do we desire to clone to enhance or eliminate certain racial features or to replicate one gender in greater numbers than the other? Or will we exploit one group such as prisoners in the process of experimenting on human cloning? We have to look at who -- which

groups are the most likely to be exploited if we went ahead into research on human cloning.

(7) Consider the best interests of children and I would really -- though it is coming to the end of my presentation I would put this at the top of my list. From a Christian perspective we can affirm that all children belong only to God. They are not our's to manipulate, control or abuse. But even for those without religious convictions there are many reasons, both compassionate and practical, for society to put the best interest of children first.

Unfortunately, no matter how a child comes into the world, through the operation of natural causes, through in vitro fertilization or eventually through cloning, we have not and no doubt will not be ravaged with admiration at every childbirth in the world.

Recent Court cases indicate that we are already confused about the best interest of children if not sometimes indifferent. We find it difficult to sever ties between abusive parents and their children, to give custody of that child to a loving nonabusive foster parent who wants to adopt. We can under value the biological and genetic tie of a so-called surrogate mother to the child she gives birth to at the same time that we can grant custody of a toddler to a biological father he never has met before.

We have sometimes considered contractual agreements and rights of biological parents with more zeal than we have pursued the best interest of children. Here if we want to anticipate what sort of policies will be put into effect if human cloning became a reality we have

an opportunity to put the best interest of children forward and I would urge you to consider that.

Finally, I would -- it is almost an aside because I do not believe that it is your -- within your responsibility but I have to mention the regulation on the treatment of animals. Although there is a point where we can clearly distinguish this is research into animals, this is research into human cloning, I think they are more closely tied than we seem to think.

Ever since I published a little piece in the Washington Post I have had calls from people all over the country like now I am an expert on cloning. I think it is just because there is not enough material and they do not know who else to call. But all of them consistently have been interested only in human cloning and there is no interest in raising the question about animal cloning.

Two ways that I think we cannot -- reasons I think we cannot divide them, research into animal cloning adds to our knowledge about research into human cloning. There is a point at which -- I mean, everybody got so nervous when it was they had cloned the monkeys because that is one step closer to doing a human being. I do not think the research can be divided quite that clearly.

The second is that animal cloning is meant for our benefit, for human beings who have been called into responsibility for them. So even if it is not your task to regulate the treatment of animals I do not agree with Peter that we should stop all cloning, all experiments and cloning of animals.

What I do agree with him on is that we should be concerned about how those animals are treated. If that is not your responsibility I would wish for you to take this opportunity to pass that concern on to some commission who does that have that responsibility.

DISCUSSION

DR. SHAPIRO: Thank you very much. I thank both of you once again.

We now turn to members of the commission who may have questions they want to raise.

Eric?

DR. CASSELL: They were both excellent presentations. I am allowed to only address one of you. Dr. Duff, you are it.

But as I listened I am struck by the fact that evolution of the human condition in this nation and people who share human spirit have widely different views about the subject, that we are a pluralist society and that whatever comes out of this commission must both meet -- must meet the needs of this diverse society. And I am interested in how you feel about what you -- not how you feel, what you think about both things being met, matters that concern you greatly and the fact that others who are good persons and true believe opposite from you.

DR. DUFF: I am concerned that we -- I do not know if we ever did have but we do not seem any longer to have a sense of the common good. So whatever, we do have incredibly diverse position on things, but where I wish we would come together is if we had some sense of serving the common good and I do not think that we have that as a society.

What I would put forward as a way to argue for in language besides just my religious language to promote an interest in the common good it does spring from my religious understanding of tending the least of the brothers and sisters.

I would have that as a primary category no matter where we stand on this as who is most likely to get hurt, who is most likely to gain, and can we use our resources to help people with the most devastating illnesses. I know we may have reached a point where we wish science would cure our mortality but if you know somebody who has a disabled child or who is mentally disoriented, I do not think that is wrong to wish for research to find ways to cure that.

So I wanted to target the worst diseases and disabilities, the people who have always been left out, and let that guide our disagreement and our decisions over what we are going to do. And there are very practical and even selfish reasons to do that as well as compassionate ones.

Thank you.

DR. SHAPIRO: Thank you. I have a message for someone who may be in the audience.

Dr. Anna Johnson Winegar, I have a message for you up here if you would just come and get it if you are here.

Zeke?

DR. EMANUEL: My question is directed to Dr. Meilaender. I really do appreciate your talk to us and I am sorry I am not sure I got all the subtlety but it was quite powerful and I want to just try -- it is difficult to summarize in a sentence and I think that is one of

the difficulties we as commissioners and other people in the debate are having. But it seemed to me that central to your concern was the issue of making and the fact that the usual connotation of making for us is to create an artificial world in which we go.

To add this being as an artificial creation of our's into the world seemed to me objectionable on your point for two related reasons. One is it robs the sort of mystery of earth and natality, and human development. The second is it sort of offends our keeping our position in the world as it were recognizing the need to have limits.

Is that right? Have I gone off? Could you maybe elaborate because I think both of those are powerful understandings that we are not used to.

DR. MEILEANDER: Well, you know, when one is asked to elaborate there is a tendency simply to repeat what one already said. I will try not to do that. Yes, I think that those are at least two aspects of what I was trying to get at. On the one hand by using the language of mystery I do not want to suggest that, well, we just cannot think about it then, you know, I guess it is something that cannot be explored. But I did want to suggest that there might be here something that we can only explicate as I put it. We cannot entirely offer more fundamental reasons that in some sense are grounded or from which we can deduce it.

It has to do with an understanding of what it means to be human and I think that what we do has implications for how we think. Perhaps not immediately in any given individual's case, I mean I do not know how to predict that exactly, but if these really are such fundamental matters then what we do teaches us to think about each

other in certain ways and there are ways we ought not think about each other. Ways that encourage us finally to think of some as at the disposal of others in some of the sense of the product of someone's will.

It is the -- I mean, there is -- you know, we get several centuries of the turn to the subject at work here and the primacy of will in moral matters, and in a sense we -- you see important philosophical idea working itself out practically here and there might be occasions when one would want to say, "Well, that idea oughten to work itself out any farther."

I do not know if that -- if I am responding or if I am making sense or not. I guess you are not allowed to respond but, yes, I mean it is that kind of concern that seems to me to be important. I realize it is not the kind of thing that one, you know, draws up a code about or something but it would be unfortunate to miss that sort of question in these deliberations.

DR. SHAPIRO: So I am not accused of being so critically rigid do you wish to respond?

DR. EMANUEL: I think I got enough. Thank you.

DR. SHAPIRO: Dr. Lo?

DR. LO: Since I actually asked a double barreled question of two people last time I will try and redeem myself by not asking a question but to request the three speakers from whom I do not have a text of your talk if you could provide that to the commission. I think for the other speakers tomorrow as well. I think that would be very helpful. I would appreciate the opportunity to sort of go back over in more detail what you presented so well orally.

Father or Reverend, I think we have your document already.

DR. SHAPIRO: Thank you very much for that suggestion, Bernie. That really would be very helpful to all of us.

I have three people on my list and I will tell what the order is so you know. Jim, then Diane and Tom.

Jim?

DR. CHILDRESS: I would like to express my appreciation to both speakers and direct a question to Gil Meileander.

It is a variation of the question I addressed to the previous panelist. You thought about human cloning or spoke about human cloning in relation to various reproductive technologies and you used the language of new. At some times it was unclear to me whether you were talking about a difference in degree or a difference in kind. Some of your language seemed to suggest that human cloning is merely different in degree from the other reproductive technologies we use.

You used language about, if I recall correctly, more emphatically and more decisively. I just wonder if you could say a bit more about how closely you are connecting human cloning with the other technologies or whether there is really something pretty distinctive about the concerns you have raised at this point?

DR. MEILAENDER: Well, these are deep puzzles in some ways. Let me put it this way: I am open -- I could be persuaded that we are talking about something that is a difference in kind here and not just a difference in degree. That does not mean that some of the issues are not, you know, roughly similar. I mean, the making versus begetting

issue does not arise only here as I noted. Although as I also said sometimes when you see where it takes you, you rethink what you thought about other matters.

But the production of someone who, you know, looks and talks, and thinks, and smells, and so forth like us, but is not the child of a man and woman, I am not sure whether I think that is -- I mean, even if it were only a matter of degree it may be an important enough matter of degree to be genuinely worried about and that is probably sufficient for my concern today.

But actually I think they are deep metaphysical puzzles about what this subject would be and it might, therefore, be actually a difference in kind. But how exactly to pursue that, you know, I mean in common talk it is the language of the soul and that sort of thing has been used. I am not sure what the best way to pursue it is but it is a question that I would not necessarily assume I am 100 percent certain of the answer to.

DR. SHAPIRO: Thank you.

Diane?

DR. SCOTT-JONES: My question is actually a version of the question that Jim just asked you so I will try to ask it a little bit differently than I had planned to and you can tell us a little bit more about how you think about this. This is for Dr. Meilaender and I should say that I enjoyed very much both your presentations.

If you think of a human cloning as part of a continuum and we can set aside for the moment the issue of whether it is different in degree or just qualitative -- or is qualitatively different, but if we think

of it as the endpoint of a continuum of techniques of having children or being able to rear children that we might find acceptable or at least questionable, how would you see other kinds of techniques that are used for having children or raising children?

For example, you talked about the importance of the link between marriage and parenthood, the importance of the contribution of both the men and women. Given that how do you see reproduction that is a result of a woman having a child from sperm from an anonymous donor or even how do you see adoption in this whole issue if you think of there being some type of continuum of ways of our wanting to have children or be able to raise children?

DR. MEILAENDER: Well, I would have gotten off the train sooner than here, in fact. Exactly where, you know, I want to get off sometimes puzzles me myself. I think adoption is a different matter. I will simply say that.

I mean, I am the father of three children who are biologically mine and one who is adopted. But I think there are different sorts of reasons that ought to move one to that. If it is only that I want to have a child somehow, I mean I would want to talk to those people myself so that adoption is a different matter. It is a matter of caring for a child who for unfortunate reasons cannot be reared by his or her biological and gestational parents.

But I blurred in my talk a little bit and I did it intentionally because I did not know -- well, I figured it was already more theology than you wanted and I did know exactly what you wanted. But I sometimes use the language of the connection between marriage and

parenthood, and I sometimes use the language of the connection between the sexual differentiation and the, you know, offspring, children.

Those are a little bit different in some respects. One might say that artificial insemination by donor breaks or at least stretches the connection between marriage and parenthood. It does not, I guess, break the connection between the sexual differentiation itself and the production of a child. It is, therefore, a further step, whether we call it degree or kind -- I mean, in that case I think degree probably. But it does not so decisively step away from what I think a lot of Christians have found as part of kind of the divinely created order that connects that sexual differentiation with, you know, the production of the child.

For other reasons I think it is a bad idea and that is why I said I would have gotten off the train sooner. I would not wish to be understood to recommend artificial insemination by a donor. If you caught me in the right mood I would even say it is wrong but I still think it stands within that general understanding that connects the sexual differentiation with the child and where the cloning is a little different I think. I do not know. I hope that is clear anyway.

DR. SHAPIRO: Thank you.

Tom?

DR. MURRAY: When I raised my hand a few minutes ago I had intended to ask a question essentially similar to Jim Childress' but another has occurred to me so I am not going to give up my place.

I do want to begin, though, by sincerely thanking you, Dr. Meilaender and Dr. Duff, as I had earlier thanked Dr. Cahill and Father Moraczewski. Anybody who was despairing of the quality of public

dialogue about some deeply important human and moral issues should have been here this afternoon. This has been something I am going to reflect on for a good deal longer and may very well come back to you for assistance in understanding some of the implications of what you said today.

Let me direct my question to Dr. Duff since we have sort of let you off rather easily so far. I very much like your list of considerations and in my artful note taking I came up with nine rather than eight points but that is fine.

Oh, there are other members --

(Simultaneous discussion.)

DR. MURRAY: So it was a richer presentation. Maybe --

DR. SHAPIRO: Replicated, Tom, not --

(Laughter.)

DR. MURRAY: I liked the points very much. I think they are morally relevant considerations that anyone I think would wish to take into account. We are going to have to make recommendations obviously to a pluralistic community and in the context of, you know, sort of legal, constitutional and political traditions, one of which is this focus on individual liberty and autonomy.

Now I have to confess I -- for coming not from -- you know, not necessarily from religious reasons but I share I think very much the kind of position that I have heard many of you express about the language of autonomy and individual liberty simply being relevant but inadequate to capture what really is important here.

But given our sort of commission's constraints and given that we have to respond to this pluralistic world that gives a lot of importance to individual liberty and autonomy, what would you suggest we do? I mean, how should we -- how can we formulate a response that does justice as I really want to do to the kinds of considerations that you have raised?

DR. DUFF: Two responses. One that I know is hard because I found it hard as I put together my own response but that is -- it is related to one of the things I said and that is honestly to give both sides of the issue. Now the reason why I think it is hard when you are giving a report like you do, and I found it hard here since I was afraid you would just accuse me of not having said anything, you just stated both sides and it was confusing.

But I think that should not keep us from being fair to both sides and being fair -- and there are more than two sides. So that really making people feel that their position has been represented even if you think it is a position that is wrong, you do not agree with it, but you have heard it and you want to present it as fairly as you can.

One of my teacher's rule of thumb for academic debate was that you should be able to state your opponent's position so clearly and so fairly that your opponent would say, "Yes, that is what I mean," and we do not do that. We certainly do not do it in politics and we do not do it in academics very well either. So that would be one way so that everyone would really -- a lot of people would feel that they had been heard.

But my other response is the same I have already given that I think that we have to proceed with a sense that we are trying to build or move towards a sense of the common good. I do not know whose original quotation it was. I heard it from Paul Lehman and maybe he got it from Luther, I do not know, but he understood the relationship between the individual and the community as saying, "In each the good of all and in all the good of each."

You cannot put individual rights and freedom, and autonomy over the concern for the community, and you cannot put concern for the community over concern for individual rights and autonomy. The two have to work together and they are not necessarily opposed.

There might be certain cases where one is limited by the other but they are related to one another from beginning to end so that we need to look after the common good. I care for fellow human beings even when I do not agree with them. A pluralistic society does not mean that we cannot have a deep concern for the good at all which is related to the good of each.

DR. SHAPIRO: Eric?

DR. CASSELL: Well, I will preface it by saying that the complexity of the problems that face us that science raises, that the world in which we live raises, cries out for an educational system that does what Aristotle wanted, right, that makes its participants able to make choices. But now time has passed, it is 25 years from now, you are very healthy because of the advances in medicine, Dr. Meilaender, and here are several children who have been cloned, and actually this is

one family that presents three. Are they -- what is your stance towards those individuals, each who have the same?

DR. MEILAENDER: What do you mean by what is my stance? Are you asking --

DR. CASSELL: Well, they --

DR. MEILAENDER: -- I think there are entological statuses, how are we going to treat them --

DR. CASSELL: -- well, how are you going to treat them? How should they be treated in this society? I mean, we are sitting here looking at misconceptions, that is one thing. But other persons in our world, are they in some sense different for us? Will we treat them differently? Should the nation treat them differently?

DR. MEILAENDER: Well, let me say a couple of things. We are back to the deep metaphysical questions here that I do not know that I am entirely prepared to answer. But I do assume that it might be -- just as a starter I do assume that it might be possible that human beings could make other beings who would not simply be one of us. I mean, I do assume that is possible and I think that actually intuitively a lot of people do not think that in this whole conversation. But I do assume that they might look like us and talk like us and so forth but not be one of us, that history affects nature in a way.

That does not mean that necessarily I would want to treat -- I would be my usual nice self but there -- Christians have always thought there was some rational species other than human beings. Angels, for instance. And you run into a rational species that is not

human and you have to ask yourself how you ought to treat them. So I think there would be questions for one thing that would arise.

But I am not -- I do not think the issue is really so much how would we treat them simply but how would we have learned to think of each other also and insofar as we come to think of the possibility that some human beings are the creation of our free will and desire, I think, you know, it is imponderable, it is incalculable how we might learn to think of some or another of us or of, you know, some other species.

So how would I treat them? Well, I, you know, if I really thought they were human beings then I would treat them the way I treat other human beings. If I thought they were some other rational species then I would sit down and try to do my best thinking about what our duties to other rational species were. But I think the real question is how will we have trained ourselves to think about each other and will we still have the kind of intellectual wherewithal to sustain a notion of equal dignity. I am not sure.

DR. DUFF: Can I respond to that?

DR. SHAPIRO: Yes?

DR. DUFF: It is just slightly different but I think it is significant. I think it is imperative to assume that they are the same human beings as the rest of us and that one of the reasons I want us to anticipate the possibility or is it an inevitability that people will be cloned is just for the reason that we would have already put in policies in place that say this is a person the same as the rest of us, the same civil rights, cannot be bought and sold, cannot be manipulated, cannot be owned, so that I cannot imagine that it would be a different species.

If possible, I guess I would have to admit that but until we found out or if we found out that this was something other had been created than a human being we have to assume they are human like the rest of us and theologically the answer to the question is they are children of God just like my children are or they would be. So they must be in a civil society be given exactly the same kinds of rights and protections.

DR. SHAPIRO: Thank you.

* * * * *

E V E N I N G S E S S I O N

DR. SHAPIRO: Zeke?

DR. EMANUEL: I want to try, I think, Tom's question a little different, Dr. Meilaender.

You couched the distinctions between making and begetting, producing and procreating in religious terms. You were invited for that. And people recognizing their limits also in religious terms in relationship to God.

The question I heard Tom ask is do we need a religious base or do we have to have a religious world view to make those kind of claims? I ask that question because if we do, we as a commission are going to be quite paralyzed and hampered. If we do not, well, how do we go about making that extension or making those arguments and justifications without invoking God?

DR. MEILAENDER: Well, the first thing I -- I have a certain resistance at this point in the sense that -- I take very seriously the -- maybe too seriously the notion that I was brought here to talk theologically and that is to say in other words to put before you one view that you ought to consider and it is kind of your job to figure out what in the world you are going to do with it. Not all together my job to do that.

(Laughter.)

I do not believe in role differentiation. But with that sort of caveat the only thing that I would -- the only sort of quick thing anyway that I would say to this is that the notion that you people on this commission could really say anything very constructive about a question like this entirely prescending from views about the good life for human

beings, whether you couch that in religious terms or not, is I think probably an illusion.

You could try, you know, accentuating autonomy, try to turn to some kind of procedural solution, couching it in the language of pluralism and so forth. That does carry a notion of what is the good life. However, in some ways it carries a notion of kind of what it means to be a human being and so forth along with it.

I do not think there is any way -- in other words, I do not think that you are going to find a language that does not itself bear normative implications, whether religious or not. So that for me, you know, the religious language is just one further complication of that problem. It is not -- you are not -- by avoiding religious language and finding some other kind of lowest common denominator language you are not actually going to avoid the problem.

Now I did try to say at the start at my presentation when I said that I, you know, on the one hand I wanted to talk theologically but I did not want to just sort of be the Protestant interest group popping in here for a moment, I do think that at least in some cases theological language of the sort that I quite deliberately used has been an attempt to get at what was thought of as really sort of fundamentally human.

I do not suppose, therefore, that the only way to articulate at least some of what I said is by talking about the relation between the first and second persons in the Trinity in Christian language. But it -- I simply wanted to try to explore some of the underlying theological reasons that are at work there. I think at least some of those insights can be articulated in other ways.

I used the phrase, I mean it is certainly not original with me, it goes back a long way, "Faith seeks understanding." Well, if faith finds understanding then understanding is presumably something that can be communicated and that one can talk about it. You can talk about equal dignity and so forth not necessarily putting it in my specifically religious terms. But you are not going to get away from value ladened language in one way or another.

DR. SHAPIRO: Thank you.

Larry?

DR. MIIKE: This is for Dr. Duff. Something that the Rev. Dr. M, and I will not pronounce his name because I defy him to pronounce mine first before I pronounce his.

(Laughter.)

What he did say was that -- I am paraphrasing -- "Cloning exceeds the limits of powers delegated to the human race." For Dr. Duff, I do not know what would convince you that there are some legitimate reasons for cloning human beings. You have given a whole bunch of areas in which one might consider it. But am I wrong in assuming that that is really also underlying the basis for much of the religious concerns about cloning, is it not, and if so how does one get beyond that issue?

DR. DUFF: I agree in large part with what was said earlier but not entirely. I would not rule cloning out of bounds apart from its consequences, that it is wrong in and of itself. I would not say automatically that it exceeds the power that human beings have and makes us like Gods. Though certainly it opens up the possibility of us attempting to be like God.

What could be some compelling reasons to stop a moratorium and we would allow research into human cloning, it is if someone could show to me that it really would enhance the well-being of future lives, that children who now suffer from incredible genetic disabilities or other kinds of illnesses that could be corrected through cloning -- see, I have never read -- that is really gene manipulation or gene therapy or other kinds of genetic research that seems to address devastating illnesses.

I have not read anywhere that human cloning addresses the correction of really those horrible things that some people face. But if you could show me that it does then I would reconsider the ban. I do think that the consequences of cloning are important and the results of those kinds of research. I guess the one place where I also differ perhaps with all the panel members that I do value has been life, having children either biologically or through adoption, I do not think that that is absolutely mandatory in every case to create a family.

DR. SHAPIRO: Thank you.

Steve?

DR. HOLTZMAN: Well, let me follow up with that, Dr. Duff, because the kind of argument that has been articulated goes along the following lines: First, it does not assume that the research will go to the end of actually trying to create a human being. What it suggests instead is that you can take a totipotent cell and now we have found out that all cells are totipotent, put them into an oocyte, and that what could come potentially out of it are autologous stem cells so that you would now have, for example, hematopoietic precursors, neural precursors,

whatever, such that if you were to get into an accident severing your spinal cord you may now have transplantable cells which you would not reject, all right, and could help yourself.

The presumption behind that, again one could say cloning a human being is out of bounds. The kind of research is the same kind of research that could lead to that but stop short of it. What is implicit in that, however, is that you at least given current technology a la Wilmut would be using oocytes, all right, as the vessel for the genetic material and you would be creating something which if reimplanted, if let go, could become a human being.

DR. DUFF: Right.

DR. HOLTZMAN: All right. And so what some of us are struggling with is the notion that does the -- even if one says I do not want to see human -- new human individuals who are clones created, do you then intellectively run into an argument from another group that says, "But to the extent that you had to use an oocyte and, therefore, created an embryo it is out of bounds."

DR. DUFF: That is -- I indicated I think we have to take that very, very seriously. If research into human cloning could lead us to the day where we could clone body parts apart from a developing embryo then I would want us fully to support such research. It is problematic for me but I am not entirely definitive that using what could develop into a human embryo for body parts we are in a different ball park. Do I automatically rule that out? It is such a difficult question.

I think we need to admit that in existing forms of artificial reproduction and I actually do not like the term "reproduction" either we

discard fertilized eggs as part of -- you know that already -- as part of the process. So is this really different from what already exists is one question legally. But morally is that okay?

I stand somewhere between prochoice and prolife groups. I cannot say that a conceived egg, a fertilized egg is exactly the same as a born human being. I do not think anybody entirely says that. We do end ectopic pregnancies and I cannot think of a parallel way where we end the life of a child already born to save the life of the mother if both are going to die. But I cannot be entirely with the prochoice either if we are unconcerned that this is human life.

It is not -- at what point does it become a person, you may have to consider all that, but it is not feline life, it is human life. So that I want us to pause over just that question. How we answer it I do not know and that really does -- I think that brings us to the heart of probably the most controversial part of this. It lands us back in the middle of the abortion debate.

DR. SHAPIRO: Thank you very much.

We only have a very few minutes left before we have our public comment section scheduled and I want to leave a chance for the committee to stretch as we have been sitting here for quite a few hours now. But before doing that I want to do two things.

One to thank once again all of the panel members. We are very grateful to you for the very thoughtful way you have addressed us this afternoon. And I want to echo the words of my colleague, Professor Murray, to just thank you for the quality of the overall

presentations and the thoughtfulness with which you took this assignment.

So thank you all very, very much.

(Applause.)

DR. SHAPIRO: I think our public comment session is scheduled for 4:15 which is five minutes from now. I think we have a federally mandated obligation to begin at 4:15 so let's stretch and reassemble. Thank you very much.

(Whereupon, a brief break was taken from 4:10 p.m. until 4:24 p.m.)

DR. SHAPIRO: I would like to move into the public comment session now. I would appreciate both the commission and our guests to please be seated so we can turn our attention to those who have signed up for public comments.

The first person -- incidently, let me just tell you what the ground rules are for public comments. Each presenter is limited to five minutes so that we have time for each and everyone who would like to address us.

The first person is Nancy Reame who is representing the American Society for Reproductive Medicine. Ms. Reame? Excuse me, Dr. Reame. I apologize.

STATEMENTS BY THE PUBLIC

NANCY REAME

DR. REAME: My name is Nancy Reame. I am a professor of nursing and reproductive sciences at the University of Michigan. You may recall that I did testify in front of you last time as a private

individual, academician, researcher. However, today I have been called into active duty. There is an executive board meeting in New York City today so I have been asked as a card carrying member of ASRM to stand in, and a very interested member I might add.

The American Society for Reproductive Medicine is a national nonprofit organization of more than 10,000 researchers and clinicians dedicated to advancing knowledge and expertise in reproductive medicine and biology. I thank you for this opportunity to speak today.

As you know, you are the third panel in less than 20 years that has been directed to explore the broad ramifications of research involving human gametes and embryos. Three years ago a distinguished panel of experts like yourselves convened in a similar setting to discuss a similar topic.

After several public hearings and extensive debate that spanned a period of nine months the Human Embryo Research Panel issued a report that established guidelines for federal funding of human embryo research. Included in those guidelines was a statement that in layman's terms said research involving transferring the DNA of an adult cell into an unfertilized egg with the goal of replicating an existing human being was unacceptable. ASRM supported then and still supports those recommendations.

Less than 24 hours after the panel's report was released, however, the President issued a directive that compromised the effectiveness of the panel's recommendations. Congress then stepped in during the appropriations process and closed the door on all federal

funding of research involving human embryos. Little did they realize that by banning federal funding of this research they ignored important panel recommendations to limit unacceptable research and they closed off the requisite oversight that federally funded research projects required.

Had the research been allowed to proceed with the panel's recommendations and guidelines in place a national standard for research on human embryos would exist today and the trepidation about science run amuck engendered by the debut of "Dolly," the sheep, would no doubt have been tempered.

Like the 1994 Human Embryo Research Panel ASRM believes that the practice of cloning an existing human being by nuclear transfer is unacceptable. We agree with John Robertson that the cloning of an adult human is replication not reproduction.

We would also like to emphasize two additional views. First, the American Society for Reproductive Medicine believes that nonhuman cloning research is acceptable as long as the research is approved by the Institutional Animal Care and Use Committees required by the Animal Welfare Act and the Public Health Service.

For example, knowledge gained from the research being conducted at the Oregon Regional Primate Center would ultimately be applied to treating age related infertility in humans. Moreover, we believe that the techniques and methods involved in this cloning research such as a nuclear transplantation and electrical activation of an unfertilized ova without transfer to a human host as considered within the broader spectrum of preimplantation human embryo research may have merit because these experimental paradigms can provide insights

into fundamental mechanisms about human fertilization that can certainly help in the development of the treatment of infertility and genetic disease.

In accordance with NIH guidelines we believe preimplantation human embryo research can be acceptable provided that careful limits are kept in place in the form of stringent research protocols and required approval by both an ethics committee and an institutional review board of the highest caliber.

It was gratifying yesterday to hear Dr. Harold Varmus' comments about the administration's support of lifting the congressional ban on appropriations of human embryo research funding.

Once again we urge you to look to the recommendations of the Human Embryo Research Panel for guidance. Furthermore, we urge you to recommend that Congress and the President lift the ban on federal funding of in vitro fertilization research both to benefit patients with infertility, cancer, inherited disease and other human afflictions, and in order to create a national standard of oversight that is clearly needed.

An outright research ban on human cloning and its techniques prompted by politics and paranoia is troubling. Similar fears surfaced 19 years ago when the first IVF baby was born. Since then 55,000 IVF children have been born to infertile parents in the United States alone and IVF is now a standard treatment for certain types of infertility. Had the fears of 20 years ago halted the research those families would still be childless.

However, this is not the success story it should be. Most recent advances in the field have taken place outside the United States as a result of 20 years without federal support and guidance the U.S. lags far behind England, Belgium and other countries that support in vitro fertilization research with restrictions.

We are now at a similar point with "Dolly." We cannot let those who fear the misuse of science ban research that could ultimately benefit those who suffer from a variety of human afflictions and diseases.

We need to have the vision to allow certain aspects of this research to go forward and at the same time we need to be vigilant in assuring that this research meets the highest ethical standards. Federally funded research with guidelines would accomplish this.

Thank you for the opportunity to testify.

DR. SHAPIRO: Thank you very much for your remarks. We appreciate it very much.

Are there any questions members of the commission would like to ask at this time?

Alta?

PROF. CHARO: I would like to ask if you could tell us a little bit about the implementation of the legislation originally introduced into the Congress by now Senator Wyden. It was legislation that asked that clinics that do work on assisted reproduction report to the Federal Government about their success rates and my understanding was that it was supposed to be reported to the CDC. To the extent that there is any private sector activity that eventually has the goal of attempting this in

humans with the idea of bringing a baby into the world, presumably that would be covered under that bill.

Can you report on what has happened in terms of implementation of that bill so we will know what is already in existence by way of reporting mechanisms?

DR. REAME: I am not a part of that activity. I am just a member representing ASRM. As I understand, though, there is efforts underway with the CDC. Finding money, first of all, was an issue and how these guidelines would be implemented to begin with. It is -- there are efforts ongoing. I do not -- we have some government relations -- people here in the audience. They may have more specific information about that but I am not directly involved in those efforts.

DR. SHAPIRO: David, do you have a question?

DR. COX: Yes. It is a follow up on this. So even without those efforts could you give us a rough idea of what the success rates are on in vitro fertilization for couples in terms of the fraction of people that come in versus the fraction? If there is 55,000 babies, so out of how many tries?

DR. REAME: It depends on the definitions and I think that is part of the problem. I think that is a big part of the problem. Take home baby rates versus pregnancy versus in vitro fertilization rates vary all over the board. I think SART, the Society of Assisted Reproductive Technology, which is a voluntary subspecialty of ASRM if you will, is trying very hard to develop and insist upon and characterize and assemble the data. But there are also clinics that do not take part in this and so it is a huge, huge problem and a black hole if you will.

On average people say it is 15 to 20 percent. It varies by site. If you are talking about egg donors it can be as high as 40 percent.

DR. SHAPIRO: Thank you. One final question, Dr. Lo?

DR. LO: I would like to ask you a question about voluntary guidelines by professional organizations as being one way of putting in place limits on technologies that people have moral concerns about.

Is it an official position of ASRM that to engage in the cloning of a human being would be unethical from their sort of professional standpoint and, if so, do you think that those professional guidelines are going to -- what do you think the impact would be on someone who might consider -- want to consider carrying out the cloning of a human being? Are most physicians who -- are most or all physicians who would be technically capable of trying to clone a human being if that became more feasible going to be members of ASRM? What impact does a policy statement from ASRM have on the actions of its members?

And let me just sort of put that in context by saying that in California, the University of Irvine, the University of California -- University of California, San Diego had a major scandal with the ART program taking oocytes from donors and giving them to other women without the knowledge or consent of the woman from whom they were harvested. It raised real questions among the public about the ability of professionals to enforce standards that in the common morality would have been thought to have been very clear.

So there are a lot of interlocking questions and I have sort of used my full compliment of questions for this session. I think that one

of the things that people are thinking about is can you trust the professionals who would be involved applying this technology in the ways that people find concerning? Can you trust them to act responsibly so to speak?

DR. REAME: Well, the short answer is we have had some experience that the answer could be no because those guidelines have been in place and we have had an -- ASRM has had an ethics committee for many, many years and when people are committed to doing unethical things it may not matter.

As part of that question you raised, are physician members especially or reproductive scientists, embryologists, who are also members of ASRM, what is the likelihood of them being involved in human cloning studies or research, or the theoretical clinical application of this and to what extent would they ignore voluntary guidelines I think is an important one. And given what we heard today about the basic science it seems unlikely that in the very near future human cloning and the creation of full-term babies per se is a long ways away.

Your first question was actually did -- does ASRM oppose human cloning for the production of children and the answer is yes. However, I think there should be some concern about other -- perhaps to what extent might other kinds of techniques, research procedures, embryo splitting go on in an environment where IVF clinics are not regulated and to what extent they may or may not be members of ASRM is open to question.

DR. SHAPIRO: Thank you very much and thank you very much for your testimony.

The next person to address us is Judith Lamb-Lion from the Lamb-Lion Institute in Utah.

JUDITH LAMB-LION

MS. LAMB-LION: Yes, that is not a given name, that is a taken name.

If we have this glass of water and we were thirsty we would take a drink from it. However, if I dropped in something that might be radioactive you may not be able to see the radiation but you would be very sure not to drink it. In fact, you would probably clear the room. Now that is a subtle energy field that we do not measure with our senses. We have only recently discovered subtle energy fields we do not know with our senses but we have extended through technology sensory capability and here we are knowing that if we put a Geiger counter to something that is radioactive we are going to get a radioactive readout but not if we walked into a room and it was sitting there and you had no knowledge with your senses.

Now the question is, and I am very surprised it has not really been brought up before, is the spirit real? Is the spirit real? If the spirit is real then who has the right to judge whether or not we meddle with the vehicle that the spirit attaches itself to? If the spirit is real is the science we need to study? Can we somehow finally mature to a sophistication of identifying whether or not there is a spirit? That is a very important question here.

Is all the art in history where we see the aura of human light, of light radiating out, the auric light of someone, just fantasy? Are the bells and the candles at the altar throughout every religion, are two

billion people out to lunch, light and sound as a phenomenon attached to subtle knowledge?

What we have to do is say if there is even the slight chance of another physics, a metaphysics, a light and sound energy field that cohabits with the physical forms of animals and plants, are the American Indians out to lunch because they talked to the great fathers in the sky? Were all the saints in history out to lunch? Were they mad? Or were they talking to entities? Were they talking to energy fields of real existence?

We have to understand that question before we move on to cloning because cloning is a different step. It is the different step that we have never taken in our history. The way we generate life. Now if the spirit is real then we have to say does the spirit like a cloned body? Does the spirit have a choice?

Now if we never get to that question I do not think we have touched metaphysics or spirituality because what is spirituality if it is not the evolution through choice to refine the consciousness to address ever more refined consciousness, subtle energy. Religion means linking back to the subtle from the gross (?) to the subtle.

Evolution means choice, selection. When you amputate selection you stop evolution.

Now if we cannot sit here and say, "Well, you know, in the old days we did not know that radium was in basalt." Madame Curie spent 17 years trying to separate them. She did not know it existed until she had basalt sitting in a desk draw on top of a key on top of a photographic plate. Then there was an image that she could not explain.

What don't we know yet? What don't we know about subtle energy yet? That is the question. Why would we distort the vehicles which we claim throughout all the world that there are spirits, that there are angels?

Why do the astronauts in the Soviet Union, whom I have talked to personally, who said they saw angels? These atheists saw angels in space. They came back and reported it. Now either there is or there is not and we cannot play a dual game here where we say on the one hand that we believe in the etheric, we believe in the subtle, but we take no account of it.

So are we as spiritual beings, are we as human beings, there are over 80 percent, well over 80 percent of the world who claim to be believers in subtle and yet it has not even been discussed.

Is there something missing when we take away subtle information from cloning that may be present only because it is in the auric field of the other data present? When we -- we actually have through coniine (?) photography been able to photograph a full auric leaf where a leaf has been amputated but where the amputation takes place there is still light defining the field where the leaf was. How do we account for these things? Do we move forward before we understand these things?

It seems to me that as people who say that they are Christian, who say that they are spiritual, I represent a philosophy of meditation on light and sound. I personally can see auras. I have since I was a child. I can tell when someone is mad. Their aura changes color.

It goes red. Now if someone in this room cannot see that how can they say that is not true?

Now if somebody can see an angel are they mad or do we have to research it? Do we move forward to change the animal form before we know whether or not they are linked with a spirit that has different laws of function? I think it is an important question.

I also represent Eastern Philosophies. Now they believe in reincarnation. I believe in reincarnation. A philosophy that maybe all Christians do not believe in. However, if reincarnation is a fact and the Dali Lama is not a fool, if all of the Eastern Philosophies are not fools but they actually know in reincarnation, what is reincarnating?

Can we as Americans, as Christians, can we say that information is important in the world? We make all the dynamic decisions and the world will follow. So if we clone and they do not believe in it and the clones are out there what do they have to do and say about it?

If there is such a thing as reincarnation what generates it? What motivates it? What motivates the choice for a reincarnated being to enter into another body?

DR. SHAPIRO: I am sorry to interrupt. I do not mean to interrupt. You really have to draw your remarks to a close since we have a five minute limit if you do not mind.

MS. LAMB-LION: Great. So as Christians we used to say, "Let thy eye be single and thy whole body shall be full of light. Do you have ears and you cannot heart? Do you have eyes and you cannot see?" What was Christ referring to?

Kabir, "If you want the truth I will tell you the truth: Listen to the sound current, the real sound, which is inside you."

Hafiz, "When in meditation I see thy beloved form of the Master, oh harmony sounds springs up the central arch stone of my forehead. No one knows where the beloved abides but surely enough comes the sound of a bell therefrom."

Sound and light have been throughout history at the base of every religious discipline, whether it is American Indian, whether it is Hindu, whether it is Moslem, whether it is Zoroastrianism, and all of these religions pay lip service to the fact that there are other energy fields present that are not seen by the average seer. Is the average seer the scientist? Does the scientist get the chance to say I cannot see it? Can you say to Mother Teresa that she cannot see it?

DR. SHAPIRO: Again I am sorry to interrupt but you really have to bring your remarks to a close.

MS. LAMB-LION: This is the close.

DR. SHAPIRO: Thank you very much. I appreciate your time.

MS. LAMB-LION: Right.

DR. SHAPIRO: Any questions from anybody on the commission?

MS. LAMB-LION: I know I have kind of dumbfounded everybody by jumping over the board here.

DR. SHAPIRO: Thank you very much. I appreciate the time and effort you have taken to come here. Thank you very much.

The next speaker is Robert W. Weise from the Lutheran Church, Missouri Synod and Concordia Seminary.

ROBERT W. WEISE

DR. WEISE: Thank you, Mr. Chairman. A little side, a little light side as to invite Weird Al Yankovic who put a parody to the song, "I think I am alone now. I think I am a clone now." So I do not know that he would have anything additional to say to this.

My name is Robert Weise. I am an Associate Professor of Practical Theology and occupy the endowed Chair of Pastoral Ministry and the Life Sciences at Concordia Seminary, The Lutheran Church, Missouri Synod, St. Louis. Before joining the faculty at Concordia I served as a parish pastor in Lutheran congregations for approximately ten years and then following -- prior to that for about five years I was a Professor of Clinical Hematopathology at Wayne State University School of Medicine.

I think personally two major areas need to be emphasized here, procreation without traditional human conception and cloning in the face of the myth of human power and the cult of progress.

Until the advent of the first test-tube baby in 1978 humans were begotten the old-fashioned way. "Adam lay with his wife, Eve, and she became pregnant and gave birth to Cain," as so recorded in Genesis. People throughout the created world viewed sexuality and procreation through Judeo-Christian lenses as unitive. "And God blessed them and said to them (Adam and Eve), 'Be fruitful and multiply..." Humans are generated by God within the marriage bond of one flesh

union. thus the meaning and value of human life originates and continues with the Divine Creator, Yahweh.

We are not creators of human life. We procreate. A husband and wife participate in the mysterious and miraculous union of the sperm and egg that form a human with potential. This human is unique and valuable because they are created in the image of God and redeemed by the death and resurrection of Jesus Christ.

This creative act of God within the union of one flesh of husband and wife is within the context of community. We are not autonomous individuals living out our lives within a vacuum of self-determination and self-preferential love. We have a history, and that history is not told apart from the community we live in.

The child in procreation is not the goal, as it seems to be in cloning. Nurturing is certainly one of the main goals of human procreation. The cloning of humans is another step it seems to me in the search of perfectibility and immortality. Children are a blessing to behold. But today they seem to be an inconvenience in a society that is running fast-forward.

As a father of five beautiful daughters I understand the identity dilemma that children puzzle over in this so-called post-modern world. Many children do not know who their parents are, either emotionally or physically or spiritually.

Since the advent of in vitro fertilization and artificial insemination there are up to 32 ways to conceive a human child. Is there any wonder that more children are seeking their biological parent or parents? Some children question their own value when they learn that

one of their biological parents donated eggs or sperm and received up to $5,000 for time and risk. A child conceived in the womb of a laboratory petri dish may have a genetic mother, a gestational mother or a social mother. With cloning we must ask who is the mother and who is the father in this pathogenically replicated human.

The human is more than 100,000 genes along 1.8 meters of DNA per cell. Isn't our identity much more than our genetic configuration? The question of identity reminds us that our human identity, who we are is a function of who we are, comes from the Creator, God, and not from our genes. We are created not to create our mere image.

What God has been doing human genetic twinning for thousands of years. This is God's creative method of cloning. He remains in control even though we seek the Holy Grail of immortality and human control in this cultic society of progress. The historicity of various individuals and cultures who have tried to regulate the world and people is replete with failure.

Left to our own vices we do fail yet we keep climbing the Mt. Everest of human perfectibility and immortality. Myself as a scientist I know that science is not evil as some people perceive it to be. But only those certainly who seek to abuse and misuse its benefits for their own goal. Therefore, the issue of cloning it seems to me is an issue of hubris. Unlike God, humans cannot regenerate something from nothing.

Only human arrogance and self pride would seek to clone itself even when used sparingly to aid infertile couples. Once the one

lone clone is let out of the clone mobile our depraved nature will seek to make the rare routine. The only improvement beyond the clone would be the improved clone. Is this human progress? No. The cloned individual is the end of progress. If the world is a mirror of itself what progress lies ahead other than to replicate itself.

This hubris of unregenerate humanity is born out in the biblical count of the true story of the Tower of Babel. Here men and women wanted to make a name for themselves, reputation was their aim. This Tower and City was so puny in the sight of the Triune God that he had to go down to His created earth to see what this city and tower was like. The hubris and decadence were foiled by the God who was their creator. Their failure demonstrates the myth of human power that fuels this cultic society of progress.

Human power within this society of progress has shifted the procreated paradigm to the reproductive paradigm to the replicative paradigm of human generation. Rather than looking to ourselves for the answers to the perplexing issues of human cloning we need to look at the community we live and serve in seeking to care and not to create, seeking to correct and not to clone.

Oliver O'Donovan on sex as artifice and its awesome power wrote in his book entitled Begotten or Made?, "If it occurs, that mankind does have the awesome technical power to exchange the humanity which God has given him for something else, to treat natural humanity itself as a raw material for constructing a form of life that is not natural humanity but is an artificial development out of humanity. The sheer difficulty of comprehending the staggering power which man

can deploy may make us incline to minimize the significance of this, as of any other, technical innovation, projected or realized. The great intellectual challenge that faces our age in view of these innovations is not to understand that this or that may or may not be done but to understand what it is that would be done if it were to be done." So says Oliver O'Donovan.

DR. SHAPIRO: Excuse me. Are your remarks nearly through?

DR. WEISE: Yes.

DR. SHAPIRO: Thank you.

DR. WEISE: The Lutheran Church, Missouri Synod supports medical and scientific technological advances to be sure that are in the service of the Word of God. While the Lutheran Church, Missouri Synod has not yet gone on record regarding an official position on human cloning, our Scriptural and Confessional teachings on the value of human life, its creation, redemption and sanctification would neither support nor condone any form or use of human cloning technology even if it were used sparingly. We believe that the children are a gift from God. They are not a right to be created or replicated as a means to an end regardless of the motive. We do not form ourselves, He the Creator forms us and gives us life.

Thank you, Mr. Chairman.

DR. SHAPIRO: Thank you very much. Thank you very much for being here.

Any questions from members of the commission?

(No response.)

DR. SHAPIRO: Thank you very much. We appreciate your time and effort.

I think at this time Michelle Theiman (?), if I pronounced that correctly, of AAAS wants to make a very brief announcement regarding an activity which might be of interest to either the members of the commission or others interested in this topic -- this area. Excuse me.

DR. THEIMAN: Michelle Theiman.

DR. SHAPIRO: I am sorry.

MICHELLE THEIMAN

DR. THEIMAN: That is okay. From AAAS. And we just want to announce that on Thursday, May 15th, the American Association for the Advancement of Science will be holding a forum on cloning open to anybody interested in the issues of cloning. It will consist of three parts. The parts will be a scientific rundown of basically what is going on. Also a portion on scientific responsibility and freedom. The third portion will be theological issues surrounding the cloning.

It is at the Museum for Women in the Arts, which is at 1215 New York Avenue, Northwest, downtown, and it is from 9:00 in the morning until 3:00 in the afternoon.

Thank you very much.

DR. SHAPIRO: Thank you.

Is there anyone in the audience who would like to address the commission at this time?

(No response.)

DR. SHAPIRO: Thank you very much. Is there any business any commissioner would like to raise at this time?

(No response.)

DR. SHAPIRO: In that case we are adjourned until tomorrow morning. Thank you all very much.

(Whereupon, the proceedings were adjourned at 4:57 p.m.)

* * * * *

234
234

1