3rd Meeting

National Bioethics Advisory Commission

Genetics Subcommittee

December 13, 1996
7:30 a.m.

National Institutes of Health
9000 Rockville Pike
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Bethesda, Maryland

I N D E X

P R O C E E D I N G S

OPENING REMARKS AND DISCUSSION BY SUBCOMMITTEE MEMBERS

DR. MURRAY: If I could ask everyone to be seated, we would like to start. Let's start with introductions in a moment and would also quickly say who they are and where they are from.

I am Thomas Murray, director, Center for Biomedical Ethics at Case Western Reserve University in Cleveland, Ohio, and a member of the Commission, and a chair of this session.

MR. DOMMEL: I am Bill Dommel, acting executive director of the Commission.

DR. LEVINSON: Rachel Levinson. I am the assistant director for life sciences at the Office of Science and Technology -- (inaudible).

DR. MIIKE: Larry Miike, director of State Department of Health in Hawaii.

MS. KRAMER: I am Bette Kramer. I am president of Richmond Bioethics Consortium in Richmond, Virginia.

DR. LO: Bernard Lo, University of California, San Francisco.

DR. GREIDER: Carol Greider, Cold Spring Harbor Laboratory in New York.

MR. HOLTZMAN: Steven Holtzman, Millenium Pharmaceuticals, Cambridge, Massachusetts.

DR. COX: David Cox -- (inaudible).

DR. EMANUEL: Ezekiel Emanuel, Dana Farber Cancer Institute, Harvard Medical School.

MS: : (Inaudible.)

MS. : (Inaudible.)

MS. : (Inaudible.)

MR. : Keith -- (inaudible) -- Journal of NIH Research.

MS. RICE: Good morning. I am Pat Rice. I am the communications director for the Commission.

MS. POLLIN: Susan Pollin -- Kennedy Institute for Ethics from Georgetown University.

MR. : (Inaudible) -- program administrator for -- -

MR. CASTLE: Joe Castle from PRI.

MS. : (Inaudible) from PRI.

MS. : Diane -- (inaudible) from PRI.

MR. GASPARIS: George Gasparis from OPRR.

DR. THOMAS: Matthew Thomas, National Center for Human Genome Research.

MR. ELLIS: I am Perry Ellis -- (inaudible).

MS. FEINSTEIN: I am Emily Feinstein. I am the Human Subjects Subcommittee of the RAC.

MR. : Tom (?), OPRR.

MR. : Don S. (?), American Health Information Data (?) Association.

MS. : (Inaudible) -- executive officer, American Society for -- (inaudible).

DR. SOBEL: Mark Sobel, National Cancer Institute.

MS. : Suzanne (?), Biotechnology Industry Organization.

MR. : (Inaudible.)

MS. : I am Terry Alberts -- (inaudible).

MR. : John Fanning (?) -- (inaudible).

MR. : Joel Mengle (?) -- (inaudible).

MR. : (Inaudible) -- Urology Institute.

MS. : Barbara -- (inaudible).

DR. MURRAY: Thank you all. Chairs are being brought in. We hope we will have enough seats for visitors. If not, there is a possible of moving the room. I want to make two quick announcements and then get down to work. One is that if anyone wishes to make a presentation in the public portion of the program, which is currently scheduled at 3:00 p.m., please let Patricia Norris know -- Pat is right here -- and she will handle scheduling for that part of the program.

The second is to clear up the mystery, which when I clear it up may still be a mystery to you. That is: Why are we starting at 7:30 in the morning. And the answer is because the members of this subcommittee who are coming in from the West Coast wanted to start at 7:30 in the morning.

That is why I said I am clearing it up, but it may not clear it up. Because, to them -- I don't want to rub it in -- but to their biological clocks, it is 4:30 in the morning.

DR. MIIKE: 2:30.

(Laughter.)

DR. MURRAY: Not even on the West Coast. Right. So that is the explanation, and we will try to close promptly at 3:30. Thank you very much.

DR. LO: We from the West Coast greatly appreciate starting early and finishing early.

DR. COX: It is a first, Tom. It is a first that anybody ever paid attention.

DR. MURRAY: We will try not to do it again. Delighted to see you all here. We are going to -- we have not a lot of time to cover a good deal of ground. I just want to say a couple of words about what I hope we will do today and then ask subcommittee members of the Commission for their thoughts about this.

We need to sort of set our goals for the day. My goal for the day is to get significant clarity on the issues of what will be on our agenda for the next N years. We know we have something less than one year of life under our current Executive Order. We are hopeful it will be extended, but we also want to have a product as quickly as possible.

So I hope out of this meeting will come at least one relatively intense short-term project that we can bring to fruition before our mandate runs out. We should also lay out a plan of work for subsequent years, potentially for subsequent years, in the hope and expectation that we will be here, but not the guarantee.

We may or may not be able to get all of that done today. I would hope that we could get at least number one on the agenda done,

that is, decide the immediate first thing that we will tackle.

It may be that we will have to do follow-up. It may take another meeting. It may be at the January meeting of the full Commission that we will flesh out our agenda more fully, but that is the goal.

The goal isn't to substantively exhaust these issues, but rather to decide for ourselves what things we shall take on as a subcommittee and as a Commission. Now, can I invite other Commission members to say what you think about that as a proposal?

DR. EMANUEL: It is correct.

DR. MURRAY: Okay. Then there is no reason to delay, is there? Why don't we begin talking about tissue samples for DNA analysis.

DR. EMANUEL: I have a question actually. We have four items on the agenda. They are presumably not exhaustive of all the potential genetic items, and I have at least a few which I think may be relevant. And I don't know if other people want to do that.

One which we haven't on here is the commercialization of diagnostic genetic tests, which some members of the Commission are working on, but it seems to me absolutely an urgent public matter, which NBAC could make a comment on.

DR. MURRAY: Can you say what context?

DR. EMANUEL: Well, the issue of -- BRCA-1 gets developed -- and the question of when and under what conditions it should be a commercial genetic test available to people.

The members, as I understand it -- I am not an expert in the area -- but the members of the Human Genome Project have a certain view, and the Administration a certain view, about how quickly those tests should be commercialized, people should be able to get them, under what conditions. Commercial biotechnology firms have a different view.

And it seems to me this is an area of controversy, an area that we could lend our view on, especially as we represent some members of the biotechnology industry, genetic scientists, as well as bioethicists. So that is one area.

Another area is group vulnerabilities. I mean, at our opening meeting for NBAC, we -- I talked about the issue of community, and it seems to me that one of the issues that arises in genetics uniquely, well, maybe not uniquely -- I don't want to stretch things -- but, strongly, is the whole issue of group vulnerabilities.

And at least one other thing I -- and I don't know how relevant this last one is -- is the distinction between disease and illness as it applies in genetics and its relevance for coverage by insurance companies.

Because it seems to me that understanding when a genetic defect or a defect is a disease versus simply a variation in the normal may have very significant consequence for insurance coverage in the future. I don't know.

DR. MURRAY: Is that between disease and normal, or is it the distinction between disease or illness and genetic mutation?

DR. EMANUEL: Maybe both. I am not clear -- again, this is -- I am not educated in the area, and I raise issues that occur to me in the context of actually thinking about coverage and what insurance companies or managed care organizations may or may not cover. And whether we could helpful in clarifying that and providing some standard that might be met.

But it seemed to me those are at least three items that did not quite get into our purview here, and I would at least personally not want to be restricted in setting the agenda toward the future. I don't think any of those except maybe diagnostics could be done intensely and shortly. But a bigger agenda setting.

DR. MURRAY: Comments on those?

DR. MIIKE: It seems to me that the last one does get covered under the rubric of genetic discrimination. There is a lot of discussion in that area about discriminating in terms of health insurance versus life insurance, etc.

The second one about group vulnerabilities is a common issue with the other subcommittee that is going on about human experimentation in general and as it applies to different types of groups.

The first one, it seems to me, that, right now, is actually going on in the home testing of HIV kits. It seems to me it raises about the same kind of issues about when government says certain things should not be available, you know, the whole issue around whether the state is -- that is the proper way for the state -- (inaudible). Anyway, those are my off-the-cuff comments.

DR. MURRAY: Bernie.

DR. LO: Well, just to continue, I think this is very fruitful to make sure we have not left out something that will we will regret leaving off in six months or a year.

To turn to your first issue, Zeke, in terms of commercialization, I think that is a tremendously important issue. Why don't you reframe it a little bit? It is not so much the commercialization as the clinical availability of diagnostic tests.

Is that what we are finding is that labs are doing this without going ahead and getting any FDA approval. The real issue is: At what point should the BRCA test be recommended by clinicians, and should that be something that professional groups have a say in?

Or should it be available on demand really, because of patients who say, we are informed consumers? We want the information. Let us work out the risks and benefits for ourselves.

DR. MURRAY: I will ask Commission members. I am getting this movement from members around the periphery here. If we could try to speak up, I know -- I believe it will be appreciated. Just ask you to try to speak a little louder. Bernie, you may not have been finished, were you?

DR. LO: Pretty much.

DR. MURRAY: David and then Bette.

DR. COX: Yes. One is a sort of point of information concerning item number one, and that is, that there is this ongoing Genetics Testing Task Force now, which is scheduled to complete its -- it

is an NIH-based task force, in HHS -- and it is scheduled to complete its work in March.

There are already interim principles written. In fact, that is one thing that we might be able to get as material for reading here.

What is happening out of that task force is a really extension discussion of these points, and although the task force hasn't completed its work, one of the key things that is coming out of it, though, is that there is no underpinning in the context of privacy or discrimination.

So that that task force is making recommendations and sort of laying out the groundwork for all of this. But it is, in many ways, punting these other issues which are really a key foundation.

So my personal view is that we should look at what they have done and said, but there is already a lot of work going on that. And then how we build on that and make our statement. Then I think we have to start that one from scratch.

The other issue, though, that is not on this and, I think, is really important for any of these discussions is: Is genetic information really different from other types of medical information? It is really, I think, make a big difference in terms of how we decide things, and there is not a consensus on that point, I would venture to say.

DR. MURRAY: Bette.

MS. KRAMER: I am glad you raised that first one, and incorporated in that, I would like to see us take a look at the question of the adequacy of information that is held by beginning with health care professionals as they interpret for the public the meaning of the genetic

tests and their significance for their lives. Because I think that is an area of tremendous need as well.

DR. MURRAY: Steve.

MR. HOLTZMAN: I think the commercialization of, or the providing of, genetic tests, as well as the patenting issue on here, at least brings to mind to me what is the question of the purview of our charge as a bioethics commission.

So that, for example, the task force, they would recommend, gets into much discussion of the fact that testing with home brews is regulated by HCFA versus products are regulated by FDA. Are we in the process here of talking about -- is our charge to talk about regulatory mechanisms, choosing between different agencies, or are we charged with looking at the bioethical issues that may be involved in these issues?

That is sometimes a hard line to draw, because we are not simply a theoretical body. What we do has impact for public policy. But I think we need to sometimes try to piece apart -- or at least I would like a better understanding of what is our purview.

DR. MIIKE: Just sort of in response to that. That was an issue that I was going to want to discuss when we talk with the lawyer from Michigan, I believe.

Because when we get into the -- it is a good question -- because I don't think a group such as this has a very distinct and well-defined expertise area. I think I already raised that when we talked about what should we get into. Because we are heavily oriented toward

genetics in the overall panel make-up.

I think it is inevitable that a lot of stuff that we get into get into public policy, get into even legal issues. I want to talk about that.

I want to get into the patenting area in terms of what might be helpful in the context of accepted legal principles and how might we be providing advice in that area. And then separating that from how might we affect legal principles by what we can bring to the discussion over here? So I think -- we are never going to answer that question, Steve.

MR. HOLTZMAN: Okay.

DR. LO: Again to go back to Steve's point, one way to look at that is maybe one of the things we should do is step back a little back from kind of the often very technical discussions about regulations and who has jurisdiction to say:

What are the underlying ethical issues and what are the implications from an ethical perspective of having it regulated versus non-regulated and then regulated by whom?

DR. EMANUEL: Absolutely. That is, I think -- absolutely. It would seem to me if we could establish the ideal, and you know, it may not be able to be realized in regulation, but we should get into who has got jurisdiction.

We should get into what would be the optimal arrangement in our view, or at least a range of optimal arrangements. And then it may or may not be implemented properly. But we can stick to the high ground, I think.

DR. MURRAY: We hope there are a few more seats. We will try to get more chairs in this room.

Can I speak to the issue of -- David mentioned this and others -- is genetic information sometimes different from other things? You know, this is one of the things I have been thinking and writing about recently.

I guess I am satisfied that it is so deeply ingrained in both the genetic discrimination question and the genetic privacy question that we can't possibly avoid grappling with it, even if we don't pull it out as a separate heading.

But if we fail to pull it out, then I would say, you are right. We ought to do it. Go ahead and treat it on its own. So I think we will get to that, I hope.

MR. HOLTZMAN: It is deeply ingrained in patenting issues also.

DR. MURRAY: Okay.

DR. COX: I just hope we can do it sooner rather later on those, because it will make a big different in how we address ---

DR. MURRAY: I agree. I should mention where the four items on the agenda came from. They came out of efforts by several of us to sort of abstract from the first meeting of NBAC what seemed to be themes that were significant and recurring, to give them a label, even if the labels might be a little crude at this point.

I mean, at least one of the people we have invited us to help us in our deliberations today will argue that you can't really pull apart

discrimination and privacy. So we should hear that, I think, and decide whether we agree.

Clearly, this set of four issues on today's agenda is not intended to be the full and exclusive set of all things that NBAC will deal with in the area of genetics. It was more of a launching pad for us, for our conversations today.

Any other comments about items that ought to be on, potentially on the agenda, for the Commission. Yes.

DR. PITLICK: I want some clarification in your discussions about whether you feel you are talking about germ line genetics or semantics of genetics or both and whether you are talking about DNA specifically or -- (inaudible) ---

-- very confusing when we talk about whether families are involved or not involved. It depends on what the genetic mutation is. I think some clarity about what kinds of genetic mutations you are talking about might be helpful at various points in the discussion.

DR. MURRAY: Any response? My sense is we are likely to be talking about all of those things, and I trust that the members of this subcommittee are familiar enough with those distinctions that they would either implicitly or explicitly try to make it clear what they are talking about.

DR. COX: I have a comment about that, because that is exactly, okay, this issue about whether genetic information is special or not.

If you conclude that genetic information and medical

information in general, okay, are -- there may be specific things about genetics, but not enough to make it a really distinct class, then I think dissecting genetics even further becomes a moot point.

TISSUE SAMPLES FOR DNA ANALYSIS

DR. MURRAY: Are we ready to turn to a conversation about tissue samples for DNA analysis? We didn't -- this is different from the other three topics. We haven't asked someone to kick this off for us. I don't know if that was a good idea or a bad idea.

I know that the subcommittee members had expressed a desire to have as much time as possible for their own conversation. My judgment was that we didn't need somebody to jump start us on this one.

That the literature was compact enough that we could read it for ourselves, and there are enough people around the table who had some first-hand knowledge about these kinds of issues that we would just do it on our own. So we are ready to begin. What do you think about the issue of tissue samples for DNA analysis as an agenda item for NBAC?

DR. COX: As we saw in our briefing book, there has really been a lot, okay, written about this, not only very recently, but over the past 10 years. There is -- I would like to just sort of start by a structural formulation.

There seems that there are a lot of general issues that one could go at to discuss this very broadly and then some specific issues that one could get at in terms of immediate problems. I think both are

important, but I see this as one area where we could have an immediate short-term focus on a specific. I would just lay that out, okay, for discussion.

Right now, because it is the general discussion, we are faced with a lot of samples that are caught sort of purgatory, samples may be anonymous, may be partially anonymous, may not be anonymous. You may be able to link them.

But it is not possible to go back and find out if the people were ever approached about they felt about doing research on the samples or not. A large series of samples in purgatory.

But it is a separate issue from ongoing collections of samples from this point on. What do we do about the samples in purgatory? My reading of a lot of these discussions is that that is an immediate issue that needs to get resolved, and there are very different feelings about it.

If we could make some statement, not that we are wiser or smarter than anybody else, but consider that issue, I think it would really help a lot. Because that is a very pregnant issue, it seems to me.

DR. MURRAY: Okay.

MR. HOLTZMAN: I also think that this is an important one and maybe the first one we should jump on. I am less sanguine than you are that we are going to be to make this break between retrospective samples versus prospective.

Because if the paradigm for the prospective is collected in the context of a research experiment with informed consent, I agree.

But there is a practice of medicine out there, and there are people who could speak to this better than I here, pathologists collecting samples.

And the prospect of thinking about those samples being collected with full, informed consent for every possible research study that could possibly be done, where there is a tradition that those samples have a different status. Effectively, they are the retrospective samples waiting to happen prospectively.

DR. COX: I didn't mean to imply, Steve, that we could make a break between those, because I think that they are intimately intertwined. But it is just focusing on that one end first.

Because if we focus on the prospective -- it is just a matter of emphasis to start with. Not trying to separate them, but we will have to bring the other one in. But just trying to focus on what we are really trying in the short term to make a statement about.

DR. EMANUEL: I think more than anything I have been asked by people who are either in the research community at my institution, because I sit on the IRB and have seen protocols related to this, and a variety of other people who aren't related in the research area that they think this is, and I would concur with both what David and Steve said, one of those areas where there has been a lot of sort of background work, an area where we could have an immediate impact within a year, and where we could produce, I think, an intelligible, intelligent report that might go some distance to providing a consensus on this.

So I would agree with the sentiment that this very well probably should be our first one, because it is doable and can have an impact.

I would, however, raise the general issue that while it has strong implications for the public, I think it is very much a research community issue. I think we have to be sensitive to that ---

DR. COX: I agree.

DR. EMANUEL: -- the impression we communicate. It would, I think, be unfortunate if we were seen as, you know, tackling this, because, you know, it would be good for them without being aware of whatever would be our next priority or putting it in a broader context.

A quick fix solution for them would be, I think, a very bad message to send.

DR. COX: Exactly.

DR. EMANUEL: But, nevertheless, I do think that for important reasons, this is a very important topic that we can act -- is manageable for us.

DR. MURRAY: You have articulated very well, Zeke, many of the things that I have thought about this.

DR. LO: Let me just try and build upon what the other three have said. I mean, I think Zeke is starting to lay out for us criteria by which we decide which of these potential topics should sort of rise to the top of our agenda.

In addition to what Zeke was saying, the implicit -- and what Dave and Steve were saying -- this is a topic that needs to be addressed

now, because things are happening, and there is a lot of controversy. If it goes the wrong way, there could be problems.

It seems to me, Zeke, the way to sort of address your final point about this being sort of a researcher's question rather than a public question is to tie it very tightly to the other issues on the agenda.

One, is genetic analysis of tissue samples different from any other type of analysis? Electron microscopy, you know, antibody probes or whatever. And, secondly, does making it anonymous take away all the issues that have been raised in terms of some people say, I just don't want my tissue being used in that way even though they have signed some generic consent form.

So I think the way to, Zeke, address your concern is to really highlight the public concerns, which are often very poorly articulated, but it really has something to do with the perception that genetics is different.

And I don't mind their studying it if it is clinically related to my disease or that if it was something kind of basic science that is not going to affect their own perception of who they are.

MS. KRAMER: Now, I think, as I read this issue, as I read this material, I couldn't help but think that from a public perspective, a lot of it turns really on the issue of discrimination.

I keep feeling as though if we could fix discrimination, which is where I think we ought to start, if we can fix discrimination, then a lot of the concerns related to the tissues disappear, or they fall in place.

DR. MURRAY: Discrimination, you mean, just in terms of

genetics or discrimination, more broadly.

MS. KRAMER: No, discrimination in terms of -- no, I am sorry, you know, in terms of genetic information.

DR. MURRAY: Because one of the fears, and Bernie, I think, one of the fears that has been expressed is that some people may wish not to have their genetic material used for research on a certain subject.

MS. KRAMER: Right.

DR. MURRAY: Doesn't because people might then try to link it to, in some negative way, to some group of which they are a member. And that would be whether it was -- you could have something sort of full anonymity. You would need some kind of ---

MS. KRAMER: But I think that, ultimately, that turns on the possibility for stigmatization and discrimination. I mean, why else, you know, why else would they be concerned about its impact on the group?

DR. LO: But this is sort of -- I think there are other concerns that are independent of discrimination. There are some people who believe it is wrong in some symbolic moral sense to be monkeying with the blueprint for life, and their concerns are not that they will be discriminated against as individuals or their group will be discriminated against.

But somehow this is beyond the bounds of what they want to see happen, and they don't want to have their tissue contribute to studies of which they have symbolic disagreements.

And I think, you know, to go back to Zeke's point, a lot of the comments I get are: Are you going to address the sorts of concerns

that, for instance, lead people to be very concerned about genetic engineering of foods, where, you know, it is not a discrimination issue. It is a sense that somehow it is not natural. It is tinkering with things that human beings shouldn't be tinkering with. I think that is a level of concern that I think we ought to try and address.

DR. COX: I really agree with you. But in order to talk about discrimination, and I would actually, you know, pick privacy first, because if you can make things private, then it is harder for people to discriminate. Right?

But there are bigger issues, okay, I mean, hard to have be our immediate focus, but if we could have something immediately that we are discussing, then I think we are going to have a specific example to discuss things about discrimination and privacy that will allow us to branch out and get better insight into how to grapple with those.

But I think, at least in my view, there is no question that if we could take care of both of those, then, you know, the specifics for each of these different things, but almost everything goes away.

DR. EMANUEL: When Bernie had said "criteria," I wasn't sure we should rush into that area, criteria for trying to decide what we should do, or whether we should talk more substantively about this topic.

But I had, at one point, drawn up before we actually had our first meeting, some criteria, and I thought that I might just mention them to see whether people think they are useful in deciding the priorities, etc.

One is what we said, many people have said, is the issue of urgency in the public domain. Is it an urgent topic that really needs attention? And I think that any of these satisfy that.

Is it solvable in some deep sense? Can we actually push the discussion in society forward, because we think we might be able to come to a consensus. It might be the pregnant time.

And here I just would mention to my fellow commissioners that if you remember the evaluation of the previous commissions, those that worked happened to have that wonderful time like the President's commission on the issue of terminating care, where it was ready to solved, and they were helpful in solving things.

Then I would suggest the issue of the breadth of the constituency might be a relevant item. How big or small? Does it affect the whole public? Does it affect really mainly researchers, policymakers, companies, etc.? Maybe internationally.

And it seems to me that priorities should be given to those broader topics. Although for various reasons, small topics may be important -- I mean, topics that affect a small constituency may be important.

The fourth criteria is its educational value. Part of our function, it seems to me, is that we can actually educate the public or provide documents that can be used. Again, I have been impressed over my career, when I have gone back to previous commissions, and read. I have learned a lot, and I think other people -- and the public has learned a lot from them.

Fifth would be this issue that Bernie just raised of social meaning. Can we help clarify what social meanings there are? This is, I think -- there is always this tension between solvability and getting into the big metaphysical, whatever, questions.

As I said at that first meeting, I think if we avoid those for the solvability, we are going to not touch a lot of people's -- and probably miss a wonderful opportunity.

And, six, is finally the issue of focus. Can we get the problem focused enough to actually write a report? And I think this focus issue is, certainly, for the first one, where there is, I think, as Tom correctly pointed out, pressure to get something done concretely before our initial stopwatch ends -- may be more important for the first issue.

For the other agenda items, on the great hope that we might last years, these are bigger issues, and my own sort of reading here is that privacy and discrimination are very big issues, and you can't do them in six, nine, ten months.

That doesn't mean we shouldn't do them, but I think it means that we should put them on a reasonable time scale; whereas, I have the feeling that this tissue samples one is, at least from my reading of the literature and talking with people, is something that can be on that kind of time line.

Anyway, those are, you know, crude criteria. But people may -- it may be helpful and added and subtracted from.

DR. MURRAY: I only disagree with you that you call them "crude." I think they are subtle and useful.

DR. MIIKE: The last point that you raised, I am sure I agree. That the larger issues are not addressable in a shorter time frame. What impresses me about any of these issues is the amount of information and study that has been -- even at that international meeting that we had.

So it seems to me it is more a caution of: Can we contribute any original thinking to this field? Or is our main charge to take a look across and say in our collective wisdom which way we tend to go or not?

So I would say that it is more a question of how many issues that we try to deal with within a particular time frame rather than the complexity of any particular issue. I think we can do any of these in the time frame that we have.

MR. HOLTZMAN: I also think we need to think about what it means for something to be solvable. So, for example, among the hand-outs the purple book, which was
-- that Tom chaired that commission.

In one sense, it is solved. The solution is proposed. But the solution proposed says, you have got to have health care for everyone. Otherwise the issue doesn't go away. So, obviously, we haven't quite solved that first part.

DR. MURRAY: I know the answer. We just -- (inaudible) ---

DR. EMANUEL In a perfect justice world.

MR. HOLTZMAN: But that tells us something. That starts to go to notions of educational function. Because what keeps coming

out here is the interweaving of all of these ideas. Even if stigmatization and discrimination isn't the whole of the issue, it certainly plays into the issue.

And so that I think that is what I found very important in this book, for example, that in trying to take on one of the issues is the elucidation and the connections.

DR. LO: I want to sort of shift a little and go back to our topic of tissue samples. I just raise the question: Do we know what the public, what patients, whose tissue is stored, how they feel about this issue? And would it be useful to either try and gather that data from existing studies or to commission a study to look at that?

And, again, it goes back to Zeke's point that in some sense, it is a researcher's issue, but somebody, some person, donated that tissue sample or yielded that tissue sample, and how do they and their families feel about these issues? Do we have funding, do we have a means for commissioning empirical studies on a timely, but rigorous basis?

MR. DOMMEL: We may. We are optimistic about that, but that is still under negotiation. So I think that by early January, we will have a better idea. But I suspect we will. It is just how much money. But we will have some.

DR. COX: I think that is -- in combination with what Larry just said, I think this is a very interesting point. I have been struck -- you can just look -- it is documented. Of all the writings, it is very clear what the stakeholders think. It is not very clear what the public thinks.

If we are here representing the public, then in terms of bringing new information -- which is what you said -- can we bring new information to what is going on? I think that is an area of missing information.

DR. MURRAY: I think it has two different components, Bernie. I, too, was struck by how many of the physician papers we have read on this, they presume certain things about public reaction, public feeling, public sentiment, but I didn't see any data on any of that.

It is two ways. One is if you were to do a kind of survey, which would give you -- it is like measuring the average depth of a lake, right -- might be three feet

-- a survey will give you that, and that is useful information.

But there might be some places in the lake, there might be some groups of people, for whom the water is 50 feet deep, for whom it is a very serious issue, and they would be deeply offended by certain practices, while whereas the majority doesn't care one way or another.

I don't know what the case is, but I would like us to do -- look at both -- to both measure the average depth, if we will, but also to do some exploration to see if there are significant cultural or religious or ethnic differences in the U.S. about some of the crucial issues.

DR. LO: And if there are, which there almost certainly will be, how does that affect the scientific research agenda?

I mean, over and over, you cannot -- having written some of the stuff -- you know, you end up having biased samples. That is clearly the case in epidemiologic studies, where you are doing population-based

research. Is it really the case in genetic research that if you have a certain subgroup who just doesn't want their tissue studied, that that is going to undermine the research agenda?

Or are there other ways of addressing the research problems with maybe a little bit more expense and trouble and time that can respect those particular concerns and yet sort of carry out the pressing research questions? So I think it feeds back.

DR. EMANUEL: I am not an expert in this area, but again, I have sat on an IRB at the Dana Farber, where we had to exactly -- we had a stored sample collected for one reason. The question is: A new test came up, and they actually went back to some of these patients to begin looking.

And as I read the literature, there really isn't very much literature about surveying on these exact things. But there are lots of stored samples out there, and there are lots of potential ways of getting to people who have already -- who are in that predicament.

At least my recollection, and I apologize for not having the data at hand, my recollection is that actually most of the people were fine with it. I don't have percentages to report, and it was a small sample of 50 or so -- who had already contributed for a specific reason. They had already contributed their samples. They had already had a disease, were identified in some way. But I have the same sentiment you do. Although -- again, how quick and fast we could do such -- especially if we are going to adhere to Tom's caveat that, you know, that make sure you get the breadth as well as the depth in

particular areas ---

DR. MURRAY: I actually think that study could be done, in a sense, more quickly, partly -- I am thinking aloud -- do surveys of major religious, cultural, ethnic groups in the U.S. for surveys.

But you go to the sources that might already be in the literature or you go to sort of leadership in thinking about those to commission. That would be more of a paper, an analytic paper, than a big social science survey. The survey of public opinion might be more complex. David and then Steve.

DR. COX: I think we have, as a commission, a responsibility and, that is, to lay out what some of the questions and issues that the public that we are trying to get information back from may not appreciate or thought about.

See, we are a bunch of people that are probably terribly representative of the public. Right? But the advantage of that is that we have read all of this stuff, and at least we can abstract questions out of it to make sure that we get adequate responses.

It is not that we want to prejudge what people are going to respond. But we want to make sure that the turf is covered enough. That is one point.

The second point is that I think this falls very much of how this subcommittee is tied together with the subcommittee that is going to meet on Monday.

It is this whole issue of the relationship of the public and the researchers to getting information. What the relationship between the

public and the researchers are. I think that that is going to be, almost for sure, an important issue in this other subcommittee. That is at least one major tie between us.

So I would say is that before we go out and commission what the information back from the public is to basically lay out what these -- if the different stakeholders were to do this, the specific questions that they would ask from their perspective and find out what the public says about those. I mean, they may even, you know, care. But at least we know.

MR. HOLTZMAN: I think we are talking about two different kinds of studies. The one you talked about is an inquiry into what are the major religious, theological, whatever positions with respect to the relationship of a body to a person.

All right? Issues of ownership versus non-ownership. And then in the political philosophy sense, issues of obligation to one's society, to help the society, versus one's autonomy rights with respect to the sample.

I think those positions can be charted out pretty well right now and have been in some of the documentation.

With respect to the survey idea on how people feel with respect to the use of the samples, it is always hard to argue against more information, but I want to at least put in a caution about methodology.

If I go out with a supposition that genetic testing is very special and frame the question in terms of genetic destiny, such that do

you want your sample -- would you like to know that this was being done to your sample, I can get one answer. If I can come -- with a different answer and a concept about medical information, etc.

DR. COX: That is what I meant about --

DR. MURRAY: They are two different, very different kinds of inquiries. I tried to say that. I am not sure that we have all the information about the tissue.

Most of what we have, at least the stuff that I am familiar with about religious and cultural ideas about the human body and its moral significance, was in the context of such things as disposition of dead bodies and body parts. The law was at least developed on -- and then about organs and organ transplantation.

One of the angles about organ and tissue transplantation is that it is life-saving, and that turns out to be a front part for many people. The use of tissue for research is not life-saving in a straightforward and direct manner, even though those of us who believe in research think that it is -- (inaudible).

MR. HOLTZMAN: I am sorry. What I think about the basic issues haven't changed since Aristotle ---

DR. MURRAY: You were trained -- Bernie, did you want to ---

MS. KRAMER: No, go ahead.

DR. LO: Let me just sort of throw out an example of where I think empirical data is helped on a related topic.

A number of years ago, there was a lot of controversy over neonatal -- prenatal screening, neonatal screening, and should it be by

consent? All this should be routine with a kind of objection right on the part of the mother.

Tony Hultzman (?) did a study where in the context of a new Maryland law that was supposed to implement specific informed consent asking mothers that would be the subjects of testing, did they want complete informed consent disclosure?

Or would they want, you know, much more superficial, routine, and to sort of consent to be told the test would be done, he found that many of the women preferred a much more abbreviated notion of consent and were willing to accept routine consent, again, in the context of a clinical situation, where there are presumably some benefit to their offspring.

But I think it is that kind of information and it is sort of the nature of their objections -- one of the things they said is that there is a lot going on after I delivered. I don't want to sit there about all these complicated things. I just want to focus on what I need to focus on at that time..

So I think it is both getting this sort of the plebiscite, yes or no, do you approve, but also what is the nature of your sort of concerns and objections from the people who would be undergoing it.

And just a sort of change in what Dave says, I think the public are stakeholders. The people who donate tissue to these sample banks, or whatever you want to call them, are key stakeholders. I mean, we need to continually remind ourselves that it is the willingness of people to have their tissue studied and stored that is going to make this

work.

DR. COX: Absolutely.

DR. MURRAY: Bette.

MS. KRAMER: That is all right. I will pass on it.

MR. HOLTZMAN: I guess the only thing I would add there is we need -- there are, I think, representative pathologists in this room, and I think our paradigm is the collection for a study or a genetic test. The house pathologists come in to sample and will continue to come in to sample is very, very different. All right?

So I think there is a broader issue of changing the whole practice of the pathologists, which we can to keep in -- we can't lose sight of that -- because we will inadvertently make rules that make absolute -- or suggestions that make no sense potentially.

MS. KRAMER: But, Steve, their consent forms do include permission for education and most of the time for research as well.

MR. HOLTZMAN: Well, to the best of my understanding, when the pathologist has a leftover sample, for example -- we will call it a sample -- there is a different terminology that is used -- that comes out of diagnostic procedure, I don't think there is any -- someone should clarify this here -- the natures of the consent are very different if there is consent at all.

DR. LO: It is a blanket consent. You sign it whenever you have an operation. That they do with the tissue -- teaching and research purposes.

MR. HOLTZMAN: Okay.

DR. LO: A, no one reads it, and secondly, no one knows what it means. So does it mean that they can show the slide anonymously to students, or does it really mean someone will do specific types of research? So there is consent in some sense, but is it truly informed as to the nature of the ----

DR. EMANUEL: And then -- the other thing is, as you point out, over time, to the extent that we want more information about the subsequent evolution of this sample and being able to connect it with its medical record, that will be very important to the power with which the research can go forward and the conclusions it can draw. But it obviously more and more implicates people.

But I think your point, on the one hand, is well taken. We have to look at this in a broad context and not just research in the narrow context.

But the other issue of the data is going to depend upon the methodology. I am sure that everyone in this room would agree. That, you know, you can ask the question in a bad way and get exactly whatever you want, and you can ask it well.

One thing I would say, I have been impressed. Past commissions, and I would cite the President's commission's surveys on informed consent as an example, were tremendously beneficial and tremendously pioneering. They actually moved the field very far forward, it seems to me, and you know, we might do the same by really focusing good data in places where no on has collected the data, or the data that exists is extremely biased, or it is not useful.

DR. MURRAY: Putting together Bernie's earlier comments about wanting to connect this issue, which, on the face of it, might be seen as sort of narrow in its size, of great concern to the research community and to pathologists and others who collect tissues, to larger issues, I think Zeke has just helped make one of those links.

And, that is, in a real sense, this issue of tissue samples for DNA analysis goes right to the large issue of the relationship between the public and the research community, and the trust, the nature of the relationship, or trust and mutual expectations might be held.

And I think if we see it in that light, at least for me, that opens it up in a way that makes it a much more significant thing than just trying to nail down some minor disagreements about research samples.

DR. COX: Tom, I couldn't agree more. I think that is where the action is, and I would say, for myself, I mean, it is unclear to me -- I think that there is what I would, I guess, like to hope is true is that there is a new time, where the public is more interested in interfacing with the researchers in a different way. So that all of society can get more information. I may be smoking dope. So how do we find that out?

Probably it is not just a questionnaire asking people, okay, do they think it is a good idea or not? But I was really struck by our meeting in San Francisco about novel ways of getting information from the public and the Danes in particular, you know, would write a book of poems or would have a play that would allow some of these scenarios to be put forward and then have people discuss them afterwards.

So that you are not really asking the questions directly, but you are putting people in the context of where they would face these issues and see what they say. So I think that is a real opportunity, where we don't go out and sort of commission information -- this sounds sort of nuts.

DR. MURRAY: It is not even 8:30, David.

DR. COX: Right. So but, I mean, being sort of creative in terms of how we get these answers. And this comes to your point, too, because if you are not careful how you phrase the questions, you are going to get back exactly what you expected in terms of what the phraseology is.

DR. EMANUEL: Fortunately, these methodologies are not usually exclusive, and you can do both and reinforce each other.

DR. MURRAY: Should we be having the National Endowment for the Arts here?

DR. MIIKE: Let me ask. All I know about this issue is what I have read, and admittedly, I speed read nowadays. I don't read the detail.

But it seems to me that the concern in this area, especially given the short discussion we have had about public perception, comes from a research and medical community, not really from the public, and I guess they are -- and professional groups like this.

So it seems to be a mixture of worries about legal liability and those kinds of things, but also issues that go to if we have information that might be beneficial to people, what is our obligation?

And yet on the other side, if we completely erase the identity of someone, and then we find something significant, you know, what have we lost?

So if we are going to be doing -- or if we are contemplating a survey of some kind of a public, I really would suggest that we key it around whether there is a matching concern between the public has and what those who are professionally interested in this ---

DR. LO: In the interest of trying to keep us on schedule and maybe push us ahead a little bit, it seems to me that this is a topic that needs to be on our list, short list, of things to attack sooner rather than later. It seems to me that there are pieces of information I would like to sort of gather quickly. One is to start to get a sense of how feasible it would be to get information on the public perspective, which I think is really crucial.

Maybe sort of ask at a next meeting some people who are skilled at conducting both quantitative and qualitative research and maybe even sort of more -- sort of open-ended pubic discussions to sort of suggest how we might go about doing it.

There clearly are sort of research perspectives we should look at, and it seems to me the pathologists are one, but also people who are doing these large prospective studies have tissue samples or serum samples at least and have the ability to go back to people.

It seems to me we ought to sort of see what are people really thinking about doing and what are the special concerns of people who have access to certain types of data.

I think it may be -- it seems to me this is a very promising topic, but if it turns out, everyone says that there is no way you can get meaningful public input in less than two years, then we may want to revise.

So that I think that we need to sort of maybe make a short -- I know, you were sort of hoping, Tom, we could get one thing to focus on. Maybe we need to make a short list and say what are the questions we need to know about each topic before we really want to proceed is our number one agenda item.

DR. MIIKE: I just want to make one comment. If we go along the line of a survey, we turn this from a short-term project into a long-term project.

We would also not be able to address your purgatory question. Because what if the results of the survey is totally opposite of what we recommended?

DR. EMANUEL: Well, then we would have to presumably rethink what we recommend. If we find out that the public ---

DR. MIIKE: Commission changes its mind.

DR. EMANUEL: I would think -- I think that is a very relevant point.

DR. MURRAY: I would hope our conclusions -- our recommendations would reflect what we learn about ---

DR. LO: But isn't -- this is also a question. Should we be making any recommendations that give a green light to this without some sense that the public, in some profound way, doesn't disagree?

To sort of say it has to be fixed now. Let's decide whether or not we are going to do it with a lot of pressure from researchers to do it. We run the risk of saying the public doesn't count, because they weren't in their ---

DR. EMANUEL: That would -- I mean, it seems to me one of the things it might do is, first of all, it would suggest that we are missing something important in our understanding and that the public might have.

But also it might undermine the credibility of any kind of -- I mean, if we are too far out of whack, completely out of whack -- it seems to me we really do have to re-examine what we are thinking about.

DR. COX: So I would like to come -- your points are really taken, Larry, and if we look at these tissue samples in this very broad context, then we have lost it if we go out for a very big survey. But if we try and get public comment in this narrower context, then I don't think we have necessarily lost it.

I think we can still stay focused, get public comment, and be able to have a timely maybe narrow answer. But it doesn't preclude, you know, a broader answer later on.

But I really think that this is the dynamic, the dynamic of how do you go out and really get extra information and still stay focused enough in a timely way to get a product out. But those competing goals, if we keep them in mind and don't let one take over or another, then I think we can do it.

DR. LO: A number of years ago, at the beginning of the HIV

epidemic, our institutions faced this question with regard to HIV testing on stored tissue samples. There was a lot of concern about what did the epidemic look like, and what is the seroconversion rate in populations that were thought to be at low risk?

And a number of researchers came forward and said, you know, we have data banks on young people who were being studied for cardiac risk factors, people being studied for all kinds of other things. Why don't we do HIV tests on them?

And, you know, there is a sense that there is a pressing issue, it would yield interesting, important data. But, on the other hand, there was a real concern that if you donate your serum in a sense for one sort of study and then it becomes -- you know, Heart, Lung Institute study finds seroprevalence in young men, you know, at whatever percent, they are going to say, wait a minute. Is that the same study I signed up for?

I think it was important to sort of say, yes, it is a pressing question. Yes, it would be nice to be able to study, but there is a potential real down side for people's willingness to enter into these sorts of studies if they find their samples being used for something very, very different than what anybody thought of at the time the study was designed.

I think one of the concerns, it seems to me, that some people have about genetics is that it is running too fast, and it is out of control and has a momentum of its own. To the extent that we are not sensitive to those concerns, are we, each step of the way, paying enough

attention to the issues and proceeding with sort of thoughtfulness?

It reinforces concerns that this is just going to sort of snowball. I think we need to kind of balance, you know, the urgency here against concerns that it is going too fast.

It seems to me, unlike public health issues, where, you know, epidemics do get out of control if they are not studied in a timely fashion, it is hard to argue that there is a public health menace by going a little bit too slowly on some of these studies.

That, it seems to me -- it is great for us researchers and scientists and clinicians and the patients we care for. But it is not quite the same as sort of the classical infectious diseases, where you ---

DR. COX: (Inaudible.)

DR. LO: -- may have a warrant for overriding -- (inaudible).

DR. MURRAY: Bernie, what happened with the study that you were describing?

DR. LO: After a lot of debate, we decided that you should not do the study without making a real honest attempt to go back to a representative sample of the original cohort and say, this is what we are planning.

And, again, it was in the context of, at the time again, that persons at risk for HIV and persons with HIV were very much demanding to be put into the design of research projects.

We thought it would really undermine that difficult, but ultimately very beneficial, tendency to sort of make our research

subjects our partners rather than our subjects.

DR. MURRAY: I am already thinking about products, and as you were describing the story of the research to look back at HIV prevalence, I began thinking about the various studies on BRCA-1 and BRCA-2, particularly in populations of Ashkenazi Jewish women. I don't know the details, but I would imagine that some of that might have been looked at samples collected for Tay-Sachs.

DR. COX: That is exactly what they did.

DR. MURRAY: That may be -- well, it is just kind of plausible -- we may want to, in our report -- reports are -- I guess I have strong feelings about -- one thing is that our reports are public documents.

They are not to be documents written in jargon just for insiders. They are to be public documents in the best tradition in the best tradition of -- and I think some President's reports are good models in that regard.

And one also thing that makes it kind of -- in the effort to communicate the ideas you are trying to communicate are examples, and to the extent that you can offer concrete examples, that may be one, going back to the Tay-Sachs samples to look at BRCA-1 and 2.

So we should probably -- and I would argue for incorporating examples like that in -- (inaudible) -- reports. So people can see really what it means. Not just what the arguments look like abstractly. But what it means in concrete examples.

DR. LO: It seems to me that is, in a popular sense, unique -- disproportionately affected by both conditions, or at least quite possibly.

So that the people whose samples you have from prior arrangements in a now closing study might either benefit as individuals or as a group from the research. Whereas that might not be the case for many other designs.

DR. COX: But those can serve as this sort of role playing, because you can set that up in a way to put people in a situation where they have to make a decision not just by checking off a box, but by being placed in a room. It is different if they are a special group, if they can benefit like you are saying, Bernie, or if it is just sort of nothing specific to them.

DR. EMANUEL: But this is also a case where we may be getting data, I mean, where they are beginning to have surveys on exactly that population of Ashkenazi Jews that have stored or are likely to be subject to big-scale testing.

I know that a lot of organizations are beginning that survey. I actually am participating in one in Boston of the community there. So we may actually have an opportunity to actually use the example but also have some real data to provide in a short order.

MR. HOLTZMAN: I guess, Bernie, when you said the rush to judgment -- it is hard to argue -- we should never rush to judgment, but as you tell stuff like -- stories like the HIV story, and you look at the literature, my sense is the issues have been all very fairly clearly articulated.

We may be lacking this piece of how the public feels. But the issues have really been played out in many different contexts. They

are not all the same. Part of what we elucidate are differences.

So that I am not sure it is an issue of rushing to judgment, and one of criteria perhaps in doability is to go and look at what is there and ask the question, not is there unanimity or even necessarily consensus, but have the salient issues been framed so that all of the participants really had their arms about -- there is agreement at least that these are the issues.

There is a fair degree of consensus of a number of points and that with respect to the remaining differences, at least there is clear disagreement, and we are no longer dealing with an irrational disagreement.

My sense of looking at all of the different statements about tissues, be it ANIS, (?) be it the pathologists, be it the geneticists, there is not a lot of -- the debate is there. The terms are agreed to.

We may be arguing now about what is the right thing to do with anonymized versus anonymous versus identified versus identifiable. All right? But that, to me, starts to smell like something where you can come to a conclusion.

DR. LO: Yes, I think you are right. There has been a lot of work to do to sort of raise issues, list issues, and I guess the concern I am trying to articulate is that there is an important voice missing, namely, the public's voice.

Someone said, you know, all the articles are written by academics and researchers, and I think it is really important that we make a special effort to say part of that discussion has to be people who

so far have not been as prominent, at least in our briefing brook, and that we may be a way to make a special effort to bring them into the discussion to try and find out what they are saying. Because they may not be able to make it to our briefing book by publishing articles in Science or whatever.

And if that is symbolic of sort of the way we want this whole discussion about genetics to be working to sort of automatically -- I mean, again, I use the HIV analogy.

Now, it is axiomatic that if you are going to design a clinical study in HIV, one of the first things you do is you go to the community of people who are affected, who may be participants in your study, and you say, this is what we are thinking. What do you think? Sometimes, they say, great idea. Sometimes, they say, way off the mark.

But it is sort of part of the process, just as you get a statistician or questionnaire made to be part of your team. If we can sort of push that, that may be helpful.

DR. MURRAY: I think, Bernie, I agree absolutely with that sentiment and also with the assertion that we need much more, much richer, fuller, deeper notions of what public sentiment is about this issue.

I do think at least a few of the people involved in some of these papers are, in fact, representatives of the public or disease groups. So I wouldn't say that there have been none, but we want much, much more than we have got available.

DR. LO: Exactly.

DR. EMANUEL: At the risk of trying to short-circuit things, I mean, it seems to me that part of the discussion, all of the discussion, as I have heard it, says that this is an important topic. This is something we should address, and the real disagreement is more substantive about how much of this we want to add and how much of that we want to add.

At least from the narrow point of trying to figure out is this or is this not on the agenda and how urgent or how high to the top, as it were, should it go, it seems to me we do have, at least I heard -- I will gladly be corrected -- some agreement that this is both an important topic and fairly high, for a variety of reasons, on the agenda.

Whether it is number one and the one we attack first, I think, probably will depend -- until we get to the end of the day and hear what everyone else has to say, what the other topics are.

But that is at least what I hear, and I do hear some sentiment for trying to get the public's view exactly, whether it is exclusively survey/survey and these other mechanisms, and whether that can be done either because of finances or time, I think, is probably the resolved questions, which we are not going to know until, you know, probably our next full panel meeting anyway.

DR. MURRAY: But if we resolve something strongly that we think this new -- this must be done, then I -- we will tell Bill that. We will tell Harold that, and we will go and tell anybody who needs to know that we think this is a priority and that we ought to go for it. Carol.

DR. GREIDER: I would just like to add to that that I agree that it would be nice to sort of get through to the end of the list of things

before we decide on the priority. Because it is nice to have this kind of discussion to really articulate what the issues are, and then after we have dealt with all of them, we can determine more what the priorities are.

DR. MURRAY: Larry.

DR. MIIKE: Just want to -- my closing comments on this area is that you started off by saying we should take a look at -- there is an addressable issue, which is the purgatory tissues.

I would agree with that in the sense that as part of that resolution, we are also really clear about what are our recommendations -- I mean, if we are going to have recommendations or whatever -- what our implications are for the forward part of that.

And also, I think, what will come out of that, which are areas in which we need more public information about before we can make decisions, as well as the question which we haven't addressed except implicitly, about what part of the public we are talking about.

I mean, clearly, you can do general opinion type of polls, but in many of these areas, I think it is a much more focused public ---

DR. COX: Actually, I just want to come back to something you said, because it really rings true for me. The issues are out there, but in terms of getting this information from the public, it is not just to get sort of get one more piece of information.

For me, it is making sure that the discussion is framed in the right way, and the issues are there. How you frame it, what the structure is by how you adjudicate things, tells the whole story. I mean, some people can take the pieces of information, and they can discuss

them in one way. Others can discuss them in another way.

What I am just concerned about is this issue anonymity, non-anonymity, how we are framing that. It may not be the right way. The input from these other people

-- it may be the general public, it may be specific stakeholders in the public -- for me, why I want that information is that in my view, it may change how we are framing, even thinking about this issue of the purgatory samples.

But I would like not to spend years getting that information. Let's get it towards a specific goal.

But then I also really agree with Carol. I mean, so this is one issue. Let's see what else is on the table.

MR. HOLTZMAN: I perhaps should clarify a little bit my comment about methodology, because that could be generically applied to any study. What I am thinking of specifically here comes out in the kind of comment you just made, which is we are now talking about the general public. We are talking about very specific groups probably.

But having said that, what is built into that is, for example, not necessarily what you meant, that we need to be talking to the groups that have genetic diseases. What we mean by genetic diseases are primarily the monogenic, highly penetrant disorders, and we are going to be talking to them.

But as the notion of genetic information gets cast much more widely, so that everyone in this room has four to five to six to ten polymorphisms that may confer a different susceptibility to a disease, all

right, when you start to talk about how samples ought to be dealt with respect to genetic information, you have got a much wider issue going.

That is the kind of methodology -- question -- I think, all of a sudden, gets to -- stake --and it sneaks up behind you without even realizing it.

DR. LO: There is even another connection that is right on us. I mean, so you study, for instance, the BRCA-1, that certain genes have certain predictive power in certain populations, but the big question now is: What do those mutations mean in other populations?

That is where you want to use these huge data banks that give you the statistical power to find out what happens in populations with a much lower prevalence of disease.

So going from your target focused population to a broader population is sort of happening now. Because the rapid progress in these areas.

DR. MURRAY: I suggest a metaphor for what we are doing right now. We are refining the map. I agree with the members of the Commission who have said that, in a way, this area has been reasonably well mapped out.

I mean, we do know the four categories that people use, fully anonymous, anonymized, etc., etc., and there seems to be pretty broad agreement in these statements. That those are useful distinctions and probably exhaustive.

That is map drawing. You are sort of creating-- you are defining the territory that you are going to want to travel in. We have

just suggested, Steve and Bernie, some new implications and distinctions and other things that need to be drawn on that map.

I think that the maps used in these various statements that we have read are pretty similar, similar enough that they can be pretty much projected onto one another. I am not sure that -- there are clearly differences -- they have opted for different terms at certain points on the map.

I am also not entirely sure that -- I read into this some more persistent and deeper disagreements about certain ethical ideas, about the meaning of informed consent, about what constitutes being a human subject for the purpose of this sort of exercise.

We can do, I think, useful work in helping both to refine the map but also into looking more deeply at these other moral disagreements that I think are latent or manifest in the documents.

DR. COX: I mean, one -- there is one key point that you could say is an overriding thing that keeps coming out of the Genetics Testing Task Force is -- not only that task force. There is a congressional committee on environmental risks. The same thing comes out of that. Mechanisms for getting -- ongoing mechanisms for gaining more information. Because decisions are having to be made in the face of insufficient information. That is my definition of medicine, but the definition of genetic tests is the definition of environmental risks. So how do you get ongoing information?

And there has to be this relationship between the people who you collect the information from and the people that are analyzing

it. That is what this goes into. So it is much broader than single gene disorders. I will tell you I think it is broader than genetics.

So that is why -- now, we come back to: Is this a genetic issue? I think not. But I think that we can focus it on this genetic issue and then have it much broader. Because I think it is very broad.

DR. MURRAY: Bernie gave us the HIV analogy and that is not genetic per se. I have to say, David, when you said decisions made on the basis of incomplete information. That was my definition of life, not medicine.

(Laughter.)

DR. MURRAY: Let's -- we might -- we are ahead of schedule, and that is fine, except I am not sure if Bob Gellman is here, who is going to lead off our next session. But we are going to have a break.

But I would like to take at least few minutes to see if we can reach a kind of, you know, tentative interim conclusion about what we would like to see happen, even if we don't say this is number one.

What do we think we would like to do or have done on our behalf in order to write a really useful report that we can take pride in and believe states the case clearly? What do -- I think we have the elements, but maybe we should just quickly go down them.

Do we want a kind of sophisticated sampling of public opinion? And I use that not to imply that it has got to be the Gallup poll. I take all the things that I have heard, particularly Steve and David have urged about, trying to get deep rather just sort of skim the surface. Do we think that is important and necessary? Is there agreement about

that?

DR. COX: Timely.

DR. MURRAY: Timely. Do we also think that it would be useful to explore cultural, religious, perhaps ethnic differences -- to see if there are significant differences in attitudes toward -- not just attitudes, but in beliefs, important moral convictions, toward these same issues? And maybe not in the form of opinion polling data. That might be a different kind of inquiry.

MS. KRAMER: Tom, do you think that we need to ask the staff to talk to people whose expertise this is and ask them how they would construct a survey?

Perhaps there is a way of doing a small introductory survey, be it focus groups or whatever, that would give them some handle on how large a survey we are going to need to get any meaningful results.

DR. MURRAY: Okay.

DR. LO: Also, sort of along the lines -- I mean, there are people like, you know, Dorothy Nelson at Cornell, who have tried to piece together public concerns from looking at, you know, newspapers and sort of TV discussions -- any information that sort of helps put it in context would be pretty useful.

So, yes, I would support having the staff explore what are the methodologies, who are there is working on it, and what is the best thinking as to how we can get this information in a timely and useful fashion.

DR. MURRAY: Is it plausible to ask for a sort of feedback on

that in time for our January meeting? Not necessarily a concrete plan but feedback along that line.

MR. DOMMEL: Sure.

DR. MURRAY: Okay.

DR. EMANUEL: I wouldn't say -- you had suggested again this issue of looking at dominant religious, cultural, ethnic groups and the possibility of commissioning papers.

I am always a little hesitant to go to supposed leaders and to take their opinion as the sine qua non of the constituency says. I only mention this in the context of looking at the Catholic church and its relationship to the abortion issue.

I mean, there is an official Catholic position, and yet we know that the vast majority of Americans who are identifiable Catholic don't necessarily heed it. And so just having the recognized or self-designated -- it depends on the group -- leaders and have them write an opinion piece for us from their philosophical standpoint may not be the exactly right approach.

DR. EMANUEL: I think this may be a case of where the stakeholders, we have their views. What we need is more creative efforts to get down into the actual people rather than the "opinion leaders."

MR. HOLTZMAN: Bernie, at the last meeting, or the two meetings, it seemed to me you made comments about informed consent, where -- they implied that studies have been done as to the effectiveness of the informed consent process per se. Do people really understand and what not? Because then by implication, that ties here

directly to the pathologists' samples.

DR. LO: Sure.

(Simultaneous discussion.)

DR. LO: -- to sort of explain to someone the situation, the alternatives, the benefits. It is hard to show that they absorb a lot of that later that day or the next day or the next week.

DR. EMANUEL: There is a body -- it is not the greatest of literature -- but there is sufficient body that can be drawn on this. And it may be that the other, I would think, subcommittee might want to raise -- might want to do some of its own work on that, and we may dovetail or use their information ---

DR. MIIKE: I prefer asking the staff to let us know what do we know and what groups are working on public (?) in this area. I would leave it at that for the next meeting. That is a big enough charge.

What I do get worried about is that when we are talking about public opinion polls, you are talking about very expensive research. I would hate to see a substantial portion of our budget eaten up what may turn out to be an interesting but not very helpful piece of information that we get.

So, again, I would like to suggest that we focus our -- we pick a topic -- and a topic appropriate -- I like your definition of purgatory as the one that sort of then focuses us down about what kinds of questions are we really going to be interested in from a public perspective.

So I don't want to put the design of a public opinion poll

before the cart or whatever, whatever analogy I am trying to make here, between horse and cart.

MS. KRAMER: I have here a consent form for tissue banking research that was done by the National Breast Cancer Coalition, and they did this after they had several focus groups and they had themselves undertaken a survey. This was a consent form that they came up with. Perhaps it would be possible -- they have made it very, very simplistic, which, of course, speaks to the point that you just made.

DR. COX: Tom, I would like to come back to your point about specific cultures and specific groups. At the risk of doing exactly what Larry asked us not to, which is come up with a methodology here, this is a -- (inaudible)

-- principle. That is, whatever the methodology is that we apply it across a variety of different groups but don't specifically go and say, well, you know, let's focus on this group's perspective or that group's perspective. We make sure we include all these different groups but ask them the same thing. If we are asking things that basically don't take into account their special situation, then we are asking the wrong stuff. And it should be general things that each group has specific slants on, but their specific slant should be relevant to everybody. I am just worried about --

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DR. MURRAY: I am unclear what you are calling for, David.

DR. COX: I am calling for not a specific study of each individual group. Right? But what individual group' perspective on the

general issue is.

DR. MURRAY: I will tell you the sort of thing that strikes me as a potential precedent, and I can't remember the citation or anything, but there were questions 10, 15, 20 years ago about different -- particularly different religious organizations felt about organ donation and organ transplant.

There was lots of myth and there was little good information. So I don't know who did the study and can't vouch that it was done well or poorly, but I remember reading it and thinking that I had been informed by it.

It found that by and large, virtually all religious organizations supported the concept, not everyone, and not without limits, but supported the concept of organ donation and the receipt of organs.

DR. COX: And that was useful information. This is exactly what I am talking about. So you come up with a very general question and you say, so, what are these different perspectives on that general question instead of going in and saying what are the unique questions for each individual group? Because that other way, you know, I think it could be a real morass.

DR. MURRAY: Is that also consistency for this sort of thing -- --

DR. COX: I think so. Yes.

MR. HOLTZMAN: That is actually -- what you are referring to, I believe, there are aspects of it in the last chapter of the OTA report

from 1987 on tissues that is in here.

DR. MURRAY: I think I actually wrote part of that chapter.

MR. HOLTZMAN: It is a great job.

DR. MURRAY: But probably not those parts.

DR. MIIKE: Probably the difference between the OTA reports and these are that -- I used to be on OTA -- you could listen to your group and decide which advice we would take.

(Laughter.)

DR. MURRAY: That is the problem. Carol.

DR. GREIDER: I would just like to agree with Larry and get back to what Steve had said -- agree with Larry on the fact that maybe for now we should see what is out there in terms of the public opinion.

Because if we are going to talk about having some sort of focus groups or small surveys, I think that what Steve said about the specific questions that are asked are going to be very important in terms of what you are going to get back.

We would have to think very carefully about that would be before going ahead with it. So maybe for now seeing what has been done before we design that kind of survey ---

DR. MURRAY: Yes. Another possibility for a product that would be -- I would propose that we might find useful would be a really thorough and good and prescriptive analysis of the -- sort of the normative, the ethical position, taken by each of these organizations and what presumptions they are making, what concerns they are raising.

I mean, part of that is -- it is not a laundry list -- but you

want to ask a question like, okay: What are -- to the extent that we can spot it in the literature, what are all the ethical objections that have been raised about the use of these, say, anonymous samples?

What are all the ethical -- and what are the reasons in favor of it? What are all the ethical objections to anonymizing samples? And it is basically a collection and then an evaluation of them. Say is this a -- who holds it and is it -- does the argument seem sound? Does it seem to embody some erroneous assumptions, that sort of thing?

That -- it is harder -- it is more difficult to write such a paper than it sounds on the surface, but it can be done. It doesn't require large public opinion surveys. It requires one or two really smart and sophisticated people to do the analysis. One hopes then that can kind of gauge.

That can be done depending on people's schedules and who we can get. That can be done relatively quickly. Is that the sort of thing that also we would want to have? That sort of collection of analysis.

DR. EMANUEL: Absolutely. What the arguments --

DR. MURRAY: Okay. I am hearing sort of three categories of things that we want at this point.

MR. HOLTZMAN: What was the first?

DR. MURRAY: The first was some sampling of public views. Right? You are not stipulating methodology. It may be that we don't even need to commission anything new. Maybe its data is there. My guess is that it isn't, not in the form we are -- but let's find out first.

The second product is looking into the regions, not just the

average depth of the lake, but looking into the important parts of the lake, the part that belongs to this religious tradition or that cultural group and see if -- do more of a kind of looking through and asking general questions about their attitudes towards tissues and DNA and such. Is that fair?

And the third is this more sort of straightforward ethical analysis. Are there significant pieces that we should have?

DR. GREIDER: Can I just ask about the second one. How do you choose which groups to look at? I mean, you could come up with 10 or a thousand or 10,000 different specific groups in the United States. So I am not sure how one decides what groups are the relevant groups to ask.

DR. MURRAY: To be decided. I mean, I think you would look at any -- you try to get any significant religious traditions in the U.S., significant in the sense that they represent a substantial percentage of the population.

And by substantial, I don't even mean 10 percent; maybe 1 percent is enough. I don't think it is going to be a thousand, but I don't know. You might want to look at -- the other cross-cutting things I am not sure how we are going to make that decision.

I suppose we will look at how other groups who have tried to do something similar have made their distinctions and whether, in fact, they have seemed to have done it right or well or poorly. And then we do it differently if we don't like the way they have done it. Steve.

MR. HOLTZMAN: I would think that the fourth part -- you

asked me what else -- you already mentioned, and that is, this notion of what is the map of the organizations? What is the conceptual framework that has been adopted, the topography of layering those maps over each other, relating those concepts that have evolved. Because I think what those concepts have evolved is in response what we are going to be looking at in one through three ---

DR. MURRAY: Drawing the map. I see that as a centerpiece. I kind of saw that as the ethical piece, but it might be useful to treat it separately.

MR. HOLTZMAN: Separately, because to me, that becomes the pragmatic embodiment from which one could then move to a series of recommendations that affect practice.

DR. COX: And it doesn't assume, Tom, that the map already exists. When you said that, I actually feel very uncomfortable with that, because I am not -- you may be right. But it is not clear to me the way it is out right now. Even though all these papers use that map. It is not clear to me that is the one we want to use.

DR. MURRAY: Oh, yes, I didn't mean to even -- suggest that. Right? I think that what I would want to say is that the maps that the different organizations are drawing look to be pretty isomorphic.

DR. COX: Exactly. Right.

DR. MURRAY: They may not be the best maps.

DR. COX: Yes.

DR. MURRAY: They may not be the ones we want to -- we

think are going to help navigate this. So what -- Steve, are you calling for the sort of just describe the maps that are currently being used? Or do you want somebody to go in and try to draw what -- propose for us what ought to be the right map?

MR. HOLTZMAN: What I would say is you that you start with those maps. You relate them back to your items one through three. That will also show you where maybe there are certain concepts not being captured at a pragmatic level with notions of anonymized versus anonymous, whatever additional concepts may be necessary.

And then the question is -- your last question, that is, what is the role of this Commission? Does it come forth and say, you know, given all of this, we believe that this is how it ought to be handled, therefore, determining the nature of the hell or heaven those purgatory samples have entered?

DR. LO: You know, to try and carry this a little further, I would first sort of suggest that we might want to do sort of almost a policy analysis for what Steve is calling the fourth project, which is to sort of lay out the different options and the pros and cons of each.

So rather than either just looking at what has already been proposed or someone's conception of the ideal, sort of look more broadly. Of the ones that might have thought of and rejected, what were the reasons they were rejected? Did they have advantages that, you know, might be useful?

My other suggestion is to sort of build on the international theme that we had in the last session in San Francisco and to include in

all four of these projects a look at what other countries are doing in terms of what the public thinks in other countries, options that other countries are using.

Are they conceptualizing things the same way? Do their cultural perspectives give them certain unique concerns or wishes about this issue?

Because I think, again, a lot of this is done, and by looking at something very -- I mean, all of the people that -- come out of sort of one tradition, in some sense, and you know, a lot of other cultures are very different.

MR. HOLTZMAN: I would like to second that. Without trying to cover the whole world, just from personal experience, we do collections and we work with Swedish investigators.

The attitude of the Swede to a sample is so very different. It is part of a more socialistic organization. They have obligations that that is there for research. And it is tied to a personal identifier, a unique identifier, from the first time they are born, allowing you to do epidemiological follow-up on it.

Many of the questions that are here in terms of autonomy rights just don't even start getting -- don't even get going.

DR. MURRAY: Bernie, I like that idea. I am just thinking about how to implement it.

Would the most useful piece of that be a kind of -- maybe one report on international perspectives on tissue samples for DNA analysis that would include both, to the extent that we have, sort

of information about social attitudes and give some of that.

Obviously, I don't think we -- primary data. We can't do social surveys out of the country. But also some policy analysis. How it is being handled, you know, in Sweden, in ---

DR. MIIKE: Well, maybe the simplest way to do that is whatever -- and it seems to me there is a lot of information generated out of that San Francisco meeting. That if you simply look at what other groups have done in countries, and you just sort of match their recommendations by area, you should get fairly quickly any kinds of differences that pop out of it.

DR. EMANUEL: You don't mean a separate report, do you, Tom?

DR. MURRAY: I am not sure.

DR. EMANUEL: It seems to me this ---

DR. COX: Because, in an interesting way, it does into possibly what Carol is asking about. Because this gives you hypotheses about how you might slice and dice groups. And they may not be along, you know, obvious lines. They may be along these kind of lines.

Like what are the different perspectives that people might have based internationally, and then we look in the U.S. and say, all right, are any of these applicable in the U.S.? And it defines our groups.

DR. GREIDER: Can we just clarify one thing about the language: You just reiterated tissue samples for DNA analysis. And when we are talking about a tissue sample is a tissue sample is a tissue sample, in this day and age, you know, this gets back to the stored

samples and those in purgatory.

Of course, DNA analysis is going to be something that people are going to do with those. And so somebody might have donated something not for DNA analysis, and now the question is: Do we use it for DNA analysis? So I am not sure we want to use the term "tissue sample for DNA analysis."

DR. MURRAY: Okay. I was actually reading the topic heading for this part of the meeting.

DR. GREIDER: Yes, yes.

DR. MURRAY: But you are right.

DR. GREIDER: I just want to clarify that, you know, if we use the language that we are talking about, it might help us.

DR. MURRAY: That is a point well taken, Carol. Bernie, can we just clarify a little bit more just what we should think about as this product?

DR. LO: I think I would leave that to the option of the staff or the people making -- (inaudible)

-- a lot would depend on sort of what is out there, how assimilatable it is, and things like that.

MR. HOLTZMAN: But I think that putting together these two ideas -- in the same way in which you said there is a policy analysis -- what have these various groups taken -- you could then layer on, extending the policy analysis, as opposed to getting into cultural attitudes, which would could be -- unless you are taking some road trips ---

DR. LO: As you just pointed out, it gets back to notions of sort of autonomy, privacy, collective good.

DR. MIIKE: Come to Hawaii. I will give you any culture you want.

(Laughter.)

DR. MURRAY: Okay.

(Simultaneous discussion.)

DR. MIIKE: Very few Swedes, though.

(Laughter.)

DR. MURRAY: Is this because of the cultural stereotype that they think to suffer more? Is this the problem?

DR. LO: They sunburn.

DR. MURRAY: Any other pieces? I don't feel that we are running out of steam, but I think we actually may be reaching a kind of -- (inaudible) -- tentative closure. Anything else that you want to have in?

MR. HOLTZMAN: When we talk about the use of the samples, and we have been largely talking, it seems to me, having to do with these issues -- mostly about informed consent and what not -- are we also thinking here about issues of, for example, compensation?

DR. MIIKE: Well, it seems to me that that gets covered in the patenting issue. That might get covered in that ---

MR. HOLTZMAN: It technically wouldn't. Okay? We could talk -- maybe there ---

MR. HOLTZMAN: Okay.

DR. MURRAY: That is a very good question.

MR. HOLTZMAN: Hey, you know ---

DR. MIIKE: That is sort of a solution looking for the question. I think what -- I would look at this, at this particular area, is that in a generic sense, what we are concerned about, uses that were not contemplated at the time of the donation. I would look at it from that point of view.

DR. COX: And compensation isn't part of that more narrow sort of purgatory sample issue.

DR. MIIKE: Right.

MR. HOLTZMAN: Are we only dealing with retrospective -- how to deal with retrospectively selected samples? I didn't think so.

DR. MIIKE: The specific issue there that David mentioned was let's start off with already existing samples, and I just sort of very obliquely mentioned that as part of that we need to sort of think about what would happen for future collections.

But I am just looking at compensation as one of our possible answers in any particular area around the commercialization once you get past the donation stage and something arises that is a commercialized product. So it is a much more narrow area than ---

DR. MURRAY: To the extent that the questions that were raised, even in this tissue sample subject, are questions about the social meaning of human tissue out of the body, the transfer of tissue into the care of researchers or pathologists, clinical person, compensation could be fit under that umbrella.

Can we keep an open mind about that and maybe revisit

that either toward the day, just to see whether, for example -- we may choose to do a report that doesn't address compensation -- a more narrow report on this.

But if we are going out and having people look at -- if we do a public opinion sort of survey, maybe that is also the place to ask a few questions about attitudes towards compensation.

If we do ask for the reviews of cultural, religious, etc. views, we might want to ask them, include them, in the question we pose to our researchers, to inquire about issues like compensation. So can we just leave that open?

DR. GREIDER: This might come up more at the January meeting. Isn't there going to be a certain amount of overlap between this and the other subcommittee in this particular area, if the other subcommittee is going to be dealing with human subjects?

DR. MIIKE: Yes. I would say yes, because ---

DR. GREIDER: So we should clarify that.

DR. MIIKE: A few years back, when we had a keystone group that was looking at liability issues about the AIDS vaccine testing, the whole issue about compensation came up. But that was compensation for injury. So, yes, it will come up in ---

DR. GREIDER: But a lot of these things with this issue of tissue samples, and are we dealing with just those in purgatory, or are we dealing with the prospective collection of samples?

I would think that that is going to be something that is going to be also taken up by the other subcommittee. Maybe we should find

out about that at the January meeting and have some sort of a meshing of what the priorities are for the different groups.

DR. MURRAY: We can do better than that. Bill has just told me that Jim Childress will be here this afternoon. We can ask him directly. By the way, my ---

DR. GREIDER: But they haven't met yet. So they don't -- he might not know what their priorities are.

DR. MURRAY: My idea is we are one Commission.

DR. GREIDER: Yes.

DR. MURRAY: We just happen to be delegated with sort of doing the scut work on this subset of issues, and they are doing the scut work on the other subset. But we are one Commission.

DR. GREIDER: But before we do the work, we should maybe find out who is doing what.

DR. EMANUEL: But there will be overlap. At the January meeting, presumably, it will be discussed.

DR. MIIKE: That is what our January meeting is about.

MR. HOLTZMAN: But my only sense about the compensation thing. We shouldn't jump ahead to define now what we think the chapter headings of a report, or whether we need one report or two reports or three reports. It seems to me compensation is one of those things we may find that we have to address and we may find we don't.

But I didn't take that, the four or five items that we would like to put on to get more information about, or need additional study of,

precluded when we finally do the -- set the framework, do the analysis of the arguments -- necessarily to include or exclude that.

MR. HOLTZMAN: I was just raising it, because it struck me that we hadn't talk about it. Let me sort of clarify why I said it comes up here. There are aspects -- there are lots of different places compensation hits. One is the fundamental question of whether it skews the informed consent process, which I think is something maybe most properly taken up by the other subcommittee.

One place it also impacts is a right to participate in downstream profits from a patentable invention, for example, made where you -- your bodily stuff participated in the invention.

But I think the issue I was focusing on here is -- ties to compensation for your donation and how that ties to concepts of the relationship in which you stand to your body. Do you stand in relation to your body as an owner?

And that runs completely through the questions about what is the nature of the informed consent that is appropriate in the case of tissue samples, whether or not anonymity is necessary and identifiability. All of those things come out with respect to what is your relationship to your bodily substance?

I don't mean to get too philosophical, but compensation goes right to the heart of that, which is why it plays out in things like the organ donation statutes. So that is why I think it comes up here.

So I was just wanted to say that we hadn't mentioned it. It was just striking to me. I wasn't very clear. I apologize.

DR. MURRAY: So we will leave that an open issue, and then we will talk about ourselves, and we will talk with Jim about what the Human Subjects Subcommittee is likely to be doing. Is there anything else we want to say at this time about tissue samples?

Well, the good news is I think we have done -- we have made excellent progress on this. And we will have an hour-and-a-half to talk about genetic privacy after the break.

The bad news is the two topics in the afternoon, we only have an hour each to spend. So we may -- if we finish with privacy, which is improbably, but not totally impossible, we will start on the first issue for the afternoon before the break. But I will be shocked if that happens. But one never knows.

Shall we go ahead with our break now? I have about 17 after. Can we reconvene at 20 of? We are a bit ahead of schedule. Is that all right? 20 of.

(Whereupon, at 9:20 p.m., a brief recess was taken.)

DR. MURRAY: That is not bad. We said 20 of. It is about a quarter of. For Washington, that is not bad I suppose.

The format changes a little bit here. We had no one lead off our conversation about tissue samples. For the next three main topics, we are going to have people leading off each.

We have asked, in every case, the individual who has been charged with the responsibility of getting our conversations started to take no more than 10 minutes to brief us on essentially what we need to know, what questions we ought to be asking.

I want to thank the individuals who have agreed to fill that role. It is an onerous task, to compress so much information into such a short time. I also want to invite them to, if they choose, there is an amplified podium there that you can use. But if you choose not to use it, that is fine, too.

Two of the people who will be doing that -- at least two -- actually three of the four people, because one of them will be shared, are around the table. One of them, Steve Holtzman, who is a Commission member. Steve and Rebecca Eisenberg are going to be helping us begin the conversation about gene patenting.

The third topic is going to be genetic discrimination, and this is Karen Rothenberg, and I wonder -- Karen is at the table, if you could introduce yourself.

MS. ROTHENBERG: Hello.

DR. MURRAY: And say who you are and ---

MS. ROTHENBERG: Okay. Do you want me to talk a little bit about what I have been doing? I am Karen Rothenberg. I am presently functioning as the chair of the Policy Section for the National Action Plan for Breast Cancer Heritable Gene Working Group.

It is primarily in that function over the last year-and-a-half that we have been looking at policy issues in genetics and working, when we can, with the ELSI Working Group, first in the area of health insurance, and we just finished a workshop on employment and the use of genetic information in the employment context.

My usual job is that I am at the University of Maryland as

the director of the Law and Health Care Program and just came off a year of being at NIH.

DR. MURRAY: Thank you, Karen. I have saved for last, if not the best, the one who is going to be speaking now, and that is Bob Gellman. Bob, could you introduce yourself and then please get us started.

GENETIC PRIVACY

MR. GELLMAN: I am Bob Gellman. I am privacy and information policy consultant, and until the Republicans took over the House, I worked for many years on a House subcommittee that dealt with information and privacy issues.

And in the 103rd Congress, when health care reform was being considered, I was involved in drafting a health privacy bill that moved part-way through the system and is still floating around somewhere on Capitol Hill.

I am otherwise also on the National Committee on Vital and Health Statistics, which is another governmental advisory committee at HHS, and under the Kennedy-Kassebaum Bill, the committee has been somewhat reoriented, and a bunch of new members have been appointed.

I am one of them, and the committee has some responsibilities for health privacy issues. We are going to make some recommendation to the Secretary. The Secretary of HHS will, in turn, make recommendations to the Congress by August and, hopefully, they will push some of the legislation a little further down the track.

What I would like to do is just sort of give you a very quick overview of what we are doing. The committee has established a Subcommittee on Privacy and Confidentiality.

What we have chosen to do is hold a series of hearings in January and February. We don't have dates yet. We are working on those right now. We will probably hold six days of hearings. The purpose of the hearings is -- I mean, this is an issue that has gotten attention now for a couple of Congresses.

The Kennedy-Kassebaum Bill says that if Congress doesn't pass a bill in three years, that the Secretary is authorized to write some regulations. I am not sure that works very well, but be that as it may, a timetable has been established, and that is what is important.

There was a lot of work in the 103rd Congress. There was work in the 104th Congress, which took place mostly in the Senate.

The main vehicle in the 104th Congress was the Bennett Bill, S 1360. I am sure that will be reintroduced. The House bill was introduced by Gary Condit, and that will be reintroduced. The number in the last Congress was HR 435.

So I think we are at a stage now where there is fairly widespread recognition of the need for some kind of uniform federal privacy legislation. The details, of course --- there is less agreement on the details, and there is a lot of work that needs to be done on that.

Given the background, the hearings that we hope to hold will be detailed, and among the people -- we will be hearing from all the usual suspects, I am sure. Again, that is not worked out yet either.

But we are likely to begin by hearing from the people who use records: public health authorities, health researchers, people involved in health oversight at various levels, law enforcement agencies.

All those people in order to have them come forward and make their case in some detail about what they need and how they use records and what kind of process and procedures they can live with and try and get into this in a more detailed way.

Also hear, of course, from the providers, the insurers, the claims processors, the people who are involved in other aspects of this and then eventually, probably toward the end, hear from the privacy and patient advocacy groups as well.

And try and use all this to build on itself and to rely on what we have learned and what we have been able to find out from one set of participants and then start using that as a basis for asking other people questions about how they can live with various restrictions or changes and what the costs of everything will be.

Because there will be a lot of trade-offs in all of this. If you have more of this, you have less of that. And that is throughout any legislation of this type. Ultimately, we will create some kind of recommendations for the Secretary.

I have no idea exactly when, or I haven't got a clue about the format of them. It will probably be sometime in the spring so that the Secretary has a chance to work on them and then develop her recommendations and float those through the government and get them out the door.

I think that the hearings that we are talking about are something really that are not likely to be held otherwise. They are likely to be day-long hearings with a lot of detail, and it is not the kind of hearing that you tend to get on Capitol Hill, because no one has the time or the expertise to deal with it.

The committee has a bunch of people with a lot of different perspectives on the health care system. So that will be useful in trying to tease out what the alternatives are, and hopefully, this will create some kind of foundation, not only for the recommendations, but it will help to sort of draw a boundary around the outside of the issue and sort of begin to push people toward the middle.

That is the plan. I hope it works, and we won't know until we try. I don't know have anything really substantive to say on behalf of the committee, because that is as far as we have gotten in our planning. We haven't had any substantive deliberations. We are not likely to for a couple of months on this issue at least.

I have lots of other views on health privacy issues and on genetic privacy issues that I would be glad to talk about. But tell me where you want to go.

DR. MURRAY: Okay. Thank you. Could I introduce one other person, who is not sitting at the table at the moment but is a senior privacy maven, and that is, John Fanning, who has introduced himself. But, John, would you introduce yourself a little more.

MR. FANNING: I am John Fanning. I work in the Office of the Assistant Secretary for Planning and Evaluation in the Department,

and our office is in charge of working up the Secretary's recommendations that Bob's committee will be feeding into.

DR. MURRAY: John has consented to being a resource person for our conversation as well. John, would you be willing to join us at the table for at least this part of the discussion? I think there is a seat up there. Thank you. It is open.

DR. EMANUEL: You gave us, I thought, useful stuff about the time line, but I wanted to ask you about the ethical framework which the committee is -- I mean, hopping to regulations assumes what we want to be doing, and I didn't know where in the development process the committee or you think others are as far as a framework for analyzing these things and for analyzing the trade-offs.

I mean, I think everyone around the table every time you look at a privacy issue, you -- sort of shakes their heads. There are lots of trade-offs. Well, do you have a framework for thinking about those trade-offs other than to say you have got to balance somehow?

MR. GELLMAN: Well, I am not sure that I have a framework in that sense, but I think that is a developed issue. There are major pieces of legislation floating around, all of which have flaws, but there is a framework in those bills. There is somewhat of a consensus as reflected in the different bills in terms of language and structure.

I think that we are at the stage where we are feeding into a specific legislative process. We are not building a framework any more. It is not -- it is -- the details of the language -- you know, what Subsection C(3) of Section 5 of the bill says is important. Because that is what you

have to get agreement on.

And I think that is likely to be -- I am not suggesting that my subcommittee is going to write legislation, but we are going to be looking at the legislation that is there and the frameworks that are established.

I don't think we can go all the way back to the beginning and start from there. Because there is not enough time to do that, and I don't think that the Congress is likely to be receptive to coming at this issue -- nor will I think the rest of the community here -- conversations have begun to gravitate around the legislation, and I think we have to accept that and try and move that process forward.

DR. MURRAY: Bernie and Larry.

DR. LO: Two questions for you. One, in what ways do you think this Commission can play a constructive role on this topic?

And, secondly, I would appreciate your thoughts on this issue that keeps confronting us as to whether genetic information is somehow particularly sensitive or different and, therefore, deserving of special protection. And is it even feasible to do that given the way medical information is stored these days?

MR. GELLMAN: Well, in terms of how the two committees, commissions, whatever can work together, I don't know enough about where you are headed and what your plans are, but there is clearly an overlap in part, and I think we need to keep talking.

It may be that we can get some help from you in terms of what we are doing with our hearings or some specific kinds of issues or

specific witnesses that we need to hear from. There may be some specific questions that you think are important that we need to think about.

And I think the second one you raised is very much one of those questions. I have views on that which I will share with you. I am not speaking here for the committee, because we haven't spoken on this.

I think it is extremely difficult to develop legislation and set up categories of different kinds of information with different standards. It is administratively impossible to do.

I use the example of a patient who has Huntington's disease, AIDS, and is a drug abuser, and as a result of all of that is depressed. That person's medical record could be subject, in some places to four or five separate pieces of legislation.

And it is simply an impossible situation for people who maintain the records and use the records to say that you have to comply with all of these different kinds of laws. We haven't even gotten into the issue of states versus -- one state versus another -- as records fly back and forth across ---

So I think that one of the things we have to look at is: Is it possible to create the high level of protection for all kinds of records, regardless of what they are? People always make arguments that one sort of record or another is more confidential.

For example, you always hear that psychiatric records are more confidential. And, in some ways, they are. But it all depends on who you are, and confidentiality is in the eye of the beholder.

One lovely example I got from talking to my dentist was of a patient of his who wore dentures. No one knew this patient wore dentures. Not even his wife. And to this guy, that had to be the biggest secret in his life.

Also, in terms of psychiatric information, I always like to say that I know lots of people who have seen psychiatrists. They talk about it. They tell me they are in therapy or whatever.

I don't know anyone who has ever seen a proctologist. Nobody ever seems to want to talk about that or say that they have been to visit one.

So the question is: What is confidential is really hard, and it is very individualistic. So I think that, too, makes it difficult to make these kinds of value judgments. And so I think we need to create some high level of protection for everything.

I think there are other areas in which differentiation between information based on its type may be supportable and advisable, and I think that when you get into the discrimination issues that you may want to have -- and I think this is probably a very good idea -- you may want to have different rules about how information can be used.

But when we are looking at the health care system and health payment system, it is -- and we are looking at privacy -- we are looking at how the information is going to be collected, compiled, used, and maintained within that system, I think you probably need more standardization rather than more differentiation.

MR. HOLTZMAN: Do you envision the legislation will

manage to deal exclusively with the issues of privacy, storage, transmittal and get into discrimination issues?

MR. GELLMAN: I think so far the legislation that is floating around only does that. Is that a fair characterization, John?

MR. FANNING: Yes.

MR. HOLTZMAN: I say that if one looks at the bill, there are bills where they do cut across.

MR. GELLMAN: Yes, there -- I mean, it is real easy to wander off and to start saying -- and it is also true that if you look at the legislation as the draft --

that is sort of the main House and Senate bills -- there are a lot of weasel words in there in terms of saying how information can be used that aren't all that clear.

And that is something that needs to be explored further and to try and draw lines that people can comply with without getting too far afield.

MR. HOLTZMAN: Because the question in the back of my mind is if we have a parallel track on one with respect to discrimination legislation be it with respect to genetic information or health information, it doesn't matter, and you are going to get a parallel set of definitions. So it is going to have impact in terms of the standards of confidentiality. I am just wondering ---

MR. GELLMAN: Well, one of the problems in this area -- none of the bills deal with this well, and I am not sure I know how to deal with it well, and maybe we will figure it out -- is there are so many

different players in the health care system, and many of them play more than one role.

So it is okay for you to have information as an employer when you are processing health claims for your employees, but it may not be okay for you to use that information to make job-related decisions about those employees.

It is very difficult to figure out how to draw those lines and how to say that. The roles of everybody are merging. I mean, all the different functions are just shifting one into another, and all of that makes it difficult.

You are probably going to have to define some things functionally, and you are going to have a statute that is likely to have weasel words in it. I mean, I think you have to do the best you can. But, ultimately, it is difficult to impose rules on such a sloppy system, and you can't change the system too much.

So you are just going to have to live with that and try and stay within whatever boundaries you have established. But it is a problem.

DR. MIIKE: I have a question from a different slant. You mentioned several things -- (inaudible) -- for my direct question. One was that it is time for standardization.

Number two is that when you said that when you have these hearings, you are going to have all these people come and maybe at the end the advocacy groups and the -- (inaudible).

Is this reactive to the legislative then? Is this to take a look

at what has been proposed by people interested in the protection of privacy from not the user's side, but the people interested in privacy for privacy -- the advocacy group, let's put it that way?

So that states that have now put these acts into place and the users have come to you and said, it is impossible for us to deal with these barriers, requirements by different states. Typically what that would -- say, insurance companies.

So my basic question is: What is the impetus behind this federal move now to have legislation? Is it because in the application of these various state statutes, it is the user groups that are worried about what the restraints are and what the rules of the game are?

MR. GELLMAN: Well, if you look at the history of this legislation, it actually dates back to the late '70s.

The Privacy Protection Study Commission in 1977 issued recommendations across the board on privacy issues. I was working at the time in the House of Representatives on the subcommittee that dealt with this, and in 1979, we decided that health privacy was an appropriate issue to take up.

It is a very complicated one, as everybody is aware, and in 1979 and 1980, we moved a bill partly through the process. It actually got to the floor of the House when it died, when it failed. It didn't get enough votes. That is a complicated issue about why it did.

But that was really the first attempt at a federal medical privacy bill, and the justifications for it then and the justifications now were the same.

There is inadequate protection for medical records. Medical records have very little confidentiality attached to them. It has gotten worse in the past 15 years, because of the way the health care system has changed.

There are more players. There is more use of information. There is more computerization. None of those things are inherently evil. The consequence, however, is that there is less and less protection.

There are fewer and fewer clear rules for people who maintain and use information, and there is really no clear definition of patients' rights or recordkeepers' responsibilities. So that is one set of problems.

The second set of problems is that medical care is an interstate business today. Treatment and payment and other functions go on across state lines routinely.

I suspect that there are lots of people who have computerized records who don't even know what state they are maintained in, because you have a contractor maintaining them. You don't know where the records are. It is almost impossible to tell what law applies.

And so we are getting into an era where things are more computerized and more electronic, these problems are -- and this has made a difference.

In 1980, there was opposition from the medical establishment to a federal bill. The response was we would rather have state legislation.

DR. MIIKE: And they got it.

MR. GELLMAN: They didn't get much of it, though. There isn't that much state legislation, and what is out there tends to be out of date and incomplete and not very good. But there is some.

This time, in 1993 and '94, when basically the same kind of legislation was proposed, the medical establishment said yes, we want uniform federal legislation. We cannot operate under 50 state laws.

I think that those two things, the lack of clear protection for records, and the need for some kind of uniformity, that is the underpinning for the legislation.

MR. HOLTZMAN: But isn't it the case that in Section 264 of Kennedy-Kassebaum, it says the legislation proposal you are coming forth with doesn't preempt state? In fact, that the state will rule if it is more stringent.

MR. GELLMAN: Yes. And I think that that is something that needs to be re-examined personally, because I don't think that works.

But I think at the same time that you have to recognize that there are some things at the state level that either for policy or political reasons, you are going to have to accommodate, and I think that is one of the harder issues that everyone is going to have to deal with.

MR. HOLTZMAN: What is more stringent taken to mean?

MR. GELLMAN: Well, no, it is very difficult to in writing on preemption to say, you know, bills that are stronger or -- it is hard to write a word formula that says -- that provides it with a clear test about whether you are preempting a particular bill. You can develop a

procedure to do that.

For example, in the Condit bill, HR 435, in dealing with the alcohol and drug abuse regulations and legislation, the procedure that was proposed there was to say, it is up to the Secretary of HHS or VA, because they are two parallel laws, to look at the relevant laws and decide which one is stronger. And a Secretary will make a decision about which one applies.

I don't know if you do that across the board. There are significant political concerns in dealing with this issue. There is a very strong and vocal AIDS community, which has gotten legislation through a lot of states, and that may have to be accommodated one way or another.

I mean, I don't know the answer to that except that it is a very hard question, and you are not going to get a one-line answer out of that that says stronger or weaker or anything like that and really deal with it. There is a lot of pressure from the medical care establishment, especially with respect to transaction information and payment information, that they not have to face a circumstance where states are either establishing contradictory standards or contradictory processes or procedures or requirements that they can't live with.

You also find in the Kennedy-Kassebaum bill that a strong push toward uniformity of standards clearly, and in some ways, I think the things are inconsistent. I think that that preemption provision was not well thought through and needs to be examined, re-examined.

DR. MIIKE: Well, I don't see how you can deal with it. The

only way you can do it is to say state law holds if there is a state law and that the federal standard becomes a default position. Otherwise I don't know you get into an issue about which one is stronger. But, as I say, this goes the goal of uniformity.

DR. MURRAY: Yes, it does. Since genetic privacy, genetic discrimination, joined at the hip, as it were, let me ask Karen to join the discussion and ---

MS. ROTHENBERG: Yes, I think maybe it would be helpful if we could just go back to genetic privacy for a minute in terms of seeing where there might be some problems. Because I think Steve has raised a number of really good points about the practical reality of what is out there, and let me just beg to differ a little bit.

The way the politics work, there are these generic bills that Bob is primarily talking about. But there is a very strong push, somewhat competing and somewhat compatible, from the push to look for specific genetic privacy and antidiscrimination laws at both the federal and state level.

The question about can you separate out genetic versus medical, I mean, that -- I don't know if there is a good answer to that. Clearly, the narrower the definition is, the easier it may be.

I think the question also becomes what is the rationale for doing that? And is the rationale for doing it that it is information that says more than something about the individual? Do we want to give it some heightened protection and put it in the category that currently exists politically with AIDS, mental health, and substance abuse?

We have in a number of these bills, in fact, purposely integrated privacy and discrimination, because some people believe that just antidiscrimination laws are going to not be that helpful.

Because the burden is on the individual being injured or thinking they are being injured to make the claim, and by making the claim, they give up their privacy. And when you are a healthy individual with a predisposition, that is not worth it in many circumstances.

So we have taken a position, we being the National Action Plan on Breast Cancer, in our recommendations, which you all have, that even if you put medical records aside for a minute, there are privacy interests in the information, independent of whether it is in your record or not that, I am not convinced, this privacy discussion has raised yet.

The example that is most significant for those of you doing research is that nothing stops anybody from asking you what the results of your test are. They don't need a medical record to ask you that on an application form or for insurance.

So in the antidiscrimination legislation that has passed at the state level over the last few years, and in the antidiscrimination legislation that has been proposed on the Hill, which in part was pulled out in Kassebaum-Kennedy for the antidiscrimination, but not with privacy except for this preemption provision that I want to come back to.

The purpose of integrating those was to try to do something about the access to the information, and that is why I think this is an arbitrary distinction.

With respect to the medical records, there may be

additional challenges or opportunities in terms of what sort of written authorization you get and how you can tease out what is genetic, what isn't genetic.

But what I am worried about as a political matter is we now have at the states, for good or for bad, laws that are primarily antidiscrimination laws, but that do integrate privacy -- put aside confidentiality -- a privacy protection, meaning don't ask, don't tell.

And would those be preempted by a federal law and how will we deal with that part? It is a very difficult legal issue, and we have asked a number of the committees to give us an interpretation.

Would we lose everything that we have, if it is worth anything at all, and if we do have a federal law that is generic for privacy like the federal law that we have now passed that is generic for health care, be it not health care reform, but maybe a baby step in the right direction, what, if anything, specifically do we want it to give a heightened level of protection for genetics?

And I think that would be something that the Commission, and I would think both commissions -- this Commission might want to look into, and your commission might want to have people focus on.

That might be then a way, in some way, to get back to your question to integrate what is going on out here right now at Congress and at the federal level -- I am sorry, at the state level.

DR. MURRAY: One clarification, Karen. At one point you said, this distinction is arbitrary. But I had lost which distinction you were talking about.

MS. ROTHENBERG: The distinction in discrimination and privacy. Sometimes it becomes arbitrary, because it depends -- and Bob may be right. That in the world out there, we have lost the battle for access. We just may have lost it.

The irony of it is, in the olden days before we had technology, medical records people could pull out the little bit of the information you wanted, but you know, we may be beyond that. I am not convinced we are.

And nor are I convinced it is necessarily so bad to have to divide things five times, because it all goes to the expectations of developing the information. What is the medical record being created for? And then the question is asking: And then who gets it?

So that is why we have decided that we integrated the two in some ways.

DR. MURRAY: Zeke.

DR. EMANUEL: I am a little frustrated, and maybe I can put it -- we started out already talking about the fine words of legislation, and if that is where the discussion is, this Commission has absolutely no role, it seems to me.

Because for two reasons: One is that is not something we have any expertise in, the fine words of legislation. Second, if it is a train moving so fast, we certainly could not move that fast, and that was the real motivation behind my question about the framework and where we might come in.

It does seem to me, and I heard this discussion when we are

talking about very fine points about preempting state law, not preempting state law, what the criteria you are going to use, that, in fact, there really are bigger ethical issues or framework issues back there that may be Congress and the political juggernaut doesn't want to attend to. Maybe HHS can't.

But which, no matter what legislation gets passed, are going to rear their head probably in the interpretation of the weasel words, etc. that really does make a difference.

And I would just point to some that I have heard here. This issue of whether you have one broad rule or you identify suspect classes of information that require heightened or lessened information, I mean, it seems to me absolutely essentially.

And to lay my cards on the table, it seems to me there is no way, if you are going to recognize that you are constantly balancing values and interests, that you aren't going to make that kind of distinction. That some things require heightened scrutiny; some things require lower scrutiny. And that the idea that you have to treat it all the same, I just don't understand.

Second, I would suggest that that relates to the issue of the roles, what Karen just said about the fact that this stuff is used multifariously. You talk about the different players. It seems to me we can say something valuable about that, again, despite the juggernaut of legislation.

And I guess for our Commission, the point isn't -- the point may be where Congress is going -- but the point is, what is our marginal

value here? With all these other groups looking, and it seems to me, the marginal value may be -- certainly is on the first. You know, do you distinguish this information, and is it valuable, that distinction and the kind of protection we would want.

And I would say the other thing that we might be able to contribute on, and I would like your reaction to it, is the kind of balancing on these various different conflict points.

That seems to me pervasive in this kind of legislation -- it is going to continue no matter what gets passed -- and trying to help articulate exactly the framework for that kind of balancing and how we might do it in specific places might be helpful.

Having said all this, and this is my last comment -- I am sorry I am going on so long -- is it does sound to me like -- and here the question is speed -- we are not going to be that fast. We are not going to say anything substantial by June or August or whenever the Secretary is going to rule.

And so we need to take a slightly longer kind of perspective on this kind of issue rather than respond to all the machinations up on Capitol Hill and the political tussles about what legislation is going go and not go.

DR. MURRAY: Could we get -- Bernie, you are next. Do you want to have -- give Bob a second to respond to that?

DR. LO: No, you go ahead.

DR. MURRAY: Or do you ---

MR. GELLMAN: Well, in terms of process, I mean, my

question is that it is going to take Congress two years to get through this legislation, if then. It may take -- it may go into the 106th Congress.

MR. GELLMAN: Yes -- right. One of the things -- in terms of -- there is always this trade-off in any issue with legislation you are dealing with, you know, it is complicated. There are a lot of ramifications. You can't deal with them all. You have got to pick a slice of issues and do something if you think the time is right to do it.

Life has changed a lot since 1979. There are lots of new users of medical records that are completely unrestricted in how they use information today that doesn't exist in 1979. The situation has gotten much worse.

My political comment is that if we pass a bill and it only addresses three-quarters of the problem today and draws some kind of baseline, that is useful. And if you have to do more later on, that is always the case.

Let me offer another comment about some of the things that -- on that -- terms of the way the legislation that is sitting around now is structured. Because this issue of definition of information, what is subject to this bill, is very important. And it really goes to some of the points that you made and that Karen made.

The bills do not have a real definition of what is medical information. You can't define medical information, and it is really hard to define subsets of medical information, too.

There are lots of medical or genetic information that I know about everyone in this room, sex, hair color, eye color, stuff like that,

that is non-sensitive in a lot of ways. It is visible to the eye, and there is other information like that. You can't define things that way and say that is the universe we are covering.

What the legislation tends to do is to say, we know what medical treatment is. We can define that. Medical treatment is something provided by a licensed medical care provider, and we have definitions that we can rely on.

And any information that results from that, that is medical information, whatever it is. Some of it may be financial information. If you are putting things into boxes, you may put some of that information -- the bills don't make that distinction.

The same thing comes at the payment system. We know what payment for medical treatment is. Those two things generate information. All of that information is covered by these bills. All of that information is covered as it moves out beyond the payment and treatment process to other players, and it remains subject to the legislation.

But there is plenty of medical information elsewhere in society that doesn't originate there that is not covered by this bill. If I come in and say, gee, I am sorry I am late. I have a broken leg, or I have cold. I just disclosed medical information.

It is not regulated by this legislation, because you can't define it, and it is practically impossible to do that, as a matter of fact, to impose duties on people that you can't clearly identify. And so that is what the legislation does. That is the way it is structured.

Are there other ways to go about it? I don't know. I mean, I think this definition problem is extremely difficult, because you have to clearly define the universe and who you are imposing the responsibilities on. Otherwise the legislation doesn't work. You can't do that casually.

That creates -- that points to some of the problem about the difficult in dealing with this and dividing the world up and some of the practical problems of taking policy and turning it into legislation that people can implement.

DR. LO: I share Zeke's frustration in trying to think this through in sort of legislative terms, and I guess my reaction is similar. That I don't think that is something that we are going to be particularly helpful with regard to.

I want to go back -- I am thinking of what happens when I am wearing my doctor's hat and how does privacy and discrimination come up. I think there are distinctions that people make, and Karen made one.

That when you are asymptomatic and you are afraid that you have a lot to lose like your job or your promotion prospects by giving out information, you know, you care a lot about who knows what about you.

Once you are sicker, people are going to know anyway, because you are not working. You look terrible. You can't do the things you used to do.

And, again, to elect the AIDS example, there are clearly a lot of problems with trying to separate out HIV status as a specially

protected type of medical information in your tight definition that people care about in different ways.

I mean, all the way, people come and say, don't put that in my chart. And then immediately -- well, what is the purpose of the record?

Is it to sort of cover me so that the next guy who sees the patient doesn't think I am an idiot because I didn't do the right tests? Is it to help the patient if he should come in for another doctor encounter and not be able to relate the information personally? Is it for the organization? Is it for the insurer?

And it seems to me that we do make -- patients do make these distinctions and ask their doctors to make these distinctions. Maybe legislation -- you are right -- doesn't -- can't address that. But it seems to me that there are dilemmas that patients and their health care providers face that are going to endure almost whether or not that legislation gets passed.

I guess my question is: What do you do for the doctor and patient when the patient says: Keep my psychiatric records separate. Keep my HIV status separate.

You can say, well, you know, I have to put you on an antidepressant in your medical record. If you get it through your pharmacy plan, it is going to show up on your record. Then they make choices about do they pay for it out of pocket, and some people pay for it out of pocket.

What I miss in this large-scale legislation approach is the

sense that individual people value different types of information differently. And sort of your -- your denture example, I think, is a very, very good example of that.

And is there some way that the medical system can help facilitate those individual concerns about privacy rather than make it more difficult? Or should it? I guess that is the other question. Maybe we should just say, sorry, that is not the way our system works. If you are going to come to a doctor, you lose your privacy, and if you really care about it, don't come in, but then forego the benefits of being tested and being informed about these great new whatever, genetic discoveries or early diagnosis of HIV.

So I think there are ethical issues that are real-life clinical in this that, you know, we see all the time. But I am not -- I think you are right.

The legislation is not going to necessarily help with those sorts of issues. I guess then the question is: What do we do in this Commission?

DR. MURRAY: David ---

DR. COX: No, it is actually -- no, I would like to hear -- John.

MR. FANNING: I want to react to Dr. Emanuel's point. We are lacking in an ethical framework for making these choices.

Privacy work has been done by public policy people, lawyers, people who are concerned about the procedure, a HEW committee back in 1973. Then there was the Privacy Protection Study Commission. They all outlined procedural helps.

You had to be asked clearly whether your information could be used for something. But it didn't give much help in helping the individual to make a decision, well, is it fair to ask me for that information? Or for an institution, is it fair to ask that question? So it has been fought out on the basis of existing interests.

We, in HHS, have been at great pains to insist on the availability without patient consent of identifiable information for research purposed, under controlled conditions, you know, where it won't be used to harm them and so on.

But if I -- we have made that argument very seriously, and we have usually prevailed, because people sort of understand what is at stake, but only barely. But if I had to prove that in some philosophical framework, you know, we don't have a way of thinking about it.

One of the other difficulties is that the issue of whether it is fair to ask someone whether he has been tested for genetic disease isn't just an information issue. That then controls some other thing like how the cost of that illness is spread.

So, you know, you necessarily then have to face up to that issue if you are going to start making decisions about whether it is fair to ask somebody whether he has been tested.

One of the areas in which this is going to come up will be law enforcement. One of the areas where I think genetics is different -- and in most areas, I think it is very hard to distinguish in the medical context -- I tend to agree, Tom, with your outlook on that ---

However, when -- if you have a system like the armed forces

has for identifying the remains of people who were killed, we will come to a stage where a bit of tissue can be checked against that system without a probable identifier.

Well, should the medical care system be used for that? I don't know -- I would have no way of thinking that out. I think that is why we have commissioners of philosophers and theologians working with the physicians. So that is the help I am looking for.

Meanwhile, meanwhile, in the next couple of months, we have to come up with a proposal to the Congress that, you know, gives answers in the case of many of these trade-offs.

DR. EMANUEL: I guess, could I ask to rephrase what you have -- if you could tell us what our charge would be in this area, what exactly would you find beneficial? Not that we will do it.

I just want to hear from the HHS side -- you know, you have got a commission. You have got lots of organizations working for you already on the privacy/confidentiality area. What, looking at who we are, what would we add, again, that is value added to you? One of my concerns here is every time I hear the talk here, I don't know whether we are extraneous or there is something that we can do that is distinctive, again, within our mechanism of time.

MR. FANNING: I think there is something you could do that is distinctive, but it may not feed into the legislation we are now designing. But I don't think that is a reason to stop, because the issues will continued and will get worse. The law can be changed later and so on.

Well, I think one of the issues is the extent to which health information can be used for purposes totally outside of that system like law enforcement, or whether your use of the health care system can be used as a method of finding you.

Take these huge pharmacy benefit systems, nationwide systems that can tell whether -- you know, that record what prescriptions have been given. You know, would it be fair to use that system to find someone?

DR. COX: For what purposes

MR. FANNING: Well, for -- that is right, for different purposes, ranging all the way from ---

DR. MURRAY: Child support.

MR. FANNING: All the way from a brutal kidnapping through conventional crimes through child support. That is right. That is the kind of thing.

And, for example, the law enforcement community would like to use pursuant to its own ethic, and you know, certain social goals that are clearly desirable in the abstract, would like to use systems like this for those purposes.

These things get fought out on the basis of, you know, how it will look to the public and so on. Not on the basis of any clear articulation of issues.

MR. GELLMAN: Can I offer an answer to your question?

DR. EMANUEL: Great.

MR. GELLMAN: I am going to answer this wearing my old

hat as congressional staffer. I mean, my job was then to develop a bill that could pass, and in doing that, I am looking to deal with, you know, the political and policy realities of the world and what is practically doable.

But at the same time, I turn around to the academic community, to whatever sources there are, is there a framework for what we are doing? I mean, I can sit and write procedures.

But if someone can offer me a nice, you know, elegant framework or philosophical approach to something that allows me to structure what I am doing and explain it to people well and to solve some of the inherent conflicts and problems that come up all the time, that is very useful.

Even though the legislative process may be going on and may lead to something successive, no one really can say that that is going to happen. There is always room for somebody to take a step back from that and say, we see the bigger picture.

We see relationships between your narrow bill, and even though it may be a 100-page monstrosity, it is still a narrow bill in terms of, you know, the whole scale of what is going on in the medical care system, in the medical payment system, in the information system involving personal information of other sorts.

And, you know, that broader view from a distance is always welcome. If it doesn't feed into the immediate process, it may feed into the next part of the process, and it may help us all understand what we are doing.

DR. MURRAY: David, Bernie, and Karen.

DR. COX: So I must say that that is my own prejudice in terms of coming up with the framework. Because we are going to have specific things that have to be dealt with.

Just like we were talking earlier this morning about a specific issue with respect to stored tissue samples, but that is not useful, okay, really outside the context of a broader framework. That is my own feeling about privacy, although I don't know anything about it. You know something about it. You guys know something about it.

But if we can't have a national framework about it, then when we deal with the one-off things, they won't have any meaning. So I would hope that this Commission really could, in the context of these specific issues, try and frame the general issues of privacy.

Because they are complicated, but I don't think that they are -- that you can't come up with big sort of issues that can be framed. That is why when you initially said -- I picked up on that very fast -- that it is no longer dealing with the framework, but it is the feeling of the specific words. I mean, I think probably not.

I mean, in the context of these bills, it probably is, but I certainly think that it can't be in our country with respect to privacy. It just doesn't make sense, or at least if it does, I haven't seen the framework written out.

DR. LO: Yes, to sort of continue this, first, I guess I would ask -- agree. Someone needs to provide the big picture framework.

Given all that is happening on the legislative front, is that

best done by a commission like us as opposed to a law professor like Karen or a philosopher like somebody else to later on look at these bills and sort of line them up and say, what are the underlying premises that may be hidden or unspoken?

I guess, to go back to the criteria Zeke was laying out before, it would be constructive to do that in some sense, but how much impact would it have on policies that are going to be developing anyway.

And do we want to put our efforts into sort of longer-term, sort of basic research, so to speak, as opposed to things where there is a ripe question, these samples in limbo or purgatory, it seems to me. What happens to those samples may, to some extent, depend on what we say.

Whereas I get the impression that what you are saying, no matter what we say, certain things will come out of your commission. It will be then passed on to HHS, and it is not clear that other than to sort of help people understand they were going to do otherwise, and to sort of tie up some loose ends that otherwise are a little messy, that anything we say will feed into that process in any direct way.

MS. ROTHENBERG: Okay. I think there is a lot you can do in this area. And it is not really -- we haven't really discussed it yet. So could I maybe name some other ones.

Actually, we currently discussed it, because I think Bernie was sort of handing out -- and then I wanted to pick up on what John said and then maybe move us in a broader direction, move you all in a broader direction.

Except most of the privacy focus on use and misuse is how are you going to get hurt by the information, by a third party? So that is the connection that we have seen about who gets to see it and who doesn't get to see it and why.

There hasn't a lot of good work, and John and Bob, correct me if I am wrong, beyond a lot of these traditional things like insurance and employment, there are many exceptions in state law for medical privacy, and the few that have genetic privacy, for things we haven't done any study on.

For example, not much on law enforcement. But the use of this information in tort liability cases, in civil litigation, in adoption, in custody -- I mean, there has been some stuff out there. But sometime just like boilerplate exceptions, that in a criminal investigation, or is it a white collar criminal investigation, or is a crime where the DNA has any relevance?

And the implications in plea pardon and in whether you bring a lawsuit and what implications that information has for other family members do maybe raise unique issues for genetic privacy.

My decision to bring a lawsuit if I have been hurt in the workplace or if I have been injured, if I know that they can not only get my records but my family's records, that might mean I don't bring that case. You have so much subpoena power right now in the courts for getting information that you deal with a little bit in the law, but maybe genetics raises those issues.

That brings me to the second theme that I think we need so

much more work on, and that is, the question of changing or not changing the paradigm. Is privacy autonomy based when you are dealing with genetics? Or is it different? Is there a communitarian view of a responsibility to share information or not share information when it involves more than the individual?

And, yes, there have been committees that have looked at this, but what is the underlying principle in genetics where geneticists, on the one hand, think there is a lot of value in this information and encourage individuals to share it with their family, on the one hand.

On the other hand, they are saying, don't tell your insurance company or your employer. Don't share it with them. Well, once you open up and go beyond this individual autonomy model, which has been our traditional paradigm in health care, and you have a model that says to individual patients, I am encouraging you to tell your siblings, tell your parents, tell your blood relatives, what does that encompass in terms of privacy model in genetics that you may or may not decide is different than contagious diseases or just any medical diagnosis?

I mean, there may be a reason to say, you should share this with your family and spouse just because they will give you support, or maybe you shouldn't share it with anybody, because the risk of losing your family from this information may be much greater than the risk of losing your health insurance. And for large portions of the population, it is.

I don't think there has been an attempt to bring privacy in that broader sense together, looking at the different categories. I don't

think that part is ripe for legislation. I don't think we want to trust our state or federal legislators.

But, boy, it would be helpful if we could have some ethical paradigms to start sorting that out. And that is an area where genetic privacy may be different. It may or may not be. That would, I think, support some of what John and Bob are saying but get beyond on a longer-term framework. That would be my plea.

DR. MURRAY: We are having a queue going here. Rachel wanted to say a word, and Larry and Zeke have wanted to speak. Did I miss anybody? Rachel.

MS. LEVINSON: I would be remiss in not reminding people of the original charter of NBAC, which is to look and make recommendations and provide advice on issues related to the ethical conduct of human biological and behavioral research and the applications of that research, which is somewhat narrow except when you talk about the application of that research, and you also consider that the intent with which the information was collected is almost arbitrary in the sense that if it is collected for research, it can still certainly be used for discriminatory purposes.

So that opens the door to the consideration of the issues that you are talking about right now, which are certainly very vital and on the table.

Having said that and gotten that out of the way, I would also say not to sell yourselves short in terms of thinking about your impact or potential impact or the limitations of your deliberations on the regulatory

or the legislative components.

That the information that you have, the discussions that you are having today, and forthcoming, would certainly be useful both for the Department of Health and Human Services and in the broader legislative arena for bringing up issues, I think, perhaps haven't been considered.

I would just ask that you keep in mind the implications for research and that some proposals that might seem particularly appropriate in a broader medical setting might have implications that feed back into the research setting that you should keep in mind when you make them. They could be different.

And the example we talked about earlier this morning, about tissue samples, is one where that particularly is -- (inaudible).

DR. MURRAY: Larry.

DR. MIIKE: Rachel said one of the points that I had wanted to make. Because I think in my written communication with you, I had expressly talked about -- perhaps we should comment on assisted suicide, but that seemed to be outside of our charter, but groups such as ours are going to be looked toward to make some kind of social comment on that. But I agree with Rachel.

I think the way to deal with this is that I certainly don't want us to have an ethical viewpoint that changes depending on the topic that we look at.

So I think that the kinds of issues that are raised -- what Karen was just mentioning about individual acts versus societal responsibility, those kinds of -- they are going to come out even when we

look at something relatively mundane like the -- your purgatory category.

Because when we look at those areas, we are going to be balancing the need for an individual's right of privacy in a particular area and maybe some overriding kinds of consideration. I would be willing to bet that how we come out with that will be directly applicable to the areas in here.

So it seems to me that we can both meet the confines of our charge and still be responsive to these kinds of issues as long as we keep that in mind that the principles that we develop are going to be applicable in these other areas.

DR. COX: Tom, to extend that to something that Karen said that we haven't talked about yet that I am actually very concerned about, wearing my genetic scientist hat now, is exactly how much information genetics really gives us.

Because part of this -- by putting genetics out special -- it implies that, you know, it is really special. It really tells us something special. And I would really like to see us examine that. Because, in some cases, it does, just like any class of information. Sometimes it really tells you something special.

But how often is it that people use the information sort of pretending that it tells you something special and acts on that when there isn't any really information content there at all. I am very concerned about this, what genetics predetermines.

So that maybe we lose our families, but not because of any substantive reason. It is because of the perception. Even though the

information that is implied to be there isn't actually there. This is a great concern to me in separating genetics off.

Because I think that our society has this view, and it has been promulgated by both society and geneticists that somehow there is this really razor sharp type of information that comes out of genetics. I, for one, think that those kinds of razor sharp situations are few and far between.

MS. ROTHENBERG: Can you give an example?

DR. COX: One of the best examples would be to look at a particular polymorphism in your blood group type, in your HLA type, that will tell you something about whether you are going to get diabetes or not. Right? It does give you some information. Okay? It is a statistical correlation.

But what gets transmitted to the family is you are going to get diabetes. It is determinism. That is very much a philosophical and ethical point. I just would like to make sure that that goes in our framework. Because we are talking about genetics as a -- already this is information. Well, there are different types of information.

I think that what you want to protect has to do with something that really has power. Information by itself, okay, you know, it is different types of power. If we just say genetics, that sort of implies, well, if it is genetic, it must be powerful. It is not true.

DR. MURRAY: Let me make just one comment prompted by David's remark about the role, particularly of this subcommittee's work on the Commission.

I think this is a -- not just a country, but a world sort of struggling to figure out what to make of genetics and what role genetic information, genetic technologies, etc., will come to play in our lives.

We have the widely remarked gene of the week phenomenon on the science pages of the larger newspapers. I suspect this Commission, and I don't want to be grandiose about it in any respect, but I suspect this Commission can play a role in helping this country at least come to terms with -- with understanding genetics.

Whether it is something that ought to be domesticated and come to be seen as not, you know, radically different, although it has very interesting implications that may be distinct from other kinds of information we have about our health or our identity, etc., or whether it comes to be seen as something that is, in some essential way, distinctive and different from other things about us, people who read my writing know where I try to come down on this.

DR. COX: Tom, can I ---

DR. MURRAY: But I just think we will play -- we may, in fact, play a role in that. That will cut through all the issues that we are going to be doing.

DR. COX: And to extent that even further, again, past genetics, that is my view with respect to this "research and science" with respect to society. Because I think that we think of research as being experimental. Lots of people do.

But yet if you think of it, change the framework and think of it in terms of information gathering, then that is an extremely different

framework about all of this is used. That is where I am coming from. I just don't know, okay, if our country is coming from it that way. But I would like to find out.

DR. MURRAY: Zeke and Carol ---

DR. EMANUEL: It seems to me that -- and I want to contrast a little to our discussion about the tissue sampling and the privacy and confidentiality -- it seems to me that the tissue sampling issue, there is a framework, if not exactly agreed by everyone, at least somewhat in place. Part of the issue there is solving a problem and making some judgments that can probably be effectively implemented in regulation

It seems to me the privacy/confidentiality, there are going to be regulations, but probably our contribution could be to put a big framework, a big term on this, which I am not sure it will bear it, it is really sorting out the social meaning we expect. How the balances come out in these various different areas.

That is a much broader, longer-term perspective. It also means it is a lot harder in some way. Because it is hard to -- I mean, as we have been talking here, just the number of things we have flown through that I find mind-boggling to try keep in our mind when we are trying to get a coherent view -- tort law, liability, adoption, law enforcement, the Defense Department, and we haven't even talked about medicine yet. You know, claims processing, pharmacies, and all of that.

It seems to me one of the problems is even to articulate a coherent view in that -- I mean, that range, at least in my -- hasn't been done.

The regulations are sort of going off probably even without even attempting to do that, and maybe what we need to see in this area is an attempt to try to be coherent about the way we view information generally with maybe a particular focus on genetics to explain why it is the same or different in particular areas.

That, it seems to me, is an enormously complicated -- and as valuable -- I mean, it complication is because it is so valuable and it is so complex, interwoven with so many aspects of our society.

But that is the way I at least would try to understand that, and I think, in that way, we should try to sort of quaintly (?) observe what is observe what is happening in the regulation area, but not be too preoccupied by it and try to really take a big, broad picture.

That also tells me that the timeline, while this is a very urgent -- the constituency is quite broad, since the whole country, the whole world probably, is very interested -- the timeline is much longer. It is just too hard mentally, I think, to, in any short way, get your brain around it.

DR. MURRAY: Karen.

DR. COX: But doable.

DR. EMANUEL: Yes, well of necessity. Someone has got to do it.

DR. MURRAY: Karen.

MS. ROTHENBERG: I just wanted to -- not to further depress you perhaps, but I am sorry I missed part of the tissue sample discussion, and it probably came up, but if not, this whole question of

the social meaning of genetics is relevant to tissue samples, because it becomes relevant to anonymized and anonymous tissue samples.

That our paradigm at present in research is that if the individual cannot be identified they don't have any real interest, and there are communities in our country, including the Native American community, as well as other communities, perhaps now the Ashkenazi Jewish community, with the recent research being done on BRCA-1 and 2, that believe that even without our name on it, a group is identified.

Depending on what the social meaning of all this means, and the history in our country of just by the very nature of genetics identifies certain ethnic groups, that really is relevant to tissue samples.

I would -- you may have already decided this -- I don't know -- I didn't see it in your construct -- maybe what David was trying to say is that you really think that one through. Because that will have an impact on how comfortable you are with these categories that have been developed.

So I encourage this idea of social meaning, but I think you have to think about that even when you are doing tissue samples.

DR. MURRAY: I think that is incorporated in the kinds of things -- propose to be done about tissue samples.

MR. ROTHENBERG: Good.

MR. HOLTZMAN: Do we keep inexorably coming back to the question of whether genetics is special? That it informs everything that we do. And then whatever we may believe is the right or wrong thing to do with this class of information -- is it special, you know -- or is it tied to

a broader class?

DR. MURRAY: If we avoid it, I think we have been -- if avoiding is necessary, we have been extremely unsuccessful.

(Laughter.)

MR. GELLMAN: Could I develop a couple of points? You know, if there were an advisory committee meeting 90 years ago to talk about the consequence of the development of the x-ray for creating new kinds of information and predictions about what people's futures were going to be, you could apply at least some of the same concerns and fears about the new technology to that that you apply here, and yet the x-ray was integrated into a less formal and less complex medical system rather routinely, I suspect, over a long period of time, and everyone got familiar with it.

That may be the case with genetics. I am not sure about that, because the parallels fall apart pretty quickly if you look at it. But there is still an interesting comment there.

I want to offer a broader picture, sort of building on what Karen said, and this may go beyond your scope, but it is not something to be ignored.

The creation and collection and compilation of personal information about people is going on apace everywhere. Government does it. Private sector especially does it. There is almost nothing that people do today that doesn't leave a trail of some sort, an identifiable trail.

Those of you who came here from out of town, the airlines

know where you started and where you went. Your travel agent knows that. The hotel you are staying at may know things about you like whether you had a smoking room or a non-smoking room and what you ate in the mini-bar, and all this information is being compiled.

People know what you buy in the supermarkets, what you charge on your credit cards. There is all of this information. It is unbelievable the amount of personal information that is out there and that is being bought and sold routinely in the private sector. It is being compiled in one way or another in government files. We are dealing here with simply another set of information, and the comment about it is not necessarily just an individual thing. It may be what group you apply to or census data may not be identifiable.

But you can find out from the census bureau what the average income of everybody on your block is. If I want to target people to buy a Mercedes, I want to know that their income is over $100,000. That is the block I send the junk mail to.

Anyway, all of this is going on, and none of the information pieces are necessarily being all that clearly related, one to another, but everything fits into this broader picture. Or the medical information and the genetic information are also -- fall in that category, and they are also trafficked in to a certain degree in the private sector.

I don't know what to do about any of that except it is happening, and it is a much broader framework for all of the discussions that go on about privacy of any sort of information. It is not just one class of information out there by itself.

There is an enormous picture of everybody, the details of their lives are floating around out there uncontrolled and unrestricted in many respects.

MR. FANNING: Well, can I just add something to that? One of the questions is: Is medical information, or information gathered in the medical care process, somehow different, you know?

It is perfectly proper for the cops to use the airline records, the American Express, your toll call records to find the fugitive. Is it proper to use the pharmacy benefit system for that purpose? A very basic question bout the medical system, and it might be different from the airline system, or maybe you will decide it isn't.

DR. COX: So to take a crack at a structure, just for me -- I am not a philosopher -- but it strikes me that this tug of war between personal autonomy and social responsibility is a pretty good foundation. You don't get much down lower than that. So as a start, we have got that. That is not going to go away. It is going to permeate everything we do.

So then if we say that somehow we have to adjudicate that and what I am hearing, and where things are right now with all this information, what the information does is that -- and you said it, I think, very nicely -- is that if this information is good, and we are getting it out to everyone, then why is it that we are trying to keep away from some people?

Well, it is because it is this tug of war between personal autonomy and public good. It is that people should buy into the public

good, but then it is not -- but they are not autonomous any more -- but they need to be protected against bad stuff happening to them.

So what is the bad stuff? Because I think there are very few people that wouldn't contribute to the public good -- that is why we live in a society -- if they weren't fearful of bad stuff happening to them.

So if we could identify what people think is the bad stuff and then figure out, okay, as John brought out, issues of fairness. What is fair? What is right in terms of doing thing?

Then that is a framework within which we could discuss this. Because I don't think you need to be -- certainly, from a philosophical point of view, this doesn't wash -- I mean, I understand. Right?

DR. EMANUEL: No, you are right.

DR. EMANUEL: I will say -- the President's Commission had tried to look at confidentiality. They made a few steps, and one of the steps they made, many years ago, was to actually ---

Henry Richardson, who then was a graduate student in philosophy, wrote out, trying to exhaustively compile, intrinsic as well as sort of instrumental, values related to privacy and confidentiality on both sides of -- I am trying to get his paper now. Make him dig it out of his files.

But that, it seems to me, one of the places we have to go. What are the values that we need to weigh, and how do they play out in some of these circumstances? We can't do it across the whole spectrum of all information of all time, but we can ---

DR. COX: We could do it with genetics.

DR. EMANUEL: We could focus on paradigmatic cases, it seems to me, and you know, particular types of genetics, maybe as genetics relates to law enforcement or other cases.

DR. COX: But it doesn't necessarily make genetics special or not special. Okay? It is a different framework within which we are considering it.

DR. MURRAY: About a half an hour ago -- I am just trying to sketch out some of the questions that we need to ask -- I wrote: Why is privacy important, which I think is on the line with what you said?

Let me complicate the picture a little bit more. You had talked about the distinction between sort of individual autonomy and social responsibility or public good.

One of the interesting things that is true about genetics that may or may not be true about some other kinds of information is that, I think, there are at least two intermediary levels. One level is family. Genetics implies family in ways that not all kinds of information implies.

And, secondly, genetics implies communities, populations, as geneticists would define it, in ways that together information may or may not imply. I am not saying it never does, but so it becomes -- it is not just me. It is not just me and my immediate family, but it is me and other people who come from similar ethnic background.

So that is why the business of BRCA-1 and the Ashkenazi community is particularly poignant -- (inaudible) -- other communities. There are other communities who become sort of implicated in certain ways with genetic information that may or may not be true of other kinds

of information.

MR. HOLTZMAN: I think what would be useful -- I keep talking about the issue of genetics, is it special or not -- is maybe to throw that out.

Do we conceive it as -- with respect to certain kinds of classes of biological information, what are the characteristics of it, be it genetic or other, that raises these questions? You were just pointing at it. Biological information which has the following characteristics. That it can tell us about another. That it can have implications for another group.

We may end up discovering that that casts a very -- we will discover it casts a very broad net. Okay? But that is an important discovery, and for those of us who want to dig their heels in and say, genetics information is not special, it is because of a stance where we are afraid of the implications of culling it out, leading to genetic determinism, genetic exceptionalism, which we think is highly offensive and problematic.

Personally, I think, starting a discourse going like that itself could be a service this Commission could serve.

DR. MURRAY: Yes, and I think some of the -- to me, this is leading me to the conclusion that anything that we can do to give a kind of fresh look, different perspectives, opening up the kind of conversations that have been going on thus far.

I think Bob has been helpful in that with your first example, the virtue of a well-crafted example of the person who came in with a

genetic disease, HIV, and on Prozac. There was another one in there.

We need to open up the conversation in a way that I think people may have made efforts to start, but we could push it. This Commission could potentially help do that.

DR. LO: The questions that we are asking are often framed by Tom's questions, partly because I think when you talk about law and regulations, it is either going to be specially protected or it isn't. The problem is that it is not that simple.

DR. LO: Under some circumstances, clinical circumstances for some individuals, the same piece of information may have special significance and may not under other clinical circumstances for other individuals. I think part of what we are trying to get at is that if you are vulnerable in other ways already, i.e., you are sick; you are worried about your job; you don't have any alternatives; you really need to bring that civil suit. You may feel your choices are constrained and that you may feel that things are really out of control, and you will be hurt even further.

So I think that, you know, that part of the problem is that we tend to say it either is or it isn't. It seems to me that is not the answer.

Sometimes it is and sometimes it isn't, and we need to look at what are the circumstances that make genetic information or any other type of medical information particularly sensitive.

And can something be crafted, probably not -- some legislation or regulation, to afford either protection or options for individual patients or groups of patients who are particularly concerned

about certain information?

DR. EMANUEL: Along -- I mean, it seems to me that the way to relate that to what David said is that under some circumstances the balance changes even for the same question depending upon your risk to harm, etc.

DR. LO: Absolutely.

DR. EMANUEL: And the way I think about this, and people who know my -- I mean, it seems to me that this is a mosaic and that the information and the balance you might do changes, and the colors, say, would change just depending upon the background and where you place it. Who is going to have access to that information? And which piece of information it is.

That is -- it is kind of filling that in that is going to be, you know, what we might be able to make a unique contribution on.

DR. MURRAY: We are at a point -- it is about 5 after 11:00 by my watch, which tends to run slow. My father is a watchmaker, by the way, and he will fix it over the holidays.

We could -- should we try to wrap this one up over the next 10 minutes and decide what we think about it, break for lunch a bit early -- is the cafeteria open? Which would give us -- come back -- and would give us some added time in the afternoon when things are -- the agenda is more compressed.

All right. Let's set that as our goal. What might we then be thinking about concretely about doing?

DR. GREIDER: Can we really wrap this one up without

dealing with what we are going to deal with in the next session? I mean, to me, again, they ---

DR. MURRAY: These are all interim wrap-ups. What do we want to say about it thus far before we hear the conversation that is going to take place after lunch? Are there specific things that we actually would like to get the staff of NBAC to begin to put together? Materials we would like to have compiled. Papers we would like written. Studies we would like to see done.

DR. LO: Well, we keep coming back to this question: In what way is genetic information sometimes special? It would be nice if someone sort of tried to compile what the current thinking is on that.

What have people said? And have people tried to identify certain characteristics that allegedly make it special? And what are the counter arguments and the rebuttals and so forth?

DR. COX: And to carry that even further. You mentioned it yourself, Tom. The utility of specific examples. So that almost always in the case of what makes genetics information special gets into how does it screw people over? Well, we would like to know about that.

But we would also like to know why some people want it in terms of how it makes them -- how it helps them. I think examples on both sides would be really useful.

Because making it special -- so it is not just helping, you know, the individual, but how is it special in terms of a positive and a negative benefit with specific examples?

Because then we start getting into this intermediate level,

you know, of specific things we can weigh. What are the situational things then and weigh between autonomy versus social good.

DR. LO: So it would be helpful to try and find an example where a lot of people have argued that the individual who is tested really has an obligation to disclose to family members. So that would be one sort of extreme.

Another set of cases -- an example would be situations in which highly valuable clinical information is foregone because people are so concerned about the discrimination consequences and how that is played out.

MR. HOLTZMAN: You know, I am going to repeat something I just said, because I ask people to consider it.

I think we could compile the historical dialogue of why it is or is not special, and I think what we will be left with at the end, there will be a group of people who will point at it and say, but it is genetic. Okay? That is where the argument often ends.

And I am wondering if having compiled that, the more constructive step we could take is to then instead go to the issues, which is what you are pointing to, and ask the question: What is the nature of information -- of whatever kind. Don't call it genetic. Don't assume that there is this thing that is genetic information as distinct from biochemical information, as opposed to anything else. And ask: What are the kinds of information which might be compiled with respect to a person where these engines of concerns get rolling.

Because I think that will then lead us to where we think

issues of privacy and protection against discrimination should be centered, namely, in terms of the content of the information.

DR. MURRAY: Karen, you have a pained look in your eye.

MS. ROTHENBERG: Yes, because I was a little pained -- what Bernie said about the example -- if I could just beg to differ.

That you don't want to trap yourself into a medical model, because the decisions about whether this information is of such medical value have to be looked at contextually, not just if it is going to be of medical benefit to other family benefits, but also what else it means.

I would like to support this idea about the nature of the information, because nobody has really brought up behavioral genetics yet, and you know, you could set out your paradigm that looks really attractive when you are dealing with familial polyposis gene.

And the paradigm looks a lot different when the NRA is saying, maybe we should start doing genetic testing on African-Americans, because, you know, that is better than gun control

DR. MURRAY: Are you making that up?

MS. ROTHENBERG: No, it was in The Washington Post a few months ago. So, I mean, that is a whole area of what is the nature, what is the value, and what has been the historical views of phenotypes, never mind genotypes. I don't want to lose that idea in terms of a concrete model that the model goes way beyond the medical model. Do you want to defend yourself?

DR. COX: He has rolled over.

DR. LO: No, but I think ---

DR. MURRAY: He wants to defend the NRA.

(Laughter.)

DR. LO: You may have -- you may feel -- people may argue that an individual has an obligation to disclose genetic type information not for medical reasons, but for a whole lot of other reasons. It seems to me there that tension between individual autonomy versus social obligation tips in one direction.

And it seems to me some of the most poignant cases are where you think there is a clear-cut benefit, which often is a medical benefit in terms of earlier diagnosis, better treatment, but that the patient doesn't think they can actually afford to get that because of the downstream consequences of losing insurance or losing a job. It seems to me ---

MS. ROTHENBERG: Or losing a spouse or a family member. I am -- okay -- it is not just discrimination.

DR. LO: Right. Okay. But it is usually the benefit is -- I mean, if this genetic information is going to be valuable, it seems to me, is the promise that clinically it will improve the lot of those who, you know, can be diagnosed and treated.

And if you have a case where the benefits in that sense are emerging, but for a whole lot of other reasons, whether it is discrimination or loss of social relationships, people don't choose to take advantage of those medical advances, then it seems to me why are we bothering?

MR. HOLTZMAN: But there can be benefits in terms of life

choices as well. I would support ---

MS. ROTHENBERG: Not much empirical data.

DR. EMANUEL: But it seems to me that we -- I don't think this is a substantive disagreement.

MS. ROTHENBERG: Yes.

DR. EMANUEL: If we ---

MS. ROTHENBERG: I think -- right.

DR. EMANUEL: If we are agreed that, you know, that we have this pyramid, and there is interlock between the medical information and all the other kinds of information in the social sphere, we are going to find out that, you know, we might have an example that is useful in the medical.

But certainly, when we peel it away and begin to elaborate it, if it doesn't have these other implications, we have chosen the wrong example for probably all sorts of other reasons.

DR. COX: Karen brought up behavioral genetics, which is a really interesting one. Because I think that there are lots of people who want to use genetics way outside the medical model for lots of social reasons. Medicine is social, too. I mean, that is why we do medicine.

So it is what these social uses are versus the individual uses. It is always -- I mean, to me, it is constantly the interplay between those things. So you look at the type of the information. There is going to be different types of information. That is what you said, Steve. I completely agree with that.

It is just that if we use all information -- genetics is just -- it

is not we are using genetics because it is special information, but we are using genetics because it is a class of information, whether it is special or not. But it allows us to come up specific examples.

Because there is different types of genetic information. But if we don't narrow it to -- I mean, we are the Genetics Subcommittee. Right? So, I mean -- because we are looking at it doesn't make genetic information special. So I think ---

DR. EMANUEL: Well, part of it, we should be able to relate it to the broader context, because we are the Genetic Subcommittee. Part of what I have heard here is that if we don't do that, we will have failed.

DR. COX: But it is just a vehicle. It is a vehicle so that we can narrow down, okay, and be able to get some specific examples of type of information. Otherwise, as you said, it is so global, where do you start? So it is a way of starting, but it doesn't mean we have to be narrow. It is a way of starting in a very broad context.

DR. MIIKE: So where are we?

DR. COX: I will recapitulate it. In my view, it is coming up with types of information that have a genetic component -- one way or another, whatever that means -- where it is used for in a perception -- that information is used to the good, and then what is the relative -- is it for the individual good, or is for society's good?

And then examples where that information is used to the detriment of either society or the individual, specific examples. We have lots of examples out there in the context of genetics right now: behavior

genetics examples, single gene examples, complex disease examples.

The different types of examples really go to their specific predictability. So I think you can slice it -- this is going to be hard for the staff to do, though. That is the problem.

DR. MIIKE: I don't think we should be using concepts like "good," because even the ones who are, from our individual perspective, is the most devious means. From their perspective, it is a good. Or why would they be pursuing it?

DR. COX: Benefit. Exactly. That is really what we are talking about is the -- where the consensus on that lies. Because you are going to have different stakeholders.

Some people will say, well, wait a minute, you know, that is bad. And somebody else will say, it is good. But I think that there is some examples that are more clear-cut than others.

DR. MURRAY: I hear possibility of three things we might ask to be done. I am not nearly as clear on these as I was on our first one.

One would be something in -- a background sort of paper -- why is privacy important? You referred to Henry Richardson's work of years ago. I don't know. There are a variety of people who could write this. I have some names, and other people might have some names. But this would be a conceptual paper. Just why is privacy important?

The second piece is this -- we are going to visit the question of is genetics different? And it has been suggested that we commission someone to go out and look at all the arguments and array them and

evaluate them and look at the rebuttals, etc., and a paper of that sort. That is another conceptual paper.

And the third, and I am the most fuzzy about this, is some collection of examples or cases of instances which we think are -- or at least are thought to be really good uses of this information, appropriate uses, and the issues which we seem to be most worried about, some of which will look like genetic discrimination, but some won't. Some will be cases where families are split.

Is that -- am I right? I don't know how to do the third.

DR. COX: Could I try to reformulate the third?

DR. MURRAY: Yes, please.

DR. COX: Because I agree with you, Larry. Good and bad isn't the way to do it. Of different classes of uses of genetic information and different types of that information. It is not an exhaustive listing of it, but some ---

DR. MURRAY: Examples.

DR. COX: Some examples to get started.

MR. HOLTZMAN: Actually, I think this third enterprise is constitutive of the second. You can't do the conceptual analysis without writing -(inaudible) is the product of the one-sided diet of examples. That has happened too often in the area of genetics. So you have got to plow the cases to get at your conceptual analysis.

DR. MURRAY: Anybody -- I don't disagree with that. I had -- in some cases, the analysis would include some description. But would we want to have sort of richer cases that would -- we would just plumb

not knowing exactly where they would lead us? Bernie.

DR. LO: I am always one who likes to start with cases and then sort of see what frameworks sort of emerge as contenders for the way we think about them rather than starting with the theoretical framework, which may be totally divorced from the real situation.

I would suggest that those of us who are on the panel who have some special expertise take the lead maybe for the next meeting in developing either cases or identifying situation, or someone else that has really thought about the particular issue, and sort of bring a couple of sort of live cases to us that we can read about and then hear about and discuss.

In the discussion, we can then address other questions about why is privacy important in this case? You know, in what sense is genetic information special in this case?

DR. COX: Just a couple of examples like that.

DR. MIIKE: Bernie, I would especially ask for someone to give a good try at bringing a case that showed genetics is a special case.

DR. EMANUEL: Is or is not?

DR. MIIKE: Is. Because we are leaning toward that it is not a special case. But I would like someone to try to give me a case that tries to prove the opposite.

DR. MURRAY: Most of the literature seems to take the view that it is different and special. So ---

DR. EMANUEL: This panel has been preselected, unfortunately.

DR. MURRAY: Well, whatever.

DR. COX: Tom, could I make a comment about that. This is sort of an aside, but something that has really -- (inaudible) -- particularly in terms of our -- all these pages.

In the past two years of my sort of delving into this area, where I came with no knowledge at all, I am really struck by how many different commissions and panels and things there are. And it is always the same people. So that although there may be lots of different views, it is ---

DR. : Have you been on them?

DR. COX: This one is different. That does make this different. I am not necessarily saying that that is bad or those people aren't really smart. All I am saying is it is a very limited number of people that always show up. Maybe they are the only ones that care.

So it makes me think that our knowledge base isn't really broad in terms of the numbers of people that are thinking about it, or at least have written about it.

So I just wanted to point that out, because it makes me nervous, and I think that this area isn't so different from anything else in life. As I think, in many areas, there is very few people, you know, who are always out there telling us about things.

But the broader this group can make that, the happier I am going to be. If we can enlist more brains thinking about it, and I think just the fact that we have a ---

DR. MURRAY: Just two quick responses. One is the report

will be a Commissioner report, and the people on the Human Subjects Committee, who may not be so identified, will have an equal voice in what we say. That will be useful.

Second, I presume that we are going to get Commission papers and all not written by members of the Commission, but by people who may or may not be the usual suspects, but certainly would have a diversity of viewpoints. And I hope that will go part of the way to satisfying your concerns.

DR. EMANUEL: I want to go back to -- I work a little different than Bernie, and I don't actually like cases, as Bernie knows. I always start out with the framework first and then look for the cases that help me elucidate some things.

We actually -- I have been working on some of this confidentiality stuff apart from the genetics area, and I would be happy to at least bring some of the framework. It may not apply. People may not find it helpful in terms of looking at some of the cases.

But I think -- my own view is that this is a very big, ungangly problem, and I think genetics is going to help us a little bit. But, again, we have a big mandate for -- you know, in terms of all kinds of research, biomedical, clinical stuff. So I would urge us not to restrict ourselves.

DR. MIIKE: I suspect that since world is not black and white, even though I like to look at the world as black and white, that we will -- the ultimate question -- or the ultimate issue to resolve for us -- is that there are differences in genetic information.

But what does that mean? And do we carve out special

procedures or whatever you want to deal with it in those particular instances? Are they important enough to be treated differently from how you treat general information?

DR. MURRAY: This person has been patiently waiting.

DR. SOBEL: Let me add another point that maybe strengthens what Rachel Levinson said before. If the focus of your Commission is on research, then address the issue of how much research information winds up inappropriately in a medical record. In most cases, it probably should not at all.

And what safeguards can you recommend we put into place to prevent research information from being put into the medical record?

MR. HOLTZMAN: I would -- remind us -- there were two charges to the Commission. Rachel read the first. The second was attention to consideration of issues in the management and use of genetic information.

DR. SOBEL: And that is correct as well.

MS. LEVINSON: That is the second. The overall is research, and the two issues within that research heading were human subjects and use and management of genetic information as it relates to ---

DR. SOBEL: There is a big distinction between research information and research studies and what is a clinically relevant study for the purpose of genetic information and of medical information that would wind up in a person's chart.

DR. EMANUEL: Can I make two responses? One is --

Rachel, maybe you will correct me if I am wrong. We actually had -- the Commission had more purview in deciding its -- that was its charge, but its charge also included the fact that we could define issues for ourselves that went beyond the genetics or the human protections for research.

MS. LEVINSON: Those were the first two that were ---

DR. EMANUEL: Right. But we do have the authority to expand things. Isn't that correct?

MS. LEVINSON: Still within research.

DR. EMANUEL: And the second -- well, okay. And the second one goes to this issue. I think, and I would venture to say this is my view -- I don't know how the committee -- the rest of the Commission would look at
it -- to address the issue of research, you are going to have to put it in this broader framework.

Because you can't pull it out so neatly, simply. The lines just don't cross.

DR. SOBEL: True. I just didn't want -- it seemed to me as if your direction was going completely away, and you should at least be addressing, at the very least, this issue within the context of everything else.

DR. MURRAY: My sense of it is that whatever we do in the way of a report, we must address the issue of genetic information in research, but our report may not perforce be limited only to genetic information in research.

Because we may decide that it just is too -- since there is

such a -- pathology samples, for example. Originally, they arise in the clinical context and may then be used for research.

We may not, you know, be able to distinguish them -- well, make the distinction analytically, but in practice, they may turn out to be so intertwined that we would feel like we would have to address the larger issues. Is that -- I think that is in concert with our charge.

MS. LEVINSON: Yes. I would say, yes. But don't neglect the research. The point was, at the time we developed the charter, there was supposed to be another body that would look at the health policy issues that related to general medical practice. We don't have that body.

But I guess some people have said that the impact of this group will be primarily for the agencies that support research, and of course, you have -- this is a public meeting. There will be broader dissemination of recommendations into the public. It is useful. It is necessary to do that. So you have -- you certainly have a larger voice.

But there is a need, on behalf of the research agencies, to get some guidance on how they design their -- (inaudible).

DR. MURRAY: And we need to respond to that whatever else we do. Two quick comments, and then I think we probably ought to break.

MS. ROTHENBERG: Both relevant to -- (inaudible) -- point, which I think is a good one, is that, as a practical matter, a lot of this information that David is raising on value is being done -- it is research, but it is being pushed into clinical care too early.

And so some of the safeguards that we think we have in

research are falling down, and I think this is maybe interesting with respect to genetics. They are falling down, because they are moving into clinical care, because of the marketing of genetic testing while it is still research.

That raises the point that I didn't hear yet about privacy that I would welcome some work on, and that is, the appropriate use of the certificate of confidentiality. Because a certificate of confidentiality, as Bob -- I was wondering if, in fact, this is being raised in the context of what you are looking at.

That was used in the context of research, but not initially genetics research -- it is not being touted as the solution, of which it isn't, of course, to privacy -- and is a human subjects research issue that is particularly of concern here is how is that being misinterpreted, misused, and people that are determining whether to be in genetics research or not are totally confused. And what is its appropriate use?

Because that at least may get at subpoena power, which may have some relevance to the points I made earlier.

DR. MURRAY: It is mentioned regularly in the various documents about tissue samples.

MS. ROTHENBERG: Right.

DR. MURRAY: Certificate of confidentiality as a possible protection ---

MS. ROTHENBERG: But that is the least ---

DR. MURRAY: Right. There was another comment.

DR. COX: So if autonomy versus social responsibility is a

basic thing -- people aren't going to want to hear this -- but I think that defining what is research and what is not is really a major issue. It is very black and white now in terms of how the laws and the legislation goes. You know, there is clinical practice, and there is research. Right?

That is not real life, folks, and I think that that is really the situation that we are in right now. The whole issue of what is research is being redefined.

MS. ROTHENBERG: In transition.

DR. COX: That is, from my point of view, a major thing about what our Commission is about.

MS. ROTHENBERG: Yes.

DR. COX: So that how we adjudicate that -- what is too fast? What is too slow? This has to do, I think, with the partnership between the people that are collecting the data and the people on which the data are being collected.

MS. ROTHENBERG: Right.

DR. COX: When is it too fast or too slow to get that information back? What is the responsibility of getting the information back? In the past, it has been really straightforward. We collect it, and we don't tell you anything. I mean, almost always. That is the deal. That is what we live under right now.

It is not going to wash any more. From the point of the view of the people who have to be in charge of the regulations, I get your drift, really clearly. This is going to be a nightmare.

Because we are changing -- we are not changing the goal

posts; we are changing the game. So I think that to talk about just -- people are probably already sick of me saying this -- but it is this relationship between the public and the people that are gathering data.

I don't like to use the word "research," because I think it is blurred now. I don't think that there is a research and then real life any more. We need new ways of conceptualizing this and an entirely new set of regulations for dealing with it. That is a pretty big charge, but I think -- live with.

MR. HOLTZMAN: I don't want to -- you characterized -- as it moves from research to clinical practice, it is the market. I wish it was so simple that it was the big, bad commercializers.

MS. ROTHENBERG: You are right.

MR. HOLTZMAN: But it ain't.

MS. ROTHENBERG: Right.

MR. HOLTZMAN: It is this conceptual change we are going on, because there is as much push out of the academic clinical research side to move ---

MS. ROTHENBERG: Right. Which is funded by the commercial market with increasing frequency.

DR. LO: Well, there has been pressure by the patients.

MR. HOLTZMAN: And drive by the public and the patients, if you think of the AIDS -- so it is not so simple.

MS. ROTHENBERG: You are right.

DR. MIIKE: I have to smile when you say it is moving too fast. (Inaudible) -- thousands of examples of new, weird medical

procedures that went into use with no validation or whatever.

DR. MURRAY: It is 11:30. I want to thank Bob Gellman and John Fanning for joining us. I invite you to stay, particularly for the "Genetic Discrimination" discussion, because I think they are tightly woven, if you can.

Karen, we will have you leading off at 12:30. We will reconvene, and we really will reconvene at 12:30. So if you want to be here for the beginning, be here at 12:30

(Whereupon, at 11:33, a luncheon recess was taken.)

A F T E R N O O N S E S S I O N

DR. MURRAY: There is a time set aside for public comment. If anyone wishes to address the subcommittee during that time and haven't already indicated that to Patricia Norris, please do that. Pat is behind me and waiting. You should let her know if you want to speak.

MS. NORRIS: Sign-up sheet.

DR. MURRAY: Thank you. All right. Thank you. Karen Rothenberg.

GENETIC DISCRIMINATION

MS. ROTHENBERG: First of all, you all should have some additional materials that we put around the table that go in Part C.

They are some up-to-date charts on the state of state

legislation on both genetic information and health insurance and genetic information in the workplace, and a series of a few articles on specifically on the issues of genetic information and employment, which were not in the original set of materials that were generated as part of the materials that were used at the -- I think I mentioned earlier -- the October 4 workshop that the National Action Plan on Breast Cancer and the ELSI Working Group held.

We are in the midst of developing recommendations now, and I will share with you that some of the debate that we are having, or that we continue to have as we send them out to more and more people for review, is at the very core of what we have already discussed this morning.

What I would like to do, and Tom is going to have to shut me up, because I try to be a little didactic, is to just give a very brief overview of sort of what the state of the law is in genetic discrimination and really what the rationale for some of these laws might have been.

And I hope that would help you to be able to evaluate whether you think this is going in a right direction and then maybe what, if any role, you think you should all have.

MS. ROTHENBERG: Can you all see this? Or do you want the -- it is okay. Okay. Because -- it is always a challenge talking after

lunch.

(Slide.)

I don't know whether Francis showed you these when he was here the last time -- and they all the "P" in front of them -- I am not quite sure why -- pathetic, I guess, is the attempt here.

But we have tried to figure out, as you have all raised already -- I think this is probably the most significant public policy question if you are deciding whether or not you want to do anything specifically in genetics is to say: Is genetics information different?

And as any good lawyer or any good ethicist, any person around this table, I could make an argument pro and con with respect to every one of these points. But I do think that the pedigree-sensitive issue, which is family, and perhaps, most importantly, the prejudicial issue.

Now, again, I could make an argument for HIV. I could make an argument for other things historically, but I do think we have in our country a need, and a continuing need, to establish differences among groups, among people. It is just our history and not to play the Nazi card.

But as many of you know around this table, the basis for the Nazi statutes came from this country. I mean, they were developed in

the early 1900s and Buck versus Bell is still out there as good law.

You all know Buck versus Bell, the Supreme Court case that declared that three imbeciles -- three generations of imbeciles are enough. What you may or may not know -- that was a challenge to the Virginia statute, compulsory sterilization statute.

What you may or may not know is that the plaintiff in that case was not an imbecile, and there was nothing to give them the significant information to make that determination. It was basically a set-up. She was from a poor family. She had been raped by a relative, and she was pregnant.

So it is a reminder for us about the use and misuse of what some people determined to be at that point genetic, when, in fact, it really had no basis as a matter of fact. But, more significantly, what it said as a matter of public policy.

So in our country at least, we have some history, and the question is not that we are still going to do things like that. We know not to do things like that in 1996, but what that can teach us from the past and how that might color the value of trying to take a particular approach at genetic discrimination.

And I think in some communities in our country, just by definition of how we do genetics, it is some of those ethnic groups in our

country that feel that they have been discriminated against that are also the groups where we have had population screening for certain genetic disorders.

Okay. With that background -- that is probably my five minutes. Right? Okay.

(Slide.)

In the early years, any attempt at genetic discrimination, and I think this is interesting, it was two states in the South, North Carolina and Florida that passed health insurance discrimination laws based on the sickle-cell trait, another trait -- actually, those were just on sickle-cell.

And at the same time, they passed employment discrimination laws. In the first few years, we had, you can see, very little attention. We didn't pass much legislation.

North Carolina and Florida were based on significant numbers of cases in which individuals who were black, who were healthy, they did not have sickle-cell disease, they had the trait, lost their health insurance and their employment.

(Slide.)

It was then at about the same time as the Human Genome Project got going that we began to see the development of state law,

starting with the State of Wisconsin, and that little star there was because it hadn't been signed by the governor. But it now has been. The most comprehensive genetic antidiscrimination law that has just passed by New Jersey.

And they follow ---

(Slide.)

And, by the way, this is just to give you a sense of how much interest there has been. Whether you want to consider it separate or not, this is what the political situation looks like. We now have over a third of the states that have considered or are considering discrimination legislation.

(Slide.)

These are the basic elements of what these laws do. They prohibit the health insurer from requiring a request -- could somebody -- maybe I can do it -- focus -- there we go -- a little bit -- too focused -- from requiring or requesting a genetic test in order to get coverage, from requiring or requesting the results of a genetic test -- the results of a genetic test.

Now, that second component is privacy, as I see it. It is not necessarily medical records privacy. In fact, it isn't. But it is basically saying, you don't have to tell us, and we don't' have to -- well, we don't

have to require of you is one part, but you don't have to tell us whether or not you had a genetic test and what it was.

And that is very significant in research. Because, in research, where we do a very good job, or we tend to do a good job of not putting it in the medical record, even though if you tell your provider, they may put it in the medical record, if they can't ask you the results of a genetic test that you got in research, that may mean more people, all other things being considered, might be willing to be in research.

And that is one of the major public policy arguments that has been made at the state and federal level to get these laws passed. It is not so much that we can prove to you that there is a lot of this going on, but rather we can help maybe allay some of the fears that people think they will be discriminated against if the information gets out.

And then you -- it prohibits conditioning coverage benefits and rates, and that becomes significant. -- because the federal law doesn't really deal with that -- based on this information.

(Slide.)

Now, the problem with these -- see, this is what happens when lawyers use slides -- the problems with this, most generally, until the last year, is that these laws have tended to focus on the genetic test, not more broadly on genetic information like family history, medical

examination of records, etc.

The New Jersey law -- the New Jersey law and the Virginia law, and now there has been a change in the California law, just within the last few months, they now have broadened the definition beyond the narrow definition of genetic test.

So that it really does cover a lot now, and of course, the devil is in the details. But the fights that go on at the state level are with this very definition.

And the point I wanted to raise, in fact, based on our morning discussion, it is not so much, is genetic information different? It is, first, what is genetic information?

And, you know, if you believe what Francis Collins said, ultimately, everything -- maybe even trauma, because maybe there is this risk gene now there -- has some genetic basis. So I think that actually becomes the first question is: How do you define? And then once you can define it, should we treat it differently?

And then, perhaps most significantly, over half of us in some states are now getting our insurance through our employers that are self-funded. And they are exempted through ERISA from any state regulation. So for those of us, this stuff that I just showed you is irrelevant. It provides absolutely no protection.

(Slide.)

So this year, in what I call a generic, not a genetic law, we passed -- and this shows Bob's partisanship -- he called the Kennedy-Kassebaum bill. I was corrected. It is the Kassebaum-Kennedy bill, because Kassebaum was in power at the time it went through.

This only happened, anything about genetics, in that generic bill, only happened because at the same time, there were genetic bills on the table. Otherwise, it would not have happened. At least, it is my perspective.

That it really opened up the debate, and said, okay, if we are not going to get a specific genetic bill, what are we going to get, if anything, in the generic bill about genetics.

Well, the only reason you were going to get that in a generic bill is if you could tell Congress that it needed some special protection. Well, this one basically specifies genetic information as one of the health status related factors that you cannot use for group health plans in establishing eligibility.

It doesn't say anything about rates, and I will show you in a minute what it does do and what it doesn't do. But it is significant. That in addition to saying medical condition and medical history, it listed genetic information. Didn't define it.

(Slide.)

However, this is, I consider, very significant. Not so much because this bill does that much, but that this language in the future may be used more broadly in other contexts. And it gets to the point, particularly of the healthy individual, who may want to get genetic information.

The example that was used in lobbying was the individual who gets the BRCA-1 test, and it is positive. But she doesn't have breast cancer. And then, a few years later, she develops breast cancer. Well, genetic information shall not be treated as a pre-existing condition in the absence of a diagnosis of the condition related to such information.

So that if we are worried about genetic discrimination, meaning that otherwise healthy people are now going to be labeled as sick, this is an attempt, in part, to counter that. How effective it will be or not is still up for grabs.

(Slide.)

So this is what it does do then. It does apply to all health insurers, whether state-regulated or self-funded. That is new. That is the first time we have done that. And it does include a recognition, although no definition, of genetic information.

(Slide.)

And this list is a lot longer. This is what it doesn't do. It doesn't do anything about prohibiting insurers from requesting or requiring collection or disclosure of information, because that is not what this generic law was all about. This was a portability and accountability law. It wasn't dealing really with that.

It doesn't require obtaining authorization for disclosure. It is not a privacy law. It doesn't, and this I think is most significant -- so we don't oversell what it does do -- it doesn't prevent plans from increasing rates, excluding coverage for particular a condition or procedure, or imposing caps on benefits.

So a particular employer could negotiate with his health plan. We are only going to cover mammography once every four years. We are only going to cover -- we are never going to cover prophylactic mastectomies/ovariectomies.

So then you have to question, well, if this information has some value in any context, does it really help you in the context of this law? And it doesn't. It doesn't do anything with respect to guaranteeing certain benefits are going to be covered.

It does very little if you are not in a group plan, and of course, it does nothing for the 40 to 45 million people who have no insurance and certainly don't have any accessibility to genetic testing

except perhaps in research.

(Slide.)

Okay. Do I have a minute or two left?

DR. MURRAY: A minute or two.

MS. ROTHENBERG: A minute or two. Okay. In the workplace context, the relevance of genetic information can be whether you get a job; what kind of job; where you work; what conditions are placed on your work; obviously, health insurance; and privacy.

(Slide.)

Similar lists of states that did things in the early years for sickle-cell and other specified traits. Are you doing something back there? All right. Thank you.

(Slide.)

More recently, you can see a number of the same states that have dealt with prohibiting the use of genetic testing in the workplace.

(Slide.)

Basically, this is what these laws do. You may not solicit, require, or administer a test. You can't use it to affect the terms of their job or to terminate their employment.

(Slide.)

It prohibits any agreement to make payment or benefit in return for taking the test or from selling to or interpreting for an employer genetic tests. Any person. That is pretty broad.

(Slide.)

Now, it does allow you, in the employment context, to do it if you get written and informed consent and then for certain particular conditions, including susceptibility to levels of exposure of potentially toxic chemicals if there is no termination or adverse action.

(Slide.)

New York just passed a law, and I just put it on. Because it just -- it is the most recent one passed with the exception of New Jersey's, which is a much more -- broader bill.

New York's appears to provide that they may -- an employer may require testing if the test is directly related to occupational environment with no informed consent. And I think that is pretty significant. How it gets played out, we will see. The people in New York aren't too worried about it. We will see.

Most of these laws pass almost unanimously in the states. Now, why is that? Either they pass almost unanimously, because they are worthless, and the employers have figured out a way to get around it, and the insurers have figures out a way to get around it.

Or they pass because genetic tests in most of the situations is so narrowly defined, it doesn't really mean that much. Or, as I would like, in my non-cynical hat to say, it is because it makes for very interesting bedfellows.

The biotech community likes antidiscrimination law, because it says to the public, we are going to solve this major public policy problem. So you don't have to worry about being discriminated against. So then we can move the product to market.

The breast cancer community, the women's health groups, the genetics community says, and people doing research say, we need this, because we are not going to be able to move forward in research if we can't tell people that this has more good than harm to them. And, in the end, have we given them some false sense of security about how much we can really guarantee?

I just wanted to leave with a federal solution, or an attempt at a federal solution, by using the interpretation of the Americans with Disabilities Act. In 1995, this EEOC interpretation I want to make clear, it is not a law. It has not been tested in the courts. All it is is an interpretation in the compliance manual by EEOC.

I wouldn't go to sleep at night being able to tell my employees that they are protected under this. The courts have been very

stingy recently about their interpretation of the ADA, and we can talk more about that if you have questions.

But it is something. What it is is a recognition in this context that maybe genetic information at least has to be clarified as being included, even if you are pre-symptomatic with the example being given of the individual with increased susceptibility to colon cancer.

So at the federal level then, we have, in employment, a quasi-generic attempt at an EEOC interpretation. And in health insurance, a generic attempt at least to get at the beginning of antidiscrimination through a generic health insurance bill.

And then we have at the state level a lot of very specific, focused, although maybe of questionable value, genetic testing and antidiscrimination statutes now on the books.

I think the challenge will be how to integrate those into these other initiatives that are going on about the federal and state level.

DR. MURRAY: Thanks, Karen. We just don't have much time.

MS. ROTHENBERG: Yes. I am done.

DR. MURRAY: I find it interesting to note that -- no, no -- susceptibility to colon cancer is a disability, but it is not a pre-existing condition. I just thought I would note that.

MS. ROTHENBERG: Right, right. And if it doesn't impact on your ability to do your job, there is really no protection you are going to get -- (inaudible).

DR. MURRAY: It is open for conversations and questions.

MS. KRAMER: Do you regard the Kennedy-Kassebaum Act as providing as much protection as the recent state laws?

MS. ROTHENBERG: No.

MS. KRAMER: No?

MS. ROTHENBERG: Well, actually, no and yes, depending on what you want the protection for. In the context of the privacy component of these state laws, it doesn't give you that. Unless you read this preemption thing -- that you said -- generically to include some protection of that, and if so, then that would neutralize that.

The advantage that it gives is that it covers everybody. The disadvantage is it doesn't speak to benefits and rates. It just speaks to eligibility and continuation of being able to be in a plan. But the plan can be of very little value to some people that have genetic problems.

DR. MURRAY: Carol.

DR. GREIDER: We have been having this discussion about genetics. Is it different? And there is a philosophical discussion, but then there is also the legal discussion. Is there any legal reason why it

should or shouldn't be different in order to afford legally more protection of people?

MS. ROTHENBERG: Well, I think that one of the things that is going on in that EEOC thing is that there is some genetic information like genetic information from a healthy person that may not be deemed to be either medical -- I mean, it might not be deemed, in the traditional sense, medical, or you are basically still healthy.

And so it has been necessary to clarify, at least with the EEOC, that what we meant by this also included that description of what looked like somebody that could be perfectly healthy.

And it also has become an issue in some health insurance cases, although none of this new law has been tested yet. In fact, this isn't even going to go into effect until 1997, until the middle of 1997, I think most of it. So it is not even protection at all yet.

But there could be situations, particularly if somebody has x-linked or recessive, that they are not -- that is not a medical condition, but that it could have an implication for discrimination, because of its implications further down the line to their family.

So I guess, clarity is good when you know what to be clear about, and I will be honest that in the context of the politics, I think that -- Tom and I have talked about this -- I mean, the ELSI Working Group

wrote a brilliant document a number of years ago, when it looked like we were going to get universal national health insurance, that is very principled.

And we didn't get universal national health insurance. In fact, a lot of these issues we are talking about today, they wouldn't go away, but they would be different -- Sweden, for example.

So that would -- I think that as a practical matter, it becomes a foot in the door to raise the issues, and the broader you can define what genetic information is, the more you actually envelope -- you know, you take with you -- in the terms of protecting people.

DR. GREIDER: You can define what it is without saying that it is intrinsically different.

MS. ROTHENBERG: No, but the definition becomes very problematic. Because if you define it so broadly, it doesn't look any different.

MR. HOLTZMAN: Well, I think -- was thinking about something Rachel said about the role we have with respect to the conduct of research. One of the things that becomes very clear with this patchwork of state laws is the research enterprise, insofar as it doesn't take place in a single state, can be significantly impacted.

For example, the New Jersey bill that was passed would

have effectively made epidemiological research, using samples collected in New Jersey, essentially impossible. We, a number of organizations got together, got Whitman to conditionally veto it and fix that, that provision.

So, to the extent that we are -- and the New York law potentially has problems now in terms of the progress of research. I think -- Suzanne, did they end up with the right provision in there?

MS. ROTHENBERG: New York? Which law?

MR. HOLTZMAN: The genetic testing -- it does have a research exemption, but then there is a provision in terms of how quickly you have to destroy samples, which effectively takes out of the realm of use for research certain kinds of samples collected under certain kinds of conditions.

So it argues for a national perspective insofar as we are interested in the research enterprise as a national enterprise.

The second thing, and I want to completely agree, so much of this now becomes not just -- as an issue of definition -- but it is not just words. It comes back to these big issues.

I mean, pre-existing condition. I mean, in a world in which we learn more and more about ourselves as biological organisms and what are the physical underlying conditions of susceptibility to this or

that, pre-existing is an anachronism.

MS. ROTHENBERG: Life is a pre-existing condition.

MR. HOLTZMAN: Right.

MS. ROTHENBERG: Well, that is an insurance term in the context of Kassebaum-Kennedy, but you are right. It has social implications way beyond that.

MR. HOLTZMAN: Right.

DR. COX: And my comments just follow on that. Because it is great to have these laws that basically say that you effectively can't use this genetic testing information. These state laws that are pretty tough, but yet at the same time, okay, I have heard, you have heard, and many people in this room have heard women whose families have breast cancer who are discriminated against.

MR. ROTHENBERG: Right.

DR. COX: Now, I am not talking about how many there are. That is not even important to me. I am thinking about it in the context right now: Are these laws doing any good? Have any of these ever been tested by these women, and if not, why not?

MS. ROTHENBERG: There has not been, to the best of my knowledge, a claim using -- I mean, the goal of this law is deterrence.

The other goal of this law is to give some -- I am not so sure

this is good or bad -- but there is some view -- I now put my cynical hat on -- that, you know, if we pass these laws, then we have solved all the problems. So now let's just test. Let's get it into the market. Let's let people test. We have solved the misuse, and people will be safe.

I don't agree with that. I think that there is still a lot of issues of interpretation. I don't even know whether these laws are being complied with.

DR. COX: Exactly.

MS. ROTHENBERG: I think -- in fact, I get calls asking me all the time from people living in these states that don't know these laws exist. If nothing else, you will now have your chart to know whether you have got -- your state has something. I mean, it would be interesting to know.

So I am not sure, just like with the Americans with Disabilities Act, the burden is on the person being injured to figure out that they have been discriminated against.

DR. COX: That is actually why I asked the question. Because I think this Commission, okay, can really think about this. Because having these laws, okay, and assessing whether they do anything, you know, is really important.

We can fall into the thing of saying, well, if we have the laws,

it is all fixed, and then we don't worry about it. But look very functionally at, you know, first, what -- is there a problem out there? Are people having a problem? And then -- do stuff -- and like doing laws is one thing, but then going back and assessing, did the laws make any difference?

And having this process, this ongoing process of first defining what it is and then assessing it and constantly getting new information, I think, is going to be really important, and I am worried about these laws in that context. Because ---

MS. ROTHENBERG: The perception.

DR. COX: It falls in the total context of insurance. Right? So you made the statement, Steve, and I actually agree with it, about pre-exiting conditions. Health insurance in this country is predicated on pre-existing conditions.

So why is it, okay, that the health insurance people aren't going bananas with these kinds of laws? They don't seem real concerned with these laws. Why is this?

MS. ROTHENBERG: Well, there are a few reasons. The life insurance industry is very concerned about these laws. The health insurance industry, to some extent, has to deal with community rating in a lot of states, and this isn't that big a piece of the market.

And, remember, they have already taken into consideration the -- they have already put to -- as I said, it doesn't mean more people aren't going to get breast cancer, because we now have the BRCA-1 gene. Right? So they can figure out other ways to get some of this information without genetic test information.

DR. COX: It sets a precedent concerning how one determines -- how one sets rates ---

MS. ROTHENBERG: Who is at risk.

DR. COX: Yes. And determines who is at risk. So I think this is a really major issue by which our Commission could consider things, too. How do you really deal with risk with respect to this discrimination?

Because I think it is being shoved under the rug right now in the context, if we have these laws, if we just get these laws, everything is okay. I think that there is a deeper fundamental thing here that is not really being addressed.

DR. MURRAY: There is -- I want to make two points. One is that personal genetic discrimination is a very complex idea. Karen certainly talked about the two areas that are more commonly discussed, that is, in insurance and employment.

There are other potential areas. We either hear of

speculation or cases of discrimination, use of genetic information in, for example, determining the suitability of a couple for adoption. Do you have a susceptibility to a disease?

MS. ROTHENBERG: Custody.

DR. MURRAY: About -- pardon?

MS. ROTHENBERG; Custody.

DR. MURRAY: Custody. In tort cases, How many more years of life would this person have when they had a genetic susceptibility to blank. Let's deduct, you know, 10 years from their otherwise projected lifespan. Are those legitimate or illegitimate pieces.

Even within insurance, which is the area that I know the best, there are very different markets and very different products. Health insurance is quite different from life insurance, which, in turn, is quite different from disability insurance, which, in turn, is quite different from long-term insurance.

We are currently got a group at our center that is working on presymptomatic testing for Alzheimer's and some of the implications there. That has some very interesting concerns, implications, for long-term care policies.

MS. ROTHENBERG: Well, there is unfair discrimination and fair discrimination.

DR. MURRAY: Fair and unfair. I am just not trying to give you an exhaustive list. Just a sense of the complexity here and it is -- we can use this as a title.

But it would clearly be a mistake to assume that all these fit neatly under the same rubric and that sort of your instincts toward one are going to translate without remainder to all the other instances. It is going to be more complicated than that.

DR. COX: I think ---

DR. MURRAY: I think Zeke had ---

DR. EMANUEL: I just wanted to -- it seems to me the more we get into the specific laws and stuff, the less we get related to what we can do.

MS. ROTHENBERG: Right.

DR. EMANUEL: Again, we are not regulators or legislators. So I want to shift back to a question. I have always, and I am not sure whether I am right, because I haven't given it that much thought, thought about discrimination as something you weigh in the balance when you are talk about privacy, confidentiality.

It either changes how you weigh the interests of someone for keeping the information private or confidential or restricting access to it. Do you see it differently?

Or are we talking about discrimination -- is it a separate category, and should we consider it a separate category? And if we should, then I want to ask you to step outside the regulatory/legal hat and again, where is our marginal benefit?

MS. ROTHENBERG: Well, I don't think that is an either or question. I think that there are certainly circumstances where your concerns about confidentiality would be based, in part, on how much you could quality and quantify the level of social risk associated with sharing that information.

But I do think there is an independent value of privacy, whether or not it is used against you by a third party.

DR. EMANUEL: I agree ---

MS. ROTHENBERG: Okay. So we agree.

DR. EMANUEL: That is talking from the privacy side. I am asking from the discrimination side. From the privacy side, yes, there is an intrinsic value, I would say. There is also an instrumental value that is related to discrimination among other instrumental values.

The question is: From the discrimination side, does it stand independent of privacy?

MS. ROTHENBERG: Well, the distinction tends to be made between the access to the information and the fair use or misuse of the

information, and I think it is the fair use or misuse of the information that follows to an antidiscrimination argument.

I guess what I am trying to argue is that sometimes things get used, and they are not necessarily -- you know, the determination of what is misused, I think, is so value-laden, and that, traditionally, it has been in the context of third parties that are employers or insurers or disability or life insurance, when we haven't really looked at the use in the context of other entities or other values or other relationships or the context of individuals' lives beyond those things.

So we see these things as quick fixes, these laws. That is we can just solve antidiscrimination, people won't get hurt. But people can get hurt independently of whether they get discriminated against. Am I not answering your question?

DR. EMANUEL: I think we are in agreement. Just put the hat on the other way. Say we solve the privacy problem. Just imagine that one of the ---

MS. ROTHENBERG: Then there wouldn't be discrimination?

DR. EMANUEL: Yes. Do we have a discrimination problem that is a residual or not?

MS. ROTHENBERG: By genotype alone? Just by ---

DR. EMANUEL: No, no, just the privacy writ large with a

focus on the genetics, as I think we have discussed before.

DR. MURRAY: I think, yes, we do. Most of the presumed uses of genetic information by insurers are not any infringements on privacy. You voluntarily relinquish your information, because otherwise they won't -- you know, it is voluntary on your part ---

MS. ROTHENBERG: No, it is not really voluntary.

DR. MURRAY: Well, it is voluntary on both sides.

MS. ROTHENBERG: If you want a ---

DR. MURRAY: If you want the contract ---

MR. HOLTZMAN: -- what would you gain by solving the privacy --

DR. MURRAY: You have got to sign over your information.

MS. ROTHENBERG: But then you are linking them together. See, you have just linked them back together, though. I think he is asking a different conceptual question.

DR. MIIKE: Let me put it this way. Suppose the knowledge about genetic information is such that insurers can look at demographic characteristics of their clientele and change their rates based on what they have finer information now in terms of predictability of disease patterns and illness in the population.

You don't get into privacy issues. But you still can get into

discrimination. Would you say that is a legitimate use?

MS. ROTHENBERG: Let's go with an example. Okay. Let's say an example of people with Jewish names on Long Island. Okay? In which they might want to rate them higher, because they are making an assumption that they may have more likelihood for breast cancer.

DR. MIIKE: But then are you saying the method is what is discriminatory and not the ---

MS. ROTHENBERG: No, I am just asking, would that be -- I am just trying to get an example ---

DR. MIIKE: Let's pick one that is ethnic neutral. Suppose they can get one where they say, women of a particular age, we know that if they stay insured for X number of years ---

DR. EMANUEL: They already do that.

DR. MIIKE: No, I understand that. But I am saying that genetic information now gets -- let's you do it more accurately.

MR. HOLTZMAN: Well, actually, it won't.

MS. ROTHENBERG: Yes and no. I don't think so.

MR. HOLTZMAN: Right. You see, because the interest of the insurer -- the insurer is interested in the phenotype, clinical ---

DR. MIIKE: I am not interested in the technical details. I am asking the question that if genetic information provides you a better

tool in which to make these actuarial adjustments ---

MS. ROTHENBERG: Basically, what you are asking is what do I think of medical underwriting, and do I think it is unethical? I think that is what you are asking. Is that what you are asking?

DR. MIIKE: No, I am asking -- it is not what I am asking. I guess it is a subset of the question: Is genetic information any different from other information?

MS. ROTHENBERG: Right. Well, it is certainly different when the individual would otherwise be deemed healthy. So if they go from healthy to being unhealthy because of the genetic test ---

DR. MIIKE: But, you know, in the life insurance situation, you pay your rates based on what age you are, etc, etc., etc. But issuing life insurance is -- I have information specific to me and I use it to go buy insurance and they don't know, then it is unfair.

I think that is the crux of why there is a distinction between the use of this kind of information as applied to prohibition in health insurance but not in life insurance.

MS. ROTHENBERG: Oh, I don't think that -- that is not a principal distinction to me. I think the principal distinction might be that, one, it is a matter of life and death, and we have different social values. But needing to get the health insurance versus needing to

get the life insurance. But whether the life insurer or the life insurer has the right to the information and wants to use it to affect the rates, I think, from the insurance perspective, they wouldn't see a difference.

DR. MIIKE: That they would ---

MS. ROTHENBERG: And, ironically ---

DR. MIIKE: But why are we not -- why is it applied only in the health insurance situation ---

MS. ROTHENBERG: It is not -- oh, why? Well, first of all, it is not totally. I mean, New Jersey now deals with life insurance and disability, although they have a different standard for it. That has been a political decision.

They tried in a number of states to pass omnibus bills that covered everything. They didn't get anywhere. So this is a one step at a time view, and that is why the life insurance companies testified in states against law that they have nothing really -- they are health insurance laws.

But they still come and testify against them, because they are worried about the trend. That next year they will amended to include them in as well. It becomes significantly a problem with respect to privacy, because some of the same insurers cover both the life insurance and health insurance. So it is very difficult to actually, in any way,

enforce ---

DR. LO: Could I ask maybe a question ---

MS. ROTHENBERG: I am sorry. I don't think I answered ---

DR. MIIKE: Did you answer my question?

MS. ROTHENBERG: I don't think so, not to your satisfaction.

DR. MIIKE: Yes or no. Can you distinguish privacy from discrimination? And I gave you an example of where I thought there was.

MS. ROTHENBERG: Yes, I can distinguish -- I think that my goal is to integrate privacy and discrimination whenever it is relevant. But there are certainly situations where privacy stands without antidiscrimination. I haven't come up with them ---

DR. EMANUEL: It is the reverse then.

MS. ROTHENBERG: -- yet in the reverse.

MR. GELLMAN: Could I just add a word on that? I mean, privacy -- privacy is a terrible term. A better term is data protection, and data -- but the concept is a set of rules that say what can and can't be done with information.

I mean, I don't think anybody today thinks that it is an invasion of privacy for a communicable disease to be reported to the public health department, at least some communicable diseases.

(Simultaneous discussion.)

MR. GELLMAN: No, no, hang on. Wait, wait, wait, wait. No, but the issue is: Do you have a set of rules that say what can be disclosed and what can't be? The values that go into making those judgments are not necessarily just privacy values.

The privacy stuff, in a lot of ways, is procedural. We need to have rules. We need to say what your rights are and what your responsibilities are.

DR. EMANUEL: I don't agree with that.

MR. GELLMAN: Okay. You can pour in different values, and you deal with different records. We would have -- if we were writing comprehensive rules, we would have different rules, substantive rules, for pizza delivery records than we would for medical records. But they would both be privacy rules, if you will.

And the content comes somewhere else, and the discrimination stuff is that content. In some contexts, we do not allow this type of disclosure in an attempt to try and prevent certain kinds of extraneous uses. I don't know if that helps.

DR. EMANUEL: It helps, but to go back to ---

MS. ROTHENBERG: Here is -- I thought of one. But I think it is more phenotype than xenotype, but certainly, you can look at

somebody who has neurofibromatosis and hurt them. They didn't give you any information. You just looked at them.

And I think one of the things that I have tried to be arguing is that why it often becomes so difficult to make the argument that we even need this kind of legislation is because we don't have empirical data to know that it is really going on.

But I would predict we will never be able to. Because there is not enough incentives in the system to make people who -- you can't look at them to tell -- you know, you can't tell they are black; you can't tell they are a woman; you can't tell they have a disability -- to come open unless they have significantly been hurt. Because they give up so much in order to make that claim.

So pheno -- I think there is an example. You could discriminate against people, and they are not telling you anything confidential. It is just because we discriminate on people based on difference or we don't like the way they look. So there is an example.

Now, is that -- you then ask, should we value those differences? Sure. I mean, I don't like that. I mean, that is just not being nice. I mean, can we legislate that? No. Certainly not -- I mean, you will figure out a way to discriminate against me if you want to.

So I guess it is an independent -- I think there is an

independent value separate and apart from privacy.

DR. COX: But I come back to the same framework that I had when we were discussing privacy as with discrimination, and it is acceptable uses of information. That there is no rule, there is no line over which you say, this -- where is the line? You can or can't use information.

It is a situational context, and so to have a discussion in NBAC of what are the considerations of how you end up using information and how -- what are the considerations that allow you to use it or not use it, and then you have specific examples.

I think that if there were a million different types and uses of information, then there is not a tractable task. And there are going to be a million.

But they are not going to be all represented -- you know, affecting the same numbers of people and at the same frequency. And so we can take and identify important classes of uses of information and talk about them.

DR. MURRAY: That is effectively, I think, what has happened. Why the conversation has tended to be about insurance, about employment, and about a handful of other things.

DR. COX: Exactly. But, to me, and again I am not a

philosopher, but I think there are deep philosophical issues here. But I don't see that NBAC is going to solve those. It also doesn't make them any less interesting to talk about. I mean, they are really important.

But it is not whether discrimination and privacy are separate or together, but it is how we use information. In some cases, it is in a privacy context. In other cases, it is in a discrimination context.

But we have to consider the examples. It is not that we don't need a framework, but this is all about examples. It is all about real life ---

DR. EMANUEL: Here is the reason I made -- tried to make a point of this. It seems to me that one question is: Do you need two frameworks or one framework in which privacy and discrimination, which are the labels we use, whether we want to get to data protection, whatever, are really part of the same framework, or are they separate?

I guess that was the goal of my question. Because here is the unspoken thing. Even back when we talked about privacy, we were not talking about regulations but looking at the social meaning in the larger context of information.

If discrimination fit in that nicely, we, for example, might not have two reports, but one framework which we could apply broadly. That, I think, would be conceptually elegant. It might be better in terms

of educational purposes.

People could see one way. They could see how discrimination, privacy, confidentiality all fit into the same structure. So that was really what is behind my question.

It is common when I go to these meetings or hear people talk that they do distinguish privacy, confidentiality issues from discrimination issues. I really, as I have said, always seen them as part and parcel of the same framework, the same problem.

Now, maybe your -- I haven't thought through your example. Your example may suggest they are different. The reason I was asking this question really goes back to -- there are going to tons of cases. Some will stress the intrinsic harm to a person and maybe their relations with the family; some will stress their employment consequences.

But if we are really dealing with the same framework, it will be much easier for us to be able to communicate that to the public, to policymakers, as well as ourselves to get our head around it and just figure out what we are balancing in each context. That was the only point.

MS. ROTHENBERG: Well, when Tom asked me to come actually and he said, first, there is going to be an hour about genetic privacy and then there is going to be an hour about genetic

discrimination, or an hour-and-a-half, I said, well, why are you doing that for?

So I guess I am sympathetic to that argument, although I think it is too simplistic to always think of them together and as the same.

Because what happens by doing that is you usually lose the social meaning part of it. You usually lose all the other contextual stuff I was talking about in the earlier hours that doesn't have to do necessarily with being harmed by an institution.

DR. COX: But that doesn't have to be the case. Right?

MS. ROTHENBERG: Right.

DR. COX: I mean, if we are thoughtful about that ---

MS. ROTHENBERG: Absolutely.

DR. COX: The reason why, to me, I quite agree with you that this discussion is so important is because if we can be thoughtful, to keep that social meaning, and to discuss -- have examples which may be more privacy or more discrimination, but in the same framework again -- then it makes the task of the Commission much easier.

We don't have to be doing a million different things. But we can be doing it in a more coherent fashion. And that is my prejudice.

DR. MURRAY: I blanched at the description of that as an easier job, but it might be a more intellectually coherent job to do these as -- it is deeply interrelated, even if we make some of the distinctions that have begun to emerge here, and I am sure you can do a better job of making them with some more reflection.

But that is what I am hearing. That it might be good to treat privacy and discrimination in genetics and the connection with research as one document, one project. Bernie and Steve.

DR. LO: Let me toss out another example, and maybe it will or maybe it won't help sort of understand these links between privacy and discrimination.

Let's think about risk adjustment as opposed to insurance. So I am -- I work at the Dana Farber maybe, and I get referral cases that have a disproportionate number of BRCA-positive tumors.

I am going to make the argument I should be paid more, because these are more difficult cases. The capitation rate for normal ordinary patients with ordinary breast cancer is not adequate. And in order to provide the services that are deemed appropriate, and the patients agree to, I need to have some way of proving that my patients are more complicated and I should get a higher reimbursement rate.

It doesn't mean I should charge the patients differently.

They can all be community rated. But from the point of view of the provider, whether it is the institution or the individual oncologist, it seems to me there are some very perverse incentives if you don't risk adjust.

Now, it is presumably possible to do that anonymously, on a population basis. Is that saying that it is an appropriate discrimination, so to speak? That I am not infringing on privacy, or I may not be infringing on privacy and the discrimination is sort of justified as opposed as unjustified?

I mean, it starts to pit -- I just thought of that as you were talking, but it seems to me there are potential ways in which this information really could make the health care of people who, we believe, really do have a different disease than sort of ordinary non-hereditary breast cancer more efficient.

DR. MURRAY: Bernie, this aberrant of that issue came up as a potentially very contentious piece of the insurance task force. This is the Purple Book, which insurers have, and others can get from the Genome Center. Just a kind of historical, maybe interesting, footnote, we came to the conclusion that individual underwriting, that is, taking into account an individual's risk of disease, whether genetic or non-genetic, was, for a variety of reasons, something we were better off

without.

And I won't go over all the rationale, the reasonings, we gave. That, by the way, was embraced by all the members of the Commission, including the representatives of the health insurance industry and the life insurance industry.

In the end, the life insurance industry, when it saw the -- I think, when the people who had not been privy to the whole conversation saw it, I think they decided this would be a very bad idea, and they rejected -- they are the only group that actually refused -- that opposed the report. The HIAA took a neutral position. The Blue Cross/Blue Shield signed the report.

But it was pretty clear that the health insurers, for one, were willing to give up individual underwriting. They were not absolutely wedded to it. Except they didn't want to give up genetic information for just the sorts of reasons you have described.

As the example that one of the representatives used, which I found pretty persuasive, he said, what we might want to know -- this community, this population, does it have a large number of people with a susceptibility for name your disease, breast cancer? Well, that is going to affect our long-range planning. We might want to have more machines to do mammographies here. We might want to have more

oncologists in that community. We would like to know.

We don't need to know who. We just need to know population. We need this thing about genetic susceptibility for -- of those regions' populations, because we can do our planning more effectively if we know that. We couldn't see any reason why that would be a bad idea.

DR. LO: See, I think my example pushes it to the next step. I mean, I could argue from the point of the view of the provider that it is unethical not to make that kind of risk adjustment, because it puts me at a terrible competitive disadvantage.

DR. MIIKE: There is a real life situation about that already, which is that I am dealing with community health centers who say, we need a higher reimbursement rate, because we serve the poor. I mean, that is the same issue.

In a different context, you would say, why are you focusing on the poor? But you have a reason for it. To me, that is exactly the same issue about the issue that you raise here. Can you agree with that Karen?

MS. ROTHENBERG: Yes. But I think you can't lose sight of what the underlying public policy is for why we have genetic discrimination laws. They are not for these reasons. Now, if that is

going to become the end result of them, then we have to fix the approach.

But that is certainly not the legislative intent to any of those things you have said, and I don't think I see that coming out of this approach. If I am wrong, let me know.

DR. LO: No, I am not saying this is a policy or laws. I am just thinking, as we think about how ---

MS. ROTHENBERG: But that is not discrimination. I mean, that the use of information, it seems to me. That maybe -- I am making your point -- is that how you characterize it in this construct that David is talking about becomes very important, and what you call discrimination ---

DR. LO: Right. It seems to me, discrimination works in two ways: one, people really are the same and you treat differently. That is wrong. The other way discrimination works is that people really are different and you treat them the same, and you shouldn't. So it is the flip side of discrimination that, up to now, I think, has dominated the discussion of genetic discrimination.

DR. MURRAY: Aristotle would be proud of you, Bernie.

DR. MIIKE: Well, also, the issue is -- somebody -- maybe it was Mr. Gellman -- said, what we are talking about is the use

of information. So let me just ask the question. I asked the question first. Is it okay to discriminate if it doesn't affect privacy?

I guess, over here is that we are talking about is it okay to use information to make, for wont of a better word, discriminatory decisions? In some contexts, yes. I think we all agree on that. Right?

MS. ROTHENBERG: It depends.

DR. MIIKE: It depends, but what we are looking for is some overarching principles that us guide it without having to -- seat of the pants -- every time you tell a person -- (inaudible).

MS. ROTHENBERG: Well, I think the first overarching principle is to do no harm. That if you are going to generate new information, you want to make sure that you are not making the person worse off, to begin with, and that is a good guiding principle. That, together with why you are generating the information to begin with.

So if you start off with that principle and then go from there, I think -- I mean, does anybody disagree with that one? That is like mother and apple pie.

DR. MIIKE: Well, I guess now we are going -- what do you mean by do no harm?

Because if I see my insurance rates rise when it wasn't directed at me personally, but I happen to be in a group of -- that we

have decided -- we, meaning collectively -- we decided it was an appropriate method to do it -- that is what I asked you the question. What do we mean by do no harm?

MS. ROTHENBERG: Well, that is why it gets back to actually who controls what happens with the information. Who makes those value decisions?

And what are the principles or the issues that you have to think about when you determine when do I have a right to say, yes, you can use that, and when is it a good to the community? It depends.

DR. MIIKE: But then is it -- would our, for example, charge stop by saying we are telling you or agreeing with and explaining to you that in instances where the use of information, as get applied in those particular situations, may -- will cause some detriment to somebody, economically, whatever, and our job stops at the point when we tell you what the possible impacts are.

But we are not the decision-makers. We are sort of like one of a group that feeds information into the policy process, and that once we have made clear what our values and our judgments are, our responsibility stops.

MS. ROTHENBERG: Let me give a concrete response to that, because actually it is a good point to tie back to the mission of the

Commission.

When you are in the context of research, and you are having a discussion about the benefits and risks of whether somebody wants to get genetic information, whether they want to be tested or not, obviously, the paradigm of -- maybe there is a close paradigm to HIV -- but other than that, you know, it is not an invasive procedure. It is taking maybe blood.

So the question of how to quantify and qualify social risk and what gets included in that and how it gets defined would be very helpful.

What do you say -- do you just say to the person, you may risk employment and insurance discrimination and you may risk privacy and confidentiality, period. Well, what does that mean?

You know, what other things might -- do you want to have as part of that discussion something about losing -- having to share the information with relatives, which maybe they should be thinking about?

So I think that I would agree with trying to put that in some concrete terms after you have gone through your analysis of what the issues are and what your constructs are and then translate it for the research community as to -- okay, how might this change then the discussion about getting genetic information?

What would be those relevant things that you would need to talk about ahead of time before somebody makes the determination that they want to generate genetic information?

DR. MURRAY: We have a problem ---

MS. ROTHENBERG: And that might be a way to talk about --

DR. MURRAY: I am sorry, Karen. We have a problem with a scarce resource, and the scarce resource is time. We have ---

MS. ROTHENBERG: A lot of people have already done some work on this.

DR. MURRAY: No, I mean today.

MS. ROTHENBERG: Oh.

(Laughter.)

(Simultaneous discussion.)

DR. MURRAY: We have a little past 1:30. We have built in a little cushion there between 2:45 and 3:00. Do we want to spend a few more minutes on this issue and then take -- we should take a break. A few more minutes on this issue. Take a brief break and then back to the gene patenting.

What do we want to say to ourselves at this point about genetic discrimination? The one thing I think I have heard for sure is

that our inclination is to see privacy and discrimination as distinguishable problems, but probably best treated in the context of a single report.

Is that a fair summary? Is there anything concrete we want to say about how we will do that? Any other reports, papers, studies that we wish to see done now? We don't have to close the door if we don't think of it today. But is there anything immediately that you can offer?

DR. COX: Because we have talked about, you know, the pluses and minuses of getting case studies. But this would fall into the same thing as we were talking under privacy.

But I would like to add one other thing to it that I think the Commission could really help a lot, and it is actually a coda to the answer to your question, Larry. This isn't a static thing, where you look and you just figure out how to use the information.

I mean, obviously, I mean, I am coming at this from what I do as a living, which is a researcher. But I say something or do something and then I look at what it did. And then I go back and reevaluate it, and I say, well, I was half right. And then I switch it.

So that the -- you made a comment earlier, which I think is very good. People look at these commissions like they are God, right, the 10 commandments. We say the way it is, and that is the way it is

going to be.

But I think if we could come out instead by saying, we are in favor of this ongoing process for figuring out how to do this, and if we could find to deal with that in terms of saying, here is a use of information.

To the best of our knowledge, right now, we think this is how it should be used and this is how it shouldn't be used, but we would like an ongoing evaluation of what the impact of doing that way is to see what happens.

So I don't know what that process should be, but it certainly -- this is in the whole process of information gathering again and not looking at things as black and white but constantly assessing them.

It is risk assessment really. So, I mean, asked for something specific and I certainly didn't give that to you. But to have process involved with this.

DR. MURRAY: Yes, thank you.

MR. HOLTZMAN: I think a specific that would be interesting, and I am not sure who could do it, is to put together the conceptual framework in which we can bring these two issues together.

DR. MURRAY: Are you volunteering for this?

MR. HOLTZMAN: It would be interesting to work on it.

DR. LO: Since you and Zeke volunteered for the first part before lunch, we would just enlarge the scope of the mandate to include the second part as well.

DR. EMANUEL: What are we volunteering ---

DR. MURRAY: In all fairness -- we may have volunteered ---

MS. ROTHENBERG: And actually related to that, if you look at the recommendations that we made on both health insurance, and what we will be making in employment, it does that.

I mean, it does take the two together and try to marry them, although in a relatively limited context. But it does marry those two together, and it is problematic. But I think it is better than the alternative.

DR. MURRAY: This conversation could go on for a long time. I want to thank Karen very much for coming and spending time with us today.

Let us take a break. My watch may be slow. I have about 38 after.

DR. MIIKE: That is right on time.

DR. MURRAY: What do you think? About 10 of? Ten of, 10 minutes to 2:00, we will reconvene.

(Whereupon, at 1:39, a brief recess was taken.)

DR. MURRAY: I feel some obligation to explain something about this aspect of our program. If you look at your agenda, you will notice it says, "Presenting: Steven Holtzman, Member, NBAC." Commenting by telephone conference call: Rebecca Eisenberg, University of Michigan Law School.

Well, initially, I had asked Professor Eisenberg to come and do what Karen Rothenberg and Bob Gellman did. She hesitated to do that, and then for a variety of reasons, she felt unable to do that and so agreed to participate by conference call from Michigan. Steve Holtzman very graciously consented to step in at the last minute and sort of pick up what Becky was going to do. Well, as it happens, that is Professor Eisenberg right there. This is Steve Holtzman right here. They are both here. I was going to propose that we have Becky -- so that we would be true to the agenda -- we get her a telephone so she can speak -- (inaudible).

But maybe we will just won't bother with that, and we will just let her speak for herself.

MS. EISENBERG: We figured this out. This isn't really me here. I am here by virtual reality, a step up in teleconferencing capabilities.

DR. MURRAY: We can thank the closure of National Airport

last night.

MS. EISENBERG: Yes.

DR. MURRAY: Steve Holtzman.

GENE PATENTING

DR. MURRAY: Give me one second.

DR. MURRAY: While you are doing that, Steve, it was recommended -- or rather it was offered by Karen Rothenberg to distribute the winter '95 issue of the *Journal of Law, Medicine, and Ethics*, which deals with, among other things, genetic privacy, genetic discrimination, and the like.

Karen has a terrific paper in here about state laws relating to genetic discrimination, and it is there for any member of the Commission who wants it.

MR. HOLTZMAN: Well, Becky and I are old friends, and we actually got together last night. We are in the same hotel. So we had a drink together, and she went over this presentation, and we agreed it is not the presentation she would have given. So I am not giving her presentation, but she thought I should go ahead and do this.

The following excuses. This was prepared on 24 hours notice. I am not a patent attorney. I am not a legal scholar, and I am not a bioethicist.

(Slide.)

So the subject is "Human Gene Patenting: Bioethical Considerations." I think part of what we need to do is --- part of what we needed -- we thought would be useful is getting some review on patent law very quickly -- so there is a bit of a primer in here on that -- and then trying to get at what are the bioethical considerations.

(Slide.)

Just to remind you, as part of the NBAC charge, one of our first priorities, to look at issues pertaining to human gene patenting, which is why we are here.

(Slide.)

I wanted to provide as a backdrop some remarks that have already been made in the context of this Commission; namely, that, potentially, the patenting of biological or genetic material is not really a bioethical issue. That it may be an economic issue.

That was suggested by one of the people who testified at our first meeting. Some members of the Commission raise that as a question. Larry Miike said, I am not sure I want to put it out of bounds at all.

My personal opinion is, regardless of how you feel about that issue, reflection on the issue of whether genetic and biological

material should be patentable raises ethical questions. They come up along the way. And, therefore, when I think about the role of this Commission as an educational force, that it needs to be taking on the issue, if for nothing more than to elucidate what may be the real issues underlying this.

(Slide.)

So what are the legal origins of the patent system in the United States. The legal origins are found in the Constitution in Article I, Section 8, "Congress shall have the power to promote the progress of science and useful arts by securing, for limited times, to authors and inventors the exclusive right to their respective writings and discoveries." Hence, patents, copyrights.

(Slide.)

In terms of conceptual origins for the patent system, fundamental to the concept of a patent system at all is that you have a system of private property rights. If there is no system of private property rights, there are no patents. There are no intellectual property rights.

And sometimes a lot of the arguments about whether this or that should be patentable really ends up asking a question about whether there should be property rights at all.

There are too conceptual bases, two philosophical bases, for patents. The first couple of points I have up here about ownership and benefit from the fruits of one's labor. Ideas, discoveries, etc., being such fruits. And then the fact that you can't protect them. You can't put a fence around your idea the same way you can put it around your land or your cow.

It comes from a natural rights theorist's perspective. Thinking of the United States, one things of Locke in this context. And that provides one basis for why there should be a patent system.

The second is a more utilitarian or pragmatic perspective reflected in the charge in the Constitution that says that it is in the public interest for the sharing of ideas. That by getting them out there, that will provide incentives and enable innovation and commerce.

So there are these two distinct bases, leading that we should have intellectual property rights, on the one hand as a reward to the inventor, and the other to encourage dissemination and commerce.

(Slide.)

As with many things, Jefferson was there long before us. The patent system and legislation was created in 1790 pursuant to an act to promote the progress of the useful arts. Jefferson effectively acted as the first commissioner of the Patent Office.

And then some 28 years later or so, in this letter to Isaac McPherson, he lays down what he believes is the basis of intellectual property rights. I don't really want to read this. Hopefully, you have been able to read it in the time I have been rambling here.

But I think you get at there why it is in the nature of an idea that it is not like a piece of tangible or real property. That once it is out there, it is everyone's, and then coming down into the last paragraph, the notion that society can arrange itself so as to provide encouragement to the dissemination and the sharing of the ideas.

So I think both strands -- people tend to think of Jefferson and our system as only being based on a utilitarian strand or a primary strand -- I think both strands are at work actually here.

(Slide.)

So what is a patent right? A patent right is the right to prevent others, absent the license to do so from the patent-holder, from making, using, importing, selling, or distributing the patented invention. We will come back to this.

It is not a tangible property right. It is a right to prevent others from doing certain kinds of things. And it is a monopoly right.

(Slide.)

Well, how long do you get that monopoly right? Well, up

until last year, you got it for 17 years from the issuance of the patent. As we have come into conformance under GATT with the rest of the world in patents, we are transitioning to a system in which your term of monopoly will be 20 years from the filing of the patent.

Becky, when I make a mistake, yell. Okay?

(Slide.)

What are the criteria of patentability? The first is your invention needs to be novel. It has got to be new. Has to be new.

Second, non-obvious. Even if it is new, it is not good enough if you simply did an extension of what anyone with half a brain who was in your field would have done anyway.

Third, it has to have utility, a practical use. It is not good enough to simply say it is beautiful. It has to have a practical utility.

And, fourth, in your patent application, you need to enable the invention, and that is, to provide a sufficient description to enable one skilled in the art effectively to make and use the invention, recreate your invention, without undue experimentation.

And that is the embodiment of the notion of that one of the reasons we have the patent system is to get those ideas out there.

DR. MURRAY: Steve, could I have that one phrase in the last one. It is without -- undue.

MR. HOLTZMAN: Without undue experimentation. There are certain artifacts of 24 hours of trying to get this done when my assistant works three days a week, and Thursday is not one of them.

DR. MURRAY: No need to -- (inaudible) -- I just wondered if it was some -- (inaudible).

(Slide.)

MR. HOLTZMAN: Okay. So what is patentable subject matter under the code? Processes; machines; objects of manufacture, or what are called manufacturers; and compositions of matter.

So let's stop there right now in terms of the basis of patent law and now move to what I -- you know, the subject of gene patents. And I will say my prejudice -- yes.

DR. EMANUEL: What does compositions of matter mean?

MR. HOLTZMAN: Stuff. We will actually come to that. Okay? Because -- good -- that is where a lot of it comes from. You got it. Okay.

So whereas the charge of the Commission pertains to gene patents, I don't think if one thinks of a gene patent as patents on some chemical substance called deoxyribonucleic acid, I don't think any energy gets going.

I think the energy gets going because we are talking about

patents on biological, including genetic, materials. So my prejudice on that is going to come out in the rest of this.

(Slide.)

So the first question that often comes up, and I think it relates somewhat in the back of your mind, Bernie, is: Is nature patentable?

And the answer is no. Things as they exist in nature are not novel; hence, they can't be patentable. Things as they exist in nature, by definition, are not embodiments of ideas. They are not inventions; hence, they are not patentable.

And why? Because only those things, those physical stuffs, which are the embodiments of acts of human creativity, embodiments of ideas or inventions, are, in fact, patentable.

(Slide.)

So are biological compositions of matter patentable? Perhaps counter-intuitively, yes. If they are embodiments of novel ideas of inventions.

(Slide.)

And if we look at a few landmark decisions and patents that have come down through the years, the first thing to note is that it is not a new idea.

Louis Pasteur got a patent on a yeast free from organic germs of disease back in 1873. Jumping some hundred years, we then get the series of cases --- Chakrabarty being perhaps the most infamous, where we get patentability of bacteria, and that we get the Berger court in the five to four decision, saying that patentable subject matter includes anything under the sun that is made by man.

We move up the organism chain, if you will, in the opinion -- in the in re: Allen, in '87. What was presented for patentability was a polyploidy oyster.

The court -- I am sorry -- the patent office, in the specific case -- the Patent Office, in the specific case, said, this is not patentable because it is not novel. However, it opined that it was not inherently unpatentable because it was a higher organism.

And that led, about a year later, to the issuance of the first patent on an animal, the Leder patent in the mic mouse, a mouse containing a recombinant-activated oncogene.

So coming back, how is it -- aren't these things -- aren't they nature, and nature is not patentable?

(Slide.)

I think you can get at that by looking at the logical form of biological composition of matter patent claims. And, again, I am going

to go beyond genes here to show you that there is a certain way this is done.

So, for example, you get protein claims of an isolated protein with an amino acid sequence of this or that weighing so many kilodaltons, etc. The point is that isolated protein doesn't exist in nature as an isolated protein like that.

Hormones. Insulin isn't in your body that way, isolated. Antibodies. Industrial food enzymes. Vaccines, the antigen used in a subunit vaccine. So, again, the issues here go beyond genes. This has been around for a while.

Second, in the organism type claims, the genetically engineered cell or organism bearing the recombinant DNA sequence specified in the figure in the patent and encoding thus and such a gene.

It could be bacteria, yeast. It could be higher organisms. The issue here is it has been altered. It doesn't exist in nature in such an altered form.

(Slide.)

Going back to the isolated case, you will then get claims and issue patents going to things like hematopoietic stem cells and embryonic stem cells, where you get an isolated cell characterized by that it bears this or that cell surface antigen. Again, it doesn't exist in

nature isolated in that fashion.

And, lastly, and you can see how it now relates, is just a series of a kind of claim in this area. You get claims of a form of isolated DNA molecule with a nucleic acid sequence of thus and such.

MS. KRAMER: What is the key word? You isolated.

MR. HOLTZMAN: The key -- Becky -- isolated and/or altered.

MS. EISENBERG: -- purified.

MR. HOLTZMAN: Purified.

MS. EISENBERG: Yes. Just some form that doesn't exist in nature. Something that distinguishes it over the form in which you can find it in nature.

DR. MIIKE: Let me ask you a question. Suppose Buckminster Fuller had patented fullerines? And, then later on, they find out that it exists in nature.

MS. EISENBERG: So it could be commonly validated by subsequently discovering -- This is not like new, the idea that you could do patents in isolates. It has been happening -- you know, it antedates modern biotechnology. There are older cases allowing patents on, you know, purified aspirin, purified ---

DR. MIIKE: One last question -- except for humans.

MS. EISENBERG: I am sorry?

DR. MIIKE: You say biological forms except for humans.

MR. HOLTZMAN: Yes.

DR. MIIKE: We can talk about that later.

MR. HOLTZMAN: No, it comes back to the issue of being the subject of a property system. That humans are excluded from being the subject of property rights; whereas ---

DR. EMANUEL: Otherwise -- your kids.

MR. HOLTZMAN: What?

DR. EMANUEL: You could patent your kid.

MS. EISENBERG: You couldn't -- but it is sort of silly. The Patent Office said that.

MR. HOLTZMAN: But, effectively, that is the genesis of it. Okay?

DR. LO: Could I ask you another question that goes back to the utility criteria that to be patentable you have to have a practical use. What exactly does that mean in the context of these older cases of sort of embryonic stem cells?

Do the utility -- can it be just a sort of hypothetical, in the future, this might be useful for transplants? Or how specific and actual do you have to be about these ---

MS. EISENBERG: This is an area where the law has wavered over time. You can see some old cases that take a sort of a minimalist approach, saying, why should we care whether something is useful or not?

If somebody patents something that is useless, the patent is going to be valueless. So there is no point in really being particularly aggressive about confining patent protection to that which is useful.

Recently, the Patent Office got quite aggressive about enforcing the utility requirement, requiring something on the order of, you know, FDA level demonstration of clinical effectiveness.

And then they retreated from that in response to a lot of complaining from the biotechnology industry, and also in response to some decisions from the court of appeals for the federal circuit, which reviews the decisions of the Patent and Trademark Office.

So now they have -- it is now waning, the strength of -- the utility requirement is in a period of decline right now. But, basically, the operative language in the Supreme Court decisions is practical utility in currently available form.

You have to show, at a minimum, that this can be put to some sort of beneficial human purpose now. Not something that might have value in the future.

MR. HOLTZMAN: And that is the two different elements in Bernie's question. The one is: What is a sufficient demonstration of the utility: Hence, you don't need the FDA trial. An *in vivo* model will suffice. Okay? The second is: Is it a real utility? Because the issue that comes up certainly in the 10,000 gene fragment cases is whether there is a real utility, you know, beyond bronze them and make bookends.

So let's turn now to how, against that backdrop, different things that look and smell like bioethical issues get going. All right? And whether or not they are is an interesting question.

(Slide.)

The first, and this perhaps relates most directly to the issues in front of people like the NIH and the Genome Project in terms of whether or not gene sequence patents should be filed as we rapidly get more and more genetic material pouring off the sequencers, is this argument that goes:

That gene patenting blocks academic research and the rapid dissemination of knowledge versus that gene patenting is essential to the pharmaceutical and biotechnology industries, and in fact, the alternative would be trade secrets, and that is much worse than patentability.

Now, some people have construed this as a bioethical issue.

All right? I personally don't think of it that way. I think of about it as an economic consequentialist argument. And that if you go back to that quote from Jefferson, society may give an exclusive right according to the will and convenience of the society.

Society could certainly decide that in this case society would be better off if patents were not filed on these things or were not filed when it came out of NIH funding. Okay? But I am not sure that that is anything special about biology or anything particularly ethical that is at stake in that case.

(Slide.)

The second set of issues, which starts this slide into an ethical realm, or what I would consider the ethical realm, really goes -- there is an argument that goes like what we are really talking about is regulating patents, or should we be talking about regulating use?

So for those who think we need to regulate patents, and this really came out heavily back in '87, for example, when we were dealing with the animal patent legislation to prohibit it, was that patents on biological or genetic materials promote or at least condone socially or morally reprehensible practices contrary to public policy.

Interestingly, for those of you who may not know it, in Europe, there is an additional criterion of patentability, that it doesn't

contravene or offend, whatever, public policy and public morality.

So, for example, they will grant, and have granted, patents on the oncomouse, a model of human cancer, but they will reject patents on other genetically engineered animals, because they don't think they serve any purpose that is good for the public and that there is something morally offensive about it.

Now, that is versus a position which says patents are value neutral. Laws and regulations constrain social and morally reprehensible practices, not patents. This is, in fact, how the patent law in the United States has operated.

You think about the examples of guns and gaming machines, which is where a lot of the case law came out on this. Is it really came out saying that this was not an issue for patents to be considering.

Fleming is a device for perfusing an animal head. That is an actual patent. It is a machine where you can keep an animal alive. One could question whether that is something we really want, is machines keeping animal heads alive.

But at least the Patent Office has always taken the case that even horrific things, it is not our decision whether or not they are patentable that they are horrific.

In the Fuller versus Berger, 1903, the court held that utility could not be negativized by the mere fact that the thing in question is sometimes injurious to morals or to health or to good order. It would be fatal to patents for many of the noblest inventions of the 19th century. The steam engine, etc., etc., were cited in that case.

So, again, it is not a new issue. Again, is it a bioethical issue? It is an issue which goes beyond biological material patents, and the question in front of you is: Do you want to fundamentally reshape the patent system of the United States to add another criterion, such as there is in Europe, which has not existed to date?

(Slide.)

So where I believe the real bioethical engine gets going is here. It is an issue we seem to get coming back around to as we think about this.

People -- not just the lay people -- but scientists speak of the genes as the stuff of life, and the human genome is our common human heritage.

When you start to think that way, the idea of someone owning it is something that -- there is something that is problematic there. There is an issue that seems to be at stake. And we see this expressed by a variety of people from the reputable to the not so

reputable. Rifkin, for example, in '87, in response to the decision in Allen, that the PTO has made organisms indistinguishable from electric toasters and automobiles. Leon Kass, in response to Chakrabarty, "Living organisms are no more than a composition of matter, no different a perfume or insecticide."

And then the World Council of Churches, in a similar vein that what we have here is a highly reductive conception of life which seeks to remove any distinction between living and non-living matter.

(Slide.)

I think this is what really comes out here is that the basic ethical questions that this reflects are these kinds of questions.

Namely, can we simultaneously maintain both an engineering perspective, which is intrinsic to the notion of genetic engineering, the perspective in which you manipulate the world to human ends, can you maintain that along with an attitude of reverence to the natural world?

And, moreover, does allowing the patenting of genetic materials fundamentally and irrevocably commit us down a path of reductionism and such an overwhelmingly materialistic view of the world?

I think this is where the engine for the ethical issues really

come from. And I am going to propose, if I may be so bold, a couple of things that I think are worth thinking about when you think about these things.

(Slide.)

The first are to make some key distinctions. First off, the physical substance, the gene, is not the invention or the idea. The physical substance is the embodiment of the invention or the idea.

This is the Shostakovich Fifth, but clearly, if I drop it and break it, the Shostakovich Fifth is not destroyed. Okay?

(Slide.)

Second, the patent right is not a property right, ownership right, in the physical embodiment. If I have a patent on the epo gene, I don't own Rachel's epo gene.

Rather the patent right is a right to prevent others from profiting the invention by making, using, and selling, etc. Again, I own the disk and I can play it, but there are certain things I cannot do with the symphony. I can't copy it, reproduce it, and resell it.

(Slide.)

So at least in my own idiosyncratic way in thinking about these, the way I come at it is the following, with reflections on what it means to be not merely a composition of matter, to go back to your

question, Bernie.

Whatever else it might be, a soaring testament to the human spirit, the Shostakovich Fifth is indeed here on this disk, and it is indeed a physical composition of a certain series of sounds. Do I really need this?

REPORTER: Yes.

MR. HOLTZMAN: All right. Whatever else it might be, the leptin gene, changing our idea of whether obesity is a metabolic disorder or a weakness of the will. Okay? And it does have a composition of material comprised of this following series of nucleic acids.

And whatever else I may be, a subject of rights, responsibilities, and obligations, I do stand physically in this place before you, and I am a certain composition of atoms. The fact that I am seen and am that doesn't commit you all to treating me in a certain way.

So I hope that was useful.

DR. MURRAY: Thank you, Steve. Becky, do you wish to ---

MS. EISENBERG: Yes, I just wanted to add a little bit. I thought that was fabulous, Steve. That was great. I want a copy of these overheads.

I wanted to add just a few words about what is at stake in the patentability of DNA sequences and genes from a pragmatic

standpoint.

That is, if you view the patent system as having the aim of motivating commercial investment in research and development, what do we stand to lose by withholding patent protection, let's say, from genes or from some category of genetic inventions.

Basically, we are dealing with a very patent sensitive industry here. To the extent that you want to motivate commercial investment in the development of biotechnology products, you are talking about the pharmaceutical industry and some of these smaller biotech companies.

These are both very patent-sensitive types of firms, although they are patent sensitive for different reasons and at different points in the R&D process.

The big pharmaceutical firms are patent sensitive, in large measure, because they spend a lot of money in bringing products to market.

They spend a lot of money in conducting in FDA-mandated clinical tests, and they want some exclusivity at the end of the day in the ones that are successful in order to ensure that they can cover the hundreds of millions of dollars that they spend in bringing that product to market.

The younger biotechnology -- but the big pharmaceutical companies typically finance their ongoing research out of profits on existing products. So what they want to have a patent position in is the thing that they ultimately put in a bottle and sell to consumers.

A patent lawyer for a major pharmaceutical firm once told me, Becky, I keep my eye on the bottle. If it is going in the bottle, I want a patent on it. If it is not going in the bottle, I don't care. It can be in the public domain.

So they have -- their outline is they want product exclusivity at the end of the day in order to recoup their investment in R&D in advance of that and particularly in their investment in the clinical testing.

The younger biotech firms are also -- and it is a bit of an oversimplification to draw this dichotomy -- there is a range from one end to the other -- but to oversimplify for expository purposes, the younger, smaller biotech companies are also patent sensitive, but for a somewhat different reason and at a much earlier stage in the process.

The younger biotech companies typically don't have existing products that are creating -- providing a revenue stream that they can funnel into their ongoing research. If they want to fund their ongoing research, they need to raise capital, but way in advance of having a

product that is ready to go on the market, or else they are never going to get to that point.

So they see a patent portfolio as something they can use in the capital markets to raise investment capital or in negotiations with potential big pharma partners in order to get people -- to get larger firms to invest in them.

So for that reason, they want to have patent rights at a much earlier stage, way before they have anything in the bottle that they are selling.

As a result of that, they have an interest in patenting discoveries that are made far upstream of the ultimate delivery of a product to a consumer in the bottle. They are going to want to see earlier stage discoveries patented. Otherwise they are never going to get to the bottle stage.

So I think it is important to keep the interests of these two different types of firms in mind in thinking about what certain ethical positions on the patentability of DNA sequences or genes might cost in terms of incentives for product development.

Now, looking from the big pharma perspective at the interest in having product exclusivity at the end of day, from that perspective, the best sort of patent right is a product patent in what it is

that you are selling. The second best type of patent would be some sort of a process patent, a method of use patent, a patent on the use of a particular unpatented product for a particular therapeutic purpose.

And sometimes a process patent position can be a very lucrative patent position. AZT is an unpatented product that is protected currently by process patents on its use for particular therapeutic purposes. Sometimes, that can be enough.

Where you get into trouble with process patents, and why they are the second choice and not the first choice, is if the unpatented product is useful for multiple purposes, and it is tricky to monitor what it is being used for.

So that if AZT turns out to be a moderately effective shoe polish, for example, so that people could put it on the market for this other purpose -- it would be suitable for some substantial non-infringing use -- you couldn't go after competing manufacturers for selling AZT, because AZT is unpatented. They are not performing the patented method.

The patients may be performing the patented method, but you don't want a remedy against the patients. You want a remedy against your commercial competitor.

So process patents can be good so long as the underlying

product is only useful for one process. Once the underlying process is useful for a variety of processes ---

DR. MIIKE: -- what you mean by a process patent specifically in the case of AZT.

MS. EISENBERG: A process on -- I am not sure exactly what the claims are -- but a method of treatment by administering AZT in a therapeutically effective dosage. That is going to be the logical form of the claim.

DR. LO: I am sorry. So you patent the administration of the drug.

MR. HOLTZMAN: It was discovered 40 years ago. The novel discovery was that a method of treating HIV infection comprising administering AZT.

DR. MIIKE: You mean to say you can put a patent on a treatment?

MS. EISENBERG: Yes. A method

DR. MIIKE: No, no. Because I thought what you meant by process was a novel way of producing AZT.

MS. EISENBERG: No. You can patent -- you can patent that, too.

DR. MIIKE: Yes, if you patent that, then you don't care

about the shoe polish. You still get your royalties. But I hadn't realized that you can patent an application?

MS. EISENBERG: Absolutely. You can patent -- a process is a series of steps to produce a desirable result.

DR. MIIKE: Then, theoretically, when they started using aspirin for prevention of heart attacks, someone could have patented that?

MS. EISENBERG: Yes, in theory. Now that is a good example of something that would not be a very valuable process patent, because aspirin is suitable for lots of other methods. You wouldn't be able to -- the fact that you have a patent on the use of aspirin for one purpose would not prevent other commercial firms from selling it for other purposes.

MS. KRAMER: But they couldn't ---

DR. EMANUEL: They couldn't advertise, say, for heart attacks ---

MS. EISENBERG: Right.

DR. EMANUEL: -- if you patented it. But they could advertise it for headaches.

MS. KRAMER: But nobody could come along and get a second patent on it for another process?

MS. EISENBERG: You could. You absolutely could, It just would be very difficult to enforce. So it would be very weak, ineffective patent protection. When you have multiple uses for a product, process protection is not very good, especially if you have a diffuse population of users.

If you have a small set of users, if it is easy to monitor who your users are and what they are doing, then process patent protection may be adequate. If you have a process on a particular diagnostic method that is only used by half a dozen labs around the country, you may have a pretty good idea who is infringing that method patent.

MS. KRAMER: A question. What is the economic logic of that going back to the AZT? Is it because the firm that holds that patent for that process patent spent large sums of money in developing that use for it?

MS. EISENBERG: Yes.

MS. KRAMER: Okay.

DR. LO: Then -- I mean, I assume the original patent was to treat at certain dosages people with a certain stage of HIV infection. Now, if I am using a different dosages with a different ---

MS. EISENBERG: It depends on the scope of your claims. This is all a matter of how you draft your claims. And, again, I don't

have those claims firmly in mind.

It is conceivable that you would put all sorts of limitations into the language of your claims that somebody would get around by using different dosages or by treating for different purposes. Once that happens, then your patent is essentially useless.

MR. HOLTZMAN: AZT was believed -- was discovered or invented as an anticancer agent. The discovery that was the subject of the patent and the experiment was the discovery that it had an antiviral activity. And that gave rise to the claim or the logic for a method of treating HIV comprising administering AZT.

MS. EISENBERG: Typically, patents will have a series of claims, some very broad and general, some quite narrow and specific, and you fight it out with the patent examiner to see how broad a claim you can obtain.

DR. EMANUEL: I want to focus us in, because part of the point of the meeting was setting the agenda for the big Commission, and getting too close into patent law to try to get a substantive question resolved about

-- I mean, I think, for us, part of the question is we are, in some sense, chartered to address this issue by the enabling statement.

And I think the question is, for us, how urgent is it, how are

we going to get our hands around it, and where on the agenda does it go? I don't think -- whatever we are going to say here, we are not going to say, it is not a problem. We don't have to focus on it. We have been told we have to focus on it, and we have to say something.

It is not merely a technical problem of law, it seems to me. Whatever we want to say about the economic incentives of the pharmaceuticals, etc., I think the quotes that Steve put up suggest that it goes beyond that. As those need to be considered, there is also this question, which we have to address, as to, you know, how does patenting affect our conception of being a human being?

Steve, you may have one approach. I am not sure I fully understood the whole logic of it, but it seems to me the question for us in the last 15 minutes has to be: How do we see this problem as a task for the Commissioner? Right?

DR. MIIKE: Can I ask -- I wanted to ask you, with the legal background and expertise that you know, within the framework that either the Patent Office supplies or the Supreme Court has -- are there areas in which there is some need for some clarity by a body such as us that could be helpful to either the Patent Office or ---

MS. EISENBERG: You mean, does the patent system require -- (inaudible) -- from a body such as this. The answer to that

would be clearly no. The patent system won't listen to -- the patent system is even outside of its mandate to assess the ethics of patenting this or that invention within -- except in really extreme cases.

DR. MURRAY: Do they have to sign oaths or something that they won't take an interest in ethical issues ---

(Laughter.)

MS. EISENBERG: --- consider -- I mean, I would not recommend to you putting forth to the Patent and Trademark Office an ethical -- I mean, you wouldn't want to propose to them that -- you wouldn't want to put them in the position of making fine-tuned ethical calculations. That is not what they are good at ---

DR. MIIKE: That is not what I asked. But your answer is no anyway. They are clearly outside of the legal analysis. Someone like Harold Varmus can make a decision that says all NIH discoveries, we are just going to leave them out in the open market.

So my second question is: Coming from the background, and I assume you have been versed in the ethical discussions, whether or not -- and Steve already has his viewpoint, which is that there really is not area in which we -- maybe I am stating this too strongly ---

But my second question is that given the legal system, from an outside perspective, is there anything that we can add to this that

may, in the long term, alter the way in which current patent decisions are made?

MS. EISENBERG: I don't know that any -- give that the patent system takes ethics as being outside of its mission and outside of its -- not my department -- I don't know that anything a body like this says is going to have an impact on the patent system.

What you might be able to do is help lend some clarity to some very fuzzy and unfocused discussion of the ethics of patenting in this area. Recently, that discussion on focused on gene patenting. But, in some ways, this is a reprise of a recurring controversy over patenting in the life sciences generally.

MS. KRAMER: Well, would either or both of you give us the arguments on the other side, the other side of Steve's argument?

MR. HOLTZMAN: Well, okay, let's be clear in my argument. All right? Maybe it is because I have a narrow definition -- I think profound bioethical issues come up when you start to think about this. This was what I was trying to acknowledge at the end. All right? And maybe it is a bit obscure and over a beer, we can talk about how that last few slides maybe get you in an area ---

I think that we have -- the arguments about regulating use versus regulating what is patented -- that is a public policy issue, and it

is a bioethical issues to the extent that one is saying, as a matter of policy, the United States ought adopt the European model by which issues of serving public policy purposes, not offending morality, should be one of the criteria of patentability.

Certainly, this body could raise that question. I don't think it is particularly a bioquestion. Okay? So I think that would be one argument. All right.

The second argument, the bioethical, is that last series of quotes I did put up, which there is a school of thought that says that if you are willing extend to nature, genes, etc,, property rights of a certain kind, that that in itself commits to a certain view of the world and view of each other, etc., which is profoundly detrimental to us as a society and us as people.

I think that is a very significant thing to be thinking about and that we could be talking about. I may, after having thought about it for 10 years, reached a certain kind of conclusion that those are important issues, but they are not about patenting and whether or not patenting is at stake.

And even if I do or don't have patents, I could still have views on those things. That my view on patenting doesn't determine how I go on to those. And I think that that is what Becky is pointing to, is

showing how those issues bear and don't bear on the issue of whether or not patents should be extended to biological materials could be a service.

DR. MURRAY: David and Bernie.

DR. COX: So this is going to seem peripheral, but I think it, in some ways, getting to what you are -- again, with a specific example. It is not whether biologicals should be patented or not. But it is an issue of fairness, and in some ways, it could come back to the stored tissue samples.

So you go to a place like New Guinea. You talk to people, and you isolated blood cells from them. At that point, there is nothing special from those blood cells.

But if you hadn't had those blood cells, you wouldn't be able to create the special invention that is specifically -- it is not because that was just one, you know, random blood cell -- but it was a specific type of blood cell that allowed you to make this invention.

Now does that mean you shouldn't patent it? Well, I think -- I mean, we have been through those discussion. But from the point of view of fairness, should there be some compensation -- that would come back to the compensation -- to the people that made it possible?

Now they made it possible, because they offered the specific

raw materials. Now, if you could have gotten those raw materials someplace else, it wasn't special. So I think that this is an issue that comes out a lot, particularly in the context of genetic research, in the context of families.

Because you can go into a certain place, a population, you can compensate individuals, but in some ways, that is not -- it is viewed by some people -- this is one viewpoint -- as, you know, very superficial compensation. So somebody else -- you know, it is like giving beads when you buy Manhattan.

So this isn't really an issues of patenting, but I think it is related to patenting. It is not whether the biologicals should be patented or not. But it is fair use. It is really back more to the compensation issue.

MS. EISENBERG: I think it is a huge can of worms. I would not recommend that you get into that issue at all.

DR. COX: I am not suggesting we get into it, Becky, but I was bringing it up because Bette asked for an opposite side from the point of view of patenting.

I think a lot of people are concerned about patenting with this issue of fairness, and they get it confused with the issue of patenting, whether it is fair to patent biologicals or not.

MS. EISENBERG: I mean, from the patent systems perspective, it is very clear that what a patent represents is an invention, not giving somebody a blood sample that turns out to facilitate an invention.

DR. LO: At our first meeting, I remember Francis Collins suggested that one of the issues was not whether or not you patented something but how widely available it was in its earlier stages, when it was basically a research -- its utility was as a research tool not as a potential product for sort of putting into the pill bottles by your large pharmaceutical firms. Is this an issue ---

MS. EISENBERG: I think that is a fascinating and very important issue. I don't think it is an ethical issue. I mean, I tend to agree with Steve. That is an utilitarian issue. How do you get the most effective use out of research materials?

Would you get more effective use by allowing them to be patented and privately appropriated by firms who are then motivated to develop more profitable research material, or would you be better off by having such research materials, as we have in the absence of those incentives, made widely available to anybody who wants them?

That is an empirical question, but I don't see it as an ethical question.

DR. EMANUEL: But you can't say it is merely utilitarian; therefore, it is not ethical.

MS. EISENBERG: No.

DR. EMANUEL: By being utilitarian, it is perforce is an ethical question. Because the question is whether that is the right way of thinking about it.

It seems to me -- here is where I got a little bothered. There are various ways of valuing human beings and their component parts. There are intrinsic ways and there are instrumental ways.

It seems to me the fundamental issue here and the reason why patenting -- and I agree -- I think its focused on patenting -- but I think it has echoes other places -- is how are we going to value people? And does patenting them suggest that that is only possible by valuing them in a certain way and, therefore, denying their value intrinsically?

That, I think, is the heart of this objection, of the visceral response people, as you quoted Kass and the National Council of Churches, have to the issue of human patenting.

If we do only look at it instrumentally -- what does it do for the biotechnology companies in terms of profits -- what does it do in terms of allowing information flow among researchers and enhancing -- we are looking at it in the utilitarian way, and we are missing this bigger

social meaning and the question of how do we value people?

It seems to me that the only -- the marginal benefit again that we can provide in this Commission is to try to sort through those competing claims on the instrumental, intrinsic value and the way they are played out in the patenting question.

Now, I think I heard Steve say, although I am not sure I understood all the argument along the line, that even if you patent a human gene, you don't necessarily the way you can value a person intrinsically.

I am not sure I agree with that. I am not sure I even understand the argument. It seems to me -- I don't want -- that kind of question or posing the question and playing out the argument -- is what we need to do to come to a resolution of whether patenting is a good idea or not.

The Patent Office may not pay attention to us, but in this case, it seems to me we are not playing for the Patent Office. They are not our constituency.

MS. EISENBERG: Right.

DR. EMANUEL: The public is our constituency, policymakers who might modify the Patent Office rules and regs. Courts eventually may come to see the issue in a different light. God knows, the

courts sometimes completely change course.

MS. EISENBERG: Congress is more like the constituency. Yes.

MR. HOLTZMAN: I agree with you 100 percent. You did understand me. Normally, when people present this, they take all of the bucket of arguments against and for patents, and what I tried to do was split them out into different categories to provide a heuristic to say: What is really at stake? Is it the kind of issue that is a bioethical issue? We won't get into whether utilitarianism is or is not ethical, a matter of ethics.

What I was suggesting at the end is that the inquiry you want to undertake, I think, is the inquiry that really counts.

Whether my resolution in the last slide -- put that aside -- the previous two slides -- was to suggest that if you are going to go down that path, I think some of the distinctions I was trying to raise is where the inquiry had better start if it wants to start to piece apart what is really at stake in the notion of a patent and what it does or does not irrevocably commit you to in terms of a view of nature.

DR. EMANUEL: But in this case, Steve -- okay, we are agreed that far -- and then, and this is the next step, does the economic questions related to whether we are going to have a vibrant

biotechnology industry, etc., is that a sort of merely economic question or is that part and parcel of the instrumental value you might attach to human beings and must be considered in that light?

It seems to me that is the correct way to do it. So you don't say it is off the table. It is not ethical. It is ethical because it is one of the values you are considering.

MR. HOLTZMAN: And in that sense -- yes, again, you are right in the following sense -- although you gets into a huge issue.

Some of the opponents who follow out their logical conclusions about the last set of issues come from a perspective in which technological progress, not only in the biological arts, in fact, is the real problem that, you know, post -- the Renaissance -- we are irrevocably committed to a reductionist view of ourselves, and the only way you are going to stop it is with technological progress.

If we want to get into that discussion and want it for all those connections, that would be -- I don't know if we could do that here. I think we do have to start to break them apart.

DR. EMANUEL: Now, we are getting into substance.

MR. HOLTZMAN: Yes ---

DR. EMANUEL: I don't think we need to talk about the technological imperative to still talk about this and its economic value as

a consideration.

MS. EISENBERG: Right. It is important to understand what is at stake though, in talking about the ethical principles that you are trying to untangle.

MR. HOLTZMAN: I guess the problem I have with it is I have sat through too many discussions, where people representing industry say, but it is important to foreign competition, and it is important to the industry. And the person on the other side of the table is saying, what I care about is how we view nature.

And those arguments are not touching each other. They are just not touching each other. And to just put them all in the bucket together again, I think, is not going to help in generating a clearer public discourse, which, I think, is one of our ---

DR. LO: So let's go back to Dr. Emanuel's criteria, we have a big issue here. It is not clear whether it is solvable. It is not clear whether we have any marginal contribution to make.

But maybe it means we need to think a little harder about just because all the -- I mean, we sort of have the sense that this is an important dialogue to start, and it hasn't happened despite a lot of meetings. Is there something we can do that is different that has a chance of making a contribution?

Because, if not, of course, you are going to repeat discussions that have been happening for years, decades, whatever, centuries. We probably should stay away.

MS. EISENBERG: I don't think this is an area where you are going to achieve widespread consensus. I think some of the ethical objections that have been raised have been motivated by ethical positions that would not commend widespread ascent, but they are strongly held by some people.

DR. MIIKE: Well, that is okay. I thought we had decided in the very beginning that we would not play it safe. If we only get into areas in which we can -- whatever we say reaches widespread consensus, what are we doing?

This raises an issue about -- I know, laws do change. When I was in law school, which was a long time ago, I had a classmate argue passionately for standing for animals and plants. That is the case law. Right now, I am nominally the defendant in the same sex marriage suit in Hawaii, and something is going to happen.

I only ask the question about whether there was something that we could do useful in terms of the Patent Office and the court system is to take a sort of look at. If there is something we can do that would be helpful to clear up some of the legal issues. They say they

don't really care. So that is fine.

MS. EISENBERG: Quite obviously, the courts don't care. That doesn't mean Congress doesn't care.

DR. MIIKE: Well, yes, that is what I mean. So the next question was then, as an external body, is there some area that is reasonable.

All I said in my letter a long time ago was that I don't think we should cut this off as an area of inquiry. How we inquiry and what we inquire is the issue which we are not going to solve today.

DR. MURRAY: Let me make two observations. The first one is let's not lose sight of Zeke's distinction, and really it was embodied in Steve's presentation between the sort of instrumental ethical concerns, and I actually subscribe to Zeke's way of -- you know, I want to say that those do count as moral concerns -- and the intrinsic concerns about the sanctity of life. We don't want to be reductionistic about living things.

That is across the patenting of genes *per se*, the patenting of animals *per se*, and the patenting of human genes, in particular, for creation -- you know, the insertion of human genes into other organisms, for example, biological cell systems. Those are all things that people think about.

And here is the second observation. This issue

-- I guess it is a Hollywood term -- has legs, you know. It has come up so there is a public consciousness, and it has aroused a lot of -- I am not sure how widespread it is. I have never done a count of how many people are interested.

But it certainly seems to get people interested, including some very smart and well-informed people and then interest subsides, and then it comes back again, and people get excited about it again. Who is it that rises

-- it is not Lazarus -- is this the Lazarus issue in genetics maybe? That it keeps rising from the dead.

Which suggests that is either it is unsolvable, or as I am more inclined to think, it hasn't really been done right yet. And if we want to be willing to take a chance to try to do it right, maybe we should.

But maybe doing it right would require a different model of process and inquiry from us than the first few things we have talked about today. My guess is that a lot o the arguments and data are out there on this one. You don't think so.

MS. EISENBERG: I don't think there actually has been. I think there has been a lot of public attention to the issue. I don't think there has been a lot of careful, scholarly discourse about the issue.

DR. MURRAY: I think if we have such a discourse, it would

have to involve some of those who have espoused positions where they express a lot of worry about the intrinsic -- sort of the message that patenting has for the intrinsic value of life, human life, animals, whatever.

So it might be a different sort of model than hiring experts to go off and write papers. But my inclination is to not be safe, not play it safe here, to take it on, to try to see if we can advance the conversation.

But I say, it is not going -- it is going to -- my instinct is that it is going to be a dialogue something broader than the composition even of the full Commission somehow. That was a show stopper.

DR. MIIKE: It is morning for me now. I am already to go.

(Laughter.)

MR. HOLTZMAN: I guess the concern I would raise, Tom, is there has been a lot of stuff written. I guess I disagree with you.

MS. EISENBERG: There has been a lot of stuff. I wouldn't say there has been a lot of serious scholarly, discourse is the thing that I mean. Maybe that is not what you want.

Maybe on the level -- you are saying -- Tom's response to that was, well, I don't even want serious, scholarly discourse. Of course, if you don't want serious, scholarly discourse, then it is already there.

DR. MURRAY: Not at all. It is just that it is important to have people who have reasonably thought-through positions passionately held, to make sure that they have some voice in the process.

It just might be that we end up commissioning papers of different sorts. It may be that we have a kind of public symposium or series of symposia that allow those voices a place.

But in the end, I think what we want is a report that is both serious and scholarly, but in plain English so that we engage the arguments, we engage both positions, and we come out with a position.

But our reasoning is quite clear and expressed very -- in a scholarly manner -- but very clearly. So that any person who can read reasonably well can pick it up and say, well, I understand what the position of these folks might be holding.

DR. EMANUEL: It seems to me one of the things -- there is a group that feel completely alienated from this kind of process -- and I think their attempts to express what they take to be the intrinsic value is completely denigrated.

I think actually that may turn out to be a very large number of people. And that is one of the reasons the issue keeps having legs. And I think the way they put it may not be ways we are particularly happy about, but I think it is a deep issue in this country.

I mean, we could say we are not going to rule on it. We could say we are going to do something original, as Tom is suggesting. I think to say these arguments aren't meeting, we are not going -- they are not going to meet, and therefore, we are going to skip over in silence -- I mean, we might end up doing that -- but I am not -- I don't know.

DR. COX: So, I mean, it didn't escape my notice that in terms of patentability, the issue that you are talking about right now is sort of the major philosophical issue. But Larry said it.

That we said that we were not going to shirk away from difficult things, and I will tell you there is a significant fraction of people out in the world that when they think about genetics and patentability, this isn't what they think about. But what they think about is the ethical issue of fairness.

Because patentability equals money. It equals money. What is fair in terms of economic compensation? So that I don't know whether it comes up here or where it comes up, but somehow for us to think about it -- because it falls into one of the unique categories with respect to genetics -- that is, the genetics of populations.

So genetics equals populations. So if certain populations are being exploited, that raises -- whether they are or are not being exploited -- just the perception that they are being exploited -- is a real

ethical issue.

And that you say, well, that is not so much an issue in our country. But I will tell you this isn't going to go away. This is something that you don't hear as much about right now -- you hear about it in the context of other countries -- but it is a major problem.

DR. MURRAY: You hear it in this country, too. I have heard a discussion about the proposal for a human genome diversity project, which contrary to what you might think, is not actually going on, and some of the greatest opposition was from Native Americans.

DR. COX: And it is a diverse opposition. But I bring it up now, because it is not -- I want to make it clear it is not in the context of patents. It is in the context of economics and patents being equated with economics.

So it is a tortuous argument and not something we should probably bring up now. But I don't want to have this fall off the table. Maybe it is not something we are going to deal with, and I take your point, Becky, it is a nightmare. But it is there.

DR. MURRAY: So that made a lot of other people unhappy.

DR. COX: Yes.

DR. LO: Let me just add to that, because I think it ties back to what Rachel reminded us earlier of our charge to address research

issues.

I think it really affects the willingness of people to participate in research, at least some individuals, thinking that somebody is going to make a lot of money, which they wouldn't make, unless I donate my tissue, and I am not going to get any of it.

DR. COX: So it comes back to the stored tissues. Again, it is complex in terms of where it comes in, but it is something that for us to not factor in here and discuss would be, I think, a mistake.

DR. LO: Let me just say one more thing. I mean, you see it in a lot of other situations. I mean, sports. How much do you pay somebody on your team who is not that good a player but plays a role that you need filled?

So the Seattle basketball team played $7 million to someone who is terrible, but they need a center, and he was the best one there. And, you know, he is not going to. So but for his contribution, you wouldn't have the scientist being able to do their work, and in that sense, it is a different -- it is different model of fairness than the economic model, which says the more you put in in terms of sort of intelligence, hard work, and the like, the more you are going to get out.

DR. COX: It directly impacts research.

DR. LO: Absolutely.

MR. HOLTZMAN: So what strikes me is that, again, the subject of patenting is the nexus for all of these issues to come up. But the patenting itself may not be the issue.

DR. COX: Exactly. We are in agreement.

MR. HOLTZMAN: So the concern I have, in terms of both research and commercial as well as academic research, is if you open up this issue in terms of the is patenting ethical -- all right -- what you are doing is

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And you say because there has not been good scholarship or there has not been good dialogue -- all right -- there has been enormous dialogue, most of it just contributing to the confusion on the issue I have tried to split apart. Most of it trying to just take that flash point of the ownership issue of human life or whatever and use it to push an agenda.

So what this Commission is going to have to face is perhaps serving an agenda which it doesn't intend to serve in the name of supposedly encouraging enlightened discourse. You need to take that seriously.

DR. MURRAY: Becky Eisenberg, do you have to leave?

MS. EISENBERG: I do.

DR. MURRAY: Anything you want to say as a parting comment?

MS. EISENBERG: No. I don't think -- I can maybe answer any parting questions if there are any particularly before me.

I think, you know -- I guess I think it is important to realize that there is a lot at stake here. That what is patentable determines not only what kinds of products can get developed, but what kinds of institutions or firms are able to summon the resources to pursue certain lines of research.

It consists of what you were saying about you cannot consider -- you cannot really unbundle the ethical issues from the economic issues, because ultimately, at some level, they have to be commensurable. That there is some cost to one's principles that has to be take into account in deciding how strongly held your ethical views are.

DR. MURRAY: Thank you, Becky. I understand better because of the even very brief presentation that you gave us and the background materials. So I really want to thank you.

MS. EISENBERG: Well, you are welcome. Good luck.

DR. MURRAY: We will talk to you again.

MS. EISENBERG: Thanks.

DR. MURRAY: Have a good trip home. Better luck getting

home today than you had last night.

MS. EISENBERG: Yes. One would hope so. Okay.

DR. MIIKE: I just wanted to add that there is an opposite side to what Steve just said -- is that what we are saying is we want to take a look at the issue. We may end up in a position that we would call apologists for the industry who wants to keep patenting, just as well as on the opposite side.

If we get into this area, and we come out with some firm opinions, obviously, there are strong feelings on both sides. So no matter what we do, we are going to be criticized.

DR. EMANUEL: I think, in this case, maybe our main focus should be on the educational value that we can serve here.

Maybe this goes back to what Tom said about, you know, there being a lot of concern here, and part of it is clarifying the issue and maybe saying, look, you think it arises in the patenting context. In fact, the patenting context is just, you know, really a displacement of this much more fundamental issue. We are really going to look at this fundamental issue.

So we could use it as a wedge, but whatever -- I think we have to get to the underlying concern, and I don't think we can say we are not going to address patenting, because there are people who have,

you know, views, and are just going to try to bamboozle us into -- hopefully, we are smarter than that.

And my only -- I think we are in heated agreement that patenting is -- it is a side issue. There is a real issue there, though, and our job is to stay focused on the real issue.

MR. HOLTZMAN: And the last thing I want is myself and this Commission to be apologists for industry. Because I think there are a real set of issues here, which reflection raises, and we would fail in our duty not to engage it. But I come out in heated agreement with you about, I think, perhaps the way to engage it.

MS. KRAMER: Perhaps what?

MR. HOLTZMAN: The way to engage it.

DR. MIIKE: No, I wouldn't say that. I am saying that we might end up there. I am saying that no matter what we do, once we get into this area, you know that that is a criticism that I can expect no matter

what came out.

DR. MURRAY: It is a criticism that there is probably no way to evade. What we can do, though, is have a kind of process, and here is why I think process will be particularly important in this topic area -- that is as open -- really is an effort to be as inclusive, to listen to these

different voices.

And then we can come up with our decision, and people can say, well, we don't like the decision. So, therefore, you are a tool of one or the other. But we can at least feel that we have been open and inclusive and reflective about it and take our stand.

Then we will see what happens. People who are going to say, well, they didn't buy what I said. We will say, well, it is because you weren't persuasive. We should be able to give them reasons. So we can give reasons.

DR. COX: But there are many things we can educate on, and I would just like to come back again to the fraction of people that are going to be interested in one question versus another. I don't necessarily know the answer to that.

But I really would like to be sensitive to the kinds of questions that most of the people out in the public would like to see us address with respect to specific points.

My impression is, although I find this issue of the sort of the philosophical basis that we are talking about now intellectually very interesting, I wonder how many people out in the public, if you were going to weigh that versus the economic issues of fairness, how they would weigh those.

I would like to find that out before we just put a lot of time and effort into one or the other.

DR. MURRAY: It is two minutes before 3:00, Bill Dommel tells me. We are scheduled to begin public testimony at 3:00. We have two individuals who have been given five minutes each for their presentations. If we have other questions for them, they can go beyond that, which would leave us as much as 20 minutes after the finish to sort of think about our next steps.

Are you comfortable at this point leaving the patenting issue and moving right to the public presentations? Okay.

We have two individuals, George Gasparis and Susan Pollin. Would you tell us briefly ---

MR. GASPARIS: Sure.

DR. MURRAY: -- who you are and what you are speaking to us about.

PUBLIC COMMENT

MR. GASPARIS: First of all, I would like to thank the Commission for providing me this opportunity to present my views.

My name is George Gasparis, and although I introduced myself as being from OPRR, I wanted to be very clear that my affiliation with the MPA institution, a university medical center teaching hospital, and that I am not a federal employee. Therefore, my comments will not be reflective of the Office of OPRR.

My comments are in regards to the very first session we had, tissues with DNA samples. But before I start, I would like to provide a little summary of my background so you can understand from which background my comments are made.

I have worked for 11 years in the clinical research arena as a data manager, and I have managed approximately 40-45 trials. Eight were federally funded; 35 or so were private industry or FDA type studies.

Then I moved on to an IRB at the medical center as the administrator and worked in that capacity for 5 years and had the opportunity to personally review over a thousand protocols. Now, I find myself at OPRR.

So I bring some insights from both the field as a researcher, from an IRB, and it is mostly from the IRB that I would like to provide some insights.

My comments revolve around the application of ethical principles found in the Belmont Report to current issues relevant to the utilization of tissue samples, especially retrospectively collected samples, for research in general and then specifically for genetic DNA sample research.

Likewise, this would also be applicable to other research in

similar confidentiality concerns arise, HIV tissue, research with illegal drug samples, etc.

The ethical principles that I am going to speak about from the Belmont Report mainly are autonomy versus beneficence. The HHS regulations protect autonomy very well in our country. And I will also later on provide a very brief comparison of our regulations compared to some other standards around the world.

Our country upholds autonomy probably higher than any other country. As a result, this leaves researchers with a lot of frustration, and as you survey the field, the comments, this is what you are going to hear from researchers.

That the regulations as they are written or they are applied by the IRB leave the researcher frustrated, because the researcher, mainly, the clinician, who spends the majority of the time with a practice, and then a certain amount with research, doesn't have the resources or the time to go out to do it the way the IRB wants them to do it or the regulations.

Specially, if we are going to think of the pathologist taking out retrospectively collected samples, and they were from many years ago, how am I, as a researcher, going to get consent when I don't have a clue where these people are to begin with. All I have is a path number

on these samples.

Or worst yet, these samples came from across the country, or they came from another country. There is no way I have a clue where these individuals are. The IRB has to deal with this issue within the design of the research study.

The regulations exempt research for which there are no identifiers, and by identifier, we must be clear to note that it is any identifier in which a link can physically be made back to the subject. So a path number is an identifier, any type of code that was used by any research program, encoded it, and it could be several codes down the road. But if there is any physical connection back to the sample -- to the person, then it is an identifier.

As a result of this, what we have is beneficence being weighed down. Just like we saw in emergency research, when we had the two issues hitting head forth, beneficence versus -- I mean, autonomy versus beneficence

-- likewise, we are having the same issues arise in this arena.

The researchers will claim there is a lot of valuable research for which I either cannot do or I am doing that is not within compliance with the regulations. And I will provide a specific example.

This is further clouded -- in some areas, where the decision

between medicine and research is not so clear -- and I will provide a specific example in a moment.

DR. MIIKE: Can I say something here? If you are going into too much detail, that it is better that you submit a written -- to you -- that we have some time to go over it.

DR. MURRAY: With all respect, you have got about a minute left.

MR. GASPARIS: What I would like to provide is a solution, a plausible solution, on such research could go forth.

The theoretical construct is that if we could allow samples to be passed forth with a little bit more flexibility, i.e., if they could be coded where the subject could not be identified, and there is some theoretical shield or standard by which it would protect the results coming back from the research back that would harm the subject, then I would hope that this could be construed by the Commission and provide the standard.

Where this standard is a codified standard much like a medical record in which authorization has to be sought after or consent to release back. This is the main focus of what I am trying to present.

Since time is running out, I would like to move to a specific example whereby IRBs deal with, and it is very difficult to construct

whether it is research or medicine.

Let's say there is an outbreak of tuberculosis within the AIDS population in a hospital and the pathologist or epidemiologist in the hospital wants to find out the source of this to contain the spread of this.

Well, within an institution, one would not say this is generalizable knowledge. Let' say this breaks beyond the hospital to other hospitals within a city. All of a sudden, it is becoming generalizable knowledge.

The pathologist would argue, no, this is within our purview or our responsibility in our practice of medicine to find the source of this and find ways that we can limit the spread of this infection.

An IRB perspective would say, no, this is research. It is increasing generalizable knowledge. So these are some of -- one example of how an IRB will struggle with such issues.

DR. MURRAY: I am going to have to ask you to make a conclusion.

MR. GASPARIS: Okay. The main thing is I hope that the Commission could come forth with some other mechanism by which we allow research to go forth, i.e., this theoretical shield or some standard by which research can go through, but results coming through would be

only permeable -- or would not be permeable where they would be harmful unless they are beneficial to the subject, i.e., the result is beneficial.

DR. MURRAY: And I request that if you have anything in writing that you submit it to us also.

MR. GASPARIS: Okay. I don't now but ---

DR. MURRAY: You can do it afterwards. Thank you. Susan Pollin.

MS. POLLIN: My name is Susan Pollin. I work at Georgetown University Kennedy Institute of Ethics. Today, I am representing myself, and I am here actually for work, because the Commission should know that starting in July a grant goes on-board, where I will be the J.D. of a M.D./Ph.D./J.D. trio putting together a database on the ethics of human patenting.

One of the issues here that has been alluded to that has not been directly addressed has to do with the notion of property. Property is not necessarily a thing. Ms. Eisenberg explained it was also intangible; it is an idea. Property is seen as a bundle of rights granted by the government, by the state, to private individuals or reserved for the state.

Four of those rights have been behind the four topics today. Tissue samples for DNA analysis goes to the right to possess. Who has those tissue samples? Genetic privacy goes to the right to exclude -- excuse me -- yes, to the right to exclude others from that knowledge.

Genetic discrimination goes to the right to prohibit. You are actually doing something, act of prohibiting them from take an action. Those two are not, I see, the same contrary to what other people may have said. And genetic patenting, again, has to do with the fruits of the labor. It is also exclusion. You get to exclude others and get profit from the fruit of your labor.

Now, the Warnock Report, back in the '70s, describes a gene as a unit of heredity. To me, that is like fungible, like a penny.

And a gene, because I worked in the early '80s in Norfolk and tissue research and in vitro fertilization, a gene existed within a genome, which exists within a cell, which exists within a mouse, which is why the mouse was granted a patent, because you can't really have one being useful without the other.

But why is genetics special? This goes back to property again, which is rooted in the individual and the law regarding also reasonableness. Back when property was actually formed as a law in England, you could grab land. It was very physical. It was a real

physical thing. Also physical was the fact of quickening. Life was seen as a woman feeling something kicking inside of her.

Roe v. Wade changed that a little bit when they talked about viability and said, okay, a doctor's ultrasound or whatever test will make this -- we moved in a little more scientific standard.

When I was working the lab, viability, to me, meant if an embryo was emitting a certain chemical signal that said, rescue the corpus luti -- on the ovary to keep the hormone regime accelerated so that the pregnancy can continue. It would have been a very different standard.

But the point is that the individual is at the root of individuals. I as an individual know that I have genes, but I don't see them. And I think this is the root of the distrust between the scientific researcher and the individual.

That, aside from the Moore case, that you have this distrust between researcher and the subject. And that you have to be very careful as a government body as to who you are going to give ownership, not property. If you call a gene a property, if you call a genome a property, you are really calling property rights in that, and you are not calling it property.

The key point here to me seems to be ownership. I wish the

other people here were -- no offense to you -- with the J.D.s to correct me if I made any mistakes -- but it has to be a burden of proof, a presumption, as to who gets the first stake in the property. In land, the government has it or the king had it depending on which area you are in.

With the gene, we like to think that bodily integrity and the person has property, has the ownership of their own gene first.

If you can find a mechanism whereby that can be authentically given to the pharmaceutical companies so they say I have got a green light. I can go. I am not going to be tripped up by John Moore or something else like that, I think you will get a lot more that way if you look at that ownership issue.

I don't know if this means something putting it in -- that the U.S. Patent and Trademark Office has to ensure that informed consent was given, if it is something that is a prospective law, and that samples that are already gathered or just grandfathered in or what.

As for the discrimination issue, I think you also need to look at the ownership issue as to who owns the gene first. I think that concludes my remarks. If you have any questions

DR. MURRAY: Thank you. And, again, if you have any written remarks that you would like to share with us, we will be grateful

for them.

MS. POLLIN: Do you have an address for that?

DR. MURRAY: NBAC's office. Yes. Margaret Quinlin will give it to you. Right. We have got about a little over 15 minutes now to decide what we want to do.

I want to correct one oversight on my part, though, in that I didn't thank Steve for coming to our rescue on very short notice and coming up with actually a very interesting argument at the end there with the Shostakovich argument as it shall heretofore be known, one that I want to reflect on a bit more. But I really appreciate it. Thank you.

NEXT STEPS

I have been asked by NBAC staff to make sure that we cover at least two things before we leave. One thing is we need to give them instruction about what we regard as the most important thing we want them to do, or things, give them a priority list, if possible. Only fair.

The second thing is to make, if we can, to decide when we want to meet again as a subcommittee. So those are the two things that ---

MS. KRAMER: Well, some of that would depend on when they could have additional materials available to us so that we can move the discussion forward, I would think. But if they can do it by the

January meeting, it seems to me it would be efficient for us to have another meeting the day before -- I guess it would have to be the day before since it is Friday -- so that people can maximize the use of their travel time.

DR. EMANUEL: On the other hand, one of the questions -- Tom, do you understand the process as we are going to cogitate; we are going to present what we have discussed today to the whole Commission; and then at this January meeting, the Commission -- as a Commission, we are going to jointly establish priorities?

So us meeting before the Commission seems to me not viable just because the marching orders, which one of these we take first, which one receives the green lights, the other will go, but recognizing it will be at a slower pace, I don't know the process.

DR. MURRAY: We are inventing the process. There is a contingency there. It probably makes sense, I think it probably is necessary that we identify one thing that we are going to try to do in the first year, at least one thing.

If we have a sense of what that is, and we can get enough material on it to actually use it on the day before the full Commission, we probably ought to go ahead with that. I think the larger questions, the bigger agenda items, are things that we ought to bring to the full

Commission.

We ought to bring to the full Commission, even if retrospectively, sort of our commitment to go forth on a particular issue, and I say that if we had the luxury of lots more time, I would say we should wait one everything until we could talk to the full Commission.

But I look to be guided by the members of the subcommittee about how we should deal with these choices. Do we know what we want to do on a sort of rapid basis? Is it the tissue sample issue?

DR. COX: Well, we said one thing that we wanted to do for sure without saying it is the tissue sample issue, we wanted to find out what had been done in terms of public input on the tissue sample issue.

DR. EMANUEL: We had several things down, right?

DR. MURRAY: We had a series of specific tasks, questions of the things that we need to ultimately issue reports. Is that the one we want to try to identify for the first year?

DR. COX: Can I make a comment after having just said that. Because this afternoon's discussion makes me feel even stronger than I did this morning that all the issues that we talked about this afternoon are embodied in that one issue as a specific example.

It doesn't mean that that issue plays them all out, but they

will all be considered in that issue.

DR. MURRAY: Not in -- they are not all exhausted by that.

DR. COX: Yes. But they will all come up in that context.

DR. MURRAY: Fair enough.

DR. EMANUEL: I would say that we discuss three things, and it seems to me that they have progressed. And you probably planned this in the morning.

To the one that where the sort of conceptual framework becomes less and less defined, and part of what we are doing -- in one issue, I think we are trying to apply that framework and trying to get a coherent set of resolutions that might be embodied in regulations.

In the next, we are struggling with a framework that is going to be encapsulating and its complexity is the problem, I think. And then the patenting issue, part of the problem is that we have just got such different kinds of values that it is going to be difficult.

It seems to me that does dictate, to some degree -- the complexity of the conceptual work means that the amount of time you are going to have to invest in it is going to be longer as it gets harder.

So, for me, it seems tissue samples is a tractable problem. We can do something in six to nine months, I think, and part of that is embodied in the fact that we can give very specific instructions to the

staff, and they could really concretely get to work.

Privacy and confidentiality, you know, is a two-three year project, I think. But it is there. We have, I think, made substantial progress in trying to focus in where we are going to be and, patenting, probably more creative work.

DR. MURRAY: Carol.

DR. GREIDER: Sort of putting together what the two of you said, it seems like although in the tissue samples, you are bringing up all of these issues, especially the genetic privacy and genetic discrimination, I am not sure how we can deal with the specific without dealing with those general issues.

So I am not sure this idea of getting that one thing done quickly and then considering the broader framework in which it sits is necessarily the best course to start.

DR. MURRAY: I guess my reaction -- that is a valid point, Carol. My reaction is it is always the case in any simple, relatively simple, issue in bioethics that there are going to be lots of interesting, deeper issues and threads that you are not going to be able to pin down precisely.

You still might be able to come with sort of reasonable consensual policy options that you can affirm and say, this is what we

ought to do about it. Granted that there are a lot of threads that are really deeper and interesting, and we need to come back and revisit them. We might, in fact, three years from now, hypothetically, when we understand them better, want to revise what we said here. But we can give a sort of good enough answer for these purposes at this time.

DR. COX: Could I comment on that? Because I get your point, and it is a logical conundrum. I mean, that is really what it is. It is a logical problem, because if you don't know what the answer is, then how can you deal with the specifics?

The way I logically get out of that is that I don't think there is a global answer. But the truth is -- dealing with these issues on a variety of examples, and then you get closer to the truth of what the global answer is. So that is how I sort of rationalize it. Whether it is right or not -- I mean. Because otherwise it is a truly logical conundrum.

MR. HOLTZMAN: That is the way science progresses.

DR. COX: Yes.

DR. MURRAY: I don't know if Steve thought that was an adequate answer or not, Carol, for how you could sort of take on the more circumscribed issue today. But is that okay?

DR. MIIKE: Well, always, when we get into these discussion, quote my an old mentor of mine. When you are faced with a difficult

problem, you define it as a more difficult problem so you don't have to face the difficult problem.

But I think it is almost generic to any kind of work like this that as you are looking at something very specific, it raises all these global issues, and you have got to do the best you can. Because you have got to deal with the specific ---

Really, if we are going to have anything done the first year, we have got to pick something that is doable.

DR. MURRAY: I hear pretty much of a consensus. The tissue sample problem, we think it is doable. We want to tackle it in the first year. That is item one of the contingency questions. We have gotten that far.

Item two is Bette's question. Could we have anything by January -- the January 8, Wednesday? Could we have enough by January 8 to do anything with? My guess is -- well, let me ask -- get your consensus and ask NBAC staff.

DR. EMANUEL: Is it a two-day meeting?

MS. KRAMER: Oh, it is a two-day meeting.

DR. MURRAY: Yes, 9th and 10th. Is that right, Bill?

MR. DOMMEL: Yes.

DR. MURRAY: Two full days?

MS. KRAMER: Oh, I didn't know that.

MR. DOMMEL: Yes, it is a two-day meeting, Thursday and Friday. What we must consider -- when there are only three NBAC staff, there are only 15 work days between now and the meeting of the Commission, including Christmas Eve and New Year's Eve and end-of-the-year leave for staff. We don't have instructions yet on gathering materials for the meeting on the 9th and 10th.

DR. MIIKE: I guess if you look at that four inch thick document, there is already is a lot of information -- by the way, can I, as an aside, tell staff, do not put it in those binders for me. It is just extra weight for me to carry. Just give it with a rubber band around.

MR. DOMMEL: Does everyone feel that way about what you received?

DR. MURRAY: No, I like the binders. We will leave it up to personal preference.

DR. MIIKE: But I think one of the other areas where we talked about the staff is what do we know about the public's interest and the public's perception of this issue? Because you were concerned that this might be a hot researcher's topic for the general public. It is like yes ---

DR. COX: Or for what the framework is for the general

public. Zeke said that, and I think it was really exactly ---

DR. MIIKE: But in terms of some of the specific things, I think we have got an adequate base in there, in the tome there. So I would say in terms of what staff research can be done is: Can you get a handle about how important is this issue for the public?

And I would guess it is once you get beyond just the statement about stored tissue samples. But you find out the specific issues around it, they would be interested.

And the other one is some sense of what it would take to get additional information about public perception and -- (inaudible).

DR. MURRAY: We might get that -- apparently, and I heard from -- she is gone -- Elizabeth Thompson of the ELSI program at the National Center for Human Genome Research that there are several projects that may be gathering data that are pertinent to that question, focus groups and the like, and also the National Action Plan for Breast Cancer, I think?

MS. KRAMER: Right.

DR. MURRAY: They also have some -- so there might be some existing data that can be -- we won't have to do the research. We just have to get in touch with people and say, please send us what you have, send it in writing, give us a presentation, whatever. So there might

be some ---

DR. LO: This is another issue I would like to think through, and that is sort of the level of staffing that we can count on for this project. We are talking about a doable project, six to nine months.

In the context of what we heard in San Francisco about the crucial role the staff plays, we, I think, at some point, I think we have to have a determination of what resources we have, both in terms of time and funds to commission papers or whatever.

Because that is really going to determine how much we are going to be able to do in the next six to nine months. I don't know what the current level of -- we keep hearing we are working on it.

But as the time starts to tick away, I think it becomes unrealistic for us to think about finishing a project under these sorts of constraints.

MR. DOMMEL: I think the chair expects by January 9-10 to be able to say with full confidence that it is this amount of money that we can use and then with some recommendations of ways to use it.

The on-board staff at a rate that would approximate the 1.5 million that he mentioned -- he also mentioned perhaps as much 2 million -- could include as many as six to eight analyst-writers on board on a spectrum of junior writer to senior analyst with perhaps three

focusing on the work of this subcommittee and three focusing on the work of the other subcommittee. That is one approach.

But that is probably realistic to anticipate something in that range. And then depending on whether it is 2 million or 1.5, the amount of money that will be left for Commission studies.

DR. EMANUEL: Is there any question of getting people detailed from other parts of the government so that it doesn't come directly out of our budget? Like from the Genome Project or from other areas?

MR. DOMMEL: Well ---

DR. EMANUEL: I don't want to raise these budgetary issues, but it seems to me that that may be a helpful thing for us as we focus in on issues of tissue samples. I mean, I don't know whether Eric Meslin, who walked out, you know -- they have ---

MR. DOMMEL: Yes, I don't know if they do either, and of course, they are part of NIH. NIH is the only component of the federal government that has put forward anything. They have detailed three employees. That is the total staff, and they have put $500,000 in a kitty, and that is the total kitty.

So I don't know -- now, we turn back to them, saying ---

MR. DOMMEL: And there are explorations, and perhaps

Rachel could speak to the explorations with the other federal agencies for contributions.

MS. LEVINSON: That would be in kind. That would take up their dollar contribution, whereas the dollar figures that we are talking, 1-1/2 to 2 million, would include contributions from other agencies. Now, it may be in the form of cash, or it may be detailed employees. So it won't help ---

DR. MURRAY: We are running a long time. Let me make a proposal of what I would intend to do between now and January 9-10, which is to work with any of you who can be helpful, to work with NBAC staff, to get a sense of what actually -- we did lay out some very discrete tasks for the tissue sample project -- to see how much it would cost to do that in a way that we felt was right. So come January 9 prepared with a rough budget for what that would take.

DR. LO: It is a budget with a research plan, so to speak.

DR. MURRAY: Yes.

DR. LO: We should treat this the way we treat our own -- plans a budget a timeline.

DR. EMANUEL: Can I add one point? I think it would be a mistake to put all our eggs in the one basket of tissue sampling.

DR. MURRAY: Right, right. I wasn't saying that.

DR. EMANUEL: I am sorry.

DR. MURRAY: Go ahead. Say what you were going to say.

DR. EMANUEL: No. You are the chair. It will take longer to get the privacy/discrimination thing off the ground. We have to, at least at a low level, get that boiling. Otherwise, you know, come October, say we issue one report, we are going to be at ground zero again.

DR. MURRAY: And the gene patenting -- no, I think in the relatively few days before that next meeting, we -- plus less well-defined projects than the others -- we can't say much more. We can't be as precise, but I think we can begin to say we think these are roughly these -- (inaudible).

So what I would propose, if it meets your wishes, is to come with something relatively concrete about the tissue sample thing with some specific projects and dollar signs; something less concrete, perhaps even more ambitious to begin the work on the other two phases, the privacy/confidentiality/discrimination piece; and the gene patenting piece. Is that all right?

DR. LO: Can you circulate that to us on the NBAC thing?

DR. MURRAY: Sure.

DR. LO: I find those discussions to be useful.

DR. MURRAY: That is going to require -- I am going to need

a lot of help, because I am not a budget expert, from Bill and other members of NBAC and from people who know what these sorts of things cost. You may know much better than I what some of these things ---

MS. KRAMER: Tom, one more thing. Would you anticipate then that we would have another meeting of this subcommittee subsequent to the January meeting, and if so, can we kind of put on some time on the calendar before it goes away?

DR. MURRAY: That is what it sounds -- is that what it sounds like to ---

DR. EMANUEL: The next meeting after January for the full Commission is March.

MS. KRAMER: March.

DR. EMANUEL: So we need an interim meeting at least.

DR. MURRAY: We probably do need a February meeting just to get our own work -- forward.

DR. MIIKE: My personal -- is going to get very busy. My legislative session starts next month, and our state legislature is -- to early May. All I am saying is that it is hard ---

DR. MURRAY: Rather than try to set dates today, can we ask that the first thing we get out of NBAC staff is could you circulate a February calendar for us? And we will mark up the February calendar.

And can I ask members of the subcommittee to be unusually brutal in the sense that, you know, only mark out the days that you absolutely cannot free up on your calendar. Granted you are going to have meetings and such, but I am going to ask you to try -- anything you can possibly reschedule or -- incur a debt on ---

DR. MIIKE: One concern, Tom, though, is that if we do it here, we have to do it on a weekday. Because one or two of us have raised the issue about could we meet on a Saturday or something like that.

DR. MURRAY: Should we leave that open, the possibility of including a Saturday in the meeting. Should we open the calendar up to the possibility of that? I mean, it is nothing any of us life. Of course, if we did it in Honolulu, it might not ---

DR. LO: In Honolulu, my family would go for it.

DR. MURRAY: Larry has asked us to come.

DR. MIIKE: In Honolulu, we wouldn't get any work done.

DR. MURRAY: All right. So we are going to do the calendar. That will happen right away. It will be great if it could happen no later than Monday, because we need to get feedback immediately.

MR. DOMMEL: We are actually not in offices until Tuesday, because of the meeting of the Human Subject Subcommittee on Monday

all day. So we will do that Tuesday. We already have your February calendars, but we want to do a fresh one.

DR. MURRAY: Yes, and again, we are going to ask for the brutally honest version of our calendars when we really, really can't ---

DR. LO: Should you also ask for April calendars?

DR. MURRAY: Listen, can I just say thank you to the staff, who arranged all this and thank you to the committee ---

MS. KRAMER: And thank you, Tom.

(Whereupon, at 3:34 p.m., the meeting was adjourned.)