U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES{PRIVATE }

SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY

Ninth Meeting

Tuesday,
March 28, 2006

Conference Room 6, Building 31C
National Institutes of Health
31 Center Drive
Bethesda, Maryland

IN ATTENDANCE:

Chair

Reed V. Tuckson, M.D.
Senior Vice President
Consumer Health and Medical Care Advancement
UnitedHealth Group
MN 008-T902
9900 Bren Road East
Minnetonka, MN 55343

Members

Sylvia Mann Au, M.S., C.G.C.
Hawaii State Genetics Coordinator
Genetics Program
Hawaii Department of Health
741 Sunset Avenue
Honolulu, HI 96816

Cynthia E. Berry, J.D.
Partner
Powell Goldstein LLP
901 New York Avenue, N.W., 3rd Floor
Washington, D.C. 20001

Chira Chen
1315 5th Avenue
San Francisco, CA 94122

James P. Evans, M.D., Ph.D.
Associate Professor of Genetics and Medicine
Director of Clinical Cancer Genetics and
the Bryson Program in Human Genetics
Departments of Medicine and Genetics
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7624

Debra G.B. Leonard, M.D., Ph.D.
Vice Chair of Laboratory Medicine
New York Presbyterian Hospital, Cornell Campus
Room F715, Mailbox 79
525 East 68th Street
New York, NY 10021

IN ATTENDANCE:

Julio Licinio, M.D.
Professor of Psychiatry and Medicine/Endocrinology
Neuropsychiatric Institute
David Geffen School of Medicine at UCLA
University of California, Los Angeles
Gonda Center, Room 3357A
695 Charles Young Drive South
Los Angeles, CA 90095-1761

Agnes Masny, R.N., M.P.H., M.S.N.
Adjunct Assistant Professor of Nursing
Temple University College of Allied Health Professionals
Research Assistant and Nurse Practitioner
Family Risk Assessment Program
Fox Chase Cancer Center
7701 Burholme Avenue
Philadelphia, PA 19111

Joseph Telfair, Dr.P.H., M.S.W., M.P.H.
Associate Professor
Department of Maternal and Child Health
School of Public Health
University of Alabama at Birmingham
1665 University Boulevard, Room 320
Birmingham, AL 35294-0022

Emily S. Winn-Deen, Ph.D.
Vice President
Strategic Planning and Business Development
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

IN ATTENDANCE:

Ex Officio Members

Centers for Disease Control and Prevention

Linda Bradley, Ph.D.
Office of Genomics and Disease Prevention
Centers for Disease Control and Prevention
4770 Buford Highway
Atlanta, GA 30341

Centers for Medicare and Medicaid Services

James Rollins, M.D.
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Department of Commerce

William Koch, Ph.D.
Deputy Director of Chemical Science and Technology
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Department of Labor

Amy J. Turner
Employee Benefits Security Administration
Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Department of Veteran Affairs

Sherrie Hans, M.D.
U.S. Department of Veteran Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

IN ATTENDANCE:

Equal Employment Opportunity Commission

Peter S. Gray, J.D.
Senior Attorney Advisor
Office of Legal Counsel
Equal Employment Opportunity Commission
1801 L Street, N.W.
Washington, D.C. 20507

Food and Drug Administration

Steven Gutman, M.D., M.B.A.
Director
Office for In Vitro Diagnostic Device
Evaluation and Safety
Food and Drug Administration
2098 Gaither Road, MSC HFZ 440
Rockville, MD 20850

National Institutes of Health

Francis S. Collins, M.D., Ph.D.
Director
National Human Genome Research Institute
National Institutes of Health
Building 31, Room 4B09
31 Center Drive, MSC 2152
Bethesda, MD 20982

Office for Civil Rights

Robinsue Frohboese, J.D., Ph.D.
Principal Deputy Director
Office for Civil Rights
200 Independence Avenue, S.W., Room 515F
Washington, D.C. 20201

Office for Human Research Protections

Michael A. Carome, M.D.
Associate Director for Regulatory Affairs
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Executive Secretary

Sarah Carr
Secretary's Advisory Committee on
Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985

C O N T E N T S

C O N T E N T S

P R O C E E D I N G S (9:02 a.m.)

DR. TUCKSON: Welcome to Day Number 2. We're ready to get started.

I want to make an announcement. For those who are on the Large Population Studies Task Force, I want to caucus with you for a few minutes right when we break for lunch. So just know that we'll get together for a few minutes off to the side and just go over some logistical issues, nothing of substance that would not be in the public domain but just some logistical technical things that I need to go over.

Well, good morning and welcome to Day Number 2. Today we're going to start off, of course, with the genetic discrimination session. As you all know, but reminding some of the newcomers to the committee, the issue of genetic discrimination in health insurance and employment has been the committee's top priority, and we've been closely monitoring federal legislative activities on this issue. In May, we sent Secretary Leavitt a compilation of public comments, a DVD of testimony we heard last fall highlighting various public perspectives on the genetic discrimination issue, and a legal analysis of the adequacy of current law. The Secretary's response to these items can be found in Tab 3 of the briefing book.

This morning we will hear an update on the status of federal genetic non-discrimination legislation and a report on public attitudes toward genetic technologies and genetic discrimination. Bio sketches of our two presenters, whom we're very pleased have joined us, are provided in Tab 1.

Let me start with Christy White, who is going to give us some of the data, and then Sharon Terry will follow up on public attitudes. What we'll probably do, Sharon, is have your presentation, and then I think it makes sense, we may take a few questions after that, and then we'll move to Ms. White, and then sort of see where we are.

So the staff doesn't think I can't read, we made a conscious decision to switch the order. So I'm not nuts.

MS. WHITE: Thank you. Well, thanks for inviting me back again. I'm sure most of you recall that I was here not that long ago talking about the data from the 2005 study. We've just completed the 2006 study, and one of the things that we talked about at the last meeting was adding some questions that would get at Americans' awareness of current laws and protections and their feelings about that. So we added a few questions to get at that.

I'm actually going to be speaking fairly briefly today for a lot of reasons. One, I've given you a lot of detail the last time I was here. Also, this data is just in. So although we've done a lot of analytics on it, we haven't really finished doing all of that yet. Most of the information also looks fairly stable, so there's not too much to report on that. So what I'm going to do is really focus on the new questions that relate to some attitudes towards the specific entities that they may be concerned about when it comes to genetic discrimination, their awareness of specific protections, their perceptions of those protections, and their feelings about what should happen with legislation moving forward.

Before I do that, I want to ground us in two key areas. One is the methodology that was used for this research, and secondly the current climate for genomics. The methodology that was used for this, as

has been for the past -- this is now the third time that we've run this study -- we use a Web survey methodology. We talked to a random sample of 1,000 Americans over the age of 18. The sampling error for this is plus or minus 3, a 95 percent confidence level. So when you're looking at these numbers, we can be 95 percent confident that they would not deviate any more than 3 points from what you see up here, and that is actually the worst-case scenario, when the data is split 50/50.

The sample for this research was obtained from Greenfield Online. They're one of the largest email panel providers in the U.S. The outgoing sample was balanced to the U.S. Census on age, education, gender, income, and ethnicity. As is always the case, certain populations are more likely than others to respond. So when the data comes back, in some cases we need to weight the data. Very minimal weighting was required, but we did weight the data by education and ethnicity to make sure that when we're looking at this data we can be sure that it represents the U.S. population, adult population.

So what I'd like to do now is talk just briefly about the current climate for genomics. Since I was here last, the climate is fairly stable. The data from last year to this year has not changed significantly. We still see about a quarter of Americans being aware of being able to use genetic information to understand and optimize health. We also see more than half of Americans continue to hold favorable views toward using genetic information to understand and optimize health. We also see that close to half of Americans are interested in being able to use genetic information to understand and optimize their own health. So this is for their own personal use. So these numbers have changed very slightly from last year.

We also know, in terms of the current climate, that concern with misuse is still very high. Seventeen percent, so about 1 in 5 Americans, is mentioning genetic discrimination as a drawback of genomics, and this is on an unaided basis. So without any prompting, when we ask them what are the good things about it, what are the bad things about it, 17 percent mention something about their information being misused.

DR. TUCKSON: Christy, one second. Let me just ask you, could you go back just for a sec?

MS. WHITE: Yes.

DR. TUCKSON: I just want to make sure. When you say one-quarter are still aware, does that mean that 73 percent are not aware, or did the others say not sure?

MS. WHITE: No. I believe the bulk of those that did not say heard or read a lot said that they have heard something. I think there's only a small number of Americans that are saying that they have heard nothing about using genetic information. We do have a follow-on question to this which asks them specifically what have they heard, and when you look at those responses, really predominantly what they're saying is they understand there's a link between genomics and health. They're not saying that they understand that they can optimize their health through use of their genetic information. So it's a very superficial understanding at this point.

DR. TUCKSON: If you're going to cover this later, stop me also. But when you say the 52 percent are favorable, again how do we infer the 48 percent? They're not unfavorable.

MS. WHITE: No. Fifty-two is the top two boxes on a 5-point scale, and then again the bulk of those are neutral. I have the numbers over there, and when we get to the Q&A I'll look them up and

report back to you on that. But I'm fairly certain that it's probably less than 1 or 2 in 10 that are -

DR. TUCKSON: Good. I just wanted to make sure that I wasn't over-reading the slides. Thank you.

MS. WHITE: No. That's a good point.

So we also know that 66 percent are concerned about how their personal genetic information will be stored and who would have access to that information. Here it's really a top box of 44 percent is pretty considerable. Typically what you'll see is more of a bell curve distribution on questions like this. So the fact that we have close to half of Americans giving the most extreme answer that they could provide in terms of concern is something pretty remarkable that you do not see very often. Again, here you can't see the full distribution, but really only 9 percent are saying that they do not have any concerns about who potentially might access their information and what would happen to it.

We also know that 30 percent of all Americans say that this concern would prevent them from having a genetic test. So about 1 in 3 Americans are saying that they're just not going to go there if they don't feel that their information is going to be protected.

There are numerous entities that are implicated in terms of who might try to gain unauthorized access to their personal genetic information, and really there's not much deviation on these responses. So life insurance companies, government and health insurance companies were all seeing about 65 percent of Americans, again with the majority being in that extremely concerned category, saying that they are extremely concerned that one or more of these entities might gain access to their information. Slightly lower, although still more than half of Americans, again, are saying that a bank or financial institution or their employer may gain access to this information.

DR. LICINIO: When you say government, who are you referring to?

MS. WHITE: It is not specified for them. We just say the government. There are other questions where we actually do start to differentiate between different government organizations, but this is one where we kept it just as the government itself.

DR. LICINIO: (Inaudible.)

MS. WHITE: Yes, although we'll see there's some positive information for him later.

Again, I think I talked about this last time, but I thought it was worth revisiting because the numbers are still high. The extent of their mistrust is pretty extreme, with 65 percent saying insurance companies will do everything possible to use genetic information to deny coverage, a similar number saying insurance companies will use information to deny coverage for drugs people need if their genetic profile indicates a low chance of responding. Also on a different type of question, we asked would your interest increase or decrease for a variety of reasons, and this was the information would become part of their medical record and obtainable by insurance companies. So 56 percent say if they knew that, that their interest would drop.

So moving on to protections, the question was asked, as far as you know, are there laws that

currently protect the privacy of your genetic information, and you can see only 18 percent of Americans believe that there are currently laws that protect them. Twelve percent are holding that viewpoint that they feel confident that there aren't laws, but really 70 percent are just saying they don't know. They have no awareness of the current laws and protections that are out there for them in particular.

We did want to ask a few questions of those people who thought that there were currently laws for them. So first we asked a question about when it comes to genetic testing issues, would you say that current medical and health privacy laws are sufficient, or is more protection needed. So again, this is among that sample of people that said that they thought there were laws. Only a fourth of them believe that the current laws are sufficient. So we have very few people knowing that there are laws, and among those that know there are laws, the vast majority of them think that they are not adequate.

We also wanted to know who they thought the laws protected them from. So under current laws, which, if any, of the following groups or organizations are prevented from accessing or using your genetic information to discriminate against you? Again, this is among the small subsample of people that believe there are laws. Most of them believe that the protections are specifically for employers. About half said health insurance companies and life insurance companies. Fewer said the government, and about 20 percent said that the laws don't protect them against anyone in particular.

DR. LEONARD: Excuse me. Are you able to correlate the responder's state with whether there are state laws that provide protection or not?

MS. WHITE: We do have region, and we could look at that. This is such a small subsample of people, though. This is about 200 people, I guess, that answered this question, given the percent of people that thought there were laws. But we do have the state that they live in. We could look at it by that.

The desire for protections is very high. Seventy-two percent of Americans agree that the government should establish laws and regulations to protect the privacy of individuals. You can see that only 5 percent or 7 percent of Americans are actually disagreeing. So you've got three-quarters of the people agreeing, and the majority of those people who are not agreeing holding neutral views but saying that there should be protections for them.

We also looked at what they thought of the current situation that's happening. So we educated them a little bit and said to them that right now Congress is considering new legislation that would amend current federal health information and privacy protections to specifically prohibit employers from using employees' personal genetic information to make hiring decisions or to set insurance rates. Then what is often done in public opinion, we gave them two views and we asked them which view they agreed with more. So the first view was some people say that business owners are responsible and would not misuse their employees' personal genetic information. Therefore, the new law would only add costly and unnecessary burden on businesses to comply. You can see that only 15 percent agreed with that. The other side of the coin was other people say that without amending the current laws to explicitly prohibit employers from misusing their employees' personal genetic information, it's only a matter of time before they use this information to discriminate against some individuals. So you can see that 85 percent -- and this is of the entire sample now -- 85 percent of Americans believe that employers will use their genetic information to discriminate against them unless there are explicit protections in the law for them.

We also asked some questions about a national databank, and this question has stated that there's been a major public health initiative proposed to create a national databank that would include detailed DNA and environmental information on up to half a million individuals. This information would provide a powerful tool for scientists to understand the link between genes and other factors and specific diseases affecting millions of Americans. To what extent do you agree or disagree with this initiative?

The question I just read is on the bottom half of this screen, and we had a split sample. We asked one just the government, and then we wanted to see what impact there would be if we actually named a specific organization. So we named NIH, and you can see overall that interest or agreement with the initiative is fairly low, with about only a quarter or a third of Americans thinking that the initiative is a good idea. But the number does increase if there's a specific organization, specifically NIH being named as being associated with that.

What's on the top of this screen, there was another question that we had for tracking purposes which was a much more simplistic question which just asked should there be a national database. It didn't go into what the benefits of that might be, and again we see a similar response to that and similar numbers.

So those are all the things we covered specifically to legislation. I do have all of the data with me if there are questions you have about things that I spoke to last time in terms of general awareness, favorability, areas of interest. There's a lot of data in there about pharmacogenomics specifically and benefits they want for that as well. But again, the data has not changed substantially from when I spoke last time, so I wanted to focus just on the legislation.

DR. TUCKSON: Any questions you want to ask? Let me just start. I think you ended with what I was curious about. The big picture is that the data has not changed significantly.

Do you have any mechanism or way to determine whether or not the awareness of the issues is any greater? Do people know any more about this field? Is the idea or the word "genetics" and "genetic discrimination" or "genetic legislation" or "confidentiality of genetics," are any of those things more in the brain of people regardless of how they may feel about it?

MS. WHITE: Awareness increased the top box. There was very little change in awareness when you look at the entire spectrum, from nothing, something, a fair amount, a lot, with the exception of the top box of a lot, which I think increased by about 4 percentage points, and it was a very small number to begin with, so that is fairly substantial and is a significant increase in awareness. It's very small, though. We're not seeing large numbers of Americans in terms of the increase, but it is a statistically significant increase in the number of people that are saying they've heard or read something. So that is certainly true.

Then the number of people that are mentioning genetic discrimination in particular has not increased in terms of proportion, but when you consider the fact that there are more Americans that are aware, it has certainly increased. If we were to work that back, there would be a slight increase in the number of people mentioning genetic discrimination.

DR. TUCKSON: So lastly on this, there are more people who are aware, but the percentage of people who are expressing significant concern is about stable.

MS. WHITE: Yes, the concern number is stable. I can look that number up from last year.

DR. TUCKSON: Take your time, because there's no way you could be prepared for which direction these questions were going to come.

MS. WHITE: I don't have all these numbers in my head, at least not yet.

DR. TUCKSON: There's no clock ticking.

MS. WHITE: Actually, it was exactly stable. I found it, exactly stable with the top box. There's a 1 point difference, but it's not statistically different.

DR. TUCKSON: Thanks.

DR. COLLINS: Thanks. That's a very interesting and important survey. I'm particularly interested in the statistics about what people's view is toward the likelihood of employers discriminating, since certainly it's been the case that with the current discussion of legislation the employer provisions seem to be particularly areas where it's been difficult to completely get to resolution.

I want to ask, though, about the national databank because that's obviously something we talked about at some length yesterday. Do you have a way in your data of assessing the correlation coefficient between the people who are most worried about who is going to have access to this information and what their response is to this question about the databank? Because I could imagine that that might be a significant reason for people not to be enthusiastic, because they're not convinced those protections are there. Can you comment on that?

MS. WHITE: Yes, that is absolutely something we can look into. I mean, we can look at regressions across a variety of different variables to see what's driving that concern, or at least driving the people who are saying that they don't agree with the initiative. I think the questions about -- we could look at it in terms of all the specific organizations that they think might discriminate against them, and I imagine there are probably other variables in terms of just their general favorability toward the idea. We can also look at it by their health status. I imagine that Americans that aren't as healthy might be more interested in something like that, because they're more aware of general clinical trials and issues like that that might be happening that could benefit them in particular. So we can certainly run all that and get back to you on what we find out.

DR. EVANS: I'm really interested in the 30 percent of people who have concerns that would prevent them from having a genetic test, because that's certainly in keeping with what we observe in the clinic, I think. I wonder, also given the level of mistrust of government, did you ask a question that said say comprehensive federal legislation is passed, would you still now feel that you wouldn't get testing, because if they mistrust government so much, are they going to be that reassured by legislation? I just wonder if you have any data that might address that.

MS. WHITE: We may have a question about that. When I mentioned that increased/decreased number, there were a few other questions that we asked along that line, and there may be a question in there that says if you are assured by law. Yes, we have a question that says what would happen to your interest if you were assured that by law no one could access your DNA information without your consent,

and there's a 60 percent increase. So 60 percent say they would be more interested in genetic testing if they were assured by law.

DR. TUCKSON: Yes?

DR. FROHBOESE: Hi. Just a couple of quick questions. Can you refresh us about how you drew your sample, and when you say that you had to weight the results for ethnicity, what were the ethnic categories that you were looking at, and what was the actual rate of response among various ethnic categories?

MS. WHITE: Again, the way that most email research is done today is there are about six or seven that I would consider most reputable email panel providers, and Greenfield Online and Survey Sampling I would say are sort of the cream of the crop when it comes to doing Web research. All they do is develop samples in the same way that survey sampling was the leader in terms of phone-based sample, RDD. So they have both taken on developing email panels, and they have anywhere between 4 to 7 million people in their panel, and they manage the panel in terms of how they recruit people. They don't only get them off the Web. They do phone recruits. So they go to great lengths to try to make sure that they have a fairly good representative sampling of Americans in their panel. They also make sure that people aren't over-surveyed and that they're not looking at the same topics all the time in issues like that.

When we go to them and we ask them to pull a sample for us, we give them the most recent population estimates and say we want you to pull out a replicate, so a large number of people that would allow us to get a 20 percent response rate that looks like the U.S. population on key Census demographic variables, the ones that I mentioned, and we go out to those. So in some ways it's actually more pure than what you can do with RDD in terms of phone, because you have a lot of control with who you mail out to. You know that it looks like the U.S. population on a variety of demographic variables, and also the interplay of those variables.

So you go out to those populations. But what happens with any type of research, really well known for mail but it's also happening with phone too, you have underrepresentation of higher socioeconomic groups via phone today. So what happens with the Web is that there are really just two groups that underrepresent, not in terms of our being able to represent them going out but in terms of their response rates, Hispanics and African Americans less so, but Hispanics, and also those Americans with less than a high school education. So what happens with those groups is we have to oversample them when we go out, and then when the data comes back, even when we set soft quotas around specific variables, there are always groups that just don't respond at the same rates that we'd like.

So the two groups here that we weighted by education and ethnicity, not surprisingly, is pretty much what we always have to do, and what we had to do was weight up the Hispanic population slightly. So I think it was like maybe -- I'm making it up. Maybe it was like 10 percent up to 14 percent, which looks more like the Hispanic population in the U.S., and also education. We had to weight up those less than high school. So at the end, what we know when we look at all the demographics once we've done that, they represent the U.S. population.

If we were not to do that and those populations were to hold different views, then the numbers would become skewed and we would not be able to feel confident that the U.S. population would respond in the same way. Does that answer all of your questions? Was there something else?

DR. FROHBOESE: No. Thanks.

MS. AU: Christy, I just want to follow up on Jim's question, that 60 percent increase in people that would have testing if there were better laws. Is that 60 percent of the 30 percent that wouldn't have testing?

MS. WHITE: That's of all Americans. So we'd have to cross that to see how many of them would. But it shows that across all Americans, 66 percent of them would move themselves from one category to another category, or would be even more likely than what they told us they would say before. So we could cross that and see where exactly we see the movement.

MS. AU: And also, did you ask a question about general feelings about government and cross-match it with the databank and whether they would want government to do this? Because as Americans' opinions of government go up or down, does that affect your results?

MS. WHITE: No. That somewhat relates to Francis' question about employers, and I was saying that we would want to look at all of the organizations. I am sure there's a correlation between their perceptions of government and what they're saying here. I mean, it's a somewhat obvious thing, but it would be good to quantify that and know that. I remember that there's something like only 1 percent of the U.S. population that says they would want the government to have their genetic information. So when you consider that, that there's only 1 percent of people that want the government to have their information, and then it jumps up to 24 and even 30 percent if they can see there's a benefit and it's anonymous, I'm sure that there's a real heavy correlation between those Americans.

DR. TUCKSON: One last thing on the high level on the African American or Hispanic. Was there, again, any statistical difference between their rates of concern versus the rest of the population?

MS. WHITE: I know, because I was looking into trying to figure out something on another question, that Hispanics are less concerned about their employers discriminating against them, but that's actually the only variable.

One thing I should say which hopefully won't come across as too defensive is that we actually just got this data out of the field, and as Suzanne can attest, she got these slides maybe yesterday. We spent all our time just cleaning the data, making sure it's correct in the top line, but there are certainly a lot of subgroup analysis that will occur as we pull together -- what will happen from this is we'll pull together what will be about a 150-page report, and there will be all the subgroup analysis for every question will be with each one. So I'd certainly be willing and happy to provide that section of the report that relates to these questions to you once we have it so that all these really very valid questions, questions that even I have, will be answered in there.

DR. TUCKSON: Well, this is terrific. I want to thank you. You've done a great service for us, including now we recognize even under great duress. So thank you.

MS. WHITE: Thanks.

DR. TUCKSON: Sharon, do you want to come forward and give us a sense of the status of the genetic information Nondiscrimination Act of 2005, S.306/H.R. 1227?

MS. TERRY: Sure. Christy and I switched order because she said she would show there was a fire, and I will show how maybe we can put it out.

I'm basically representing the Coalition for Genetic Fairness as their chair. This is a familiar timeline that many of you have been involved in as we've gone through this, various events that have occurred along the way since 1996 regarding genetic information on discrimination, and you've had much testimony and many individuals stand here and give you a description of various things, and you yourselves have engaged in a number of things, including the letter and DVD to the Secretary last May.

More recently, and again most of you know this, in the 109th Congress we had President Bush say that he supported this fully. It passed. 306 passed unanimously in the Senate for the second time in a second Congress. 1227 was introduced and referred to three committees in March of last year, and today there are 170 sponsors. Actually, that's of yesterday, so I'm not sure this is correct today, 94 Democrats, 75 Republicans, and 1 Independent. Those numbers are fairly important because we've been working fairly hard and steadily on increasing the number of Republicans. These were fairly skewed numbers when we first started out.

So the coalition has really been working on supporting Representative Judy Biggert from Illinois, Anna Eshoo from California, Ney from Ohio, and Slaughter from New York, and increasing the Republican sponsorship. So our grassroots work has primarily been on finding Republicans who would sponsor this legislation. We've noted almost a 1-to-1 correspondence. In other words, if we go to see a Republican, usually he or she signs on. It's really a matter of them just getting this particular piece of legislation on their radar screen.

There is some indication that if we could level out those numbers, make them approximately equal, then perhaps the committees would start to move the legislation forward, assuming of course that many Democrats would sign on right away, and we have in fact been holding off Democrats and believe that we're well over 220 when we do a count of who would sign on.

Another major activity of ours has been engaging the Chamber of Commerce, the National Association of Manufacturers, and the Society of Human Resource Managers in a dialogue. As some of you may recall, some of those individuals have presented here, in fact, and have answered questions for you. We've basically engaged for many, many months with some of the steering committee from the coalition working to find some commonality, some common ground, and had very productive and good discussion with them such that we feel that we are, in fact, moving toward a position where we might be able to give the Congress an indication that we're really ready to see this bill move and that there has been substantial dialogue that has established some common ground.

The other thing that we're doing is working with companies and trade associations. So some of you know, perhaps, the IBM established a company policy last fall after much looking at this bill in many ways, decided not to endorse the bill but to endorse the principles company-wide and really took a very strong stance, including announcing it internationally, giving their company employees education around the issue, and even holding a national teleconference that Tim Leshan from NHGRI participated in, giving privacy officials from companies all around the world information about what IBM did and why they did it.

The other piece of information that's important here is that more recently the biotechnology trade

association industry organization has signed a letter and sent it to Anna Eshoo saying that they support this legislation, and that's fairly significant since, of course, the companies that would most benefit from this legislation are members of BIO and PhRMA.

So when I look at what this august body can do, and I know that you have done a great deal, and I certainly wish you could do more but I also know that your charter is limited by what all charters for the Secretary's committees are, so I'm not certain that you can do these things, but here are the things that I would recommend. I would have you request a meeting with the Coalition for Genetic Fairness, the Chamber, and the National Association of Manufacturers. I think it would be very interesting for you to hear from them firsthand what their concerns are with the legislation, because I think they're fairly limited. I think there's some solid basis. I think that while maybe two years ago we would have stood here and said that many bodies aren't really sure that there's discrimination occurring, I think now they're not questioning that we do need this legislation. It's just the precise details that are of some concern.

You could ask the Secretary to invite these same organizations and the Whit House Domestic Policy Office to a meeting. We've met with the White House Domestic Policy Office. They have said that, again, President Bush is ready to sign his bill as soon as it comes across his desk and that they're supportive of this legislation. So it would be interesting to hear perhaps maybe some more ways that the Executive Office could be involved and could encourage the Congress to move this legislation.

To remind the Secretary that as he works with Congress on getting the genes and environment initiative funded, that he should explain to Congress the importance of H.R. 1227 and the relationship, and I think Christy's data illustrates that very well, and I'm sure that perhaps he has some sense of the correlation between those two things, but given the large number of bills in Congress all the time, I think it might be a good idea to make it explicit in some way.

To make a clear and strong statement from this committee expressing concern about the chill on research and its impact on the investment made for biomedical research in this country, including the trend toward offshoring clinical trials by pharma and biotech companies. I think that for me as a patient advocate and the individuals I work with, that is of most concern, that we are seeing the kinds of things that Christy showed in her data. We're not capitalizing in this investment that's been made, and it's really critical for us to bring this to the next level, and we're not going to be able to do it until this simple piece of legislation is passed.

Send the Genetic Discrimination Report, what you called the phone book, to the new chairman of the Education and Workforce Committee. He is the brand new chairman and would be very interested, I'm sure, in receiving your report. Then if you as individuals as members of this committee -- I know that while you're here as members and representing this committee you cannot do this, but when you're on your own time, so to speak, and not representing the committee but representing the organizations you come from -- could work with your constituencies as knowledgeable experts around this issue to move them to support the legislation, that certainly would be very beneficial as well.

And then again, the coalition is made up of about 140 organizations. Many industry groups have signed on with us, as well as certainly all the advocacy organizations and health professional associations, hospitals, clinics, et cetera.

That's all I have.

DR. TUCKSON: Can you put the previous slide up again? On the first point, let me just try to go through this for a minute. Just so the committee, and especially the folks who are new to the committee will know, we did spend a considerable amount of time on the phone with the Chamber and AHIP -- we didn't do it with the National Association of Manufacturers -- and also with the coalition, to go over in some detail a point by point in the legislation where were the synergies and where were the differences, and why were there differences. So we have done that about a year ago, ballpark a year ago.

So the thought would be, if I understand your point, enough time has gone by, positions may have modified, and so maybe we might do that. The way we did it so that we didn't get ourselves into trouble was we did it as a fact-finding exercise that allowed us to write in our report more authoritatively what was the exact position of the organization. So it required enormous drilling down to detail by staff and us to sort of get their position. So I think that's a possibility that the committee may want to look at as Agnes takes us through the discussion. But I'm pretty sure that's what you're saying, that things have shifted and changed.

Now, NAM was not a part of our original group, and you're identifying NAM as being an important player.

MS. TERRY: Yes.

DR. TUCKSON: Okay. AHIP was in that original list as well. AHIP's issues were, as I recall -- this is the insurance industry association. Their issues were very specifically around the notion of not being able to use the information to coordinate care for complex people who required a variety of medical and non-medical social supports, and having the data there that allowed you to be able to coordinate care for individuals was a concern, an unintended consequence that they were worried about.

You don't have them listed. Is that because we've pretty much gotten that out of the way?

MS. TERRY: Yes.

DR. TUCKSON: So AHIP is off the table?

MS. TERRY: Off the table.

DR. TUCKSON: Terrific. So now I understand your point.

Ask the Secretary to invite the same organizations the White House -- we have done that in a letter to the Secretary previously. What we have actually said is here is what we understand the position of these organizations to be. You may want to try to bring them together to have a conversation about resolving these issues, having defined them, if I can speak reasonably that that was the strategy that we did. I'm just checking reality here.

Remind the Secretary that he works with Congress. Get the Genes and Environment Initiative funded. Cool. Make a clear and strong statement expressing concern about the chill. Cool. Send the Chairman the phone book. Cool. Okay, I think I got it.

Any questions that you have here?

MS. BERRY: I realize that the cogent data that was presented just now is brand new. Have there been briefings on the Hill of the prior data that we received in our earlier meetings, and are there plans to brief, for example, the House Republican Policy Committee, which has a new chairman, the High-Tech Caucus and the House Republican Conference, which is led by Deborah Price? I don't know if she's a co-sponsor of this bill or not, but she has a strong interest in cancer and I would think would be very receptive, because the challenge seems to be that we're in an election year and it's a very compressed legislative calendar, and in order to pop something loose and get floor time in this environment where they have district work periods every single month, they're gone the entire month of August and they plan to adjourn in early October at the latest, you would have to convince members of Congress, and more particularly the House Republican leadership, that this is an election year issue that they need to pay attention to.

They do focus quite a bit on polling data. So to the extent that you can get this latest information in their conferences, in their policy committee discussions, I would think that would help, and I was interested to know what plans you might have. I mean, I have other suggestions, town hall meetings during these district work periods. If you have people in your coalition know in advance when the town hall meetings are taking place and you can have someone there to raise the issue --

DR. TUCKSON: Before you comment on that, let me turn the chair to Agnes, who is going to lead the discussion, because I think given what Cindy has done, we're in the discussion section now and I want Agnes to lead that.

By the way, I just want to make one other comment, because everything we do is on the record, and I just want to be very careful. It's nothing that you said.

We have names of organizations up here, and we're going to inevitably discuss some of these organizations. I want to be very clear and careful about how we categorize the participation of some of these organizations, like the Chamber and others. I will say that the Chamber was extremely responsive to our request for collaboration and participation and getting their position known; the same with AHIP and others.

The committee seeks to serve a brokering role, a coordinating and facilitative role, as appropriate to our mission. So I just want to make sure that as the record reflects conversation about the positions or the interpretation of positions of organizations, it is not done with any sense of disrespect to those organizations, any pejorativeness for those organizations, but respect for their having legitimate points of view which we seek to better understand and then harmonize. I just want to make sure the record is extremely clear on that point.

Now let me turn it over to Agnes.

MS. MASNY: Thank you, and thank you, Sharon.

I just wanted to ask also about AHIP. You said AHIP is off the table now for your whole trying to go after them, but have they have endorsed?

MS. TERRY: They've not endorsed, no.

MS. MASNY: They've not endorsed.

MS. TERRY: They've done what usually is the best in these conditions, and that is to say they're not going to oppose. I think in our discussions with the employer community, they've been much more robust and wanted to engage and understand what we're doing. So it was quite different, whereas the insurance community seemed to say we're okay, we don't really even need to engage around this, it seems to be off the table for us.

MS. MASNY: Thank you.

I think now our goal actually as a committee is if we have any further questions to ask, we can do that, but with the focus of what then can we as an advisory committee come up with for recommendations from the Genetic Anti-Discrimination Task Force, and possibly even maybe back to the Large Population Studies Task Force, since some of the points that were brought up were about concerns that the public has for these large population studies, and maybe there's something specific that we can add to the large population study recommendation about the genetic anti-discrimination legislation. So I'll open it up to the committee.

DR. TUCKSON: And our speakers are still here to answer questions.

MS. WHITE: I just want to add one thing. As I was sitting here looking to see if there was any additional data regarding their willingness to participate in the national databank, we did ask the following question, which said if you could be assured that your identity would be protected and that you would in no way be discriminated against, how willing would you be to allow your genetic information to be included as part of the proposed volunteer national DNA information databank? So this was asked of the entire population, with a split sample being those who had heard the government terminology and those having heard the NIH terminology, and the number does jump from 25 percent for government to 37 percent, and 31 percent to 43 percent. So in the top two box. If we want to look at just the top box, which is often how you can draw projections of how might potentially actually participate, it's about 20 percent of Americans if they're assured that their information would not be -- that they would not be discriminated against.

DR. LICINIO: I think I asked the same question the last time you were here, but here it goes again. This sounds so reasonable, but what are the roadblocks to get this legislation passed, particularly in Congress since it has passed in the Senate? I'd like to know not only the legislators themselves but I'd like to know the interest behind them, like what's opposing this.

MS. TERRY: So I think the concern is in the employer community, and it is about details in the bill, and they are very small details on one scale and large to them on another. I also think that as we've gone through especially these last two years, and certainly the last eight years, we've created a better understanding about what our goal is. Our goal is reducing the misuse of genetic information and not encouraging, as was originally assumed, frivolous lawsuits. So I think what we're seeing is an interesting conundrum that occurs in politics, and that is, as Cindy says, there's a lot of action right now. There are a lot of bills that need to be processed, et cetera, and this is low on the radar screen of most people. It's obviously very high on the radar screen of Mrs. Biggert, and she's worked very hard to do a lot of networking, a lot of bringing people on board.

What I think the Congress doesn't like to do is to cross entities like the Chamber of Commerce or the National Association of Manufacturers, and I think that what we will be seeing over the next few months -- and Cindy is also right that it has to be very fast, that we do this from here on or we're going to lose our window -- I think we'll be seeing the Congress and the committees begin to understand that, in fact, while the Chamber and NAM are not endorsing this bill, that they may be assured that we aren't going after such high and stringent difficulties or hurdles that they have to be as concerned as they have been in the past.

DR. TUCKSON: In that regard, then, I think clearly, as I understood the position of the Chamber and others, these people are very -- I'm taking it at face value and trying not to be naive and so forth and so on, but trying to understand where they are. They are very concerned about this idea of these frivolous lawsuits and what that means for people trying to run businesses every day in the country. I mean, this is not an insignificant concern that they have.

The question becomes has there been any change in the legislation or the provisions that speaks to that in ways that speak to them in terms of their concerns, or has the work been to just try to get them to be less concerned about that given the overall burden of the problem in terms of the risk/benefit ratio? What's the strategy here?

MS. TERRY: That's an excellent question, and I think we're actually doing a sort of two-pronged attack here, and that is that the legislation has not changed. Mrs. Biggert intends to put essentially 1227 into committee and onto the Floor, which is exactly the same bill as 306 in the Senate. There will be, however, some slight changes in some things that were quite reasonable in our discussions that emerged, and I think even some of those things came up on the phone call that you were on.

So while there will be some slight changes to the language or to various provisions in the bill, for the most part what has happened is a discussion that's allowed the Chamber and us to understand each other well and to, in fact, feel like we're working productively together so that they're assured that our intentions are not malevolent in any way and we're assured the same.

DR. TUCKSON: One last question, and this is a hard question for you to answer, I'm sure, but let me just make sure I get it the best I can. Why is it that there cannot be any provisions in the bill that help to protect from this problem, the potential of these frivolous lawsuits, or is it that it is the very essence of the bill that the opportunity to sue if bad things happen is basically the core of the whole deal? I mean, help me to understand why can't we do a little bit more, or if doing a little bit more basically cuts out the guts of the bill.

MS. TERRY: I'm going to answer that in lay language because I'm not a lawyer. From what I can see, of course, people who want to be protected want the right to sue if their rights are violated in some way, and we already have a body of law in this land that allows some action or some remedy, and what this bill seeks to do, and I think it seeks to do it pretty well because we have to remember we're coming all the way from the original Slaughter bill in whatever year that was to today, and it has changed during those years to a place where we're in a kind of moderate zone, we believe. So the coalition believes that, no, this doesn't give you the right, the minute someone looks at you funny, to sue, nor does it give you such limited protections that it really is just frivolous on our side either, and I think the employer community is finally understanding as well that there are, in fact, methods in the bill, methods for remedy that allow steps before a person could actually bring something to lawsuit, for example, and

that there would be some iterative process that people would have to go through to get to a point where they would be able to seek a remedy.

It's extremely complicated, and my colleagues, Frank Swain and others, have helped us kind of wade through this mess to see where we are at and certainly not to get into the sausage making that is legislation but to keep always on the table that the intent is we don't want this to be onerous for employers. I'm an employer. It would be horrible to have another law that makes things difficult, and on the other hand we can't let things like Burlington Northern continue.

MS. MASNY: So from the committee's perspective, are there any particular recommendations that you would like to make for the Genetic Anti-Discrimination Task Force to go forward from here?

DR. FROHBOESE: I think, as has been pointed out, this committee really has served a very valuable role in terms of gathering information, distilling the issues, trying to understand varying positions, and to get information out both within the Department as well as to Congress about our findings. Given that, and given the Secretary's response to the last compilation of material that we sent, I do think it would be worthwhile to explore another meeting with both the coalition as well as groups that continue to have concerns with the legislation and to identify any issues there where we can serve a role of helping to further explore potential ways to address concerns. Certainly I think with a changing leadership in Congress, getting information, as has been suggested, to the chair of the Education and Workforce Committee is important as well.

DR. TUCKSON: With that, given that you have the chair, I would propose that we would focus our strategy on point 2, which is that we would send a letter to the Secretary as expeditiously as possible urging him to use his good offices to bring together these organizations and the White House Domestic Policy Office to move the administration's position forward. In preparation for such a letter and for clarification of status and issues, it would mean that we would request a meeting on the first bullet to gather the facts and data and information necessary to write such a letter.

So taking those first two for now, I would propose that we do that, and we can work through the same mechanism that we used the last time to achieve that. So let me stop there and put that on the table as a proposal.

DR. TELFAIR: I just have two questions, one for each. The first one is on the research that you're doing. You may not have this in your database at all, but one of the things in the large population studies project was a real concern about not only just what your finding the basic understanding is but the other side, which is the education side of things. I was wondering are there any questions in there from the point of view that are being surveyed about what would be needed essentially to provide them with information? I mean, you've given them questions that clearly are asking them specific types of things, but I was kind of bothered by the fact of how big the numbers were, 70 percent I think it was, that knew nothing about anything going on related to protections and that sort of thing, and I was wondering is there anything in your data that speaks to better ways of getting that information to them.

MS. WHITE: This research doesn't look at the actual ways in which to communicate with them, but there's other research that we have but not specific to genetic information but just health. We do a lot of work in nutrition and communicating with consumers about health and nutrition. There may be some learnings from there, but I'd have to go look at that information and let you know.

DR. TELFAIR: The other question is for Ms. Terry. In relationship to this, I was wondering what is your sense of -- and you may have already answered this, so just correct me if I'm wrong, but I'm still concerned because it seems that education is a pretty critical thing. What is the understanding that people have related to this? I mean, it seems to me that if what you answered as to why it's not moving forward, it seems to me there's a gap there.

MS. TERRY: And I think in fact one of the things that we've agreed completely on with our comrades at the table is that both the employment community and we will have to do an education campaign. One of the things that I think will happen right away is that some of our partners are the American Society for Human Genetics, the National Society for Genetic Counselors, and I know Don Hadley presented his information here. I think if researchers could say I don't have to tell you that your information could be misused, when they're asked is my information going to be misused, if they could say in fact your information is protected by federal law across all 50 states, I think that will allay fears for at least a clinical trials scene.

As far as the genetic testing scene, I think again the workforce, whether it be the laboratories, clinicians, genetic counselors, et cetera, are going to be able to say, no, in fact, you can be tested and not worry about being a carrier for something and having your employment or insurance disturbed. So I think there's going to be grassroots education, but I think there will also be very practical clinical education that will have to happen around this.

DR. TELFAIR: So the grassroots education is targeted to what groups specifically? I mean, you mentioned a few. It sounds like part of it is not just the general public but part of it is also those who are in practice at some level or another. I guess I was also concerned about their level of communication to those who are in positions much higher up who make these kinds of decisions.

MS. TERRY: So are you asking should those individuals also be speaking to administrators of hospitals, legislators, et cetera? Yes, and I think the societies that we're working with are going to educate their workforce that way. I would hope that the employer community would educate itself, and then I think we're going to have to have regular old public service announcements around this stuff as well. We see that sort of as a second prong if we could at least allay the fears of people who today are going to go somewhere and try to have a test done and can't have it done.

DR. TELFAIR: Given that information, it seems to me that that's a clear recommendation that we can make. I mean, that's something that we can suggest. If we're going to do number 2, which is invite organizations and groups, part of what we might want to say to them is sort of taking some of the structure here in terms of what targeted types of groups to educate, what are some of the targeted issues are that we need to educate about, if we're going to do that. I'm speaking as a Large Population Studies Task Force member.

MS. MASNY: I'll just ask the committee that. Are we asking for that for another meeting, or would that be sort of what Reed was proposing, like the way we did it in the past with some behind-the-scenes telephone conversations to gather that information so that we could present that to the Secretary?

DR. COLLINS: Let me just say, as has already been pointed out, time is of the essence here. The window for legislative action in this current year will close. If we wait until the next meeting of

SACGHS to invite these discussions with the Chamber and NAM, precious time will have been lost. So I think the telephone route, just from a practical perspective, would make a lot more sense.

MS. MASNY: So then would the committee be in agreement with the proposal that Reed made that we do behind-the-scenes telephone conversations so that we could include that information from these organizations to the Secretary?

DR. LEONARD: I agree with that and would like to extend what's the content of the letter, not simply asking for the meeting but also including the next two bullets in the letter, which would be the third and fourth bullets, asking him to mention H.R. 1227, the importance of that for the Genes and Environment Initiative, and as you do, you provide background information. I mean, that's kind of what this fourth bullet would be, making a clear and strong statement. Then also I don't know whether we send the phone book or the Secretary does, but asking him to do that, not only to McCann but also to the people that Cindy mentioned. I don't remember their names, but there were others who should be getting this information.

So I do agree that it has to move quickly. It should be a behind-the-scenes meeting or phone conversations, and then the letter should go as promptly as possible to the Secretary.

MS. MASNY: I think we can recommend that we send the phone book with the DVD disk. We don't know whether that will actually happen because I think we did already send the phone book and an analysis of the law and the DVD with about 150 copies so that that could be distributed. Is that correct, Sarah?

DR. LEONARD: But these are new people in new positions, so they may have left their phone book in their old office.

MS. CARR: We can request that that be sent forward by the Secretary, yes.

MS. MASNY: And then also maybe what we could do is give some of these to Sharon so that if Sharon sees them, that she could distribute the things directly to them, rather than waiting for the whole group.

DR. COLLINS: They are public documents.

MS. MASNY: Right, exactly.

MS. CARR: They're also on our website, too. You can just point people to our website.

MS. TERRY: Yes, and we certainly do regularly, but to have more copies of it, I would definitely distribute it freely and frequently.

MS. MASNY: So I think we have a plan. Just one other question is would we want to ask the Large Population Studies group specifically under the heading of privacy and confidentiality to sort of make a stronger statement about supporting genetic anti-discrimination legislation in that context?

DR. TELFAIR: That makes sense.

MS. MASNY: Cindy?

MS. BERRY: Just to clarify, is the purpose of the meeting, the White House meeting with the organizations, is there some hope that the Chamber and NAM and others would, after this session, work out some kind of an agreement and then say, okay, we're satisfied, we will communicate to the Republican leadership in the House that we don't have any opposition to this and you can go forward with it, or is there really no hope of that? In which case perhaps the meeting focus might be not necessarily exclusive of but in addition to this the leadership in the House, because if we think they may say, okay, here are our concerns, you've addressed them, we're fine with it, that would pop it loose from the standpoint of the folks in the House. But is that a realistic expectation or hope, or are we in the mode of just continuing to find out what their concerns are and hoping that we can understand them better? That won't really get us to the next point.

MS. TERRY: I think that it's not at all unrealistic to think that we might come to common ground, and I think we're just about there. I think the advantage of a higher-level meeting is to give them a place to express these concerns in a more formal forum. They've done so with us. I think they're ready now to make those concerns, in the more moderate form, to the public, and also they are ready to at least sign off, if not say that they will in fact help move the right kind of legislation forward. I think what we're seeing in the committee chairs is it has been for a long time a chicken and egg kind of situation where the chairs have said we're ready to go as soon as they're ready to sign off, and they've said they're ready to sign off as soon as the chairs are ready to go. I think we just need to have everybody in the same room, so to speak, to say we're ready to go and we understand that it's timely, it's important, and we have the forces behind it now.

We have more momentum, and I've personally been working on this for nine years and have never seen this much momentum. I mean, we have this huge rock to the edge of the precipice and just need a little more momentum to get it over the edge, and we do need to do that very, very soon, I would say within months, or we're going to have to go back to a new Congress with it.

MS. MASNY: Cindy?

MS. BERRY: One more follow-up. Maybe this was addressed while I was making my pit stop, but the data that Christy presented was very, very compelling, and do we intend or did we talk about incorporating some of that in this communication to the Secretary?

MS. MASNY: I think that would be essential, yes.

DR. TUCKSON: Let me just try to keep track, then, of where we are on this issue. Let me just try to summarize this because we've got about 12 things. If I recall where we are, and everybody can add on from here, I just want to make sure, we've agreed to do number 2, which requires number 1. We have agreed to do number 3, and we've agreed to do number 4. Then we've agreed just now to include in that some of Christy's data. So we've added that to it. So for those who are keeping score, of whom I hope there is someone, that is what the committee is getting ready to vote to accept.

Now, we're going to have some other comments, and you need to decide where it fits, either addition to that or if you're trying to subtract something.

DR. TELFAIR: Can I just ask for a modification on the last point there? Just that if we are going to add the information from Ms. White, that we actually get the more refined, because she made it very clear that this is preliminary data, and if you're going to send something forward, you want to make sure that -

DR. TUCKSON: That's good. Also, Madam Chair, I also forgot in my summary to indicate that there was a timeline of expeditiousness that was brought forward by Francis that would be a part of the spirit of the motion.

MS. MASNY: Debra?

DR. LEONARD: You mentioned that the chairs -- is that the chairs of the committee who are going to go with the bill? Should they be at this meeting also?

MS. TERRY: Yes, that would be terrific.

DR. LEONARD: So I think that that needs to be requested of the Secretary, that not only the same organizations and the White House Domestic Policy Office, but also the chairs of the committee that the bill is in are at that meeting, because then the communications are direct and everybody is hearing the same thing at the same time.

DR. TUCKSON: I'm just trying to think technically. Does the Secretary have that opportunity?

DR. LEONARD: And people other than me know that. I don't think he does.

DR. TUCKSON: He has to go through the Domestic Policy. That's why he's got to meet first with the -- Debra, I think he has to meet first with the Domestic Policy Office. You can't jump that.

DR. LEONARD: But can't the Domestic Policy Office organize the meeting?

DR. TUCKSON: That's why he's got to go to them and get them to buy in, and then it's like a jump scotch thing.

DR. LEONARD: Okay.

DR. TUCKSON: But let me just say, I think in terms of the spirit of what you're asking, let me just try to rephrase what I think I hear you saying. You're saying that given the press of time, we would urge the Secretary to try to arrange a meeting with the Domestic Policy Office, and also to try to urge them to have the Congress people decide to come as well, recognize that they're the ones who have to do it, as opposed to him.

DR. LEONARD: Right.

DR. TUCKSON: I think we can try to figure that out.

DR. LEONARD: Can we also make sure we have on the work list that all of the new members of Congress, the appropriate members of Congress get the phone book and the DVD? So they're all equally

educated.

DR. TUCKSON: That's in addition to the summary that we had.

MS. MASNY: So is everybody in agreement, then, with the proposal that Reed so aptly pulled together, be accepted by the committee members?

PARTICIPANT: So moved.

MS. MASNY: Anybody opposed?

(No response.)

MS. MASNY: Okay.

DR. TUCKSON: Terrific. Thank you, Agnes, for getting us through that. Thanks to everybody. Thank you very much, Christy and Sharon. We appreciate it. We will go forward.

We now have the opportunity before the break to hear from public comments. Again, we continue to emphasize that one of our critical functions is to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies.

By the way, I want to make sure -- where are the responses to the survey about how well we as a committee work? I want to make sure that everybody goes back. I keep reiterating the mission, but I want to make sure that we get 100 next time on the mission. Where is our charter statement? I wanted to take this opportunity, because I want to make sure we get 100 every time. We keep saying it over and over again, and people may not realize that we're reciting the mission every time we talk about one of our critical functions is to serve as a public forum for deliberations on a broad range of health and societal issues raised by the development and use of genetic technologies. So we do greatly value the input we receive from the public.

So again, that's pretty much word for word what we are, but I'm remembering again that our mission as an organization is, the purpose is -- well, actually I want to read from the function. Here it is. We have the responsibility to provide a forum for expert discussion and deliberation and the formulation of advice and recommendations on the range of complex and sensitive medical, ethical, legal and social issues raised by new technological developments in human genetics; to assist the Department of Health and Human Services and, at their request, other federal agencies in exploring issues raised by the development and application of genetic technologies; and to make recommendations to the Secretary concerning how these issues should be addressed.

The public forum for that is essential. So I wanted to make sure of that. I now see people looking at the survey, so let me just quickly do that.

"Are you aware of what is expected of you on the committee?" To be brilliant and sharp and smart, and to bring your particular expertise to bear. If you're not sure about your expertise, see me at the end of the meeting and we'll remind you of what you're supposed to be expert about.

"Do your opinions count?" Well, they absolutely do, and you need to make sure that we do respect them very much. In fact, most of the committees -- I mean, we've got a bunch of committees that are chaired by you or that you are participating in. So there is nothing that can count other than you. You're it. So if you don't like something, look in the mirror.

"The committee's mission is clearly defined." I think you've got it in front of you.

Our procedures. Again, I think we put a lot of attention to form and formality around how we behave, and particularly how the subcommittees behave and how you can influence that. But again, if you're concerned about that, let me know.

If you're not being given enough time to view the materials, it's only because I screw the staff up by basically micro-managing every word that they write and making them rewrite it 12 times if I don't like something, which is never rational anyway. So if I would just be less irrational, they would get it out to you sooner. So I'll try to be better on that.

"We have clear agendas." I hope you see that, and they are dictatorially adhered to by the chairman. So hopefully we're doing a good job on that.

I really do feel strongly about this issue of is the committee accomplishing its mission. I do require the staff to always put up at the beginning of every meeting that slide on our strategic direction and what is our status on that. So we're being pretty strict about looking at our scorecard and seeing where we are for our scorecard. So I hope that you think we're doing that.

DR. LEONARD: Reed?

DR. TUCKSON: Yes?

DR. LEONARD: This is probably anonymous, but do we know which of the ex officios are in the 3 category of neutral as to whether we're accomplishing our mission, and do they have any feedback to us as to what we could do better?

MS. CARR: It was an anonymous survey, so we don't know which ex officios responded that way. But we are having a meeting of the ex officios next month, and we'll explore that with them, and also explore with them the concern that the committee members had about feedback on their recommendations.

DR. TUCKSON: So that's serious, and we'll find out which of you are unhappy with us.

I will leave it to you about whether the meetings are productive. I'll make no comment. I certainly will make no comment about the efficiency with which the meetings are probably not run.

DR. LEONARD: But you don't take feedback?

DR. TUCKSON: In the sense that I wouldn't embarrass you now. You can call me off sides, beat me up later. I'm not going to put anybody on the spot to agree that they're run inefficiently now. See me later.

But given that wonderful point, it proves that points of view are balanced. I'm just kidding. So I guess the question would be to ask the ex officios in that meeting what points of view are not balanced and where they see that as a concern. That is serious, and I think Debra is absolutely right for raising it. We're two issues for the ex officios.

"Meetings are open and participatory." Again, we got into this whole jag by the fact that we're about to go to public testimony.

"The work of the committee is appreciated by HHS and other departments and agencies." Here is where our big issue is, and we talked about that at the beginning of the meeting.

"Federal officials provide sufficient feedback when recommendations are made." I think that this is an issue, again, that I think we could get more from the ex officios on. So we will clearly be bringing that forward for conversation.

"Open-ended comment questions." People want more time to review. Our agendas are apparently too ambitious, and I think that's a legitimate concern. On the other hand, we might want to talk more about that. On this issue of the agenda, if people would like to email me about that if there are some issues from the committee members on that, let me know, because every time we have an issue it's almost always we don't have much time to respond to it. I don't know what we can dial back, so we'll see. People do enjoy having different individuals lead the discussions, and I certainly do as well.

New members need better orientation to the committee. I'll try to be more sensitive to that.

Membership needs to be more balanced so that certain perspectives aren't overrepresented. We'll need to try to learn. Again, if anybody would like to send forward an email about that, we would appreciate it.

Recommendations should advise many agencies, not just a few. Better feedback on recommendations needed from federal officials. Disconnect between the committee efforts and the Secretary.

This is a very legitimate exercise. When did we do this, in October?

MS. CARR: Right.

DR. TUCKSON: That was October of '05, so let's really look forward to doing this again in October of '06. But staff, help me out on this, because I really want to get 100 percent the next time around on this. So it's up to you.

All right. With that, the public. I've got written comments from the College of American Pathologists. They are in the table folders. Are they going to speak also?

MS. CARR: No.

DR. TUCKSON: Okay. They have comments on the patents issue, so we'll be looking at that during the break because we're getting ready to go to patents in a minute, so you might want to pay

attention. In fact, you really do want to pay attention to what the College of American Pathologists has to say about patents.

Let me ask Anthony Lakavage -- did I say that properly? Say it right.

MR. LAKAVAGE: Lakavage.

DR. TUCKSON: Lakavage. That wasn't even near what I said.

Anthony is from the Research Use Exemption Coalition.

Thank you for taking the time to join us. You can either have the podium or one of the chairs, wherever you're most comfortable. That's fine. Thank you. Welcome.

MR. LAKAVAGE: Thank you.

Good morning, everyone. My name is Tony Lakavage. I'm senior director of Government Affairs and Public Policy at Applied Biosystems, which is headquartered in Foster City, California. Just a little context for those of you who don't know who we are, our gene sequencing equipment was used by our sister company, Celera Genomics, to be the first commercial entity to map the human genome a number of years ago.

But actually, I'm here on behalf of the Preserve the RUE Coalition, of which Applied Biosystems is a member. We greatly appreciate the opportunity to comment on the recommendations made by the National Academy's Committee on Intellectual Property Rights in Genomics and Protein Research and Innovation. Specifically on behalf of the Coalition, I'd like to comment on the committee's recommendation to broaden and codify the research use exemption, known commonly as the RUE.

First, by way of background, the Preserve the RUE Coalition is a coalition of life sciences and biotech companies and organizations, including some academic organizations, dedicated to maintaining the fundamental and underlying objectives of the patent system. To that end, we strongly support preserving the existing research use exemption, which has functioned well for the past 200 years.

Our companies are part of the $17 billion commercial life sciences industry, and we are dedicated to improving the human condition. We provide essential life-saving life science technologies for disease research, drug discovery and commercial bioproduction, and our products can be found in nearly every major laboratory in the world, probably in almost every room on this campus. We share with policymakers, researchers and other key stakeholders the desire to ensure that the patent system is a tool to drive rather than inhibit innovation. So in the interest of our companies and society, to have innovative research tools available to researchers and pharmaceutical and biotech companies to support advances in public health and in human health.

The fundamental policy underlying the patent system is to provide exclusive rights for a limited time period to investors in new and useful technologies in exchange for those technologies being fully disclosed to the public. The disclosure of these new technologies then promotes further innovation by allowing even newer, more innovative technologies to be developed from the foundation space upon the patents of the previous innovators. In effect, the patent system encourages the development of new

technologies by balancing the benefits of innovation to society with the interest of investors.

In keeping with these principles, there are only a few very limited circumstances under which the use of a patented invention is in the broader public interest. One of those exceptions is the common law doctrine of research use exemption, or RUE, to patent infringement. The RUE allows conduct that would otherwise constitute infringement of the patents when that conduct is purely for philosophical and non-commercial inquiry. In its report, the IP in Genomics and Proteomics Committee diverges from current application of the RUE and recommends that the RUE be expanded and codified to provide a regulatory or statutory exemption from infringement from research "on" a patented invention. Paradoxically, the committee at the same time acknowledges that today and historically there has been little evidence to suggest that the RUE as currently applied imposes any significant burden on biomedical research.

Academic researchers acknowledge that patents rarely inhibit their ability to perform research. That fact is one that's in the proceedings of the committee that made this recommendation. Notwithstanding these facts, the committee made the recommendation predicated on the hypothetical concern that future academic and non-profit research could potentially be frustrated or limited and that universities could be subject to greater licensing demands in the wake of recent court cases.

Since its inception nearly two centuries ago, the courts have confirmed and narrowly applied the RUE. The courts have distinguished between, on the one hand, profit and business motivated conduct, including organized scientific research, and on the other hand activities strictly limited to scientific and philosophical research, protecting the latter from liability for infringements.

In Madey v. Duke University, the federal court reiterated the narrow scope of the RUE and found Duke University's use of patented technology in furtherance of other research not protected by the RUE. The court stated that the RUE "does not immunize use that is in any way commercial in nature. Similarly, the RUE does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."

While the Madey decision was met with alarm because when it was first issued it found the university guilty of patent infringement, these facts were unique, and there's no empirical evidence that there has been an epidemic of university researchers being sued or threatened with suit for patent infringement since the decision, nor has there been significant evidence that patent holders are holding universities or other non-profit research institutions hostage by increasing patent licensing fees or dictating more onerous licensing fees.

We believe that any expansion of the RUE, such as that proposed in the NAS report, would be counter-productive, discourage innovation, and have serious consequences for those who would have traditionally invested in the innovative research tools industry. Expanding the RUE would do a number of things to diminish the value of research tool inventions, undermine innovation in developing new time- and money-saving tools, increase litigation uncertainty where little uncertainty exists today, delay access to technologies and the overall research to market period while litigation makes its way through the courts, and limit access to valuable research as patent holders might seek to invoke trade secret law to protect their intellectual property.

More broadly, the committee's RUE recommendation is not based on sound public policy or legal

reasons. First, the recommendation presumes that there's a genuine functional problem with the current state of law concerning the RUE. In our view, those advocating a change to the RUE should carry the burden of presenting clear, convincing and quantifiable evidence that a practical problem exists. Anecdotes should not suffice given the serious potential consequences the change would present. We do not believe that this burden has been met. The record simply does not include concrete evidence of a real problem.

Second, the RUE as currently applied in patent law is working. Preclusion from access to research tools is rarely an issue, especially within the academic community. The primary commercial goal of the research tools industry is to further research, and their principal market is research applications. Therefore, such patent holders seek to widely distribute their products and/or license their inventions. In general, patent holders do not wish to obtain the negative public relations impact associated with suing research institutions over patent infringements.

Third, we believe that an exemption expansion of the RUE will weaken the current patent system. The research-intensive companies that comprise our coalition and the burgeoning life sciences industry needs certainty in their ability to protect and enforce their patents. Without it, these companies will have difficulty attracting and maintaining investment capital, may forego investments in research tools, and may limit access to their existing research technologies, all of which would reduce access to valuable research tools and ultimately hinder scientific innovation, particularly in the genomics field.

Fourth, with the RUE expansion, tool inventors may seek to protect their intellectual property under trade secret protection law, eliminating access to those innovations altogether.

As the advisory committee considers these recommendations, we hope that you will consider our views and not support any expansion or codification of the RUE, again noting that the NIH's own report makes clear that patents are not inhibiting the work of academic researchers, and in light of the potentially devastating impact such an expansion could have on innovation.

Sorry about those sort of long remarks. It's just that it's a complicated issue.

DR. TUCKSON: No, actually, I found it well written and cogent. Do we have hard copies of that, by the way?

MR. LAKAVAGE: If you don't, you're going to.

DR. TUCKSON: Let's make sure you do.

So you're sort of seeing it differently than this report. Is that it in a nutshell?

MR. LAKAVAGE: That's right. Actually, the recommendations don't seem to have their basis in that report. If you look at the proceedings of the committee making the recommendations, there's presentation after presentation where they say that patents are not inhibiting research. Apparently the deliberations, from what we understand, were some academic researchers simply concerned that this could become a problem in the future.

DR. TUCKSON: Will you be around when our good friend Dr. Korn testifies, or do you have to

fly back?

MR. LAKAVAGE: I will, I will, and we'd be happy to come back and have a longer substantive conversation.

DR. TUCKSON: Any other questions?

Please don't apologize. It was very well presented and very well written, and we'll take a good hard look at what you have. Thank you very much. We appreciate your time.

MR. LAKAVAGE: Thank you.

DR. TUCKSON: Next will be Mr. Jaydee Hanson from the International Center for Technology Assessment.

Mr. Hanson, welcome. Your choice as to sitting at the table or going to the podium, wherever you feel most comfortable.

MR. HANSON: Thank you. I'm glad you provided an opportunity for public comment here today.

Our organization is working with a number of other groups, mostly in the progressive side of the political spectrum, on these issues. We are glad that the National Research Council has taken on this issue to advise NIH. I need to preface my comments by saying we actually flat-out oppose gene patents. While we welcome the comments of the National Research Council, we think they're moving in the right direction, we think there are ethical, scientific and health reasons to not patent genes to begin with. So that's the context for the rest of my comments.

We look and see that thousands of gene patent applications have been granted. Recent estimates suggest that about 20 percent of human genes have now been patented. Knowing the chemical makeup of a gene does allow researchers to determine which mutations in a gene cause disease, and subsequent research could lead to the development of techniques to produce the protein created by the gene in a laboratory to provide pharmacological treatment for the genetic disease. Research has also been undertaken to find ways to correct copies of the mutated genes in patients, and NIH has been very involved in gene therapy. We're concerned that future developments in gene therapy could also be limited by gene patents.

Patents covering human genetic material are a recent and, we would argue, controversial development. They claim exclusive control over naturally occurring human genes and limit how the genes can be used in research and diagnosis. More than 10 years ago, some 200 religious leaders called for an end of gene patenting and animal patenting for a variety of reasons. One of the religious leaders said, "What we're seeing is the new colonialism, where whoever gets to something first gets to claim it. Once we divided up the continents of the world; now we're dividing up the human genome."

Because many human gene patents either directly claim or include genes and the corresponding proteins that are essential to genetic diagnosis, a grant of exclusivity may hinder both health care and the advancement of scientific technology. Patents can obstruct future innovations by preventing researchers

from looking for alternative uses of a patented gene. Bob Cook-Deegan, who is the director of the Duke University Center for Genome Ethics, Law and Policy, says it rather well. "You may find dozens of ways to heat a room besides a Franklin Stove, but there's only one gene that can make human growth hormone. If one institution owns all the rights, it may well work to introduce a new product, but it may also block other uses, including research."

The U.S. situation with gene patents is not universally shared. Gene patents are under siege worldwide because they have granted exclusive rights to specific sequences of genes. Gene patents are being challenged in courtrooms and legislatures. International organizations such as the Council of Europe's Committee on Legal Affairs and Human Rights and UNESCO now view genes as belonging to the common heritage of humanity. Intensive opposition to gene patents is also coming from researchers and politicians and organized religion. Since the religious leaders statement, a number of denominations -- the Southern Baptists, whose perspectives on issues are probably more conservative than mine, has called for an end to gene patenting. The United Methodists have, and the World Council of Churches has. Indigenous groups have called for an end, patients groups, and some medical associations.

I disagree with the previous speaker. I believe that evidence is increasing that gene patents have a detrimental impact on health care and research. Patents held by a company on one or two genes may prevent another company from offering a test that covers all known genetic mutations. A patient may be told they don't have a gene that causes a certain kind of cancer, only to later learn they have another kind of gene that also causes the cancer. This is already happening with breast cancer gene testing. The study published this year in the Journal of American Medicine found that 12 percent of persons from high-risk families with breast cancer and with negative wild-type commercial genetic test results for BRCA1 and BRCA2 nonetheless carry other mutations that could lead to cancer.

Increasingly, the appropriate treatment for an individual patient may include diagnostic testing, but having a particular gene for a disease does not mean that person will develop the disease. Most genetic tests offer only an estimate of the chances for developing a particular disease and fail to account for the influence of other genes and environmental factors. As we learn more about the human genome and how genes interact, we need the ability to look at all genes together and not be prevented from looking at them together.

Myriad Genetics says it's going to be developing broader tests that will help detect additional mutations, but we should not have to wait on just one company to develop a test. Allowing one company to control the market for one whole area of testing does harm patients. We think it already is.

One commercial aspect of diagnostic gene patents requires doctors to either obtain a license to provide such a test or else charge the patient a fee for sending a sample to be tested at a corporation or research institution that holds the patent. In many situations, this fee can be exorbitant. As an alternative to utilizing a patented procedure that may cost the patient, the insurance company, the managed care organization, or the government a significant amount of money, the doctor may choose to perform an inferior procedure, resulting in inaccurate results or even failure to screen for a particular disease.

Furthermore, there's concern that the monopoly over genetic testing inevitably leads to a loss of expertise and information among researchers and physicians. This arises from the fact that researchers and physicians are often completely barred from using any gene or protein sequence claimed within the patent, and thus prevented from undertaking or improving diagnostic technology related to that particular

gene. A complete bar to use may have a deleterious effect on innovation and future research and ultimately result in an intellectual standstill. Because researchers and physicians cannot use the patented gene itself, no improvements to the inaccuracies of current testing mechanisms will be discovered.

Research and diagnosis has undoubtedly already been hindered in the U.S. by the exclusivity of genetic material essential to human gene detection. In the United States, 35 percent of geneticists reported that even sharing basic data and research material substantially decreased between 1992 and 2000, and 21 percent claimed that failure to access such data from another researcher resulted in their abandonment of a promising line of research. A 1998 survey of 200 genetic testing laboratories found that 25 percent of the laboratories even then had been prevented from offering a test due to the enforcement of a patent or license. In addition, approximately 50 percent reported they did not attempt to develop new tests due to commercial constraints brought on by a patent.

DR. TUCKSON: Mr. Hanson, by the way, I need you to sort of start to get to closure. You're terrific, but we've got to start to close.

MR. HANSON: I've got three paragraphs left.

In 1998, SmithKlineBeecham sent letters to labs ordering them to stop performing or developing tests for the hemochromatosis gene. Research collaboration is being stifled as well. A 2002 study found that 47 percent of geneticists surveyed had been denied requests from other faculty members for information, data or materials regarding published research. When geneticists were asked why they intentionally withheld data, more than 20 percent listed the need to protect the commercial value of their results. Even more troubling, 28 percent of geneticists reported that they were unable to duplicate published research because other academic scientists refused to share information, data or material. This goes to the very heart of science, which is supposed to involve hypothesis testing and replication.

We are delighted that the National Research Council was so concerned about the effects on patents on research related to genetics that it is recommending that the U.S. Congress should explicitly provide an exemption to patents for research on the effectiveness of the research tools related to genetics. We also are glad to see that the Council has called to reject claims of patent infringement when gene patent monopolies threaten public health. We, like the Council, are especially concerned that independent testing verify the accuracy of genetic tests.

Finally, we think the U.S. could follow Europe's example in protecting its citizens by denying broad patent claims on genes that correlate with particular diseases.

In closing, we'd say we're not opposed to all kinds of patents in this field. To use an analogy from many, many years ago, we think that granting patents on genes is a little bit like granting Galileo a patent on the moons of Jupiter. We think that there should not be patents on naturally occurring objects, whether they're in the heavens or whether they're in your bodies. We do think that if Galileo were here today, he should get a patent on his improved telescope, but not a patent on the moons of Jupiter.

DR. TUCKSON: Thank you very much. We appreciate it.

Unfortunately, we're not going to be able to take questions at this point. I assume you'll be around for the discussion later. If you'll please give the team a copy of your remarks so that we might be

able to refer to them during that discussion. Thank you for taking the trouble to come.

Lastly but not leastly, our good friend and colleague Joann Boughman, who is going to -- I have no idea, but it's going to be wonderful.

(Laughter.)

DR. TUCKSON: Update us on something, and I know one thing is that I'm listening carefully.

DR. BOUGHMAN: Thank you very much.

My name is Joann Boughman, and I'm the executive vice president of the American Society of Human Genetics. Today I'm not going to ask you to do anything specific but rather thank you for your time and effort on many of the issues that are priorities for the American Society of Human Genetics, as well as priorities on your agenda. I would like to share with you just a few points of information that I think you may find useful as background in your deliberations.

First of all, our 2005 ASHG annual meeting happened to be in Salt Lake City, Secretary Leavitt's home territory, and we were able to arrange to have Secretary Leavitt, in fact, open our meeting. He was there in conjunction with the NHGRI announcement regarding the HapMap, and although the logistics weren't quite easy, we were able to have him come over and open our meeting. I can tell you that the Secretary was clearly engaged in genetics topics and issues, including the advancement of genetics research, investigation in gene/environment interactions, the importance of bioinformatics in the enhancement of health care, including electronic medical records, and the importance of predictive and quality information in personalized medicine.

This is the first time our organization has ever had an elected or an executive branch official, and we were pleased that it was Secretary Leavitt. His remarks were very well received, and we also heard very positive feedback from the Secretary's office. So, in fact, you are talking to an engaged Secretary, which I think is helpful for you to know.

On the topic of genetic information non-discrimination, our board of directors chose D.C. as their spring meeting site this year, the first time we have met in D.C., and the entire board did what I call storming the Hill one of the days they were here. We met with eight House offices, five representatives actually sat through those meetings, and 10 Senate offices. We believe we got commitments from four representatives to co-sponsor H.R. 1227, but I have to follow up on that. I would reemphasize that engaging the representatives directly and informing them is a very important first step in getting them to sign on.

I also think we have an energized Society leadership when it comes to legislative and policy engagement.

Finally, I'd like to address Chairman Tuckson's comment and his articulated issue about public education and just update you very briefly on a major educational effort at the American Society of Human Genetics. We have a new director of education and we have greatly expanded our educational resources for K through 12 at a Web portal we're calling GenEdNet, for Genetics Education Network. It contains the teaching standards for every grade and in every state and province related to a dozen key

words around genetics. Therefore, our mentored network of 1,200 volunteer members of our organization can now go to this website and, for example, if a colleague of mine is asked to teach 6th graders in Ohio or 12th graders in Colorado, they can go to this website and find exactly the genetics content in that grade curriculum in that area.

In Phase 2 of this website development which is now underway, every standard is being related to at least one vetted website with information that is age appropriate and accurate in genetics content. Phase 3, which is a few months off, will add active teaching activities and actually hands-on activities for the classroom so that teachers as well as other people can engage directly in these activities.

While this is not public education in the general sense, we think it does support one aspect of what we call our pre-K to gray educational initiatives. We also have under graduate education activities going on, and in addition we are working with NHGRI on DNA Day activities. Don't forget, April 25th is DNA Day, including an essay contest where we now have almost 400 submissions. One of the two questions that students are asked to answer is why is it important for everybody to know about genetics, and about 250 of the essays are answering that question.

We also are engaging in a special initiative in the northeast around this DNA Day, with between 50 and 100 geneticists already identified to go into classrooms during that week.

The 2005 presidential address by Peter Byers at ASHG focused on genetic advocacy of all types, including the essential partnership with patient and advocate organizations. His presidential symposium was entitled "Genetics in the Public Eye" and brought other perspectives to the genetics research community. So I think we are actively engaging in bridging gaps that have existed. We believe that these activities will also enhance public education in the fullest sense.

The genetics community is more active than ever in areas of translational research, including pharmacogenetics and genomics, with several scientific sessions planned for our 2006 meeting in these areas.

Again, ASHG applauds the members of SACGHS on their important endeavors. We look forward to your next products, and our society will be responsive in any way that you might find helpful. Thank you again.

DR. TUCKSON: Thank you so much. That's terrific.

Can you get that website to the team so that we can have that distributed to everybody?

DR. BOUGHMAN: Absolutely.

DR. TUCKSON: I think everybody was sort of trying to jot that down and seemed pretty excited by getting that news. Terrific.

DR. BOUGHMAN: Thank you.

DR. TUCKSON: Thank you.

We're going to go to a break a few minutes late. By the way, Debra and I were teasing during the session on the survey business, and she was saying did I not want to take comments on the efficiency with which I run the meetings, and I really don't.

(Laughter.)

DR. TUCKSON: So see me at the break so you can beat me up, because I didn't want this to happen, but your break is going to be short because I'm inefficient.

Bottom line, we're going to start on the hour because we've got guests coming. So you have to go now and then run right back because we've got guests. That's the way it is, so thanks.

(Recess.)

DR. TUCKSON: We're going to get started again. I am very pleased that Debra Leonard came to me, in very somber tones, and said we need to get started. So this time it's not me being the bad guy, which is great. We are really, actually, though, excited to get into this next agenda, and we're going to start to talk now about the patent issues.

I just will say, since Debra is going to lead us through it, that I am just personally pleased by the way one of my mentors in health care, David Korn, is actually with us, and I just want to take the privilege of personally welcoming David to the committee again, and I'm always pleased when he is in our presence.

With that, Debra, please take it away.

DR. LEONARD: Thank you. It's my pleasure to head up this session on patents and access. The goals today for this session are to first be briefed about the NAS Report on Intellectual Property Rights in Genomics and Protein Research and Innovation by Dr. Korn, review the report and recommendations of the SACGHS Patent and Access Task Force, and then open up the discussion to the committee as to whether there are next steps that SACGHS would like to take.

So a little background before David walks us through the report. In March 2004, during our priority-setting process, we did rank DNA-based patents and licenses and the impact those are having on research and clinical practice as a high-priority issue. But at that same time, NIH let us know that they had just commissioned the NAS to review the patenting and licensing of human genetic material and proteins and the impact that this was having on research and clinical practice. So we deferred consideration of this topic until the NAS work was completed.

So that report was available in November 2005, and in anticipation of this in October SACGHS charged a small working group, the Patents and Access Task Force, to review the NAS report and correlate the NAS report with the questions that we had raised during our priority-setting process and determine whether there are still areas that warrant further exploration or attention or whether the report really addresses all of our concerns.

I just want to review for you the areas of concern that SACGHS did identify in its priority-setting process so you keep those in mind when Dr. Korn is going through his presentation. We had raised issues

specific to patents and then the licensing practices used for licensing those patents, and the impacts that the patents and licensing practices were having on research, clinical practice, and economic issues.

So in the area of patent issues specifically, we raised the following questions. Do DNA-based patents blur the distinction between information or natural phenomena and products or things that are created or invented? Are DNA-based patents too broad or obvious to a person practiced in the art? Which means someone who knows genetics and molecular biology. Have the changes in the PTO's utility guidelines, basically raising the bar that you have to show the usefulness of the thing that is being patented, been effective in reducing DNA-based patent submissions whose utility is questionable?

Regarding licensing practice issues, which licensing terms are creating the majority of problems for genetic/genomic test providers? There are a number of issues that the committee became aware of, high royalty fees, the field of use being constrained by the patent, sub-licensing issues, reach-through rights in which a patent holder or licensee would have the ability to gain control of future knowledge, and exclusivity clauses. Do exclusive licenses raise particular concerns for genetic/genomic test providers, and how prevalent are exclusive licenses? Patents are exclusive by definition.

Then SACGHS raised questions on the impact on research. To what extent do gene patents and licensing practices inhibit research progress? To what extent do delays in publication due to patent submissions affect the progress of science? Does patent stacking inhibit scientific discovery and technology development by making it difficult for a researcher to obtain all of the licenses necessary to carry out specific research projects?

Further, on the impacts on research, in 2000 technology transfer laws were amended to prohibit federally funded researchers from imposing undue restrictions on future research and discovery. Is the impact of this amendment being monitored and analyzed, and has it had an effect?

In the area of clinical practice, there were a number of questions that were raised. Do patents facilitate or inhibit the translation of scientific information into medical practice? Are patent incentives needed for the translation of genetic/genomic discoveries in the area of genetic or genomic testing? How do patent and licensing policies affect the availability of and equitable access to genetic test services in the practice of medicine? Does the current system of patents and licensing genetic technologies affect the training of laboratory clinicians?

A final slide on clinical practice. DNA-based patent holders can license their inventions to a single provider of a genetic test or be that single provider in themselves. Is there being a sole provider of a medical test in the best interest of the public health given the difficulty of sending samples to multiple labs, lack of competition for the way the testing is done or the accuracy of the testing, and absence of independent test validation? Do DNA-based patents and licenses reduce access by either increasing costs due to licensing fees, reduced availability, or other reasons? Is there a mechanism for balancing the protection of an inventor's intellectual property with the broad utilization of gene discoveries for health care purposes? Do DNA-based patents require special consideration due to their potential ability to improve public health?

In the area of economic impacts of patents and licenses, there were a number of questions as well. Do patent and licensing policies increase the cost of medical products, including genetic tests and gene technology-based treatments? Are current patenting policies and practices critical to the success of the

biotechnology and pharmaceutical industries? Could any changes in current law undermine innovation, thus doing more harm than good?

So with that as background as questions that SACGHS had raised, I would like to introduce David Korn to give us an overview of the NAS report, which you all have received at your place, the nice hard-bound copy for your keeping and reference, which is the NAS report.

David?

DR. KORN: Good morning, everybody. First of all, let me thank Reed, whom I've known for at least 25 years, and Debra, and the rest of you for asking that I come out to talk to you about this National Academy of Sciences report that was only just recently printed, although it was released in October.

I spent seven years in this room chairing the National Cancer Advisory Board, and I think this is the first time I've been back since the spring of 1991, and the carpet is new, and I think the upholstery on those chairs is new, but not much else has changed. So I'm glad there's continuity in life.

The National Academy was asked to form a committee to do a study by NIH mainly, and mainly by the Genome Institute and the National Institute of General Medical Sciences. I don't know what other NIH funding might have been in this study. In its typical fashion, the Academy, fiercely independent, formed a committee, and the committee is actually shown here. The committee is there, and it was co-chaired by Shirley Tilghman, who is a well-known reproductive biologist and now president of Princeton University, and by Judge Rod McKelvie, who is now in private law practice but for many, many years was a judge in the State of Delaware on what I think is called the Chancery Court, but I'm not positive. Anyway, he adjudicated a vast number of issues in litigation regarding patents and is really quite an authority on patent law.

Ashish Arora is an economist at Carnegie Mellon who studies the economics of scientific innovation, technical innovation. Helen Berman is a protein chemist, biochemist, who runs the International Protein Databank at Rutgers. Joyce Brinton for almost 30 years was in charge of all intellectual property matters at Harvard University. Steve Burley is a former, quite renowned crystallographer, I think at Rockefeller, who is now in a small company. I don't know if it's still a start-up; maybe it is. It's very into proteomics. Todd Dickinson, now senior counsel to General Electric Company for intellectual property matters, served under the Clinton administration as the director of the U.S. Patent and Trademark Office, the PTO, and I guess has spent his entire life in patent law issues and their interpretations. Rochelle Dreyfuss is a professor of law at NYU. Rebecca Eisenberg is a professor of law at the University of Michigan. Both of those ladies are very highly respected academic legal scholars who have written extensively on issues of patent law and patent interpretations and so forth. Charles Hartman was a venture capitalist who died during the course of this committee's work. His company was very involved in biotech start-up companies. Dan Kevles is a very distinguished historian of medical science, a long time at Cal Tech, now a professor of Yale. I am myself. George Milny, who is now in venture capital and start-ups, was for a long, long time the senior V.P. for global research development at Pfizer. Richard Sheller, a former faculty member of mine at Stanford, is now a senior person, maybe V.P. for research, at Genentech. He's a neurobiologist. Rochelle Site is a patent lawyer in private practice in a large firm. Nancy Wexler you all know. Bob Waterston you all know, a very distinguished genomics researcher at the University of Washington. Brian Wright is a professor at U.C. Berkeley whose field is agro-biotech, and he has also been involved in issues relating to biotech R&D and

the patent system.

Now, the charge to the committee is here, and I know you have all this stuff, so I'm not going to read it to you. It's in your packet. It was basically to look at how the U.S. patent system is working with regard to technologies in genomics and proteomics, evaluate our systems against those of Europe and Japan, try to get some information on whether the application of patent law and practice are inhibiting research and innovation. Notice research and innovation. There was nothing in this charge explicitly about the practice of medicine. I did not write the charge.

Let me just say that I agreed to deliver this report straight, and that's what I'm going to do. I was supposed to have been joined by Judge McKelvie, but some time ago he got into an irreconcilable schedule conflict, so he can't be here, and I promised the Academy people I would be faithful to the report. But afterwards we can talk about it.

(Laughter.)

DR. KORN: And then make recommendations to NIH and others.

Now, what did the committee find, in brief? That patenting varies greatly among biotech categories; that patenting seems to have leveled off. That is, there's this spate of application that flooded the patent office beginning in the late '80s and early '90s seems to have been leveling off a bit, sort of like the D.C. housing market, but pendency has increased. That means applications that have not yet been ruled on -- and there is a huge backlog of genomic and proteomic applications sitting in the patent office waiting for a decision to be made. The fourth bullet on here is that U.S. inventors and their signees dominate patents in almost all the categories of interest in genomics and proteomics. So it's more a U.S. problem at the moment than an international problem from that perspective.

The committee found, and I think this is important, that perhaps the chief difference in how the U.S. as compared to Japan and Europe deal with patent issues is in the requirement that we call non-obviousness, that a claim to a patent must be non-obvious, which means that a person skilled in the field would not have thought of it, perhaps, obviously based on his or her knowledge. In Europe and Japan, it's called the inventor's step, and inventor's step implies something creative, invention. In the U.S., some time ago, court rulings changed the patent laws consideration of inventiveness to discovery. Again, we can talk about this later, but there is a big difference between discovering something and inventing something. Other countries respect that difference. Our country, in law, seems not to as much. So the bar is higher in Europe and Japan.

Then another difference that's on here at the bottom, the last bullet, is that other countries, most other countries have a statutory provision for compulsory licensing, which may be relevant to some of the issues that Debra posed to you, and they shield research on patented inventions from infringement liability. In other words, Europe and Japan, the way the U.S. does, sort of, allow research to be done -- and I'll get back to this -- on patented inventions, on and not with, which is a very important legal distinction.

Concerns that were raised to the committee -- and Rebecca Eisenberg is the creator of this concept, an anti-commons, that there are so many patents out there on enabling technologies that marshaling licenses or permission to do something that requires the agreement of 10 or 50 different patent

owners could be a great inhibitor of valuable research and development and commercialization of new therapies and so forth. When golden rice was produced, the rice that contains the precursor of Vitamin A, one of the committee members was involved, the one at Berkeley was involved in that work, I think something like 67 patents had to be negotiated to enable the people who were trying to develop golden rice to use the tools and technologies that they needed to get golden rice, and I think that Francis Collins made a very persuasive presentation to the committee at one of its very first meetings, pointing out that for certain kinds of biomedical or biotechnological research that involves sophisticated inputs, like knockout animals or this or that, monoclonal antibodies or whatever, you could also generate a list of 10 or 20 patent owners who technically control one's ability to use these particular steps of a process. So that's what the concerns are about.

The second bullet on here has to do with access, which I think we've already talked about. The patent system in the United States, and to some extent worldwide, in the last 25 years has been moving steadily upstream toward the basic research end of the research discovery product chain. It's not a perfect chain. It isn't uni-directional. We all know that. But the point is that the Supreme Court in 1980 made a ruling on a challenged patent on a genetically engineered bacteria that was able to digest oil, and the inventor thought it would be a useful biological weapon against oil spills, for example. You just toss these bacteria in an oil spill and they start chewing up the globules. The Supreme Court ruled that this was patentable even though it was a living thing, and they also said in their opinion that anything under the sun made by man is patentable, anything, and that really opened up patenting in biotechnology with a full faucet. I mean, before that it was not clear what the boundaries were in biotech and biodiscovery of what you could patent. But that ruling essentially opened the floodgates, and we've been struggling, we being our society and lawyers and courts, ever since to figure out what the limits are on patenting, if there are any limits.

Then the last concern was that there might be an erosion of the norms of open science that would inhibit research and restrictions on sharing research materials. I'm not going to go through all the slides that you have in your packet. I kind of reorganized these last night to make them a little bit easier to digest, but there was a survey commissioned by the committee while it was at work. Walsh and Cohen are both very well known economists who study innovation, and I don't know who Dr. Cho is but he was a member of that team, and they did a quick and dirty survey to ask the questions that are on your handout, really trying to understand whether academic investigators were being inhibited by the application of patent laws and licenses.

What they found -- and again, I've pulled a few slides out of the several that are in your handout -- was that the academics that were sampled -- this was a smaller sample with a 30 percent response rate, so I don't know how generalizable this is. But there was substantial commercial activity reported by the faculty who responded. Nineteen percent have some industry funding. I'm surprised it's that low, to be honest with you. Twenty-two percent had personally been engaged in patenting their own discoveries in the last two years. That's a pretty good chunk of the community. Thirty-five percent of these academic researchers had been involved in such business activities as start-ups and so on. There was a prevalence of those who were doing drug discovery.

Now, this is important. The question was asked: What are the main reasons that you and your team are doing the science that you're doing right now when we're asking you the question? If you look at this, you will see that the most important reasons are the ones that are obvious to all of us who have lived long enough. We may be out of date, but we think these are obvious. They are scientific

importance, interest, feasibility, and sufficient funding, because without those things, why would anybody in his or her right mind want to do the hard work of research? But it is nice to see that those still are the motivators of research, in academia at least.

Health benefit. This was not limited to biomedical scientists. So health benefit was only 60 percent, which is not surprising to this group. Then there were the usual other things. But notice that patentability and personal income are way down here. So yes, a few people thought those were important reasons why they chose projects, but it clearly wasn't the prevalent dominator of why people were doing research.

This result -- I mean, I just have to tell you, I think I'm older than anybody in this room, but it really made me feel good because I would have been so distraught if this chart had been inverted and people said, gee, the reason we're doing this is to get patents and make money. So that made me feel good.

Now, similarly, complimentarily, the reasons for not pursuing projects also kind of makes sense. There's no funding available. Research costs money. I'm too busy. It's not feasible. It's not scientifically important. It's not interesting. Again, it's not rocket science. I mean, that's what we would expect a sane person, a mentating person, to tell you. Some said little social benefit. But again, notice that very few people, a very tiny fraction thought that there were too many patents out there or I wouldn't be able to patent what I did or I wouldn't get income from it. The economics of research did not seem to be predominant motivators of either pursuing or not pursuing projects. I like that. I personally just felt good about that.

Now, 8 percent -- but remember, it's a small sample, thought they needed knowledge or information covered by patents. The key thing here is that most of these academic researchers didn't know from patents, or at least they didn't care about patents. They did what they wanted to do. They didn't say, oh gee, I'd better go call a lawyer and do a patent search and see if I can use this tool or this material or whatever. This is something that even since the Madey decision of 2002 I think it was, or 2000, I don't remember, that we can talk about later but which worries a lot of us. It doesn't seem to have had much impact on how academic research has behaved.

Now, a fifth of them did say they had received "instruction from their institution." I don't know what that means. It might have been a letter from the general counsel's office saying please be aware that there's a patent system in the United States and if you're thinking of using materials, tools, animals, you might want to check on whether or not somebody owns those things and we have to negotiate a license. That figure I think is higher than it would have been a decade ago, but I can't prove that to you.

Several of us joined with the AAAS to do a study of how Madey, the decision, was affecting the major research universities, and you see that only about 14 percent of the institutions said they give instructions. The survey didn't find that even if you got instructions, it didn't change behavior, and anybody that's been a faculty member or the dean of a faculty knows damn well that the faculty don't listen to instructions. They ignore them most of the time, and that's what a faculty member is. It's a person who thinks otherwise.

(Laughter.)

DR. KORN: Now, sharing. This actually now becomes important. About 75 percent of the respondents had requested materials from some other person or institution in the last two years, and 19 percent said they did not receive the last requested input. Input is the way the economist talks about tools. They did not receive it. That's a fifth. A fifth of the requests according to this survey were not granted. These economists think that problem may be increasing. I don't know if that's really relevant or not, but the point of the matter is that for most people -- I'm sorry, let me say it differently. For the people who were requesting inputs, there was some delay of their research in a small percentage, and that seemed to be higher when the request involved pure intellectual property, and I'll explain what that means in a minute.

You see that about 40 percent of these require what's called a material transfer agreement. A material transfer agreement is a legal document, like a contract, that a provider of a research tool, usually the general counsel of the provider's institution, develops that tells the recipient of this research tool what he or she may or may not do with that tool. Usually they restrict dissemination. That is, if I give you my knockout mouse, I may say you may not disseminate it to anybody else outside your lab group. If somebody else wants it, I will deal with it. It may say that you can do whatever research you want to do with my knockout mouse, but if you develop a commercial product, you've got to come talk to me about what my share of the economic benefits may be from this product. Again, these aren't patents and licenses so much. These are just I have it, you want it, and there has developed this culture of contractualizing the transaction between me and you in handing over my material.

The NIH has been very worried about MTAs for quite a long time, and in 1999 I think Rebecca Eisenberg, a member of this committee, chaired a special panel to the advisory committee to the director of NIH, I think it was then Harold Varmus, and wrote a superb report pointing out that this kind of restriction was very, very threatening to research, very worrisome, and advising that NIH flex its muscles in trying to have grantees, those who get money, behave better. In particular, they proposed a simple one-page agreement for material transfers, a simplified one-page universal agreement and urged NIH to enforce that.

NIH has urged and exhorted, has not really, at least until recently maybe, enforced. Now why is this a problem? Because in 38 percent of these cases, you want reach-through rights. A reach-through right is what I just described. I'm going to give you my mouse, but if you get something really interesting that you can commercialize out of it, I have a right to some portion of your return. That's a reach-through right. Reach-through rights can be extremely irritating, and the more material transfer agreement stuff you have, each with its own research rights, you can be working on a project and owe 200 percent of the benefit to the people that gave you the tools, and that's kind of not very encouraging -- royalties, manuscript review, this sort of thing.

So why do scientists not provide materials? Competition. This is as old as I am. It's older than I am. When you work real hard to get a breakthrough on something, and everybody knows about it right away because we all talk about these things, then everybody wants it, and you haven't even had a chance sort of to digest your meal, and all of a sudden people want to share your dinner. So people often -- and this doesn't have anything to do with patents. This just has to do with personal motivations and stuff. That still remains the major reason why people are reluctant to share some of these tools, which can in fact be very, very hard to (inaudible). They're not trivial.

Anyway, let me skip away from that. So what did the committee conclude? It concluded that it

appears that access to patents or information inputs really are a significant burden, information inputs, but the committee agreed that the patent landscape could become much more complex and troublesome over time. There is no evidence right now that patent stacking is causing a lot of concern in academic research, but institutions are aware since Madey that they do not have the kind of immunity from patent infringement charges that they had before Madey. We all grew up believing that patents didn't involve anything we did as academic researchers. We didn't have to worry about it. Madey said we do. Clearly, most people are still not worried about it, but at some point that could change, and patent holders could try to get benefits by asserting their patent rights against universities. There are some anecdotal cases where that has occurred. In the both of them that I know, the university essentially told the claimant to go away, they were too busy to deal with them. I don't know how much longer that's going to work.

There again is this concern that as research becomes very complicated and multidisciplinary and this and that, that needing tools and inputs and reagents and things of that sort could really get to be a problem if everything you need is owned by somebody who really wants to control access to it.

So there was no evidence that this was causing problems in research -- that is, patents -- but there was awareness that it could become a problem. Conjecture. There was concern about these MTAs, which may or may not deal with patents, and there was a lot of committee concern about MTAs being a burden.

So now, after almost a year of deliberation, often extremely tense, with very strong positions that were difficult to bridge, the committee almost miraculously at one meeting decided to agree on some recommendations. None of these came easy. I'll just tell you that. None of these came easy. There were very strong opinions in this committee, as one expected, that the patent law kind of came down to Moses on Mt. Sinai, it's perfect, it's not up to man to tinker with it, and there were other people who thought that the way patent law was applied to genomics and proteomics was troubling. It's sort of like arguing abortion, I guess. You believe in it or you don't believe in it, and it's very hard to convince either side that the other side has any merit.

There was a lot of that kind of almost ideological polarization in this committee, which comes with balancing a committee. You get people on all sides of the issue. So what the committee did agree with was that NIH should continue to encourage the free exchange of research materials and data. It went a little further to say that NIH should monitor the actions of their grantees and contractors with regard to this, and if necessary require, require grantees and contractors to comply with their approved intellectual property and data-sharing plans. When you apply for a grant at NIH now, as part of the application you have to spell out how you are going to share either data or materials that you discover in the course of your research.

NIH really requires things. I mean, sometimes it does, but most of the time it urges things. It gives guidance rather than regulations. So this is actually much stronger language in this recommendation than you might recognize at first reading. The NIH should adopt, adapt and extend the Bermuda Rules, and you know the Bermuda Rules were the basic operating agreement for the human genome sequencing project -- should adapt and extend these rules to structural biology data generated by NIH-funded centers for large-scale structural genomics efforts and so on, and make the data promptly and freely available in a database like the protein database, operated under an NIH grant or contract by the committee member at Rutgers University, which has a huge collection of protein crystal structures that have been freely deposited for anybody to see and make use of. It's almost like the deposition of the

human genome sequencing information every 24 hours. It's that kind of spirit of sharing.

The third recommendation was, again, focused on structural biology. So they wanted the European and Japanese patent holders to establish mechanisms to getting structural biology data from published patent applications into the protein database, and so on, and to the extent feasible all researchers, including those in the private sector, should be encouraged to submit their sequence data to GenBank, the DNA Databank of Japan, or the European Molecular Biology Databank. So again, this is urging the community to behave well.

The fourth recommendation, which is dense on that slide, is really endorsing already published guidances of the NIH. It's lending the Academy's strong endorsement to these already existing NIH documents. The first document, which is about six years old, was from the Becky Eisenberg committee study back at the end of the 1900s, and the more recent one was issued from the Genome Institute which has to do with best practices for the licensing of genomic inventions.

Now, the recommendation then goes on to say that NIH should require, again require, not guide, require, that all award recipients adhere to and comply with these guidance documents. That kind of language has never appeared to date. So even though I realize this committee will have some difficulties with portions of the report, this is very, very strong language if NIH decides to adhere to it -- require adherence, compliance with these sharing documents, and then they urged other non-profit funders and agencies to do similarly.

The fifth recommendation is directed to universities, urging that they retain in any license agreements the authority to disseminate research materials to other research institutions and permit them, the other institutions, to use this patented technology in their non-profit activities. This you would think is ABC, right? The university patents something, which everybody does now. Every intellectual hiccup is patented by everybody looking for the big winner. They ought to retain in their licensing agreements the right to disseminate this material for research. Some universities have not done this, and there are others who have been in the business a long time who routinely do it. So there's a great diversity in the community about that.

This long recommendation basically urges that inter-institutional transfer of research materials use a simple so-called Uniform Biological Material Transfer Agreement, which could be the one-pager that Rebecca Eisenberg's committee crafted in their report. But they urge NIH to adapt such a thing, and they even encourage industry to adopt similar practices. Again, this is urging people to behave well.

Now, this is an important one, and this asks that the patent office should create a regular formal mechanism whereby they can bring leading scientists in relevant emerging fields to the patent office, just like this committee comes periodically, to inform examiners about what's going on in their fields. There really is a concern that the patent office is underfunded and overwhelmed and that the examiners do not recognize what experts in the art know is commonplace, and they regard that as novel and non-obvious and so on and so forth. If the patent office adopted this, there would be a regular advisory committee of top-grade scientists that would meet on a regular schedule to talk about what's happening in their fields.

This is kind of legal jargon, but in general this has to do with this non-obvious standard criterion that I mentioned before is quite weaker in our country than it is in Europe or Japan. It asks that the patent office really think hard about whether a scientist of ordinary skill would have been motivated to make the

invention with a reasonable expectation of success -- this is all patent jargon -- at the time the invention was made. In other words, you may try to patent something, but then the question is would I and others of you who are working in the field regard it as obvious. I mean, yes, so what? Anybody could have done that. This is the only way that the committee was able to agree to get at strengthening the non-obvious obviousness criterion. We can talk about that later if you want to.

It urges PIs and their institutions to be familiar with the heightened utility guidelines that Debra mentioned. They are, in fact, much more stringent than existed before those guidelines came out, and avoid seeking patents on hypothetical proteins, random single-nucleotide polymorphisms and haplotypes and things that have only research as opposed to therapeutic, diagnostic or preventive functions. Again, this was as far as the committee was willing to go in urging institutions to refrain from some of their patent-seeking behavior. But if everybody adhered to this, I think we would be better off than we are right now.

This has to do with the research exemption, which the Madey decision has already weakened considerably. It proposes language for a Congressional action -- that is, a legal amendment to the patent law, which is what would be required here -- to permit without worries about infringement certain kinds of research on but not with patented inventions. Again, you can read these things because you've got this slide in your book, but why is "on" versus "with" so important? Because consider a balance. I mean, there's a circuit court judge downtown I know who loves this analogy. If I own a balance and you have one in your lab, you can take it apart, you can do research on the balance. You can take it apart, you can see how it works, you can try to make a better one. All that stuff is okay, but you can't use it to weigh anything because that's what its intended use is, and I have the right to that use because I own the patent on the balance. So "on," not "with," is central to discussions of the research exemption.

Indeed, there is a document that was handed to me by somebody who either talked to you this morning or sent it in to this committee expressing great unhappiness with this recommendation on behalf of an industry organization, I guess, of small biotechnology and start-up companies. I think that's what the organization is, RUE, or something like that. But in any event, this is a limited research exemption which some people think doesn't really go far enough to do what really needs to be done, but it's the only way to protect the inventors of research tools, because research tools, by definition, are useful in research. I mean, that's what a research tool is. So to allow somebody to use it to do research with it clearly says to the inventor that your research tool has no economic value whatever because anybody who wants to use it is able to use it. They don't have to buy it, they don't have to get permission. So keep in mind the "on" versus "with." It's very important.

So now we get into the meat here. This is simply another direction to NIH to study how universities, government and industry may be engaging in cross-licensing and pooling of patents to enable research to go forward. Number 12 is important. The courts should continue to decline, to prevent and join patent infringement in those extraordinary situations -- there were a lot of hours spent over that one -- extraordinary situations in which the restricted availability of genomic or proteomic inventions threatens the public health or sound medical practice.

This is, from this committee, a major give, whether you think so or not. It is a major give. It gets close to the issue you're concerned about. It doesn't quite get there, but it does say that there are instances where public health needs or sound medical practice would justify infringement. That's what this really says. Much blood was spilled to get this. Of course, extraordinary situations, not just ordinary situations.

Number 13, the last one, has to do with your issue of genomic- or proteomic-based diagnostic tests. The only part of this issue that the committee was able to come to any agreement on was that independent verification of test results ought to be allowed just for sound medical practice. The concern they did resonate to was that a monopoly provider of a test, if there's a monopoly provider of a test, that an individual or a physician or whatever could not get an independent verification if the only place that does the test is the monopoly holder, or the one or two labs that the monopoly holder allows. So this and the preceding were as close to your issue of gene-based diagnostic testing as we could get.

That's the end of my formal report, which is my committee obligation. I am now David Korn. I am just talking about my own personal opinions, okay? I want to be really clear about that.

We struggled very, very hard to get this committee to understand the issues that are exemplified by BRCA. In fact, Debra came to a committee meeting on a cold, miserable day in Princeton, as I remember, and gave a very strong presentation that simply did not move the committee at all. So for people like Bob Waterston and me and Rochelle Dreyfuss, who did come to understand this problem, not at the beginning but as the committee went on really did come to understand this problem very well, tried very hard to push for something that would have been a little bit stronger than this, but the way the committee was constituted, we couldn't. So that is why the recommendations are what they are. I just will remind you that I think some of them that deal with what NIH should require are very strong, and if NIH really exercised its ability to require on these things, it would help a lot to allow research to go on.

On the public health side of the issue, I think probably the committee's best efforts fall short of what many would have liked to see, but that's the way it is.

Now I am finished and I would be happy to do as the chair wishes.

DR. LEONARD: Thank you, David.

What I'd like to do is anyone with questions for David regarding the NAS report, please feel free to ask questions now, and then I have another presentation that basically walks through what the task force did in reviewing the report and what our recommendations are, and then time for discussion of next steps that SACGHS would like to take.

So if there are any questions for David.

DR. TUCKSON: David, two questions. One, the relationship between the international granting of a patent and the United States granting of a patent, regardless of the process and the criteria being different, does any one trump the other? Is there any relationship? If you get a patent in the United States or a patent in Japan, does it matter?

DR. KORN: I think the answer to that is that generally the international community will respect a patent from Japan, Europe or the United States as valid. However, as you well know, in Western Europe at least, there has been strong pushback on some of the BRCA patents for various reasons, and at least to some extent the action in Western Europe has been articulated as public health access cost stuff. It hasn't really gotten into the fine points of patent law. It's simply been that this is not in the best interest of the health of the citizens of our country. The actions of the European Patent Commission, however, have been, in fact, very technical in terms of their actions against some of the BRCA patents. They have not

been based on public health at all. They've been based on things that are normal parts of patent litigation.

So the advocacy is public health-based, access or whatever. The action of the patent authority in Western Europe has been very limited to the technicalities of patent law.

DR. TUCKSON: Okay, because it would seem that with the globalization of everything today, it would seem to be a very important reality.

Secondly, and I think the answer must be no, but since it wasn't talked about at all, was there any look at the relationship between granting of patents and any escalation in health care costs and the expense of health care products?

DR. KORN: No, there wasn't.

DR. LEONARD: Reed, I think Emily has information on your first question.

DR. WINN-DEEN: I just wanted to say something in terms of someone who manufactures a test kit for sale. If there is a U.S. patent and you make, use, or sell something related to that patent in the United States, it covers you worldwide. So I can't make a product to sell in Europe or Japan or Timbuktu in the U.S. if there's a U.S. patent that covers it. So it does have, in some cases, a global effect, particularly when you get into the concept of making test kits rather than providing test results.

DR. TUCKSON: Very quickly, if somebody has a patent in Japan for something, can you sell a product in the United States that is patented in Japan?

DR. WINN-DEEN: If I don't make it in Japan, as long as I completely stay out of Japan, I'm okay. But if I either make, use, or sell anything in that country, it's covered by that country's patent.

DR. TUCKSON: And is this another example where the United States -- I mean, do other countries play the same game, or are we basically, as sometimes we might do, say we're going to do it the way we're going to do it?

DR. WINN-DEEN: Well, I think what we're doing is we're sort of shooting our own industry in the foot because we have a more broad interpretation, and so where in the U.S. a gene patent might issue, which means that, say, any U.S. company except the patent holder can't make a test for that, a company in Europe based in wherever can go right ahead and make a test kit, sell it anywhere in the world except the U.S. So we do, from a commerce point of view, hurt ourselves by having this differential with Europe and Japan.

DR. LEONARD: I would like to ask David a question. It was my understanding that when NIH gave the charge to NAS, the clinical aspects were included in the request, if you will, but then when the charge went to the committee, you clearly stated that the emphasis was on the research and innovation impact and not on clinical practice. So does the paucity of recommendations related to that, are they related to the charge that the committee was given or the inability to reach consensus? Because within the report there's a list of six bullets that basically identify clinical areas where there are concerns that the committee had, but could they not reach consensus on how to address those or was that not their charge, and so they didn't make specific recommendations?

DR. KORN: Debra, you know, I don't remember. I must confess, I just don't remember the exact charge that was delivered to us. But what I have is what the committee staff gave me for your slide on the charge, and it doesn't mention clinical or public health issues. So if this is accurate, then this is what it was.

Getting the six bullets into the final report also consumed a fair amount of energy. I just have to say it didn't flow naturally. It was kind of forced in there because some of us just felt strongly that the report had to acknowledge those issues, and in the end we were able to let it stay.

DR. LEONARD: The six bullets we're discussing on page 148 of your book. I think they're also at the beginning as well. But these were the issues that were identified by this committee as being clinical impact issues.

DR. KORN: Right.

DR. LEONARD: And we'll get to this also later on.

DR. KORN: But the recommendations were as far as the committee could go to achieve consensus, and that's what they are.

Can I just make one other point? There have been a number of recent legal cases that you all might want to be aware of that are kind of related to this topic. One of them was a case in the circuit court last year that upheld the utility criteria of the patent office. So the criteria were published in about 2000 or 2001, and it took this long for a case to be litigated challenging those criteria, and in the one case that has been adjudicated to date, the court upheld the patent office's criteria.

There was another case decided by the Supreme Court this year called Integra that strongly reinforced the validity of a research exemption for work that is leading toward an FDA application, something that's going to go to the FDA, and that was highly contested by the other side that wanted that research exemption also narrowed down the way the common exemption was.

There is a case before the court right now that's very clinical that involves a claim to owning a thought process. In just 30 seconds, it involves the use of a method to measure blood homocysteine, which has correlates with a bunch of things, and the patent says that if a physician receives the results of this test and thinks that they may suggest a Vitamin B deficiency, that that thought is a violation of their patent. So we ain't seen nothing yet in terms of that part of the law. That case is called Metabolite, and you can follow it on the Supreme Court docket.

DR. LEONARD: I'll have information about that also in my presentation.

Any other questions?

DR. LICINIO: I have a comment, which is that I hear this from both sides and get a little confused. So on the one hand you hear the explanation that someone may be a postdoctoral fellow or junior faculty struggling, has no resources, and wants to investigate something important, and the person can't because of the obstruction of all these patents, and that the research exception should really be there. On the other hand, when you hear from the companies, they say we are a small little company. Harvard

University is not an ivory tower anymore. It's a corporation. It has $26 billion in endowments and makes more money than we will ever dream of making. So why don't they have to pay us for what we invented? So you hear one side, you hear the other. Who is really struggling? Is it the small biotech company versus the rich university, or the other way around?

DR. KORN: That's a fair question. The problem with the research tools is that, unlike a company, a large research university will often have thousands of faculty, each pursuing his or her own research direction, and often the need for a reagent or a tool sometimes is premeditated. That is, you know that if you're going to do something, you'll need something, and I suppose you could argue that one could make the arrangements necessary to get it. But often the need for something arises very spontaneously during the course of the research, or you hear something at a seminar or a meeting and you come back to the lab and you say, gee, let's try that because it might be the breakthrough we're looking for on this problem, and there's a kind of a spontaneity and a non-planned quality to a lot of basic research that would be exceedingly difficult to put into patent clearance process.

A company has a centrally managed research plan. So they know up front what they're going to be doing, and if they want to check on patents, they have plenty of time and a lot of lawyers and they can do it, but for faculty members to have to worry every time they get a bright idea that somebody might own this antibody or this animal or whatever, this enzyme, it would be exceedingly stultifying of research progress, I think.

That doesn't mean that people who invent and market and research tools are not entitled to make money from them. I'm not arguing that at all. But somehow there needs to be a mechanism. For example, NIH in past years has negotiated on behalf of NIH and its awardees with the makers of important research tools a license agreement that is negotiated in what NIH regards as fair, and that agreement supposedly covers all the awardees. So, for example, the oncomouse supposedly is covered by such an agreement. There's a genetic recombination method, the CRE/lox mechanism, where again NIH said, look, this is really screwing up research for us and our awardees. We've got to make a deal with the owner, Dupont in one case, and they did. They negotiated on behalf of the research community.

So these things are perfectly good ways of making sure the owner gets money and the research is not screwed up.

MS. MASNY: Dr. Korn, I just wanted to ask to whom is this report given, and do you foresee any actions on the recommendations that you have listed in the report? Lastly, is there anything that this committee could do to take up any actions based on your recommendations?

DR. LEONARD: I'll intervene, if you will. At this point maybe, Francis, you want to make a comment in that there has been a committee formed to respond, take action on, decide what to do with this report. So, Francis, do you want to update the committee on that?

DR. COLLINS: Sure. Thanks. We appreciate very much the hard work that went into this report and the leadership of Dr. Tilghman as the chair and the dedicated service of all the people who participated in what was clearly a very challenging set of questions with no easy answers. While I'm sure various people will come down in different places about, gee, I wish you'd been a little more aggressive here or a little less aggressive there, I think the committee took their charge very seriously and put a lot of hard work and time and effort into it.

The report now does come back primarily to NIH as the sponsors of the initiative, and Dr. Zerhouni has reviewed this report with great interest, certainly welcomed I think a number of the recommendations, and realized that some of them have implications, if something is actually going to happen, for what NIH needs to do as far as their own policy decisions. So there is a committee that Dr. Zerhouni has formed to review these recommendations, all 13 of them, and to develop a response to bring back to him in order for him to decide exactly what steps to take in order to make sure these recommendations actually lead somewhere.

I am probably not in a great position to precisely say what the timetable of that review committee will be, but I can tell you that they are certainly vigorously looking at this, have been at it already for some time. So I think NIH is taking this with great seriousness. We see this as a potentially very important issue. There continue to be issues surrounding patents and licenses that are popping up all over the place. In fact, maybe, Debra, with your permission, right after the lunch break, I'd like maybe five minutes to tell this committee about a specific example that relates to the GAIN and GEI initiatives, because I would really be appreciative of your reaction to a strategy we've decided to take in those instances to try to make sure as much of the information as possible stays in the public domain, and it's a strategy that I think is fairly unprecedented. So we'd be interested in your response, if you'd have a few minutes for me to say something about that. But I don't want to do that right now. Thank you.

DR. LEONARD: Given the time, I think we'll move on to the task force's recommendations and what they did, and then break for lunch, leave you pending, and then come back from lunch to discuss what our next steps should be, what the task force recommendations are, discuss those, and what next steps would be.

DR. TUCKSON: Debra, can I just say one thing while you do that? Is there any presumed timetable for this NIH review of the 13 recommendations?

DR. COLLINS: I was warned not to get boxed into a corner on this, so I will try not to give a really precise answer. I think I can assure you there is great energy and hard work going into this, but it's not one of those things where you can just necessarily pinpoint exactly what steps are necessary to get to the closure. So as soon as we can.

DR. TUCKSON: Debra, obviously, I was just trying to see what the timeline was for that effort, and as you guide us through your analysis what, if any, relationship, sequential versus concentric paths, that activity at NIH is having and what that means for us, which things are sequential and which things happen at the same time.

DR. LEONARD: Right.

DR. TUCKSON: Does that make any sense?

DR. LEONARD: Maybe.

(Laughter.)

DR. TUCKSON: I await your guidance.

DR. LEONARD: So the task force did look at the NAS report, and at this point I want to make a disclaimer in that I am chair of this, and when Reed asked me to chair this I immediately asked him is that like the fox guarding the henhouse? Because I do have very strong opinions about gene patents and the impact that those are having, and I think everyone in this room probably knows that. I am trying to be measured and take a balanced viewpoint, and thus when this task force was being formed I specifically asked Emily, who has an industry perspective, to be on this as well, and Jim Evans volunteered, and I'm grateful for their working on this project together. My disclaimer is that when I was at the University of Pennsylvania I was stopped from doing a number of tests because of gene patent enforcement. I'm no longer at the University of Pennsylvania. I'm vice chair at Cornell, so a little more removed from the actual enforcements.

So our charge was first to review the NAS report and assess whether issues and questions raised by SACGHS were addressed in the report and then determine whether there are areas that warrant further exploration and/or attention by SACGHS. So as background, Sarah and staff, as they are wont to do, brought to our attention that the gene patenting and licensing issue was also raised by SACGT, and there's a quote from SACGT that "Gene patenting and licensing practices may be having adverse effects on accessibility to and the cost and quality of genetic tests," and that was from a November 17, 2000 meeting.

So SACGT sent recommendations to HHS, and in that recommendation they raised concerns and questions about possible adverse effects on access and that this should be assessed more fully by HHS, and that this may warrant further study by appropriate experts, and they urged HHS to initiate this further study. So the response that SACGT got back from HHS is that they agreed that patents raised important issues that need further exploration. The NHGRI ELSI program was initiating a study to gather further data on DNA-based patents, and the NIH Office of Technology Transfer planned to work with HHS to determine whether further steps needed to be taken. As you are well aware, SACGT was reformulated as us, SACGHS.

In the meantime, there has been NHGRI-funded research on gene patents. There's a Pressman article that was just published in January 2006 that focused on DNA-based patents and licensing practices at research institutions. So again, this article focuses, like the NAS report, very much on the research impact of patents. There are other studies of DNA-based patents that are more related to the clinical aspects or impacts of these gene patents. So one of the things that the committee may want to consider is that there is additional research out there since SACGT has looked at this issue that SACGHS may want to look at and investigate and see what this has to do with health care.

So the first part of the charge was to review the NAS report and assess whether the issues and questions raised by SACGHS are addressed by the NAS report. Basically, the task force is generally supportive of the first 12 NAS recommendations that relate to research issues and focus on ensuring that the public investment in genomics and proteomics is optimally benefiting society. If I can paraphrase the task force's discussions, basically we felt that the NAS committee had very thoroughly investigated the research issues, research and innovation issues, and felt that they had done a very good job of coming to recommendations that really addressed many of the issues, and I think the task force at this point felt like NIH needed a chance to look at those recommendations, respond, and not really interrupt this process.

So recommendations 1 through 11 basically address the concerns related to research, as David outlined for us. Recommendation 12 addresses extraordinary circumstances where the public health is

threatened and suggests remedies through the courts.

Recommendation 13 is the only recommendation that relates specifically to clinical practice if you say that 12 is related to public health. We spent a lot of time discussing this recommendation and basically felt that it was untenable as written because if you look at laboratory practice, what this recommendation states is that there should be other laboratories that can validate the test results of a sole provider of a laboratory test. Those other laboratories will not go through the hardship, expense, work of validating a CLIA-certified test that could be used to check the results of a sole provider laboratory when a second opinion is requested. So basically, we felt like this was nice in theory, but when you get down to the implementation of this, it's untenable that laboratories would set themselves up just to give second opinions or to validate results of a sole provider laboratory.

So in reviewing the NAS report, basically none of the recommendations address questions related to the economic impact questions or issues that the SACGHS had raised in its priority-setting process. So research issues we felt were thoroughly investigated, and the recommendations address most of the research concerns that SACGHS had raised. The clinical practice and economic impact issues of concern to SACGHS were not addressed by the NAS recommendations.

So this is where I was supposed to turn to Francis Collins and he was to tell you that they formed a committee. So since we've done that, I think we will want to also follow up with NIH on what they are doing with this.

So what do we recommend based on this initial analysis? We recommend to the full committee that we convey in a letter to the Secretary of HHS support for the first 12 NAS recommendations, emphasizing those recommendations over which the Secretary has authority to have some effect, specifically Recommendations 1, 2, 3, 4 and 11. In particular, the task force felt that it was important to emphasize or encourage the need to implement Recommendation 4, which is the requirement, this emphasis that David stated of enforcing and monitoring that funded investigators share published materials. And consider recommending that the Secretary use HHS' resources to educate researchers and clinicians on their rights and responsibilities with regard to intellectual property, especially on the lack of a true research exemption as evidence by the Madey case for use of patented information and materials.

I don't know. At this point we're not going to stop and have discussion about this, but we'll go back to these three recommendations as the initial discussion after lunch. So be thinking about these three recommendations, whether you want to tweak them, change them, throw them out, support them, whatever.

Then the second part of the charge to the task force was to determine whether there are areas that warrant further exploration and/or attention by this committee. The task force basically made three official recommendations, that SACGHS may want to consider exploring issues related to licensing of genomic inventions and its impact on clinical practice, the economic impact of patenting and licensing of genomic inventions, and even get into the issue of the patent thicket or patent pooling, and there's current legislation regarding this that this committee may want to follow that was mentioned in the NAS report.

I want to bring to your attention on page 148 of the NAS report that in this NAS committee's work, they did identify concerns related to clinical practice, and some of these overlap with the concerns that SACGHS had raised, specifically whether or not patents and licensing practices are affecting patient

access to genetic and genomic technologies; whether the current patent system allows competition in doing a better test in a better way of identifying genetic mutations that are either more accurate, more cost effective, shorter turn-around time, whatever; IRB-approved clinical research in academic medical centers regardless of funding sources.

I think, and maybe, David, you can comment, that this implies that when you do clinical testing, you also are making new discoveries, particularly in the area of genetics and genomics. There may be additional mutations identified, and can this be inhibited? Professional education and training could be inhibited, independent validation of test results, which is the one that Recommendation 13 tries to address, and then regulatory compliance issues.

So the goals for the discussion after lunch are to discuss and come to consensus on whether to forward a letter to the Secretary related to the NAS report, and whether to include the task force recommendations basically supporting the first 12 recommendations, highlighting Recommendation 4, and suggesting educational efforts for researchers and clinicians on intellectual property issues. Then secondly the discussion would turn to determining also whether the SACGHS research questions are sufficiently addressed by the NAS report.

Then given that the NAS report -- we may want to reach agreement that the NAS report doesn't address SACGHS' concerns related to clinical practice and economic impacts. So we can decide whether everyone agrees with that statement. But if so, should SACGHS move this issue from monitoring, where it currently is on our list, to a working issue that SACGHS now wants to do work on, and to facilitate the answering of this question, in doing the work of the task force we basically came up with proposed ways to move forward if the full committee would decide that this was something they wanted to do.

One was to follow the progress of the NIH committee in looking at what they will do with this report and the recommendations; to review data from the research supported by ELSI programs as a result of SACGT concerns, basically looking at the published research that may address some of the either research concerns or clinical practice concerns raised by patents and licensing practices. Since NAS did identify areas of concern, we could potentially hear from the same people that NAS heard from to understand where the concerns came from on the clinical practice issues.

We could also explore the experiences and patent policies of other countries and see if those can enlighten the committee on how to address concerns. Then also, finally, monitor the outcome of the Supreme Court patent case that David was mentioning. Basically, this Supreme Court case is LabCorp v. Metabolite Laboratories, and the question before the court is can a monopoly be validly claimed over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result? This does not directly bear on the gene patent issue, but some of the gene patents basically are claiming a mutation/disease relationship, and so there may be a relationship of the outcome of this court decision to the gene patent discussion, and we could follow that and see if it does.

So at this point, unless there are specific questions about our path forward, I think that we'll break for lunch on time and then start the discussion after lunch.

DR. TUCKSON: Dr. Korn has one comment.

DR. KORN: I appreciated listening to Debra's recount of the committee's task force. The only concern I would raise is on the third recommendation, I think, to the Secretary about reminding awardees of the current lack of a robust research exemption. Sometimes it's better to let sleeping dogs lie. I'm not sure that getting the Secretary involved in this issue would be very helpful to the research enterprise. But that's a personal opinion only.

DR. LEONARD: Well, David, I hope that you will remain at the table. I hope you can stay for the discussions after lunch. I don't know if you can.

DR. KORN: I can stay for a while, yes.

DR. TUCKSON: It's a free lunch, David.

(Laughter.)

DR. KORN: There is no free lunch in this building.

(Laughter.)

DR. TUCKSON: I'll pay for it for you.

DR. LEONARD: So if you are available to remain here for the discussions, at least a portion of them, then you can feel free to chime in on our discussions of the recommendations from the task force.

DR. TUCKSON: By the way, we are breaking for lunch on time, for which I am assuming credit.

(Laughter.)

DR. LEONARD: So noted.

DR. TUCKSON: Return at exactly what it says on the program.

(Whereupon, at 12:30 p.m., the meeting was recessed for lunch, to reconvene at 1:15 p.m.)

AFTERNOON SESSION (1:18 p.m.)

DR. TUCKSON: We are officially resumed and back in session, and we turn the gavel back over to Debra.

DR. LEONARD: So, Francis, do you want to give us the update on the Genetic Association Information Network IP policy?

DR. COLLINS: Yes, thanks, and I won't take very long, but I thought this would be something of interest to your task force and to the SACGHS as a whole because it's directly relevant to this

discussion about intellectual property policies.

I think everybody is aware that GAIN is this public/private partnership which was announced on February 8, which is an effort to provide resources to enable whole genome association studies of common diseases. This is a partnership between NIH, the Foundation for NIH, Pfizer, Affymetrix, and we hope additional funding from other private sector contributors as well. Basically, investigators can come forward, and they are being invited to do so right now with a deadline of May 9, if they have 1,000 or thereabouts cases and controls of a common disorder. They can come forward with a fairly simple application indicating their desire to have this kind of genotyping carried out. It will go through a peer review process. The genotypes will be determined, and then all of the data, genotypes and phenotypes, but in a de-identified fashion so there are no personal identifiers left, go into a database that NCBI is constructing. That database will be accessible to anybody who signs a user certification agreement which agrees to various things such as not making an effort to identify the individual participants in the original research study. That means the principal investigators and the rest of the world get access to the genotype and phenotype data at the same moment.

Now, obviously, there is a big question here about how will intellectual property be handled. Just to remind you, a whole genome association study means that you are going to see something like 300,000 or 400,000 single nucleotide polymorphisms genotyped for each of these DNA samples. They are basically serving as proxies for the variation in the entire genome based on what HapMap has told us about how genetic variation is organized into neighborhoods, which is to say you don't have to sample every SNP in the neighborhood to know that you found an interesting neighborhood.

So the initial findings of this kind of study are likely to be, if all goes well, associations where you see a particular SNP is associated with disease at some statistical P value that's pretty convincing. But that SNP itself is probably not the causative variant that is responsible for the risk. It's basically a proxy for others in the neighborhood, and a good deal of follow-up work will be necessary to figure that out.

Based on many conversations in both academia and in the private sector, I think it really has been interesting to see just how much consensus has now developed around this. The strong sense is that this is the kind of data that ought to be considered pre-competitive, ought not to be the subject of intellectual property claims, ought to basically be placed in the public domain. Follow-on discoveries that will be in many steps down the line will ultimately lead, we hope, to diagnostics and therapeutics, some of which might very well have appropriate intellectual property value. But this early stage we don't think should fit that description. Again, "we" in this case is a fairly broad group of interested parties who have weighed in on this.

Notice, however, that this does tread into territory which is a bit closer to what things in the past have been claimed as far as patenting, because if you have found a SNP that is associated with the risk of diabetes, with a P value of 10 to the minus 12, then somebody might decide right then and there that that could be a useful diagnostic. Even if it's not the causative SNP, it still carries that statistical kind of association. Weighing the pros and cons of that kind of patenting versus putting this in the public domain, the strong conclusion of this group has been that this ought to be something that is just put out there.

So what you have in front of you, this one-page document, was arrived at over the course of

about nine months by a distinguished group, the steering committee for the GAIN project, which consists of three NIH institute directors, myself, Betsy Nabel and Tom Insel, a variety of distinguished extramural scientists, including people like Eric Lander and Mike Brown -- not the FEMA Mike Brown, the other Mike Brown.

(Laughter.)

DR. COLLINS: And the conclusion was that this is really the kind of policy that we ought to try to inspire.

Now, notice that in this circumstance, the people whose behavior you are trying to in some way influence are the users. The users need not be NIH grantees. Many of them won't be. They may be from the public sector, the private sector, they may be international. All they have to do to become a user is to check a few boxes in this certification agreement, but one of the boxes will be about intellectual property.

Because they are not grantees, we don't really have legal authority over them. We could not, for instance, decide that we're going to do a declaration of exceptional circumstances and legally enforce a no-patent policy. But what we can do is exhort them. So what you see in this document is what you would call very strong hortatory language about what is expected of users of this database and language that they will have to certify that they acknowledge in order to look at this information.

So what this basically says is if you are using this data, you are basically accepting it as a gift here, and that it is best left unencumbered by intellectual property claims. If you go to the third paragraph, the first sentence gives some examples of the kinds of things that we expect this data ought to be available for without requirement for licensing. So it includes such things as use of markers in developing assays and diagnostic tools, utilizing single or multiple technical platforms, the use of combinations or markers in multiplex assays, and the use of markers as guides toward identification of new drug targets, all of which we think ought to be applications that are pre-competitive. So this also references the NIH's best practices and research tools policy.

The other thing that we are doing with this study, which I thought you'd be interested in, is to also, as sort of the suspenders -- I just told you about the belt. So the suspenders is that the associations that come out of this genotype and phenotype data will be pre-computed. They will appear in the database at the same time the data does so that nobody will be able to say, well, I did the chi-square and I found that this SNP has a P value of 10 to the minus 9. That will already be apparent as soon as the database goes live. We will also identify what genes are nearby that associated SNP so nobody can say, well, I figured out that it's gene 229, because it will already be identified as in the neighborhood. We might even, if we can do so in an automated fashion, suggest which genes in the neighborhood might make reasonable candidates based on their known function and the disease that's currently showing the association. So doing everything possible to try to render as prior art in the public domain the sort of obvious first steps. Meanwhile, of course, not trying to say very much or inhibit anything about what follows after this downstream.

Another thing that has been recommended to us by the intellectual property experts who have weighed in on this -- and again, we've had conference calls with people who are patent experts in the private sector as well as here at NIH and in academia -- is that it would be helpful to have some public statements by distinguished scientific experts about the importance of keeping this kind of information in

the public domain and not having it claimed. So there is some interest in having publications of that sort put together and published in visible places.

I guess just to finish this little description, if SACGHS, for instance, were to agree that this is the kind of data which, to benefit science and public health, is best kept in the public domain, your comments in that regard might also have some potential influence on the PTO who, when faced with circumstances of this sort, are always sort of looking around to see what do the experts say, should we consider this as something that ought to be patented or not.

DR. LEONARD: So can I ask -- no. Go ahead, Reed.

DR. TUCKSON: Just a quick question. So in addition to its being high-minded and idealistic, is it, in the opinion of the lawyers, scoundrel-proof?

DR. COLLINS: Nothing is scoundrel-proof, especially not in Washington. So you can't be assured of that, and there is no legal enforceability to these particular statements. One would expect, though, that someone who is an obvious violator of this, and that will come to be apparent, might in the next application to NIH be seen in a slightly different light.

DR. TUCKSON: And there's no way, obviously, otherwise you would have done it, for information like this -- the government doesn't have any special opportunity to use its extraordinary influence and clout to say that if you are using -- because this information was developed in significant part by the public taxpayers, there would be the clear enforceable expectation that you are not to gain privately for its use.

DR. COLLINS: If we were to say that, we would be violating the Bayh-Dole Act, although I think that the flavor of what's here very much tries to make that case.

DR. LEONARD: How do you account for existing patents on genes already in this system?

DR. COLLINS: There's not a lot that we can do with this document or this project about patents that have already been issued or others that are about to issue. But the hope would be that this general philosophy, that the discovery of an association with a disease is itself not a discovery that the public benefits from if it is immediately claimed as patented material, might have some influence on what the PTO does in the future. We're powerless to change what's already happened.

DR. LEONARD: I know, but will you have asterisks next to the genes that you name that are the ones that are already patented so people know that they are walking right into a patent thicket if they're going to investigate that P equals 10 to the minus 12 relationship?

DR. COLLINS: Well, I hadn't thought of that asterisk, and you could say that would be sort of up to the person who is going to be doing the next step. I suppose we could do that. I think that's going to happen fairly uncommonly. I mean, again, most of the genes we expect to find here are not going to be ones that people know about. This is for common disease. This is diabetes, heart disease, cancer, schizophrenia. How many genes do you think we really know about that are associated with those common illnesses? I would say maybe 10.

DR. LEONARD: What percentage of the human genome is already patented?

DR. COLLINS: Oh, but not for this application. So if you have a gene that's been patented as a composition of matter because somebody filed an EST on it somewhere down the road, would that in fact prevent somebody from working with that gene for this purpose? If this new data is in the public domain, they are no more or less inhibited than they were before. You could argue they're somewhat less inhibited because the utility of the gene -- that is, its association with the disease -- was not in that original patent and is now publicly accessible. You have to go beyond my level of expertise to be quite sure what the answer to that is, though.

DR. LEONARD: Emily?

DR. WINN-DEEN: So I guess I'm trying to understand if what you're actually asking is to try and move the -- the patent office has already moved back a little bit from we'll just patent something if it's an EST to we'll patent something if it's a gene that's well described to we'll patent something if it's a gene or a polymorphism with some clear utility, as in diagnosis of risk for Disease X. Are you actually hoping that you'll move them back off of that utility claim to a SNP associated with Disease X not being something patentable? And if so, where would you want to move them back to? At what point, then, do you view something -- a test for that? Is that patentable? A drug directed at people carrying that? Where would you sort of like to see that move in the patent office?

DR. COLLINS: I think that's well put. I think NIH has, by a series of guidelines, been attempting to make the case that public benefit, which is our standard for whether something should be patented or not, has not necessarily been well served by claims on genetic variants that are associated with some disease risk, which then lead to exclusive licensed patents on diagnostics. So yes, we are attempting, I think, in a fairly straightforward way here, to move the boundary again a little further, or move the threshold a little higher.

Part of the argument -- again, let's not pass it by too quickly -- is that what you discover in this first pass of a whole genome association will rarely be the thing that is functionally relevant, and in many instances it may not even hold up because, of course, the replication study, if it wasn't a P value of 10 to the minus 12, but maybe it was just 10 to the minus 6, may turn out not to be true, and better not to have the whole place littered up with claims that turn out to be subsequently invalidated.

So again, I think the effort here, with a specific study in mind, is to try to say this sort of stage 1 whole genome pass-through on a number of diseases is going to generate data which is far enough away from public benefit in the way of a product that it ought to be kept in the public domain if that's at all possible. And yes, I think when it comes to diagnostics, the philosophy that this group has very much felt and which is somewhat reflected in this document is that the intellectual property is in the platform. It's not necessarily in the discovery of the association, and if we're ever going to get to the point where multiplex analysis of lots and lots of genetic variants that are associated with prediction of future disease risk is feasible, you don't want those all tangled up in some thicket of patents that are owned by multiple different individuals, and this is a specific attempt to try to avoid that outcome.

DR. LEONARD: You also end up saving the cost of having every individual investigator do this study which is not cheap to do, a HapMap analysis of all the 300,000 SNPs on a thousand patients and controls -- it's very costly.

DR. COLLINS: And so are the patents. That's another point that I should have made. The other argument to try to discourage this kind of intellectual property claim is that it will be pretty hard to actually have anybody gain much from it, because if you found that SNP in this database and you claim its association, what's to prevent somebody else to claiming another SNP that's right next door that's also associated, because it probably will be? Until you've gotten to the point where you can say, well, that SNP is functionally the cause, which is quite a bit of additional work, are you really going to be able to have broad enough claims to justify the cost of all these patents that all these people will be filing, or is it better to just say let's wait until we get a little further down the road here and really know what we're talking about?

DR. LICINIO: If someone goes to the next step and they just get that finding in one of the adjacent genes that you put there, like in the public domain, and they find a specific variant, that then is part of the (inaudible)? I'm just asking. So let's say there is a haplotype-tagging SNP that's identified with a P of 10 to the minus 12, and you put that adjacent to these, in the vicinity of this particular SNP, there are these genes, A, B, C, that you can either say are relevant to the disease, but you just say what the genes are and the person can put two and two together, and then you go in your own samples and you re-sequence those genes and you find a specific mutation that could be attributable to the disease, is that discovery then patentable? I'm just asking.

DR. COLLINS: I think by PTO's current standards, it probably would be, though raising the question about whether in the long term for public benefit, that's a good thing or not. Now, don't get me wrong. I'm not so naive to think that we're going to have a strong influence on the PTO's decisionmaking about where to set the bar for utility standards. I do think it's useful for the scientific community to say things in this regard. The real reason to bring this forward to you is that what GAIN is trying to do here is to recognize that if the PTO standards stay pretty much the same as they currently are, what steps could we take to try to make sure we don't end up with that thicket of claims on the associations that are going to be coming out of this study and other studies like it in the next two or three years? How can we try to make sure that that information remains as much as possible in the public domain? This is not a foolproof method, as Reed asked the question. It can certainly be got around by scoundrels and legalities. But again, I think this is a way of NIH and FNIH, and Pfizer, who strongly supported this effort, basically putting down the philosophy of why this project is being done and what we hope the outcome will be.

DR. LICINIO: And just going one step further, if you put in the NIH site that people would have access to, if you put the haplotype-tagging SNP and say this variation or a variation in the following genes, and then you put the genes there that could be related to the disease, could someone make a claim if they actually find the specific variation, if you make the site even more explicit and say it's highly probable that a variation in one of these genes here would be associated with a disease?

DR. COLLINS: I think that would depend on the breadth of the claims of the original patent application and the degree to which the patent office allowed those whether then, when you got to the point of having the specific variant, that would be considered an infringement and whether you would have to cross-license or not.

DR. LEONARD: David?

DR. KORN: I think this is a very exciting step forward, and I was just curious. I mean, it may not be proper to answer this in public, but I'm going to ask it anyway. Were other, let's say, large

pharmaceutical companies or large biotech companies invited to the party and to date declined to play?

DR. COLLINS: In this public/private partnership?

DR. KORN: Yes.

DR. COLLINS: They're in the process of being invited right now, actually. So that's underway through the auspices of the Foundation for NIH, who are empowered to do that sort of thing, whereas NIH, as you could imagine, is somewhat inhibited in raising such conversations when money is involved.

DR. LEONARD: Francis, thanks very much. This is very exciting, a step in the right direction.

Reed, should we have a discussion as to whether we want to take action in supporting this, or if the committee feels this is a good thing?

DR. TUCKSON: Always concerned about things that have deadlines, and I don't know what the timing is again. As I ask for that, what's the timing again?

DR. COLLINS: I don't think this one is under any great pressure. This is already issued. This information is on the website that you see there.

DR. TUCKSON: First of all, let the record state that this is the first time that Francis has ever brought anything to our attention that does not have a deadline of tomorrow, which is nice.

(Laughter.)

DR. TUCKSON: I would suggest that the committee put this into its deliberative package and then report back out a package of things that work together.

DR. LEONARD: Great.

So I have rearranged the order of the discussion a slight bit, and you can see that the first question to be deliberated by the committee is whether or not you feel that the NAS report addresses the research questions that we had. If so, good. If not, what's missing? Then we'll move on to discussing the second point.

Jim?

DR. EVANS: I think the answer to the first question is no. I think the NAS report is great, but I do think, as you pointed out, there's a paucity of consideration of the clinical implications.

DR. LEONARD: Right, but at this point let's talk about whether it addresses the research questions, and I think that's mostly what the letter that we're recommending to the Secretary addresses, the NAS report itself and the research questions.

So are there other issues? As I stated before, the task force felt that the NAS committee had done a very thorough job of investigating the different options, the types of recommendations that could be

made, the research impact, not only for genetics and genomics but also proteomics, and the task force felt that we couldn't add a whole lot more to the work that had already been done.

Do we just go for a vote since there doesn't seem to be much discussion? I mean, is there consensus that the NAS report is addressing most of the research questions raised? Yes, I'm seeing shaking heads. Okay.

So then given that, and given that the NAS report really did focus predominantly on research, do we want to send a letter to the Secretary making some statements about this NAS report?

Emily?

DR. WINN-DEEN: I think if we send some kind of letter it's going to have to be sort of yes, but. So it addresses some things, but here are all the things that we're still concerned about. I think it would be better for us to wait on what letter to send the Secretary until we've discussed all the other stuff as well, and then come back to that.

DR. LEONARD: Okay.

DR. EVANS: I agree with that. I think that we should talk about the other issues and send a two-part letter at one time, instead of sending two halves.

DR. LEONARD: Great. Can you advance the slide one? So the task force reached the conclusion that there were areas that were not addressed in the NAS report. Can everybody shake heads if you agree? Okay. So the question is should we move this gene patents and access or DNA-based patents and access issue from a monitoring standpoint, which is we had this as an issue that was high priority for the committee but we basically left it as monitoring until the NAS report was issued. Do we now want to move it from a monitoring to a working issue?

DR. TUCKSON: If I understand the thesis of the question, it is that given that we think that the NAS report did what it should do and that it has its own cycle of activity, if we were happy with just that agenda, we would monitor. I think what you're asking is given that there is an additional part that was not covered by them, basically the clinical and the economic access, do we then feel, I think is your question, that that's important enough that we want to tackle that on our own?

DR. LEONARD: Right.

DR. TUCKSON: Got it. Now I understand the question.

DR. LEONARD: Can you go one more slide forward? We have identified a number of steps that this committee could take. So it's not like it's sort of theoretical. We have some fairly concrete things that over the next meetings this committee could do, and just so everybody is on the same page, that's following the NIH committee's follow-up to the NAS report, looking at whatever research data has been generated since SACGT basically raised this same question, because there has been research, and we could have those investigators come as panelists, do descriptions of the work. The NAS committee in its own work did identify areas of concern related to clinical practice. So we could either go on their website or talk to them, find out who they spoke with and have those people come and talk with us in the same

way. We could also look at the other ways that patents are handled in relationship to clinical practice and economic issues in Europe and in Canada and Japan since even David said that these countries do have a different system for handling these, and then whether we follow the Supreme Court case or not, it's going to happen.

DR. TUCKSON: As one member of the committee, and I'm going to be listening carefully to my colleagues, I think for me on this, first of all, I'm very happy that we have this whole other area being addressed and that it's got its own train, and we'll monitor.

Where I'm concerned is as we think about the protection of the public. Can we find out the answer to the question does the issue of patenting increase the cost of these technologies, thereby decreasing access to care for people. I keep getting stuck on the notion that as it is, health care costs continue to be costing more and more and more and more and more, and people can't afford this stuff. We went through a lot on the coverage and reimbursement report that really tried to talk about the notion that the context for all of these issues is that genetic technologies and genetic interventions are part of an overall challenge in health care today.

So if it is true, and I don't know if it is, but if it is true that the patenting issue does directly result in unnecessary or preventably high costs for tests, then that becomes an issue that I think I would hope that we would attend to. I think it's unavoidable given what we've already talked about in terms of the coverage and reimbursement issues. But what I'm not sure of, to conclude, is that that is in fact proven yet, because the National Academy committee didn't look at it. So I would sort of start with trying to determine whether or not that is, in fact, a fact and a legitimate concern.

DR. LEONARD: But Reed, I would just point out that cost isn't the only thing that prevents access.

DR. TUCKSON: Right.

DR. LEONARD: If you have a sole provider of a service, that may be more limiting to access than anything that cost would do since when you talk about cost inhibiting access, that's the 43 million or whatever uninsured. That's a different perspective, and it also combines with the fact that from the data we heard this morning, there's evidence that people may not have genetic tests anyway.

DR. TUCKSON: Let me take that as a friendly amendment. I would see both. So I'm saying cost in the sense that if I have the patent on it and therefore I'm going to allow you to build your test, but you've got to pay me double the price of what I normally would have charged, now that's got to be passed off to the poor consumer, paying for the patent, license fee, and da-da-da. That's what I'm worried about. I'm equally worried about the issue that you described. So I would sort of put the ability to control access through limited distribution portals -- you phrased it better than I did. I was saying it's both, worthy of at least exploration, and I'm not making a point that I know that it exists. I'm just raising the concern.

DR. WINN-DEEN: I think we have to face the reality that any time there's a patent, it's going to increase the cost because anyone who is going to use that patented technology, except the patent holder, has to pay a royalty. So even if it's non-exclusively licensed and broadly available, there is a cost. There's also a pretty significant royalty stacking issue in genetic testing. Probably two-thirds of it right

now is associated with the platform technology of choice, and the rest is associated with gene patents and polymorphism patents and other things that you need to run the assay, like dyes or whatever.

So the royalty stacking issue is there, and until all these things expire, it's going to be there. So the question, I think, is really just going forward how do we want to manage this? There is the NIH approach of trying to find things first and put them in the public domain, which was the goal with the Genome Project and the SNP Consortium, and now this GAIN Project. That puts a certain amount of things in the public domain, but there are lots of things that are not in the public domain, whether they're genetic tests or infectious disease tests. There's a lot of infectious organisms whose entire sequence is patented. If you want to make a test to any part of that genome, you have to pay a royalty. So it's not something that's unique to genetics, but it is something that is a focus of molecular diagnostic testing.

So I think really what we have to try to get a handle on is do we want to model best practices? Do we want to recommend to the Secretary that, for example, although the Bayh-Dole Act allows NIH-funded researchers to license things, the reality is that the tech transfer offices have absolutely no incentive to do non-exclusive licensing? It's a pain in the butt for them. They have to deal with multiple licensees. It's much easier to do an exclusive license with just one party than to have a non-exclusive licensing program.

So in order to change that practice, because they're going to do the practice that's easiest for them, and they are not the recipient of the grant, they're in some different office, how do we try and change behavior if we're going to allow -- well, we do under current circumstances. Patenting is allowed, and the U.S. Patent Office has certain things that they've said they will accept as patents. So we can work to change what the U.S. Patent Office does, but we also I think have a better chance to change licensing practices within NIH-funded programs and to really try to take up what the NAS study did, which was to use that very slight wording emphasis really to try to force a licensing practice which, to my knowledge, is really out there as a guideline that nobody follows.

So that's just my view as someone who has to do licensing.

DR. LEONARD: Francis, are you responding to Emily?

DR. COLLINS: I completely endorse what you're saying, and that was the motivation for the NIH Best Practices for the Licensing of Genomic Inventions, which has only been out now for about a year. If you look at the article in Nature Biotechnology that came out of the ELSI research grant, Pressman et al., which is focused specifically on licensing practices, it does provide some glimmer of optimism there that, in fact, such practices may be improving a bit, moving a bit more away from the exclusive license for diagnostics, which we all agree has been the biggest problem. But we certainly have a way to go.

I think NIH is prepared, with that document out there, and they ought to bring it to the attention of grantees, and basically while we can't, short of doing a declaration of exceptional circumstances, which in many instances we can't do, we certainly can exhort people to pay attention to this and tell them we're watching.

DR. WINN-DEEN: I can just tell you that I have, on more than one occasion, sent a PDF of that document to a tech transfer office and said you should be following these guidelines, here's what the NIH

is recommending, and basically had them totally blow me off.

DR. COLLINS: I want their names.

(Laughter.)

DR. WINN-DEEN: Well, we'll talk about that privately. But I think there needs to be some stronger carrot because there's a disconnect between the research who you interact with as the grantee and their institution's tech transfer office, which has a different set of goals and objectives and workload issues to deal with. Unless we figure out how to deal with that disconnect between what you're asking the grantees to do -- maybe their institutions have to sign on as well as the individual grantees when they get the money and make sure that the tech transfer office is re-trained. But there needs to be something else. There's a disconnect in that system.

DR. LEONARD: So is that something that is not addressed in the NAS report that is a hole? I don't know whether the tech transfer -

DR. KORN: No, we did not address that specifically, I think. But just to clarify, a grant is awarded by the NIH to an institution, not an individual. The institution is the legal recipient and the responsible agent for that grant. So presumably if the institution knows that all of its faculty applicants are making some kind of commitment in their grant application, like the data sharing requirement right now, presumably the institution is aware that it has to enforce that.

I think there is a disconnect in institutions, and I think it's between the academic leadership of the institutions and the tech transfer offices, which in too many places are separated by a yawning chasm. Not all, and you can see that in their practices. The ones where academic values are informing tech transfer, you can see that in some of the institutions, and then you can see others where the practices are problematic and less informed. I'm not sure what this committee can do about that, though.

DR. LEONARD: Jim?

DR. EVANS: I just wanted to point out a couple of things that I think are relatively unique to the genetics field that make the potential public health problems and the access for patients to be magnified in the future, and I think it could get a lot worse. I think it boils down to the fact that right now genetic testing, a major barrier to it is its cost and the fact that there are oftentimes a number of genes that would need to be assayed and sequenced if you're looking at a monogenic disorder, and certainly when it comes to common disorders there will be many genes.

But that barrier is falling really rapidly, and I think that unless we re-think the issue of broad patents with exclusive licenses, we could be locking in a situation where the actual cost of genetic testing is going to be falling, and therefore one could see great access and great utility to this kind of information for patients, and yet there will be this huge barrier because of patents and exclusive licenses.

I think that genetics is one of those rare areas where things actually get cheaper, right? It's like computers. The cost per base pair of sequencing has plummeted largely because of the Human Genome Project, and the thing that really worries me about the current patent atmosphere is that we could lock in a situation of very expensive testing that's artificial that could have an incredible chilling effect on the

access to care, and the public health impact, the deleterious public health impact of this could really be magnified.

So I think this is a very important issue for this committee, one that requires more work, and I think that we have to look at the issue of licensing as part of this and not just the patent segment.

DR. LEONARD: Cynthia?

MS. BERRY: I have a somewhat ignorant question but fundamental nonetheless, so I'll ask it. Are we focused solely on patent issues as they relate to genetic tests, or is there any application at all to the development of biologics and other therapies? In other words, gene patents. Are we venturing into that?

DR. LEONARD: Do you mean gene therapies?

MS. BERRY: Yes.

DR. LEONARD: I don't think it has to be. I mean, our mandate is broad enough. Correct me if I'm wrong, Sarah and Reed, but our mandate is broad enough that anything that's controlled by patents could be relevant to this discussion.

DR. EVANS: And it's my understanding that many of the patents that are issued are broad enough so that if the entity that patents it chose to, they could exert tremendous pressure on almost any use of that gene. That's my understanding.

DR. LEONARD: Some of them.

MS. BERRY: On a separate note, while not much can be done with regard to patents that have already been issued, since genetic technologies are new and the human genome was just relatively recently mapped out, we haven't faced this yet, but I know in the drug realm, after the life of a patent or when it's about to expire, there are often legislative efforts to extend those patents. It would seem to me that if the data support the theory that these things are having a detrimental effect on clinical access, outcomes, clinical practice and what-not, then collecting that information would be useful when we get to the point where some of these patents are about to expire, because undoubtedly I would imagine there will be legislative efforts to extend them. If we don't have that information, there won't be much ammunition to prevent that from happening on the legislative front. But if the data don't support that, then carry on. There's not much we could do or should do, I would suspect.

DR. LEONARD: Jim?

DR. EVANS: I have a question, and I don't know the answer to this. That's why I'm asking the question. What data do we have or how could we get data that address the question of cost impact of an exclusively licensed patent? I'm thinking, for example, about the BRCA1 and 2, which I deal with on a regular basis. How would one go about trying to acquire the data to figure out what is the real cost, what is the effect of the patent?

DR. LEONARD: I've given many grand rounds talks on gene patents, and in my talk is some

data that relates to this in which we were performing a test and charging $100.50, and we were required then to send that to an exclusively licensed laboratory for $195 per test. So I can't say that therefore it's increasing the health care costs, but that's some data. I know that the BRCA1 testing was thought to be relatively expensive. Did the NIH negotiate -- that was on research pricing for BRCA testing for research purposes. But I think if you did a cost comparison of labs that had previously been doing that test, then the pricing would be less than the Myriad price.

So if this is the kind of data that you're talking about, then that can be gathered.

DR. TUCKSON: I think what I like about the question is, and I keep coming back to it, you have so much more experience than the rest of us do on this. Maybe one of the utilities that we will have is not only to explore whether this is a concern -- I keep coming back to questioning my own thesis, which is this a concern. But secondly, how would one rationally approach the analysis of it? It could be within the public interest just trying to figure out whether you can, in fact, do that. So I think those are questions that would be contributions that we might make, and it may turn out at the end of the day that it can't be done, which is an important finding, or it's so confused and chaotic that you can't get anything substantive out of it, and number three, you may discover that, in fact, it doesn't lead to problems with access. So I don't want to presuppose the work, but this is a long way to say that I think I'm supporting the thesis that I hear you saying, which is ultimately maybe that's something that we might try to figure out, or figure out what the state of the art is on how do you figure it out.

DR. LEONARD: Right.

Any other comments, questions, concerns?

(No response.)

DR. LEONARD: So can we go back to my original question, which was is this an issue which SACGHS wants to do work on, looking at the impact of patents on access and cost? We may just collect information. There may not be solutions that we could suggest that are under the purview of the Secretary of Health and Human Services, but at least we could get information that might be useful to the Secretary, or to the public, or to other organizations.

DR. KORN: I have to leave and I'm very grateful to the committee for letting me be here for as long as I have today.

I would just like to offer you some unsolicited observation on this. I think trying to change the patent law in the United States is an extraordinarily difficult, low-odds effort.

(Laughter.)

DR. KORN: No, I mean that. It is exceedingly hard to get agreement in the Congress on any changes in patent law, and right now two efforts, one in the House and one in the Senate, to reform the patent statute and the battling over the most technical language is fierce, and I mean really, really fierce. So I think going after patenting is not a profitable enterprise right now.

I do think there are two things you could do or think about. One of them is to focus on licensing

practices, as several of your members have said, because if something if patented and widely licensed, then a lot of the access problem goes away, I think. I mean, if you were able to practice the test -

DR. LEONARD: But broadly and reasonably.

DR. KORN: And reasonably, sure, broadly and reasonably, because you can punitively price the royalty to prevent the broad license from having any meaning.

The other opening that you could explore, although it isn't easy, is the amendment to the statute that allows physicians and surgeons to practice medicine without fear of infringement. That is, you can patent a surgical incision, but a surgeon cannot be prevented from using that incision in violation of your patent. There's a protection for doctors, for physicians practicing medicine. That exemption does not include -- in fact, it explicitly excludes laboratory diagnostics.

DR. LEONARD: And biotechnology patents.

DR. KORN: And biotechnology patents. This was done by the biotech industry, obviously, when that law was being written in 1996, I think. You could go back to that and argue that the exclusion of the practices of laboratory diagnostics from that protection was ill considered, and you'd have to be very cautious in doing that because you certainly don't want to violate people's legitimate patent rights. That's a second potential route over this mountain. But a frontal assault on the patent system I really think is not going to be a good use of your time. That's really just some advice.

DR. TUCKSON: Debra, I just want to make sure. I think David does a good job of making sure that we're being precise in our thinking, and I absolutely agree and hope that nothing that I suggested is -- because first of all, it makes my hair hurt as it is on this. So I'm not interested in going after the patent law. It is a matter of, as you said, looking at those kinds of issues, and also shining light on this issue of how does it work, what is the effect. I mean, if you think about it, there is no area in health care today in terms of this not being looked at in terms of medical technologies and those sort of things that people aren't trying to look at. But I don't think anybody is looking, and no one has gotten ahead of the curve on a whole new field of clinical interventions like in this field.

So the idea that we would bring some light to bear on that early -- it's probably arguably already too late, but to bring light at least at this stage I think is an important thing, but definitely not to try to go after the entire patent law.

DR. LEONARD: Right, and in fact there was a bill introduced by Lynn Rivers back in I don't know when, several years back that was targeted at amending the Ganske-Frist law. So there is wording of a bill that's actually available.

So I agree with David completely. I don't think we're going to change the U.S. PTO laws or practices. So where do we go from here?

DR. WINN-DEEN: I think what we should do is probably go back to what you were talking about earlier. To what extent do we want to write a letter to the Secretary? Do we want to just write a letter that says we endorse this report but we think it still falls short and we intend to work on the following areas which we feel were important to our committee but this report really didn't deal with? I

think we first should decide if we want to work on this, if we want to put it out of monitoring and into active, and if we do then we can get to some specific action items. If the team doesn't feel like it's the right time to move it from monitor to active, then we should deal with that in a different way.

I personally think that this is the right time to start thinking about where the gaps are in this report and dealing with them, but we do have a couple of other big things ongoing right now, so I don't know how much either staff bandwidth or meeting time bandwidth we have to take on something additional.

DR. LEONARD: Sarah, do you want to comment on that, or not?

MS. CARR: Well, we've always known that it was a possibility that you would take this on, and I think that the pharmacogenomics and the large population studies projects will be hopefully in good shape by June to maybe put those to bed.

DR. LEONARD: And we're done with coverage and reimbursement.

MS. CARR: We're done with coverage. So there is, I think, room for another big project. Now, I think Reed is going to talk about a revisiting of our priorities in June, and that may add some other things to our plate.

DR. TUCKSON: Let me make this proposal.

DR. LEONARD: Do Jim and Cynthia have comments? Are they related to this? Good.

DR. TUCKSON: Okay.

DR. EVANS: In reference to what Emily was saying, I think that there is no huge time pressure as far as getting a letter to the Secretary. I think we could, therefore, certainly tackle this general issue, and I think we could wait to issue a letter, part of which would be that we endorse the specific issues in the NAS report, but here are some other things.

DR. LEONARD: Cynthia?

MS. BERRY: I just pose this question because I don't have a strong feeling one way or the other, but are we the best group to assess and review the data, take in new data, hear from people and make an evaluation of the potential effect of this issue on clinical practice? Is it us? If it's not us, is there somebody better positioned or better qualified to do this type of analysis? I just pose that as sort of a threshold question, because if there's somebody else better suited to this, then perhaps we should continue to monitor and then see if things are being addressed. But if there is no one else out there and it falls to us, then that would advocate for a more active role.

DR. TUCKSON: Maybe one way to do this, and maybe I could propose it this way to give you something to shoot at, is that we would say that this is an issue, this issue of access is an issue of interest to the committee, that we charge our subcommittee to go back and ask the Cindy Berry question, is this something that we should be interested in, how to help us to think about whether or not we are an organization that could look at it, ask our subcommittee -

DR. LEONARD: Reed, could I just interrupt here? It is in our charge to look at this. I believe that that's true, isn't it Sarah? Yes.

DR. TUCKSON: I'm sorry. Yes. So more the sense that is it something that with our expertise, our resource availability, is this something that makes sense for us to try to take on?

DR. LEONARD: I don't think you have to send that back to the task force because I don't think we've had the expertise for pharmacogenomics, we haven't had the expertise for coverage and reimbursement, we haven't had the expertise for large population studies, but we are a deliberative body that can bring experts to provide us with information. Sorry.

DR. TUCKSON: No, no, you're doing good. But I'm going to try to march down a road -- but you're terrific. I think you're right, by the way.

DR. LEONARD: Okay. Sorry.

DR. TUCKSON: So first, though, is this something that we can do? You've already answered it, but we're asking anyway if this is something we can do.

Secondly was what you said. Jim said something -- timing. It was something else. So anyway, secondly is, then, starting to ask the subcommittee how might we approach analyzing these issues.

DR. EVANS: Probably you mean collecting information about what is the impact.

DR. TUCKSON: Exactly. So what would be a battle plan for trying to get our arms around this? What would be the mechanism in asking our committee to start thinking about who might be invited to come, are there places that we might go for information, who would be the kind of people we'd bring forward.

Third would be a sense of what, if anything, just helping us to look at what does the Secretary have available in his armamentarium that would be relevant to this. I mean, what part of the domain of HHS would be important, and then getting those ex officios sort of involved as a part of that.

So really sort of saying to the subcommittee, just to make this more contained, is we are expressing that we are interested, we are expressing that we would like to look at it. We would like to get a battle plan from our subcommittee as to how they might think about us proceeding and then bring that back to us at the next meeting, whereupon we can then start to work it.

DR. LEONARD: We did, and that's the list that's on the board. So that was our proposal for an approach. Now, we could get down to more specifically the names of the people to invite, but that would be planning the session for the next meeting, and the task force certainly can take that on if this is something that the full committee decides they want to do, and I think also asking for ex officio input is extremely important and a valuable comment to see where everyone who sits around this table is.

DR. TUCKSON: I think what I'm looking at, and maybe it's buried in the part about the ELSI program, I think if we could sort of take it down to another level of granularity then, is that what we're sort of saying is we want to know whether or not it is possible to determine whether the licensure of tests

based on patents causes there to be a delay or a lack of access for care that's meaningful to people. We want to know whether or not the process of patenting and the stacking, the royalty stacking that Emily talks about, causes there to be -- what is the relationship between that and the costs of this technology, and what is the effect that it has? Is it significant or is it not? What we're asking the committee is give us those kinds of granularity of questions, and then sort of say -- and I'm trying to see if it's up here. You're saying the way you would explore that, the way you would try to get at the answer to that question would require certain inputs. Are those there yet?

DR. LEONARD: We would certainly get input by looking at the data that's been generated since SACGT in research studies that have been done. I think also the NAS committee heard from certain individuals that made them concerned about patient access. So who did they hear from, and can we hear from those people? In fact, those six bullets -- I hate to keep referring to them, but it's one of the most valuable things in the clinical practice area that these were concerns that the NAS committee identified somehow by people that they heard from, presenters or studies that they did or whatever, and that's access to testing for patients, allowing competitive perfection of the tests, facilitating professional education and training, the other research that goes on when you're doing this clinical testing, independent validation of test results. So they heard from someone, some groups.

DR. TUCKSON: I don't want to monopolize this, and I'm going to try to stop my comments and let the rest of the committee decide how they want to proceed with this because I think I'm getting to be too pushy from my end. I like what you said a little while ago when you said you have experience where you do a test for this amount of money, but you have to send it on to the patent folk and it costs you this amount of money. I mean, that level of specificity is pretty interesting. So it's like how do you capture more of what you are experiencing? Who are the other people who know that? And maybe you're saying that's what they must have heard from to cause them to write those six bullets.

DR. LEONARD: One of the people they heard from was me, and John Meers.

DR. EVANS: One of the other things -- and again, we don't need to get into the nitty-gritty details of it now, but one of the things that makes this so difficult is it's a rapidly moving target. These platforms are changing, the costs are changing, that is going down, more genes are being discovered and attempts at patents. So it's a very difficult -

DR. LEONARD: It would also be interesting to hear from biotech companies who are trying to develop tests who have the patent stacking -- I mean, they are faced, face on, with the patent stacking issue. If you want to create a Jewish panel, you've got to get cystic fibrosis and Canavan and Tay-Sachs, and how much does each one of those cost? I don't know, because most academic institutions will try to fly under the radar screen of the patent enforcers until they're caught. But biotech can't do that because they have to be up front. So that may be where you get at the cost, because more and more companies are putting together tests for FDA approval.

DR. TUCKSON: By the way, Tim, does NIH have any plans to look at this?

MR. LESHAN: To look at the clinical issues you're saying?

DR. TUCKSON: Yes, the things we're talking about.

MR. LESHAN: Not specifically, but I think in the deliberation following up on the IP study, it will be considered. But it's not a major focus. It's the research focus we're going to be looking at.

DR. TUCKSON: Since I've blocked everything up here pretty good, I want to try to see how can we then give the subcommittee a little more focus. The only other focusing comment I want to make is based on what Debra just said, which I thought was pretty good. I keep coming back to the notion that I know I'm not smart enough to know whether this is a problem, and I'm also not smart enough to know whether or not people are behaving inappropriately. I mean, you've got folks who are trying to develop these tests, and they have some business issues that causes them to need some of this protection. So I'm not saying that it's all wrong. I'm just trying to figure out at the end of the day does the result of this system as it exists today cause a problem for people to be able to afford life-saving diagnostic technology. Is this a problem or not? I just simply wanted -- I can't phrase it any more specifically. I want us to determine whether or not this is a problem.

DR. LEONARD: Well, we could also hear from genetic counselors and patients, like we did on the genetic non-discrimination process that we went through, to know whether genetic counselors have -- I mean, one-third of patients won't have the test just because they're afraid of the information getting to the insurance company or employer. But the genetic counselors must be on the forefront of knowing whether or not they don't have it because they can't afford it or it's not covered by their insurance.

DR. TELFAIR: I actually, like Ms. Berry, have a basic question because this is not an area that I understand. But I'm just wondering, in terms of just gathering information to be able to make decisions, to what degree do you need to go through that process? It seems to me that one of the things is to have enough information to make a decision to influence recommendations. That's sort of the path that we need to go to, and I'm wondering, for those who know this well, is there some idea, at least from the task force, how much information we should be gathering? Because I've heard a lot of discussion and sort of the list of who you can speak to, but it seems to me that even some of the persons at different levels, there are different ways this influences them. You just mentioned genetic counselors, which is on the supply side of things, the clinical side, the practice side. But then there's the question about researchers and other things.

It would help me to make a decision in terms of whether or not we should, to answer your first question. If I had some idea of what you all as a task force were thinking, what level of information do you need to make that decision that you do not already have? I mean, I know this is a tough question. It's just that if you look at the amount of information that you have, the way you can make a decision, is it enough to make decisions where you can come up with some very solid recommendations that this committee can then go over, or do you need additional information?

DR. LEONARD: I think that it is possible to identify problems that patents are creating. The NAS committee, when they did their deliberations and identified fairly and investigated fairly thoroughly the research problems that patents create, they identified some concerns on the clinical side. They really didn't look at the economic side, which, in a sense, what we're talking about on the economic side is really the clinical economics of this.

So there is information out there that can be brought to this committee to inform them about what the basic patent issues are. I mean, I think we'd have to start with a primer of what are patents, what are they supposed to do, who is patenting what in genetics and genomics, what's being restricted, and then go

from there about enforcement. So there are patent holders. They have enforced against clinical laboratories and prevented doing testing. There is data out there that's been done by researchers demonstrating the extent of that enforcement issue.

When you get down to costs, I think individual laboratories may have that information. I don't know that it's been compiled in any one area. When you get down to the impact on patients, I don't know how you get to that except through genetic counselors who may be seeing the face of that impact. Certainly biotech companies -- clinical laboratories want biotech companies to do FDA-approved tests. But if they're being prevented and their test kits are so much more expensive than what we can do by in-house-developed testing, then is that an issue that needs to be addressed? Because indirectly it has a cost effect on the clinical testing that can be done. I don't know if there are other areas in medical practice -- I don't know in medical genetics, Jim, if there are issues that are related to patents. I think in genetic counseling there are genetic counselors who can speak to those issues.

DR. EVANS: I think there are huge issues in medical genetics related to patents. I think that the hard part is quantifying it, and I think that will be a difficult task for the subcommittee and for the committee, but I think it's something that we need to tackle, in my opinion.

DR. LEONARD: Agnes?

MS. MASNY: Just as you asked about the clinical impact, I think that sometimes the insurers themselves are people who we might get information from as to actually what is paid for or covered just in view of the cost of some of the testing. I know in the oncology field, the nurses would have information specifically with regard to some of the newer genomic tests, like this oncotype testing that's doing tumor expression profiles. So not just for single-gene things but more broadly genomic types of tests. So I think there would be other health professionals that could respond to that question as well.

DR. LEONARD: I think that's a good point, because genetics is broader than just medical genetics and genetic counselors as it moves more and more into clinical practice.

Chira?

MS. CHEN: I was thinking that we kind of just talked about one side of the issue. There's also the other side. There is a reason why a company sets this price, and we should also know why they set that price before we can tackle the patent issues. I actually had heard about how come Herceptin is being charged the way it's charged, because the amount of time it took for doing the research, going through the Phase I trial, Phase II and Phase III and all that. So they use that to kind of do a calculation estimation of how much is sort of spent around that time, and that's how they charge the price for Herceptin.

Then for the second drug that they came out with, this is about how much we charged for Herceptin and this has even more impact, so that's why they charge X amount more or whatever. So we need to know why companies choose that information before we can decide, in addition to the patent.

DR. TUCKSON: I think that's very important. I would just sort of say that part of the challenge to the committee would be how far to take this to an overall understanding of how they set the charge versus how much to emphasize within that how much does a patent issue or a license issue then affect it. Because let's say at the end of the day the Herceptin price was -- just the normal process of developing it

was a million dollars, but they couldn't do it unless they got a license for something that one person controlled because of something they did at the university of who knows where -- and, by the way, that was half a million. That's what I'm trying to discover, is that half a million of the million was because of a patent or license issue. I'm just trying to figure out how it works.

DR. LEONARD: Well, I also don't know whether biotech companies are going to be willing to share or able to share their licensing fees.

DR. WINN-DEEN: I think you could go through the basics. There's the cost to develop the test, there's the cost of physically making it in your manufacturing, there's the cost of getting regulatory approval, and then there's the profit that you need to make to pay back all your investment. I'd be happy to go through that with the committee in general terms, what companies look for when they are trying to make a decision to even start, and I can tell you that if at the end it's not a positive number, that you don't even start.

DR. LEONARD: Cynthia, did you have a comment, or did I get you? No, okay.

Julio, did you have a comment or a question?

DR. LICINIO: I think the issue of the cost is crucial and can affect access and all of that, but I think that the issue that was discussed briefly but I think is even, in my view, more alarming is the issue of validation, because if a designated laboratory has a license for that gene or gene product, and therefore a test, and others cannot validate it, then irrespective of cost -- and it could be that the test is for free. But if there is a lot of error, there is going to be a huge impact on public health.

So you tell somebody that they have or don't have the risk for a disease, which could reach surgery in BRCA, et cetera, and there is an error, it's a huge problem. There is an error rate in laboratory tests, and if you're not constantly doing quality control and optimizing and checking, the error rate begins to creep up. If you had a test that you just had running in your lab and it hadn't been optimized and compared to others, validated and tested, really validated for a long time, there will be errors creeping in over time, even if it was very good to begin with. So how do you address that if the laboratory has a patent and others cannot validate it?

DR. LEONARD: Sylvia?

MS. AU: I just wanted to mention that besides the one-on-one patients that the clinical geneticists, genetic counselors, nurses and other clinical people see, this issue can also have a chilling effect on public health programs, because personally we were going to start a breast cancer counseling program for our low-income women, but because of the patent issue and the cost we could not ethically do that because we could not cover the cost of testing for the women that would accept the testing. So there could be some chilling effects to public health programs, too.

DR. LEONARD: And there was no other way to have the testing done other than through the sole provider.

MS. AU: We did try to negotiate with the company, but they said that there was no provision for us to get a discount for the purpose that we were using it for, for these low-income women, that they

could go through some kind of -- there's an application you can go through for hardship, and then it's a gamble whether or not they would get that hardship lower cost testing or not, and we just couldn't ethically do that with our population.

DR. LEONARD: Linda, do you see other kinds of public health impacts of gene patents or DNA-based genomics patents?

DR. BRADLEY: Yes. I mean, I think the one that we struggle with a bit is the ability to collect data, because the data is proprietary and the company has issues about sharing it, some of which are good reasons, and that really frustrates data collection efforts. So that's the one that we've talked about quite a bit.

DR. LEONARD: Jim?

DR. EVANS: One that I hadn't really thought of until just now but I think is the case is that translational research can be thought of in some ways as having a public health benefit, and translational research can definitely be inhibited by this situation because of exactly what Sylvia brings up. You can negotiate a bit lower price for a project, say sequencing BRCA1 and 2, but it takes it from $3,000 per individual to, say, $2,700. It's still very difficult.

DR. WINN-DEEN: I think you have to also recognize that a fair amount of that cost is real cost. You're sequencing 27 exons in both directions.

DR. EVANS: Right, and that's why I completely agree that we have to figure out what is the real cost and all, because people have to make a profit too. It's just that we also would like to keep it from being usury.

DR. LEONARD: I think if the committee wants to take on this as an issue, you have to understand that it's very complex. There are many aspects to it. It's not going to be simple and straightforward. As complex as the large population cohort project has been, this has many, many different aspects to it, and I don't know also whether we want to confine it to a narrower field or whether we want to look at the full impact of DNA-based patents.

DR. LICINIO: Could I suggest that before we even make a decision, do you think that a good way to look at this is would there be a cost benefit? In other words, if we have the best possible outcome of a task force, what kind of impact would that have? If we think that the impact would be something of value, then I think we have something to discuss and to pursue. If we think that even if we put our best effort forward it's really not going to result in very much change in policy or in outcome, then we should think more cautiously.

DR. LEONARD: For people who have thought about this over the years, I think David's statement right before he exited is exactly what people who have spent a tremendous amount of time thinking about this is, to try and achieve broad licensing practices at a reasonable royalty rate, and I don't know if that's something we can influence from this committee, and then the second is to try to amend the Ganske-Frist law to extend that to genetic testing services, which there was some effort in that direction, except Lynn Rivers wasn't reelected. So that has to do with the political system.

So I think there are very concrete things that we may or may not conclude are appropriate actions that may be taken to help remedy problems if we find that there are problems. I mean, I don't want to pre-determine what the committee does because I'm one of those people who have thought about this long and hard and I don't want to drag you all kicking and screaming into something that is not worthwhile to do.

DR. TUCKSON: Well, given that you're trying to moderate this and be the chairperson of the committee, I think that the committee has given you an awful lot of input. I think we're starting to say the same things over and over again, so I think that what we would like to do is to trust in our committee and trust in you as the leader of that committee to take the input that you've received and bring back something to the committee in terms of your next steps. I think you've made some recommendations already in a slide there. I think we're asking you to probably revisit those recommendations and all the input that you've had and can come back and let us know if and how you would like to proceed and give us something to react to, because I think we've given you a lot of thoughts and input. But I don't think right now we're able to formulate for you -- and I'm more than willing, by the way, in terms of the time. We have enough time. If the committee senses that you want to drill a little deeper and give a specific guidance to the subcommittee at any more levels of specificity, I'm more than willing to take the time to do it. It's really the will of the committee. Or would you rather like them to take back what they've got and then reformulate it and come back to you with something? What is the will of the committee?

DR. LEONARD: As Fay is whispering in my ear, and it's very accurate, I think part of the concern here is that many of the members currently on SACGHS weren't part of the priority-setting process, may not know a lot about gene patents and the issues. So maybe what needs to be done in June is some level of informational session to inform the committee about what gene patents are, some of the issues that you've raised here that you'd like to know about so that the whole committee could have a better background to be able to choose whether or not to go forward on this or not, and the task force could put together an informational session for the committee.

DR. TUCKSON: Just to remind the committee that this has been a difficult discussion, and we like to always have discussions that have an A plus B equals C, leading to a logical D by timeline Z. This is not going to happen in this case. This is complicated and it's difficult. I do want to remind you so that you're not frustrated that the function of the committee, among many things listed, is to examine current patent policy and licensing practices for their impact on access to genetic technologies. So it's right there. It's right in front of us. It's what our charge is, and so we know it's there, and now the question is how to get at it. So if you would come back, that would be great.

So you will have time on the next agenda. You have time to make a presentation, and we can negotiate how much time you want and whether you want to bring speakers, the whole thing that you want to do. I think that's going to be important. So we thank you for taking what is complex stuff and agreeing to come back and make it simple and crystal clear.

DR. LEONARD: Jim and Emily, you're okay with this? Okay.

DR. TUCKSON: Right. Thank you very much for a very good discussion. We really appreciate it.

Actually, by the way, we're going to wind up ending early, probably, but we'll see.

Did I catch you too quickly there, ma'am? We're going to just ask you to revisit very quickly -- we've got a technical emergency here. We're going to ask the committee to take a look at the priorities, and let's just go back and review that real quick.

Let's take the first one, which is genetic discrimination. By the way, the goal of this discussion that we're trying to get at here is based on what you just heard. We were asking the question of what is our bandwidth. What is the ability of the committee to juggle how many balls simultaneously. I want you to be looking at this list for not only what's on it but also any glaring errors of omission, making sure that we're not being ostrich-like with our head in the sand and are missing a major challenge that we want to start paying attention to.

So the genetic discrimination, we are pretty well moving forward. We've discussed that pretty much. I don't think there is -

DR. LEONARD: We're missing one of these overarching things down at the bottom.

DR. TUCKSON: We're going to scroll. Great.

So genetic discrimination. I don't think other than the committee having a couple of conference calls, this is not a major time constraint for staff and/or the full committee. The subcommittee's got a little work to do, but it's not overwhelming. Am I missing that?

MS. CARR: Well, you want to have a meeting of the Chamber, the Coalition, and -

DR. TUCKSON: But I'm saying those are conference calls, and that involves a couple of members of the committee but not the full committee.

MS. CARR: Yes, correct.

DR. TUCKSON: Although it does take staff time and I don't want to diminish it, it's not an overwhelming commitment.

MS. CARR: Right.

DR. TUCKSON: All right. So we're wrestling that one forward.

Number two is genetics education and training. That's sort of a consistent across the board for us, and again, Sarah, you'll check me but not involving a lot of time at all. It's part of just built into everything that we do.

By the way, that being said, let me be provocative on these as we go through. The committee has always identified the concern about how do you get the profession ramped up to be prepared to manage and handle this new era. Those of us that went to med school, we didn't even know what a gene was, darn near. It is still, by the experience I have, difficult to get clinicians to go to continuing medical education programs for genetics unless it's very, very narrowly defined. It's still tough.

PARTICIPANT: Or in Barbados.

(Laughter.)

DR. TUCKSON: So one of the things that I don't know whether or not there ever needs to be, and I'm not calling for it but I want to raise the point, is should we ever take this off of the built into every stuff kind of deal and turn this into its own priority. I'm not advocating. I'm just raising it, especially trying to catch the new members of the committee up to sort of how we got to this list. We again decided not to make it its own thing but to build it into everything.

MS. AU: Reed, as part of this, did you include genetics training for genetics professionals? Because, obviously, we are starting to feel a pinch in that area.

DR. TUCKSON: Yes. Actually, that was a workforce concern, and it's a great point, Sylvia. We have alluded in numerous things, including in the coverage and reimbursement document, being concerned about the numbers of counselors. One of the things that we can supply for you is an awful lot of testimony on behalf of the genetics counseling community as well, who have been really leaning on this issue. So you've raised an important one.

Patents and access we have just discussed and are looking now to elevate that even more into what we're doing.

Oversight. This issue of oversight is one that I want to raise up for -- maybe what I'll do is go through them all but come back to the oversight one, and some of the members of the committee who have been around a while might want to also get ready to comment on this when we come back to it.

The original committee, the original SACGT, whatever it was back then -- what was it called? SACGT, the original one -- did spend a lot of time on this oversight issue, CLIA, the FDA, yadda yadda. So we've got it back on this list, and we did have some gentle review of it a couple of meetings ago. The question becomes, based on what we sort of heard, some testimony yesterday, do we want to revisit and look at any of that oversight stuff and see what's falling through the cracks a little more carefully. So I want to make sure that we decide one way or the other on that.

The vision statement is straightforward.

Coverage and reimbursement now out. The key thing on coverage and reimbursement is the dissemination.

Sarah, press release? Yes, no? Don't know?

MS. CARR: Don't know.

DR. TUCKSON: We have written a press release. It is beautiful. It's gorgeous. So if it never comes out, too bad. We can email it to you all and you can just marvel at how wonderful the press release was.

The point is that I feel a very heavy responsibility to this committee, and I feel like I have to advocate and fight for my committee, and the fight that I have to have for you is that if you put that much energy into that report, everybody in America needs to read it. So I am basically saying to Sarah and the

team that I expect us to do everything in our power to try to get the government to put pressure so at least everybody knows about the report and can go online and get it. Now, there may be a lot of rules why we can't, so I'm just going to tell you that I'm going to irritate people to the point where I lose the battle. But if you're going to put in months and months and months and months of work on this thing, we're going to get people to look at it. I'm not interested in doing reports for shelves. Otherwise I don't have any point in being here, and I'm sure you feel the same way.

I also need you to, again, assign yourselves accountability for disseminating the report. Meanwhile the staff has done a good job. We've got 8 zillion people who are going to get it. So as far as I'm concerned, coverage and reimbursement is moving forward. We'll get the report out there. We will have, I'm sure, Sarah, a report back. You'll help me with that.

Who is our subcommittee chair? At some point I think you might want to be assigned responsibility for sort of seeing what was the reception of the report, did it get out there, do we have some way to monitor what the effect was, if any, so that we will know if we need to come back and revisit it and do some other refreshment of the issue. Okay? But basically, by and large, for practical purposes, coverage and reimbursement is off the table for us pretty much now and has got a life of its own. It's out there making its way as our child.

Large population studies. We've had a lot of discussion about that and we clearly do have more work to do there. The subcommittee will need to meet as a committee shortly to determine the next steps in terms of the timing of it. We're particularly waiting to hear some guidance from Dr. Zerhouni, which we are waiting to hear. We've queried him since this meeting is going on and waiting to get an opinion back. We are not going to try to rush a public study out into the hands of the public. You've got 12 hours, public, to respond, and we're going to write that up as an official report. I think we've made the sober determination that we have never violated our integrity with the public in soliciting mature comment, and we're not about to start now to try to just ad hoc something out there just for the sake of ad hocing it. It's not right, it's not fair, and we're not going to do it.

So at the end of the day we are going to determine what the timetable is for legitimate weighing in and what we might reasonably do, and our subcommittee is going to come back and advise us. So large pop is on the table, and there is work that we will be engaged in, so we need to put that in our workload.

The pharmacogenomics. Who wants to describe what you think the workload is for pharmacogenomics going forward?

DR. WINN-DEEN: I think what we need to do is to take all of the discussion that we had and come back and translate that into potential recommendations for us to discuss as real recommendations at the June meeting. The task force report, where we have an outside group helping us with the actual writing, we'll have as a draft May 1. So I think we should have a reasonably complete first draft of the work product at the June meeting. Then I guess after the June meeting it would probably go through the normal finalization of that draft, public comments, and then finalization after public comments. So it could still be some time, but hopefully at the end of 2006 we could potentially have it out. I think that's sort of what we're aiming for right now.

So there will be work for the task force between this meeting and the next one, and then there will

be work which will include staff, and then between the June meeting and the fall meeting there will be a lot of staff involvement to get the public comments and then organize them and digest them into something that we can deal with at the fall meeting.

DR. TUCKSON: So a significant bolus of work. This is a major priority, and it took a lot of effort. So that's one that's going to occupy a lot of energy, and our receptor sites will be saturated.

DTC marketing. I continue to be very excited, and I want the committee to be excited by the fact that here was a great example, at least at an early stage, and we've got more work to do on it, where we called the question, organized government, challenged government, government reorganized itself, new relationships, new synergies between agencies who are now tackling the problem.

I think that's good. I think we ought to count that in our win column as being good.

DR. LEONARD: Given that it looks like they will have certain actions coming out, could we ask for an update on that from that group at the June meeting?

MS. CARR: You might want to also hear from the group that the CDC is heading up, which is developing some plans for assessing the public health impact as well.

Linda, do you think CDC might be ready to report out in June?

DR. BRADLEY: (Inaudible.)

DR. WINN-DEEN: I think Steve said that they're going to have their advice to consumers letter written between now and then. Is that what you mean by letter 206 DTC marketing?

MS. CARR: No. The consumer alert is something that's in development. That's a letter we wrote already.

DR. WINN-DEEN: We probably should have something up there that that's the next deliverable, the joint FDA-FTC consumer alert. That's sort of what we're looking for.

MS. CARR: But do you think of that as our deliverable?

DR. LEONARD: We can have an update.

MS. CARR: Oh, an update. Yes.

DR. LEONARD: From FDA-FTC.

MS. CARR: Yes, but remember there are two groups that use (inaudible), really, that one and the one that CDC is -- so hearing from both might be a good thing.

DR. TUCKSON: And I think the expectation would be that we would expect government to coordinate its presentation so that there is a sense of a relationship between the two, and by simply asking it to be done that way, perhaps that is a small -- although they don't need us to do it because they're

mature people -- but a subtle way of suggesting that they are actually going to talk to each other.

MS. CARR: And there's a lot of overlap between those two groups.

PARTICIPANT: They talk to each other frequently.

DR. TUCKSON: So the explicit assumption/expectation is you will bring together a combined report that will speak to how you're trying to solve a problem and all the tools in HHS and how they're coordinated to solve the problem. That's essentially what we're looking for. Okay, great. Done. So that's not going to take a lot of the committee's time. It's government working but not subcommittees of us and doesn't thereby completely overwhelm our team.

Access is built into everything we're doing, and we'll leave it that way, I think.

Then public awareness and understanding built in, but I raise that issue the same way I raised earlier the question about the physician education and health professional education across the board. I'm not necessarily calling for it, but do we recognize a need for any special activity? We've thought about that long and hard when we captured these priorities, and it did not make the list as the top couple of things, but again build it into everything. I have no reason to suggest it should change today, but I want to highlight it for the new members of the committee.

Please, Tim.

MR. LESHAN: Can I just put in a plug for DNA Day? I know that Joann Boughman mentioned it, but April 25 is DNA Day, and there's a bunch of information on genome.gov if you want to figure out how you might participate in DNA Day. It's a way to get the word out about genetics and genomics to the public.

DR. TUCKSON: So, let's see, that's important. By the way, we do have a history of support for little terrific and brilliant initiatives, like the family history Thanksgiving deal, which we really got behind.

When is DNA Day again?

MR. LESHAN: April 25 is the exact date, but there are activities all through April on that. But that will be the day when people will be going out -

DR. TUCKSON: That's like tomorrow.

MR. LESHAN: No. April.

DR. TUCKSON: Where am I now?

MR. LESHAN: It's March.

DR. TUCKSON: April is next week.

MR. LESHAN: But April 25 is the day.

DR. TUCKSON: I'm already through April in my schedule.

MR. LESHAN: I know the feeling.

But we will be having a webcast on our webpage, there will be interactive activities for students, and then a lot of genetics professionals are going out into the community to talk about genetics and genomics at high schools. So we welcome the participation of everybody.

DR. TUCKSON: Terrific. I think what we're going to do, by the way -- we'd like to hear back from you. We'll charge you, Tim, at the next meeting to give us a brief update on how DNA Day went, lessons learned, which I think would be important for us to know. So let us know lessons learned from DNA Day, and that way we can get ahead of the curve for next year.

MR. LESHAN: Be glad to.

DR. TUCKSON: So let me come back to another issue I wanted to raise, which is oversight. I think, based on what happened today and the amount of stuff that's on our agenda, I'm not sure that I have a lot of appetite to go much further on oversight. But let me just raise it and see if anybody else has any interest on that.

DR. LEONARD: I do think we need to nudge significantly CLIAC or CLIA or whoever to CMS to get the genetic part of the CLIA regulations out. It's been missing in action for way too long, and I don't know if that's done by a letter. I mean, I don't know whether we want to go to the Secretary and down through CMS, or whether we can encourage CMS to bring us an update on CLIA with the specific timeline that we can then keep track of at the next meeting or something. But I don't think we're doing our monitoring function of the oversight of genetic testing if we're not sort of making sure that's happening in a timely fashion.

DR. TUCKSON: Sherrie, you had your hand up?

DR. HANS: Just that it can be very helpful to have CMS, as Debra just said, to have them come present to the committee and let you know what's going on. That tends to be an effective forum for it.

DR. LEONARD: And I think we should give them equal time because I know I've been asking Steve to come and give us FDA monitoring updates on a regular basis. So we ought to ask CMS to do the same. Really, they're both in that same category.

DR. TUCKSON: Could I ask you or Debra, for the members of the committee that are new, and even though they've read every word of every committee meeting prior to their arriving, could you just give me an update on what actually is it that we are concerned about and what's the impact of those things not being out, those regs? What's the problem?

DR. LEONARD: This started back with SACGT, and even before that with, I think, ELSI, that they were concerned that there are genetic tests being performed that are not reviewed for the quality of the testing, the accuracy of the testing, et cetera. This was a major issue for SACGT. SACGT moved to

ask the FDA to provide oversight of genetic testing, which the FDA looked into, and basically I think in the interim between SACGT and SACGHS they got a ruling from their legal department. I don't mean to misquote Steve, so make sure that I'm -- oh, he's not paying attention. That's good, so I can say whatever I want.

(Laughter.)

DR. GUTMAN: No, actually I am.

(Laughter.)

DR. TUCKSON: He's writing every word down.

(Laughter.)

DR. GUTMAN: Ruling is probably too strong.

DR. LEONARD: A suggestion.

DR. GUTMAN: There actually hasn't been a definitive policy statement. But it would be fair to say that we did signal this group that there was not enthusiasm for pursuing regulation of home brews. So the issue has been tabled, and the agency right now is actually focused predominantly on clarifying the regulation of analyte-specific reagents and demonstrating that they're not as scary as they might have been thought to be, and hoping that with a stick and a carrot we might be able to encourage people to standardize and bring products to us.

DR. LEONARD: But I think the SACGT efforts weren't without effect in that the CAP, at least, which is one of the laboratory inspection bodies that has deemed status under CLIA, did add to their molecular pathology checklist, which is laboratories that do molecular DNA-based testing of all types, including genetic tests, I think it's about 12 questions, because I think I wrote them, that address how a test is validated so that when a laboratory is inspected, any test that's been brought online as a laboratory-developed test since the last inspection will be reviewed by the inspector, and there are also molecular-specific inspectors who are supposed to be inspecting molecular pathology laboratories.

One of the reasons I'm interested in hearing about the CLIA regulations is that CAP did this. This isn't required in the CLIA regs at all. So it would be nice if CLIA also adopted some of that language or questions or standards such that there is some review of laboratory-developed tests in the CLIA review process. I think there's one question, which is what there was previously in the CLIA regulations. But maybe to expand that, as CAP had, so that when laboratories say they are performing tests under CLIA that they developed in their laboratories, that has some teeth to it.

So that's basically -- I think Judy Yost came and spoke to the committee about CLIA and how it works, but right now there isn't a genetic component specifically addressing genetic-specific issues within the CLIA regs. So that's why I'm interested in seeing those. They had been drafted, they went out for comment, they got comments back, but then nothing ever appeared to move those forward into new standards or regulations or whatever they're called. Some of the things that were in those initial regs were kind of scary, and labs and professional organizations did provide comments back to CLIA and CMS.

So where the final version would be, I don't know, but that's kind of the overview of what's been going on with oversight. I hope I didn't misstate too much.

DR. TUCKSON: So the issue ultimately, as so well defined there, is I think the issue we're worried about is that there are things that can fall through the cracks. I got this when the coverage and reimbursement policy document went out. People were sort of saying what about this issue? I mean, you're providing coverage and reimbursement for things that are not being approved, and how is that supposed to be handled?

How do we bring that to the committee? Who do we ask?

MS. CARR: Well, Dr. Rollins, we can certainly contact Judy Yost and see if she could come, or would you want to do that?

DR. ROLLINS: What? Contacting Judy Yost?

MS. CARR: Yes.

DR. ROLLINS: You can contact Judy Yost.

MS. CARR: Okay.

DR. ROLLINS: I don't even know who Judy Yost is.

MS. CARR: Oh, she's the head of the CLIA program.

DR. ROLLINS: I don't know her.

MS. CARR: Okay. You'll meet her at the meeting.

DR. TUCKSON: So with the comments of Debra and Emily, that will help phrase what we want them to do.

I think that I would ask, though -- and, Sarah, you can tackle me on this and just say that the staff doesn't have time because they've got a lot to do. So let me just ask this question, and then you give me your input as to what's possible.

In preparation for that presentation, it would be useful if we could develop a simple chart that laid out where the authority is today for oversight of genetic tests, where it is and where it ain't, what's missing, so that everybody can sort of just have a nice little map that sort of says, okay, here's who's got authority over these things, who's got authority over those things, and here's where the question mark is, so that when we listen to this presentation, especially for those who are new to the issue, that you're not floundering around trying to figure it out.

DR. HANS: I might just suggest that you add to that also, since there are a lot of new faces and this does extend back to the previous committee and to NBAC, maybe a little timeline on what CLIA had said they were going to do when and what progress they have made over that period of time so that we

can all remember.

DR. TUCKSON: Good. That's a very helpful amendment.

And then finally on this assignment, I think I'm not sure what Steve said in terms of FDA made some decision not to do something. So again, that would be helpful in our map if we knew what it was that they were going to do, what it is that they ain't gonna do, and what gap does that leave exposed, which is I think really what I think the issue is, which is where are the gaps. I appreciate the staff taking the leadership in getting that done.

Well, with that, I think we did decide to do something about oversight, and that's terrific. I feel a lot better and I can sleep a lot better at night.

Would you, Sarah, conclude our meeting with a summary again, just take us through what we did in this meeting? We've already covered a lot of those issues, but take us through.

MS. CARR: Sure. Regarding the large population studies report, as a result of the discussion with the task force at lunch, there was a slight revision of the timetable. As Reed said, the group decided that it would be important to allow for a longer public comment period. So the staff will work on revising and augmenting the draft report in April, reflecting the deliberations of the committee today, and get a solicitation out through various vehicles. We'll use the official Federal Register, as well as some others, our listserv and website, and we'll want the task force input on this but maybe make a special effort to reach out to a broader range of scientific communities, as well as the general public and patient communities. This is what we're waiting to get some clarification from Dr. Zerhouni on, as to whether it would be important for the committee to write a letter to the Secretary before the next meeting, or right after it, to let the Secretary know where the committee is on this issue, and that letter might, if we did decide to do it, would provide an update on the status of our draft report and the solicitation of public comments, the policy issues that have been identified so far, and we'd discuss the importance of seeking broad scientific and public input concerning the potential large population study or resource. I guess we haven't figured out what to call it ourselves.

This last bullet is somewhat tentative, I'd say. If it's decided that it's important for the full final report to be transmitted to the Secretary before the next meeting of the committee after June, which is November, we could convene a special meeting of the committee on teleconference, and it would be important obviously to make the public aware of that and allow participation in that, but there is a way to do that. So we can consider doing that in June.

Emily?

DR. WINN-DEEN: Is there a way to get the survey data that might pertain to this in terms of people's interest and -

MS. CARR: The Cogent data?

DR. WINN-DEEN: Yes.

MS. CARR: Yes, we were intending to do that, definitely to follow up on that.

DR. WINN-DEEN: I just don't see that as a bullet up there.

MS. CARR: It isn't. You're right. We'll add that. I'll add that as soon as we're done.

On pharmacogenomics, Emily, if there needs to be any augmentation here, let me know. But I think it was agreed that the task force would further develop the recommendations or find them reflecting the committee's deliberations and discussion, and that you would be preparing, with the great help of ASPE, the Assistant Secretary for Planning and Evaluation and their contractor, prepare the draft report for the committee's consideration in June, and that would include the revised recommendations.

Then if the committee were comfortable with that report, it would go out for public comment after the June meeting, and it would probably be another 60-day comment period. We'd be ready probably by November for a final report if all goes well.

Then on genetic discrimination, the committee decided to write a letter to the Secretary that would urge the Secretary to request a meeting of the White House Domestic Policy Office that would include the Coalition for Genetic Fairness, the Chamber of Commerce, the National Association of Manufacturers, and possibly, if it's appropriate, relevant House committee chairs, or if necessary that would be done at a subsequent meeting, to discuss the unresolved concerns about the pending federal legislation to prohibit genetic discrimination in employment and health insurance.

This letter would also express our concerns about the effect of the fear of genetic discrimination on research, and this is especially important given the new research projects related to genes and environment, and possibly even the large population study, if it were to go forward. This would include Cogent's data as well, and we would also ask the Secretary to send our compendium of public comments and the DVD to the House committee chairs.

Then as preparatory to this letter, the task force itself would need to meet with those three groups, the Coalition, the Chamber, and the manufacturer's group. We will also provide additional copies of the compendium to the Coalition for their use on their visits to the Hill. Then we were also going to augment or revise the large pop draft to point out the need for federal legislation, that that might be a possible approach.

On patents, I think it was decided that the task force would reconvene and consider the committee's discussion today, revisit the proposed approaches for a way forward, further study, and then come back to the committee in June. I guess this would involve a sort of investigation and consultation about what data is possible to obtain about cost and effects on access, and we would organize an informational session in June that would bring the committee up to an even playing field, especially for new members who haven't really been as steeped in this issue as others have.

Just to review the other topics that got added just now, Reed, we sort of went through some of our priorities today, and you certainly walked through them. We had talked about possibly doing that in June with the idea of considering other issues that aren't on our strategic plan, and I know, and I think we've mentioned, that AHRQ has some ideas about what else this committee might do, and perhaps we could either do that in a comprehensive way or just ask AHRQ for its explanation of what it wants the committee to do.

DR. TUCKSON: First of all, I think what we did today was important. We spent a lot of time on it, and I'm trying to signal to the committee that I want to make sure that your ideas, your issues, your concerns, your observations have a chance to be floated and to be reflected in the committee. I also want to be sure that we're not stuck in the mud and, as I said, missing something that's important.

Having said that, I think we clearly identified that we've got a lot on our plate now, so we're not absent things to do. Having said that, I think I just would keep it as an open-ended invitation for the individual members of the committee and our ex officios and AHRQ to bring things to our attention that they think are important and give the committee a chance to determine whether or not it's more important than some other things and to bump some things.

As I saw that analysis, Sarah, in my mind, some real heavy bolus stuff that's in the process that you can't do anything about. You've got to follow through. I saw some stuff that's sort of in the middle, just sort of flopping around, lesser committed but important. Then I see some things that are just built in to everything that we do. So if there's something urgent that AHRQ brings, we can put it in and deliberate it. But as far as I'm concerned, we've done that, but the invitation is open to AHRQ to bring it, just as it's open to anybody to bring anything to us.

MS. CARR: Well, you know, the other thing we were thinking of doing in the context of that kind of session was to hear from the Academy about the genomics roundtable that's being formed. Lyla Hernandez is here today. I don't know if, Reed, you would want the committee to hear a little bit more about that now or in June, either way. As I understand their timetable, June would be good.

She's right behind you if you turn to your right.

DR. TUCKSON: I just want to be sure that we end exactly on time, but we do have seven minutes, and we've completed your report, so we actually don't have anything else other than to let the committee members decide what they want to talk about for six minutes.

Can you give us a quick tease on it? Please, and we appreciate your being here. Thank you.

MS. HERNANDEZ: Hello. The Institute of Medicine, in cooperation with the Division of Earth and Life Sciences at the Academy, is convening a roundtable. A roundtable is an activity that is very different from the kinds of committee studies, a report of which you heard today. Roundtables never issue recommendations. They bring together people who would not normally be able to serve together on an Academy committee because they would be perceived as having conflict and bias.

So, for example, the roundtable could bring together NIH, FDA, pharmaceutical companies, genetic technology companies to sit in a room, talk about things, have those conversations be off the record and not open to the public, and the way we can do that is to not issue recommendations.

So this roundtable is going to be focused on translating genomic-based research for health. I think you have a description in your packet about the kinds of topics that we might address, some of which you have been talking about today and are concerned about, clinical utility, validation of clinical tests, education of providers, the workforce issues, ELSI issues.

We're very interested in making sure that we don't duplicate or in any way cause problems for the

Secretary's Advisory Committee. We're very much in contact with Sarah and hope to continue to work with you.

That's kind of generally an overview. It's probably not as much as you'd like to hear.

DR. TUCKSON: First of all, thank you, and thanks for being here and sitting through the whole meeting. Can you send us some background stuff that can be distributed with our next mailings to our committee?

MS. HERNANDEZ: Absolutely, yes.

DR. TUCKSON: So that we can see it and see the chart or the charge? Who is the chair?

MS. HERNANDEZ: The chair is Wylie Burke.

DR. TUCKSON: My gosh, formerly from our original committee and ubiquitously wonderful.

MS. HERNANDEZ: So far she's the only member.

(Laughter.)

DR. TUCKSON: And there's great disagreement among the committee.

(Laughter.)

MS. HERNANDEZ: The members will be -- those who sit on the roundtable are those who contribute to the sponsorship. So, for example, Affymetrix, UnitedHealth Care, GSK, FDA, Human Genome, VA, CDC, Genomic Health have all agreed to sponsor, so they'll all have a seat on the roundtable, and we're continuing to contact others.

DR. TUCKSON: Thank you very much.

Let me, before we close out, ask the members, this is your committee, is there any issue that has not been discussed, any observations, anything that anybody on the committee wants to state? We have time. So does anybody have anything on their mind at all that you want to raise?

(No response.)

DR. TUCKSON: I think they want to go home.

Listen, thank you all, and Sarah and team, you guys are terrific. Great staff support. Thank you all. See you next time.

(Whereupon, at 3:27 p.m., the meeting was adjourned.)