U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Seventh Meeting

Wednesday,
June 15, 2005

Grand Ballroom Salon D
Marriott Bethesda North Hotel and
Montgomery County Conference Center
5701 Marinelli Road
North 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. (appointment pending)
Hawaii State Genetics Coordinator
Hawaii Department of Health Genetics Program
741 Sunset Avenue
Honolulu, HI 96816

Cynthia E. Berry, J.D.
Partner
Powell Goldstein Frazer & Murphy
1001 Pennsylvania Avenue, N.W., 6th Floor
Washington, D.C. 20004-2582

Chira Chen (appointment pending)
Staff Research Associate II
Life Sciences Division
Lawrence Berkeley National Laboratory
One Cyclotron Road, 84-171
Berkeley, CA 94720-8268

James P. Evans, M.D., Ph.D. (appointment pending)
Associate Professor of Genetics and Medicine
Department of Medicine
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7624

Kevin T. Fitzgerald, S.J., Ph.D. (appointment pending)
Dr. David P. Lauler Chair in Catholic Health Care Ethics
Research Associate Professor
Department of Oncology
Georgetown University Medical Center
Building D, Suite 236
4000 Reservoir Road, N.W.
Washington, D.C. 20057

IN ATTENDANCE:

Barbara Willis Harrison, M.S.
Certified Genetic Counselor and Instructor
Division of Medical Genetics
Department of Pediatrics
Howard University College of Medicine
Box 75, 520 W Street, N.W.
Washington, D.C. 20059

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

Julio Licinio, M.D. (appointment pending)
Professor of Psychiatry and Medicine/Endocrinology
Neuropsychiatric Institute
David Geffen School of Medicine at UCLA
3357A Gonda Center
695 Charles Young Drive South
Los Angeles, CA 900095-1761

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

Edward R.B. McCabe, M.D., Ph.D.
Professor and Executive Chair
Department of Pediatrics
David Geffen School of Medicine at UCLA
Physician-in-Chief
Mattel Children's Hospital at UCLA
10833 Le Conte Avenue, 22-412 MDCC
Los Angeles, CA 90095

Huntington F. Willard, Ph.D.
Director
Institute for Genome Sciences and Policy
Vice Chancellor for Genome Sciences
101 Science Drive, CIEMAS 2379
Duke University
Durham, NC 27708

IN ATTENDANCE:

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

Ex Officio Members

Administration for Children and Families

Martin Dannenfelser
Deputy Assistant Secretary for Policy and External Affairs
Administration for Children and Families
370 L'Enfant Promenade, S.W., Suite 600-W
Washington, D.C. 20447

Centers for Disease Control and Prevention

Muin J. Khoury, M.D., Ph.D.
Director
Office of Genomics and Disease Prevention
Centers for Disease Control and Prevention
4770 Buford Highway, MS K-89
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

Ellyn Beary
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20889

Department of Defense

Colonel Martha Turner, USAF NC, Ph.D.
USAF Surgeon General's Consultant for Medical Ethics
U.S. Department of Defense
Preventive Medicine and Biometrics
International Health Specialist Program
Uniformed Services University
4301 Jones Bridge Road
Bethesda, MD 20814

IN ATTENDANCE:

Department of Energy

Daniel Drell, Ph.D.
Biologist
Life Sciences Division
Office of Biological and Environmental Research
Department of Energy
1000 Independence Avenue, S.W.
Washington, D.C. 20585-1290

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

Equal Employment Opportunity Commission

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

Federal Trade Commission

Matthew Daynard, J.D.
Senior Attorney
Bureau of Consumer Protection
Division of Advertising Practices
Federal Trade Commission
601 New Jersey Avenue, S.W., Room 3221
Washington, D.C. 20580

Food and Drug Administration

Joe Hackett
Food and Drug Administration
2098 Gaither Road, MSC HFZ 440
Rockville, MD 20850

IN ATTENDANCE:

Health Resources and Services Administration

Sam Shekar, M.D., M.P.H.
Assistant Surgeon General
Associate Administrator
Bureau of Primary Care
Health Resources and Services Administration
4350 East-West Highway, 11th Floor
Bethesda, MD 20814

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

Julia Gorey, J.D.
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
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985

C O N T E N T S

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P R O C E E D I N G S (8:35 a.m.)

DR. TUCKSON: Good morning. Let me thank everyone for coming and welcome everyone to this meeting of the Secretary's Advisory Committee on Genetics, Health, and Society.

This is our seventh meeting and, quite frankly, I'm very proud of the work that we collectively have done over the life of this committee. Having said that, we have much more work ahead and a great deal of work to do today and tomorrow.

The public was made aware of this meeting through notices in the Federal Register as well as announcements on the SACGHS website and listserv.

Today is actually somewhat of a sad day for us because three of our key members are leaving us in their official capacity as members, but hopefully we will have access to their input both informally and formally. But let me thank our colleagues Ed McCabe, Barbara Harrison, and Joan Reede for all they have done, and we'll have an opportunity later to more formally thank them.

We are also happy today that there are some new members that have joined us.

Let me welcome Ms. Sylvia Au. She joins us from the Hawaii Department of Health, where she is the state genetics coordinator. She is a board-certified

genetic counselor and current president of the Coalition of State Genetics Coordinators.

Second, Ms. Chira Chen joins us from the Lawrence Berkeley National Laboratory at the University of California, San Francisco, where she is a staff research associate. Ms. Chen is a representative of the San Francisco Advocacy Core, a volunteer group that shares the patient's perspective with breast cancer researchers at UCSF. She will be serving as one of the committee's two consumer representatives, and we're very pleased about that.

Dr. Jim Evans is from the University of North Carolina, where he is associate professor of medicine in the Department of Genetics and Medicine. He is also the director of Cancer Genetics Services at the University of North Carolina.

Finally, Dr. Julio Licinio joins us from the University of California, Los Angeles, where he is associate program director of the UCLA General Clinical Research Center and he is senior research scientist at UCLA's Neuropsychiatric Institute. He is a network scientist in the Pharmacogenetics Research Network, a nationwide research effort that is sponsored by NIGMS and other NIH components.

Sylvia, Chira, Jim, and Julio, please feel free

to stop us and ask questions to either your fellow committee members or me. You are not expected to knock our socks off the first half-hour of the meeting. Don't be anxious if you're wondering, "How did I get on this committee and what are they expecting from me? I don't understand all this. What's the history of all this?"

That's okay, because Muin Khoury has been here forever, and I don't think he understands all of it.

(Laughter.)

DR. TUCKSON: And he was on the last committee, too.

I think one thing that Ed McCabe has taught me, and he has taught me many things as he has chaired both this committee and the predecessor, is that what's most important for us is that we develop the relationships between all of us because we have to depend on each other for judgement and guidance, both in the meeting and outside of the meeting.

So take your time and relax. We want this to be an enjoyable opportunity for all of you, and we thank you all for joining the committee.

Our new members, by the way, will be participating in the meeting as ad hoc members while the processing of their appointment papers is completed, and their complete bio sketches can be found at Tab 2 of your

briefing folders.

Joan Reede will be joining us tomorrow. Chris Hook, Joe Telfair, and Kim Zellmer are unable to attend this meeting.

We have some new faces among our ex officios. Dr. Barry Straube will be here as the ex officio member from CMS. He'll be here shortly.

Ellyn Beary joins us today representing the Department of Commerce. Ellyn? There you are.

Julia Gorey joins us today representing the Office for Human Research Protections.

Now, let me acknowledge the outside activities of two of our members. Joan Reede represented SACGHS at the NCHPEG meeting here in Bethesda in January and covered our work on education and training, and we thank Joan for that extra effort.

Cindy Berry represented us at America's Health Insurance Plans' meeting of their Chief Medical Officers Committee last week and covered our work on coverage and reimbursement and genetic discrimination, and Cindy, thank you for your important work there.

We've got one bit of housekeeping that I need to go through formally. At the end of the last meeting, Drs. Joe Boone and Stephen Groft gave us a presentation on ongoing efforts to improve access to quality genetic tests

for rare diseases. Unfortunately, there was not a quorum by the time their presentation was given. As such, I need, while all of us are here, for the record to review a couple of points that were made. Here's what they had to say.

Though individually these diseases are rare, rare diseases and conditions collectively affect a significant portion of our population. The majority of the 6,000 to 7,000 known rare diseases are considered genetic conditions, making genetic testing essential to the diagnosis and management of patients with these conditions. However, the development of tests for rare genetic diseases has not kept pace with the progress of our knowledge of the genetic basis of these diseases.

We were told about a conference that's being planned in September of 2005 in D.C. The goals of the conference are to raise national awareness of the growing public need to improve the availability, quality, and accessibility of genetic testing for rare diseases, and to promote development of multiple processes and models to enhance the translation of genetic tests from research to clinical practice.

The ultimate goals of their efforts are to improve health outcomes for individuals and families through access to quality rare disease tests, ease of access and third-party payment, usefulness of test results,

adequate follow-up systems, and education and support after testing is completed.

The conference in September will build on the success of an earlier meeting held in May of 2004 entitled "Promoting Quality Laboratory Testing for Rare Diseases: Key to Ensuring Quality Genetic Testing for Rare Diseases." At that meeting, recommendations were developed by multidisciplinary experts and participants to begin to address this important aspect of health care.

With that as a summary, are there any questions or further discussion on that bit of past history before we proceed to review this meeting's agenda?

(No response.)

DR. TUCKSON: So having read that into the record of what happened with a very important presentation, let's look now to what we intend to accomplish today and tomorrow.

As you recall, and as you see on the following slide, we have listed the 12 issues that we first organized ourselves around as a committee. We identified and then prioritized them to devote various levels of attention for them. The slide notes where we are now in the process. This is especially, I think, useful not only for the new members, but also for all of us.

This, again, is our roadmap, and I want to, at

least as your chairman, make sure that we are always aware of where we are on the roadmap and whether we are meeting our targets and our deadlines.

Now, that may be hard for some of you to read, so feel free to get up and look at it more carefully, but what that basically says is that in keeping with our strategic plan, we will be considering in-depth at this meeting two of our high-priority issues, coverage and reimbursement of genetic tests and services, and pharmacogenomics. We will also hear updates on three other topics that are important to us: genetic discrimination, direct-to-consumer marketing of genetic tests and services, and large population studies.

You will recall that the committee deferred consideration of the patents and access issue until the National Academy's Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions issues its report. That report is expected to be completed later this summer. The committee will receive that report as soon as possible, and then we will invite a representative from the NAS committee to update us on the findings and recommendations at our October meeting. So this issue is being dealt with safely in the process, and we need to do nothing further until October.

We will start this meeting, our seventh, with

an update on the genetic discrimination package that was transmitted to the Secretary and a briefing on the status of pending legislation in Congress. Related materials can be found in Tab 3 of your briefing books.

Following the genetic discrimination update this morning, we will be briefed about the Secretary's response to the committee's letter on direct-to-consumer marketing of genetic tests and services, relevant agency activities, and FDA's role in the oversight of direct-to-consumer advertising of genetic tests, which is found in Tab 5.

We will consider next steps to be taken with regard to the issue of large population studies. That's going to be a very, very important and interesting conversation. It is unfortunately only a half hour. So one thing I really want to make sure is if any of you have any stuff that you've got, one little small thing that you have to do where you may have to step out or something, don't miss that half hour. It is a very key one. We are going to need you really focused on that, because we're going to have to be very specific about some guidance, and we don't have a lot of time to give that guidance to our task force. So I want to really highlight this is an important part of this meeting.

We will spend this afternoon completing our

work on coverage and reimbursement, in which we have spent a substantial amount of time over the past year. We will consider the numerous public comments received, and we will finalize the report and the recommendation. We will finalize the report and recommendation. We will finalize, because Cindy Berry will lead us through that.

Let me say on this one, we are going to be focused in our conversation. We're going to listen very carefully to each other. We practiced this a lot last time. We're really good at listening to each other and not going off into the wild blue yonder, painting outside of the lines with all kind of intellectual discourse. We're going to stay in the lines, and we're going to run this thing through and get to a consensus. So I'm very confident about this one.

Tomorrow we will focus on another one of our high priority issues, and that's pharmacogenomics. The Pharmacogenomics Task Force, with excellent support from SACGHS staff -- and in particular our Fay Shamanski has done an outstanding job of putting together a very informative session tomorrow to give us a solid foundation moving forward with our work on this topic, and our goal will be to determine how to proceed with the development of a report and recommendation to the Secretary on this topic.

Public comment sessions are scheduled for both

days. One of the things our new members will find, this is a relentlessly open process. We spend and benefit from very significant input always from the public. We are always glad to be able to take time to do that.

At 1:00, right after lunch, we will hear from the public. Individuals who would like to provide testimony and have not already signed up should do so at the registration desk.

A final reminder. Members and ex officios who would like to order lunch, which is fairly important, do so at the table at the registration desk no later than 9:00 a.m, or else.

Finally, as I turn to Sarah for a few reminders about the rules governing us as special government employees, let me just say one thing, Sarah. You and your team are performing spectacularly. The amount of effort that goes into staffing this committee is extraordinary. The number of late night phone calls where people can't get home and the number of hours we are pulling staff is just extraordinary. I just want the committee to be well aware, and hopefully whoever your boss is is listening, and I'll make sure they find out, but this is an extraordinary staff, and we are well served by you and all of them.

MS. CARR: Thank you very much for that. I can't take any credit. I don't do any of the work,

actually. Amanda Sarata, Suzanne Goodwin, and Fay Shamanski do it all, and this summer we also have a summer intern. Abby Rives is here with us, so we're putting her to work as well. But thank you very much, Reed.

I'm going to remind the committee about the conflicts of interest rules that you all have to follow. Because you are appointed as special government employees, even though you are special, you are obliged to follow the rules of conduct that apply to regular government employees.

These rules are outlined in a document called "The Standards of Ethical Conduct for Special Government Employees of the Executive Branch." Each of you received one of these books when you were appointed to the committee. I'm going to just highlight three of the rules today.

The first one is conflicts of interest. Before every meeting, you provide us with information about your personal, professional, and financial interests. Information we use to determine whether you have any real potential or apparent conflicts of interest that could compromise your ability to be objective in giving advice during committee meetings.

While we waive conflicts of interest for general matters, because we believe your ability to be

objective will not be affected by your interests in such matters, we also rely to a great degree on you to be attentive during the meetings to the possibility that an issue will arise that could affect, or appear to affect your interests in a specific way.

In addition, we have provided each of you with a list of your financial interests and covered relationships that would pose a conflict for you if they became a focal point of our deliberations. If this happens, we ask you to recuse yourself.

The other rule I want to talk about briefly is the Emoluments Clause. The Emoluments Clause prohibits you from being employed by or accepting emoluments from a foreign government, including political subdivisions of a foreign government, such as foreign universities that are government operated. An emolument includes salary, honoraria, transportation, and per diem.

The restriction on accepting gifts extends to your spouse and dependents, and it also applies at all times during your appointment, not just during our meetings. These restrictions are constitutional and are not matters of policy that can be waived or reconsidered.

The last rule I want to talk about is lobbying. Government employees are prohibited from lobbying, and thus, we may not lobby. Not as individuals, and not as a

committee. If you lobby in your professional capacity, or as a private citizen, it is important that you keep this activity separate from the activities associated with our committee.

Just keep in mind that we advise the Secretary of Health and Human Services, not the Congress. I want to thank you for being so attentive to the rules. It is very important that we do so, and I appreciate it.

DR. TUCKSON: Great. Thank you.

By the way, in that emoluments part, was that part also about foreign travel?

MS. CARR: Yes. Yes, and I should have said that. In your table folders is a little summary of the emoluments clause. So if you have any questions about it, you can refer to that. If you have any other questions that aren't answered by this, our committee management officer, David Alperin, is here, and he can answer questions of a more specific nature.

DR. TUCKSON: So don't spend a lot of time on it this second, but I was caught a little off guard as well on this foreign travel business. In fact, I didn't even know about it until I did some foreign travel that was paid for by, or requested to be paid for by another government.

So there are some very technical parts of this rule, and you've got to be careful about it. Anyway, I

just wanted to make sure that you all saw that. Look at it, but not now, because now we are into the heart of the meeting.

For those new members of the committee, the number one issue that we have identified as being most important for the life of this committee has been the effort around the appropriate protections of genetic discrimination in employment and health insurance. This has been a real key focus. We put a tremendous amount of our energy on that.

To give us an update on genetic nondiscrimination legislation and where efforts are, let me turn to Agnes Masny.

MS. MASNY: Thank you, Reed.

I also would like to take this opportunity to once again thank the Committee on Genetic Discrimination, as well as to all the committee members for all of their input. Most specifically, to Sarah and to her staff, and Amanda Sarata, who has been exceptionally helpful in pulling all of these materials together that you're going to be hearing about. Most importantly, to thank the public for their continued input that has been so helpful in directing us on this important issue.

So what I'm just going to do, we're going to briefly just go over sort of where we are to date with what

has been happening in this whole area of genetic discrimination. I'll give you an update on some of the recent developments that include the correspondence and what has been sent to Secretary Leavitt, as well as to a brief legislative updating of what is happening in the House.

Then we're going to have a presentation by Peter Gray on the legal analysis that was requested by this committee to look at the current legislation, what exists and where potentially there are gaps. Then we're going to have a legislative briefing from Jaimie Vickery. She is from the staff representative Judy Biggert's office. Then we'll have a committee discussion to see what further things we need to do as a committee to move this forward.

The task force members have been myself, Cindy Berry, Barbara Harrison, Debra Leonard, Reed Tuckson, Emily Winn-Deen, Joann Boughman, Robinsue Frohboese, Peter Gray, Tim Leshan, and Mildred Rivera.

So with regards to the congressional developments, the Genetic Information and Nondiscrimination Act was introduced to the House in March. This was a bill that was sponsored by representative Judy Biggert, and co-sponsored by Bob Ney, Anna Eshoo, and Louise Slaughter, and has a total of 101 co-sponsors.

What has happened is that after the bill was

introduced, it has been referred to three subcommittees. One, to the Energy and Commerce Committee, second to the Education and Workforce Committee, and third to the Ways and Means Committee. The Education and Workforce Committee has also referred it to a subcommittee on Employer and Employee Relations.

The bill that was introduced into the House is very, very similar to that of what was passed by the Senate, but it differed in only one way. There were some provisions in the Senate bill that addressed and potentially would amend the internal revenue code. So these have been omitted from the House bill.

These were measures, though, that only affected church plans. So there is some thinking that at any point in the future, they could be put back in, but currently they have been omitted. We'll hear more detail, of course, from Ms. Vickery regarding the legislative update.

So onto the correspondence that has been sent on to Secretary Leavitt. After our last meeting, we drafted and sent on then another letter to the Secretary. That was included in your briefing books. There are also four enclosures that were sent on. One was the compilation of the public comments. We wanted to make a telephone book, and we received our own telephone books in the mail, along with the DVD that was a compilation of the public

comments, summarized though and abridged, it wasn't the total version. We're going to actually view that in a few minutes.

Then there was a copy of the America's Health Insurance Plans' letter of February 22nd to Representative Boehner, and an analysis that we're going to be hearing about shortly of the current law. So this was all transmitted to the Secretary by the NIH Director.

So all of the public comments that had been received either by email, by mail, or people that presented here to the committee between September 24th and November 24th, as well as any research articles that were also sent to the committee, all of these were compiled in that book that were sent along to the Secretary.

The content of the letter, we were urging the Secretary of course to exert his influence and leadership to bring about enactment of federal genetic nondiscrimination legislation. In the letter, we reviewed some of the stakeholder's perspectives. That was the perspectives of the patients, the general public, and the Coalition for Genetic Fairness.

In brief, we summarized the deep-seeded fears that the public has about potential misuse of genetic discrimination. Health care decisions being shaped by fear rather than by best medical practice, patients who are

seeking genetic testing outside the formal health care system, patients requesting that the results be kept out of medical records, and opting for anonymous testing, or potentially even foregoing testing that could actually prevent disease. The concerns about the lack of specific federal protection against genetic discrimination was also summarized in that letter.

We also pointed out the perspective of some of the other stakeholders and consumers, such as AHIP and the Chamber of Commerce, noting that these are complex issues and deserve further analysis. So we recommended that the Secretary meet with any key stakeholders and groups that were interested to advance this consensus building regarding genetic legislation.

Lastly, the Secretary's letter gave a summary conclusion about the analysis of the current law. The goal for including this analysis of the law was to inform the Secretary and provide a debate around the claims that the current law provides adequate protection against genetic discrimination.

So we specifically wanted to look at and analyze the law and identify if there were, and point out where there were potential gaps. So to date, in summary then what was said to the Secretary was that no federal law directly addresses the issues raised by the use of genetic

information. The current law and court decision does leave substantial gaps in coverage, and offers inconsistent and uncertain safeguards. The current avenues for relief are uncertain and likely to lead to confusion, and as well, maybe costly litigation.

So from the perspectives of the public regarding genetic discrimination, we put together the compelling testimony in an abridged version of the public from our October, 2004 meeting. We are actually going to view that now. But before we do, I just wanted to credit and thank those people who were instrumental in putting this DVD together.

That's Scott Tuddenham and Peter Tuddenham from WebConferences.com, Larry Thompson from the National Human Genome Research Institute, and Alvaro Encinas from Medical Arts at the NIH.

(DVD played.)

MS. MASNY: I think that this DVD is as compelling in its shorter version as it was for the testimony that we heard that day. I think that it was done extremely well. Later in our discussion, we can look at what we'll be able to do even with the DVDs, because more than one copy of course of what was sent to the committee members, there have been 150 copies, the same number that matches all the members of the House, so that we could look

at what we might want to do with these DVDs.

So I again want to thank the committee, because I think this sort of shows almost the fulfillment and the culmination of so much hard work regarding this issue. I think it is very compelling. It says that we are moving this issue on, and hopefully we'll have some positive outcomes from all the work of the committee.

So next what I'm going to do is turn the podium over to Peter Gray, who is going to give us the summary of the legal analysis. This was the analysis that was sent onto Secretary Leavitt.

DR. TUCKSON: As Peter gets ready, let me introduce him. Peter is from the Equal Employment Opportunity Commission. He, as you heard, will review the legal analysis that we commissioned.

Now, understand and I remind you all that there was a very important point that Agnes made. That is that we have had some pretty intense discussions with all of the stakeholders who care about this issue. One of the elements that really kept popping out from some constituencies was do you really need new legislation? Why doesn't the existing legislation solve the problem? Why reinvent all of this?

I want you as a committee also to understand. Not only did you see this video here which we are doing,

but we are an advisory committee, but we are an active advisory committee. We are engaged. So the conversations that we have had with different stakeholders in all of this have been to elicit and elucidate positions, but also quite frankly they have been trying very hard to try to see if there was common ground, and to see where that common ground is.

I want to be very clear to the committee. We are not sort of sitting back on this. We are really trying to find common ground. Out of that need, we're trying to determine common ground comes this idea of well, is current legislation adequate. So that's the context for this analysis, which was prepared by Mr. Robert Lanman, a consultant to NIH Office of Biotechnology Activities. Mr. Lanman has subsequently retired from HHS after three decades of service. So he is not able to be here today, but we are really glad that Peter consented to present the analysis on his behalf.

Let me also acknowledge the agencies with jurisdiction over the laws that were analyzed, namely EOC, DOJ, Department of Labor, and HHS, CMS, and the Office of Civil Rights also reviewed this analysis for technical accuracy. So we thank all of you around the table who had a role in that also.

Thank you, Peter.

MR. GRAY: Good morning. Let me just start right at the outset with just a couple of little caveats. As Reed mentioned, I was asked to present the report that Mr. Lanman had prepared because he was unable to be here.

What I know about the health insurance part of this, what I know about health insurance is that I have some.

(Laughter.)

MR. GRAY: Beyond that, I really don't know that much, but there are folks here who can provide you with some assistance if you have questions following my presentation.

Second, let me note that neither the contents of the report, nor my participation or my presentation of it, especially the sections concerning employment discrimination should be in any way seen as the EEOC's endorsement of the report conclusions.

During the question and answer, I can explain it. Actually, during the course of the presentation, the report does reflect the Commission's views on the legislation. I will reflect those at that time.

The report begins by noting that the bill that passed the Senate and is pending in the House cited gaps in the protection for persons in the area of health insurance and employment. These gaps have become especially

significant over the past several years because of the advances in the science of genetics and the potential that these advances present in the area of medical progress.

The bill notes specifically that deciphering of the human genome opened new opportunities for medical progress. The report also reflects concern among the public that the fear regarding the loss of privacy with respect to genetic information and the effect that that fear is having. Of course the DVD we just saw sort of I think drives home that point.

In this regard, I would note that some of you may have seen a couple of weeks ago, there was a new study printed in the May/June 2005 issue of Genetics in Medicine, reporting that 40 percent of almost 87,000 study participants in this particular study raised concern about genetic testing and the potential loss or inability to obtain health insurance as a key concern.

The report itself if you look at it, contains discreet sections addressing federal law and health insurance, privacy of medical information, state law, federal employment nondiscrimination law, constitutional protections, and protections geared for federal employees contained in Executive Order 13145 that President Clinton signed in February of 2000.

The section on health insurance covers HIPAA,

the Social Security Act, and Title III of the ADA. The section on federal employment law covers Title I of the ADA, as well as Title VII of the Civil Rights Act of 1964.

We're going to first move into the health insurance part of this. One of the interesting facts noted in that recent Genetics in Medicine study regarding the concerns of the public relative to genetic information in health insurance is that the fear of discrimination is lower among persons in the U.S. over 65 and among Canadians generally. One segment of the study included a large number of Canadians.

The authors of the study suggest that this may be because of Medicare for U.S. seniors and national health insurance for Canadians where coverage is not at issue. For most of the rest of us, as the report and this slide note, health insurance is employment based. The report notes about 60 percent of the U.S. population is covered by employer-provided health insurance. Of those who are insured by employers, most of these plans are covered by ERISA, and by the Health Insurance Portability and Accountability Act.

The report notes that one basic purpose of HIPAA was to ensure that in some circumstances, individuals who change employers, and thus health coverage, should not have new coverage denied or restricted because of a

preexisting condition. In other circumstances, the report continues, an employer would be permitted to impose limited restrictions on coverage, limited in terms of time based on preexisting conditions that fell within certain noted parameters.

The report further makes plain that under HIPAA, group health plans and group health insurance issuers cannot impose a preexisting condition exclusion on the basis of genetic information unless there is an actual diagnosis of the condition related to the information.

In the example noted in the report, an individual who tests positive for the mutation in the gene linked to breast cancer would not be deemed to have a preexisting condition in the absence of a diagnosis of breast cancer. As this slide notes, the report includes a reference to the HIPAA rule limiting covered plans from establishing eligibility requirements for individuals or charging specific individuals more based on genetic information, though nothing bars establishment of a group rate based on or in part on genetic information.

The report states that the HIPAA provision in the small group market prohibit an employer from refusing to renew a policy based on genetic information about an enrollee or potential enrollee, but it would not restrict an issuer from taking genetic information into account when

determining the employer's overall premium.

The report states that an insurer could require that an individual take a genetic test as a condition of coverage, not to deny coverage to any individual, but for the purpose of determining the premium to charge the group and its members.

In the individual market, HIPAA guarantees that certain individuals who have lost group coverage have the opportunity to purchase individual coverage without an exclusion based on genetic information. As I noted before with regard to the individual market, the report indicates that although the issuer can't deny or refuse to issue a policy, it can set the premium based on whatever genetic information it obtains.

Some of what HIPAA does now, the report focuses on gaps in HIPAA coverage, or protection. First, as noted here, HIPAA doesn't prevent a group health plan from requesting, purchasing, or otherwise obtaining genetic information about an individual, or requiring an individual to submit to a genetic test as a condition of coverage.

On the basis of genetic information, the information obtained, charging all members of the group higher premiums. The report states that charging higher premiums could make health insurance too costly for small employers, and thus have the same effect as denying

coverage.

Other gaps noted according to the report. HIPAA protections do not apply to small groups. From what the report notes, these are plans with fewer than two participants who were current employees on the first day of the plan year. Nor does HIPAA apply to plans that cover retirees only, or to plans that elect under HIPAA to be exempt from the nondiscrimination requirement. I'm going to leave it to others to explain later if you need or want an explanation of what plans may make this election to be exempt from these particular requirements.

The report identifies as a significant gap the fact that HIPAA nondiscrimination provisions do not apply to individual health insurance policies. Even though 10 to 15 percent of those covered have such policies, and even though the number of Americans seeking insurance outside of employment is likely to increase rather than decrease in the future.

HIPAA does, of course, guarantee that certain individuals who lose group health coverage have the opportunity to purchase individual coverage without any preexisting condition exclusion, which I mentioned earlier. But of course as I also mentioned, it doesn't prohibit issuers from taking health factors, including genetic information, into account when setting premiums.

The report looks at the Social Security Act and notes that federal law sets national standards for Medicare, supplemental, or Medigap policies which are health insurance policies that cover out of pocket costs under Medicare such as coinsurance and deductibles, as well as specific costs not covered by Medicare.

The report states that Medigap issuers are prohibited from conditioning the issuance or effectiveness of a Medicare supplemental policy or discriminating in the pricing of the policy because of health status claims experience receipt of health care or medical condition of the applicant. But the report notes that unlike HIPAA which expressly includes genetic information within the coverage of the term "health information," that is not the case here.

The report suggests that there is some ambiguity with respect to whether, and if so, to what extent a Medigap policy might limit access to and use of genetic information.

Title III of the Americans With Disabilities Act provides that no individual shall be discriminated against on the basis of disability and the full enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any public accommodation by any person who owns, leases, or leases to or operates a place of

public accommodation.

Places of public accommodation include insurance offices. But according to the report, the real issue is not Title VII coverage of the physical location where insurance is written, but rather the content of insurance policies, what is covered by the policies.

Although there are federal court cases and some comments by legal scholars arguing that Title III requires equal access not only to insurance offices, but also the terms included insurance policies, prevailing sense is that ADA does not cover insurance policies.

As the slide notes, most of the federal appellate courts addressing this issue have ruled against coverage. Specifically, these include decisions from the 3rd, 5th, 6th, 7th, 9th and 10th circuits. Only the 1st and 2nd have ruled the other way. Apparently the 4th, 11th, and the D.C. Circuit have not yet ruled. But the trend clearly is against coverage.

The report notes that even if coverage might be included within Title III's protection, there is a separate provision in the ADA called the safe harbor provision which arguably would limit the reach of the ADA. According to the report, the safe harbor provision means that Titles I through IV of the ADA are not to be construed to prohibit or restrict an issuer from underwriting risks, classifying

risks, or administering risks that are based on or consistent with state law.

A key requirement of the safe harbor provision is that the terms at issue not be deemed a subterfuge to evade the purposes of the ADA. Most courts deciding cases under the safe harbor provision have taken a broad view of what the safe harbor provision means. Some courts have even allowed issuers of insurance provisions that even lack actuarial justification.

The argument is that so long as the provision in the insurance policy was adopted before passage of the ADA, one can't argue that the use of that particular provision constitutes a subterfuge to evade the purposes of the Act. On the flip side, the contrary argument is that the current use of a provision that does in fact evade the purposes of the Act should be deemed violated because of the present use of that provision. But that argument has not gained currency with the courts.

The report looks at the HIPAA privacy rule. It is a relatively new rule. Final regulations were issued just a couple of years ago. The rule establishes the minimum national standard for protecting the privacy of protected health information. The definition of health information under the rule is quite broad, covering all individually identifiable health information, which

encompasses genetic information, including family history.

A covered entity is defined as including a health plan, a health care clearing house, health care providers, and whoever transmits any health information in electronic form with a transaction covered by the HIPAA regulations.

The report suggests that there are some gaps, though, in the coverage of the HIPAA privacy rule. Basically the privacy rule does not bar the use of any medical information, including genetic information. Rather it merely sets the standards for getting access to the information.

So that in this regard, the report notes that health information which could include genetic information is available for use in underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits.

The report also notes that the privacy rule does not limit employer access to health information or genetic information. Under the privacy rule, once protected health information is lawfully provided to an employer, that information becomes an employment record and is no longer considered to be protected health information.

The report looks at state law. It notes that

there are many different state laws providing all sorts of differing levels of protection. The report identifies 47 states and the District of Columbia that restrict or limit the use of genetic information to determine health insurance rates or eligibility in group or individual insurance plans.

These laws vary in scope, and they vary in how they define genetic information. Some states, for example, exclude family medical history from their definition of genetic information. According to the report, the three states without specific health insurance protection are Mississippi, Pennsylvania, and Washington.

The report also notes that some states have enacted widely varying laws dealing with genetic information generally. Of these laws, the report notes that they treat genetic information differently, or most of these laws treat genetic information differently from other medical records. They focus on the information rather than on user or use. They rely on various measures to safeguard genetic information at different stages of its acquisition and retention, and they provide for greater individual control over personal genetic information through varying means such as consent requirements, rights of access, civil remedies, and property rights.

But the bottom line -- oh, and before I get to

the bottom line. One other point to remember with respect to these state laws is as I discussed with respect to the laws affecting insurance is that they also contain different definitions of what constitutes genetic information. Again, most of these laws include genetic tests and will not include family medical history.

So the bottom line is that different laws provide different scopes of coverage and protection and allow for different enforcement methods. So we could have 20 state laws and 20 different ways of enforcing 20 different levels of protection and 20 different ways of enforcing the law.

I'm going to move into the area of genetic discrimination and employment. I'll repeat my earlier caveat that I'm merely the presenter and not speaking as if I could, officially as an employee of the Equal Employment Opportunity Commission.

The report notes that as of August of 2004, 32 states have enacted laws restricting the use of genetic information in the workplace, and that nine states were considering such legislation. Most of these state laws establish greater protection for genetic information than for medical information generally. But again, as I have said now a couple of times, while these statutes do offer some protections in the workplace, there remains the

problem that they again have very widely differing scopes of protection and definitions. Many of these laws also do not encompass family medical history within the definition of genetic information.

As the report notes, and as we've heard earlier, there is no specific one federal law that directly prohibits or protects against genetic discrimination and employment. The main federal law that addresses issues relating to genetic discrimination is the Americans With Disabilities Act, specifically Title I of that act.

This slide sets forth the basic coverage of the statute, the three prongs of coverage. Prong one covers a person who has an actual disability, someone who is substantially limited in major life activity. Prong two is somebody who has a record of a disability. Prong three is an individual who is regarded as disabled.

Now, the report notes, and the slide notes, that the Commission, the EEOC, has interpreted the ADA as protecting against genetic discrimination. In this regard, the report cites to a 1995 EEOC compliance manual chapter in which the Commission elaborated on the definition of the term "disability."

In the compliance manual, we included an example regarded as discrimination that include the following facts. An individual applied for and was

conditionally offered a job, and was then given a medical examination, at which time a genetic profile revealed an increased susceptibility to colon cancer.

The individual currently was asymptomatic. The employer, seeing this medical report, then withdrew the job offer based on concerns about productivity, insurance costs, and attendance. The compliance manual notes that this would be considered a violation under the ADA under the "regarded as" prong of the statute. In the Commission's view, the employer was regarding this person as disabled.

The report also notes that the Commission settled its first case addressing genetic discrimination in 2002. This is in reference to a case that started in 2001 involving the Burlington Northern Railroad. I'm going to assume that most of you are aware of this case, and not discuss it here in any detail. Suffice it to say that it involved an employer secretly testing employees to determine whether they had a genetic predisposition to carpal tunnel syndrome.

As it turned out, the test that the employer was using only determined whether an individual had a rare genetic condition affecting 1 in 20,000 to 50,000 persons called hereditary neuropathy with liability to pressure palsy, HNPP. Apparently, carpal tunnel syndrome and one

form of HNPP share certain characteristics.

It was the Commission's position that this test was not job related or consistent with business necessity, the standard that is required to be used when conducting a medical exam of a current employee. As the slide notes, the EEOC and Burlington Northern eventually settled this case, so no court was required to look at, or to address the Commission's view with regard to the ADA's coverage.

Limitations. This slide discusses some of the limitations. Specifically it notes that the scope of the ADA has been narrowed since 1995, and particularly beginning in 1999 with respect to how the term "disability" has been defined.

In particular, the report notes three cases, one decided in '99, and one case decided in 2002 in which the court said that courts need to pay very special or careful attention to the person at the moment an employer makes an employment decision. Specifically it noted that the ADA uses the present tense to determine whether an individual is impaired, and if so, whether that person's impairment rises to the level of a substantial limit on a major life activity.

The key is that the language defining disability should be read as requiring that a person presently, not potentially or hypothetically, be

substantially limited in order to demonstrate a disability.

The report suggests that the upshot of these cases makes it unlikely that the Supreme Court would find that a mere genetic predisposition to disease or disorder would constitute a disability. A person who was asymptomatic would be unable to establish disability under prong one actual or prong two record, and in fact it might be hard for the person to further establish a prong three violation of regarded as.

As an employer would certainly argue, that they were taking actions against a non-disabled individual who might develop a future impairment, but they had no misconception with regard to his current status.

Other limitations. The ADA does not prevent an employer from gaining access to your genetic information. Specifically, and in this context, an employer is permitted when in the hiring process to get information. Once an employer makes a conditional offer of employment to an individual, the employer is permitted to conduct a medical examination of that employee. There is no limit at that point on the information the employer is allowed to obtain. No limit. So if an employer wants to spend lots of money, he can get every genetic test available.

There is a limit presently with respect to what an employer can do with that information. Under the

statute, an employer is limited with respect to making employment decisions based on medical information conducted in the post-offer phase of employment. But I will note this. Again, that where an employer withdraws a job offer to somebody who is asymptomatic based on the genetic predisposition, it is at least questionable, according to the report, whether the individual would be able to argue that he or she, or whether the employer considered that person, regarded that person as disabled when withdrawing the offer based on fear of future impairment.

As for current employees, the standard that exists to conduct a medical exam is that the exam has to be job-related and consistent with business necessity. Although it may be less likely that an employer would be able to meet this standard with respect to ordering a genetic test, it is not outside the realm of the possible. For example, during discussions that led to the adoption of the federal executive order for federal workers, some agencies argued that they should be allowed to conduct a genetic test of current employees if they plan to assign an employee to a remote location.

For example, to do a BRCA1 test, even of an asymptomatic employee before assigning her to a place where it would be hard for her to get medical care. This situation could arise in a situation where in the post

employment scenario, an employer gets genetic information and then based on that genetic information before it assigns somebody else where the employer could argue that it wanted to do a follow up exam. It might be hard to argue that that would be not job related.

The report addresses some of the more traditional defenses that are available to employers in ADA cases which are reflected on this slide. The report also notes that the EEOC has expressed support for legislation addressing genetic discrimination. Even though the Commission has and continues to argue that the ADA offers protections against genetic discrimination, Cari Dominguez, who sends her regrets and is unable to be here today, testified before the Senate HELP Committee in 2002, noting that the application of the ADA to genetic information is less than clear. Because it is less than clear, both individuals and employers need understandable rules so that they can be guided in the future with respect to how they handle and use such information.

The report looks at Title VII of the Civil Rights Act of '64 which prohibits discrimination as noted on the slide. The report notes that if an employer discriminates on the basis of a genetic condition that affects a discreet, protected group. Here, for example, people of Eastern European Jewish Ethnic background. This

use of genetic information would violate Title VII.

Similarly, the report notes that if the employer were to selected a specific protected group for genetic testing, say women only for BRCA testing, this would also violate Title VII. Title VII doesn't bar use of genetic information or testing. It just prohibits treating discreet groups differently with respect to that testing.

This slide on constitutional protection references a case that is discussed in your materials called Bledsoe v. the Lawrence Berkeley Lab. It's on page 20. In that case, they talked about federal constitutional protections. Again, you should note that federal constitutional protections are limited, in that it only applies to governmental action, and that there is a weighing that goes on between individual rights against the public health or other interests of the government in taking action. So it is quite limited.

Protection for federal employees, I referenced earlier. Executive Order 13145. It applies to federal sector workers. But enforcement of the Executive Order requires use of the Rehabilitation Act, in that there is no remedy for a violation of the Executive Order itself. So unless the conduct also is deemed to violate the Rehabilitation Act, the protections included in the Executive Order are not enforceable in a court.

In the report's conclusions, the report notes that there is no one federal law addressing access to and use of genetic information, that the laws that are out there that may be used have significant weaknesses and gaps in their coverage. In the absence of a federal law, we may enter a period of litigation using these different and divergent federal and state laws, thus spending a lot of money and a lot of time trying to figure out what kinds of protections these laws offer, and at the end of the day finding out that for all these costs and all this time, that there is little that protects against the use or abuse of genetic information.

I believe that after the next presentation there will be an opportunity for public comment, or for committee comment and discussion of the report.

Thank you.

DR. TUCKSON: Thank you very much for a very excellent presentation, and for a significant body of very great work.

We are very happy that we have been able to be joined today by Ms. Jaimie Vickery, who is a legislative assistant from the Office of the Honorable Judy Biggert, U.S. House of Representatives. As you've heard, Representative Biggert is the original sponsor of the House bill. It is very timely that we hear some perspectives

sort of from the Hill and how you all see where the status is.

Feel free to present either from your chair there or from the podium. Thank you very much for taking the time to join us.

MS. VICKERY: Good morning. Thank you for giving me this opportunity to speak. I'm very pleased to be here this morning. It's very nice to be able to get off the Hill. I feel like I've been chained to my desk and forgot what fresh air and sunshine feels like.

Let me warn you, first of all, I'm not a scientist. There is a reason I was a political science major and not a hard science major. So I'll leave the nitty gritty details of genetics to all of the scientists and researchers in the room, and focus on the political efforts to prevent genetic discrimination.

Now, as you know, my boss, Congresswoman Judy Biggert, along with Louise Slaughter of New York, Bob Ney of Ohio, and Anna Eshoo of California, has introduced H.R. 1227, the Genetic Nondiscrimination Act of 2005. Congresswoman Biggert sits on the House Science Committee, where she is the chair of the Subcommittee on Energy. This is the subcommittee that has jurisdiction over the Human Genome Project.

Now, I don't have to tell you all that the

sequencing of the human genome was one of the most significant scientific breakthroughs of the past century. The implications of this breakthrough are mind boggling. Because of the genetic testing made possible by this discovery, individuals can, for the first time, know their risk of developing more than 1,000 genetic disorders.

They can adopt better habits such as exercising, eating better, going to the doctor, or going to the gym to lessen the impact of their condition, and they can mentally prepare themselves and their families for what may happen down the road.

However, as we have heard today, the ability to predict disease through genetic testing and family history opens the door for discrimination, particularly in the employment and health insurance fields. When individuals are afraid that this information will be used against them or their families, they will not be tested. The research is not being used to its full advantage.

Some people have said that they wouldn't want to know. No doubt finding out that you or your child could suffer from a debilitating disease could be disconcerting. But this should be an individual's choice to make for themselves. The fear of losing their job or their health insurance shouldn't be a factor.

As we have just heard, existing laws, including

ERISA and HIPAA, are unclear on the topic, and are really no more than a patchwork. To be frank, they're Swiss cheese. This means that in order to protect an individual's genetic privacy, we have to enact legislation specifically prohibiting differential treatment on the basis of genetic information.

That is why it is so important that we get H.R. 1227 passed. Opponents of the bill say it's not necessary, that's it's a solution and need of a problem. But no one should lose their job or their health insurance before we enact legislation.

Specifically the bill prohibits employers or health insurance from making employment or coverage decisions based solely on someone's genetic information. The bill is very, very similar to the bill Louise Slaughter introduced in the last Congress. However, we realize that given the current political climate, a bill introduced by a Democrat probably wasn't going to go very far.

So she and her staff very graciously let Congresswoman Biggert take the bill. In keeping with this current political environment, we made a couple little changes to make the bill more business friendly, and to make it easier for Republicans to get on board. None of these changes substantially change the bill or take away any of the enforcement mechanisms.

The bill now places limits on the amount of damages a wronged employee can seek based on the size of the company, and contains protections against frivolous or opportune lawsuits. It also includes so-called water cooler gossip. If your office is anything like mine, everybody knows everybody's business, and it is not always true. There is nothing that your boss, as much as they try and control it, can do about it.

This is the exact same legislation that passed unanimously in the Senate, and is strongly supported by the Bush administration. So what is happening with the bill? Unlike the Senate bill which only went through the Health, Education, Labor, and Pensions Committee, the House version has been referred to three committees. Education in the Workforce, Energy and Commerce, and Ways and Means.

Because the nondiscrimination provisions apply to the Medigap insurance people can buy to cover what Medicare doesn't cover, Ways and Means needs to sign off on this bill. One tiny provision in the bill, and it goes to a separate committee.

However, the ranking member of the full committee, Charlie Rangel from New York, and the chair of the Health Subcommittee, Nancy Johnson from Connecticut, are both cosponsors of the bill, so I don't think we'll have any problems in Ways and Means.

I'll be honest with you. Like I said before, there are some in the business community that are opposed to this bill. Although the Education and Workforce Committee held a hearing on genetic nondiscrimination in July of last year, nothing more came out of it.

These business groups are afraid that this new legislation will set up a new regulation on how they do business, or that it will create an administrative burden. Let me assure you this is the last thing we want to do. Ms. Biggert is a member of the Education and Workforce Committee and a member of the Employer/Employee Relations Subcommittee that has jurisdiction over this bill.

She understands these concerns. We're trying to work with these business groups to address their concerns without taking away any of the guarantees of genetic privacy. Although these groups are still opposed, they're not nearly as adamantly opposed as they once were. So I'm cautiously optimistic that they will adopt a neutral stance and not work against H.R. 1227.

Right now we have 105 cosponsors. When you consider that there are 435 members of Congress, this means we've got nearly one quarter of them on this bill. However, the problem is that a majority of the cosponsors are Democrats. We've got 74 Democrats to only 31 Republicans. In the Republican controlled Congress, that

is not all that helpful.

This is a bipartisan bill, and we need the cosponsorship to reflect this fact. So right now we are focusing on getting Republican cosponsors. For a lot of members, it's a good way to show that they are pro-patient and pro-medical research without having to deal with this sticky stem cell issue.

It is also a good way for members with large genetic labs or biotech companies to show their support for their constituency in their districts. Ideally you'd hope members would get on this bill because it is a good bill and it's the right thing to do, but in reality, you've got to sell a bill as what it can do for a member. That's what we are trying to do.

Here is where you all come in. Now, I know it's sort of a delicate position because working for the administration, you can't really lobby for the bill, even though the White House does support it. I'd encourage you to let agency leadership, including Secretary Leavitt, know how important this bill is, and encourage them to encourage House leadership to get the ball rolling.

There has been two statements of administrative policy in both the 108th and 109th Congress, but we haven't heard much from the White House other than that. They're not getting real involved. So anything that the

administration can do to sort of kick leadership in the pants on this would be very helpful.

As you know, this issue has been around for quite some time. In fact, Congresswoman Slaughter has introduced this bill, or something very similar to it, in every Congress since 1997. This is the furthest we have ever come in the legislative process, but we've still got a long way to go. I'm confident this is the year we can finally do it and protect individuals' genetic privacy. We all know that these provisions are long overdue.

I know you've got a lot to fit in today, so I'll wrap it up. Once again, thank you so much for this opportunity to be here with you today, and thank you for all that you've done on this issue in bringing it to the forefront. I look forward in working with all of you in getting this bill passed.

Thank you.

DR. TUCKSON: Well, thank you very much. We very much appreciate your taking the time, and also your offer that we'll be able to be connected to not only you, but the Congresswoman as well.

MS. VICKERY: Yes.

DR. TUCKSON: I think now with that, if you could still please join us at the table still, we would appreciate it. The floor is open for some discussion.

By the way, I do want to say that we actually don't quite work for the administration. We are advisory to the Secretary, so that gives us a little more latitude. I'm glad that you sort of put that there so that we can underscore, particularly for the new members of the committee, again, that we are an advisory group to the Secretary.

There are certainly some constraints there, but there are multiple opportunities there. The floor is now open.

Ed, I see your hand.

DR. McCABE: First, I want to thank you for coming and presenting. Please take our thanks to your boss as well for sponsoring this bill. This is something that has run in the six years that I have been involved on advisory committees, it has been one of the top issues for both administrations and each of the Secretaries. Or at least we have taken it to each of the Secretaries. So please thank your boss for sponsoring this.

You gave us some guidance in terms of how we could help. The opposition, the opposition you said you think they may go neutral on this. Is there anything that needs to be done in terms of getting more support from appropriate business friendly groups to help with this?

MS. VICKERY: We are actually working with

those groups, like I said before, and they probably have about ten concerns. There are certain things that we are having to sit down and negotiate with them. There are some things that are not negotiable. It is a matter of finding something that people can live with on both sides of the aisle.

Basically our strategy right now is to get as many people on as we possibly can. The more people you have supporting this bill, the harder it is for groups to oppose it, politically and PR-wise. So that's our strategy right now, focusing in on bringing people in, any sort of constituency within their district of people who are affected by this.

It is very hard to say no to people from your district, and it's very hard to say no to sick people.

DR. TUCKSON: Yes?

DR. McCABE: As a follow-up to that, for those of us who are rotating off of the committee, when is our last day of service? Is it the end of this meeting? Okay. Thank you very much. Because I'm taking a mini-sabbatical. I have met the representative who is a Republican for the district in which I have a small business in Colorado. I may pay him a visit then as I start my sabbatical.

MS. VICKERY: Come see me, and we'll get you

everything you need to go in and meet with him.

DR. McCABE: Thank you very much.

DR. TUCKSON: Agnes?

MS. MASNY: As I mentioned earlier, one of the options that we have is we actually have 150 of the CD-ROMs of the testimony from the public. Maybe what we could do would be to identify the people that were previewed in this public comment, what areas they came from, and specifically send it to those representatives, and of course maybe to all the House members as well.

We can't send it, of course, but we can recommend that the Secretary of course send it onto them. But maybe we could highlight what areas those people who spoke, what areas they came from.

DR. TUCKSON: Great. We've got in the queue Francis, Emily, and Julio.

I just want to make sure, though, that Jaimie has been given a copy of the letters that we have sent to the Secretary already. If we have not, Jaimie, if you don't have those, I'm going to see if somebody has a handy copy somewhere around and they can hand it to you so that you can take it with you before you go.

Obviously we're thinking about now what is the next step. But I want you to know we have been pushing hard in that regard.

Francis?

DR. COLLINS: I would also like to express my thanks to Representative Biggert, and to you, Jaimie, for being here today to tell us about the status of this. Having worked on this issue, some of us for more than a decade, it is gratifying to see the activity that's going on this year with the unanimous vote in the Senate, and now the bill being introduced in the House, and at least assigned to committees, although I guess I'd like to hear a little bit more about your impressions about whether hearings are likely to happen. Without them, it is generally the conclusion that not much forward motion is going to be occurring.

I must say I'm deeply disappointed to see the opposition that seems to be largely responsible for the current logjam coming from the business community. After all, as pointed out in the nice presentation by Peter, a very large number of states have passed legislation that prohibit the use of genetic information in hiring, firing, and promotion. To our knowledge, there has been not a single instance where that legislation has led to frivolous lawsuits, which I think has been one of the community's concerns coming from the Chamber of Commerce and the National Association of Manufacturers.

So the evidence for this being a risk to their

business practices does not appear to be very compelling. The argument for the need for this is nicely outlined in the testimonies we heard here and reproduced on the DVD. From the public's perspective, it is really very compelling.

So I guess I had two questions. One is what is your estimate about the likelihood of hearings. The second relates to rumors that one has heard that perhaps the bill would have a better chance if the employment provisions were stripped out and it was reduced simply to a health insurance protection.

I just want to comment that I don't think that is what the public is looking for. If people are anxious about genetic information and how it might be used against them, employment is clearly a serious issue. It is not just about health insurance. I think that would be unfortunate to see that particular part of the bill lost in this particular shuffle. So maybe you could comment on whether that particular idea of recrafting the bill to limit it only to health insurance is something that's likely to have any legs at the moment, and as well if you could comment about hearings.

MS. VICKERY: To answer your second question first, there has been legislation introduced previously that was just health insurance. I'm not entirely sure that

that is something that Ms. Biggert and Ms. Slaughter are amenable to. From what we've heard, the insurance industry is not nearly as opposed to it as the business community. So it would be easier to do. But I guess it comes down to the question of do we want what we need, or do we want what we can do?

I think from everything that we've heard, the employment arena is where the problems seem to be cropping up. I think that we certainly need to address the employment issue as well.

To answer your first question about committees. From what I can tell, the committees are more open than they ever have been. Certainly Ed and Workforce had a hearing in July. It is hard to say what committees are going to do and what they're not going to do. A lot of it depends on what else is on the slate, and the timing.

All I can say is that we're working on this, and they seem to be more amenable to moving this bill than they have in the past.

DR. TUCKSON: Good. Thank you.

Let me just make sure that I understand also, Jaimie, in this regard. Is there any active discussion with the employment community, are there ways in which the bill can deal with their concerns regarding frivolous or unnecessary lawsuits? It is not even, as I understand

their position, we did a lot of work listening to them very carefully. They were very generous about their time and helping us to understand it.

As I understand their position, just as the public is concerned about the potential fear issues, they are concerned about the potential of frivolous lawsuits, which is important to their conduct of their activities.

Is there any sense of sensitivity to those concerns? Is there any way in which the bill might modify or in some way take into account those concerns?

MS. VICKERY: And that was something that was brought up with the Slaughter bill in the 108th Congress. If you look at the current bill 1227, there are some provisions in there. There are certain steps that have to be followed before you can take a claim to court.

Also, it is broken down into three categories, the amount of awards that can be received. There is a limitation on awards based on the size of the company. So obviously if you have a problem with IBM, IBM is going to be able to take care of that claim much more than a mom and pop bakery or something.

We are still open to negotiating with them. Like I said before, it's a matter of finding that balance between still having some effective enforcement mechanisms and some teeth to the law, and at the same time, finding a

way to make it work for business people.

DR. TUCKSON: Thank you.

Emily?

DR. WINN-DEEN: So I think one of the things this committee has tried to do in the past to move this legislation forward was to understand what the objections were. What we had heard previously was there were two objections.

One was that it's not really happening. We have testimony, we have a DVD. Please use these tools. The other comment we heard was there is adequate protection under the law. We commissioned a report to really review that in a very analytical way to look at what actually are the existing protections, and to create a set of data that could be presented, again, in a very analytical way to individuals who are making those kind of just brush it off kind of comments, we don't need to be wasting our time with this. There are other things to be taken care of.

Are there any additional points that we could address very specifically through the mechanism that this committee has, which is basically public comment and the ability to commission special reports of sort of the state of the state that would be helpful at this point in time to move the legislation forward?

MS. VICKERY: I think that report is going to

be phenomenally helpful. Again, like you said, again and again, people are saying there are existing protections in law. It is HIPAA. HIPAA takes care of it. ERISA is fine. There are already protections in the law.

But to be able to present them in a very concise way and say this doesn't cover this, this doesn't cover this, this doesn't cover this, is going to be tremendously helpful. If there was some way to send that up to the Hill in a very concise format that staffers could look at and that we could use would be incredibly helpful in getting people to understand that there really is no legal protection.

DR. WINN-DEEN: Okay, and the other question I had for you is of the individuals who have not yet signed on, have they not yet signed on because they just have not yet really been educated and come to a decision? Or are they not signed on because they are opposed for some specific reasons?

MS. VICKERY: I think it's a combination of both. We have certainly, health staffers are overwhelmed. This stem cell issue on the Hill consumed everyone for the past three months it feels like. So as that settles down and people are starting to move on from that, I think this is a prime time to educate members on the importance of this legislation.

DR. TUCKSON: I just want to clarify one thing that I think you just said in response to Emily. Sarah, let me make sure. I want to make sure that I heard clearly.

I think you alluded to it, but I want to make sure you were specific. Did you actually request that we send your office a copy of the analysis that we have done?

MS. VICKERY: That would be incredibly helpful. I would very much appreciate a copy.

DR. TUCKSON: I just wanted for the record to note that we had been asked to send a copy of the report to the Congresswoman's office. We will be happy to do so. Thank you for the clarity.

Julio?

DR. LICINIO: I have a question on the same issue. Where does like a preexisting condition, where does that begin? Where does it overlap with actual genetic testing?

In other words, you can get genetically tested and be shown to have a predisposition to a disease that you don't have yet, or you could already have the disease and also have the gene.

Then for preexisting conditions, health care has been traditionally problematic. Does the genetic testing that's discussed in the legislation overlap with

this issue of preexisting condition? In other words, are we talking about only the test for someone who is healthy, or a test for someone who may already have a condition?

MS. TURNER: I'm from the Labor Department, and maybe I could just speak up. I know that may seem kind of random that a Labor Department person is speaking up, but I think when Peter gave his presentation, he talked a little bit about the HIPAA portability provisions and protections they have against sort of in health insurance and self insured employment based coverage plans restricting coverage based on the fact that a condition is preexisting.

I think the analysis that was done supports the finding that preexisting conditions, once you actually have a diagnosis of a condition, I think you are pretty clearly within the HIPAA protections. What is unclear is if you don't have a diagnosis of a condition and there is just genetic information, there are still a lot of gaps there, and I think that is what the legislation is looking to address.

So there is a question whether or not an attending provider or a licensed medical professional has actually diagnosed a condition. Then I think you cross the line into a preexisting condition, and certain protections apply. It's up until that point that there are a lot of gaps that I think the legislation is trying to address.

DR. TUCKSON: Aren't our ex officios terrific? Yes?

DR. LEONARD: Can I clarify whether the request is for the legal assessment report, or whether you are also requesting our telephone book of the public comments, and whether you have that already, and whether that would be useful for distribution?

MS. VICKERY: I would actually like both. I'd appreciate both of them.

DR. TUCKSON: We appreciate that we are very clear in what the request is. Thank you.

DR. McCABE: I would just encourage those who speak on this issue include it in your talks.

One of the first things I did when we received the telephone book in my office was take a picture of it so that one could see the thickness of it. I think this has been an issue. Why develop legislation when there is no discrimination.

I was on record at the last meeting for saying that the individuals who have written, and they are geneticists, my colleagues, who have written that this is a non problem should be ashamed of themselves. I received comment back from them arguing that I should not say that. But I'll go on record again and say it. They should be ashamed.

It's like when you catch the fox in the hen house and ask him what he's doing there and he says he's just visiting. Then why does he have blood on his cheeks? He says, I cut myself shaving. You don't ask the insurance companies whether they are discriminating. What did we think they were going to say?

DR. TUCKSON: Let's do this. By the way, Ed, there are a couple of folks who are sort of wanting your picture. Not your picture, but the picture you took. They probably want your picture, too. If you would send that around to the team, I think everybody would sort of appreciate it.

Well, as we bring this portion of the meeting to closure, let me try to get, and again, we've got just a couple of seconds before the break. I want to make sure that we're clear on next steps here.

I think the committee has gone pretty far in terms of what it can do. The Secretary now has the materials that have been referenced. He has the letter. We will of course use every mechanism to keep that in front of him for moving forward.

What I want to sort of get a sense of is is there anything else left? I still would say to you, Ms. Vickery, that if there is any role that we can play, and I'm not volunteering or think that there is, but to help

try to, again, look at some of where the "opposition" is and common ground, trying to, again, get some language that helps to mitigate some of the concerns that they have that are not related perhaps to the issue, but perhaps more of the unintended consequences of the issue.

That's really what I think I'm hearing a large part on that community. It's the unintended concerns about the legislation. If there is a role that we can play in terms of brokering, talking, clarifying, I mean, I think we really want to get there. So know that the committee is open to whatever role that we can appropriately play within the confines of our charter and responsibility.

A couple of quick thoughts then to get us if we have some other next steps.

DR. LEONARD: From Agnes' comments, did we specifically ask the Secretary to do a broad distribution of the public comments and the legal analysis?

DR. TUCKSON: Let me just reread the letter real quick.

DR. LEONARD: Can we do that? Or recommend it? Ask it of the Secretary?

MS. CARR: Actually, Dr. Zerhouni, in transmitting the recommendations of the committee, suggested that the Secretary do that.

DR. TUCKSON: Good.

Hunt?

DR. WILLARD: Just a point of clarification. Can we or can we not as individuals contact our representatives? Especially those who might be on the wrong side of this particular issue, as long as we don't make reference to the fact that we're a member of this advisory committee.

MS. CARR: Yes, as long as you don't do it today or tomorrow.

(Laughter.)

DR. TUCKSON: All right. Yes, last comments, Agnes.

MS. MASNY: In our last summary, we had made a recommendation to the Secretary that he pull together the stakeholders to actually analyze some of the concerns from the business community. I don't know if that has been moved on, or if we could make another attempt to say something to that effect.

Just to mention that in the reports and public comments that we've had on the coverage and reimbursement issues, there were several professional organizations and business organizations that voiced their support for the antigenetic discrimination legislation, one of which was the American Academy of Actuaries, the other the American Association for Clinical Chemistry.

I'm just wondering whether we should kind of go through that report and pull out even some of those comments. If we were going to send on another report from this meeting, to sort of even say that we've received even further comment from the business community, and that maybe some of these organizations could be included in the stakeholder meeting, if in fact that is where that would go.

DR. TUCKSON: All right. It's a good suggestion. What I'm a little bit, what I'm hoping is you'll give us a little leeway to analyze the situation in terms of the Secretary is still fairly new, and there is a lot of paper bombarding his office.

Our report is pretty voluminous and pretty specific, and it is pretty recently there. It was also with Dr. Zerhouni's transmittal letter. Let us try to work the system as well as we can to make sure that our stuff is getting onto his desk.

I'm a little concerned about just sort of bombarding him anymore with any miscellaneous parts, because it may take away from the sense of what we've got there. It's a great suggestion. Let us use it with flexibility. I assure the committee that we will do everything we can to make sure that our stuff is in front of the Secretary and owe you a report afterwards.

I'm not sure there is anything else to be done. Yes?

DR. McCABE: In 48 hours, several of us will not be as constrained as the rest of you are. I know that I would volunteer to be of any assistance that I could be, and I'm sure the others would as well.

DR. TUCKSON: Well, thank you all very much. Ms. Vickery, if you will keep us connected to what is going on, especially to our staff team as we monitor this. We have regular conference calls and subcommittee reports, so we're more fluid than, you know, the next meeting in October. So let us know what we need to know.

Thank you all very much for a good discussion.

The drill is -- and by the way, I keep alluding to the new folks because you all don't know how crazy the chairperson is -- we start on time. So 10:30, if you're not in here, oh my God, the woe that will befall you. So 10:30 exactly.

(Recess.)

DR. TUCKSON: We're going to begin again. We are now at the section on updating on direct-to-consumer marketing of genetic tests. We identified, as you will recall, direct-to-consumer marketing of genetic tests and services as an important issue.

We had several discussions during our priority setting process about the advertising and sale of dubious

genetic tests over the Internet. Examples of ads such as genetic tests for personalized face cream, and even more alarming, for addictive behavior, a slide by the way that Francis Collins shared that I use regularly in my presentations, which never fails to get people's attention on this subject.

We heard from Matthew Daynard about the role of the FTC -- that's the Federal Trade Commission -- in regulating false and misleading advertisements, and their need for documentation of harm before they can pursue advertisers. Some of the areas touched upon during committee discussions include how spurious claims may drive the consumers to waste precious health care resources, or delay the introduction of valid therapies.

There is no gate keeper guarding patients from the dangers unique to genetic technology. Genetics is a field that already confuses much of the public. Direct-to-consumer marketing may create more confusion and could be a serious roadblock to progress.

In December of 2004, we sent a letter to the Secretary that first expressed our concern about potential harm to consumers from direct-to-consumer marketing of genetic tests and services. Second, that requested clarification on the role of FDA in monitoring such marketing, and third, that recommended that HHS collect

data on the public health impact of DTC marketing, and collaborate with the Federal Trade Commission on the monitoring of such advertising.

In March, we received a response from Secretary Leavitt, and you can find that in Tab 5 of your briefing book. Since that time, there have been some efforts to address our concerns. During an interagency conference call on this topic in April, two working groups were established to respond to our recommendations. We will be hearing updates on those working groups shortly.

Following the working group updates, Deborah Wolf from FDA's Center for Devices and Radiological Health Office of Compliance is with us, and we're happy that she is able to provide an update on FDA's role in monitoring the marketing of genetic tests and services.

Before we hear Deborah's formal presentation, I'd like to ask Matt Daynard from the FTC and Deborah Wolf from FDA to update us on collaborative efforts within the federal government to monitor such advertising.

Matt and Deborah, can you give us that update, please?

MR. DAYNARD: Thank you, yes. Matt Daynard.

I'm happy to report that the FDA/FTC/NIH DTC Advertising Task Force is up and running and working well, due largely to the wonderful efforts of Steve Gutman and

Deborah Wolf sitting next to me, and Fay Shamanski of NIH.

What they have done is put together a wonderful chart that has potential targets. On the left side there are claims, somewhere in the middle, a synopsis of the science supporting those claims of potential consequences, both health-wise and economic.

They presented that to me, and we had a telephone conference about that. I commented on those in terms of what was good, what more we needed. What the FTC needs in this area since the lawsuit here, if this is what we're looking at down the road, would be an entirely new application of the FTC Act. We need the proverbial slam dunk.

We don't want any scientific issues that anybody on the other side could debate. So this is what we're looking at. The FDA and NIH are going back and doing a little bit more work, for which I'm eternally grateful. They're going to come back to me after this committee meeting, sometime in the very near future, and we'll discuss it again.

When we have a consensus on good targets, I'm going to take that to my folks in the Division of Advertising Practices and the Bureau of Consumer Protection and say listen, I have told you about this, you have been a bit excited, we wanted to see what we'd come up with. Here

are the potential targets. Hopefully I'll be able to say this is a good case. If they agree, we will take this to the Bureau of Consumer Protection folks and get their heads up sort of agreement, and we'll take it from there.

You have to realize that unlike the FDA, our hook is not the public health, although that's an enormous criteria in our case selection. Our hook is advertising. We've got to find a strong claim, which is not supported by competent or reliable scientific evidence, and then we take it either to court or to an administrative law judge.

Part of that of course scenario is well, what is the potential public health consequence? What's the economic consequence? How strong is the claim? What is the science?

What we're looking at are claims that some of these tests can help you lose weight over the long term, or can help you determine whether you're susceptible to serious diseases like cancer, or that they can prescribe a nutritional diet for you in the future that in fact will help you avoid some of these diseases or avoid obesity. FDA in particular is checking into the science on these, and how the tests are performed. That does make a difference as to how predictable they are and projectable they are.

So they are doing all this work. It is quite

wonderful, and I think we are off to a great start.

DR. TUCKSON: Matt, thank you for that.

Let me just ask one quick question here. I mean, given the ones we've seen in terms of this addictive behavior, does your child suffer from the predisposition to alcoholism, drug abuse, or learning disabilities, just send in your swab and we will give you the right nutriceuticals that will, based on this genetic profile, solve the problem.

I mean, there are some pretty interesting examples out there. I guess where I'm sort of struggling with is wondering why you're having such a hard time finding or narrowing down the right test case.

MR. DAYNARD: Because what we're talking about are specific facts. What is the exact claim. What is the science supporting that claim? How serious is the condition that the test that the advertiser purports the claim that the test is going to show you?

Addictive behavior, that affects us all, and we're all concerned about that. But the kind of claims that we deal with on a daily basis are cancer cures, AIDS cures, bogus HIV test kits, which we just did with the FDA. So that's the kind of claim that gets our attention.

DR. TUCKSON: Got it. Well, we'll have a chance to dialogue. By the way, again, I'm glad you're

moving forward. One of the things that I must say as we listen to Muin, who is coming next, and then we'll get to the formal presentation, then we have questions after that is apparently observers in prominent scientific publications in commenting on this process have decided to label our activity as a committee on this moving at a glacial pace.

(Laughter.)

DR. TUCKSON: While they are apparently pleased that we're doing things, apparently we are characterized as moving at a glacial pace. Hopefully whatever commentator that is that wrote this will after this meeting decide that maybe we are at least moving at a more aggressive glacial pace, but that we are trying to do this seriously.

Let me also take this opportunity, again, for the new members, to remind you. There are a lot of people that pay attention to what we do. We may not always agree with how they interpret our activity, but we are being interpreted. So be mindful that there is a lot of scrutiny of what we are doing, as it should be, because we exist in the public domain.

Muin from CDC.

DR. KHOURY: Yes. Thank you, Reed, very much.

Actually in that same article I was quoted as saying that my friends at the FDA are doing nothing. So

that tells you how your words can be distorted. So my apologies to the FDA if my words said the wrong thing at the wrong time.

Anyway, we had a conference call last week to begin the process of discussion of how HHS is going to respond to kind of collect data on the public health impact on the direct-to-consumer marketing of genetic tests. We have a working group that has a representative from NHGRI, NCI, FDA, Joe Hackett serves on it, and a few folks from CDC. I would welcome any of the new members on this effort. Our work has just gotten started.

I want to thank Sarah and the SACGHS staff for keeping us on target. Our job is not as easy as it seems. Measuring public health impact has multiple facets to it. First you have to define what that means. As I said, we had a brainstorming session.

At the outset, we kind of decided to break into two groups, two types of tests, if you will. The ones that are squarely within the health care delivery systems where you have direct-to-consumer advertisement that is done within the context of health care providers. Examples of this is the BRCA1 analysis campaign a couple of years ago. The other ones are the ones that are outside the system, direct access to that.

It impacts on our ability to how we can measure

impact if something is within the health care system, as I mentioned briefly with the public health response to the BRCA1 analysis campaign. Presumably if people do this outside the system, then there is really not too many immediate ways of finding the outcomes or impact of such advertisement.

But we kind of began to kick around a few questions. Obviously the ultimate impact is to find out the outcomes of people who are tested and not tested, whether people are being helped or served by such targeting. I think, as I said, it will be a few steps before we can devise the kind of data collection instruments to get there.

There are a few more I guess what I call process measures that one can use. Consumers knowledge, attitudes, and behaviors. I mean, other people have heard about these things and whether it affected their knowledge or their behavior in seeking them and why they seek them, who are they, and whether or not the outcomes have changed.

So we started that discussion. Let me just give you a quick summary. In your tab I guess there is an example of a public health response to the BRCA1 campaign that happened two years ago, which was in a way a natural experiment. It happened in an intensive way over a six month period in two cities in the U.S., in Denver at

Atlanta.

At that time, there were at least two responses that happened. We partnered with health departments in Colorado and Georgia to mount surveys to health care providers and women of the right age group. Random surveys to find out what is going on. There is an MMWR article in your packet, and a peer reviewed publication on its way. At the same time, Kaiser in Colorado did a similar analysis in the Kaiser community. The advantage of using HMOs is that you have numerators and denominators. You have a closed system, although it may not be representative of the population, but you know referral patterns.

The paper in Nature Medicine just appeared in March this year. You guys can peruse it. Both of these surveys showed an impact of such campaigns. I mean, it is a no brainer. Advertisement works. It makes people think, it makes people act. Whether it changes outcomes or appropriateness of referrals, that's something to be looked at.

But during our discussion last week on the phone, we kind of began to think about the ways to essentially tackle the problem. I'd be curious to get some more input from the committee here. One is to partner directly with these companies. We were cautioned to work more with the other subgroup here, because on the one hand,

if some other part of the government is pursuing them, I think partnering with them to seek data on who uses their services, and obviously there are privacy concerns and business practices that may not allow us to do this.

But for us, I think finding out why people use these services and what the impact of these services on their own health is what we're after, to try to document these things. So we decided to shelf this for the moment until we figure out what the other group is doing.

We talked about HMO research networks as a good place to do these kinds of activities and surveys. We'll be trying to pursue this. But of course this methodology will miss out of pocket purchases and direct access. In other words, if it doesn't come back to the health care providers and be in the chart, there is no way you can capture the impact of such a practice.

The third methodology is to piggyback on existing surveys that CDC and state health departments do on an ongoing basis. One of the surveys CDC does on a yearly basis is the Health Styles survey, which is a random sample of a representative sample of the U.S. population, about 45,000 people. We are going to be adding Doc Styles this year, which is a random sample of physicians to find out what people do, and what practices look like.

Again, if the magnitude of the issue is small,

I mean, 4,000 people may not be enough to pick up if it is only one person in 5,000 that uses these services, it would be very difficult to pick up. But at least establishing baseline rates of different things will be important, and you can track it over time.

Now, of course states have different surveys. One of them is the Behavioral Risk Factor Surveillance System which is a state based survey. We will be looking to partner with several states to evaluate the data collection systems as long as we are able to devise sort of minimum sort of core elements for how we can do this.

So anyway, we are going to be exploring different things over the next few months, adding questions to existing surveys, both state and federal, and working with HMOs. I look forward to working more with different members of this committee and trying to get a better handle on this public health issue.

DR. TUCKSON: Great.

DR. KHOURY: Thank you, Reed.

DR. TUCKSON: All right. Let me just march into the presentation, and I'll come back and we'll do the questions at the end. Is that all right, or do you have something?

DR. McCABE: It's very brief.

DR. TUCKSON: Okay.

DR. McCABE: It is appropriate now. I would suggest that Emma Marris, who wrote the piece that you commented on before for Nature Genetics, that you contact her, Mr. Chairman, about the genetic nondiscrimination, since she seems interested in genetics.

DR. TUCKSON: Good. Thank you for connecting the dots. That's great.

Let's move now then to Deborah Wolf's presentation. Deborah is going to update us on the FDA's role in the oversight of direct-to-consumer marketing of genetic tests. She is with the Office of Compliance, Center for Devices and Radiological Health at FDA.

Then after Deborah's comments, we'll come back and put all of the pieces together and determine as you listen to what she has to say, and what you heard, how we might move forward in terms of our agenda in this regard.

Deborah, thank you so much.

MS. WOLF: You're welcome. I'm glad to be here. Good morning, everybody.

I want to make a couple of quick points before I start my slides. One is that I would acknowledge that we do work slowly in general. I think in part that's because of the bureaucracy itself and the way that government works in general. Part of it has to do with resources, and part of it has to do with these issues being complicated.

There is not always consist opinion or agreement inside the agency or within the department. These things just require a great deal of discussion before there is really any movement.

The other thing I wanted to say is that my presentation includes a lot of references to specific statutory and regulatory provisions. I hope that you don't find that off putting. I think here a lot of the specific language in the statute and the regs is important. That's why I kind of did it this legalistic way.

Direct-to-consumer marketing of genetic testing is taking place in a much larger context of direct-to-consumer marketing of all kinds of medical products and services. So I think that's one part of how you look at the entire field of consumer reaction, what prompts consumers to have a specific test.

There have been a number of studies done on the impact of different aspects of DTC marketing of drugs, especially. There really are a lot of mixed opinions in the consumer and medical communities.

The advertising and access of genetic testing raised concerns that are different from those of advertising or direct access of drugs and medical devices. Some of them are the same in terms of who is making certain decisions, what kind of guidance they have. But

there are also, as we've heard, a lot of much larger consequences.

The FDA's role is uncertain.

In vitro diagnostics provide information rather than treatment. So when the agency approves or clears a diagnostic test, the safety and efficacy are reviewed in a different way, or they are viewed differently from the way that they would be viewed for drugs and devices that are used in therapy. The consequences are sort of one step removed. The test itself generally isn't causing any sort of danger. It is what happens with how good the test is, how reliable it is, and what happens with the information that you glean from it.

These are kind of the basic aspects of promotion and advertising of medical devices that we look at. Premarket notification and premarket approval are the two ways that medical devices get to market. The labeling and advertising authority that FDA has over medical devices, intended use has to do with the kinds of claims that company makes for the use of its products. All of this touches the practice of medicine, which FDA doesn't regulate. I'm going to touch on our work with the Federal Trade Commission.

For premarket notification, these are generally lower risk devices. Essentially these are devices that are

cleared for marketing based on being equivalent to a product that either is on the market now or was on the market prior to the date that the Medical Device Amendments were enacted in 1976.

For the most part, general controls and special controls apply to these devices. They don't get the same rigorous review that products that require premarket approval do. The company submits a premarket approval application, and the product will be approved if the way that the conditions of use are presented in the labeling provide reasonable assurance that the product, if it is used according to the label, is generally safe and effective.

Central to our regulation of analyte-specific reagents and how that affects genetic testing, an approval order granted to a Class III device that requires premarket approval. The approval order can restrict the sale or the use and distribution of the device. To the same extent that is permitted by Section 520(e) of the statute which basically says that if FDA believes it is necessary, they can require that the sale, distribution, and use of the device be restricted by regulation so that it is either made into a prescription product or upon any other kinds of conditions that FDA thinks are necessary to provide safety and effectiveness.

520(e) referred to restricting devices through regulation. There are only three devices currently restricted by regulation. Any other restricted devices are restricted through its approval order, and those are all the Class III, more rigorously reviewed devices. The only three that are restricted by regulation are analyte-specific reagents, drug of abuse test kits, and hearing aids. As I said, most restricted devices are Class III that require premarket approval and they are restricted through their approval order.

Section 502(q) Of the Food, Drug, and Cosmetic Act provides that a restricted device and restricted either by regulation or by approval order, that a restricted device is misbranded if the advertising is false or misleading in any particular or it is sold, distributed, or used in violation of any regs prescribed under Section 520(e).

So for analyte-specific reagents, which are restricted by regulation, 502(q) means that it would be misbranded if the advertising for that ASR is false, misleading, or it is sold in violation of the restrictions captured in the regulations, which I'm going to mention in a minute.

Section 502(r) of the Act provides that that same restricted device is misbranded if the advertising

doesn't include a statement of product's intended use, and a summary of relevant risk information.

Device labeling, which is a broad category of material, it includes any sort of handout, a glossy brochure, any piece of material essentially that a company distributes is labeling. A device is misbranded if its labeling is false or misleading in any particular. That applies to all devices, and not only restricted devices. The advertising limitations that I talked about were for only restricted devices, but FDA has labeling authority over all devices.

Labeling, as I said, is interpreted broadly. The material doesn't have to be physically with the product to be considered labeling. As long as it is textually related, it has been determined through case law that essentially if it is about the product, it is labeling.

Advertising is not really defined in the Food, Drug, and Cosmetic Act. It's mentioned, as you saw, but it isn't defined. So the Center for Drug Evaluation and Research has regulations. The way that they define advertisements basically is ads that you think about sort of intuitively as an ad in published journals and magazines, other periodicals and broadcast ads.

Our review of advertising as opposed to labeling brings us closely into working with the Federal

Trade Commission. In 1971, there was a memorandum of understanding between the two agencies that essentially decided that FDA would have primary jurisdiction over the advertising of prescription drugs and of restricted devices, those devices restricted by approval order or by regulation, and over the labeling of all products. The Federal Trade Commission has primary jurisdiction over advertising of other than restricted devices, and of over-the-counter drugs.

One thing that's very important in terms of the genetic testing issue is that FDA hasn't really clearly defined the Internet as either labeling or advertising. So while we do apply our jurisdiction, it is not clear for the most part whether we are actually defining it as labeling or advertising. In the substance of the claim that we look at, we did have an Internet working group a number of years ago that was attempting to make that determination. That group was disbanded.

The Federal Trade Commission has a broader authority over advertising in general which is why their role is very important in this area.

Analyte-specific reagents used in IVD testing are restricted, as I said, by regulation under the authority of 520(e). This is the regulation that I have shown here, 21 CFR 809.30, which restricts the sale of

ASRs. They can be sold to IVD manufacturers, they can be sold to labs that are regulated under CLIA and granted high complexity determination, and then they can be sold to organizations that use the reagents for other than medical diagnostic purposes.

The labeling for ASRs is limited as well. The labeling has to make clear that analytical and performance characteristics are not established. For Class II and Class III, products get a higher review analyte-specific reagent, except as a component of a specific test, analytical and performance characteristics are not established.

The reason that's important is that when the tests are marketed and they are marketed only to labs, they are not allowed to make a claim for the intended use of the ASR. Once they do that, it becomes a device subject to FDA's jurisdiction.

The advertising, the regs on ASRs require that the advertising and promotion, which includes their labeling and their advertising, include the identity of the analyte, and again, the limitations. For Class II and Class III, as I said, they're limited to whatever tests they may have been shown to be used for.

Class II and Class III are higher risk uses essentially. Class II are mostly blood bank kinds of

analytes, and Class III are HIV tests and TB tests, and a number of others.

This is also in the regs. Ordering in-house tests developed using analyte-specific reagents is limited under Section 520(e) of the Act, the restriction, to physicians and other persons authorized by applicable state law to order such tests, unless, as I said, it is sold to IVD manufacturers or organizations using it for other than medical diagnostic purposes.

So what happens here is that in all of this direct marketing to consumers, the tests that are used in labs, the home-brew tests that are developed using the analyte-specific reagents are technically limited by regulation. No one should be ordering the tests except physicians.

You do have the way that a lot of medical device, contact lenses, and a lot of prescription drugs, a lot of the websites that sell those will have a physician on their staff who is perfectly willing to write you a prescription. Whether that's valid, the prescription itself in that setting where you have no relationship with the physician, depends mostly on state law. So the states regulate pharmacy and the boards of medicine. So who can actually prescribe a test is up to the states.

This would be helpful in terms of our

regulation of tests used, developed by labs using ASRs if we knew how to apply this, and if there were support in the agency to support it. It's not clear here actually whether this would restrict the lab from accepting an order.

The problem here is it doesn't really discuss who comes under the jurisdiction, and who would be responsible for basically not ordering in-house tests.

So the question is this genetic testing involving home brew and laboratory developed testing is really whether the combination of the ASR, which we do regulate, and the lab process, become a device. Whether the conjunction of those two things become a device, and how would we limit the ordering of those things to physicians, first establishing whether it is a device, and then, as I said, this issue of Internet prescribers.

Limiting access to the tests, even if we could enforce that part of the regulations, wouldn't prevent labs from advertising the tests. A question is whether advertising a specific use for an ASR by the lab creates a device that requires premarket approval.

Generally what starts FDA's jurisdiction over the product is the claim that a company is making for it. So if a lab is establishing a use, then they could misbrand the device if that were an inappropriate claim for the ASR.

When we look at enforcement as a whole, and

with specific reference to IVDs and tests, FDA is focusing right now on risk-based reviews, both in terms of public health priorities and in terms of resources. Here for ASRs and laboratory tests, there are a lot of issues about whether the tests are valid, whether they have been shown to provide the information that they claim to provide, look at the consequences of false negative or false positive results with these tests, as several of you have talked about. The kinds of decisions, health care decisions that people will make, or employment decisions, or all sorts of things that may result from an incorrect answer.

We would look at the seriousness of the disease or condition, the role of genetic counseling, and then the issue about whether genetic information places a certain burden on people that they may not want. All of these things are broader issues that FDA really can't decide itself, but that go into our calculus.

The agency has cleared about 12 genetic test kits. These last three are among the more recent. Dr. Joe Hackett, who is here, can speak more specifically about these tests if anybody has specific questions. I'm not a scientist, I don't really know what exactly they do.

Then these are some of the kinds of claims that we are worried about. As Matt said, we need a slam dunk. There are a lot of claims out there, but in trying to

identify, here we talked about the impact of wrong information or the seriousness of the disease. We need to put all of those together when we're looking at how to best use resources.

So these are the ones that we have identified, as Matt said, a chart with a number of Internet companies. These are the kinds of claims that we've sent for now. Companies have claimed that their test can predict how someone will metabolize drugs or have adverse drug reactions, nutritional counseling, tendencies toward obesity, and detecting susceptibility to serious kinds of conditions. Cardiac disease, cancers, bone mineral density, and risk for osteoporosis, autoimmune diseases, chronic fatigue, and a number of infectious diseases.

As we have said, FDA and FTC are working now together to coordinate some of the information we've collected, the information on websites. I want to sort of point out that right now we're focused on Internet websites. There are other kinds of advertising for these products. I haven't actually seen a lot of it. The use of the Internet has become so widespread, and it's national. This is a good place for us to start.

Thank you.

DR. TUCKSON: Thank you very much, and also the other comments that were made by Matt and Muin as well.

Why don't you take a seat, because I know we'll have a lot of questions and it would probably be easier to take them from your seat.

The floor is now open. Let's start with Emily.

DR. WINN-DEEN: Joe, I had a question for you, because I'm concerned that your use of analyte-specific reagents, which my understanding of that, there is a very specific claim made by the manufacturer of an ASR that it is in fact an ASR and it can be used as a component of a home brew test.

My guess is that most of the labs we're concerned about are not buying analyte-specific reagents from a certified GMP manufacturer. They are just going to a regular research supply house and buying the components they need. Does that mean that FDA really doesn't have any control over what is going on there?

DR. HACKETT: It would be the same type of situation. We're not looking at the laboratory offering the services. Only if they were selling that test to another laboratory. So whether they use an ASR or not, or make up their regions entirely in-house, that doesn't make a difference.

DR. WINN-DEEN: So let's just take a concrete example of one of these Internet companies that's offering to test for risk of future development of osteoporosis. If

they make up everything completely in-house home brew, does that constitute any kind of an ASR that FDA would be able to regulate?

DR. HACKETT: Not if they do everything in-house.

DR. WINN-DEEN: Okay.

DR. HACKETT: If they buy the reagents outside, then they come into ASR concerns.

DR. WINN-DEEN: So if they buy oligos from XYZ Research Oligo House, does that fall under the FDA?

MS. WOLF: The ASR would. I mean, this is part of the problem. Part of the problem is whether the combination of an ASR that's sold to a lab and what goes on in the lab can be regulated by FDA. The other question is whether the home brew, which is where they do everything, whether that can be regulated.

DR. WINN-DEEN: Right. So my big concern is that most of these folks, ASRs are made in general by legitimate GMP manufacturers who are making them with the knowledge that there is a real medical utility for them.

The places that we are primarily concerned about are doing it totally home brew. They're not actually using any component that's marketed as an ASR. So what can we do to control the proliferation of those kind of assays?

MS. WOLF: That aspect is not my strength

actually. I mean, I don't work in the IVD group. I think they probably are in a better position, and we can look into that sort of how widespread that is. I don't know enough about it.

DR. WINN-DEEN: It's very widespread, even in clinical laboratories that are offering legitimate tests. So my guess is that it is there in the ones that are not offering legitimate tests as well.

MS. WOLF: We don't know for sure that none of these tests is legitimate either.

DR. WINN-DEEN: Right. But with the assumption that some of them might not be, my guess is that they're not getting components from a legitimate IVD manufacturer, or GMP manufacturer, I guess.

MS. WOLF: I don't know. We can talk about that at FDA. We can get in touch with you.

DR. TUCKSON: Good.

MS. WOLF: But I don't know how else to answer that question.

DR. TUCKSON: That's good. I think if you can look into that, that would be terrific. We've got Julio, Ed, and Debra.

DR. LICINIO: One comment is that this issue of trying to control something seldom works. If there is a need for something, people will jump through whatever hoop

to fill that need. If there is a need for workers in one area, it can put every type of immigration barrier, people will jump and go and get the job.

The situation the way I see it is the taxpayers pay the taxes. The money goes to research. The research is done, the results are published in the scientific literature. Then stories are written and the covers of the New York Times, Time Magazine, anything you open, there is something about the genetic risk for this, for that, for the next thing.

Then you go to the doctor, or you go to like a reputable traditional medical institution and try to get yourself tested. People shrug their shoulders and do nothing. You can talk about like, you know, risk for impulsivity, which there are genes related to that, to novelty-seeking. But I'm not even talking like that.

Let's say in my own area, pharmacogenetics, the oldest thing in the world like cytochrome P450 2E6 metabolites, 50 percent of the best selling drugs in the country. Just under 10 percent of the average Caucasian population has a variant of the gene that has no activity. So people take the drugs.

Well, the same number, 10 percent, have multiple copies of the gene in which you give the drug that metabolizes very fast, and there is no effect. So it is a

real concern in the clinic. Some people go to the doctor and they have side effect after side effect, they do have no activity of cytochrome P450 2E6. We've had several patients like that.

The Mayo Clinic is beginning to test for that, so some major medical centers are beginning to do that. But to go to your average like Ivy League medical clinic and you say can I get tested for this in the Costco lab? They say no. If you come up with a test, people have a hard time finding a doctor who can understand that.

We fund the research, we let it be done. The results are there. Some of them are more controversial. Some are not so controversial. People go to the regular health care system. Nobody uses the test, nobody can handle it. If there is a need, they're going to find somebody.

They can put every regulation they want in the United States, and people will send the sample to Canada and it will be done in Europe someplace. As long as we say that the issue is important, advertise the results, and then the traditional health care system cannot handle it at all. There is going to be a gap, and the gap is going to be filled.

I mean, you can regulate it as much as you want. I mean, I'm against people saying send your tests

here and will tell if your son is going to become a drug addict. I don't think you can make that kind of claim. So yes, we should watch for blatantly false claims, which I think is what you are very correctly trying to do.

But this kind of marginal or impressionable predisposition risks, as long as we try to justify the funding by saying that the issue is important, then we don't offer people anything. So there is a need, and it's going to be filled.

DR. TUCKSON: Thank you.

Ed?

DR. McCABE: Yes. One of your comments that the FDA is not clearly defining the Internet promotion as labeling or advertising was interesting, I thought.

Is there something that this committee could do, at least in this context, to try and help a decision be made there? Is it such a big issue that we'd be spitting in the ocean for us to do anything?

MS. WOLF: My guess is that it wouldn't be very helpful. I mean, I think this is something that just has a lot to do with FDA's variously evolving attitudes about promotion and how to regulate it. I think it has been an issue for so long, and it is dealt with on a case by case basis a lot of times that you can certainly comment on it.

My guess is that it is not something that is

going to get a lot of concrete action.

DR. McCABE: Well, I think that we should write to Secretary Leavitt about direct-to-consumer marketing and make a recommendation to the Secretary that we might wish to include in there this issue that I would certainly, I don't know. Maybe there are people on the committee who would not feel that the Internet is a legitimate source of information. But given how often I use it, every day, I certainly think it is a legitimate source of information. My guess is that it's more powerful than most other media these days for the public. I would hope that we could include at least a sentence or a brief paragraph saying that this should not be an impediment to pursuing these companies.

DR. TUCKSON: One of the things, by the way, that I do hope that the people in line, Debra, Hunt, and James, as you start to question, but also given that we're getting near the 11:30 hour, I want to make sure that you're also doing what Ed did, which is start to formulate what you see as being next steps, if any. I think Ed is starting to try to push some of that together.

Julio had his comments about what we ought not be doing. Just be thinking of action steps as you ask your questions.

Debra?

DR. LEONARD: I would like to just follow up on Emily's comment, because I was a little taken aback by the inclusion of ASRs in this discussion, because I see ASRs as part of the regulatory framework in which laboratories work, set up by the FDA to allow types of testing in a regulated fashion that are not necessarily able to be brought as PMA or 510(k) approved full device test kits.

I don't think that that is what the committee was asking about or targeting when they were looking at the direct-to-consumer marketing that was being done. I don't know how they are doing their testing, but I doubt it is using ASRs that are manufactured.

MS. WOLF: Well, I think that's, I mean, I think that's what I said we would discuss and get back to you about, right?

DR. TUCKSON: Good. All right.

Hunt?

DR. WILLARD: I wanted to raise another area. I guess my question is whether this falls into the purview of any of the groups that are discussing this, or whether this is just one of those things that Hunt should not worry about, or worry about in his own time.

In addition to the direct-to-consumer marketing for tests for genetic diseases or trait predisposition, there is also a growing number of tests that are much more

frivolous in their intent, or they have no intent at all, it is more like sport.

So you can, for example, any member of the public can go out and they can buy for $29.95 a little kit, take a swab, send it off, and get some genotyping done, and/or some sequencing done either, depending on how you read the inserts on these packages, either to be the first in the neighborhood to have a little bit of your genome done, which could be cool in some neighborhoods, or because it actually is sort of telling you something that might be important in a very vague and unstated way.

You can imagine some of these could be for paternity issues, parental issues that come up in some households, or markers that are described that may eventually become linked to some trait predisposition.

This is widespread. A family member of mine tripped over this advertisement on the Target website. I confess I don't spend a lot of time myself going on the Target website. But for $29.95, you can get this.

The question is I guess my concern on why this might be not the best possible testing to be out there, is that most members of the public, not withstanding my desire to have the public think it's cool to have perhaps bits of their genome sequence, they are not prepared to know how to interpret the information either in terms of the genetic

makeup of a Y chromosome that's floating around the family, or in terms of mini satellite repeats or trinucleotide repeats.

So they will read something about a genotype of a trinucleotide repeat, and then they see something in the newspaper in which "a trinucleotide repeat expansion has been connected to some disease," and who knows who is connecting the dots between those, even if that's an unintended consequence.

So my question is is anyone looking at this kind of direct-to-consumer marketing? Or is that something we should just let go because there are far bigger fish to try? My concern is that public education is just not at the level where we are quite ready to have potentially millions of people having a little bit of their genome sequenced or genotyped and have that information in front of them.

MS. WOLF: Well, do you send that tissue to a lab?

DR. WILLARD: Yes. So you send this swab off somewhere, and 3 to 6 weeks later, the test result comes back with a suitable for framing little certificate that says this is what you've got.

DR. HACKETT: Well, that would be continuing our work with FTC, trying to find the slam dunk case, if

that would fit in.

MR. DAYNARD: I don't think that's the slam dunk for the FTC. I mean, first you have to decide what is deceptive about it and what the injury is, and how serious the injury is.

I think on our scale, case selection criteria, the case where a test purportedly determines your susceptibility to cancer or something would be far higher on our case selection criteria than that would. But I'm not going to eliminate it if you want to talk further about it.

MS. WOLF: I mean, if you want to send the name of it to us, we can look into it and see what it is. I mean, there are products out there that shouldn't be there. I don't know enough about that one from what you said to know exactly. But I'd be happy to look into it.

DR. WILLARD: It's cleverly marketed as TCAGee, gee as in gee whiz.

DR. TUCKSON: Thank you, Hunt.

James?

DR. EVANS: Thanks. I just wanted to emphasize that when we are talking about tests being obtained some way or another, if they are fairly restricted in the expertise that underlies them, or their availability, that's one thing. But I think we should also remember that

the entire advertising oftentimes is to create a need where there hasn't been a need.

While advertisers are certainly able to do that and free to do that, it seems to me that the interest that we have is to make sure that they aren't creating a need that's harmful to people, or using blatant misinformation to mislead an uneducated and unsuspecting public.

I think that perhaps one of the roles of the expertise on this committee can be to try to help find those types of slam dunk cases that are clearly not supported by science that could have potential harm to people, as opposed to those types of advertised types of activities that, well, they are backed up by good science and may not be available.

DR. TUCKSON: Well, let me, as we start in the five minutes that remain to try to sort of see where we come out on this. First is I think that the committee has grappled I think responsibly with our obligation to the public. We are raising this as an issue of concern.

Because of our efforts, we have caused the creation of several task forces within government that are looking to how they can do their job appropriately. We don't want to cause problems in what we're trying to do, we're trying to act appropriately. Finding the right cases where there really is egregious behavior.

Let me ask, because I think one of the recommendations I'm going to make is that we respond back to the Secretary saying that we are gratified that there are these committees formed, these interagency activities, that are ongoing, and that we are aware that they are seeking out appropriate cases for review. We will say in our letter that I'm suggesting that we would say sort of that our members are willing to find or recommend examples that are of particular concern to us from our experience for the committee's consideration.

I wonder whether or not there is any experience with just the fact that you all have targeted an area, just generically, that you've targeted and area and made it widely known that you are looking carefully at bad behavior. Does that in and of itself have a chilling effect on egregious activity? The fact that manufacturers or advertisers know that you are looking to take somebody to the hoop, as it were. Basketball playoffs right now. That you are willing to look at it. Does that start in and of itself have people start to behave a little bit more responsibly? Do you have any experience in that regard?

MR. DAYNARD: The FTC does, but because we are a law enforcement agency, we tread a very fine line between what is appropriate and what isn't. We don't want to chill legitimate businesses from doing their jobs. So typically

we have a law enforcement matter that we make public at the same time that we, for example, issue a consumer brochure, a consumer alert saying watch out for this kind of advertising, because the only disease it is going to cure is too much money in your wallet or whatever.

So yes, it does have an effect. For that very reason, we are very cautious about doing that.

DR. TUCKSON: Matt, please finish.

MR. DAYNARD: That's okay. Go ahead.

DR. TUCKSON: No, no. I really like what you're saying. Go ahead.

MR. DAYNARD: Well, I mean, so in some cases, we might issue a brochure. For example, I did in the LASIK area with the American Academy of Ophthalmology a few years ago. We hadn't brought a case yet, but there was a lot of bad advertising going around.

So we issued a brochure saying go into this with your eyes wide open, because there are some problems. You are still going to need reading glasses, and there are side effects. So we did that, and I brought a case later. But it's very unusual for the FTC to do that.

It's possible, and no one other than myself at the Federal Trade Commission has made any official statement about our interest in this area. So we have to be very cautious is all I'm saying.

DR. TUCKSON: I really think that's a very balanced and appropriate statement, Matt.

Deborah, just real quick in terms of FDA. I mean, the same thing I assume.

MS. WOLF: I think with some industries it does, and with others, it probably doesn't. There are times when we have sent 30 letters to the same kind of industry. Companies that were making SARS claims for masks, filter masks, there were about 30 letters sent to these websites.

I don't know how many more were out there. We will take an action against one company, and then that company will send a letter about its competitor two weeks later. So I mean, I think it depends really. I don't think it's consistent.

DR. TUCKSON: All right. Well, one thing I just want to make sure that we do at least is, and I think Matt's point is important. I mean, we are not looking, and that's apropos the comments that Julio made.

I don't think that I would assume that our committee is not looking to chill or have a negative effect on appropriate behavior. What we are just trying to do is to make sure that the public is not being preyed upon by inappropriate people who are attempting to do things to them in an area that has special significance. To the

extent that we can make it be known that this is being looked at carefully, I think is important.

Deborah, you wanted to make one more comment?

MS. WOLF: Yes. FDA, in addition to some of the enforcement actions, provides some educational information on the website. I mean, there is an area for hot topics where it talks about breast cancer. We recently, this was a couple of years ago, all of these full body scans that are being advertised where it's not really thought to be necessarily safe and effective, the tradeoff in terms of finding things that may be absolutely benign. In a sense, there is a parallel with some of these genetic tests where you create a need to go get it by advertising it, and should you or should you not really use that information.

What FDA did, because we had authority over the devices, but it wasn't the devices that were being advertised, it was the services. So on FDA's website, we put a discussion about the CT scans, the body scans. I mean, that might be an approach for the committee to look at in terms of public education that FDA can't do by itself. It would be helpful in terms of adding.

DR. TUCKSON: Great.

Matt?

MR. DAYNARD: Yes, I just want to say one more

thing. That is that it's possible in this area that what I said we typically don't do, we might in fact want to do here. That is to issue some kind of alert about this area, what is going on, and for consumers to watch out.

But, for example, if we don't find the slam dunk case, or even if we do, issue this brochure or something like that before we do. I can talk to my folks about that.

DR. TUCKSON: All right. Let me just do a process check here. We're three minutes into the time for the next presentation, and lunch is right after that. But this is important, so we've got two hands up. We've got Ed and Kevin.

What is on the table in terms of specific recommendations are, and I'm going to allude from what the group, what they have already said as well. One is short term, and one which is longer term. One is a follow-up letter back to the Secretary saying that we note with interest and approval the committees that are forming, urging them to find the appropriate cases.

Number two, that we ourselves will send to them cases that we are made aware of that may be good examples. So those two are the ones at least now in the letter. Part B of the recommendation I think is, which we cannot discuss in the time we have here, is the idea of public

education. We have had that issue on our table before, and I think we are getting to the point where we really need to deal with that. We'll probably have to debate that at some length later in the meeting today, perhaps squeeze in a few minutes to see whether or not that's appropriate.

But I just wanted to put on the table for my own personal interest is something I think we need to start to talk about.

Matt and Deborah both indicated that perhaps there is a potential of doing something collaboratively with government that sort of gets out useful information for a consumer to use in this area.

Ed, and Kevin.

DR. LEONARD: Reed, you forgot to include defining the Internet as advertising in the letter.

DR. TUCKSON: Terrific. Good for you.

Ed?

DR. McCABE: Well, I would argue that we have heard that there could be increased public education, and that we should include that in the letter. We have heard in testimony before about the misleading advertising that's there. We could go back to that to document it. So I think we should encourage increased education about this issue.

The other thing, and this is a question to Matt

and Deborah. We all work better with deadlines. Would it be helpful to you also in the letter to recommend that the task force get back to us by some point in time? Would that help you, or would it be damaging?

MR. DAYNARD: It would be damaging for me, I'm afraid to say, just because this is the new area. Although I'm happy to work under deadlines, the folks I'm responsible to don't when they haven't gotten a heads up from anybody else. It's not a good thing right here, I don't think.

DR. TUCKSON: Would you mind, though, because of the interest on this on the committee, and even if you have to, you have given yourself sort of a pass there, but we would like to at least get an update at the next October meeting as to where things are.

MR. DAYNARD: Absolutely. Absolutely.

DR. TUCKSON: Thank you. That would be the way to do it.

Kevin, last comment.

DR. FITZGERALD: Yes, just a quick question on this public education piece. I'm glad to hear that you have the information on your website. Has anybody in your organization done a check to see if you Google or use some other search engine, these particular genetic diseases or a particular idea about finding genetic genealogies or

whatever, that your website comes up in the search engines?

Can we look to see what possibilities there might be in cooperation with search engines to make sure that these websites come up? Because the information is there, and I think it should be getting to the public.

MS. WOLF: I can check into that. I know FDA's website gets a lot of hits. I mean, it gets millions of hits. So the public is aware of it, and that it has information. On that specific issue, I can find out.

DR. TUCKSON: Great. Matthew and Deborah, I want to just really, really thank you. You have done your jobs very well. Muin, thank you again, also. This interconnection, I mean, I just feel like for the committee's sake, whether or not somebody wants to write that we're moving at a glacial pace or not, because of what we've done, we've caused people to move on this issue. It is clearly in the minds of agencies that have extraordinary clout, and also though have a responsibility to proceed appropriately and carefully and cautiously so that they do no harm.

I think that's what we're hearing here. So I think this is a good outcome. I think we are moving forward, and clearly you can expect that we'll ask you back for our meeting. We've got a few recommendations, which we'll summarize at the end of the day to move forward.

With that, let me from a process check announce that we'll be five minutes over 12 for lunch, so I'm sorry.

DR. FITZGERALD: Just one other thing on that. Considering the rapid decrease in the size of glaciers around the world, I took it as actually a compliment.

(Laughter.)

DR. TUCKSON: A true scientist thinking about things. We're going to be five minutes over 12:00 for lunch, so we'll build that in.

We're going to get now an update on SACGHS' focus on large population studies, a really big and important area. Again, as we go through this in a half an hour, I want the committee to again remain focused on what do you see as being the recommendations, the action steps that we want to recommend back to our subcommittee at the end of this half hour. So really be thinking about what you want to charge your subcommittee to do.

With that, the chairman of the subcommittee, Hunt Willard.

DR. WILLARD: Thank you, Reed.

I thought the best way to begin would be to do a little bit of a review of how this task force was formed, and how the committee decided to take on this issue. In part is a review for all of us, and in part an introduction to our four new members so that you're more up to speed on

this issue and can help us decide where we want to go from here.

The issue of studying large populations came up in deliberations by the committee as we began to prioritize the kind of topics that we would tackle soon after we took office, I was going to say, but formed our committee in June a couple of years ago. For the purpose of definition, large population studies are considered to be longitudinal studies of a large and usually diverse cohort of subjects with the purpose of elucidating the influence of genomic variation or genetic variation, as well as environmental factors on complex diseases and/or other traits.

Occasionally in some countries these are referred to as biobanks, but for our purposes, we are treating those as the same. A number of large population studies are already underway in a number of countries around the world. There is certainly interest in a number of corridors in this country to discuss the need for and potential value of large population studies.

Planning is already underway for a National Children's Study that will focus on studying the influence of environmental exposures on childhood disease and development, and the VA has also been examining or considering a project in clinical genomic medicine.

So shortly after we listed large population

studies as one of the I believe 12 priority items that the committee wanted to focus on, we formed a task force in the fall of 2004, a task force consisting of not only myself, but Joan Reede, Kevin Fitzgerald, Deborah Leonard, Chris Hook, Ed McCabe, and three of our ex officios, Ellen Fox from the VA, Alan Guttmacher from NIH, and Muin Khoury from CDC.

That task force was charged with designing a session at a meeting that was held in March of this year where the task force decided the best way to spend time at that meeting was to review not only some of the scientific issues that were at play for the benefit of educating our committee, but also to focus on the social policy and legal issues that were either of concern, or that we wanted to touch base on in deciding how those activities might go forward.

We received an update as well on federal programmatic activities exploring the kinds of studies that might be undertaken by one or more of the federal agencies.

After that session, the task force was charged again with deciding what to do and what to potentially put into a letter or recommendation to the Secretary.

The task force had a conference call shortly after that meeting in April of this year, and the sense of that call was that there were still a large number of

questions that various members of the task force still wanted to explore or gain some traction on. What was the potential predicted scientific payoff of a study like this? Were there various methodologies that might be needed to carry out those studies? Did we have those in hand, or were there identifiable gaps in terms of developing those methods?

What kind of results might result from such a study? What would they mean? How would we, meaning society, act upon that kind of information? How could such a study be carried out in a way that was fair and equitable to all of the different populations or communities that might be involved without increasing health disparities which in principle would be one of the issues we'd be trying to reduce.

What also came up in that task force phone conversation was that both from our own perspective, and by reflecting on some of the international experiences with other large population studies was that we would need to proceed with careful deliberation and in particular, with extensive public consultation, both to educate the public and to get their engagement in this kind of a project, what it would entail, what would be involved, and what the potential benefits, as well as the potential anxiety provoking aspects of such a study might be.

At the same time, it was clear to some members of the task force that we also should touch base with the broader scientific community in order to get their engagement, or find out if there might be concerns in the broad scientific community either about the potential scientific payoff from such a study and/or the costs, and/or the processes that might be involved in carrying out such a study.

So in the end, we decided to propose back to this full committee that a letter to the Secretary endorsing the need for a large population study was probably premature and should be deferred until we could gather additional information about views from the public at large, from the scientific community about such a study and its ethical, legal, and social implications.

Most recently there has been one other notable development. Just this week on June 9th, NHGRI on behalf of the NIH posted a report of a group of experts that several of the NIH institutes, but in particular, NHGRI, had commissioned to examine the scientific foundations and do logistical issues of how one might mount such a large population study in the United States.

This is a report that Alan Guttmacher had referred to in the March meeting of this year. It finally has been posted. I should say as part of that group of

experts that worked diligently in examining those scientific and logistical issues, Chris Hook served as a liaison from this committee to that task force, and to our own task force to keep up apprized of what was going on.

So one approach given that that report has just come out, and that probably very few of us have looked at it in any depth, even though you have a copy in front of you at your places, and you should hope the full committee will in time take a very careful look at that.

One approach would be that the task force in particular have an opportunity to review the report in some detail and determine the extent to which and whether it sufficiently addresses at least the scientific and logistical questions that we had raised during our telephone conference. If it does, then of course we might consider that that part of our job has been well handled, and those questions well addressed.

At the same time, the task force might, though, and this is where we need input from the full committee, might wish to identify the salient remaining issues where we need further examination and further development, framing the kinds of particular policy questions and process questions about how such a study might be carried out, what gaps are there with respect particularly to public consultation and broad scientific consultation. Not

from the standpoint of figuring out the scientific basis for such a study, because that is in part in the report in front of you. The question of whether there is broad buy-in from the scientific community at large around this question.

We have also received some guidance from Dr. Zerhouni's office in his role of being responsible. His office is responsible for the management of this advisory committee, and he is the one who transmits our recommendations to the Secretary. He would certainly like us to provide advice in particular on the processes and pathways that NIH or HHS itself might use in reaching an optimal decision about taking such a study.

I interpret that to mean that we should focus not on the issues of the scientific merits or the scientific topics that such a large population study might tackle, but rather again, these questions of processes and pathways. What are the gaps? Who should be brought into the decisionmaking process, and how do we identify the types of questions that need to be addressed, rather than us specifically trying to answer those questions, simply provide guidance as a committee as we try to identify what those areas are of some concern.

So that's where the task force stands at the moment. I think for the remaining time this morning that

we should open it up to a full discussion on the committee in order to get full input from the other members of the committee, including our new members, and to get specific guidance back to the task force so that we know what jobs we're supposed to do two days from now in order to continue examining this important issue.

DR. TUCKSON: As we go around the room, and I see Francis' hand and a few others, let me again focus. So what you are trying to do in your questions and your guidance is to help the committee grapple with our role of do we and how do we help to give guidance around the idea of the process of going forward with this study.

As I look at my notes, again, do we look at buy in and how do you achieve buy in? Or do we have a role in helping to achieve buy in by the scientific community? Public perceptions and public perspectives on this matter. Other issues that have to do with the process of getting this done.

What we're saying is we do not see, at least from the subcommittee, a responsibility that we have to get into the scientific issues involved, but more of these other sorts of issues. So with that, let me start with Francis.

DR. COLLINS: I very much appreciate Hunt's summary of the work the task force has been doing, and

Reed's exhortation that followed. I hope the committee will, when things are allowing it in terms of your time, take a close look at this report of this expert panel representing the work of more than 60 people who worked quite intensively last year in considering the design considerations that would be important to think about if we were going to mount a study of this sort in the United States.

There is a great deal of detail in there about power calculations and what kinds of expectations you would have based on particular study designs about how the study design might be carried out. What would go into the clinical and laboratory component, what kind of technology would be needed in order to advance our ability to collect information about environmental exposures, ambulatory physiology, dietary intake, and so on.

We would be very interested in the thoughts of the task force and the committee about the way in which these recommendations are phrased. I do think, and again, picking up on what Hunt and Reed have said, that SACGHS represented by the task force could play a useful role, particularly in this area of trying to seek public input about the wisdom of such an undertaking.

When this was undertaken in the U.K., for instance, there was a good deal of public consultation, and

you heard about that at the last meeting. That's obviously critical for anything of this magnitude which will require not only sort of grudging assent, but I think actually enthusiastic embrace by the general public if we're going to undertake a project of considerable magnitude that has long range consequences for our understanding of health issues.

Given SACGHS' visibility and your connection to the Secretary, it seems to me that this might provide a very useful venue for that kind of a discussion. If I could be so bold to even suggest that perhaps in the October meeting, you organize a session to receive public input about the wisdom of such a study. That could be very helpful in considering the next steps in getting this underway or not, depending on a whole variety of factors.

I think if we went much further down this pathway without soliciting that kind of broad public input from advocates from a variety of different populations that have had different experiences with medical research, then we really potentially could be accused of just riding over those concerns without listening.

This would be a great venue to try to organize that kind of a very public discussion.

DR. TUCKSON: Francis, this is a very tangible, concrete suggestion for us to consider. How would you feel

about in addition to the public perceptions, but also if we were to bring in representatives from the "scientific" community also. Would that be a friendly amendment to your suggestion?

DR. COLLINS: It would indeed.

DR. TUCKSON: Thank you very much, Francis.

Ed has his hand up.

DR. McCABE: Yes, I was going to actually, my hand was up before Francis talked about the public input. That's what I was going to suggest.

I would look back to the model from SACGT. Maybe even think about it as more than a half a day session. The thing we did over at the University of Maryland which really was what began to open my eyes about the genetic discrimination issue at that meeting. So I don't know if logistically that would be possible to do, but think about at least maybe a full day session and whether it was connected or disconnected to this meeting, the meeting of the committee. Look back to that model.

DR. TUCKSON: Great. Thank you, Ed.

Agnes?

MS. MASNY: I also agree with the recommendations that have been made by Dr. Collins and Ed. I think that besides the scientific and the public input that could be garnered from a public hearing like this, to

also consider having people from the ethical background, since that is one of the things that we've been commissioned to look at the impact on the legal, social, and ethical issues.

DR. McCABE: And also perhaps the companies, because there are companies that are in essence doing large population studies as part of SNP studies. A lot of the drug companies are doing this now, so I would look at what is already being done in the private sector as well.

DR. TUCKSON: Very good. Other questions or suggestions?

Yes, Debra?

DR. LEONARD: What would be the mechanism for soliciting this kind of input? I'm not familiar with how SACGT did this process, but would it be in a Federal Register notice that won't get the people that you really want to have and come make comment? What are the mechanisms for doing this? Do we have the ability to use this report in some truncated format?

DR. TUCKSON: I think it's a terrific question. I think maybe, and first of all, I'm glad you raised it in this meeting. It may be the kind of question that we leave the task force to grapple with. But maybe there are just a few general comments that you want to give to the task force to consider.

Ed?

DR. McCABE: Well, when we did the public comment with SACGT preceding that meeting, we used an email network, and also posted on our website that we were interested in feedback from the public and got a bit of comment.

DR. TUCKSON: I think, if I understand Debra's point, let me try to read into it. On the one hand, I think first of all it's important that we cast a wide net, because we always want to get opinions from people of whom we may not be familiar. I think that may also though be saying that we also want to specifically invite some folks who are known to be thoughtful in these areas who represent the community. So maybe it's a mix of both. Am I reading you right?

DR. LEONARD: Right. And there are issues like if you hold the meeting in Washington, you'll get certain responders, where if you held it in St. Louis or Minnesota, Texas, or California, you might have other responders.

So I don't know how you get -- this is a U.S.-wide initiative. I remember from the U.K discussions of their biobank, their discussions were town hall meetings, very widely distributed. I don't know that SACGHS can do that kind of initiative. But I'm concerned that we may think we're allowing a venue for public dialogue when we're

really not.

DR. TUCKSON: These are good things for the committee to have to grapple with, for the subcommittee. But a couple of comments.

Francis, Ed, and then Emily. You're on a different topic, I think, right?

DR. COLLINS: Just a quick response to the concern about how to do this so that you really hear from all parties. I would make it clear I think that this would not be the only venue for soliciting public opinion on something as important as this. If you look at what's in the report in that regard, there is a recommendation about having surveys, about having focus groups. Those could be set up separately, and having town meetings.

Obviously if SACGHS wanted to go on the road for a few weeks and meet all over the country, that would be fabulous. I have a feeling that's not quite what you think you signed up for. So this would be a component, not the only feature of public consultation.

DR. TUCKSON: That's a key thing.

Ed?

DR. McCABE: For the meeting that we had that I'm referring to at the University of Maryland, we did get people from all over the country. I remember one woman from Hawaii. It was through networking with consumer

groups that we were able to identify also the purpose of the email or website.

We got individuals who told us what they felt about this issue. To us, it all makes sense why we need this. Linda McCabe and I just finished a course for the spring quarter where this came up in the course with some undergraduate students. Half the class or more was very fearful of this when it first came up. I think it is very important.

Also to look at what the concerns of the public are, and then some public education about why this is so important.

DR. TUCKSON: Terrific.

Emily?

DR. WINN-DEEN: Yes. So I just wanted to make a couple of comments. One is I think Kathy Hudson had a good model that she used when she took some things around to town hall meetings. I'm sure you're aware of that. I would encourage you to do that kind of broad geographic and socioeconomic outreach kind of effort in discussing how this kind of a study should be done.

The other comment I have is that although I think our committee could certainly serve as an adjunct to that, we shouldn't get involved in thinking that it is only our role to do that, that we can be one of many public

forums. As you said, I don't think we can take the group on the road for an extensive road trip city to city, but I think that's the kind of outreach that it's going to take to really pull out the varying levels of public comment that you need.

There has to be some active outreach to groups who aren't going to see things in the Federal Register, who aren't going to come on a SACGHS website. So there has to be some kind of a proactive outreach.

DR. TUCKSON: All right.

Hunt?

DR. WILLARD: I want to raise a question for the committee members specifically, because I do think we need some feedback on this. The question is so I hear some broad support for organizing a session at the October meeting as perhaps the first, but by no means the last of the kinds of efforts that would be needed to do this.

However, I think we need to examine as a committee whether the recommended course of action would be that the NIH itself lead the charge for the majority of these kinds of public town meetings and sessions around the country. Or whether because there is a perceived and/or real vested interest that the NIH has in seeing this approved and going forward, whether in fact there is an ongoing role for this committee as an advisory committee

with public representation for the Secretary, that that provides a greater level, a little bit of an arm's length view on working with the public to see where the public's feelings were, rather than having this fall back on the expert panel, or on NHGRI, or the NIH more broadly.

I think it would be useful to the task force, because we can examine this in some depth, it would be useful to get a little bit of feedback from the committee members at large on that question.

DR. TUCKSON: The question is there. Guidance? Yes?

DR. McCABE: Well, I would agree with you. I think the NIH will probably have a role in doing this, but I think we should, or you all should continue to look at this issue.

I think we can be a public forum, and we can even be a broader public forum than we are in this room. I would look to how we could embrace the public more about this issue.

DR. TUCKSON: Francis?

DR. COLLINS: And I would say NIH would welcome that. I should also point out this is not just an NIH discussion. The CDC has been involved in this planning process, EPA has a bit as well.

Certainly if NIH was going to be of assistance

in mounting this kind of public consultation, we'd want lots of advice, and we'd probably want to do it by a contract to an outside organization, again, to keep this sort of arm's length relationship.

The worst thing you can do in a public consultation is to set it up so that it looks like it has a guaranteed outcome, and then nobody believes it anyway. We wouldn't want to make that mistake.

DR. TUCKSON: And Debra?

DR. LEONARD: Just some quick comments. I think as we read this, we need to keep in mind our overarching issues, particularly the access issues and how that is addressed in this document. Then two more structural things.

I think many of the task force members are rotating off the committee. So do we need to relook at the members of the task force, and will Chris Hook remain as the representative? Or does this report basically mean it's over?

DR. WILLARD: It basically means it's over.

DR. LEONARD: Okay.

DR. TUCKSON: Good. As we start to think about then summarizing this discussion and keeping to our time limit, I just want to make sure, and I know that Lana Skirboll is here from Dr. Zerhouni's office. I'm not

asking to put her on the spot, but I just wanted to give you the opportunity.

If there is anything that you either would like to say regarding Dr. Zerhouni's perspective on this and/or any sense of the timeline relevance in terms of our talking about doing something at the October meeting, whether or not that is a realistic or legitimate contribution given the timelines that the Director's Office may be on, I just wanted to give you the chance to comment if you felt inclined to do so. If not, you can just sort of wave me off.

DR. SKIRBOLL: I think the committee got Dr. Zerhouni's wishes just right. Clearly Dr. Collins is responsive to where the committee wants to go here, the issue of public consultation.

It was important to point out that Elias' point in tasking the committee was to look not only at the public consultation that you all might do, but to also make recommendations about the pathways and processes, meaning other consultations we might engage in that you can't design yourselves, but what you might recommend to NIH as part of Francis' and the NIH community, along with the department, EPA, and outside the department.

So there are two levels of here of what consultation you do, and recommendations about what other

pathways and processes you feel the government should engage in as it makes an optimal decision about whether to proceed. And then if so, how to proceed.

DR. TUCKSON: Well, the fact that you are here and paying attention to this I think give some sense of the interest that the Director has in this matter, not implying endorsement of any particular course of action, but it is clear that this must be important to send such notable a person as Lana to be here with us today. Thank you.

DR. SKIRBOLL: I didn't pay anything for that.

(Laughter.)

DR. TUCKSON: Thank you.

Let's summarize what I think we have heard. Hunt will be the first one to tell me where I think I've got this wrong.

The proposal on the table for the committee is that we recommend to the Subcommittee on Large Population Studies that they plan for a meeting which we hope will be in conjunction with our October meeting, but they may decide after they look at it that it can't be done for whatever logistics reasons. But they would plan on a meeting, hopefully in some juxtaposition to our next meeting in October as a timeline sort of guidance that would solicit public comment and comment from the "scientific" community, to include also some perspectives

from emphasis that would be focused on giving guidance and advice about proceeding or elements of issues to consider in proceeding forward with a large population study.

The mechanism and logistics for how long such a meeting should occur, whether it's a day or half day, whether it ought to be here in Washington or someplace else, we need for the subcommittee to wrestle with and grapple with.

We have been given models and examples of how the predecessor committee did it in the past. The Kathy Hudson model has come up. We've got examples for the committee to look at of ways of doing that.

I think that's pretty much what we have tasked the committee to do, and to work on. Am I missing anything in the summary of what we're giving them to do? I'll come back to that, that's good. Debra is concerned about do we have enough people on the task force anymore, but that's a technical issue. I don't want to put it as part of the proposal, the guidance to the committee.

Am I missing anything in terms of guidance to the committee? All right.

MS. CARR: Also, I think you want the task force to consider what other consultations should be carried out, by others possibly. You were getting to that.

DR. TUCKSON: I think what this is is that the

framework for the work, the guidance to the committee -- I've given the guidance to the committee summary. The context of that is that the committee will enjoy the input from Francis' team and those who are responsible for trying to look at whether there will be any other public education activities out there, and anybody that is doing stuff in government.

I think that the context as we recognize, I guess, I should make it a preamble to this recommendation, is that our committee is not the be all and end all on gaining these inputs. We're providing an input to the process. We're not the only input into the process. We can't assume that our activity is the complete record of public and scientific input into this process.

We are providing an important and significant input, but not the only. Therefore, you may be guided by what you do by other activities that may or may not be going on simultaneously in government. That's the preamble to the recommendation.

Let me stop with the preamble and that charge and see who wants to challenge that as a focus.

DR. LEONARD: That's a lot for the task force to do. But should we also look at the public education aspects that are needed? That was also brought up during the discussions.

DR. TUCKSON: Yes. It would be my recommendation that the public education around this would come from understanding and listening to the public concerns. So you sort of have form follow function, if that would be a friendly amendment to yours.

All right. I'm looking for some committee member that doesn't agree that this is what the summary of the discussion was. Given that this was the summary of the discussion, let me ask the chairman of the task force before we ask for a vote. Do you feel this gives you enough specificity to do your work?

DR. WILLARD: Yes.

DR. TUCKSON: With that, those who are new are apparently not allowed to vote, but we love you anyway. Those who can vote need to decide. All in favor of the motion by raising hands?

(Show of hands.)

DR. TUCKSON: And anyone who is against it?

(No response.)

DR. TUCKSON: Done. Thank you very much.

Task force, good luck. We see this as being important. I'm glad I'm not on it. It's a lot of work.

We're going to have lunch.

DR. WILLARD: But before you go to lunch, before you do that, do we wish to ask for a volunteer?

We're losing two of our six members.

DR. TUCKSON: Oh, yes. Let's do that now.

DR. WILLARD: It would be terrific if one or more of the new members in particular would wish to join us. Especially those who represent the public on this committee, representing the public on the task force would be terrific.

DR. TUCKSON: That was a good arm twisting.

PARTICIPANT: Yes, I will participate.

DR. TUCKSON: That's one.

PARTICIPANT: I will, too.

DR. TUCKSON: There we go. Look how that works. Hunt, you're a master.

Let me tell you about lunch. Committee members and ex officios, the lunches you ordered at 9:00, I hope, will be brought here so you can actually mill about in this room and eat. For members of the public, lunch is available in the hotel restaurant, as well as from a variety of local restaurant establishments, many of whom I understand are in walking distance.

We will reconvene at 1:00. But let me be fair for the public and the people that don't get to get your lunch right here. Because you all have to go out and you need an hour at least, I'm going to be fair and cut you five minutes of slack, because I don't want you to be mad

at me when I come back out there.

So 1:05. But you all know, I'm starting at 1:05. Now, you know that. See you at 1:05.

(Whereupon, at 12:10 p.m., the meeting was recessed for lunch, to reconvene at 1:05 p.m.)

AFTERNOON SESSION (1:07 p.m.)

DR. TUCKSON: For the record, I need to make two comments. One, the vote that we took right before the lunch break was unanimous, and I'm supposed to let somebody know for the record that the vote was unanimous. So I've done that. So whoever needs to know that the vote was unanimous, please know that the vote was unanimous. It was unanimous. That meant everybody agreed.

Secondly, some people asked about the DVD. Apparently, until and unless we outsell Amazon's site, it is actually available for the public to get a copy. Debra put hers on eBay and it sold well, she said. But you can get a copy. Now, the question is how do they do it.

MS. CARR: Actually, we're going to explore the possibility of posting it in our website so that people can download it or at least look at it from there.

DR. TUCKSON: If the committee members wanted one, what would they do?

MS. CARR: If the committee members would like another copy, we can send you another DVD. We do have extras. If the demand is that great, we can always make more copies, too.

DR. TUCKSON: Great. All right. So with that,

that's terrific.

Now it's time for the public comment portion of the meeting. 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, so we greatly value the input we receive from the public.

We set aside time each day of our meetings to hear from the public, and we welcome and appreciate the views that they share with us. We have also received a number of written comments that can be found in your table folders. We, again, appreciate the effort that people have made to make those available to us and the staff for duplicating those. So I would urge you to pay attention to those.

As always, in the interest of our full schedule, we do ask the commentators to please keep their remarks to five minutes and submit the rest for the record. Today we'll be hearing from first Greg Rabb representing Advamed. Is Greg here? Thank you. Please come right to this table right there.

MR. RABB: Thank you.

DR. TUCKSON: Thank you.

MR. RABB: Thank you. My name is Greg Rabb, and I'm an independent consultant here on behalf of

Advamed, the Advanced Medical Technology Association, a technology association representing the medical device industry.

It has more than 1,200 manufacturers of all sizes, and it has in its membership many, many in vitro diagnostics firms. Advamed has followed the work of this advisory committee closely, especially your work surrounding the coverage and reimbursement of genetic tests.

We submitted comments on your June, 2004 staff draft dealing with this matter, as well as the April, 2005 draft. We hope that you and your staff have viewed our comments favorably.

Advamed would like you to know that in the next week or two, we'll be releasing a report on the value of in vitro diagnostic tests. This report prepared by the Lewin Group will address factors associated with innovation, adoption, and diffusion of diagnostic tests.

Advamed commissioned the reported to serve as a source document to both inform various audiences about the diagnostics industry, and to identify and describe barriers that exist, hindering innovation and patient access.

As you might expect, the current coverage and payment system is addressed and found wanting. There will be a number of recommendations for reform so that new

tests, like the genetic tests that are your concern, are properly handled.

We think that you might find this report valuable as you continue your work, and we will provide copies to you and your staff if you'd like.

I'd like to conclude my remarks by reading a sentence or two from an Institute of Medicine report on the Medicare Laboratory Payment Policy that was published five years ago.

The report, which called for a series of fundamental reforms in Medicare's clinical laboratory fee schedule, most of which have gone unaddressed, concluded by saying that we have, "The opportunity to fix the current payment system for clinical laboratory services, averting the possibility of a crisis in the future. Payments for some individual tests likely do not reflect the cost of providing services. Anticipated advances in laboratory technology will exacerbate the flaws in the current system. Problems with the outdated payment system could threaten beneficiary access to care and the use of enhanced testing methodologies in the future. While Advamed believes that the current Medicare payment system for tests is a poor foundation for new tests, including genetic tests, the anticipated advances referenced in the IOM report are here today and both device innovation and patient access are

threatened if we do not correct the way new tests are valued and priced. We encourage the advisory committee to make this point as it moves forward."

Thank you.

DR. TUCKSON: Thank you very much. We appreciate that. Thank you for making the supplementary material available and taking the time.

We will next year from Sharon Terry from the Coalition for Genetic Fairness. Always appreciate your coming by and sharing thoughts with us.

MS. TERRY: Thank you. I appreciate the opportunity.

Today I represent both the Genetic Alliance and the Coalition for Genetic Fairness. The Alliance has over 600 organizational members, largely genetic disease advocacy organizations and community-based organizations that are underserved. The Coalition for Genetic Fairness is composed of the Genetic Alliance and over 100 other organizations and companies dedicated to the enactment of substantial genetic nondiscrimination legislation. This coalition includes an executive committee that is comprised of nonprofit consumer organizations, industry partners, and health professional societies, and is guided by Robert Mells of Affymetrix, Joann Boughman of the American Society of Human Genetics, Marla Gilson of HADASA, Brian Monroe of

Millennium, Jill Fonda Allan of the National Society of Genetic Counselors, Jeremy Gruber of the National Work Rights Foundation, and myself.

We are at your service, and we invite your comments and your questions. We are also welcoming departing committee members to our effort.

(Laughter.)

MS. TERRY: The Coalition for Genetic Fairness has been here advocating for this legislation both literally and figuratively before. Earlier today you heard all the major arguments supporting genetic information, nondiscrimination legislation, and you saw a video of very powerful testimony of some of our fellow Americans whose lives have been negatively impacted by genetic discrimination, or the fear thereof.

As such, I'm not going to rehash the major points you heard today. Instead, I'm going to ask you as a committee advising the Secretary to continue to articulate the urgency of this issue. Americans need to be protected from discrimination in insurance and employment, and they need this protection now.

Yes, we've been here before standing with a Senate that has unanimously passed legislation, and with a President who has issued a statement of administrative policy again this year in favor of this legislation.

However, this year the House of Representatives, a body that in the past has not been able to move this, is very much engaged.

Our coalition has been and is currently working with the House, particularly with Congresswoman Biggert and her staff to move H.R. 1227 as evidence of this fact. As noted this morning, the major opposition to this legislation is the business community, particularly the Chamber of Commerce and the National Association of Manufacturers.

We do not believe that the House, and ultimately Congress as a whole, will choose to allow the interests of business groups to override the basic rights of individuals to manage their own health care in the most appropriate manner, which is to make use of genetic tests and emerging technologies.

Additionally, we do not believe that this Congress would not seize this opportunity to leverage the amazing investments that they've made in the human genome and in the sequence of the human genome as raw material to be developed into tools, tests, and technologies that should be integrated into medicine today.

However, now research has been impacted. In fact, it has experienced a significant chill. In my mind, a deep freeze by fear of genetic discrimination. As we

learned from the Genetics in Medicine article, increasing numbers of individuals shy away from clinical research because of the very real fear of discrimination.

Remarkably, it is we, those who are impacted by genetics that have to take up this gauntlet, and are working to prove to Congress that this legislation will not hurt employers as it protects ordinary people. The Coalition for Genetic Fairness is working hard to rally Republicans in all states. We continue to mobilize our grass roots members, over 14 million of them, encouraging them to speak with the congressional members in their districts. We have met multiple times with those that oversee the business community working with them to limit liability, and to make them more comfortable with this legislation.

At the end of the day, we believe that Congress will make the right choice, making it possible for individuals to use their genetic information for health purposes for which it was elucidated. None of us have any choice over our gender, our ancestry, our disabilities, or our genetic makeup. However, as a nation, we do have a choice about how we treat that information.

Support for this legislation is support for improved health care for all Americans. We are confident that Congress will make the right choice in this regard.

Finally, we would like to thank the committee for all your work. We ask you to make sure the Secretary and all relevant parties receive the information you have compiled, along with your careful and insightful analysis.

In this manner, the millions of individuals who carry genetic mutations they did not choose are asking us to do what is necessary to alleviate the burden of discrimination and the fear of discrimination on our nation.

Thank you.

DR. TUCKSON: Thank you, and I see you've provoked a couple of questions. Let's start with Ed.

DR. McCABE: Thank you, Sharon.

I'm sure you're already doing this, but in terms of trying to enlist other Republican members with I'm sure you're using the members of the Alliance to go out and bang on some doors.

MS. TERRY: Yes. We've used the members of the Alliance, as well as the biotech and pharma industry have been both involved with us a great deal. They have gone also to their Republican members.

We've also really focused on Republicans who last year did cosign and haven't cosigned yet. I think as Jaimie said, it's really a combination of some people not having this on the radar screen with all the other things

like Medicare on their plates, as well as the Chamber less so and NAM more so this year has raised more red flags that have made it difficult for some Republicans to sign on.

DR. TUCKSON: Yes?

DR. McCABE: In follow-up, do you have anyone in any of your groups who have an affiliation with the Chamber? That run small businesses that have been impacted by genetic discrimination, or with manufacturers groups?

MS. TERRY: So we do, and they have been less inclined to comment. It has been this chicken and egg thing. They say if the Chamber and NAM will back off, then we'll be more vocal.

The Chamber and NAM tell us we'll be more vocal and back off, back off and be less vocal, if these groups will come forward more overtly. So it's very hard. What we have been trying to appeal to is to the biotech and pharma companies that have lots of employees and are major employers that in fact them joining our coalition and supporting this would give the right signal to those trade associations.

DR. TUCKSON: Agnes?

MS. MASNY: Mine is just a comment actually to commend you and to thank you for all the work that you're doing for the Coalition for Genetic Fairness. The task force on the antigenetic discrimination legislation has

really been well aware of the work that you've been doing, and we feel that we have a wonderful partner in the trenches. So thank you.

MS. TERRY: And the feeling is quite mutual. We're very happy that you see this as such a serious issue. Thank you.

DR. TUCKSON: Great. Thank you again very much.

Now we're going to move into an important section of the meeting. We'll devote in fact almost the rest of today until 5:00 with a break for a very wonderful awards ceremony for some people who seem eager to leave us so they can get more involved in activities.

As I noted last year, as I noted earlier, we determined last year that the coverage and reimbursement of genetic tests and services were a high priority requiring in-depth study. We started working at it in our March, 2004 meeting.

We gathered perspectives on the issues from experts on this issue on public and private coverage payment policies and genetic tests and service providers. We appointed a task force to investigate the issues more deeply and discussed the finer points out our recommendations at the February/March meeting.

After the last meeting, we solicited public

comments on our what we considered to be our really ultimate draft report. Cindy Berry, who has been just terrific leading our task force on this issue, will provide us in a moment with a summary of the public feedback and lead our discussion.

You have in your briefing books a compendium and summary of those public comments in Tab 4. I want to tell you that the task force members, Emily Winn-Deen, Debra Leonard, Mark Williams, Muin Khoury and Jim Rollins at CMS, have really done a terrific job and have worked hard. I also want to acknowledge Suzanne Goodwin, who has been nothing short of terrific in providing support for this committee.

Now, let me just sort of say, again, as I sort of alluded to at the beginning of the meeting. We really worked hard at the February/March meeting to get some decisions made. We made some decisions. Now, that meeting was challenging, not only for the complexity of the decisions, but also we have a lot of people moving in and out, people here and not here, I mean, it was just really hard work.

I think that the committee owes it to itself today to be fairly disciplined about how it approaches this. Cindy and Suzanne have worked real hard to give a fundamental foundation of sort of the recommendations. How

we got here. What the decision points are and were that sort of led us to where we are. By the way, this is the 18th time we've gotten public feedback. We have been getting public feedback and rewriting this thing. This is the 800th draft of this thing. I want to tell you, it has been seen by so many people and gone through so many revisions.

The point I'm getting at is I hope that we'll listen carefully to the public comment and our comments and see how they fit into the decision points, not starting us back all over again from ground zero. How do specific comments fit into yes/no decisions. Go down this road, go down that road, does it change it. But let's just stay focused on the task at hand as opposed to going all over God's green earth again. So I just give you that in my role as being the bad guy.

Now I'll turn it over to the good guy. So Cindy Berry, take us away.

MS. BERRY: Reed doesn't want me to tell you this, but he's got a little buzzer in there. So if any of us gets out of line, we get shocked with some juice there.

I also wanted to thank Suzanne and others on staff. Tremendous, tremendous, work. If you can imagine, you've seen the report and you've seen the different iterations, how difficult it is to not only write that

report, but then to synthesize, analyze, and incorporate all of the public comments to the extent that they could be incorporated into the report, organize them. It was a lot of difficult work, and I certainly was not responsible for that. So I wanted to mention that.

This afternoon, this small presentation, which is a preface to our discussion and our rolling up of our sleeves to finalize the report will cover three things. Provide an overview of the report, we'll go over some of the public comments on the draft report, and then the third part of course as I mentioned, where we do the hard work, where we actually finalize the recommendations.

As you will recall, the report had several objectives. We identified a problem in the committee based on testimony that we've heard and other evidence that we gathered that coverage and reimbursement of genetic tests and services was a problem, and as a result, access was limited. We needed to do something about that.

So the purpose of the report was to describe the current state of play. What is going on in terms of coverage and reimbursement of genetic tests and services? Who is covering them under what circumstances? What is covered? What's not covered? Then the second purpose of the report is to offer recommendations to the Secretary on what we can do to fix some of the barriers that we

identified.

The ultimate objective of course is to improve access and appropriate utilization of genetic tests and services throughout the health care system.

We came up with, as you will recall from our last meeting, nine recommendations. The report of course goes into great detail, as I mentioned, of the current state of play and all the different elements of our health care system. Peppered throughout the report are these nine recommendations.

This is the timeline we were operating under for the new members. This is just a quick overview for you. We did receive formal presentations by experts in March of last year. We had several drafts of the report that we were reviewing that we wrote and rewrote and considered. We put out a request for public comments formally in the spring of this year. We held a conference call within our task force to consider the public comments and determine what could be incorporated into the report, what revisions were necessary. Of course now we are in the phase where we are reviewing at the full committee level the public comments and trying to finalize the recommendations.

We hope to have another iteration of the report, a final version of the report sometime this summer,

and transmit it to the Secretary in the fall of this year.

Briefly, I will describe the public comment process. As I mentioned, there was a notice that was published soliciting public comment. This comment was received, the deadline was May 6th of this year. We had other outreach mechanisms. We have a website, of course, as you are aware, the Federal Register notice. We have a distribution list which reaches almost 1,000 individuals, and through notices via that distribution list, we solicited comments from individuals and organizations. Then we did a targeted mailing to 34 individuals and organizations that we thought had particular expertise and that could help inform us on key issues that should be considered in the report.

We received a total of 86 separate comments. Sixty-one individuals commented, and 25 organizations. There is a pretty broad base of stakeholders represented here in these comments. We have health providers, including physicians, genetic counselors, hospitals, public health agencies, nurses, health plans, academia, patients of course, and we even had some students commenting.

There was a school, let's see, Westfield State College in Massachusetts. They deserve special recognition for their public participation in exercising their civic duty. But they really actually had no choice in the

matter. It was a final exam.

(Laughter.)

MS. BERRY: Their professor of human genetics, it was a human genetics course at the university, asked them to submit public comments, and they did. We of course read all of them. We considered all of them. Actually, I shouldn't say that we were surprised, but some folks might have been a little surprised at how thoughtful and insightful they were. So we thank them for those comments.

As I mentioned earlier, we had a conference call of our task force where we reviewed the public comments. Everybody had a copy, and everybody here at the full committee level has a copy. There was a chart that was also prepared for us so that we could organize the comments. We organized them in terms of the types of comments that they were, and what they were addressing.

Then we considered modifications to our recommendations based on the public comments. We did this at the task force level, because as you can imagine, when you have 86 different comments from different organizations and individuals, it's very difficult to weed through all of those at the full committee level. We don't intend to go through them now one by one.

What we thought we would do, and what we have done so far is to do that at the task force level. We

waded through all of it. Then what we're presenting to the full committee are the public comments that address specifically the nine recommendations that are in our report. We are not going to go over today all of the other comments that dealt with language changes in the body of the report and some technical change and whatnot. We are incorporating those. They will be reflected in the new draft.

What we're focused on this afternoon are the comments that specifically address the nine recommendations. I also want to make a point that just because you don't hear, if someone in the audience who is listening doesn't hear their particular comment addressed, it's not because it was not reviewed and not considered and not even incorporated. What we're focusing on now are the areas where we made a very specific change to the recommendation, or it may be an area of controversy, or it may be an area that needs fuller committee debate and consideration.

So rest assured we have considered all of them, we have read all of them, and we are incorporating as many as we can. Today we are going to be a little bit more focused and precise.

As I mentioned, we had a list, and I think, is it in the binder, or is it in sort of the chart that

catalogs all of the different comments? It is in the binder. You'll find it there.

These tables and the charts that are in your briefing book, they have a list of the modifications. You have copies of the public comments. If you want to review the full panoply of comments, we can do that now. But you can refer to your charts as a way of better organizing your thoughts.

We can talk a little bit about some of the themes that we saw in the public comments presented. In general, folks were very positive about the draft recommendations. They thought that we were addressing something very important, and they in general agreed with our committee's approach to addressing them.

There were some concerns expressed about how we characterized the extent of the access barrier. Some organizations felt that perhaps we may have been overstating it a little bit. Some individuals and organization have proffered different approaches for refining their recommendations. Then of course as I mentioned, there are others who provided more technical points and comments with regard to the language in the body of the report.

Carrying on the discussion of themes from the public comments. A common thread was the anecdotes that

people were readily providing to us, illustrating the link between inadequate coverage and reimbursement and access problems that they face. We have a quote here where one of the commentors said, "My Medicaid patients cannot get the testing performed, which is recommended since they are unable to cover the remainder of the cost out of pocket." That's just an example of the types of comments we received there.

The second bullet goes to the comments that we received having to do with the problems resulting from inadequate reimbursement and billing mechanisms for non-physician genetic counseling providers. We received several comments there, concerns about out of pocket payment by patients, their reluctance to refer patients, problems finding and maintaining employment, salary issues.

I can read to you an example of some of the comments we received there. One commentor said, "As I cannot bill incident to my supervising oncologist, I cannot bill Medicare, and most private insurance and HMO plans are directly under my name. Patients, therefore, must pay for my services out of pocket without hope of insurance or Medicare reimbursement."

Someone else commented, "Many institutions are unwilling to hire enough of these skilled certified professionals because there is no reimbursement available

for their services." Those are just a few examples. We had several to illustrate that point.

Many of the commentors encouraged us to specifically recognize ABGC and GNCC, the American Board of Genetic Counseling and the Genetic Nursing Credentialing Commission, in our recommendation regarding direct billing. Another series of comments had to do with considering the impact of the recommendations on health care resources and the long-term financing capacity of the health care system. Folks want to make sure that we keep in mind that any recommendations we put forward for coverage and reimbursement consider the fact that we do have finite resources in this country, and that we need to be cautious as we move forward. That last bullet characterizes the nature of those types of comments.

Now we'll go through some specific public comments on the recommendations, and how our task force proposed addressing them. We'll go through each one, making sure that we have the input from everyone on the committee, and that we can further refine our suggestions and recommendations. We'll get this up on the screen.

DR. TUCKSON: By the way, for the new folks, as this is going up on the screen, the other thing to keep in mind, which is one of the real struggles that we all have to do is because we all want to do a lot of things to

change the world.

We've got to keep remembering that these are recommendations and things that the Secretary of Health can do. We are an advisory committee to the Secretary of Health. This is one of the other issues that we have to stay focused on. Stay within the realm of what's possible, given our authority and mandate. That's key.

MS. BERRY: If you want to follow along, was this in the folders now? I just had it on the top of my chair.

MS. GOODWIN: It's in the packet.

MS. BERRY: Right. Where you have the first part of this packet as the slides that I just went over, behind that is a document entitled "Coverage and Reimbursement of Genetic Tests and Services: Revisions Proposed by SACGHS."

Follow along with that document, because that document contains the recommendation, it contains the edited changes that the task force has made, and then below that, it highlights some of the public comments, what we received, what we decided to accept, and the changes that we made. That will help facilitate the discussion.

The first recommendation pertains to the Secretary tasking a group or body to develop a set of principles to guide coverage decisionmaking for genetic

tests. We made a few changes there. Some comments we received saying that the second sentence of the recommendation that was originally in there, and you can see the blue line edits. People had some heartburn about that. They felt that that was either inappropriate or could cause some trouble. So we had some folks suggest that we actually just take that sentence out. We didn't really need it, that the rest of the recommendation adequately addressed the problems that we were focused on.

Another comment that we had, folks were concerned about the wording "therapeutic versus informational" benefit, and suggested instead some alternative language. We tried to address that comment there.

So you will see the two changes in blue in your document. We eliminated the second sentence of the original recommendation, and then addressed the issue of therapeutic and informational benefit.

I don't know, Reed, if you want me to go through and read the full text of the recommendation as it is, or just give everyone an opportunity to just review it themselves, and then solicit comment from the group.

DR. TUCKSON: I think giving them just a couple of quick minutes. Discussion is always informed best by actually knowing what the heck we're talking about. So

we'll give you a couple of quick minutes, like study hall, but a couple quick minutes, and then go forward.

MS. BERRY: Any comments? Debra?

DR. LEONARD: Can we just take out the "and" in front of "informational utility"? We had those two things linked, so it is kind of like there's an extra "and" where we're making a list of items. This would be in the now second sentence. "Prevention, rare disease tests, informational utility and therapeutic benefit." We don't need to link informational utility to therapeutic benefit anymore. They're two separate items.

MS. BERRY: Take out the "and." Does anyone else have any comments on this first recommendation? Suggested changes?

Emily?

DR. WINN-DEEN: I just agree with what Debra suggested. I think they were really intended to be two separate things.

MS. BERRY: Agnes?

MS. MASNY: This is just a question. As we are looking in the recommendation to establish particular criteria to guide this decisionmaking for appropriate genetic tests, I wondered what sort of bridging work we could do with the work that Muin had described this morning.

Now, I know that was on the direct-to-consumer marketing, but looking at some of the outcomes of this specific genetic test, and this might be extremely helpful to help in establishing some of these criteria, that there may be some bridging work that could be done between that committee and these criteria.

MS. BERRY: Do you think, Muin, the reference to EGAPP in the recommendation does the trick? Or are you talking, Agnes, about something else?

MS. MASNY: Well, I think here we're describing establishing sort of criteria that would guide analytic validity, clinical validity, and clinical utility. I think when we get into the area of clinical utility, we are starting to address some clinical outcomes. It sounded this morning from Muin's report that these were some of the measures that they were going to be looking at, and that if there was any overlap, that maybe his committee could help guide some of the criteria.

DR. KHOURY: I'm going to give the committee a more detailed update about EGAPP tomorrow. But what I was describing this morning was a very specific set of activities in relation to measuring outcomes in communities of direct-to-consumer campaign, both in terms of people's knowledge, attitudes, and behaviors, as well as health outcomes.

Now, as part of the EGAPP discussions, which I'll present tomorrow, there will be, I mean, the purpose of such a group, one of the purposes is to review what we know and what we don't know, identify the gaps and areas where more data need to be collected. Those two things will probably dovetail into each other in the long run. I don't necessarily see anything you need to change with respect to this paragraph right now.

I mean, you just have to watch and see. What you're saying, this is an example of the activities. If this committee likes what that group is doing, you can make stronger recommendations in the future.

MS. BERRY: Any other comments on Recommendation 1?

James?

DR. EVANS: Many insurers, both public as well as private, do not take cost or cost effectiveness into consideration when considering a technology. I'm not saying that it should be removed, but it does say should address. For those insurers which do not look at cost before approving a technology, that might cause a problem.

MS. BERRY: Do you think the wording is broad enough that it would enable this group, whatever form it takes, to look at it and then determine well, perhaps that's not an appropriate factor to include in guidelines?

Or do you think it's problematic that it's even in there?

DR. EVANS: I think the word "should," you may want to alter it slightly and say "could consider." But "should" sort of implies that something should be done.

MS. BERRY: "Could address"?

DR. WINN-DEEN: I think we have the word "for example" right in front of that list. I think the intention was that you should address this list of things as appropriate, or maybe you want to add some kind of caveat like that. But I think the intention of what we were saying by putting "for example" in, you can see that was something that was added.

MS. BERRY: Or how about, "should consider." Does that soften it a little bit, saying that they should consider these things, and then however they come out on that is their decision?

DR. LEONARD: You could use the words "may include" for example. Rather than "should address," is "may include."

MS. BERRY: "May include"?

DR. WILLARD: I think this is getting to be wordsmithing. "Should address" covers all the other entities or suggestions we just covered. It doesn't say which side of the line you have to come down on. It just says you have to address it. I would urge us to just leave

it as is.

DR. TUCKSON: I think we're in violent agreement, here. So with that, on that one, the question, Madam Chairperson, is it time to call a vote on this issue? Or do you want to add a couple of other things and lump them together? Or do you want to go issue by issue?

MS. BERRY: You want to go recommendation by recommendation?

DR. TUCKSON: Yes, I think so. So are there any other things in this recommendation? Nothing else changed.

Let me give everyone a chance quickly to scan the rest of the recommendation. This is the only change. So take a good look at the rest of the recommendation.

Now, what are these here? Just ignore that.

MS. BERRY: Did you have a comment?

DR. McCABE: I was going to move approval.

DR. TUCKSON: That's what I'm looking for. Which are we approving? "Should address," or "may include"?

MS. BERRY: "May include" is up there now.

DR. TUCKSON: "May include." Done.

DR. FITZGERALD: Leaving it at "should address."

DR. TUCKSON: We're approving "should address."

The legislative intent of this is transparent and clear. We all know what we mean by it, so we think we're there. Should address.

All right. We have a motion to approve this recommendation. I'm looking for a second.

PARTICIPANT: Second.

DR. TUCKSON: Good. By a show of hands, again, knowing that unfortunately our new colleagues are not in the position to vote today, but for all those that can vote, please raise your hand yes.

(Show of hands.)

DR. TUCKSON: Those who are no?

(No response.)

DR. TUCKSON: For the record, that's unanimous.

We move onto the next recommendation.

MS. BERRY: Recommendation 2 really addresses the issue of the general desire that people would have that public and private payers would have the same types of coverage and reimbursement policies, and that we would want to make sure that those types of services and tests for the prevention or screening component that are beneficial should be considered.

It recognizes that we're never going to achieve the ideal. So with regard to the private sector, what we could recommend that the Secretary do is to have a

supportive role and make sure that private payers have all the necessary information at their disposal so that they can make their own proper coverage determinations about what they're going to cover.

The change that we made is that we did receive some comments about the specific mention of pediatrics. There was another change asking that we include the word "especially" to emphasize the prevention and screening types of services. So we put those changes in in response to the public comments.

Are there any additional suggestions or comments with regard to this recommendation, Number 2?

(No response.)

MS. BERRY: They're not all going to be this easy, I know.

DR. TUCKSON: We see no change. Motion, please, for acceptance?

PARTICIPANT: So moved.

PARTICIPANT: Second.

DR. TUCKSON: All those in favor?

(Show of hands.)

DR. TUCKSON: Anyone opposed?

(No response.)

DR. TUCKSON: The motion carries unanimously.

Next?

MS. BERRY: The third recommendation has to do with the mixed national local coverage decisionmaking process that we have at CMS. There was a comment which we received which the task force felt was very constructive and worth consideration. So we incorporated it in this version of the recommendation, and wanted to have the full committee look at it and provide feedback on it.

That was if there were a certain number of local carriers who determined that they were going to cover something, and no one suggested a particular number, but if a certain critical mass occurred, then that would or could trigger an automatic trigger for a national coverage review process at CMS.

If a certain number of local carriers said we're going to cover this, then that all of a sudden bumps the issue to CMS to issue a national coverage decision on that item, on that service, on that test. We thought that was an idea worth considering. We certainly did not consider it at the last meeting.

We put it in as a placeholder revision to this recommendation, but wanted the benefit of the full committee's feedback and response.

DR. ROLLINS: Actually, that's something that CMS already does.

MS. BERRY: What is the threshold number?

DR. ROLLINS: I can't give you a specific number. I can't give a specific number. But if there are a number of local decisions, especially if there may be some inconsistencies in those decisions, CMS will look into the possibility of creating a national coverage decision on the topic.

MS. BERRY: Is it something that they can do, or they might look at? Someone might sort of flag and say hey, here is an issue we should consider? Or is it more of an automatic trigger, which I think this commentor was suggesting an automatic thing. That there really isn't discretion. There would be a certain number, and then boom, CMS has to take a look at it.

DR. ROLLINS: There is no automatic trigger. It is something that is looked at, and then a decision is made.

MS. BERRY: Do you think there is any benefit to an automatic trigger? Or to put it in the reverse, is there a problem with an automatic trigger? Do you think that that would create difficulties for CMS if we suggested something like that?

DR. ROLLINS: I think that depending on resources available, that might be a problem in terms of establishing an automatic threshold. So it would depend on the resources available.

MS. BERRY: Ed?

DR. McCABE: Maybe with James' comment, we may want to consider a mechanism that would automatically initiate.

DR. WILLARD: I'd split the difference and say they should consider establishing a mechanism.

DR. McCABE: Does that give you a little more leeway, James, within the agency?

MS. BERRY: So "should consider establishing."

DR. FITZGERALD: Why not just "should consider"? You don't need "establishing." I mean, if they consider it, they consider they should establish it, they'll establish it. If they consider it and they consider not --

DR. WILLARD: But there are two separate things, Kevin. One is considering establishing a mechanism. The other is considering what the mechanism should be if you've chosen to establish it.

DR. FITZGERALD: Right. That's what I'm saying. So if you throw "establishing" out, that includes both of those.

DR. LEONARD: We could also get rid of the "should" or "want to" or anything, just saying that this committee recommends CMS establish a mechanism. Because then it is our recommendation, they can do what they want

with it.

MS. BERRY: James, are you saying that there is already a mechanism in existence? It is just perhaps not an automatic trigger for it? Is that the case?

DR. ROLLINS: There's not an automatic trigger. We do look at local coverage decisions. If there is inconsistency, then we do consider establishing national coverage decisions.

DR. WILLARD: But I think the value of the sentence is the automatic trigger, which is how it is worded. So the first part matters a little less. It depends on where we learned our English grammar on which is the better phrase.

MS. BERRY: Does this capture the way it is currently worded as edited? Eliminating that "may want to"? "CMS should consider a mechanism that would automatically initiate a national coverage review process."

DR. WINN-DEEN: Do we mean to have "SHOULD" all caps? That sort of shouts at you.

MS. BERRY: We feel very strongly about this recommendation.

(Laughter.)

MS. BERRY: Any other comments and suggestions?

(No response.)

MS. BERRY: Hearing none, Reed?

DR. TUCKSON: Can we entertain a motion and second it?

PARTICIPANT: So moved.

PARTICIPANT: Second.

DR. TUCKSON: All in favor?

(Show of hands.)

DR. TUCKSON: Anyone in disagreement?

(No response.)

DR. TUCKSON: Motion carries unanimously.

Next?

MS. BERRY: This is a tough one. We sort of eased into it, right, Reed? We wanted to start out with the really easy ones. We're building.

This recommendation addresses the problem that we identified in the report having to do with the screening exclusion in Medicare and the challenge that that poses for so many genetic tests and services.

We have not revised this recommendation since the last iteration. We did receive some public comments on this, and we have also solicited some input from CMS because this most directly affects them, how the statute is interpreted, how the Medicare statute is interpreted.

The first part of the recommendation basically recommends that preventive services, including predispositional genetic tests and services that meet

certain evidence standards should be covered under Medicare, and it's not really a recommendation. It's more of a declaration.

Then we move onto the second part which urges the Secretary to work with Congress and urge them to add a specific benefit category for preventative services so that CMS could determine through its national coverage decisionmaking process whether something is reasonable and necessary and could be covered.

This recognizes that there is a need for a legislative change, a change in the Medicare statute in order to cover these types of preventative services and tests.

But the third part of the recommendation is the real nettlesome part. That is where we tried to think outside the box. If you'll recall, we discussed this a bit at the last meeting. In some respects, it is trying to fit a square peg into a round hole. It has been done before. We thought in the interim, because congressional action really is very difficult, and it's a long process. We know that it is years and years before you might ultimately see any final piece of legislation signed into law, we thought well, is there some creative thing that we can do that the Secretary can do within his existing regulatory authority to help cover at least some subgroup of genetic tests and

services, keeping in mind what the parameters of the statute are and CMS' guidance.

We did solicit some input from CMS. We feel, we don't have a formal opinion from anyone on this, but in looking at the Medicare statute, it is our determination, staff and myself, that the screening exclusion is not something that is specifically identified in the Medicare statute itself. It is something that pops up in the course of regulatory either regs or guidance documents that CMS has issued over the years, interpreting the general Medicare statute.

We thought, and I should bring out my little handy dandy cheat sheet. Okay. The screening exclusion. CMS has interpreted the Medicare statute in the past as prohibiting coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute.

So if you don't have signs of a disease, you don't have symptoms, and you don't have any personal history, it is considered then a screening test, and therefore would not be covered under Medicare. So we thought, and I can't remember now who is responsible for this, I take no credit for it or blame, but I think it's creative that what if an individual has a significant

family history of particular disease, say breast cancer? Say every woman in the person's family has breast cancer.

Could that family history then be interpreted as being part of personal history, which then would say in that case, a genetic test would be a diagnostic test. It wouldn't fall within this screening exclusion. So that's the point of this recommendation, which is to get the Secretary to use his authority to in certain circumstances, however he would want to identify them, say that family history of a particular disease constitutes personal history which would then take the test out of the screening exclusion box and put it into the diagnostic test box, and therefore be eligible for coverage.

Here is where it gets really tricky. I think CMS' official position is that in general, any type of coverage for tests that could be considered screening tests really requires a legislative change, a statutory change. We don't have a formal legal opinion from CMS or anyone else at HHS confirming what I stated earlier, which was we think the Secretary has the authority to do this. Whether he wants to is another question. But does he have the legal authority to do it? I think he does.

We don't have any formal written or verbal opinion to that effect. So we want to consider whether we should leave this recommendation in as revised based on

comments that you all may have, or whether we want to take it out, recognizing that there is just some controversy, I think, within HHS or CMS as to whether this would be an appropriate thing to do, or whether CMS would even consider, or whether the Secretary would even consider doing it.

DR. TUCKSON: I think, if I understand where the issue is, is after done homework, it is unclear. So the bottom line is that what we are clear about is that we want this issue to be explored. So what I would sort of, and this is not with my chair hat on, but just a committee member's hat.

What I sort of see us doing here, cognizant of my admonitions earlier about what is in the power of the Secretary and being relevant in terms of what we send him, is there is an issue of which there is unclarity, but there is a course of action that we think needs and deserves to be studied.

I think we ought to ask him to in fact study this issue. If it turns out that he after exhaustive detail says that he doesn't have the authority to do it, then that's the answer. But I think we're being responsible about sending something forward because in fact we do not know after a lot of homework, whether or not he does or does not. So let's go forward, ask for the answer,

and then let the chips fall where they may. That's my suggestion.

MS. BERRY: Yes, James?

DR. EVANS: It does seem relevant, isn't it, that Medicare criteria currently for the coverage of BRCA1 and 2 testing includes clinically unaffected patients with a family member with a known mutation. So this is an unaffected person, and it certainly seems that a known mutation in the family is in many ways akin to family history. So it is already covered by Medicare, right? It's a short jump. I'm no lawyer, but it seems a short jump to go from there is a known mutation in the family, the person is unaffected, it is already covered by Medicare, to saying that family history could be --

DR. ROLLINS: But in that situation, that is a local coverage decision. That's not a national coverage decision.

DR. EVANS: Is that right? Okay.

MS. BERRY: Agnes?

MS. MASNY: My question is that before we would send this to the Secretary then to explore this issue, could someone from CMS actually give us an answer on this, whether a change like could be made without legislative -- in other words, we'll just take one step to check this out before we start asking the Secretary to.

MS. BERRY: We've been trying to do that. I think we will have difficulty in getting anything formal. Some formal here is our written opinion as to this, I don't think that they would be willing to do that. It would have to be kicked up to the level of the administrator and perhaps the general counsel.

We have more informally solicited that type of information from others within the agency, but I'm not sure that we'll succeed in getting anything more formal.

DR. FITZGERALD: Right. So on that thing, and to follow up on what Reed brought up, what about saying the Secretary should explore the possibility of directing CMS to clarify. So if the possibility isn't there, it's moot.

DR. LEONARD: But if it does exist, we do want him to do the directing.

DR. FITZGERALD: Right.

DR. LEONARD: I don't think he has to explore the possibility. If he takes this recommendation seriously, then he will explore the possibility of doing it. I mean, that's the next step. I don't know that we need to state that in there.

MS. BERRY: Leave it? Is the consensus to leave it?

Ed?

DR. McCABE: Yes, I would leave it as it was.

And I would move approval.

DR. TUCKSON: Looking for a second. We have a comment on the motion.

DR. WILLARD: Can we remove the split infinitive in the first sentence?

DR. TUCKSON: Who taught this man high school English?

DR. WILLARD: Have it be to benefit clinically, not to clinically benefit.

DR. TUCKSON: We knew that. All right. We are looking for a second.

DR. McCABE: I don't know if I accept that amendment.

(Laughter.)

DR. TUCKSON: We are looking for a second on the motion. Do we have a second?

PARTICIPANT: Second.

DR. TUCKSON: All those in favor, with the correction of the split infinitive, say aye.

(Show of hands.)

DR. TUCKSON: Against?

(No response.)

DR. TUCKSON: All right. Thank you.

Next issue?

MS. BERRY: All right. Recommendation 5. We

made a real whopping change in this one. We actually just referred back to Recommendation 1. This is that we're trying to encourage the Secretary to disseminate to states given the fact that they run Medicaid programs, as much information as is necessary and appropriate to help them make the best decisions and assess the evidence-base.

We refer back to Recommendation 1, because of course that's the body that the Secretary would establish to come up with criteria, principles for coverage and reimbursement.

We received no points of debate or disagreement from the public on this particular recommendation.

PARTICIPANT: Move that it be accepted.

DR. TUCKSON: Looking for a second.

PARTICIPANT: Second.

DR. TUCKSON: All in favor?

(Show of hands.)

DR. TUCKSON: Anyone opposed?

(No response.)

DR. TUCKSON: It passes unanimously. As, by the way, for the record, the one prior to that as well.

We go to the next recommendation.

MS. BERRY: Recommendation 6 pertains to payment rates for genetic tests, recognizing that in many cases, the reimbursement is below the cost of performing

the test. Until the fee schedule can be reconsidered in a comprehensive way, the recommendation asks that the Secretary direct CMS to use its inherent reasonableness authority to adjust, where appropriate, certain payment rates for certain genetic tests.

We received no points of debate or disagreement in the public comments on this particular recommendation.

Debra?

DR. LEONARD: Can I ask for a note of clarification? Are there rules now that direct how inherent reasonableness evaluations will be done? We may be suggesting a recommendation for which CMS currently has no mechanisms to do this. Therefore, this recommendation would go nowhere.

DR. ROLLINS: I don't know the answer to that question. I don't know.

DR. LEONARD: I'm just concerned that the evaluation process that we're asking CMS to use, they don't have access to yet. So therefore, nothing would be done. The overwhelming comments that we got was agreement with having this done.

So I think we at least have to evaluate whether or not the mechanism by which we're recommending having this done exists.

MS. BERRY: It's my understanding they have the

authority to go down this path, but they may not have established a path for exercising that authority, if that's what you're getting at.

DR. LEONARD: Well, right now we have been working for three years to have them do an evaluation of HCV viral loads to pay the same amount as HIV viral loads. They say they just keep going around in circles because they say they don't have the inherent reasonableness guidelines to work with yet.

MS. GOODWIN: I think at the time it was true that they didn't have the authority, but recently, at least within the past year, whatever freeze there was on that authority has been lifted. Now I think they are looking to --

DR. LEONARD: The freeze has been lifted, but they still are saying there are no guidelines by which to take action through inherent reasonableness mechanism.

DR. McCABE: Well, then I would suggest, and I think this is an extremely important part of the recommendations. I would say if there is no mechanism for use of the inherent reasonableness authority, then we would recommend that such a mechanism be established rapidly. You could wordsmith it. But basically get it done.

MS. BERRY: Do you think the language as is currently written kind of like in our earlier

recommendation where we didn't say he should consider establishing, we just said do it. That sort of implies that he's going to consider the process. Is it sort of the same thing? Or if we leave it as is --

DR. McCABE: No, I was just adding another sentence. I was just adding another sentence to try and block the bureaucratic sidestep. If there is no mechanism to accomplish this, then please establish the mechanism.

DR. WILLARD: Rather than add a sentence, why not just delete the phrase, "through its inherent reasonableness authority." We are just telling them to solve the problem. If the authority is there, great. If it isn't there, figure it out.

MS. BERRY: I think that inherent reasonableness authority is sort of a roadmap. If you don't have it in there, the response may well be, well, there is this freeze in the statute where we can't adjust the fee schedule because of the freeze in rates.

So by adding the inherent reasonableness authority, it is sort of explaining yes, we recognize that, but you do have this authority that allows you to make some adjustments here and there.

DR. WILLARD: I thought that was the question. You don't know if the authority is there.

MS. BERRY: The authority is there, but they

don't have guidelines for how they actually utilize the authority to achieve the particular objective.

DR. WINN-DEEN: So maybe we need to add something to sort of strengthen the need. Instead of just saying through immediate implementation if its inherent reasonableness authority, or something that sort of stresses that it is one thing to have the authority, and it's another thing to implement it. Or through timely implementation, something like that.

DR. FITZGERALD: Or say something along the lines of through its inherent reasonableness authority, and you used the word "guidelines," right, Cindy? If guidelines for this authority do not yet exist, they should be generated as soon as possible. Something along those lines. Then you can just add one simple sentence like Ed was saying.

DR. LEONARD: I think the last sentence can go if you just say, "The CPT codes through immediate implementation of its inherent reasonableness authority," or "expeditious implementation." Like Emily said, I don't think you need the last sentence, then.

MS. BERRY: Take out the last sentence.

DR. McCABE: James, is there a problem? Is this not doable?

DR. ROLLINS: I think it's doable. My only

concern is the word "expeditiously." That's all.

DR. McCABE: But since we move at glacial speed, then expeditious is sometimes in the next decade.

DR. ROLLINS: You and I know what glacial speed is based on our conversation here. But CMS might not.

MS. BERRY: In the next millennium.

DR. WINN-DEEN: I think from the point of view of a recommendation, I think what we're trying to convey is that this is not something that we want to just sit around and whenever CMS happens to get around to it, it happens. We are trying to convey that we would like to see this happen expeditiously. Whatever that means in the context of the speed at which government bureaucracies make forward progress.

DR. ROLLINS: Expeditiously or in a timely manner.

DR. LEONARD: I like the word "expeditious" better.

DR. ROLLINS: I like the words "timely manner" better.

DR. TUCKSON: I would suggest that we need to be clear that we want this done expeditiously. What CMS can do, that's on them, but we can't buy into, I don't think, the inevitable inertia.

Jim is doing a good job of making sure, you

know, he makes a comment for his agency. At the end of the day, we want this done expeditiously.

MS. BERRY: Any other comments?

PARTICIPANT: Move acceptance.

DR. TUCKSON: We have a motion for acceptance.

PARTICIPANT: Second.

DR. TUCKSON: We have a second. All those in favor, raise your hand.

(Show of hands.)

DR. TUCKSON: Those not in favor?

(No response.)

DR. TUCKSON: It passes unanimously.

Next recommendation?

MS. BERRY: Recommendation Number 7 pertains to genetic counseling. This is going to be another tough one. I think what I'd like to do, I will go over all of these bullets, because it is a multiprong recommendation. I'll summarize them briefly.

I think 2, 3, 4, and 5 are not going to pose the same challenges as the first one, so I'd like to go through those and then go back to the first one, which I think we'll want to spend a little bit more time on and be very thoughtful about.

The underlying premise, of course, is that qualified health providers should be allowed to bill

directly for genetic counseling services. The inability to bill directly was identified as a barrier, a problem, a barrier to access. So the very first bullet which we're going to discuss, I think, in depth, encourages or asks the Secretary to determine an appropriate mechanism for assessing the credentials and criteria that are needed for a health care provider to be deemed qualified to directly bill.

The second component of this recommendation asks the Secretary to direct government programs, federal programs, to reimburse prolonged service codes when reasonable and necessary, recognizing the fact that oftentimes genetic counseling sessions are much longer than a traditional office visit, and therefore it would be in those circumstances, appropriate to recognize and reimburse and use prolonged service codes.

The third bullet says that HHS with input from a variety of input from organizations and providers should take a look at existing CPT E&M codes, and any inadequacies that are identified should be addressed as deemed appropriate. We don't specify how they should be addressed, but urge the Secretary to take a look.

The next part of recommendation states that CMS should deem all non-physician health providers who are currently permitted to directly bill any health plan,

public or private, deem them eligible for a national provider identifier.

The last bullet, the Secretary should direct CMS to allow non-physician health providers who are qualified to provide genetic counseling and who currently bill incident to a physician to utilize the full range of CPT codes that are available for genetic counseling services.

We received a good deal of feedback from the public in the public comments. I would say the one that I want to call particular attention to is the very first prong of the recommendation in terms of how do we appropriately recommend who should be able to directly bill for these types of services.

There were some comments, and again, I mentioned earlier in the presentation suggesting that we specifically recognize particular organizations, ABGC and GNCC, recognize them and their members as being currently qualified to bill independently, and therefore exempt from the proposed review mechanism.

We received a lot of comments, different versions and iterations of that. I think the difficult questions that we need to ask ourselves is how specific do we want to be in this particular recommendation? Do we want to name particular organizations? Do we want to

identify particular providers, or should we leave it more generic so that it is something for the Secretary to determine, and for this body to determine?

Because associated with the ability to directly bill has to do with scope of practice. Is someone capable of and permitted to provide services without the supervision of a physician? Is that something that we can assess here, or is that something best left to a body that specifically is tasked to undertake that?

DR. TUCKSON: Just for foundational sake again before we launch down this road. I don't know whether you are in a position now, Cindy, to summarize, or Suzanne, a position to summarize what we spent a couple of hours on at the last meeting regarding this point.

Let me just stop there and ask. Are you in a position to summarize why the committee had difficulty at being able to wave a wand and say we believe that these two named organizations ought to be anointed with the ability to be this certifying body, or should there be some other mechanism that needs to be in place.

The other part of that discussion was should we leave it to the Secretary to try to use his convening power to be able to create the discussion that solved that dilemma? The question really becomes are we in a position to recommend that those folks be appointed with that role,

or does there need to be a process that figures that out.

That is really what I think our debate was about. But let me just make sure, Cindy, that we're accurately restating how we got to the decision not to anoint in the recommendation itself.

MS. BERRY: Right. There was some testimony presented and some written comments and feedback provided by various groups that we had requested, some of which addressed specific questions that we asked. In other cases, our question about what are the reasons, or how do you justify a particular provider being able to directly bill.

Some of those answers were not provided. Some of those questions were not answered. So we felt at the full committee level we had an extensive debate at the last meeting about that. Who do we pick? Did the organizations present sufficient evidence for us to make that assessment? Or are there still gaps in our knowledge?

At the task force level, we struggled with it a little bit as well, because we said it may be very difficult to just pick and choose at this stage. Who are we to say well, this group of genetic counselors is qualified, but this group of some other type of professional is or is not. If we start naming organizations and provider categories in this

recommendation, we may be leaving some folks out who otherwise should be included in there.

So at the task force level, we thought it best to leave the recommendation more general and leave it up to the Secretary to task a qualified body to make those assessments.

DR. TUCKSON: One other thing I'd note, and I see Ed's hand up, and others to comment, I just want to make sure, again, that everybody is playing with the same database as you ask your question.

So one other question, Cindy and Suzanne, I want to be clear about. We were pretty clear in our discussion as we struggled over this question of how do you solve some of these problems? How do you know whether it should be a Master's level person or a bachelor's person? Who gets to create the organization that supervises this? Should it be something like an American Board of Medical Specialties for Genetic Counseling? How do you do these things?

We struggled with all of those things and could not resolve it. Thus we got to the recommendation we got to. My question is for foundational sake, in the public testimony that we have received, or any consultation that we have received since our meeting, do we have anymore specificity of guidance around how to solve those problems,

other than testimony since we have met that says you ought to anoint or appoint?

What I'm wondering is did we learn anything that we did not know that would inform the committee's deliberations around these kinds of specific questions that we didn't have available to us at the last meeting.

MS. BERRY: We have not received anything formally at the committee level or at the task force level that addresses all of the issues that we've identified.

I should point out, it is on page, well, it says it is page 2, but it's not really page 2. It is behind Recommendation 7. You'll see a chart. Page 2 of that chart in the middle of the page you'll see, "Proposed Revision to Recommendation 7A (Cindy and Reed)."

We had a discussion that we wanted to put forth, and this was sort of the result of that discussion, as a way to reword that first bullet, that first prong of the recommendation to more concretely identify the issues that we face with regard to direct billing.

I think we should give folks an opportunity to read that. But in answer to your question, Reed, we still lack some information that I think would enable us or any group to make a comprehensive review or assessment as to who should bill, who shouldn't bill, and who is qualified or not.

So that's why we came up with this alternative recommendation, or alternative wording.

DR. WINN-DEEN: Cindy, I think it's important to point out that we did as a task force add the footnote, which refers you to the appendix and talks about the fact that there are groups out there that may be the right groups, but we just weren't prepared to make that comment.

DR. TUCKSON: Well, I'm scared about butting in in front of Ed again, who has had his hand up. I just want to be very precise about foundational data.

Cindy, I think you sort of responded to my question, but I want to be very specific about my point. That is not around the question of who is qualified. It is around the question of how do you create a mechanism that decides who and how you determine the organizations or organization that says that people are qualified for certain scope of practice activities.

That is a point that we were very clear about needing guidance on at the end of our last meeting. We were extremely explicit about the dilemma that this committee faced on that specific point. What I'm trying to make sure, because I think it is very determinant for, at least in my mind going forward, I'm trying to just get it straight, is have we learned anything more about that specific point than we did when we left out of here last

time. It sounds like we do not have comments on that point.

I just want to make sure everybody knows what we know and what we don't know based on where we were last time. I'll leave that there, because that helps me at least to know whether I'm missing something, or whether I'm not as smart as I ought to be about solving certain problems. So now please entertain the conversation.

MS. BERRY: Yes, Barbara?

And then Ed.

MS. HARRISON: Similar to what I said at our last meeting about this, I guess I'm a little unclear about what remaining questions there are. I mean, we asked the genetic counseling workforce to come up with a very detailed report, which they did. It just seems like given the amount of public comment that was given on this, and we had also said that was something we would take into account when we relooked at this recommendation when we had our last meeting that we would put this out for public comment, and we would get that public comment back.

There was a significant amount of comment. The majority of which, vast majority of which support both the ABGC and the GNCC being listed specifically in the recommendation.

On top of that, I think it's also clear that

even the way the recommendation is worded now, that is not to the exclusion of other health care providers. It is just simply stating that at this time, these professionals that are part of these credentialing bodies, or members of these credentialing bodies have the appropriate training to be able to provide this service, and that there may be others out there. But that information is lacking, because you know that information wasn't given to us.

So I guess I just want to put out there once more to challenge the committee to put those two organizations in this recommendation.

MS. BERRY: I'll just address that, and then go to Ed. We received a lot of information, as you mentioned, the last time in public comments, verbal and written, about the nature of the profession, about the value of genetic counseling services and the members of these organizations and the worthwhile efforts that they undertake and the services that they provide.

There is no question about it. Where we still are lacking information is yes, they can provide genetic counseling services. They do admirably. It is all worthwhile. But then the next step, and I'll call your attention to this flowchart that staff have put together. It is also in this same packet of materials where it guides us through the decisionmaking tree as to whether someone

should be able to directly bill, whether it's Medicare in this case, or a private health plan.

As far as genetic counselors, you immediately go to the yes column when you ask the question are they qualified to provide genetic counseling services. I think a resounding yes. There would be no dispute about that based on all of the information that they gave us.

The next question is are they qualified to provide genetic counseling services without physician supervision? If it's no, they have to bill incident to a physician. If it's yes, then they can bill private payers directly, but still there is another decision tree that they have to follow in order to bill Medicare.

These are scope of practice issues as to whether someone should be able to bill, or someone should be able to provide services without physician supervision. There is also the question of the credentials that a particular organization, the credentialing requirements that a particular organization has.

Are there specific criteria that we think any credentialing body should have so that any blessing that they give to their members is deemed adequate to them directly bill? I don't think we received any detailed information along those lines that would enable us to make a very specific recommendation in that regard.

That's why we were struggling at the task force level. Fearful of going down the path of naming particular organizations when we really didn't have all of the information that we might need in order to make a declaration like that. It's sort of a long winded response. I know Ed has some points, too.

DR. McCABE: I guess I disagree with Barbara. I think by having Appendix B, I thought the footnote was a masterful way of dealing with the issue without appearing too self-serving as genetic professionals.

You would use the criteria for those two organizations obviously in Appendix B, so you do sort of single them out as the ones that are established, but you don't put it in the body of the recommendation. I prefer that approach to it.

The other thing about Reed's comment about an ABMS-type structure then, because someone could set up a fly by night genetic credentialing service for non-doctoral level people, I don't think that's our business. I really think that's the business of the genetics community to establish that in order to prevent that from occurring. I don't see that as a federal issue.

DR. TUCKSON: By the way, just for the record, I don't disagree. I was trying to just get clarity. If I could put on my regular hat here for a minute, I think

you're right. I think the point is what we got to in that discussion, as I recall, was we could feel the pressure and the pain from the genetics counseling community for faster action. So what we had been debating and kicking around was could, and by the way, clarify where we were in terms of how we got to where we were. Especially to those who are new to the discussion.

Because we felt the pain and the frustration of the genetic counseling community to get this moving faster, we were sort of wondering, could we request the Secretary to use his good offices to stimulate that kind of conversation? To be a convener that would move it forward so that it would support the genetics community in getting that done, and what we were sort of looking for and hoping for, we would get some advice and guidance in the public comments about how do you in fact make something like that happen faster.

So I agree with you. It was just a sense of trying to respect the impatience and jump start the process, as I recall our discussion.

MS. BERRY: Agnes, and then, well, let's see. Agnes, Ed, Hunt, Barbara, and Sylvia.

MS. MASNY: Sort of just reiterating what Reed had said is at the last meeting, I think that one of the key issues that we wanted to address as a committee was the

issue of genetic counselors becoming recognized providers being able to get reimbursed for the services they provided.

I agree with Ed, though, that I think that it is appropriate that we don't specify a particular organization because in many ways, what we want to see happen is genetic counseling services whether it is "genetic counseling" or genetic services provided by other provides integrated into medical care.

I think the Oncology Nursing Society in their comments have actually asked us to define what we were talking about when we said genetic counseling and other types of services. I'm even wondering whether we shouldn't even ask for reimbursement for genetic counseling, but for the counselors, but that they be recognized as providers who are doing these services that are reimbursable under the regular evaluation and management codes.

That's what were asking for. So rather than making sort of genetic exceptionalist terminology of creating another category for billing, genetic counseling, let's integrate that into what is existing, but get the genetic counselors recognized as billable providers.

MS. BERRY: Who's next? Ed?

DR. McCABE: In follow-up to Reed's comment about the Secretary in convening authority, I would think

the people sitting around the table already have that message. If we wait for it to go up to the Secretary and come back down, that's going to take quite a long time, as we've experienced. But perhaps we could ask groups like CDC, NIH, HRSA to think about and perhaps report back to us what it would take to convene a group of these genetics professionals, genetic providers, to begin to think about developing this.

So without the government being responsible, could it at least be a catalyst to bring people together outside of this group that reports back to us of what they found.

Is that clear, Reed, what I'm asking for?

DR. TUCKSON: To me, as one listener, it's very clear. It's a different strategy. I think at the end of the day, what I'm hearing here is another member of the committee expressing an interest and a desire to try to move forward to accomplish a goal that is so clearly articulated to us by 100 different presentations by the genetic counseling community. You're trying to solve that problem by instead of waiting for the Secretary to use his individual power, take the ex officio members who are here from those agencies and try to mobilize them together to try to get that done. I think if I'm hearing you, that's just another way of trying to fast forward the process.

DR. McCABE: So with representatives from HRSA, NIH, CDC sitting at the table, would you be willing to try and put together a group that could begin to think about what it would take to have an umbrella that would say this is a legitimate genetics provider credentialing group so that we could prevent what will undoubtedly happen without that sort of umbrella?

DR. KHOURY: Can I just say, Ed, I'm not sure that these are mutually exclusive categories, what you are recommending.

I think if you put a recommendation to the Secretary, the Secretary will come to us anyway.

DR. McCABE: It'll just take a lot longer.

DR. KHOURY: Right. But, I mean, a lot of the activities and recommendations that this and other committees have been making have been taken up by the agencies. By elevating them to the level of the Secretary, I think this committee is more likely to make a more lasting impact.

In other words, what I'm suggesting, leave the recommendation here, but a group of us can begin a process of the interagency discussion about how is the best way to do this without waiting for marching orders from the Secretary. I think you can have your cake and eat it too, but it's not going to be easy or simple either way.

There is no need to exclude it from your recommendation to the Secretary. If we have already started the process, the Secretary will ah hah, there is an existing process. If we haven't, then he or she will lean on us, whenever that's appropriate.

But if this issue was easy to solve by the feds, I have a feeling that it could have been solved many years ago. I think it would require deliberate efforts and partnership with professional organizations on the best way to do it.

DR. McCABE: Well, I don't see that that recommendation is here now. Is there a recommendation for the Secretary under the convening authority of the Secretary to do this? That's not here. So this would be a new recommendation.

DR. WILLARD: That's an appropriate mechanism. It's just unspecified, which is in the spirit of what we had decided to do. It's just that we don't have the authority to make specific recommendations of the path he should go down, but simply urge him to go down a path that he feels is appropriate.

My comment would be, and I applaud the chairman for his efforts to be extremely even-handed here, and you're being very successful at it. But on the other hand, I would urge us to focus on the words, which we're trying

to get to a recommendation that we all can support, or the most possible of us can support.

I don't sense an enormous amount of disagreement around the table, and I agree with Ed. I think this was a masterful decision by the task force to add this footnote. I think it gets us as close as we could possibly get to providing the helpful information that is necessary.

It may not satisfy every group, but at least from what I've heard around the committee, most of us think there are legitimate reasons for not going anymore specifically in that direction. So I would urge us to stare at the language and decide whether we can support it or not support it, and keep to that task.

MS. BERRY: I think it was Barbara, Sylvia, and then Emily, and then Agnes.

MS. AU: I can understand Ed's comment about trying not to appear self-serving. I think that the majority of people, I don't think anyone would argue there is evidence, the majority of people who provide genetic counseling are genetic counselors or advanced practice nurses.

I think that in this recommendation, to reduce it to a footnote that they should consider the credentialing of ABGC, or the advanced practice nurses,

reduces it to a footnote. I think that somehow the wording should be put in the actual recommendation.

Because a lot of times I'll get the recommendation, but the footnote won't be included. I don't want that to be lost in the recommendation.

MS. BERRY: Some of the comments, though, that we received were not to the extent of just mentioning those organizations specifically, but also saying that anybody who is a member of those organizations and credentialed by them should be exempt from this review process. That's a different step. That goes beyond simply recognizing the organization.

MS. AU: So my comment is that I agree with Ed that to actually name the organization that they get exempt would be self-serving, and that's not what we want to do. But I don't want to reduce it to a footnote in the recommendation because I believe that as we said, we are looking for foundation, the evidence is that the majority of people who provide genetic counseling are genetic counselors and advanced practice nurses.

So I want to move the footnote to a more prominent part as part of the recommendation. I'm not saying that you exempt these people. I'm saying use the wording that you look at those organization's credentialing procedures in the recommendation, not at a footnote.

DR. LEONARD: I don't think there's any problem with putting it, instead of as a footnote, putting it as part of that bullet with the exact same wording that's in the footnote. I agree with Sylvia.

DR. McCABE: And you could even specify what is in Appendix B. So you could say a number of professional societies such as, have developed credentialing standards, and then put it in Appendix B, if that's a significant issue.

MS. BERRY: Emily, Agnes.

DR. WINN-DEEN: Okay, so I also agree that this is maybe a good compromise. I think my biggest concern was I didn't want to give any appearance that somehow this committee has anointed itself as a professional practices committee that can deem groups as having certain categories.

I think that that has to be left to groups that actually have that authority. We're an advisory committee. We're not a committee that is going to have active oversight or interviewing of different groups to determine if they indeed should be allowed to be billable entities as genetic counselors.

On the other hand, we've heard a lot of testimony that there are some really good credentialing organizations out there, and we want to recognize those.

MS. MASNY: That's a nice follow-up, Emily, because just to mention as an example, that the Oncology Nursing Society has their own certification organization that has already been in touch with GNCC to look at collaborating and helping ONS actually come up with their own certification or credentialing for nurses who are working in this area of cancer genetics. That, I think, will happen.

Again, if we just give the examples professional organizations that already have credentialing or certification bodies, we'll then just make use of the criteria or the template that the ABCG and the GNCC already has to help them in establishing certification.

I think that the issue, just giving the examples of the qualified health professionals, though, as a second point, is a better way to go. When we even say to recognize the GNCC-certified providers, nurses who are advanced practice already can bill, so they do not have to go through the mechanism of even going through the GNCC, but nurses are just trying to get an extra credential to show that they have the specific specialty in genetics.

So they're already billing, and I'm coming back to that point, under evaluation and management codes. I don't know whether in this whole document whether we are actually asking to create another billable entity for

genetic counseling. I still would suggest that we look at it as an integrative process and have the genetic counselors be able to bill for the regular Evaluation and Management Codes, rather than establishing a specific service for which people are already billing other qualified providers that have their UPIN numbers, which will soon be the NPI numbers, are already billing for those services.

DR. FITZGERALD: My question is, is that the wording that you have up there right now? That's what we've been talking about, right? Because it looks good to me right now.

MS. BERRY: What this is is sort of the Tuckson/Berry amendment to the original recommendation. It has since been modified to reflect the comments that we're hearing here. We took the footnote, it was previously a footnote, and moved it into the body of the recommendation.

This is really an attempt to really clarify the issue of direct billing, and kind of going through the decision tree in an actual sentence structure, as opposed to the chart.

DR. LEONARD: But Cindy, because you are taking out the first bullets, so you're removing then the bullets, and this is the full recommendation without any of the bullets below it?

MS. BERRY: This is just the first bullet. This replaces the first. So in your packet --

DR. LEONARD: The first non-bulleted part?

MS. BERRY: Under Recommendation 7 in your thing here, you see Recommendation 7 has one, two, three, four, five bullets.

DR. LEONARD: Right.

MS. BERRY: This wording up here is intended to replace just the first bullet.

DR. LEONARD: Okay. So it's just not bulleted, and we can't see the intro thing number seven that is still there?

MS. BERRY: Right.

DR. LEONARD: Okay.

MS. BERRY: Agnes?

MS. MASNY: Just one other comment. We're at the provider should be able to bill without supervision of the physician as deemed by the State Practice Act. Because in Pennsylvania, nurse practitioners cannot provide services except incident to the physician. That's deemed by the Nurse Practitioner Practice Act in Pennsylvania.

So although they're allowed to be billable providers, some of the supervision of the physician will be based by the state practice acts.

MS. BERRY: Or should it be "state scope of

practice laws"? Are they all in statute? Or are some by regulation at the state level? What's the best way to characterize?

DR. LEONARD: From what Agnes said, it's not the professions scope of practice, it's the state.

MS. MASNY: But it is the state's scope of practice for that particular profession.

DR. WINN-DEEN: So as deemed by each state.

MS. MASNY: But it's the state.

DR. WINN-DEEN: Each State, State with a capital S, probably. I think you have to add at the end of scope of practice, for each professional group, or whatever Agnes said.

MS. BERRY: All right. The question is, the next sentence was really designed to get to that point. It wasn't as direct and didn't mention states specifically. Should we just eliminate that sentence, then? Does the addition of the language we just put in there about the state scope of practice laws, does that obviate the need for this next sentence?

DR. McCABE: Before we leave that sentence, I would get rid of "laws," because I think you're going to find a mix of laws and regulations. Make it "policies," and then it covers whatever it is.

MS. BERRY: Or "requirements."

DR. McCABE: Or "requirements."

PARTICIPANT: In the next sentence, "The criteria used." It needs a D on the end.

MS. BERRY: The issue that Suzanne points out, is it just genetic counselors or others that may not have any state scope of practice criteria or laws?

MS. MASNY: That's a thing, I mean, I know that the genetic counseling community is actively looking at this. In each place where they are looking to get licensure passed, that's one of the things that they have to define is their scope and standards of practice.

So I think the organization in general will be looking to develop the scope and standards of practice that then could be presented to each state when they look to get licensure or practice in that state.

MS. BERRY: I'm going to advocate a little bit for the version prior to the additions that we just made. If you think, and if we can tweak this next sentence, the criteria used to address what you're saying, because I think adding all this other stuff up earlier makes this sentence really unwieldy and very difficult to understand.

If we can get it back to the way it was before, and then start a new sentence and add, that might be better.

DR. LEONARD: So why can't you just take out

what was added and put it in the criteria used to guide these physicians should consider that addition that we made to the first sentence.

DR. WILLARD: It says scope of practice.

DR. LEONARD: But it's not state.

DR. WILLARD: Correct. But it's all inclusive. It doesn't matter whether it is state, local, federal.

DR. McCABE: I agree. I would take out the additions that we made to that prior sentence, leave it the way it was. If we're going to wait for each state to pass laws or regulations to accept genetic counselors, it will be even slower than glacial.

DR. WINN-DEEN: Can we get clarity on states versus federal? I mean, I don't think any of this stuff, it was my understanding that you had to be licensed at a state level, and then you could bill wherever.

DR. McCABE: But there will be issues like with the uniformed services where if they don't come under state, again, I think it's good to leave state out.

DR. WINN-DEEN: Okay.

DR. McCABE: Because there will be areas where that would not hold up.

DR. TURNER: (Inaudible.)

DR. McCABE: But even when you're overseas?

DR. TURNER: (Inaudible.)

DR. SHEKAR: What I think we're both agreeing on is that even though it is the case that federal practitioners have different requirements than those in private practice, the fact of the matter is that you must be licensed in at least one state or jurisdiction. So ultimately licensure is at the state level for all practitioners.

MS. BERRY: Agnes?

DR. McCABE: I would still recommend that we leave the state out, because it will come up, then. If that's the scope of practices, then it will come up.

MS. BERRY: We're not excluding them, in other words.

MS. MASNY: I'm fine with that, but I'm going to come back to a thing that I've already said, and this will be my third time. So three strikes, and then I'll be out.

I think we're missing a tremendous opportunity with some of the wording that we currently have in there of looking at how what we're talking about could apply to all of health care practice. This is I think one of the things that we've been chartered to actually do is to look at how genetic services are going to move into all of health care.

I give as the example that in cancer care, we are already providing genetic services and genetic

information to patients who are now having genetic tests done for their tumors. It looks like even for the area of colon cancer, a recommendation is out there to have MSI or genetic testing done on every single colon cancer patient.

So then that in turn will mean that health care providers have to be knowledgeable about genetic information and possibly even going on then to provide HNPCC testing for a select group of patients so that those will probably be referred to genetic counselors, but that health care providers in general, nurses, oncologists, surgeons, are all getting involved into providing this genetic information.

I'm just going to say that I think we need to keep this integrated approach in our minds, and that maybe another group that we should include in our list, not that it is a certification organization, but would be NCHPEG. NCHPEG has already come out with established competencies for all health care providers of what they need to have in place to be able to integrate genetic information into the up and coming health care systems.

If we need any further information about that, I see Jean Jenkins in the audience, who actually helped develop the core competencies. The U.K. health care practices already have integrated the competencies that were put in place by NCHPEG into their recommendations for

all health care providers must have these specific competencies. I would hate to see us miss this opportunity for helping all health care providers to integrate genetic information into their practice by just focusing on those who will be working in the specialty area. That's the third time, and I won't say it again.

DR. LEONARD: But Agnes, it's not a coverage and reimbursement issue for physicians. I mean, a lot of what you're talking about are physicians knowing what to do with this information. They can bill for that already, so it's not really a coverage and reimbursement issue as much as it is an education issue.

MS. MASNY: But I think where we start to look at determining the qualifications of providers, then it does become an education issue.

MS. BERRY: I was building on what Debra said. We might want to look elsewhere in the report where this issue can be addressed. It is a coverage and reimbursement report, but we do address other related issues in boxes and other sections of the report.

Keep in mind, the problem that we have right now is that these recommendations, we're looking at wording in isolation. They fit within certain chapters or sections of the report dealing with very specific barriers.

The barrier here was that people who provide

genetic counseling services, a lot of them can't directly bill. So this recommendation is designed to address that. What you're talking about is something bigger, broader, and has a pretty big scope, but it might be appropriately addressed someplace else in the report. Perhaps not in this recommendation, but maybe we should take a look.

DR. LEONARD: Basically what you have is, I mean, this one is addressing people who are trained to do genetic counseling who can't bill. The other is those who aren't trained to do genetic counseling who can bill.

MR. LESHAN: Cindy, I just want to support what Agnes is saying, but I agree that there is no need to have it necessarily in this recommendation. But I think the intent of what she's saying should be reflected in the report somehow.

PARTICIPANT: The recommendation would be in Number 8, the next one.

DR. McCABE: There is a section of provider education and training, where it would seem to fit naturally.

MS. BERRY: Right. So I think that might be a good spot for it.

Barbara?

MS. HARRISON: What we have come to has settled better with me than what we had before. I also just feel

compelled to say that I think we also need to appreciate that this is more than just a self-serving issue on behalf of genetic counselors or genetic nurses. It really is an access issue.

That was kind of the whole purpose of even going down this path was to increase the amount, to allow more of the public to have access to these types of services. As we talk more about it, it is just very much linked to this coverage and reimbursement issue.

So that I guess just to take the focus off that it's not just because genetic counselors want to be paid to make a living, it is really because it becomes an access issue. As was shared by some of the public comments, sometimes the genetic counselors, there is only one in a large regional area who needs to be able to bill. Without that, individuals in that community would have to travel hours and hours to get to quality genetic services. So I just want to make sure that that stays in the front of our minds as to what was the purpose of this whole recommendation.

MS. BERRY: Are folks satisfied with this Tuckson/Berry amendment as further amended? Are there any other changes, edits, suggestions, comments to this version up here for the first bullet of Recommendation 7?

(No response.)

MS. BERRY: We haven't gotten to the other ones yet. This is probably the hardest one.

Let's go back to the other bullets. Go back to your Recommendation 7 list. Do you want to vote on each bullet?

DR. TUCKSON: I was actually just sort of thinking that.

What are you saying, Deb?

DR. LEONARD: Why don't we just do all of 7?

DR. TUCKSON: All right.

DR. LEONARD: Are there other issues?

DR. TUCKSON: Well, we'll go through the other ones, but let's just say that even without a formal vote, we'll do it. So if anybody goes back over this again, you're in deep trouble.

(Laughter.)

DR. TUCKSON: So we got this one. It's locked away.

Go ahead.

MS. BERRY: All right. How do we get this Number 2 bullet? The second bullet has to do with prolonged service codes. Secretary, directing government programs to reimburse prolonged service codes. Does anybody have any problem with that? Objection? Edit, wordsmithing suggestions?

Emily?

DR. WINN-DEEN: So the only question I have on that was I thought one of the issues was that even the prolonged service codes are prolonged enough for some of the genetic counseling services. So do we need to say something about establishing codes that have appropriate time frames for genetic counseling?

MS. BERRY: Do you think about the following bullet where we go into assessing CPT codes, E&M codes, to determine their adequacies?

DR. LEONARD: Maybe we should reverse the order of those two bullets.

MS. BERRY: That might help.

DR. LEONARD: Yes.

MS. BERRY: Does that do the trick you think? It's hard to tell. We are having formatting issues. We've just moved the third bullet to be ahead of the second bullet.

Hunt?

DR. WILLARD: Well, my memory on that issue was that although Emily's point was one of the points we considered, we didn't want to be on record as trying to tell people what the right amount of time was for genetic counseling services. There are physicians who are supposed to see patients every 15 minutes, and yet I don't think any

physician would claim that was adequate to do what they're supposed to be doing.

PARTICIPANT: The other bullet addresses that.

DR. WINN-DEEN: I'm fine with just changing the order and having it handled that way.

MS. BERRY: We've kind of moved to Number 3, so let's take 2 and 3 collectively. Any suggested edits and changes to either of those?

(No response.)

MS. BERRY: Hearing none, the next bullet, this has to do with the National Provider Identifier.

DR. WILLARD: Can you clarify the problem that this is supposed to be addressing? I'm stumbling on the use of the word "currently" here. The word "currently" suggests that if the Secretary changes anything, or if CMS ever changes anything, then this recommendation wouldn't carry forward to new people who are added to the list. So is the word "currently" actually needed here?

MS. BERRY: No. Plus that, it's a split infinitive.

MS. GOODWIN: The word "currently," the provider identifier system that CMS currently uses is in transition at the moment. So currently they use the UNI provider identifier number as our system. Right now any health care provider cannot bill Medicare directly for

their services that's not eligible for a UPIN number.

In 2006, they have a new system that's being implemented called the National Provider Identifier. In that case, anyone who can bill any health plan directly in the U.S., public or private, is eligible for a national provider identifier. So the "currently" is inserted just because of the transition point.

DR. TUCKSON: Is there a way to refer, rather than using this term, which, I mean, I agreed with Hunt until you made that point, but it's kind of an arcane point of what the interpretation of "currently" is.

What is the system referred to now? I mean, could we just specify so that somebody is not reading this in 2008 and thinking currently in 2008.

DR. LEONARD: Can we insert under the whatever the current identifier number is system?

DR. McCABE: Can we name the system that is currently in place?

DR. LEONARD: Can we get the attention of Cindy and Suzanne first, and then we can ask that question.

MS. BERRY: We're trying to figure out is there a way to mention the current existing mechanism.

DR. McCABE: Can you say "prior to 2006," or "prior to implementation of the National Provider Identifier" would be another way.

MS. BERRY: Who suggested taking this out?

MS. AU: I think that there was some testimony saying that it was not. You should take it out because you can do it already. Could it just say starting in 2006, they'll start it? By the time this report comes out, they'll probably have it.

DR. TUCKSON: So James, do you know the answer to this? I mean, is it already done?

DR. ROLLINS: Currently, we use the UPIN number. But as of January of '06, it is going to be the National Provider ID Number. I'm sorry, National Provider Identifier Number.

DR. McCABE: Will there be a natural transition? I mean, everybody who is currently under the current system will move over to the new system?

DR. ROLLINS: I will make the assumption. I'm not sure.

DR. TUCKSON: We've got some people in the audience who seem like they really know. You're going yes, yes, yes. Heads are bobbing up and down.

DR. McCABE: So then I suggest we delete it.

MS. BERRY: Well, apparently there are some people who do not currently have a UPIN. Therefore, they wouldn't be swept up in the transition to automatically receive the National Provider Identifier. So this

recommendation is aimed at that little group. For the life of me, I couldn't tell you who they are. But apparently there is this group.

So if they don't have a UPIN, we want to make sure that when the NPI takes effect, that they would be eligible for that if they can directly bill.

DR. McCABE: But that's not what this says. I mean, it is getting more and more arcane the more we discuss it.

DR. TUCKSON: In other words, isn't it simply saying, are we overreading this? That basically if you are able to bill directly, you need a National Provider Identifier? So we are simply saying that they should all be eligible to get it. If they are automatically eligible, then the point is moot.

DR. LEONARD: As long as they're permitted to bill directly.

DR. TUCKSON: Right. Who are permitted. So take out "currently" and you've got this done. "Currently" goes, and you're solved. Going, going, gone. Next?

MS. BERRY: Do you want to take out the word?

DR. TUCKSON: Just take out "currently." It's a philosophical issue. So you're now down to the last one. Don't get happy, because you're still going to have to work. You've still got one more thing to do after you

approve this.

MS. BERRY: All right. The last bullet here, this addresses the issue identified in the report that having to do with the inadequacy of certain codes. It is asking the Secretary to direct CMS to allow non-physician health providers who can provide genetic counseling services and who bill incident to to be able to utilize the full range of CPT and E&M codes available for genetic counseling services.

I think there was somewhere in the report a mention of the fact, if I recall correctly, that there were some codes that were not widely used. They can only use 99211 CPT code. So there are others that may be more appropriate.

So this bullet within the Recommendation 7 is aimed at that particular problem. Any suggestions or edits?

DR. TUCKSON: What is the change from professionals to providers? What was the difference there?

MS. GOODWIN: Consistency in terminology.

DR. TUCKSON: Consistency in terminology. Thank you.

DR. TURNER: Is the attachment going to go as part of the document? Because I would offer a correction to it, if it is. The chart.

MS. BERRY: The chart? No.

DR. TURNER: Okay.

MS. BERRY: That's just for our discussion.

DR. TURNER: This terminology of certified nurse specialist is clinical nurse specialists is how the profession addresses that group of people.

MS. BERRY: The chart won't be part of the report.

DR. TURNER: Okay.

MS. BERRY: Or the recommendation.

DR. TUCKSON: The chart was to keep us straight.

MS. BERRY: Deb?

DR. LEONARD: Could I also suggest that we move this last bullet up under what is now the second bullet? So that we talk about evaluating the E&M codes, that those E&M codes can be used to bill, and that they pay for them would be now the third bullet.

MS. BERRY: Does that capture it? We just moved it up.

DR. TUCKSON: All right.

MS. BERRY: Hunt had something.

DR. TUCKSON: We are going to listen to Hunt.

DR. WILLARD: I would like to react to Barbara's comment earlier for the preamble here, and

consider adding in the second sentence. It currently reads as such, "SACGHS recommends the following." Say something like, "As such, to ensure full access to genetic counseling services for all Americans, SACGHS recommends the following." Just clarify our motivation and get it out there and take the high road. I think Barbara's point was an excellent one, and we should jump on it.

MS. BERRY: Say that again.

DR. WILLARD: "To ensure full access to genetic counseling services."

MS. BERRY: She is angry again here. She needs some anger management.

DR. WILLARD: I would leave "as such." There is nothing wrong with "as such." "To ensure full access to genetic counseling services for all Americans."

DR. McCABE: I liked it in all caps.

DR. WILLARD: "For access to" or "for access for."

MS. BERRY: Access to.

DR. WILLARD: "All those who live in the" --

DR. TUCKSON: All right. We have a pretty clear statement here. Does anybody have any issue with this? I think it's actually a very nice addition. Is anybody concerned about it?

(No response.)

DR. TUCKSON: If not, we have a full range of recommendations for this Number 7 that we have discussed at length. I think a very productive discussion. I am looking for a motion.

DR. McCABE: So moved.

DR. TUCKSON: I'm looking for a second.

PARTICIPANT: Second.

DR. TUCKSON: All approve, raise your hands, please.

(Show of hands.)

DR. TUCKSON: Anyone against?

(No response.)

DR. TUCKSON: This is important to note. It was unanimous.

Let's move onto the next one.

DR. McCABE: I just want to applaud the committee for being both logical and consistent.

DR. LEONARD: Can I make another motion to take a break now? Or do we have other stuff?

DR. TUCKSON: Okay. That's actually a pretty good thought, actually. Here is how it works, though. We want to be fair to you and your brains. At 4:00, our friend Raynard Kington comes in for our ceremony, which we are looking forward to. Then we come back and continue to work. So it is sort of an artificial break.

Why don't we do this? Let's take a 5-minute break now, and then we just keep plowing through until Raynard comes, and then we come back and finish up. I'm more than happy to do that. A 15-minute break? We're way ahead? All right, 3:30 is a convenient, round number. So 3:30.

(Recess.)

DR. TUCKSON: We're going to continue on. I do hope, though, and I just want to make something, and I'm terrified of saying this, because if I open up this doggone door again, I'm going to kill myself, and I want to be very clear, because the committee, I think, has been very clear. If we're not clear on this, talk to me afterwards. Don't say anything now.

We have never, the committee in all of our discussions, we were very clear, but I've had enough people ask me outside, not people from the committee, but people that are in the audience, and I just want to be very clear.

We all recognize that in our Recommendation 7 which we just did, that we are very clear that the government cannot itself create the mechanism around these criteria. We are talking about the government is using its convening authority, its leadership to develop the mechanisms to make this happen.

We have been very clear that we have been, and

I mean, exceedingly clear, and I want to continue to be exceedingly clear that we are calling upon the government to use its leadership, its authority, the Secretary of Health, to bring the right people in place to make something happen. Apropos this recommendation.

I think that's a very important thing around that very first point. There are a zillion examples that we have of responsible government leadership that serves to be a catalyst for action. I will give one example, again, which I am personally involved in, which is around electronic medical records.

Levitt, not the HHS Secretary, but the electronic medical records czar, electronic czar, Mike Levitt, I'm blanking on his name. I mean, anyway, the guy in charge of the health information technology, caused there to be a public/private partnership to create a certification criteria for electronic medical records.

Government can't do it, but they can say we need people from this community, this community, this community, all of you all come on into the conference room, and now because you are all in one place at one time, we urge you to take on this charge, this goal, and make it so. Then the private sector or whoever it is that's responsible, goes forth and makes it so. Thank God the government was there to be the sand in the oyster to create

the pearl, as it were. Catalytic opportunities.

That's what I think we're trying to get at. So please be comforted, those who are in the audience who are worried that we are somehow ceding to government powers that -- the wording is very clear here. The committee has tried to be very precise. So I just want to make sure that those who are not wrestling with this at the table are as on the same page as those of us who are at the table.

It's a responsible call for government leadership to cause something to happen that might now and well may not happen were it not for the convening power of the Secretary of Health to identify a problem, raise it up in the light of public day as a priority, and then urge the appropriate people to come together to solve the problem. That's what this really is all about. Nothing more, nothing less. So having said that, I hope we're clear. What I don't want is folks in the audience to feel like they're going to go, because I'm going to tell you what is going to happen. It will drive poor Sarah and the team crazy.

If folks do not understand that point, they're going to go back out and they're going to talk about it back in government circles. The next thing you know, we're going to wind up trying to answer 5,000 emails about the fact that we are ceding power to the government that it

doesn't deserve.

So again, it's responsible leadership to identify a problem and cause the necessary people to come together to be able to solve it. That's what it's all about.

All right. Moving forward. Until Raynard comes, we're going to keep pressing. By the way, the people that raised this in the hallway with me, thank God for you, because it would have been terrible if you had these misconceptions or concerns, not even misconceptions, concerns, and you don't feel like you have a chance to raise them for us to deal with it.

So I'll tell you, your counsel in the hallways and the lunch breaks and the bathroom, I don't care where it is, is just wonderful. So don't stop, because we love you to death. Besides, I don't think any committee gets the kind of loyal folk who hang in there every meeting until the clock finally ticks.

We've got a group of people that pay attention. So thank God for you, because we would not be as good as we are, however good we are, were it not for you, if that makes sense.

Thank you. Moving on.

MS. BERRY: That's my cue. Okay. We're on Recommendation 8. This recommendation pertains to

education and training of health care providers.

The addition in red comes from a public comment we received suggesting supporting studies that link education and training tools to improved health outcomes. This particular change doesn't specifically mention health outcomes, but it does say that the Secretary should provide financial support for assessments of the effectiveness of educational and training tools.

I wanted to also bring us back to the point that Agnes had raised earlier about integrating training health care professionals and making sure that they are able to integrate genetics into their practices. I wanted to get her input, because there may be some tweaks that we might want to make to this recommendation. If it doesn't currently address her point adequately, we may want to make some further changes.

MS. MASNY: I don't know exactly where this would go, but maybe some type of beginning comment that would say something to the effect of since genetic information is being integrated into all aspects of health care and providers act as intermediaries. I don't know if that would sort of do it.

Then the other recommendation that I had made earlier was that where we are giving the examples, so that about midway down the paragraph, where it says, "HHS

agencies to work collaboratively with state, federal, and private organizations to support the development, cataloging, and dissemination of case studies, practice models and genetic competencies (as proposed by NCHPEG)."

MS. BERRY: This sort of is a regurgitation of a recommendation that we made in 2004. That language that you have, was that what we said in 2004? Or are you adding something new?

MS. MASNY: No, that is what I was adding new.

MS. BERRY: Right. But this part of the recommendation, that simply says back in 2004, this is what we said. So it's kind of regurgitating what we said. We can't change what we said, so can we put it someplace else?

MS. MASNY: Yes. Okay. Specifically to look at the genetic competencies for all health care providers as recommended by NCHPEG.

MS. BERRY: So should we add another separate standalone bullet? The first part is kind of an introductory, saying what we recommended before. The blue change talks about supporting studies into the effectiveness of training tools.

Should we amend that, or do you think we should add a separate part to the recommendation that addresses your suggestion?

MS. MASNY: I think you could go as a separate

bullet.

DR. WILLARD: Well, one point is the genetic competencies are put forward by several groups, not just NCHPEG. I'm not sure, again, if I'd single out --

MS. MASNY: Could we say, "such as" NCHPEG, and name the other organizations?

DR. WILLARD: But there could be a dozen organizations. We're getting dangerously close to where we've been.

MS. MASNY: Where we've been before, okay.

DR. WILLARD: The blue end, or red, depending on whether you are looking at the screen or the printed page, the wording of that is ambiguous to me, and maybe it's purposely so on your part.

Effectiveness is not clear whether it refers to effectiveness in training, or clinical effectiveness because of that training.

The public comment certainly by referring to health outcomes, made me believe it was the second, and not the former. So if you meant it to be related to clinical outcomes, I'd probably say something like, "provide financial support to assess the clinical impact of educational and training tools."

DR. WINN-DEEN: You know, I think we could add something about the competencies at the end of the sentence

for education and training of health providers in genetics and genomics to a level of accepted competency.

MS. MASNY: For all health care providers.

DR. WILLARD: If push came to shove, wouldn't you rather assess it against clinical impact than you would against some stated list of genetic competencies, right? I mean, if you're relating it to outcomes, you're relating it to outcomes, which is a much more direct measure.

MS. BERRY: I sometimes think when we make amendments, we create these monstrous sentences. We should break it up, I think, into two parts.

The first part is funding studies to link education and training to improve outcomes, period. Then we can address the point about clinical competencies in some way. So I think there is probably a more direct, easy way to address that point by just creating a separate sentence. So I think I would add a period and get rid of the rest of that, all that.

DR. LEONARD: Maybe it can be added up at the first sentence. I'm not sure what is not said by the first sentence. We're asking for support of ongoing training, continued education of health providers in genetics and genomics. I mean, maybe you could add, "to achieve genetic competency," but I don't know that that adds anything to what we're already stating.

MS. BERRY: Right.

DR. McCABE: I would argue that you could add something as another sentence here that would be in essence saying that health providers who are utilizing or who are giving genetic or providing genetic services should meet an adequate level of competency, or something like that.

So that all of it leads down to the fact that there needs to be some, certainly all physicians at least can bill for genetic services, but they need to meet some level of competency. The way you get them there is through all the stuff up until then, because we don't hold them accountable.

DR. WINN-DEEN: I think Agnes' point is that at some point, we're going to stop thinking about physicians as providing genetic services, and that it's just integrated into the normal practice of medicine. So I don't want to create an exceptionalism view of this.

What we want to do is we want to just see genetics and education rolled out in such a way that it's integral to the competency in all phases of medical practice. I think that is what Agnes was trying to get to.

DR. McCABE: I agree, but I think what we're trying to say is that because I see it now, that people are providing genetic services, but they don't really have the resources to provide that. The information is erroneous.

So saying that people should get educated is a good thing, but then I think they need to be held accountable at some point as well.

DR. WINN-DEEN: And I think that was the point of saying that they need to come to some competency level in their knowledge of genetics as it relates to their particular whatever it is they do in the practice of medicine, whether they're a nurse practitioner, a physician, whatever allied health professional.

DR. EVANS: I don't know how much editorializing or justification we want to do, but in relation to Agnes' first sentence, it might be worth putting something in there about the fact that yes, genetics is permeating medicine, and providers are acting as intermediaries, and they also consistently say that they are not prepared or do not have sufficient training.

I don't know if we want to justify what we're saying in those terms, but certainly that's a heard comment among providers.

DR. LEONARD: And it's documented in the literature, too.

MS. BERRY: The word keeps popping in my head that we should try to emphasize somewhere the point that these educational and training tools, and we're not just talking about professionals in training, in residency, or

in schools, but actually ongoing training for providers who are in practice, and that these tools should also in addition to ultimately leading to improved outcomes, facilitate the integration of genetics and genomics in the practice of medicine, nursing, or whatever.

So if we can maybe get those two thoughts. So there are two goals, really. One is to assess the clinical impact, i.e. improve outcomes, but before you can even get there, I think the threshold is these tools have to enable docs, nurses, and counselors and everybody else to integrate genetics into their practice areas.

DR. SHEKAR: I think that I would be remiss as ex officio from HRSA if I didn't mention the concept of diverse populations being served, particularly with a 10-year lag time of research to patient bedside, particularly important with regard to genetics and genomics that we have the opportunity that all populations ultimately through these tools get served.

So somehow if the concept of across diverse populations or multiple populations could be employed somewhere within those paragraphs, it would I believe strengthen that comment.

DR. TUCKSON: I'm going to also sort of break, Cindy, one of my little rules as chairman and just sort of raise a question. I hate to bring things back, but I just

for the first time sort of read in a different way this first sentence.

Since providers act as intermediaries between health plans and plan members, it sort of leaped out at me that it's a little strange. I don't think that we view the role of the health professional as an intermediary between the essential dyad in health care, it was between health plans and the members.

Somehow or another, the health professional is an intermediary, and thank you very much for helping out. I sort of see the essential dyad as being more the professional and the patient.

MS. BERRY: I think what's meant there, and Suzanne reminded me, I think in a sense the gatekeeper function of the provider. In other words, the provider determines when a test is ordered. It doesn't have to do with the health provider is some sort of interpreter or insignificant middle man role, but mainly as it deals with access issues, it is the provider and the health plan kind of determining what a patient would have access to.

DR. EVANS: But I think like Reed says, that's not at all the primary way we see ourselves when we are dealing with patients. That's a secondary onerous task.

MS. BERRY: I don't think it adds an enormous amount anyway. What was the reason for that language to be

in there? I mean, I know what was meant by it. But if we remove it, are we losing some critical thought that someone had?

DR. McCABE: I think you could stick the access back in there. You can get rid of intermediary and make it clear that providers have an important role in ensuring access, or a critical role in ensuring access.

DR. LEONARD: I think given what the end of that sentence says, that, "There is a need to support the ongoing training and continued education of health providers in genetic and genomics," we need to point out I think as Dr. Evans said, is that they are insufficiently trained at the current time. The way that is looking now is that genetic information is being integrated, and the providers are going to do this.

So it doesn't really follow that we need all this education and training without stating that providers, a majority of providers are inadequately trained currently, or something to that effect.

DR. TUCKSON: I'm going to need to do one short process check and trust in the attention span of the committee. It is 4:00 exactly. Raynard Kington is here. I need to just suspend for just a moment what we're doing, and also because I have to step out for 10 seconds also simultaneously. I didn't want to lose the opportunity to

introduce Raynard, and also for me to say also what I wanted to say as far as our three committee members who are going off.

Raynard, if you could come forward. We know you well, but let me introduce you formally for the record. Raynard Kington is the Deputy Director of the NIH. I can't think of a better person who has been with us since the beginning to present the mementos that he's about to present.

Let me just say as I step off for a minute and turn this over to Raynard, this is a personal point. I have learned so much from Ed McCabe. I have so appreciated the counsel of Barbara Harrison and Joan Reede. I just think you all are terrific, terrific people. We are the worse for not having you go forward. But I hope that you will stay with us.

Let me turn this over now to Raynard. As soon as he finishes, Cindy, would you resume back up? Thanks.

DR. KINGTON: Thank you. It's a pleasure to be here, even though my good friend Reed is leaving.

(Laughter.)

DR. KINGTON: No, you're efficient. Please, we have to use our time efficiently.

Thank you. It's a pleasure to be here representing the Secretary and Dr. Zerhouni in honoring the

service of three members of this committee. This committee is incredibly important to the Department in helping the agency to come to terms with the complex medical, scientific, ethical, legal, and social issues related to the development of the use of genetic and genomic technologies. I was here in the fall, I believe, at a meeting. It is a pleasure to really recognize three members in particular who are rotating off.

First, Dr. McCabe, who I met, I believe, last time. Thank you again on behalf of the Department for your service. I know that you have particular interest in genetic discrimination.

As Reed said, I've heard great things about your contribution to the committee. Thanks for the service.

(Applause.)

DR. KINGTON: Next is Ms. Barbara Harrison. I know you have been involved particularly in genetics education and training issues. Again, on behalf of the Department, thank you again for your service to the committee and this important effort. Thank you.

(Applause.)

DR. KINGTON: And the third person is Dr. Joan Reede, who was not able to be here today. I know Joan very well, as I know many of the people around this table. She

was appointed to the committee for her expertise in the area of public health and community outreach.

She was involved in a number of initiatives, including a survey of organizations on the activities of genetics education and training. She chaired a roundtable on the topic, was involved in drafting and finalizing a resolution on genetic education and training that was given to the Secretary in August of 2004, and has made great contributions to this committee.

I want to forewarn all three of you though that just because your service has ended doesn't mean we won't call upon you. We have no shame in asking members of various constituencies to advise us on how we can do a better job with our policies.

I understand there are four new members, Sylvia Au, Chira Chen, Jim Evans, and Julio Licinio. Is that anywhere close to being correctly pronounced? Welcome to the committee. You'll one day have the privilege as well to have a plaque honoring your service. We will call upon you again as well.

Thanks again, and thank you again for your service.

(Applause.)

DR. McCABE: I'll just comment. Somebody at a recent plaque ceremony, somebody made the comment that

dementia is lined with plaques, or something.

(Laughter.)

MS. BERRY: How about this? Agnes, we're going to need your help. I'll just read it out loud, but you can follow along. "Since genetic information has the potential to be integrated into all areas of health care and providers have an important role in ensuring appropriate access to genetic tests and services, there is a critical need to support the ongoing training and continued education of health providers in genetics and genomics."

Then it goes on to reaffirm the recommendations that we made to the Secretary in 2004, recommendations which included blah, blah, blah. Then we still haven't fixed this last part. But let's take that first paragraph. Does that capture what people are getting at? We have to fix the second one, but I want to make sure the first one is okay. The second part. This gets to the studies.

DR. McCABE: Well, we haven't done, Cindy, in the first part, and maybe there needs to be a separate one so that we don't get too many run on sentences. But we do need to acknowledge the diverse population somewhere.

MS. BERRY: Should we have that in the part about ensuring appropriate access to genetic tests and services? We want to add to everyone or to --

DR. FITZGERALD: (Inaudible.)

MS. BERRY: Not just for them, but for everyone. Okay. Diverse populations. Does that do it? All right. So here is the question. I almost think we don't need to have this second sentence.

DR. WILLARD: You almost have it. You can combine those two. Just say, "These tools should enable health providers to meet standards of genetic competency and to thereby integrate genetics into their respective practice areas."

MS. BERRY: Yes.

DR. WILLARD: To thereby.

MS. BERRY: And then get rid of this last -- competencies or competency? Singular, or plural?

PARTICIPANT: Cies.

PARTICIPANT: Plural standards, you have singular competency, yes.

DR. McCABE: The term of art in regulatory medicine is competencies.

DR. WILLARD: Right, but then you don't need standards.

DR. LEONARD: Yes, you don't need standards at all.

DR. WILLARD: Or to meet a standard of genetic competencies. They can't be the same.

MS. BERRY: I'll take that standards out,

right? Do you want to take "standards" out? I liked it better, just "meet genetic competencies," don't you think?

DR. WILLARD: That's fine.

DR. EVANS: There certainly could be different standards for different levels of providers, right?

MS. MASNY: Thank God Reed's not here for him to bring up something from the past.

MS. BERRY: I won't tell. Go ahead.

MS. MASNY: No, just what we recommend as one of the tools to help with education and training was only one of the aspects in that 2004 report. It makes it sound like including, just maybe to say one of the training mechanisms. Remember we had all the suggestions for integrating genetic information into credentialing exams. What could be done for ongoing education to get training of faculty.

This was one of the recommendations that was made based on the survey that we did with the health professional organizations. They said that the providers needed these tools of cases to see how it was actually applying to their practice. But that was just one aspect of what we were looking at with the education recommendations.

MS. BERRY: So do you want to emphasize that?

MS. MASNY: Well, it makes it sound like when

you say "which included," it makes it sound like that that was the complete list.

MS. BERRY: Included is like it sort of included these things, but there were more.

MS. MASNY: Okay. All right.

MS. BERRY: Ed?

DR. McCABE: We should discuss this, but I would say "meet adequate genetic competencies." That's usually, there is some level that is set as inadequacy. To meet genetic competencies, I think we should specify a level.

I would say, "And thereby to integrate genetics effectively into their respective practice areas."

MS. BERRY: Does "adequate" sound good enough? Or does it sound like we just want a bunch of mediocre providers?

MS. AU: Can you put, "Established genetic competencies?" I mean, adequate, who's adequate?

PARTICIPANT: But some of them haven't been established for every --

DR. McCABE: I think it needs something more than, to say "meet genetic competencies," that seems too vague. "Establish" is better.

DR. TURNER: The word "tools" to me doesn't seem -- education and training programs, maybe. Tools are

a part of the program. "Tools" seems to be a very particular subset of what we mean. It's like a checklist or an exam. Those are the tools, but it's the larger training programs and educational programs that we want support for.

MS. BERRY: Would you still call it a program if you're talking to a doc who has been in practice for 20 years and you are providing him with some kind of CME? Is that a program still?

DR. TURNER: A short course.

DR. WILLARD: Or just call it "genetic education and training."

MS. BERRY: Yes. Right. So get rid of "tools." Just say, "Impact of genetic education and training."

DR. TURNER: Because it asks the question then, what are these tools. We don't define those or describe them.

MS. BERRY: Okay. How's that?

DR. LEONARD: In the second sentence, you need to change "these tools."

MS. BERRY: Right. This training should enable health providers? Or education? This training or education?

DR. McCABE: I would go "education" rather than

"training." Training is the old fashioned way.

MS. BERRY: Or "these efforts." Okay. Any other changes?

Agnes?

MS. MASNY: Again, coming back to that initial paragraph, do you think that we should say, though, that SACGHS recommendations, I'm not reading it off the screen there, regarding the education and training of health professionals, so it's a reference back to that original document that we sent?

Because as was just reminded to us when the awards were given out, there actually were resolutions that we came up with. So there is a specific document on that, just as a reference point.

MS. BERRY: I think maybe "the Secretary" should go up here. "SACGHS reaffirms the recommendations it made to the Secretary in 2004 regarding." Does that do it?

Muin?

DR. KHOURY: Can you scroll down a little bit? Just come down a bit more. I want to show you, okay. The selected division suggested by public comment recommends supporting studies that link education and training tools to improved health outcomes.

This is a document about coverage and

reimbursement. It is not a document about general education and training in genetics. Of course they go hand in hand. I'm feeling that we may have lost something in the translation, because we are talking here about making a set of recommendations to HHS about coverage and reimbursement of genetic tests and services that should be evidence-based, and that should follow all the other recommendations.

Somehow this Recommendation 8 has evolved into sort of a catch all stuff of some sort. I'd like us to go back and rethink a little bit why we have Recommendation 8 to begin with, and what are we trying to do to answer the public comments about linking the training of the health providers with improved health outcomes?

At the end of the day, you want to show that coverage and reimbursement of appropriate genetic services can lead to improved health outcomes among patients and the population. You'd like to link those things together.

I thought what the task force responded to, and somehow this paragraph has become something else.

MS. BERRY: Well, to answer the first part of your question, this recommendation, again, it's hard for us because we're taking them in isolation. It's hard to see the context. But where it fits in is in the report under provider education and training. That was mentioned as a

key component to coverage and reimbursement, insofar as if a provider is not properly trained in the area of genetics, they don't know what they don't know, and they won't necessarily provide their patients with access to these services because they won't necessarily order them, or they won't know that the patient needs them.

It is also addressed in that section, the fact that a lot of health plans have physicians and other providers making coverage decisions. If they don't have a good knowledge base of genetics, they won't necessarily make appropriate coverage decisions. So this is where in the report this recommendation fits.

So it is in a provider education and training section. It's not a major part of the report, so we don't really go off onto too big of a tangent in the report, but it is identified as an issue that pertains to coverage and reimbursement.

Now, you asked about the commentors health outcomes point. That may be something that we need to think about.

DR. KHOURY: Yes, and I think that's something we may need to think about. Why are we training health providers in the new genomics era so that they can provide the evidence-based services to improve health outcomes.

If we're asking the Secretary to provide

financial support for the assessment of that link between education and health outcomes, I think we are focusing on the first part, but we're not focusing on the second part.

If you can do outcomes research that considers as part of the analysis the level of training of the health care providers in genetics and genomics and how that might be related to changes in the outcomes of patients and populations. So just see whether or not the committee can somehow pick up the theme of linking all of that stuff with improved health outcomes. That's what I thought we were responding to.

Maybe it requires a creative way of putting improved health outcomes in this paragraph somehow.

MS. BERRY: Well, this language in that last paragraph there is supposed to address that, but it may not do it well enough. Maybe we need to actually use the words "improved health outcomes."

This part where it says, "The Secretary should provide financial support to assess the clinical impact of genetics education and training." What is meant there is is it making a difference? Is it improving outcomes? But maybe we just need to state that more directly.

DR. KHOURY: Let's do that.

DR. LEONARD: But it's the words, "the clinical impact" that was used in place of "health outcomes." So I

think it's redundant to put the clinical impact. I mean, what clinical impact means is improved health outcomes.

MS. BERRY: How about get rid of the word "clinical" to assess the impact of genetics education and training on improved health outcomes.

DR. TURNER: (Inaudible.)

DR. WILLARD: That would be the hope.

DR. TURNER: Or just the impact on health outcomes.

MS. BERRY: Does that do it, Muin, do you think? Can you see it?

DR. KHOURY: I think clinical impact was okay. I was maybe working from this.

MS. BERRY: Yes, look at it.

DR. KHOURY: There are so many changes that have happened since then.

MS. BERRY: Right now it reads, "The Secretary also should provide financial support to assess the impact of genetics education and training on health outcomes." Then it goes on about competency.

DR. EVANS: You can probably get rid of the two after the "thereby," and "thereby integrate genetics."

DR. WILLARD: I think we're reaching the saturation point on this recommendation.

MS. BERRY: Is everybody okay with it?

DR. LEONARD: Can we vote without Reed?

DR. WILLARD: I can jump in ahead of my role tomorrow, if need be. Do we have a recommendation on this one?

PARTICIPANT: Can you read it all together?

DR. WILLARD: If you can scroll it, Suzanne, so people can see the top of it. Do we have a motion?

DR. McCABE: So moved.

PARTICIPANT: Second.

DR. WILLARD: All those in favor, if you can raise your hand.

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: The recommendation passes unanimously.

We can move onto Number 9.

MS. BERRY: Number 9. One more.

DR. McCABE: Well, there are some more after that.

MS. BERRY: Well, the other stuff has to do with kind of the body of the report, some technical changes and things like that, so it's not as critical. We can get to that if there's time. It doesn't go to the meat of the recommendations.

This last recommendation, Number 9, has to do with a little bit of public education, making sure that the public has reliable, accurate, trustworthy information about how to gather and utilize family history, genetics, and genetic technology so that they can make informed decisions with regard to their health care.

We received some public comments on this. One of the comments caused us to make this change here in the second paragraph. "The Secretary should leverage HHS resources to develop and make widely available reliable and trustworthy information about how to gather and utilize family history, genetics, and genetic technologies to guide and promote informed decisionmaking."

We didn't have too many comments on that, just a few. That was the one change that we made at the task force level. Does anyone have anything?

DR. EVANS: As a newcomer, reading this, the very first sentence struck me as being rather confusing. At first I thought it was talking about reliable and trustworthy information about family history. That makes it being available on the web, that makes it sound like it is quite concerning. I don't want my family history on the web, right?

Maybe we should use that same phrase, "reliable and trustworthy information" gathering pertinent family

history and information about genetic technologies. Something like that.

DR. WINN-DEEN: I think we meant to have a comma after genetics. So by gathering family history, genetics, and genetic technologies. Genetic and genetic technologies are meant to be two separate thoughts, right?

MS. BERRY: Is there a way to squish this?

DR. McCABE: Cindy?

MS. BERRY: What?

DR. McCABE: I would suggest that we start, and we can decide whether we have a need for that first phrase now, but that we should let people know where we're going. So patients and consumers need the tools to evaluate health plans, or need to have the information to evaluate health plan benefits and health providers so that they may make the most appropriate and the most financially responsible decisions about themselves and their families.

DR. WILLARD: Or just begin at "in order to allow patients and consumers," and just take that bottom phrase and move it to the top.

DR. McCABE: Yes, and we need to throw genetics in there somewhere, too. I see what you did. But still, it is a pretty long sentence.

MS. BERRY: We haven't fixed it yet. So what part do you want to move up?

DR. McCABE: If you do it Hunt's way, and then we can see whether it's too long a sentence, but patients and consumers need the genetic information --

DR. WILLARD: That wasn't my way.

DR. McCABE: Oh.

DR. WILLARD: I would just start the sentence "To allow." Take the last two lines of the existing recommendation. "To allow patients and consumers to evaluate health plan benefits and health providers and their families."

MS. MASNY: But are they evaluating these plans and benefits related to genetic services?

DR. McCABE: See, the way Hunt is doing it, then it's a comma, reliable and trustworthy information about family history. So it comes in, but at the end.

DR. LEONARD: It's my thought that this isn't really related to choosing health plan benefits and health providers, as much as it is in helping in the medical decisionmaking for their own care, and the care of their families.

There are two aspects to this. But I think evaluating health plans and health providers is really sort of secondary to really helping to participate in their own medical care and the decisionmaking. Genetics is very much this is your choice, what do you want to do.

If they are not informed, they can't participate in that process as effectively.

DR. WILLARD: But it does bring in Muin's point. It ties it back into coverage and reimbursement, because some plans may provide coverage, some may not. That's relevant, therefore, to their choice between Plan A and Plan B.

DR. WINN-DEEN: Could we add the word "clinically appropriate?" "To make the most clinically appropriate and financially responsible decisions for themselves." So that ties in sort of the medical side and the -- I mean, it's always a balance, right?

MS. AU: What was your definition of financially responsible?

DR. WINN-DEEN: I think each family has to determine do they have the means to pay for something. If they are in a health plan that has a huge deductible, is that the kind of thing they want to be in? Or do they want a $10 copay? I think that's what we were trying to get at with financial. It is within your own personal financial resources. What is financially responsible for you as a consumer.

MS. AU: I guess my problem with that working in a public health agency is financially responsible to us is societal, financial responsibility versus personal

financial responsibility. I didn't know what you were qualifying it as.

PARTICIPANT: Do you mean financially feasible?

DR. LEONARD: So why can't we just say that the most appropriate clinical and financial decisions for themselves and their families?

MS. AU: Yes. That's good.

DR. KHOURY: How about just the most appropriate decision? The most appropriate decision involves all of the above. Clinical. The most appropriate decision.

DR. WINN-DEEN: So can we add the same comment after "genetics" in the second paragraph?

DR. LEONARD: Is this now getting redundant? What's the difference? Maybe I'm missing something, but what's the difference between the second paragraph and the first? Why are they separated as two?

MS. BERRY: Well, they don't have to be. We can mush them together. The first paragraph just sort of says patients need access to information. The second part of it is what the Secretary can do to help get them information.

DR. LEONARD: So you can stick it up there. It won't go?

DR. WILLARD: If that's all you're trying to

say, I think you could just say, "The Secretary should leverage HHS resources to develop and make widely available, reliable, and trustworthy information." It refers to the previous sentence. Otherwise, you're repeating the same words two sentences in a row.

MS. BERRY: Put, "To make such information widely available."

DR. KHOURY: Cynthia, what does the term "should leverage HHS resources" mean? If you look at Recommendation 8, it was different. It was, "Should provide financial support for assessment." Are we asking HHS to -- I mean, leveraging HHS resources somehow implies a zero sum game to me.

You have all these resources and you move things from here to there. That image, I'm not sure who came up with that word. Aren't we asking the Secretary to do something to develop and make widely available?

DR. McCABE: Well, I think leveraging does mean something different than a zero sum gain. What leverage means is we want the Secretary to invest some money. So you get more. Leveraging to me means you get more than the money you invest. There is some strategies where you're going to get more out of it than just putting the money in and getting a product out.

DR. LEONARD: Can we just say "Should make such

information widely available," and then just come to the end, "through federal government websites and other appropriate mechanisms," and take out everything in between?

MS. BERRY: Maybe we should take out "develop." Because you don't develop such information through websites, do you necessarily?

DR. LEONARD: Well, you make it available.

MS. BERRY: So just add, "make it available." So "leverage resources to make such information widely available through federal government websites and other appropriate" --

DR. LEONARD: No, I think it does need to be developed.

DR. WINN-DEEN: Yes, you have to develop the content that you're going to put on the websites.

MS. BERRY: But you don't develop such information, do you, necessarily?

DR. WINN-DEEN: Sure you do.

MS. BERRY: Do you develop content to put on a website?

DR. WINN-DEEN: Even if you're just pulling stuff from the literature, you have to develop the content and put it together in such a way you can post it to a website.

DR. McCABE: And if it's going to be evidence-based, there may even be a research component to check the validity of the information before you put it up.

DR. KHOURY: Remember the Surgeon General family history tool that was developed.

MS. BERRY: Right. All right. How does it look?

DR. WILLARD: Why don't we take a moment to read through it?

DR. LEONARD: Could we accept the changes so that we can see it all as if it is written normally?

DR. McCABE: We need a synonym for information.

DR. FITZGERALD: That's right, because you're referring to it again, though, right? I think it should stay as information, because you're saying such information refers back. This isn't meant to be a best seller. It's simply meant to be understandable.

DR. LEONARD: But you could say they need reliable and trustworthy information about family history, about gathering family history, genetics, and genetic technologies.

DR. WILLARD: Suzanne, don't touch it. Consider changing the order so that it is trustworthy information about genetics, genetic technologies, and gather and utilizing. So just change that order so that

it's clear.

DR. EVANS: Don't they really need trustworthy guidance about gathering this information, as opposed to trustworthy information about gathering information?

DR. LEONARD: I agree with what Hunt said about moving the genetic technologies.

MS. BERRY: You can say trustworthy information about genetics, genetic technologies, and gathering and utilizing family history.

DR. TURNER: Cindy? Over here again.

MS. BERRY: I keep hearing it over there.

DR. TURNER: To start it with "To allow" I think frames it in a way that gives it a paternalism that we probably don't need. So if we were to say, "In order for patients and consumers to evaluate health plans and benefits to make the most appropriate," and take out that "so that they."

DR. WILLARD: Maybe with that change, we can look at it one more time and see if this does about what we can expect it to do at 5:00 in the afternoon.

MS. HARRISON: In order to utilize family history, you have to gather it. Can you just take out "gathering" and it will cut down on the wording.

MS. BERRY: Unless -- oh, he's gone. I was going to say Muin thinks that the gathering part is a part

of the Surgeon General's family history initiative. Do we need to leave it in there for that? I have no strong opinion at all.

DR. McCABE: Let's get rid of the utilizing if we're going to do it. Let's just, about genetics, genetic technologies, and family history.

DR. WILLARD: Let's read it and see if we can't get to a motion.

DR. LEONARD: But Jim, yo had raised the concern about family history. I think in this context, though, it's differently worded such that it is not saying that individual family histories are going to be published on the website.

DR. WILLARD: So if Suzanne will put her hands in her lap, don't touch the keyboard, let people read it and see if we're getting close.

DR. FITZGERALD: Now the way it reads, I think you need a comma after "family history" just to set all that aside. Thanks.

DR. McCABE: With that comma, I move approval.

PARTICIPANT: I second.

DR. WILLARD: All in favor?

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: We are unanimous in accepting that recommendation. We have soldiered through all nine recommendations.

Cindy, what else do you have for us?

DR. McCABE: Could I ask that at the end of the day, I know this is hard on staff, but maybe if this could be printed up for us so that we could look at it one more time tomorrow on a piece of paper.

DR. WILLARD: A clean version of the recommendations? Did any staff hear that request? Okay.

MS. BERRY: Hunt, I don't know if you want us to do this or not, but there really were a couple of minor, and then one a little bit more significant, changes to the body of the report that we made at the task force level in response to public comments. I don't know if you want us to go through those now.

DR. WILLARD: Well, I think we've been in the spirit of accepting the task force's good work on behalf of the committee as summarized here. They don't look too substantial to my eye, unless anyone would like to discuss them.

DR. WINN-DEEN: Do you want to just give a brief outline of what the areas were so that everybody knows what they were?

MS. BERRY: Sure. The first has to do with

revising the introduction section of the report. We rephrased the sentence so that it now reads, you can look at the blue part in your paper there, I won't read it out loud, but it addresses the issue of reimbursement levels for covered tests.

DR. McCABE: Move approval.

PARTICIPANT: Second.

DR. WILLARD: I'm not sure we need to vote on this.

DR. McCABE: I think we do, because it's the final.

DR. WILLARD: Okay.

DR. McCABE: Unless we're going to have a vote on the final document.

DR. WILLARD: And I don't believe we are.

There has been a motion to accept that change and a second. All in favor?

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: That's unanimous.

MS. BERRY: The next one had to do with we had a section on what is genetic/genomic tests and technologies, what are they. There were a lot of public comments about that, fearing that it is too long, it's too

confusing. So our task force recommendation was to indicate that really the text is meant to be a description rather than any kind of hard and fast definition. Discussion?

DR. WILLARD: Any discussion on that point from around the table?

DR. McCABE: We've always had this very long definition of genetic tests. Partly it was historical that we were using the definition that had been developed two committees ago. Have we already buried it, Suzanne or Sarah? Have we wavered from that definition of a genetic test already?

DR. WILLARD: I think we spent some time discussing that. At least it was modified to also include genomic tests.

DR. McCABE: Okay. That's fine.

DR. WILLARD: Any further comments on this change?

(No response.)

MS. BERRY: And the last, we have already talked about, which was to be consistent when we talk about providers so that the terminology is the same throughout the report.

DR. McCABE: Why don't we just for formality sake, I'll move to accept those changes as well.

PARTICIPANT: Second.

DR. WILLARD: All in favor of accepting those?

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: With that, Cindy, are you done?

MS. BERRY: Done. Fini.

DR. WILLARD: Well, I'm sure I speak for our real chairman in thanking Cindy and the task force and staff, especially Suzanne, for an extraordinary amount of work in getting this document done and shepherded through both public comments and our own attention to it.

As is traditional, Dr. McCabe always has something to ask. Yes?

DR. McCABE: Well, it's just we had said that according to the schedule, these changes were going to be made, and we were going to approve it, you all were going to approve it in October. The question is does the committee need to see it again, or is it approved as it is now? Could it move forward at this point, rather than waiting another quite a few months?

MS. BERRY: I think we have to go through and still where we are in the process of incorporating some technical changes and comments that were made.

DR. McCABE: But I looked at those, and those

are grammar, that we spelled "peck" instead of "pack" for lawsuit and some things like that. I trust that staff could do that.

DR. WILLARD: Right, and I believe that's the spirit of the timeline that Cindy proposed to use earlier, that there will be final minor revisions through the summer, and then in the fall, it will be transmitted. There isn't a step, at least not written, as to come back before this committee.

DR. McCABE: Okay. So it will be transmitted without coming back to the committee.

MS. GOODWIN: Well, the committee will get one last chance by email to review the entire text of the report once we've gone through all of the public comments. But that will be done by email probably.

DR. McCABE: Any guess at a schedule on that?

MS. GOODWIN: We'll probably have a final draft ready by the end of the summer, possibly earlier. We hope that the report will be approved by the next meeting in October.

DR. McCABE: So that email will include a letter to the Secretary that will go along with this?

MS. GOODWIN: Yes.

DR. McCABE: Okay.

MS. GOODWIN: The report will also, what is not

in the report now is an executive summary, and staff will be preparing an executive summary, in addition to making some other technical changes to the report.

The committee will have an opportunity to have one last look at the entire thing before it gets transmitted to the Secretary in the fall.

DR. McCABE: I just think that we've belabored this, and I'm sure we could wordsmith it for another 18 months. But I think it's important that it move forward as quickly as possible.

DR. WILLARD: This glacier is done.

Mr. Chairman, or Sarah, are there any final announcements before we adjourn for the day? I believe we're done.

DR. TUCKSON: We have to talk about dinner. We need to get the information on dinner.

MS. CARR: Actually more than that, I was wondering if you'd like to go over what decisions we made today. You might tell everybody about, Hunt, tomorrow, and then that would free Hunt up from having to do this tomorrow.

The three things we did today. You know what? We have them written out.

DR. TUCKSON: Good. I was just going to grab my notes, though.

MS. CARR: We just need a moment.

DR. McCABE: As usual, Sarah is way ahead of us.

MS. CARR: Yes, members who are joining us for dinner tonight should meet in the lobby at 6:40. We're having dinner at 7:00 at Clyde's. Would you like to go earlier? We could certainly see to that. If so, when?

MS. BERRY: As our reward for finishing early.

MS. CARR: 5:00? 5:30? 6:00?

MS. HARRISON: As a local person, the earlier, the better.

MS. CARR: Okay. We'll meet at 5:45 in the lobby.

DR. TUCKSON: And then as far as tomorrow, our friend Hunt will take the chair role tomorrow. I have to be away with an unavoidable conflict that I just have to attend to. I apologize to the committee. It's the first time I have missed one, but thank you, Hunt. He's well prepared. We've gone over all this. You're in terrific hands. Besides, you can take a sigh of relief that you don't have to deal with the crazy guy.

With that, the summaries on genetic discrimination, copies of the DVD are available to the committee. You can get it, and copies will be made available to the public on the website. As you see,

continue to monitor developments in the House of Representatives, make compilation of public comment DVD of public perspective analysis, I've already said that. That's good.

DR. LEONARD: Does broadly available include giving it to Ms. Biggert's office specifically?

MS. CARR: If she asks.

DR. McCABE: She already has a copy because she asked.

DR. TUCKSON: Right, she asked for it, and we gave it to her. We were very clear on that.

Number two, large pop studies. Yes, review report of NIH. We all are asked to read that report carefully.

MS. CARR: Well, this is the charge to the task force. But yes, the rest of the committee should review.

DR. TUCKSON: The committee is supposed to read the report.

MS. CARR: Yes.

DR. TUCKSON: Okay. Now, from that, let's go to the task force. They have to read the report, too. Identify other potential policies that need to be addressed, and recommended process or pathways for addressing them. Plan a public consultation meeting or meetings in October if possible to gather perspectives of

the general public and the scientific community. You left out the scientific community.

MS. CARR: That's in the third bullet.

DR. TUCKSON: Third bullet? Okay. About the idea of the U.S. mounting a large population study and whether they would support such a study.

Just an addendum to that is the challenge the committee is going to have is how do you in fact ask for public comment on something that nobody understands? So the task force is going to have to take a good, hard look at explaining what this thing is, and then making that part and parcel of the announcement.

DR. LEONARD: Tim, is there any sort of summary, executive summary kind of thing of that report?

MR. LESHAN: Yes, I believe there is. I haven't read it in the last little while, but I believe there is an executive summary to that report.

DR. TUCKSON: Then plan a public consultation meeting or meetings in October to gather perspectives from the scientific community broadly.

I think the idea would be though, at least the assumption is you need to think about whether those go together, or are separate. I want to be careful about the administrative burden of trying to do separate things. You may determine that you can't do them together for time

reasons or whatever, but it is something the committee needs to think about.

DR. McCABE: This is one where I would encourage the committee to move forward deliberatively as opposed to expeditiously. First of all, I doubt that there are the resources currently in hand to engage in such a study. I think that the U.K. ran into problems where the public was not prepared when they tried to roll it out.

So I think there is an opportunity for this one to be deliberate. You may save time in the long run by being deliberate.

DR. TUCKSON: Good. I just want to make sure I didn't miss anything. They got them all.

Then direct-to-consumer marketing. We're going to send a letter back to the Secretary describing that we are pleased with the initiatives that are ongoing, that there has been movement there. We are going to commend the agency's efforts to respond, and recommendations about the public impact, recommend increased efforts to enhance public understanding offered directly to consumers.

So we are asking the Secretary to think about this, recommending increased efforts to enhance public education of genetic tests, including the issuance of a general consumer alert, and then urging the FDA to consider the Internet a form of advertising and labeling.

Those are the things I had in my summary. Did we miss anything? Then we just did the stuff.

It has been an extremely productive day. You ought to feel good about yourselves. You did a good job. Thank you all very much.

Tomorrow morning at 8:30. You should be on time or, oh my God, the woe that will befall you.

(Whereupon, at 4:55 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Thursday, June 16, 2005.)