

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 (Laughter.)

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

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

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

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

1 briefing folders.

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

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

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

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

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

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

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

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

5 Though individually these diseases are rare,
6 rare diseases and conditions collectively affect a
7 significant portion of our population. The majority of the
8 6,000 to 7,000 known rare diseases are considered genetic
9 conditions, making genetic testing essential to the
10 diagnosis and management of patients with these conditions.

11 However, the development of tests for rare genetic
12 diseases has not kept pace with the progress of our
13 knowledge of the genetic basis of these diseases.

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

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

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

3 The conference in September will build on the
4 success of an earlier meeting held in May of 2004 entitled
5 "Promoting Quality Laboratory Testing for Rare Diseases:
6 Key to Ensuring Quality Genetic Testing for Rare Diseases."

7 At that meeting, recommendations were developed by
8 multidisciplinary experts and participants to begin to
9 address this important aspect of health care.

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

13 (No response.)

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

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

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

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

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

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

25 We will start this meeting, our seventh, with

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

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

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

25 We will spend this afternoon completing our

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

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

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

25 Public comment sessions are scheduled for both

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 DR. TUCKSON: Great. Thank you.

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

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

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

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

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

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

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

14 MS. MASNY: Thank you, Reed.

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

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

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

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

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

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

25 What has happened is that after the bill was

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

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

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

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

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

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

9 So all of the public comments that had been
10 received either by email, by mail, or people that presented
11 here to the committee between September 24th and November
12 24th, as well as any research articles that were also sent
13 to the committee, all of these were compiled in that book
14 that were sent along to the Secretary.

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

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

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

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

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

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

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

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

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

17 (DVD played.)

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

1 at what we might want to do with these DVDs.

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

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

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

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

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

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

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

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

25 Thank you, Peter.

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

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

8 (Laughter.)

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

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

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

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

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

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

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

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

25 The section on health insurance covers HIPAA,

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

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

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

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

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

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

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

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

1 determining the employer's overall premium.

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

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

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

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

1 coverage.

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

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

19 HIPAA does, of course, guarantee that certain
20 individuals who lose group health coverage have the
21 opportunity to purchase individual coverage without any
22 preexisting condition exclusion, which I mentioned earlier.

23 But of course as I also mentioned, it doesn't prohibit
24 issuers from taking health factors, including genetic
25 information, into account when setting premiums.

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

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

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

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

1 public accommodation.

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

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

12 As the slide notes, most of the federal
13 appellate courts addressing this issue have ruled against
14 coverage. Specifically, these include decisions from the
15 3rd, 5th, 6th, 7th, 9th and 10th circuits. Only the 1st
16 and 2nd have ruled the other way. Apparently the 4th,
17 11th, and the D.C. Circuit have not yet ruled. But the
18 trend clearly is against coverage.

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

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

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

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

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

1 encompasses genetic information, including family history.

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

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

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

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

25 The report looks at state law. It notes that

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

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

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

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

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

7 So the bottom line is that different laws
8 provide different scopes of coverage and protection and
9 allow for different enforcement methods. So we could have
10 20 state laws and 20 different ways of enforcing 20
11 different levels of protection and 20 different ways of
12 enforcing the law.

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

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

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

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

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

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

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

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

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

12 The report also notes that the Commission
13 settled its first case addressing genetic discrimination in
14 2002. This is in reference to a case that started in 2001
15 involving the Burlington Northern Railroad. I'm going to
16 assume that most of you are aware of this case, and not
17 discuss it here in any detail. Suffice it to say that it
18 involved an employer secretly testing employees to
19 determine whether they had a genetic predisposition to
20 carpal tunnel syndrome.

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

1 form of HNPP share certain characteristics.

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

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

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

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

1 substantially limited in order to demonstrate a disability.

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

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

14 Other limitations. The ADA does not prevent an
15 employer from gaining access to your genetic information.
16 Specifically, and in this context, an employer is permitted
17 when in the hiring process to get information. Once an
18 employer makes a conditional offer of employment to an
19 individual, the employer is permitted to conduct a medical
20 examination of that employee. There is no limit at that
21 point on the information the employer is allowed to obtain.

22 No limit. So if an employer wants to spend lots of money,
23 he can get every genetic test available.

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

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

11 As for current employees, the standard that
12 exists to conduct a medical exam is that the exam has to be
13 job-related and consistent with business necessity.

14 Although it may be less likely that an employer would be
15 able to meet this standard with respect to ordering a
16 genetic test, it is not outside the realm of the possible.

17 For example, during discussions that led to the adoption
18 of the federal executive order for federal workers, some
19 agencies argued that they should be allowed to conduct a
20 genetic test of current employees if they plan to assign an
21 employee to a remote location.

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

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

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

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

1 use of genetic information would violate Title VII.

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

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

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

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

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

16 Thank you.

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

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

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

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

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

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

17 Now, as you know, my boss, Congresswoman Judy
18 Biggert, along with Louise Slaughter of New York, Bob Ney
19 of Ohio, and Anna Eshoo of California, has introduced H.R.
20 1227, the Genetic Nondiscrimination Act of 2005.
21 Congresswoman Biggert sits on the House Science Committee,
22 where she is the chair of the Subcommittee on Energy. This
23 is the subcommittee that has jurisdiction over the Human
24 Genome Project.

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

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

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

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

19 Some people have said that they wouldn't want
20 to know. No doubt finding out that you or your child could
21 suffer from a debilitating disease could be disconcerting.

22 But this should be an individual's choice to make for
23 themselves. The fear of losing their job or their health
24 insurance shouldn't be a factor.

25 As we have just heard, existing laws, including

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

7 That is why it is so important that we get H.R.
8 1227 passed. Opponents of the bill say it's not necessary,
9 that's it's a solution and need of a problem. But no one
10 should lose their job or their health insurance before we
11 enact legislation.

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

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

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

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

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

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

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

6 These business groups are afraid that this new
7 legislation will set up a new regulation on how they do
8 business, or that it will create an administrative burden.

9 Let me assure you this is the last thing we want to do.
10 Ms. Biggert is a member of the Education and Workforce
11 Committee and a member of the Employer/Employee Relations
12 Subcommittee that has jurisdiction over this bill.

13 She understands these concerns. We're trying
14 to work with these business groups to address their
15 concerns without taking away any of the guarantees of
16 genetic privacy. Although these groups are still opposed,
17 they're not nearly as adamantly opposed as they once were.

18 So I'm cautiously optimistic that they will adopt a
19 neutral stance and not work against H.R. 1227.

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

1 is not all that helpful.

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

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

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

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

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

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

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

17 Thank you.

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

22 MS. VICKERY: Yes.

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

1 By the way, I do want to say that we actually
2 don't quite work for the administration. We are advisory
3 to the Secretary, so that gives us a little more latitude.

4 I'm glad that you sort of put that there so that we can
5 underscore, particularly for the new members of the
6 committee, again, that we are an advisory group to the
7 Secretary.

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

11 Ed, I see your hand.

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

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

25 MS. VICKERY: We are actually working with

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

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

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

16 DR. TUCKSON: Yes?

17 DR. McCABE: As a follow-up to that, for those
18 of us who are rotating off of the committee, when is our
19 last day of service? Is it the end of this meeting? Okay.

20 Thank you very much. Because I'm taking a mini-
21 sabbatical. I have met the representative who is a
22 Republican for the district in which I have a small
23 business in Colorado. I may pay him a visit then as I
24 start my sabbatical.

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

1 everything you need to go in and meet with him.

2 DR. McCABE: Thank you very much.

3 DR. TUCKSON: Agnes?

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

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

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

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

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

1 Francis?

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

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

25 So the evidence for this being a risk to their

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

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

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

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

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

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

11 To answer your first question about committees.

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

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

20 DR. TUCKSON: Good. Thank you.

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

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

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

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

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

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

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

1 way to make it work for business people.

2 DR. TUCKSON: Thank you.

3 Emily?

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

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

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

25 MS. VICKERY: I think that report is going to

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

4 There are already protections in the law.

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

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

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

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

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

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

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

14 Julio?

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

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

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

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

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

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

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

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

2 Yes?

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

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

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

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

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

19 I was on record at the last meeting for saying
20 that the individuals who have written, and they are
21 geneticists, my colleagues, who have written that this is a
22 non problem should be ashamed of themselves. I received
23 comment back from them arguing that I should not say that.

24 But I'll go on record again and say it. They should be
25 ashamed.

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

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

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

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

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

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

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

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

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

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

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

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

25 DR. TUCKSON: Good.

1 Hunt?

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

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

10 (Laughter.)

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

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

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

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

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

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

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

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

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

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

12 Thank you all very much for a good discussion.

13 The drill is -- and by the way, I keep alluding
14 to the new folks because you all don't know how crazy the
15 chairperson is -- we start on time. So 10:30, if you're
16 not in here, oh my God, the woe that will befall you. So
17 10:30 exactly.

18 (Recess.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So they are doing all this work. It is quite

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

2 DR. TUCKSON: Matt, thank you for that.

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

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

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

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

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

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

8 (Laughter.)

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

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

22 Muin from CDC.

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

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

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

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

12 I want to thank Sarah and the SACGHS staff for
13 keeping us on target. Our job is not as easy as it seems.

14 Measuring public health impact has multiple facets to it.

15 First you have to define what that means. As I said, we
16 had a brainstorming session.

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

23 The other ones are the ones that are outside the system,
24 direct access to that.

25 It impacts on our ability to how we can measure

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

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

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

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

1 Atlanta.

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

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

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

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

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

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

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

25 Again, if the magnitude of the issue is small,

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

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

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

18 DR. TUCKSON: Great.

19 DR. KHOURY: Thank you, Reed.

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

24 DR. McCABE: It's very brief.

25 DR. TUCKSON: Okay.

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

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

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

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

17 Deborah, thank you so much.

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

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

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

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

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

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

21 The advertising and access of genetic testing
22 raised concerns that are different from those of
23 advertising or direct access of drugs and medical devices.

24 Some of them are the same in terms of who is making
25 certain decisions, what kind of guidance they have. But

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

3 The FDA's role is uncertain.

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

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

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

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

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

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

1 520(e) referred to restricting devices through
2 regulation. There are only three devices currently
3 restricted by regulation. Any other restricted devices are
4 restricted through its approval order, and those are all
5 the Class III, more rigorously reviewed devices. The only
6 three that are restricted by regulation are analyte-
7 specific reagents, drug of abuse test kits, and hearing
8 aids. As I said, most restricted devices are Class III
9 that require premarket approval and they are restricted
10 through their approval order.

11 Section 502(q) Of the Food, Drug, and Cosmetic
12 Act provides that a restricted device and restricted either
13 by regulation or by approval order, that a restricted
14 device is misbranded if the advertising is false or
15 misleading in any particular or it is sold, distributed, or
16 used in violation of any regs prescribed under Section
17 520(e).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 This would be helpful in terms of our

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

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

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

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

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

25 When we look at enforcement as a whole, and

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

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

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

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

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

5 So these are the ones that we have identified,
6 as Matt said, a chart with a number of Internet companies.

7 These are the kinds of claims that we've sent for now.
8 Companies have claimed that their test can predict how
9 someone will metabolize drugs or have adverse drug
10 reactions, nutritional counseling, tendencies toward
11 obesity, and detecting susceptibility to serious kinds of
12 conditions. Cardiac disease, cancers, bone mineral
13 density, and risk for osteoporosis, autoimmune diseases,
14 chronic fatigue, and a number of infectious diseases.

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

23 Thank you.

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

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

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

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

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

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

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

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

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

6 DR. WINN-DEEN: Okay.

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

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

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

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

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

25 MS. WOLF: That aspect is not my strength

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

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

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

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

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

17 DR. TUCKSON: Good.

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

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

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

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

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

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

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

22 So people take the drugs.

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

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

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

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

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

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

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

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

10 DR. TUCKSON: Thank you.

11 Ed?

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

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

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

25 My guess is that it is not something that is

1 going to get a lot of concrete action.

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

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

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

25 Debra?

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

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

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

16 DR. TUCKSON: Good. All right.
17 Hunt?

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

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

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

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

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

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

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

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

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

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

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

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

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

1 that would fit in.

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

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

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

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

19 DR. TUCKSON: Thank you, Hunt.

20 James?

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

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

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

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

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

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

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

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

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

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

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

8 DR. TUCKSON: Matt, please finish.

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

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

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

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

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

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

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

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

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

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

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

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

3 Deborah, you wanted to make one more comment?

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

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

23 DR. TUCKSON: Great.

24 Matt?

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

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

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

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

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

21 Number two, that we ourselves will send to them
22 cases that we are made aware of that may be good examples.

23 So those two are the ones at least now in the letter.
24 Part B of the recommendation I think is, which we cannot
25 discuss in the time we have here, is the idea of public

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

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

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

13 Ed, and Kevin.

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

16 DR. TUCKSON: Terrific. Good for you.

17 Ed?

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

25 The other thing, and this is a question to Matt

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

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

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

16 MR. DAYNARD: Absolutely. Absolutely.

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

19 Kevin, last comment.

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

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

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

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

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

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

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

3 DR. FITZGERALD: Just one other thing on that.

4 Considering the rapid decrease in the size of glaciers
5 around the world, I took it as actually a compliment.

6 (Laughter.)

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

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

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

20 DR. WILLARD: Thank you, Reed.

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

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

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

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

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

25 So shortly after we listed large population

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

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

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

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

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

1 questions that various members of the task force still
2 wanted to explore or gain some traction on. What was the
3 potential predicted scientific payoff of a study like this?

4 Were there various methodologies that might be needed to
5 carry out those studies? Did we have those in hand, or
6 were there identifiable gaps in terms of developing those
7 methods?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 DR. COLLINS: It would indeed.

6 DR. TUCKSON: Thank you very much, Francis.

7 Ed has his hand up.

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

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

20 DR. TUCKSON: Great. Thank you, Ed.

21 Agnes?

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

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

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

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

12 Yes, Debra?

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

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

1 Ed?

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

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

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

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

1 really not.

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

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

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

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

20 DR. TUCKSON: That's a key thing.

21 Ed?

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

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

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

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

13 DR. TUCKSON: Terrific.

14 Emily?

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

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

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

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

10 DR. TUCKSON: All right.

11 Hunt?

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

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

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

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

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

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

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

20 DR. TUCKSON: Francis?

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

25 Certainly if NIH was going to be of assistance

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

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

9 DR. TUCKSON: And Debra?

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

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

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

21 DR. LEONARD: Okay.

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

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

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

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

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

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

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

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

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

11 (Laughter.)

12 DR. TUCKSON: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 DR. WILLARD: Yes.

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

17 (Show of hands.)

18 DR. TUCKSON: And anyone who is against it?

19 (No response.)

20 DR. TUCKSON: Done. Thank you very much.

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

23 We're going to have lunch.

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

1 We're losing two of our six members.

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

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

8 DR. TUCKSON: That was a good arm twisting.

9 PARTICIPANT: Yes, I will participate.

10 DR. TUCKSON: That's one.

11 PARTICIPANT: I will, too.

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

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

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

1 at me when I come back out there.

2 So 1:05. But you all know, I'm starting at
3 1:05. Now, you know that. See you at 1:05.

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

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AFTERNOON SESSION

(1:07 p.m.)

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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,

1 that's terrific.

2 Now it's time for the public comment portion of
3 the meeting. One of our critical functions is to serve as
4 a public forum for deliberations on the broad range of
5 human health and societal issues raised by the development
6 and use of genetic technologies, so we greatly value the
7 input we receive from the public.

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

16 As always, in the interest of our full
17 schedule, we do ask the commentators to please keep their
18 remarks to five minutes and submit the rest for the record.

19 Today we'll be hearing from first Greg Rabb representing
20 Advamed. Is Greg here? Thank you. Please come right to
21 this table right there.

22 MR. RABB: Thank you.

23 DR. TUCKSON: Thank you.

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

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

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

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

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

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

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

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

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

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

10 The report, which called for a series of
11 fundamental reforms in Medicare's clinical laboratory fee
12 schedule, most of which have gone unaddressed, concluded by
13 saying that we have, "The opportunity to fix the current
14 payment system for clinical laboratory services, averting
15 the possibility of a crisis in the future. Payments for
16 some individual tests likely do not reflect the cost of
17 providing services. Anticipated advances in laboratory
18 technology will exacerbate the flaws in the current system.

19 Problems with the outdated payment system could threaten
20 beneficiary access to care and the use of enhanced testing
21 methodologies in the future. While Advamed believes that
22 the current Medicare payment system for tests is a poor
23 foundation for new tests, including genetic tests, the
24 anticipated advances referenced in the IOM report are here
25 today and both device innovation and patient access are

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

4 Thank you.

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

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

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

13 Today I represent both the Genetic Alliance and
14 the Coalition for Genetic Fairness. The Alliance has over
15 600 organizational members, largely genetic disease
16 advocacy organizations and community-based organizations
17 that are underserved. The Coalition for Genetic Fairness
18 is composed of the Genetic Alliance and over 100 other
19 organizations and companies dedicated to the enactment of
20 substantial genetic nondiscrimination legislation. This
21 coalition includes an executive committee that is comprised
22 of nonprofit consumer organizations, industry partners, and
23 health professional societies, and is guided by Robert
24 Mells of Affymetrix, Joann Boughman of the American Society
25 of Human Genetics, Marla Gilson of HADASA, Brian Monroe of

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

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

7 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 Thank you.

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

13 DR. McCABE: Thank you, Sharon.

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

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

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

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

4 DR. TUCKSON: Yes?

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

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

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

21 DR. TUCKSON: Agnes?

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

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

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

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

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

14 As I noted last year, as I noted earlier, we
15 determined last year that the coverage and reimbursement of
16 genetic tests and services were a high priority requiring
17 in-depth study. We started working at it in our March,
18 2004 meeting.

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

25 After the last meeting, we solicited public

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

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

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

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

1 we got here. What the decision points are and were that
2 sort of led us to where we are. By the way, this is the
3 18th time we've gotten public feedback. We have been
4 getting public feedback and rewriting this thing. This is
5 the 800th draft of this thing. I want to tell you, it has
6 been seen by so many people and gone through so many
7 revisions.

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

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

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

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

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

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

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

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

1 identified.

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

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

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

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

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

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

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

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

1 matter. It was a final exam.

2 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 Many of the commentators encouraged us to
4 specifically recognize ABGC and GNCC, the American Board of
5 Genetic Counseling and the Genetic Nursing Credentialing
6 Commission, in our recommendation regarding direct billing.

7 Another series of comments had to do with considering the
8 impact of the recommendations on health care resources and
9 the long-term financing capacity of the health care system.

10 Folks want to make sure that we keep in mind that any
11 recommendations we put forward for coverage and
12 reimbursement consider the fact that we do have finite
13 resources in this country, and that we need to be cautious
14 as we move forward. That last bullet characterizes the
15 nature of those types of comments.

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

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

1 change the world.

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

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

11 MS. GOODWIN: It's in the packet.

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

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

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

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

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

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

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

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

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

3 MS. BERRY: Any comments? Debra?

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

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

15 Emily?

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

19 MS. BERRY: Agnes?

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

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

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

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

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

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

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

13 MS. BERRY: Any other comments on
14 Recommendation 1?

15 James?

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

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

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

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

5 MS. BERRY: "Could address"?

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

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

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

20 MS. BERRY: "May include"?

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

1 it as is.

2 DR. TUCKSON: I think we're in violent
3 agreement, here. So with that, on that one, the question,
4 Madam Chairperson, is it time to call a vote on this issue?

5 Or do you want to add a couple of other things and lump
6 them together? Or do you want to go issue by issue?

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

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

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

15 Now, what are these here? Just ignore that.

16 MS. BERRY: Did you have a comment?

17 DR. McCABE: I was going to move approval.

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

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

22 DR. TUCKSON: "May include." Done.

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

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

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

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

6 PARTICIPANT: Second.

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

11 (Show of hands.)

12 DR. TUCKSON: Those who are no?

13 (No response.)

14 DR. TUCKSON: For the record, that's unanimous.
15 We move onto the next recommendation.

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

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

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

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

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

13 (No response.)

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

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

18 PARTICIPANT: So moved.

19 PARTICIPANT: Second.

20 DR. TUCKSON: All those in favor?

21 (Show of hands.)

22 DR. TUCKSON: Anyone opposed?

23 (No response.)

24 DR. TUCKSON: The motion carries unanimously.

25 Next?

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

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

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

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

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

25 MS. BERRY: What is the threshold number?

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

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

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

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

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

1 MS. BERRY: Ed?

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

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

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

9 MS. BERRY: So "should consider establishing."

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

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

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

22 DR. LEONARD: We could also get rid of the
23 "should" or "want to" or anything, just saying that this
24 committee recommends CMS establish a mechanism. Because
25 then it is our recommendation, they can do what they want

1 with it.

2 MS. BERRY: James, are you saying that there is
3 already a mechanism in existence? It is just perhaps not
4 an automatic trigger for it? Is that the case?

5 DR. ROLLINS: There's not an automatic trigger.
6 We do look at local coverage decisions. If there is
7 inconsistency, then we do consider establishing national
8 coverage decisions.

9 DR. WILLARD: But I think the value of the
10 sentence is the automatic trigger, which is how it is
11 worded. So the first part matters a little less. It
12 depends on where we learned our English grammar on which is
13 the better phrase.

14 MS. BERRY: Does this capture the way it is
15 currently worded as edited? Eliminating that "may want
16 to"? "CMS should consider a mechanism that would
17 automatically initiate a national coverage review process."

18 DR. WINN-DEEN: Do we mean to have "SHOULD" all
19 caps? That sort of shouts at you.

20 MS. BERRY: We feel very strongly about this
21 recommendation.

22 (Laughter.)

23 MS. BERRY: Any other comments and suggestions?

24 (No response.)

25 MS. BERRY: Hearing none, Reed?

1 DR. TUCKSON: Can we entertain a motion and
2 second it?

3 PARTICIPANT: So moved.

4 PARTICIPANT: Second.

5 DR. TUCKSON: All in favor?

6 (Show of hands.)

7 DR. TUCKSON: Anyone in disagreement?

8 (No response.)

9 DR. TUCKSON: Motion carries unanimously.
10 Next?

11 MS. BERRY: This is a tough one. We sort of
12 eased into it, right, Reed? We wanted to start out with
13 the really easy ones. We're building.

14 This recommendation addresses the problem that
15 we identified in the report having to do with the screening
16 exclusion in Medicare and the challenge that that poses for
17 so many genetic tests and services.

18 We have not revised this recommendation since
19 the last iteration. We did receive some public comments on
20 this, and we have also solicited some input from CMS
21 because this most directly affects them, how the statute is
22 interpreted, how the Medicare statute is interpreted.

23 The first part of the recommendation basically
24 recommends that preventive services, including
25 predispositional genetic tests and services that meet

1 certain evidence standards should be covered under
2 Medicare, and it's not really a recommendation. It's more
3 of a declaration.

4 Then we move onto the second part which urges
5 the Secretary to work with Congress and urge them to add a
6 specific benefit category for preventative services so that
7 CMS could determine through its national coverage
8 decisionmaking process whether something is reasonable and
9 necessary and could be covered.

10 This recognizes that there is a need for a
11 legislative change, a change in the Medicare statute in
12 order to cover these types of preventative services and
13 tests.

14 But the third part of the recommendation is the
15 real nettlesome part. That is where we tried to think
16 outside the box. If you'll recall, we discussed this a bit
17 at the last meeting. In some respects, it is trying to fit
18 a square peg into a round hole. It has been done before.
19 We thought in the interim, because congressional action
20 really is very difficult, and it's a long process. We know
21 that it is years and years before you might ultimately see
22 any final piece of legislation signed into law, we thought
23 well, is there some creative thing that we can do that the
24 Secretary can do within his existing regulatory authority
25 to help cover at least some subgroup of genetic tests and

1 services, keeping in mind what the parameters of the
2 statute are and CMS' guidance.

3 We did solicit some input from CMS. We feel,
4 we don't have a formal opinion from anyone on this, but in
5 looking at the Medicare statute, it is our determination,
6 staff and myself, that the screening exclusion is not
7 something that is specifically identified in the Medicare
8 statute itself. It is something that pops up in the course
9 of regulatory either regs or guidance documents that CMS
10 has issued over the years, interpreting the general
11 Medicare statute.

12 We thought, and I should bring out my little
13 handy dandy cheat sheet. Okay. The screening exclusion.
14 CMS has interpreted the Medicare statute in the past as
15 prohibiting coverage of screening services, including
16 laboratory tests furnished in the absence of signs,
17 symptoms, or personal history of disease or injury, except
18 as explicitly authorized by statute.

19 So if you don't have signs of a disease, you
20 don't have symptoms, and you don't have any personal
21 history, it is considered then a screening test, and
22 therefore would not be covered under Medicare. So we
23 thought, and I can't remember now who is responsible for
24 this, I take no credit for it or blame, but I think it's
25 creative that what if an individual has a significant

1 family history of particular disease, say breast cancer?

2 Say every woman in the person's family has breast cancer.

3 Could that family history then be interpreted
4 as being part of personal history, which then would say in
5 that case, a genetic test would be a diagnostic test. It
6 wouldn't fall within this screening exclusion. So that's
7 the point of this recommendation, which is to get the
8 Secretary to use his authority to in certain circumstances,
9 however he would want to identify them, say that family
10 history of a particular disease constitutes personal
11 history which would then take the test out of the screening
12 exclusion box and put it into the diagnostic test box, and
13 therefore be eligible for coverage.

14 Here is where it gets really tricky. I think
15 CMS' official position is that in general, any type of
16 coverage for tests that could be considered screening tests
17 really requires a legislative change, a statutory change.
18 We don't have a formal legal opinion from CMS or anyone
19 else at HHS confirming what I stated earlier, which was we
20 think the Secretary has the authority to do this. Whether
21 he wants to is another question. But does he have the
22 legal authority to do it? I think he does.

23 We don't have any formal written or verbal
24 opinion to that effect. So we want to consider whether we
25 should leave this recommendation in as revised based on

1 comments that you all may have, or whether we want to take
2 it out, recognizing that there is just some controversy, I
3 think, within HHS or CMS as to whether this would be an
4 appropriate thing to do, or whether CMS would even
5 consider, or whether the Secretary would even consider
6 doing it.

7 DR. TUCKSON: I think, if I understand where
8 the issue is, is after done homework, it is unclear. So
9 the bottom line is that what we are clear about is that we
10 want this issue to be explored. So what I would sort of,
11 and this is not with my chair hat on, but just a committee
12 member's hat.

13 What I sort of see us doing here, cognizant of
14 my admonitions earlier about what is in the power of the
15 Secretary and being relevant in terms of what we send him,
16 is there is an issue of which there is unclarity, but there
17 is a course of action that we think needs and deserves to
18 be studied.

19 I think we ought to ask him to in fact study
20 this issue. If it turns out that he after exhaustive
21 detail says that he doesn't have the authority to do it,
22 then that's the answer. But I think we're being
23 responsible about sending something forward because in fact
24 we do not know after a lot of homework, whether or not he
25 does or does not. So let's go forward, ask for the answer,

1 and then let the chips fall where they may. That's my
2 suggestion.

3 MS. BERRY: Yes, James?

4 DR. EVANS: It does seem relevant, isn't it,
5 that Medicare criteria currently for the coverage of BRCA1
6 and 2 testing includes clinically unaffected patients with
7 a family member with a known mutation. So this is an
8 unaffected person, and it certainly seems that a known
9 mutation in the family is in many ways akin to family
10 history. So it is already covered by Medicare, right?
11 It's a short jump. I'm no lawyer, but it seems a short
12 jump to go from there is a known mutation in the family,
13 the person is unaffected, it is already covered by
14 Medicare, to saying that family history could be --

15 DR. ROLLINS: But in that situation, that is a
16 local coverage decision. That's not a national coverage
17 decision.

18 DR. EVANS: Is that right? Okay.

19 MS. BERRY: Agnes?

20 MS. MASNY: My question is that before we would
21 send this to the Secretary then to explore this issue,
22 could someone from CMS actually give us an answer on this,
23 whether a change like could be made without legislative --
24 in other words, we'll just take one step to check this out
25 before we start asking the Secretary to.

1 MS. BERRY: We've been trying to do that. I
2 think we will have difficulty in getting anything formal.
3 Some formal here is our written opinion as to this, I don't
4 think that they would be willing to do that. It would have
5 to be kicked up to the level of the administrator and
6 perhaps the general counsel.

7 We have more informally solicited that type of
8 information from others within the agency, but I'm not sure
9 that we'll succeed in getting anything more formal.

10 DR. FITZGERALD: Right. So on that thing, and
11 to follow up on what Reed brought up, what about saying the
12 Secretary should explore the possibility of directing CMS
13 to clarify. So if the possibility isn't there, it's moot.

14 DR. LEONARD: But if it does exist, we do want
15 him to do the directing.

16 DR. FITZGERALD: Right.

17 DR. LEONARD: I don't think he has to explore
18 the possibility. If he takes this recommendation
19 seriously, then he will explore the possibility of doing
20 it. I mean, that's the next step. I don't know that we
21 need to state that in there.

22 MS. BERRY: Leave it? Is the consensus to
23 leave it?

24 Ed?

25 DR. McCABE: Yes, I would leave it as it was.

1 And I would move approval.

2 DR. TUCKSON: Looking for a second. We have a
3 comment on the motion.

4 DR. WILLARD: Can we remove the split
5 infinitive in the first sentence?

6 DR. TUCKSON: Who taught this man high school
7 English?

8 DR. WILLARD: Have it be to benefit clinically,
9 not to clinically benefit.

10 DR. TUCKSON: We knew that. All right. We are
11 looking for a second.

12 DR. McCABE: I don't know if I accept that
13 amendment.

14 (Laughter.)

15 DR. TUCKSON: We are looking for a second on
16 the motion. Do we have a second?

17 PARTICIPANT: Second.

18 DR. TUCKSON: All those in favor, with the
19 correction of the split infinitive, say aye.

20 (Show of hands.)

21 DR. TUCKSON: Against?

22 (No response.)

23 DR. TUCKSON: All right. Thank you.

24 Next issue?

25 MS. BERRY: All right. Recommendation 5. We

1 made a real whopping change in this one. We actually just
2 referred back to Recommendation 1. This is that we're
3 trying to encourage the Secretary to disseminate to states
4 given the fact that they run Medicaid programs, as much
5 information as is necessary and appropriate to help them
6 make the best decisions and assess the evidence-base.

7 We refer back to Recommendation 1, because of
8 course that's the body that the Secretary would establish
9 to come up with criteria, principles for coverage and
10 reimbursement.

11 We received no points of debate or disagreement
12 from the public on this particular recommendation.

13 PARTICIPANT: Move that it be accepted.

14 DR. TUCKSON: Looking for a second.

15 PARTICIPANT: Second.

16 DR. TUCKSON: All in favor?

17 (Show of hands.)

18 DR. TUCKSON: Anyone opposed?

19 (No response.)

20 DR. TUCKSON: It passes unanimously. As, by
21 the way, for the record, the one prior to that as well.

22 We go to the next recommendation.

23 MS. BERRY: Recommendation 6 pertains to
24 payment rates for genetic tests, recognizing that in many
25 cases, the reimbursement is below the cost of performing

1 the test. Until the fee schedule can be reconsidered in a
2 comprehensive way, the recommendation asks that the
3 Secretary direct CMS to use its inherent reasonableness
4 authority to adjust, where appropriate, certain payment
5 rates for certain genetic tests.

6 We received no points of debate or disagreement
7 in the public comments on this particular recommendation.

8 Debra?

9 DR. LEONARD: Can I ask for a note of
10 clarification? Are there rules now that direct how
11 inherent reasonableness evaluations will be done? We may
12 be suggesting a recommendation for which CMS currently has
13 no mechanisms to do this. Therefore, this recommendation
14 would go nowhere.

15 DR. ROLLINS: I don't know the answer to that
16 question. I don't know.

17 DR. LEONARD: I'm just concerned that the
18 evaluation process that we're asking CMS to use, they don't
19 have access to yet. So therefore, nothing would be done.
20 The overwhelming comments that we got was agreement with
21 having this done.

22 So I think we at least have to evaluate whether
23 or not the mechanism by which we're recommending having
24 this done exists.

25 MS. BERRY: It's my understanding they have the

1 authority to go down this path, but they may not have
2 established a path for exercising that authority, if that's
3 what you're getting at.

4 DR. LEONARD: Well, right now we have been
5 working for three years to have them do an evaluation of
6 HCV viral loads to pay the same amount as HIV viral loads.
7 They say they just keep going around in circles because
8 they say they don't have the inherent reasonableness
9 guidelines to work with yet.

10 MS. GOODWIN: I think at the time it was true
11 that they didn't have the authority, but recently, at least
12 within the past year, whatever freeze there was on that
13 authority has been lifted. Now I think they are looking
14 to --

15 DR. LEONARD: The freeze has been lifted, but
16 they still are saying there are no guidelines by which to
17 take action through inherent reasonableness mechanism.

18 DR. McCABE: Well, then I would suggest, and I
19 think this is an extremely important part of the
20 recommendations. I would say if there is no mechanism for
21 use of the inherent reasonableness authority, then we would
22 recommend that such a mechanism be established rapidly.
23 You could wordsmith it. But basically get it done.

24 MS. BERRY: Do you think the language as is
25 currently written kind of like in our earlier

1 recommendation where we didn't say he should consider
2 establishing, we just said do it. That sort of implies
3 that he's going to consider the process. Is it sort of the
4 same thing? Or if we leave it as is --

5 DR. McCABE: No, I was just adding another
6 sentence. I was just adding another sentence to try and
7 block the bureaucratic sidestep. If there is no mechanism
8 to accomplish this, then please establish the mechanism.

9 DR. WILLARD: Rather than add a sentence, why
10 not just delete the phrase, "through its inherent
11 reasonableness authority." We are just telling them to
12 solve the problem. If the authority is there, great. If
13 it isn't there, figure it out.

14 MS. BERRY: I think that inherent
15 reasonableness authority is sort of a roadmap. If you
16 don't have it in there, the response may well be, well,
17 there is this freeze in the statute where we can't adjust
18 the fee schedule because of the freeze in rates.

19 So by adding the inherent reasonableness
20 authority, it is sort of explaining yes, we recognize that,
21 but you do have this authority that allows you to make some
22 adjustments here and there.

23 DR. WILLARD: I thought that was the question.
24 You don't know if the authority is there.

25 MS. BERRY: The authority is there, but they

1 don't have guidelines for how they actually utilize the
2 authority to achieve the particular objective.

3 DR. WINN-DEEN: So maybe we need to add
4 something to sort of strengthen the need. Instead of just
5 saying through immediate implementation if its inherent
6 reasonableness authority, or something that sort of
7 stresses that it is one thing to have the authority, and
8 it's another thing to implement it. Or through timely
9 implementation, something like that.

10 DR. FITZGERALD: Or say something along the
11 lines of through its inherent reasonableness authority, and
12 you used the word "guidelines," right, Cindy? If
13 guidelines for this authority do not yet exist, they should
14 be generated as soon as possible. Something along those
15 lines. Then you can just add one simple sentence like Ed
16 was saying.

17 DR. LEONARD: I think the last sentence can go
18 if you just say, "The CPT codes through immediate
19 implementation of its inherent reasonableness authority,"
20 or "expeditious implementation." Like Emily said, I don't
21 think you need the last sentence, then.

22 MS. BERRY: Take out the last sentence.

23 DR. McCABE: James, is there a problem? Is
24 this not doable?

25 DR. ROLLINS: I think it's doable. My only

1 concern is the word "expeditiously." That's all.

2 DR. McCABE: But since we move at glacial
3 speed, then expeditious is sometimes in the next decade.

4 DR. ROLLINS: You and I know what glacial speed
5 is based on our conversation here. But CMS might not.

6 MS. BERRY: In the next millennium.

7 DR. WINN-DEEN: I think from the point of view
8 of a recommendation, I think what we're trying to convey is
9 that this is not something that we want to just sit around
10 and whenever CMS happens to get around to it, it happens.
11 We are trying to convey that we would like to see this
12 happen expeditiously. Whatever that means in the context
13 of the speed at which government bureaucracies make forward
14 progress.

15 DR. ROLLINS: Expeditiously or in a timely
16 manner.

17 DR. LEONARD: I like the word "expeditious"
18 better.

19 DR. ROLLINS: I like the words "timely manner"
20 better.

21 DR. TUCKSON: I would suggest that we need to
22 be clear that we want this done expeditiously. What CMS
23 can do, that's on them, but we can't buy into, I don't
24 think, the inevitable inertia.

25 Jim is doing a good job of making sure, you

1 know, he makes a comment for his agency. At the end of the
2 day, we want this done expeditiously.

3 MS. BERRY: Any other comments?

4 PARTICIPANT: Move acceptance.

5 DR. TUCKSON: We have a motion for acceptance.

6 PARTICIPANT: Second.

7 DR. TUCKSON: We have a second. All those in
8 favor, raise your hand.

9 (Show of hands.)

10 DR. TUCKSON: Those not in favor?

11 (No response.)

12 DR. TUCKSON: It passes unanimously.

13 Next recommendation?

14 MS. BERRY: Recommendation Number 7 pertains to
15 genetic counseling. This is going to be another tough one.

16 I think what I'd like to do, I will go over all of these
17 bullets, because it is a multiprong recommendation. I'll
18 summarize them briefly.

19 I think 2, 3, 4, and 5 are not going to pose
20 the same challenges as the first one, so I'd like to go
21 through those and then go back to the first one, which I
22 think we'll want to spend a little bit more time on and be
23 very thoughtful about.

24 The underlying premise, of course, is that
25 qualified health providers should be allowed to bill

1 directly for genetic counseling services. The inability to
2 bill directly was identified as a barrier, a problem, a
3 barrier to access. So the very first bullet which we're
4 going to discuss, I think, in depth, encourages or asks the
5 Secretary to determine an appropriate mechanism for
6 assessing the credentials and criteria that are needed for
7 a health care provider to be deemed qualified to directly
8 bill.

9 The second component of this recommendation
10 asks the Secretary to direct government programs, federal
11 programs, to reimburse prolonged service codes when
12 reasonable and necessary, recognizing the fact that
13 oftentimes genetic counseling sessions are much longer than
14 a traditional office visit, and therefore it would be in
15 those circumstances, appropriate to recognize and reimburse
16 and use prolonged service codes.

17 The third bullet says that HHS with input from
18 a variety of input from organizations and providers should
19 take a look at existing CPT E&M codes, and any inadequacies
20 that are identified should be addressed as deemed
21 appropriate. We don't specify how they should be
22 addressed, but urge the Secretary to take a look.

23 The next part of recommendation states that CMS
24 should deem all non-physician health providers who are
25 currently permitted to directly bill any health plan,

1 public or private, deem them eligible for a national
2 provider identifier.

3 The last bullet, the Secretary should direct
4 CMS to allow non-physician health providers who are
5 qualified to provide genetic counseling and who currently
6 bill incident to a physician to utilize the full range of
7 CPT codes that are available for genetic counseling
8 services.

9 We received a good deal of feedback from the
10 public in the public comments. I would say the one that I
11 want to call particular attention to is the very first
12 prong of the recommendation in terms of how do we
13 appropriately recommend who should be able to directly bill
14 for these types of services.

15 There were some comments, and again, I
16 mentioned earlier in the presentation suggesting that we
17 specifically recognize particular organizations, ABGC and
18 GNCC, recognize them and their members as being currently
19 qualified to bill independently, and therefore exempt from
20 the proposed review mechanism.

21 We received a lot of comments, different
22 versions and iterations of that. I think the difficult
23 questions that we need to ask ourselves is how specific do
24 we want to be in this particular recommendation? Do we
25 want to name particular organizations? Do we want to

1 identify particular providers, or should we leave it more
2 generic so that it is something for the Secretary to
3 determine, and for this body to determine?

4 Because associated with the ability to directly
5 bill has to do with scope of practice. Is someone capable
6 of and permitted to provide services without the
7 supervision of a physician? Is that something that we can
8 assess here, or is that something best left to a body that
9 specifically is tasked to undertake that?

10 DR. TUCKSON: Just for foundational sake again
11 before we launch down this road. I don't know whether you
12 are in a position now, Cindy, to summarize, or Suzanne, a
13 position to summarize what we spent a couple of hours on at
14 the last meeting regarding this point.

15 Let me just stop there and ask. Are you in a
16 position to summarize why the committee had difficulty at
17 being able to wave a wand and say we believe that these two
18 named organizations ought to be anointed with the ability
19 to be this certifying body, or should there be some other
20 mechanism that needs to be in place.

21 The other part of that discussion was should we
22 leave it to the Secretary to try to use his convening power
23 to be able to create the discussion that solved that
24 dilemma? The question really becomes are we in a position
25 to recommend that those folks be appointed with that role,

1 or does there need to be a process that figures that out.

2 That is really what I think our debate was
3 about. But let me just make sure, Cindy, that we're
4 accurately restating how we got to the decision not to
5 anoint in the recommendation itself.

6 MS. BERRY: Right. There was some testimony
7 presented and some written comments and feedback provided
8 by various groups that we had requested, some of which
9 addressed specific questions that we asked. In other
10 cases, our question about what are the reasons, or how do
11 you justify a particular provider being able to directly
12 bill.

13 Some of those answers were not provided. Some
14 of those questions were not answered. So we felt at the
15 full committee level we had an extensive debate at the last
16 meeting about that. Who do we pick? Did the organizations
17 present sufficient evidence for us to make that assessment?
18 Or are there still gaps in our knowledge?

19 At the task force level, we struggled with it a
20 little bit as well, because we said it may be very
21 difficult to just pick and choose at this stage. Who are
22 we to say well, this group of genetic counselors is
23 qualified, but this group of some other type of
24 professional is or is not. If we start naming
25 organizations and provider categories in this

1 recommendation, we may be leaving some folks out who
2 otherwise should be included in there.

3 So at the task force level, we thought it best
4 to leave the recommendation more general and leave it up to
5 the Secretary to task a qualified body to make those
6 assessments.

7 DR. TUCKSON: One other thing I'd note, and I
8 see Ed's hand up, and others to comment, I just want to
9 make sure, again, that everybody is playing with the same
10 database as you ask your question.

11 So one other question, Cindy and Suzanne, I
12 want to be clear about. We were pretty clear in our
13 discussion as we struggled over this question of how do you
14 solve some of these problems? How do you know whether it
15 should be a Master's level person or a bachelor's person?
16 Who gets to create the organization that supervises this?
17 Should it be something like an American Board of Medical
18 Specialties for Genetic Counseling? How do you do these
19 things?

20 We struggled with all of those things and could
21 not resolve it. Thus we got to the recommendation we got
22 to. My question is for foundational sake, in the public
23 testimony that we have received, or any consultation that
24 we have received since our meeting, do we have anymore
25 specificity of guidance around how to solve those problems,

1 other than testimony since we have met that says you ought
2 to anoint or appoint?

3 What I'm wondering is did we learn anything
4 that we did not know that would inform the committee's
5 deliberations around these kinds of specific questions that
6 we didn't have available to us at the last meeting.

7 MS. BERRY: We have not received anything
8 formally at the committee level or at the task force level
9 that addresses all of the issues that we've identified.

10 I should point out, it is on page, well, it
11 says it is page 2, but it's not really page 2. It is
12 behind Recommendation 7. You'll see a chart. Page 2 of
13 that chart in the middle of the page you'll see, "Proposed
14 Revision to Recommendation 7A (Cindy and Reed)."

15 We had a discussion that we wanted to put
16 forth, and this was sort of the result of that discussion,
17 as a way to reword that first bullet, that first prong of
18 the recommendation to more concretely identify the issues
19 that we face with regard to direct billing.

20 I think we should give folks an opportunity to
21 read that. But in answer to your question, Reed, we still
22 lack some information that I think would enable us or any
23 group to make a comprehensive review or assessment as to
24 who should bill, who shouldn't bill, and who is qualified
25 or not.

1 So that's why we came up with this alternative
2 recommendation, or alternative wording.

3 DR. WINN-DEEN: Cindy, I think it's important
4 to point out that we did as a task force add the footnote,
5 which refers you to the appendix and talks about the fact
6 that there are groups out there that may be the right
7 groups, but we just weren't prepared to make that comment.

8 DR. TUCKSON: Well, I'm scared about butting in
9 in front of Ed again, who has had his hand up. I just want
10 to be very precise about foundational data.

11 Cindy, I think you sort of responded to my
12 question, but I want to be very specific about my point.
13 That is not around the question of who is qualified. It is
14 around the question of how do you create a mechanism that
15 decides who and how you determine the organizations or
16 organization that says that people are qualified for
17 certain scope of practice activities.

18 That is a point that we were very clear about
19 needing guidance on at the end of our last meeting. We
20 were extremely explicit about the dilemma that this
21 committee faced on that specific point. What I'm trying to
22 make sure, because I think it is very determinant for, at
23 least in my mind going forward, I'm trying to just get it
24 straight, is have we learned anything more about that
25 specific point than we did when we left out of here last

1 time. It sounds like we do not have comments on that
2 point.

3 I just want to make sure everybody knows what
4 we know and what we don't know based on where we were last
5 time. I'll leave that there, because that helps me at
6 least to know whether I'm missing something, or whether I'm
7 not as smart as I ought to be about solving certain
8 problems. So now please entertain the conversation.

9 MS. BERRY: Yes, Barbara?

10 And then Ed.

11 MS. HARRISON: Similar to what I said at our
12 last meeting about this, I guess I'm a little unclear about
13 what remaining questions there are. I mean, we asked the
14 genetic counseling workforce to come up with a very
15 detailed report, which they did. It just seems like given
16 the amount of public comment that was given on this, and we
17 had also said that was something we would take into account
18 when we relooked at this recommendation when we had our
19 last meeting that we would put this out for public comment,
20 and we would get that public comment back.

21 There was a significant amount of comment. The
22 majority of which, vast majority of which support both the
23 ABGC and the GNCC being listed specifically in the
24 recommendation.

25 On top of that, I think it's also clear that

1 even the way the recommendation is worded now, that is not
2 to the exclusion of other health care providers. It is
3 just simply stating that at this time, these professionals
4 that are part of these credentialing bodies, or members of
5 these credentialing bodies have the appropriate training to
6 be able to provide this service, and that there may be
7 others out there. But that information is lacking, because
8 you know that information wasn't given to us.

9 So I guess I just want to put out there once
10 more to challenge the committee to put those two
11 organizations in this recommendation.

12 MS. BERRY: I'll just address that, and then go
13 to Ed. We received a lot of information, as you mentioned,
14 the last time in public comments, verbal and written, about
15 the nature of the profession, about the value of genetic
16 counseling services and the members of these organizations
17 and the worthwhile efforts that they undertake and the
18 services that they provide.

19 There is no question about it. Where we still
20 are lacking information is yes, they can provide genetic
21 counseling services. They do admirably. It is all
22 worthwhile. But then the next step, and I'll call your
23 attention to this flowchart that staff have put together.
24 It is also in this same packet of materials where it guides
25 us through the decisionmaking tree as to whether someone

1 should be able to directly bill, whether it's Medicare in
2 this case, or a private health plan.

3 As far as genetic counselors, you immediately
4 go to the yes column when you ask the question are they
5 qualified to provide genetic counseling services. I think
6 a resounding yes. There would be no dispute about that
7 based on all of the information that they gave us.

8 The next question is are they qualified to
9 provide genetic counseling services without physician
10 supervision? If it's no, they have to bill incident to a
11 physician. If it's yes, then they can bill private payers
12 directly, but still there is another decision tree that
13 they have to follow in order to bill Medicare.

14 These are scope of practice issues as to
15 whether someone should be able to bill, or someone should
16 be able to provide services without physician supervision.

17 There is also the question of the credentials that a
18 particular organization, the credentialing requirements
19 that a particular organization has.

20 Are there specific criteria that we think any
21 credentialing body should have so that any blessing that
22 they give to their members is deemed adequate to them
23 directly bill? I don't think we received any detailed
24 information along those lines that would enable us to make
25 a very specific recommendation in that regard.

1 That's why we were struggling at the task force
2 level. Fearful of going down the path of naming particular
3 organizations when we really didn't have all of the
4 information that we might need in order to make a
5 declaration like that. It's sort of a long winded
6 response. I know Ed has some points, too.

7 DR. McCABE: I guess I disagree with Barbara.
8 I think by having Appendix B, I thought the footnote was a
9 masterful way of dealing with the issue without appearing
10 too self-serving as genetic professionals.

11 You would use the criteria for those two
12 organizations obviously in Appendix B, so you do sort of
13 single them out as the ones that are established, but you
14 don't put it in the body of the recommendation. I prefer
15 that approach to it.

16 The other thing about Reed's comment about an
17 ABMS-type structure then, because someone could set up a
18 fly by night genetic credentialing service for non-doctoral
19 level people, I don't think that's our business. I really
20 think that's the business of the genetics community to
21 establish that in order to prevent that from occurring. I
22 don't see that as a federal issue.

23 DR. TUCKSON: By the way, just for the record,
24 I don't disagree. I was trying to just get clarity. If I
25 could put on my regular hat here for a minute, I think

1 you're right. I think the point is what we got to in that
2 discussion, as I recall, was we could feel the pressure and
3 the pain from the genetics counseling community for faster
4 action. So what we had been debating and kicking around
5 was could, and by the way, clarify where we were in terms
6 of how we got to where we were. Especially to those who
7 are new to the discussion.

8 Because we felt the pain and the frustration of
9 the genetic counseling community to get this moving faster,
10 we were sort of wondering, could we request the Secretary
11 to use his good offices to stimulate that kind of
12 conversation? To be a convener that would move it forward
13 so that it would support the genetics community in getting
14 that done, and what we were sort of looking for and hoping
15 for, we would get some advice and guidance in the public
16 comments about how do you in fact make something like that
17 happen faster.

18 So I agree with you. It was just a sense of
19 trying to respect the impatience and jump start the
20 process, as I recall our discussion.

21 MS. BERRY: Agnes, and then, well, let's see.
22 Agnes, Ed, Hunt, Barbara, and Sylvia.

23 MS. MASNY: Sort of just reiterating what Reed
24 had said is at the last meeting, I think that one of the
25 key issues that we wanted to address as a committee was the

1 issue of genetic counselors becoming recognized providers
2 being able to get reimbursed for the services they
3 provided.

4 I agree with Ed, though, that I think that it
5 is appropriate that we don't specify a particular
6 organization because in many ways, what we want to see
7 happen is genetic counseling services whether it is
8 "genetic counseling" or genetic services provided by other
9 provides integrated into medical care.

10 I think the Oncology Nursing Society in their
11 comments have actually asked us to define what we were
12 talking about when we said genetic counseling and other
13 types of services. I'm even wondering whether we shouldn't
14 even ask for reimbursement for genetic counseling, but for
15 the counselors, but that they be recognized as providers
16 who are doing these services that are reimbursable under
17 the regular evaluation and management codes.

18 That's what were asking for. So rather than
19 making sort of genetic exceptionalist terminology of
20 creating another category for billing, genetic counseling,
21 let's integrate that into what is existing, but get the
22 genetic counselors recognized as billable providers.

23 MS. BERRY: Who's next? Ed?

24 DR. McCABE: In follow-up to Reed's comment
25 about the Secretary in convening authority, I would think

1 the people sitting around the table already have that
2 message. If we wait for it to go up to the Secretary and
3 come back down, that's going to take quite a long time, as
4 we've experienced. But perhaps we could ask groups like
5 CDC, NIH, HRSA to think about and perhaps report back to us
6 what it would take to convene a group of these genetics
7 professionals, genetic providers, to begin to think about
8 developing this.

9 So without the government being responsible,
10 could it at least be a catalyst to bring people together
11 outside of this group that reports back to us of what they
12 found.

13 Is that clear, Reed, what I'm asking for?

14 DR. TUCKSON: To me, as one listener, it's very
15 clear. It's a different strategy. I think at the end of
16 the day, what I'm hearing here is another member of the
17 committee expressing an interest and a desire to try to
18 move forward to accomplish a goal that is so clearly
19 articulated to us by 100 different presentations by the
20 genetic counseling community. You're trying to solve that
21 problem by instead of waiting for the Secretary to use his
22 individual power, take the ex officio members who are here
23 from those agencies and try to mobilize them together to
24 try to get that done. I think if I'm hearing you, that's
25 just another way of trying to fast forward the process.

1 DR. McCABE: So with representatives from HRSA,
2 NIH, CDC sitting at the table, would you be willing to try
3 and put together a group that could begin to think about
4 what it would take to have an umbrella that would say this
5 is a legitimate genetics provider credentialing group so
6 that we could prevent what will undoubtedly happen without
7 that sort of umbrella?

8 DR. KHOURY: Can I just say, Ed, I'm not sure
9 that these are mutually exclusive categories, what you are
10 recommending.

11 I think if you put a recommendation to the
12 Secretary, the Secretary will come to us anyway.

13 DR. McCABE: It'll just take a lot longer.

14 DR. KHOURY: Right. But, I mean, a lot of the
15 activities and recommendations that this and other
16 committees have been making have been taken up by the
17 agencies. By elevating them to the level of the Secretary,
18 I think this committee is more likely to make a more
19 lasting impact.

20 In other words, what I'm suggesting, leave the
21 recommendation here, but a group of us can begin a process
22 of the interagency discussion about how is the best way to
23 do this without waiting for marching orders from the
24 Secretary. I think you can have your cake and eat it too,
25 but it's not going to be easy or simple either way.

1 There is no need to exclude it from your
2 recommendation to the Secretary. If we have already
3 started the process, the Secretary will ah hah, there is an
4 existing process. If we haven't, then he or she will lean
5 on us, whenever that's appropriate.

6 But if this issue was easy to solve by the
7 feds, I have a feeling that it could have been solved many
8 years ago. I think it would require deliberate efforts and
9 partnership with professional organizations on the best way
10 to do it.

11 DR. McCABE: Well, I don't see that that
12 recommendation is here now. Is there a recommendation for
13 the Secretary under the convening authority of the
14 Secretary to do this? That's not here. So this would be a
15 new recommendation.

16 DR. WILLARD: That's an appropriate mechanism.
17 It's just unspecified, which is in the spirit of what we
18 had decided to do. It's just that we don't have the
19 authority to make specific recommendations of the path he
20 should go down, but simply urge him to go down a path that
21 he feels is appropriate.

22 My comment would be, and I applaud the chairman
23 for his efforts to be extremely even-handed here, and
24 you're being very successful at it. But on the other hand,
25 I would urge us to focus on the words, which we're trying

1 to get to a recommendation that we all can support, or the
2 most possible of us can support.

3 I don't sense an enormous amount of
4 disagreement around the table, and I agree with Ed. I
5 think this was a masterful decision by the task force to
6 add this footnote. I think it gets us as close as we could
7 possibly get to providing the helpful information that is
8 necessary.

9 It may not satisfy every group, but at least
10 from what I've heard around the committee, most of us think
11 there are legitimate reasons for not going anymore
12 specifically in that direction. So I would urge us to
13 stare at the language and decide whether we can support it
14 or not support it, and keep to that task.

15 MS. BERRY: I think it was Barbara, Sylvia, and
16 then Emily, and then Agnes.

17 MS. AU: I can understand Ed's comment about
18 trying not to appear self-serving. I think that the
19 majority of people, I don't think anyone would argue there
20 is evidence, the majority of people who provide genetic
21 counseling are genetic counselors or advanced practice
22 nurses.

23 I think that in this recommendation, to reduce
24 it to a footnote that they should consider the
25 credentialing of ABGC, or the advanced practice nurses,

1 reduces it to a footnote. I think that somehow the wording
2 should be put in the actual recommendation.

3 Because a lot of times I'll get the
4 recommendation, but the footnote won't be included. I
5 don't want that to be lost in the recommendation.

6 MS. BERRY: Some of the comments, though, that
7 we received were not to the extent of just mentioning those
8 organizations specifically, but also saying that anybody
9 who is a member of those organizations and credentialed by
10 them should be exempt from this review process. That's a
11 different step. That goes beyond simply recognizing the
12 organization.

13 MS. AU: So my comment is that I agree with Ed
14 that to actually name the organization that they get exempt
15 would be self-serving, and that's not what we want to do.
16 But I don't want to reduce it to a footnote in the
17 recommendation because I believe that as we said, we are
18 looking for foundation, the evidence is that the majority
19 of people who provide genetic counseling are genetic
20 counselors and advanced practice nurses.

21 So I want to move the footnote to a more
22 prominent part as part of the recommendation. I'm not
23 saying that you exempt these people. I'm saying use the
24 wording that you look at those organization's credentialing
25 procedures in the recommendation, not at a footnote.

1 DR. LEONARD: I don't think there's any problem
2 with putting it, instead of as a footnote, putting it as
3 part of that bullet with the exact same wording that's in
4 the footnote. I agree with Sylvia.

5 DR. McCABE: And you could even specify what is
6 in Appendix B. So you could say a number of professional
7 societies such as, have developed credentialing standards,
8 and then put it in Appendix B, if that's a significant
9 issue.

10 MS. BERRY: Emily, Agnes.

11 DR. WINN-DEEN: Okay, so I also agree that this
12 is maybe a good compromise. I think my biggest concern was
13 I didn't want to give any appearance that somehow this
14 committee has anointed itself as a professional practices
15 committee that can deem groups as having certain
16 categories.

17 I think that that has to be left to groups that
18 actually have that authority. We're an advisory committee.
19 We're not a committee that is going to have active
20 oversight or interviewing of different groups to determine
21 if they indeed should be allowed to be billable entities as
22 genetic counselors.

23 On the other hand, we've heard a lot of
24 testimony that there are some really good credentialing
25 organizations out there, and we want to recognize those.

1 MS. MASNY: That's a nice follow-up, Emily,
2 because just to mention as an example, that the Oncology
3 Nursing Society has their own certification organization
4 that has already been in touch with GNCC to look at
5 collaborating and helping ONS actually come up with their
6 own certification or credentialing for nurses who are
7 working in this area of cancer genetics. That, I think,
8 will happen.

9 Again, if we just give the examples
10 professional organizations that already have credentialing
11 or certification bodies, we'll then just make use of the
12 criteria or the template that the ABCG and the GNCC already
13 has to help them in establishing certification.

14 I think that the issue, just giving the
15 examples of the qualified health professionals, though, as
16 a second point, is a better way to go. When we even say to
17 recognize the GNCC-certified providers, nurses who are
18 advanced practice already can bill, so they do not have to
19 go through the mechanism of even going through the GNCC,
20 but nurses are just trying to get an extra credential to
21 show that they have the specific specialty in genetics.

22 So they're already billing, and I'm coming back
23 to that point, under evaluation and management codes. I
24 don't know whether in this whole document whether we are
25 actually asking to create another billable entity for

1 genetic counseling. I still would suggest that we look at
2 it as an integrative process and have the genetic
3 counselors be able to bill for the regular Evaluation and
4 Management Codes, rather than establishing a specific
5 service for which people are already billing other
6 qualified providers that have their UPIN numbers, which
7 will soon be the NPI numbers, are already billing for those
8 services.

9 DR. FITZGERALD: My question is, is that the
10 wording that you have up there right now? That's what
11 we've been talking about, right? Because it looks good to
12 me right now.

13 MS. BERRY: What this is is sort of the
14 Tuckson/Berry amendment to the original recommendation. It
15 has since been modified to reflect the comments that we're
16 hearing here. We took the footnote, it was previously a
17 footnote, and moved it into the body of the recommendation.

18 This is really an attempt to really clarify the
19 issue of direct billing, and kind of going through the
20 decision tree in an actual sentence structure, as opposed
21 to the chart.

22 DR. LEONARD: But Cindy, because you are taking
23 out the first bullets, so you're removing then the bullets,
24 and this is the full recommendation without any of the
25 bullets below it?

1 MS. BERRY: This is just the first bullet.
2 This replaces the first. So in your packet --

3 DR. LEONARD: The first non-bulleted part?

4 MS. BERRY: Under Recommendation 7 in your
5 thing here, you see Recommendation 7 has one, two, three,
6 four, five bullets.

7 DR. LEONARD: Right.

8 MS. BERRY: This wording up here is intended to
9 replace just the first bullet.

10 DR. LEONARD: Okay. So it's just not bulleted,
11 and we can't see the intro thing number seven that is still
12 there?

13 MS. BERRY: Right.

14 DR. LEONARD: Okay.

15 MS. BERRY: Agnes?

16 MS. MASNY: Just one other comment. We're at
17 the provider should be able to bill without supervision of
18 the physician as deemed by the State Practice Act. Because
19 in Pennsylvania, nurse practitioners cannot provide
20 services except incident to the physician. That's deemed
21 by the Nurse Practitioner Practice Act in Pennsylvania.

22 So although they're allowed to be billable
23 providers, some of the supervision of the physician will be
24 based by the state practice acts.

25 MS. BERRY: Or should it be "state scope of

1 practice laws"? Are they all in statute? Or are some by
2 regulation at the state level? What's the best way to
3 characterize?

4 DR. LEONARD: From what Agnes said, it's not
5 the professions scope of practice, it's the state.

6 MS. MASNY: But it is the state's scope of
7 practice for that particular profession.

8 DR. WINN-DEEN: So as deemed by each state.

9 MS. MASNY: But it's the state.

10 DR. WINN-DEEN: Each State, State with a
11 capital S, probably. I think you have to add at the end of
12 scope of practice, for each professional group, or whatever
13 Agnes said.

14 MS. BERRY: All right. The question is, the
15 next sentence was really designed to get to that point. It
16 wasn't as direct and didn't mention states specifically.
17 Should we just eliminate that sentence, then? Does the
18 addition of the language we just put in there about the
19 state scope of practice laws, does that obviate the need
20 for this next sentence?

21 DR. McCABE: Before we leave that sentence, I
22 would get rid of "laws," because I think you're going to
23 find a mix of laws and regulations. Make it "policies,"
24 and then it covers whatever it is.

25 MS. BERRY: Or "requirements."

1 DR. McCABE: Or "requirements."

2 PARTICIPANT: In the next sentence, "The
3 criteria used." It needs a D on the end.

4 MS. BERRY: The issue that Suzanne points out,
5 is it just genetic counselors or others that may not have
6 any state scope of practice criteria or laws?

7 MS. MASNY: That's a thing, I mean, I know that
8 the genetic counseling community is actively looking at
9 this. In each place where they are looking to get
10 licensure passed, that's one of the things that they have
11 to define is their scope and standards of practice.

12 So I think the organization in general will be
13 looking to develop the scope and standards of practice that
14 then could be presented to each state when they look to get
15 licensure or practice in that state.

16 MS. BERRY: I'm going to advocate a little bit
17 for the version prior to the additions that we just made.
18 If you think, and if we can tweak this next sentence, the
19 criteria used to address what you're saying, because I
20 think adding all this other stuff up earlier makes this
21 sentence really unwieldy and very difficult to understand.

22 If we can get it back to the way it was before,
23 and then start a new sentence and add, that might be
24 better.

25 DR. LEONARD: So why can't you just take out

1 what was added and put it in the criteria used to guide
2 these physicians should consider that addition that we made
3 to the first sentence.

4 DR. WILLARD: It says scope of practice.

5 DR. LEONARD: But it's not state.

6 DR. WILLARD: Correct. But it's all inclusive.
7 It doesn't matter whether it is state, local, federal.

8 DR. McCABE: I agree. I would take out the
9 additions that we made to that prior sentence, leave it the
10 way it was. If we're going to wait for each state to pass
11 laws or regulations to accept genetic counselors, it will
12 be even slower than glacial.

13 DR. WINN-DEEN: Can we get clarity on states
14 versus federal? I mean, I don't think any of this stuff,
15 it was my understanding that you had to be licensed at a
16 state level, and then you could bill wherever.

17 DR. McCABE: But there will be issues like with
18 the uniformed services where if they don't come under
19 state, again, I think it's good to leave state out.

20 DR. WINN-DEEN: Okay.

21 DR. McCABE: Because there will be areas where
22 that would not hold up.

23 DR. TURNER: (Inaudible.)

24 DR. McCABE: But even when you're overseas?

25 DR. TURNER: (Inaudible.)

1 DR. SHEKAR: What I think we're both agreeing
2 on is that even though it is the case that federal
3 practitioners have different requirements than those in
4 private practice, the fact of the matter is that you must
5 be licensed in at least one state or jurisdiction. So
6 ultimately licensure is at the state level for all
7 practitioners.

8 MS. BERRY: Agnes?

9 DR. McCABE: I would still recommend that we
10 leave the state out, because it will come up, then. If
11 that's the scope of practices, then it will come up.

12 MS. BERRY: We're not excluding them, in other
13 words.

14 MS. MASNY: I'm fine with that, but I'm going
15 to come back to a thing that I've already said, and this
16 will be my third time. So three strikes, and then I'll be
17 out.

18 I think we're missing a tremendous opportunity
19 with some of the wording that we currently have in there of
20 looking at how what we're talking about could apply to all
21 of health care practice. This is I think one of the things
22 that we've been chartered to actually do is to look at how
23 genetic services are going to move into all of health care.

24 I give as the example that in cancer care, we
25 are already providing genetic services and genetic

1 information to patients who are now having genetic tests
2 done for their tumors. It looks like even for the area of
3 colon cancer, a recommendation is out there to have MSI or
4 genetic testing done on every single colon cancer patient.

5 So then that in turn will mean that health care
6 providers have to be knowledgeable about genetic
7 information and possibly even going on then to provide
8 HNPCC testing for a select group of patients so that those
9 will probably be referred to genetic counselors, but that
10 health care providers in general, nurses, oncologists,
11 surgeons, are all getting involved into providing this
12 genetic information.

13 I'm just going to say that I think we need to
14 keep this integrated approach in our minds, and that maybe
15 another group that we should include in our list, not that
16 it is a certification organization, but would be NCHPEG.
17 NCHPEG has already come out with established competencies
18 for all health care providers of what they need to have in
19 place to be able to integrate genetic information into the
20 up and coming health care systems.

21 If we need any further information about that,
22 I see Jean Jenkins in the audience, who actually helped
23 develop the core competencies. The U.K. health care
24 practices already have integrated the competencies that
25 were put in place by NCHPEG into their recommendations for

1 all health care providers must have these specific
2 competencies. I would hate to see us miss this opportunity
3 for helping all health care providers to integrate genetic
4 information into their practice by just focusing on those
5 who will be working in the specialty area. That's the
6 third time, and I won't say it again.

7 DR. LEONARD: But Agnes, it's not a coverage
8 and reimbursement issue for physicians. I mean, a lot of
9 what you're talking about are physicians knowing what to do
10 with this information. They can bill for that already, so
11 it's not really a coverage and reimbursement issue as much
12 as it is an education issue.

13 MS. MASNY: But I think where we start to look
14 at determining the qualifications of providers, then it
15 does become an education issue.

16 MS. BERRY: I was building on what Debra said.
17 We might want to look elsewhere in the report where this
18 issue can be addressed. It is a coverage and reimbursement
19 report, but we do address other related issues in boxes and
20 other sections of the report.

21 Keep in mind, the problem that we have right
22 now is that these recommendations, we're looking at wording
23 in isolation. They fit within certain chapters or sections
24 of the report dealing with very specific barriers.

25 The barrier here was that people who provide

1 genetic counseling services, a lot of them can't directly
2 bill. So this recommendation is designed to address that.

3 What you're talking about is something bigger, broader,
4 and has a pretty big scope, but it might be appropriately
5 addressed someplace else in the report. Perhaps not in
6 this recommendation, but maybe we should take a look.

7 DR. LEONARD: Basically what you have is, I
8 mean, this one is addressing people who are trained to do
9 genetic counseling who can't bill. The other is those who
10 aren't trained to do genetic counseling who can bill.

11 MR. LESHAN: Cindy, I just want to support what
12 Agnes is saying, but I agree that there is no need to have
13 it necessarily in this recommendation. But I think the
14 intent of what she's saying should be reflected in the
15 report somehow.

16 PARTICIPANT: The recommendation would be in
17 Number 8, the next one.

18 DR. McCABE: There is a section of provider
19 education and training, where it would seem to fit
20 naturally.

21 MS. BERRY: Right. So I think that might be a
22 good spot for it.

23 Barbara?

24 MS. HARRISON: What we have come to has settled
25 better with me than what we had before. I also just feel

1 compelled to say that I think we also need to appreciate
2 that this is more than just a self-serving issue on behalf
3 of genetic counselors or genetic nurses. It really is an
4 access issue.

5 That was kind of the whole purpose of even
6 going down this path was to increase the amount, to allow
7 more of the public to have access to these types of
8 services. As we talk more about it, it is just very much
9 linked to this coverage and reimbursement issue.

10 So that I guess just to take the focus off that
11 it's not just because genetic counselors want to be paid to
12 make a living, it is really because it becomes an access
13 issue. As was shared by some of the public comments,
14 sometimes the genetic counselors, there is only one in a
15 large regional area who needs to be able to bill. Without
16 that, individuals in that community would have to travel
17 hours and hours to get to quality genetic services. So I
18 just want to make sure that that stays in the front of our
19 minds as to what was the purpose of this whole
20 recommendation.

21 MS. BERRY: Are folks satisfied with this
22 Tuckson/Berry amendment as further amended? Are there any
23 other changes, edits, suggestions, comments to this version
24 up here for the first bullet of Recommendation 7?

25 (No response.)

1 MS. BERRY: We haven't gotten to the other ones
2 yet. This is probably the hardest one.

3 Let's go back to the other bullets. Go back to
4 your Recommendation 7 list. Do you want to vote on each
5 bullet?

6 DR. TUCKSON: I was actually just sort of
7 thinking that.

8 What are you saying, Deb?

9 DR. LEONARD: Why don't we just do all of 7?

10 DR. TUCKSON: All right.

11 DR. LEONARD: Are there other issues?

12 DR. TUCKSON: Well, we'll go through the other
13 ones, but let's just say that even without a formal vote,
14 we'll do it. So if anybody goes back over this again,
15 you're in deep trouble.

16 (Laughter.)

17 DR. TUCKSON: So we got this one. It's locked
18 away.

19 Go ahead.

20 MS. BERRY: All right. How do we get this
21 Number 2 bullet? The second bullet has to do with
22 prolonged service codes. Secretary, directing government
23 programs to reimburse prolonged service codes. Does
24 anybody have any problem with that? Objection? Edit,
25 wordsmithing suggestions?

1 Emily?

2 DR. WINN-DEEN: So the only question I have on
3 that was I thought one of the issues was that even the
4 prolonged service codes are prolonged enough for some of
5 the genetic counseling services. So do we need to say
6 something about establishing codes that have appropriate
7 time frames for genetic counseling?

8 MS. BERRY: Do you think about the following
9 bullet where we go into assessing CPT codes, E&M codes, to
10 determine their adequacies?

11 DR. LEONARD: Maybe we should reverse the order
12 of those two bullets.

13 MS. BERRY: That might help.

14 DR. LEONARD: Yes.

15 MS. BERRY: Does that do the trick you think?
16 It's hard to tell. We are having formatting issues. We've
17 just moved the third bullet to be ahead of the second
18 bullet.

19 Hunt?

20 DR. WILLARD: Well, my memory on that issue was
21 that although Emily's point was one of the points we
22 considered, we didn't want to be on record as trying to
23 tell people what the right amount of time was for genetic
24 counseling services. There are physicians who are supposed
25 to see patients every 15 minutes, and yet I don't think any

1 physician would claim that was adequate to do what they're
2 supposed to be doing.

3 PARTICIPANT: The other bullet addresses that.

4 DR. WINN-DEEN: I'm fine with just changing the
5 order and having it handled that way.

6 MS. BERRY: We've kind of moved to Number 3, so
7 let's take 2 and 3 collectively. Any suggested edits and
8 changes to either of those?

9 (No response.)

10 MS. BERRY: Hearing none, the next bullet, this
11 has to do with the National Provider Identifier.

12 DR. WILLARD: Can you clarify the problem that
13 this is supposed to be addressing? I'm stumbling on the
14 use of the word "currently" here. The word "currently"
15 suggests that if the Secretary changes anything, or if CMS
16 ever changes anything, then this recommendation wouldn't
17 carry forward to new people who are added to the list. So
18 is the word "currently" actually needed here?

19 MS. BERRY: No. Plus that, it's a split
20 infinitive.

21 MS. GOODWIN: The word "currently," the
22 provider identifier system that CMS currently uses is in
23 transition at the moment. So currently they use the UNI
24 provider identifier number as our system. Right now any
25 health care provider cannot bill Medicare directly for

1 their services that's not eligible for a UPIN number.

2 In 2006, they have a new system that's being
3 implemented called the National Provider Identifier. In
4 that case, anyone who can bill any health plan directly in
5 the U.S., public or private, is eligible for a national
6 provider identifier. So the "currently" is inserted just
7 because of the transition point.

8 DR. TUCKSON: Is there a way to refer, rather
9 than using this term, which, I mean, I agreed with Hunt
10 until you made that point, but it's kind of an arcane point
11 of what the interpretation of "currently" is.

12 What is the system referred to now? I mean,
13 could we just specify so that somebody is not reading this
14 in 2008 and thinking currently in 2008.

15 DR. LEONARD: Can we insert under the whatever
16 the current identifier number is system?

17 DR. McCABE: Can we name the system that is
18 currently in place?

19 DR. LEONARD: Can we get the attention of Cindy
20 and Suzanne first, and then we can ask that question.

21 MS. BERRY: We're trying to figure out is there
22 a way to mention the current existing mechanism.

23 DR. McCABE: Can you say "prior to 2006," or
24 "prior to implementation of the National Provider
25 Identifier" would be another way.

1 MS. BERRY: Who suggested taking this out?

2 MS. AU: I think that there was some testimony
3 saying that it was not. You should take it out because you
4 can do it already. Could it just say starting in 2006,
5 they'll start it? By the time this report comes out,
6 they'll probably have it.

7 DR. TUCKSON: So James, do you know the answer
8 to this? I mean, is it already done?

9 DR. ROLLINS: Currently, we use the UPIN
10 number. But as of January of '06, it is going to be the
11 National Provider ID Number. I'm sorry, National Provider
12 Identifier Number.

13 DR. McCABE: Will there be a natural
14 transition? I mean, everybody who is currently under the
15 current system will move over to the new system?

16 DR. ROLLINS: I will make the assumption. I'm
17 not sure.

18 DR. TUCKSON: We've got some people in the
19 audience who seem like they really know. You're going yes,
20 yes, yes. Heads are bobbing up and down.

21 DR. McCABE: So then I suggest we delete it.

22 MS. BERRY: Well, apparently there are some
23 people who do not currently have a UPIN. Therefore, they
24 wouldn't be swept up in the transition to automatically
25 receive the National Provider Identifier. So this

1 recommendation is aimed at that little group. For the life
2 of me, I couldn't tell you who they are. But apparently
3 there is this group.

4 So if they don't have a UPIN, we want to make
5 sure that when the NPI takes effect, that they would be
6 eligible for that if they can directly bill.

7 DR. McCABE: But that's not what this says. I
8 mean, it is getting more and more arcane the more we
9 discuss it.

10 DR. TUCKSON: In other words, isn't it simply
11 saying, are we overreading this? That basically if you are
12 able to bill directly, you need a National Provider
13 Identifier? So we are simply saying that they should all
14 be eligible to get it. If they are automatically eligible,
15 then the point is moot.

16 DR. LEONARD: As long as they're permitted to
17 bill directly.

18 DR. TUCKSON: Right. Who are permitted. So
19 take out "currently" and you've got this done. "Currently"
20 goes, and you're solved. Going, going, gone. Next?

21 MS. BERRY: Do you want to take out the word?

22 DR. TUCKSON: Just take out "currently." It's
23 a philosophical issue. So you're now down to the last
24 one. Don't get happy, because you're still going to have
25 to work. You've still got one more thing to do after you

1 approve this.

2 MS. BERRY: All right. The last bullet here,
3 this addresses the issue identified in the report that
4 having to do with the inadequacy of certain codes. It is
5 asking the Secretary to direct CMS to allow non-physician
6 health providers who can provide genetic counseling
7 services and who bill incident to to be able to utilize the
8 full range of CPT and E&M codes available for genetic
9 counseling services.

10 I think there was somewhere in the report a
11 mention of the fact, if I recall correctly, that there were
12 some codes that were not widely used. They can only use
13 99211 CPT code. So there are others that may be more
14 appropriate.

15 So this bullet within the Recommendation 7 is
16 aimed at that particular problem. Any suggestions or
17 edits?

18 DR. TUCKSON: What is the change from
19 professionals to providers? What was the difference there?

20 MS. GOODWIN: Consistency in terminology.

21 DR. TUCKSON: Consistency in terminology.

22 Thank you.

23 DR. TURNER: Is the attachment going to go as
24 part of the document? Because I would offer a correction
25 to it, if it is. The chart.

1 MS. BERRY: The chart? No.

2 DR. TURNER: Okay.

3 MS. BERRY: That's just for our discussion.

4 DR. TURNER: This terminology of certified
5 nurse specialist is clinical nurse specialists is how the
6 profession addresses that group of people.

7 MS. BERRY: The chart won't be part of the
8 report.

9 DR. TURNER: Okay.

10 MS. BERRY: Or the recommendation.

11 DR. TUCKSON: The chart was to keep us
12 straight.

13 MS. BERRY: Deb?

14 DR. LEONARD: Could I also suggest that we move
15 this last bullet up under what is now the second bullet?
16 So that we talk about evaluating the E&M codes, that those
17 E&M codes can be used to bill, and that they pay for them
18 would be now the third bullet.

19 MS. BERRY: Does that capture it? We just
20 moved it up.

21 DR. TUCKSON: All right.

22 MS. BERRY: Hunt had something.

23 DR. TUCKSON: We are going to listen to Hunt.

24 DR. WILLARD: I would like to react to
25 Barbara's comment earlier for the preamble here, and

1 consider adding in the second sentence. It currently reads
2 as such, "SACGHS recommends the following." Say something
3 like, "As such, to ensure full access to genetic counseling
4 services for all Americans, SACGHS recommends the
5 following." Just clarify our motivation and get it out
6 there and take the high road. I think Barbara's point was
7 an excellent one, and we should jump on it.

8 MS. BERRY: Say that again.

9 DR. WILLARD: "To ensure full access to genetic
10 counseling services."

11 MS. BERRY: She is angry again here. She needs
12 some anger management.

13 DR. WILLARD: I would leave "as such." There
14 is nothing wrong with "as such." "To ensure full access to
15 genetic counseling services for all Americans."

16 DR. McCABE: I liked it in all caps.

17 DR. WILLARD: "For access to" or "for access
18 for."

19 MS. BERRY: Access to.

20 DR. WILLARD: "All those who live in the" --

21 DR. TUCKSON: All right. We have a pretty
22 clear statement here. Does anybody have any issue with
23 this? I think it's actually a very nice addition. Is
24 anybody concerned about it?

25 (No response.)

1 DR. TUCKSON: If not, we have a full range of
2 recommendations for this Number 7 that we have discussed at
3 length. I think a very productive discussion. I am
4 looking for a motion.

5 DR. McCABE: So moved.

6 DR. TUCKSON: I'm looking for a second.

7 PARTICIPANT: Second.

8 DR. TUCKSON: All approve, raise your hands,
9 please.

10 (Show of hands.)

11 DR. TUCKSON: Anyone against?

12 (No response.)

13 DR. TUCKSON: This is important to note. It
14 was unanimous.

15 Let's move onto the next one.

16 DR. McCABE: I just want to applaud the
17 committee for being both logical and consistent.

18 DR. LEONARD: Can I make another motion to take
19 a break now? Or do we have other stuff?

20 DR. TUCKSON: Okay. That's actually a pretty
21 good thought, actually. Here is how it works, though. We
22 want to be fair to you and your brains. At 4:00, our
23 friend Raynard Kington comes in for our ceremony, which we
24 are looking forward to. Then we come back and continue to
25 work. So it is sort of an artificial break.

1 Why don't we do this? Let's take a 5-minute
2 break now, and then we just keep plowing through until
3 Raynard comes, and then we come back and finish up. I'm
4 more than happy to do that. A 15-minute break? We're way
5 ahead? All right, 3:30 is a convenient, round number. So
6 3:30.

7 (Recess.)

8 DR. TUCKSON: We're going to continue on. I do
9 hope, though, and I just want to make something, and I'm
10 terrified of saying this, because if I open up this doggone
11 door again, I'm going to kill myself, and I want to be very
12 clear, because the committee, I think, has been very clear.
13 If we're not clear on this, talk to me afterwards. Don't
14 say anything now.

15 We have never, the committee in all of our
16 discussions, we were very clear, but I've had enough people
17 ask me outside, not people from the committee, but people
18 that are in the audience, and I just want to be very clear.

19 We all recognize that in our Recommendation 7
20 which we just did, that we are very clear that the
21 government cannot itself create the mechanism around these
22 criteria. We are talking about the government is using its
23 convening authority, its leadership to develop the
24 mechanisms to make this happen.

25 We have been very clear that we have been, and

1 I mean, exceedingly clear, and I want to continue to be
2 exceedingly clear that we are calling upon the government
3 to use its leadership, its authority, the Secretary of
4 Health, to bring the right people in place to make
5 something happen. Apropos this recommendation.

6 I think that's a very important thing around
7 that very first point. There are a zillion examples that
8 we have of responsible government leadership that serves to
9 be a catalyst for action. I will give one example, again,
10 which I am personally involved in, which is around
11 electronic medical records.

12 Levitt, not the HHS Secretary, but the
13 electronic medical records czar, electronic czar, Mike
14 Levitt, I'm blanking on his name. I mean, anyway, the guy
15 in charge of the health information technology, caused
16 there to be a public/private partnership to create a
17 certification criteria for electronic medical records.

18 Government can't do it, but they can say we
19 need people from this community, this community, this
20 community, all of you all come on into the conference room,
21 and now because you are all in one place at one time, we
22 urge you to take on this charge, this goal, and make it so.

23 Then the private sector or whoever it is that's
24 responsible, goes forth and makes it so. Thank God the
25 government was there to be the sand in the oyster to create

1 the pearl, as it were. Catalytic opportunities.

2 That's what I think we're trying to get at. So
3 please be comforted, those who are in the audience who are
4 worried that we are somehow ceding to government powers
5 that -- the wording is very clear here. The committee has
6 tried to be very precise. So I just want to make sure that
7 those who are not wrestling with this at the table are as
8 on the same page as those of us who are at the table.

9 It's a responsible call for government
10 leadership to cause something to happen that might now and
11 well may not happen were it not for the convening power of
12 the Secretary of Health to identify a problem, raise it up
13 in the light of public day as a priority, and then urge the
14 appropriate people to come together to solve the problem.
15 That's what this really is all about. Nothing more,
16 nothing less. So having said that, I hope we're clear.
17 What I don't want is folks in the audience to feel like
18 they're going to go, because I'm going to tell you what is
19 going to happen. It will drive poor Sarah and the team
20 crazy.

21 If folks do not understand that point, they're
22 going to go back out and they're going to talk about it
23 back in government circles. The next thing you know, we're
24 going to wind up trying to answer 5,000 emails about the
25 fact that we are ceding power to the government that it

1 doesn't deserve.

2 So again, it's responsible leadership to
3 identify a problem and cause the necessary people to come
4 together to be able to solve it. That's what it's all
5 about.

6 All right. Moving forward. Until Raynard
7 comes, we're going to keep pressing. By the way, the
8 people that raised this in the hallway with me, thank God
9 for you, because it would have been terrible if you had
10 these misconceptions or concerns, not even misconceptions,
11 concerns, and you don't feel like you have a chance to
12 raise them for us to deal with it.

13 So I'll tell you, your counsel in the hallways
14 and the lunch breaks and the bathroom, I don't care where
15 it is, is just wonderful. So don't stop, because we love
16 you to death. Besides, I don't think any committee gets
17 the kind of loyal folk who hang in there every meeting
18 until the clock finally ticks.

19 We've got a group of people that pay attention.
20 So thank God for you, because we would not be as good as
21 we are, however good we are, were it not for you, if that
22 makes sense.

23 Thank you. Moving on.

24 MS. BERRY: That's my cue. Okay. We're on
25 Recommendation 8. This recommendation pertains to

1 education and training of health care providers.

2 The addition in red comes from a public comment
3 we received suggesting supporting studies that link
4 education and training tools to improved health outcomes.
5 This particular change doesn't specifically mention health
6 outcomes, but it does say that the Secretary should provide
7 financial support for assessments of the effectiveness of
8 educational and training tools.

9 I wanted to also bring us back to the point
10 that Agnes had raised earlier about integrating training
11 health care professionals and making sure that they are
12 able to integrate genetics into their practices. I wanted
13 to get her input, because there may be some tweaks that we
14 might want to make to this recommendation. If it doesn't
15 currently address her point adequately, we may want to make
16 some further changes.

17 MS. MASNY: I don't know exactly where this
18 would go, but maybe some type of beginning comment that
19 would say something to the effect of since genetic
20 information is being integrated into all aspects of health
21 care and providers act as intermediaries. I don't know if
22 that would sort of do it.

23 Then the other recommendation that I had made
24 earlier was that where we are giving the examples, so that
25 about midway down the paragraph, where it says, "HHS

1 agencies to work collaboratively with state, federal, and
2 private organizations to support the development,
3 cataloging, and dissemination of case studies, practice
4 models and genetic competencies (as proposed by NCHPEG)."

5 MS. BERRY: This sort of is a regurgitation of
6 a recommendation that we made in 2004. That language that
7 you have, was that what we said in 2004? Or are you adding
8 something new?

9 MS. MASNY: No, that is what I was adding new.

10 MS. BERRY: Right. But this part of the
11 recommendation, that simply says back in 2004, this is what
12 we said. So it's kind of regurgitating what we said. We
13 can't change what we said, so can we put it someplace else?

14 MS. MASNY: Yes. Okay. Specifically to look
15 at the genetic competencies for all health care providers
16 as recommended by NCHPEG.

17 MS. BERRY: So should we add another separate
18 standalone bullet? The first part is kind of an
19 introductory, saying what we recommended before. The blue
20 change talks about supporting studies into the
21 effectiveness of training tools.

22 Should we amend that, or do you think we should
23 add a separate part to the recommendation that addresses
24 your suggestion?

25 MS. MASNY: I think you could go as a separate

1 bullet.

2 DR. WILLARD: Well, one point is the genetic
3 competencies are put forward by several groups, not just
4 NCHPEG. I'm not sure, again, if I'd single out --

5 MS. MASNY: Could we say, "such as" NCHPEG, and
6 name the other organizations?

7 DR. WILLARD: But there could be a dozen
8 organizations. We're getting dangerously close to where
9 we've been.

10 MS. MASNY: Where we've been before, okay.

11 DR. WILLARD: The blue end, or red, depending
12 on whether you are looking at the screen or the printed
13 page, the wording of that is ambiguous to me, and maybe
14 it's purposely so on your part.

15 Effectiveness is not clear whether it refers to
16 effectiveness in training, or clinical effectiveness
17 because of that training.

18 The public comment certainly by referring to
19 health outcomes, made me believe it was the second, and not
20 the former. So if you meant it to be related to clinical
21 outcomes, I'd probably say something like, "provide
22 financial support to assess the clinical impact of
23 educational and training tools."

24 DR. WINN-DEEN: You know, I think we could add
25 something about the competencies at the end of the sentence

1 for education and training of health providers in genetics
2 and genomics to a level of accepted competency.

3 MS. MASNY: For all health care providers.

4 DR. WILLARD: If push came to shove, wouldn't
5 you rather assess it against clinical impact than you would
6 against some stated list of genetic competencies, right? I
7 mean, if you're relating it to outcomes, you're relating it
8 to outcomes, which is a much more direct measure.

9 MS. BERRY: I sometimes think when we make
10 amendments, we create these monstrous sentences. We should
11 break it up, I think, into two parts.

12 The first part is funding studies to link
13 education and training to improve outcomes, period. Then
14 we can address the point about clinical competencies in
15 some way. So I think there is probably a more direct, easy
16 way to address that point by just creating a separate
17 sentence. So I think I would add a period and get rid of
18 the rest of that, all that.

19 DR. LEONARD: Maybe it can be added up at the
20 first sentence. I'm not sure what is not said by the first
21 sentence. We're asking for support of ongoing training,
22 continued education of health providers in genetics and
23 genomics. I mean, maybe you could add, "to achieve genetic
24 competency," but I don't know that that adds anything to
25 what we're already stating.

1 MS. BERRY: Right.

2 DR. McCABE: I would argue that you could add
3 something as another sentence here that would be in essence
4 saying that health providers who are utilizing or who are
5 giving genetic or providing genetic services should meet an
6 adequate level of competency, or something like that.

7 So that all of it leads down to the fact that
8 there needs to be some, certainly all physicians at least
9 can bill for genetic services, but they need to meet some
10 level of competency. The way you get them there is through
11 all the stuff up until then, because we don't hold them
12 accountable.

13 DR. WINN-DEEN: I think Agnes' point is that at
14 some point, we're going to stop thinking about physicians
15 as providing genetic services, and that it's just
16 integrated into the normal practice of medicine. So I
17 don't want to create an exceptionalism view of this.

18 What we want to do is we want to just see
19 genetics and education rolled out in such a way that it's
20 integral to the competency in all phases of medical
21 practice. I think that is what Agnes was trying to get to.

22 DR. McCABE: I agree, but I think what we're
23 trying to say is that because I see it now, that people are
24 providing genetic services, but they don't really have the
25 resources to provide that. The information is erroneous.

1 So saying that people should get educated is a
2 good thing, but then I think they need to be held
3 accountable at some point as well.

4 DR. WINN-DEEN: And I think that was the point
5 of saying that they need to come to some competency level
6 in their knowledge of genetics as it relates to their
7 particular whatever it is they do in the practice of
8 medicine, whether they're a nurse practitioner, a
9 physician, whatever allied health professional.

10 DR. EVANS: I don't know how much
11 editorializing or justification we want to do, but in
12 relation to Agnes' first sentence, it might be worth
13 putting something in there about the fact that yes,
14 genetics is permeating medicine, and providers are acting
15 as intermediaries, and they also consistently say that they
16 are not prepared or do not have sufficient training.

17 I don't know if we want to justify what we're
18 saying in those terms, but certainly that's a heard comment
19 among providers.

20 DR. LEONARD: And it's documented in the
21 literature, too.

22 MS. BERRY: The word keeps popping in my head
23 that we should try to emphasize somewhere the point that
24 these educational and training tools, and we're not just
25 talking about professionals in training, in residency, or

1 in schools, but actually ongoing training for providers who
2 are in practice, and that these tools should also in
3 addition to ultimately leading to improved outcomes,
4 facilitate the integration of genetics and genomics in the
5 practice of medicine, nursing, or whatever.

6 So if we can maybe get those two thoughts. So
7 there are two goals, really. One is to assess the clinical
8 impact, i.e. improve outcomes, but before you can even get
9 there, I think the threshold is these tools have to enable
10 docs, nurses, and counselors and everybody else to
11 integrate genetics into their practice areas.

12 DR. SHEKAR: I think that I would be remiss as
13 ex officio from HRSA if I didn't mention the concept of
14 diverse populations being served, particularly with a 10-
15 year lag time of research to patient bedside, particularly
16 important with regard to genetics and genomics that we have
17 the opportunity that all populations ultimately through
18 these tools get served.

19 So somehow if the concept of across diverse
20 populations or multiple populations could be employed
21 somewhere within those paragraphs, it would I believe
22 strengthen that comment.

23 DR. TUCKSON: I'm going to also sort of break,
24 Cindy, one of my little rules as chairman and just sort of
25 raise a question. I hate to bring things back, but I just

1 for the first time sort of read in a different way this
2 first sentence.

3 Since providers act as intermediaries between
4 health plans and plan members, it sort of leaped out at me
5 that it's a little strange. I don't think that we view the
6 role of the health professional as an intermediary between
7 the essential dyad in health care, it was between health
8 plans and the members.

9 Somehow or another, the health professional is
10 an intermediary, and thank you very much for helping out.
11 I sort of see the essential dyad as being more the
12 professional and the patient.

13 MS. BERRY: I think what's meant there, and
14 Suzanne reminded me, I think in a sense the gatekeeper
15 function of the provider. In other words, the provider
16 determines when a test is ordered. It doesn't have to do
17 with the health provider is some sort of interpreter or
18 insignificant middle man role, but mainly as it deals with
19 access issues, it is the provider and the health plan kind
20 of determining what a patient would have access to.

21 DR. EVANS: But I think like Reed says, that's
22 not at all the primary way we see ourselves when we are
23 dealing with patients. That's a secondary onerous task.

24 MS. BERRY: I don't think it adds an enormous
25 amount anyway. What was the reason for that language to be

1 in there? I mean, I know what was meant by it. But if we
2 remove it, are we losing some critical thought that someone
3 had?

4 DR. McCABE: I think you could stick the access
5 back in there. You can get rid of intermediary and make it
6 clear that providers have an important role in ensuring
7 access, or a critical role in ensuring access.

8 DR. LEONARD: I think given what the end of
9 that sentence says, that, "There is a need to support the
10 ongoing training and continued education of health
11 providers in genetic and genomics," we need to point out I
12 think as Dr. Evans said, is that they are insufficiently
13 trained at the current time. The way that is looking now
14 is that genetic information is being integrated, and the
15 providers are going to do this.

16 So it doesn't really follow that we need all
17 this education and training without stating that providers,
18 a majority of providers are inadequately trained currently,
19 or something to that effect.

20 DR. TUCKSON: I'm going to need to do one short
21 process check and trust in the attention span of the
22 committee. It is 4:00 exactly. Raynard Kington is here.
23 I need to just suspend for just a moment what we're doing,
24 and also because I have to step out for 10 seconds also
25 simultaneously. I didn't want to lose the opportunity to

1 introduce Raynard, and also for me to say also what I
2 wanted to say as far as our three committee members who are
3 going off.

4 Raynard, if you could come forward. We know
5 you well, but let me introduce you formally for the record.

6 Raynard Kington is the Deputy Director of the NIH. I
7 can't think of a better person who has been with us since
8 the beginning to present the mementos that he's about to
9 present.

10 Let me just say as I step off for a minute and
11 turn this over to Raynard, this is a personal point. I
12 have learned so much from Ed McCabe. I have so appreciated
13 the counsel of Barbara Harrison and Joan Reede. I just
14 think you all are terrific, terrific people. We are the
15 worse for not having you go forward. But I hope that you
16 will stay with us.

17 Let me turn this over now to Raynard. As soon
18 as he finishes, Cindy, would you resume back up? Thanks.

19 DR. KINGTON: Thank you. It's a pleasure to be
20 here, even though my good friend Reed is leaving.

21 (Laughter.)

22 DR. KINGTON: No, you're efficient. Please, we
23 have to use our time efficiently.

24 Thank you. It's a pleasure to be here
25 representing the Secretary and Dr. Zerhouni in honoring the

1 service of three members of this committee. This committee
2 is incredibly important to the Department in helping the
3 agency to come to terms with the complex medical,
4 scientific, ethical, legal, and social issues related to
5 the development of the use of genetic and genomic
6 technologies. I was here in the fall, I believe, at a
7 meeting. It is a pleasure to really recognize three
8 members in particular who are rotating off.

9 First, Dr. McCabe, who I met, I believe, last
10 time. Thank you again on behalf of the Department for your
11 service. I know that you have particular interest in
12 genetic discrimination.

13 As Reed said, I've heard great things about
14 your contribution to the committee. Thanks for the
15 service.

16 (Applause.)

17 DR. KINGTON: Next is Ms. Barbara Harrison. I
18 know you have been involved particularly in genetics
19 education and training issues. Again, on behalf of the
20 Department, thank you again for your service to the
21 committee and this important effort. Thank you.

22 (Applause.)

23 DR. KINGTON: And the third person is Dr. Joan
24 Reede, who was not able to be here today. I know Joan very
25 well, as I know many of the people around this table. She

1 was appointed to the committee for her expertise in the
2 area of public health and community outreach.

3 She was involved in a number of initiatives,
4 including a survey of organizations on the activities of
5 genetics education and training. She chaired a roundtable
6 on the topic, was involved in drafting and finalizing a
7 resolution on genetic education and training that was given
8 to the Secretary in August of 2004, and has made great
9 contributions to this committee.

10 I want to forewarn all three of you though that
11 just because your service has ended doesn't mean we won't
12 call upon you. We have no shame in asking members of
13 various constituencies to advise us on how we can do a
14 better job with our policies.

15 I understand there are four new members, Sylvia
16 Au, Chira Chen, Jim Evans, and Julio Licinio. Is that
17 anywhere close to being correctly pronounced? Welcome to
18 the committee. You'll one day have the privilege as well
19 to have a plaque honoring your service. We will call upon
20 you again as well.

21 Thanks again, and thank you again for your
22 service.

23 (Applause.)

24 DR. McCABE: I'll just comment. Somebody at a
25 recent plaque ceremony, somebody made the comment that

1 dementia is lined with plaques, or something.

2 (Laughter.)

3 MS. BERRY: How about this? Agnes, we're going
4 to need your help. I'll just read it out loud, but you can
5 follow along. "Since genetic information has the potential
6 to be integrated into all areas of health care and
7 providers have an important role in ensuring appropriate
8 access to genetic tests and services, there is a critical
9 need to support the ongoing training and continued
10 education of health providers in genetics and genomics."

11 Then it goes on to reaffirm the recommendations
12 that we made to the Secretary in 2004, recommendations
13 which included blah, blah, blah. Then we still haven't
14 fixed this last part. But let's take that first paragraph.

15 Does that capture what people are getting at? We have to
16 fix the second one, but I want to make sure the first one
17 is okay. The second part. This gets to the studies.

18 DR. McCABE: Well, we haven't done, Cindy, in
19 the first part, and maybe there needs to be a separate one
20 so that we don't get too many run on sentences. But we do
21 need to acknowledge the diverse population somewhere.

22 MS. BERRY: Should we have that in the part
23 about ensuring appropriate access to genetic tests and
24 services? We want to add to everyone or to --

25 DR. FITZGERALD: (Inaudible.)

1 MS. BERRY: Not just for them, but for
2 everyone. Okay. Diverse populations. Does that do it?
3 All right. So here is the question. I almost think we
4 don't need to have this second sentence.

5 DR. WILLARD: You almost have it. You can
6 combine those two. Just say, "These tools should enable
7 health providers to meet standards of genetic competency
8 and to thereby integrate genetics into their respective
9 practice areas."

10 MS. BERRY: Yes.

11 DR. WILLARD: To thereby.

12 MS. BERRY: And then get rid of this last --
13 competencies or competency? Singular, or plural?

14 PARTICIPANT: Cies.

15 PARTICIPANT: Plural standards, you have
16 singular competency, yes.

17 DR. McCABE: The term of art in regulatory
18 medicine is competencies.

19 DR. WILLARD: Right, but then you don't need
20 standards.

21 DR. LEONARD: Yes, you don't need standards at
22 all.

23 DR. WILLARD: Or to meet a standard of genetic
24 competencies. They can't be the same.

25 MS. BERRY: I'll take that standards out,

1 right? Do you want to take "standards" out? I liked it
2 better, just "meet genetic competencies," don't you think?

3 DR. WILLARD: That's fine.

4 DR. EVANS: There certainly could be different
5 standards for different levels of providers, right?

6 MS. MASNY: Thank God Reed's not here for him
7 to bring up something from the past.

8 MS. BERRY: I won't tell. Go ahead.

9 MS. MASNY: No, just what we recommend as one
10 of the tools to help with education and training was only
11 one of the aspects in that 2004 report. It makes it sound
12 like including, just maybe to say one of the training
13 mechanisms. Remember we had all the suggestions for
14 integrating genetic information into credentialing exams.
15 What could be done for ongoing education to get training of
16 faculty.

17 This was one of the recommendations that was
18 made based on the survey that we did with the health
19 professional organizations. They said that the providers
20 needed these tools of cases to see how it was actually
21 applying to their practice. But that was just one aspect
22 of what we were looking at with the education
23 recommendations.

24 MS. BERRY: So do you want to emphasize that?

25 MS. MASNY: Well, it makes it sound like when

1 you say "which included," it makes it sound like that that
2 was the complete list.

3 MS. BERRY: Included is like it sort of
4 included these things, but there were more.

5 MS. MASNY: Okay. All right.

6 MS. BERRY: Ed?

7 DR. McCABE: We should discuss this, but I
8 would say "meet adequate genetic competencies." That's
9 usually, there is some level that is set as inadequacy. To
10 meet genetic competencies, I think we should specify a
11 level.

12 I would say, "And thereby to integrate genetics
13 effectively into their respective practice areas."

14 MS. BERRY: Does "adequate" sound good enough?
15 Or does it sound like we just want a bunch of mediocre
16 providers?

17 MS. AU: Can you put, "Established genetic
18 competencies?" I mean, adequate, who's adequate?

19 PARTICIPANT: But some of them haven't been
20 established for every --

21 DR. McCABE: I think it needs something more
22 than, to say "meet genetic competencies," that seems too
23 vague. "Establish" is better.

24 DR. TURNER: The word "tools" to me doesn't
25 seem -- education and training programs, maybe. Tools are

1 a part of the program. "Tools" seems to be a very
2 particular subset of what we mean. It's like a checklist
3 or an exam. Those are the tools, but it's the larger
4 training programs and educational programs that we want
5 support for.

6 MS. BERRY: Would you still call it a program
7 if you're talking to a doc who has been in practice for 20
8 years and you are providing him with some kind of CME? Is
9 that a program still?

10 DR. TURNER: A short course.

11 DR. WILLARD: Or just call it "genetic
12 education and training."

13 MS. BERRY: Yes. Right. So get rid of
14 "tools." Just say, "Impact of genetic education and
15 training."

16 DR. TURNER: Because it asks the question then,
17 what are these tools. We don't define those or describe
18 them.

19 MS. BERRY: Okay. How's that?

20 DR. LEONARD: In the second sentence, you need
21 to change "these tools."

22 MS. BERRY: Right. This training should enable
23 health providers? Or education? This training or
24 education?

25 DR. McCABE: I would go "education" rather than

1 "training." Training is the old fashioned way.

2 MS. BERRY: Or "these efforts." Okay. Any
3 other changes?

4 Agnes?

5 MS. MASNY: Again, coming back to that initial
6 paragraph, do you think that we should say, though, that
7 SACGHS recommendations, I'm not reading it off the screen
8 there, regarding the education and training of health
9 professionals, so it's a reference back to that original
10 document that we sent?

11 Because as was just reminded to us when the
12 awards were given out, there actually were resolutions that
13 we came up with. So there is a specific document on that,
14 just as a reference point.

15 MS. BERRY: I think maybe "the Secretary"
16 should go up here. "SACGHS reaffirms the recommendations it
17 made to the Secretary in 2004 regarding." Does that do
18 it?

19 Muin?

20 DR. KHOURY: Can you scroll down a little bit?
21 Just come down a bit more. I want to show you, okay. The
22 selected division suggested by public comment recommends
23 supporting studies that link education and training tools
24 to improved health outcomes.

25 This is a document about coverage and

1 reimbursement. It is not a document about general
2 education and training in genetics. Of course they go hand
3 in hand. I'm feeling that we may have lost something in
4 the translation, because we are talking here about making a
5 set of recommendations to HHS about coverage and
6 reimbursement of genetic tests and services that should be
7 evidence-based, and that should follow all the other
8 recommendations.

9 Somehow this Recommendation 8 has evolved into
10 sort of a catch all stuff of some sort. I'd like us to go
11 back and rethink a little bit why we have Recommendation 8
12 to begin with, and what are we trying to do to answer the
13 public comments about linking the training of the health
14 providers with improved health outcomes?

15 At the end of the day, you want to show that
16 coverage and reimbursement of appropriate genetic services
17 can lead to improved health outcomes among patients and the
18 population. You'd like to link those things together.

19 I thought what the task force responded to, and
20 somehow this paragraph has become something else.

21 MS. BERRY: Well, to answer the first part of
22 your question, this recommendation, again, it's hard for us
23 because we're taking them in isolation. It's hard to see
24 the context. But where it fits in is in the report under
25 provider education and training. That was mentioned as a

1 key component to coverage and reimbursement, insofar as if
2 a provider is not properly trained in the area of genetics,
3 they don't know what they don't know, and they won't
4 necessarily provide their patients with access to these
5 services because they won't necessarily order them, or they
6 won't know that the patient needs them.

7 It is also addressed in that section, the fact
8 that a lot of health plans have physicians and other
9 providers making coverage decisions. If they don't have a
10 good knowledge base of genetics, they won't necessarily
11 make appropriate coverage decisions. So this is where in
12 the report this recommendation fits.

13 So it is in a provider education and training
14 section. It's not a major part of the report, so we don't
15 really go off onto too big of a tangent in the report, but
16 it is identified as an issue that pertains to coverage and
17 reimbursement.

18 Now, you asked about the commentors health
19 outcomes point. That may be something that we need to
20 think about.

21 DR. KHOURY: Yes, and I think that's something
22 we may need to think about. Why are we training health
23 providers in the new genomics era so that they can provide
24 the evidence-based services to improve health outcomes.

25 If we're asking the Secretary to provide

1 financial support for the assessment of that link between
2 education and health outcomes, I think we are focusing on
3 the first part, but we're not focusing on the second part.

4 If you can do outcomes research that considers
5 as part of the analysis the level of training of the health
6 care providers in genetics and genomics and how that might
7 be related to changes in the outcomes of patients and
8 populations. So just see whether or not the committee can
9 somehow pick up the theme of linking all of that stuff with
10 improved health outcomes. That's what I thought we were
11 responding to.

12 Maybe it requires a creative way of putting
13 improved health outcomes in this paragraph somehow.

14 MS. BERRY: Well, this language in that last
15 paragraph there is supposed to address that, but it may not
16 do it well enough. Maybe we need to actually use the words
17 "improved health outcomes."

18 This part where it says, "The Secretary should
19 provide financial support to assess the clinical impact of
20 genetics education and training." What is meant there is
21 is it making a difference? Is it improving outcomes? But
22 maybe we just need to state that more directly.

23 DR. KHOURY: Let's do that.

24 DR. LEONARD: But it's the words, "the clinical
25 impact" that was used in place of "health outcomes." So I

1 think it's redundant to put the clinical impact. I mean,
2 what clinical impact means is improved health outcomes.

3 MS. BERRY: How about get rid of the word
4 "clinical" to assess the impact of genetics education and
5 training on improved health outcomes.

6 DR. TURNER: (Inaudible.)

7 DR. WILLARD: That would be the hope.

8 DR. TURNER: Or just the impact on health
9 outcomes.

10 MS. BERRY: Does that do it, Muin, do you
11 think? Can you see it?

12 DR. KHOURY: I think clinical impact was okay.
13 I was maybe working from this.

14 MS. BERRY: Yes, look at it.

15 DR. KHOURY: There are so many changes that
16 have happened since then.

17 MS. BERRY: Right now it reads, "The Secretary
18 also should provide financial support to assess the impact
19 of genetics education and training on health outcomes."
20 Then it goes on about competency.

21 DR. EVANS: You can probably get rid of the two
22 after the "thereby," and "thereby integrate genetics."

23 DR. WILLARD: I think we're reaching the
24 saturation point on this recommendation.

25 MS. BERRY: Is everybody okay with it?

1 DR. LEONARD: Can we vote without Reed?

2 DR. WILLARD: I can jump in ahead of my role
3 tomorrow, if need be. Do we have a recommendation on this
4 one?

5 PARTICIPANT: Can you read it all together?

6 DR. WILLARD: If you can scroll it, Suzanne, so
7 people can see the top of it. Do we have a motion?

8 DR. McCABE: So moved.

9 PARTICIPANT: Second.

10 DR. WILLARD: All those in favor, if you can
11 raise your hand.

12 (Show of hands.)

13 DR. WILLARD: Any opposed?

14 (No response.)

15 DR. WILLARD: The recommendation passes
16 unanimously.

17 We can move onto Number 9.

18 MS. BERRY: Number 9. One more.

19 DR. McCABE: Well, there are some more after
20 that.

21 MS. BERRY: Well, the other stuff has to do
22 with kind of the body of the report, some technical changes
23 and things like that, so it's not as critical. We can get
24 to that if there's time. It doesn't go to the meat of the
25 recommendations.

1 This last recommendation, Number 9, has to do
2 with a little bit of public education, making sure that the
3 public has reliable, accurate, trustworthy information
4 about how to gather and utilize family history, genetics,
5 and genetic technology so that they can make informed
6 decisions with regard to their health care.

7 We received some public comments on this. One
8 of the comments caused us to make this change here in the
9 second paragraph. "The Secretary should leverage HHS
10 resources to develop and make widely available reliable and
11 trustworthy information about how to gather and utilize
12 family history, genetics, and genetic technologies to guide
13 and promote informed decisionmaking."

14 We didn't have too many comments on that, just
15 a few. That was the one change that we made at the task
16 force level. Does anyone have anything?

17 DR. EVANS: As a newcomer, reading this, the
18 very first sentence struck me as being rather confusing.
19 At first I thought it was talking about reliable and
20 trustworthy information about family history. That makes
21 it being available on the web, that makes it sound like it
22 is quite concerning. I don't want my family history on the
23 web, right?

24 Maybe we should use that same phrase, "reliable
25 and trustworthy information" gathering pertinent family

1 history and information about genetic technologies.

2 Something like that.

3 DR. WINN-DEEN: I think we meant to have a
4 comma after genetics. So by gathering family history,
5 genetics, and genetic technologies. Genetic and genetic
6 technologies are meant to be two separate thoughts, right?

7 MS. BERRY: Is there a way to squish this?

8 DR. McCABE: Cindy?

9 MS. BERRY: What?

10 DR. McCABE: I would suggest that we start, and
11 we can decide whether we have a need for that first phrase
12 now, but that we should let people know where we're going.

13 So patients and consumers need the tools to evaluate
14 health plans, or need to have the information to evaluate
15 health plan benefits and health providers so that they may
16 make the most appropriate and the most financially
17 responsible decisions about themselves and their families.

18 DR. WILLARD: Or just begin at "in order to
19 allow patients and consumers," and just take that bottom
20 phrase and move it to the top.

21 DR. McCABE: Yes, and we need to throw genetics
22 in there somewhere, too. I see what you did. But still,
23 it is a pretty long sentence.

24 MS. BERRY: We haven't fixed it yet. So what
25 part do you want to move up?

1 DR. McCABE: If you do it Hunt's way, and then
2 we can see whether it's too long a sentence, but patients
3 and consumers need the genetic information --

4 DR. WILLARD: That wasn't my way.

5 DR. McCABE: Oh.

6 DR. WILLARD: I would just start the sentence
7 "To allow." Take the last two lines of the existing
8 recommendation. "To allow patients and consumers to
9 evaluate health plan benefits and health providers and
10 their families."

11 MS. MASNY: But are they evaluating these plans
12 and benefits related to genetic services?

13 DR. McCABE: See, the way Hunt is doing it,
14 then it's a comma, reliable and trustworthy information
15 about family history. So it comes in, but at the end.

16 DR. LEONARD: It's my thought that this isn't
17 really related to choosing health plan benefits and health
18 providers, as much as it is in helping in the medical
19 decisionmaking for their own care, and the care of their
20 families.

21 There are two aspects to this. But I think
22 evaluating health plans and health providers is really sort
23 of secondary to really helping to participate in their own
24 medical care and the decisionmaking. Genetics is very much
25 this is your choice, what do you want to do.

1 If they are not informed, they can't
2 participate in that process as effectively.

3 DR. WILLARD: But it does bring in Muin's
4 point. It ties it back into coverage and reimbursement,
5 because some plans may provide coverage, some may not.
6 That's relevant, therefore, to their choice between Plan A
7 and Plan B.

8 DR. WINN-DEEN: Could we add the word
9 "clinically appropriate?" "To make the most clinically
10 appropriate and financially responsible decisions for
11 themselves." So that ties in sort of the medical side and
12 the -- I mean, it's always a balance, right?

13 MS. AU: What was your definition of
14 financially responsible?

15 DR. WINN-DEEN: I think each family has to
16 determine do they have the means to pay for something. If
17 they are in a health plan that has a huge deductible, is
18 that the kind of thing they want to be in? Or do they want
19 a \$10 copay? I think that's what we were trying to get at
20 with financial. It is within your own personal financial
21 resources. What is financially responsible for you as a
22 consumer.

23 MS. AU: I guess my problem with that working
24 in a public health agency is financially responsible to us
25 is societal, financial responsibility versus personal

1 financial responsibility. I didn't know what you were
2 qualifying it as.

3 PARTICIPANT: Do you mean financially feasible?

4 DR. LEONARD: So why can't we just say that the
5 most appropriate clinical and financial decisions for
6 themselves and their families?

7 MS. AU: Yes. That's good.

8 DR. KHOURY: How about just the most
9 appropriate decision? The most appropriate decision
10 involves all of the above. Clinical. The most appropriate
11 decision.

12 DR. WINN-DEEN: So can we add the same comment
13 after "genetics" in the second paragraph?

14 DR. LEONARD: Is this now getting redundant?
15 What's the difference? Maybe I'm missing something, but
16 what's the difference between the second paragraph and the
17 first? Why are they separated as two?

18 MS. BERRY: Well, they don't have to be. We
19 can mush them together. The first paragraph just sort of
20 says patients need access to information. The second part
21 of it is what the Secretary can do to help get them
22 information.

23 DR. LEONARD: So you can stick it up there. It
24 won't go?

25 DR. WILLARD: If that's all you're trying to

1 say, I think you could just say, "The Secretary should
2 leverage HHS resources to develop and make widely
3 available, reliable, and trustworthy information." It
4 refers to the previous sentence. Otherwise, you're
5 repeating the same words two sentences in a row.

6 MS. BERRY: Put, "To make such information
7 widely available."

8 DR. KHOURY: Cynthia, what does the term
9 "should leverage HHS resources" mean? If you look at
10 Recommendation 8, it was different. It was, "Should
11 provide financial support for assessment." Are we asking
12 HHS to -- I mean, leveraging HHS resources somehow implies
13 a zero sum game to me.

14 You have all these resources and you move
15 things from here to there. That image, I'm not sure who
16 came up with that word. Aren't we asking the Secretary to
17 do something to develop and make widely available?

18 DR. McCABE: Well, I think leveraging does mean
19 something different than a zero sum gain. What leverage
20 means is we want the Secretary to invest some money. So
21 you get more. Leveraging to me means you get more than the
22 money you invest. There is some strategies where you're
23 going to get more out of it than just putting the money in
24 and getting a product out.

25 DR. LEONARD: Can we just say "Should make such

1 information widely available," and then just come to the
2 end, "through federal government websites and other
3 appropriate mechanisms," and take out everything in
4 between?

5 MS. BERRY: Maybe we should take out "develop."
6 Because you don't develop such information through
7 websites, do you necessarily?

8 DR. LEONARD: Well, you make it available.

9 MS. BERRY: So just add, "make it available."
10 So "leverage resources to make such information widely
11 available through federal government websites and other
12 appropriate" --

13 DR. LEONARD: No, I think it does need to be
14 developed.

15 DR. WINN-DEEN: Yes, you have to develop the
16 content that you're going to put on the websites.

17 MS. BERRY: But you don't develop such
18 information, do you, necessarily?

19 DR. WINN-DEEN: Sure you do.

20 MS. BERRY: Do you develop content to put on a
21 website?

22 DR. WINN-DEEN: Even if you're just pulling
23 stuff from the literature, you have to develop the content
24 and put it together in such a way you can post it to a
25 website.

1 DR. McCABE: And if it's going to be evidence-
2 based, there may even be a research component to check the
3 validity of the information before you put it up.

4 DR. KHOURY: Remember the Surgeon General
5 family history tool that was developed.

6 MS. BERRY: Right. All right. How does it
7 look?

8 DR. WILLARD: Why don't we take a moment to
9 read through it?

10 DR. LEONARD: Could we accept the changes so
11 that we can see it all as if it is written normally?

12 DR. McCABE: We need a synonym for information.

13 DR. FITZGERALD: That's right, because you're
14 referring to it again, though, right? I think it should
15 stay as information, because you're saying such information
16 refers back. This isn't meant to be a best seller. It's
17 simply meant to be understandable.

18 DR. LEONARD: But you could say they need
19 reliable and trustworthy information about family history,
20 about gathering family history, genetics, and genetic
21 technologies.

22 DR. WILLARD: Suzanne, don't touch it.
23 Consider changing the order so that it is trustworthy
24 information about genetics, genetic technologies, and
25 gather and utilizing. So just change that order so that

1 it's clear.

2 DR. EVANS: Don't they really need trustworthy
3 guidance about gathering this information, as opposed to
4 trustworthy information about gathering information?

5 DR. LEONARD: I agree with what Hunt said about
6 moving the genetic technologies.

7 MS. BERRY: You can say trustworthy information
8 about genetics, genetic technologies, and gathering and
9 utilizing family history.

10 DR. TURNER: Cindy? Over here again.

11 MS. BERRY: I keep hearing it over there.

12 DR. TURNER: To start it with "To allow" I
13 think frames it in a way that gives it a paternalism that
14 we probably don't need. So if we were to say, "In order
15 for patients and consumers to evaluate health plans and
16 benefits to make the most appropriate," and take out that
17 "so that they."

18 DR. WILLARD: Maybe with that change, we can
19 look at it one more time and see if this does about what we
20 can expect it to do at 5:00 in the afternoon.

21 MS. HARRISON: In order to utilize family
22 history, you have to gather it. Can you just take out
23 "gathering" and it will cut down on the wording.

24 MS. BERRY: Unless -- oh, he's gone. I was
25 going to say Muin thinks that the gathering part is a part

1 of the Surgeon General's family history initiative. Do we
2 need to leave it in there for that? I have no strong
3 opinion at all.

4 DR. McCABE: Let's get rid of the utilizing if
5 we're going to do it. Let's just, about genetics, genetic
6 technologies, and family history.

7 DR. WILLARD: Let's read it and see if we can't
8 get to a motion.

9 DR. LEONARD: But Jim, yo had raised the
10 concern about family history. I think in this context,
11 though, it's differently worded such that it is not saying
12 that individual family histories are going to be published
13 on the website.

14 DR. WILLARD: So if Suzanne will put her hands
15 in her lap, don't touch the keyboard, let people read it
16 and see if we're getting close.

17 DR. FITZGERALD: Now the way it reads, I think
18 you need a comma after "family history" just to set all
19 that aside. Thanks.

20 DR. McCABE: With that comma, I move approval.

21 PARTICIPANT: I second.

22 DR. WILLARD: All in favor?

23 (Show of hands.)

24 DR. WILLARD: Any opposed?

25 (No response.)

1 DR. WILLARD: We are unanimous in accepting
2 that recommendation. We have soldiered through all nine
3 recommendations.

4 Cindy, what else do you have for us?

5 DR. McCABE: Could I ask that at the end of the
6 day, I know this is hard on staff, but maybe if this could
7 be printed up for us so that we could look at it one more
8 time tomorrow on a piece of paper.

9 DR. WILLARD: A clean version of the
10 recommendations? Did any staff hear that request? Okay.

11 MS. BERRY: Hunt, I don't know if you want us
12 to do this or not, but there really were a couple of minor,
13 and then one a little bit more significant, changes to the
14 body of the report that we made at the task force level in
15 response to public comments. I don't know if you want us
16 to go through those now.

17 DR. WILLARD: Well, I think we've been in the
18 spirit of accepting the task force's good work on behalf of
19 the committee as summarized here. They don't look too
20 substantial to my eye, unless anyone would like to discuss
21 them.

22 DR. WINN-DEEN: Do you want to just give a
23 brief outline of what the areas were so that everybody
24 knows what they were?

25 MS. BERRY: Sure. The first has to do with

1 revising the introduction section of the report. We
2 rephrased the sentence so that it now reads, you can look
3 at the blue part in your paper there, I won't read it out
4 loud, but it addresses the issue of reimbursement levels
5 for covered tests.

6 DR. McCABE: Move approval.

7 PARTICIPANT: Second.

8 DR. WILLARD: I'm not sure we need to vote on
9 this.

10 DR. McCABE: I think we do, because it's the
11 final.

12 DR. WILLARD: Okay.

13 DR. McCABE: Unless we're going to have a vote
14 on the final document.

15 DR. WILLARD: And I don't believe we are.

16 There has been a motion to accept that change
17 and a second. All in favor?

18 (Show of hands.)

19 DR. WILLARD: Any opposed?

20 (No response.)

21 DR. WILLARD: That's unanimous.

22 MS. BERRY: The next one had to do with we had
23 a section on what is genetic/genomic tests and
24 technologies, what are they. There were a lot of public
25 comments about that, fearing that it is too long, it's too

1 confusing. So our task force recommendation was to
2 indicate that really the text is meant to be a description
3 rather than any kind of hard and fast definition.
4 Discussion?

5 DR. WILLARD: Any discussion on that point from
6 around the table?

7 DR. McCABE: We've always had this very long
8 definition of genetic tests. Partly it was historical that
9 we were using the definition that had been developed two
10 committees ago. Have we already buried it, Suzanne or
11 Sarah? Have we wavered from that definition of a genetic
12 test already?

13 DR. WILLARD: I think we spent some time
14 discussing that. At least it was modified to also include
15 genomic tests.

16 DR. McCABE: Okay. That's fine.

17 DR. WILLARD: Any further comments on this
18 change?

19 (No response.)

20 MS. BERRY: And the last, we have already
21 talked about, which was to be consistent when we talk about
22 providers so that the terminology is the same throughout
23 the report.

24 DR. McCABE: Why don't we just for formality
25 sake, I'll move to accept those changes as well.

1 PARTICIPANT: Second.

2 DR. WILLARD: All in favor of accepting those?

3 (Show of hands.)

4 DR. WILLARD: Any opposed?

5 (No response.)

6 DR. WILLARD: With that, Cindy, are you done?

7 MS. BERRY: Done. Fini.

8 DR. WILLARD: Well, I'm sure I speak for our
9 real chairman in thanking Cindy and the task force and
10 staff, especially Suzanne, for an extraordinary amount of
11 work in getting this document done and shepherded through
12 both public comments and our own attention to it.

13 As is traditional, Dr. McCabe always has
14 something to ask. Yes?

15 DR. McCABE: Well, it's just we had said that
16 according to the schedule, these changes were going to be
17 made, and we were going to approve it, you all were going
18 to approve it in October. The question is does the
19 committee need to see it again, or is it approved as it is
20 now? Could it move forward at this point, rather than
21 waiting another quite a few months?

22 MS. BERRY: I think we have to go through and
23 still where we are in the process of incorporating some
24 technical changes and comments that were made.

25 DR. McCABE: But I looked at those, and those

1 are grammar, that we spelled "peck" instead of "pack" for
2 lawsuit and some things like that. I trust that staff
3 could do that.

4 DR. WILLARD: Right, and I believe that's the
5 spirit of the timeline that Cindy proposed to use earlier,
6 that there will be final minor revisions through the
7 summer, and then in the fall, it will be transmitted.
8 There isn't a step, at least not written, as to come back
9 before this committee.

10 DR. McCABE: Okay. So it will be transmitted
11 without coming back to the committee.

12 MS. GOODWIN: Well, the committee will get one
13 last chance by email to review the entire text of the
14 report once we've gone through all of the public comments.
15 But that will be done by email probably.

16 DR. McCABE: Any guess at a schedule on that?

17 MS. GOODWIN: We'll probably have a final draft
18 ready by the end of the summer, possibly earlier. We hope
19 that the report will be approved by the next meeting in
20 October.

21 DR. McCABE: So that email will include a
22 letter to the Secretary that will go along with this?

23 MS. GOODWIN: Yes.

24 DR. McCABE: Okay.

25 MS. GOODWIN: The report will also, what is not

1 in the report now is an executive summary, and staff will
2 be preparing an executive summary, in addition to making
3 some other technical changes to the report.

4 The committee will have an opportunity to have
5 one last look at the entire thing before it gets
6 transmitted to the Secretary in the fall.

7 DR. McCABE: I just think that we've belabored
8 this, and I'm sure we could wordsmith it for another 18
9 months. But I think it's important that it move forward as
10 quickly as possible.

11 DR. WILLARD: This glacier is done.

12 Mr. Chairman, or Sarah, are there any final
13 announcements before we adjourn for the day? I believe
14 we're done.

15 DR. TUCKSON: We have to talk about dinner. We
16 need to get the information on dinner.

17 MS. CARR: Actually more than that, I was
18 wondering if you'd like to go over what decisions we made
19 today. You might tell everybody about, Hunt, tomorrow, and
20 then that would free Hunt up from having to do this
21 tomorrow.

22 The three things we did today. You know what?
23 We have them written out.

24 DR. TUCKSON: Good. I was just going to grab
25 my notes, though.

1 MS. CARR: We just need a moment.

2 DR. McCABE: As usual, Sarah is way ahead of
3 us.

4 MS. CARR: Yes, members who are joining us for
5 dinner tonight should meet in the lobby at 6:40. We're
6 having dinner at 7:00 at Clyde's. Would you like to go
7 earlier? We could certainly see to that. If so, when?

8 MS. BERRY: As our reward for finishing early.

9 MS. CARR: 5:00? 5:30? 6:00?

10 MS. HARRISON: As a local person, the earlier,
11 the better.

12 MS. CARR: Okay. We'll meet at 5:45 in the
13 lobby.

14 DR. TUCKSON: And then as far as tomorrow, our
15 friend Hunt will take the chair role tomorrow. I have to
16 be away with an unavoidable conflict that I just have to
17 attend to. I apologize to the committee. It's the first
18 time I have missed one, but thank you, Hunt. He's well
19 prepared. We've gone over all this. You're in terrific
20 hands. Besides, you can take a sigh of relief that you
21 don't have to deal with the crazy guy.

22 With that, the summaries on genetic
23 discrimination, copies of the DVD are available to the
24 committee. You can get it, and copies will be made
25 available to the public on the website. As you see,

1 continue to monitor developments in the House of
2 Representatives, make compilation of public comment DVD of
3 public perspective analysis, I've already said that.
4 That's good.

5 DR. LEONARD: Does broadly available include
6 giving it to Ms. Biggert's office specifically?

7 MS. CARR: If she asks.

8 DR. McCABE: She already has a copy because she
9 asked.

10 DR. TUCKSON: Right, she asked for it, and we
11 gave it to her. We were very clear on that.

12 Number two, large pop studies. Yes, review
13 report of NIH. We all are asked to read that report
14 carefully.

15 MS. CARR: Well, this is the charge to the task
16 force. But yes, the rest of the committee should review.

17 DR. TUCKSON: The committee is supposed to read
18 the report.

19 MS. CARR: Yes.

20 DR. TUCKSON: Okay. Now, from that, let's go
21 to the task force. They have to read the report, too.
22 Identify other potential policies that need to be
23 addressed, and recommended process or pathways for
24 addressing them. Plan a public consultation meeting or
25 meetings in October if possible to gather perspectives of

1 the general public and the scientific community. You left
2 out the scientific community.

3 MS. CARR: That's in the third bullet.

4 DR. TUCKSON: Third bullet? Okay. About the
5 idea of the U.S. mounting a large population study and
6 whether they would support such a study.

7 Just an addendum to that is the challenge the
8 committee is going to have is how do you in fact ask for
9 public comment on something that nobody understands? So
10 the task force is going to have to take a good, hard look
11 at explaining what this thing is, and then making that part
12 and parcel of the announcement.

13 DR. LEONARD: Tim, is there any sort of
14 summary, executive summary kind of thing of that report?

15 MR. LESHAN: Yes, I believe there is. I
16 haven't read it in the last little while, but I believe
17 there is an executive summary to that report.

18 DR. TUCKSON: Then plan a public consultation
19 meeting or meetings in October to gather perspectives from
20 the scientific community broadly.

21 I think the idea would be though, at least the
22 assumption is you need to think about whether those go
23 together, or are separate. I want to be careful about the
24 administrative burden of trying to do separate things. You
25 may determine that you can't do them together for time

1 reasons or whatever, but it is something the committee
2 needs to think about.

3 DR. McCABE: This is one where I would
4 encourage the committee to move forward deliberatively as
5 opposed to expeditiously. First of all, I doubt that there
6 are the resources currently in hand to engage in such a
7 study. I think that the U.K. ran into problems where the
8 public was not prepared when they tried to roll it out.

9 So I think there is an opportunity for this one
10 to be deliberate. You may save time in the long run by
11 being deliberate.

12 DR. TUCKSON: Good. I just want to make sure I
13 didn't miss anything. They got them all.

14 Then direct-to-consumer marketing. We're going
15 to send a letter back to the Secretary describing that we
16 are pleased with the initiatives that are ongoing, that
17 there has been movement there. We are going to commend the
18 agency's efforts to respond, and recommendations about the
19 public impact, recommend increased efforts to enhance
20 public understanding offered directly to consumers.

21 So we are asking the Secretary to think about
22 this, recommending increased efforts to enhance public
23 education of genetic tests, including the issuance of a
24 general consumer alert, and then urging the FDA to consider
25 the Internet a form of advertising and labeling.

1 Those are the things I had in my summary. Did
2 we miss anything? Then we just did the stuff.

3 It has been an extremely productive day. You
4 ought to feel good about yourselves. You did a good job.
5 Thank you all very much.

6 Tomorrow morning at 8:30. You should be on
7 time or, oh my God, the woe that will befall you.

8 (Whereupon, at 4:55 p.m., the meeting was
9 recessed, to reconvene at 8:30 a.m. on Thursday, June 16,
10 2005.)

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