Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Good morning.

(No response.)

DR. TUCKSON: Good morning.

PARTICIPANTS: Good morning.

DR. TUCKSON: There we go. 8:30 exactly. We run a tight ship around here.

We want to thank everyone for attending the 13th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society.

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

I want to welcome members of the public who are in attendance today, as well as the viewers who are tuning in through the web cast.

We're meeting today at the headquarters of the Department of Health and Human Services, the Humphrey Building in Washington, D.C.

Let me just make everyone aware that because of the web cast and the microphone system, that if you have the wireless stuff, your telephones and -- there it is. That's the warning. That is exactly the warning. If you put any of these electronic devices next to these microphones, you will get that horrible noise which will go out, and all of your private information will be dispensed to all the world.

(Laughter.)

DR. TUCKSON: If you don't mind that, it's okay.

A public comment session is scheduled just prior to the lunch break, and we encourage members of the public in attendance that wish to address the committee to sign up at the registration desk.

Typically our SACGHS quarterly meetings take place over a period of two full days. However, because of the importance of the charge given to us by the Secretary at our March meeting on the oversight of genetic testing, yesterday was devoted to a very special and very productive all-day working meeting of the Oversight Task Force. Later this morning, we'll hear actually from Marc Williams who will give us an update on what occurred yesterday. There was an awful lot of work and we're very proud of what they have been achieving so far.

At the March meeting, you will recall that we created a new Evaluation Task Force led by Steve Teutsch. The new priority developed as an integration of our two proposals that were presented to SACGHS: outcomes research for genetic technologies and economic implications of genomic innovations. After an in-depth study, the two study proposals were combined when it became clear that an investigation of the outcomes of gene-based applications must include their economic consequences.

Initially this new task force planned to start work immediately. However, several members of this task force also decided to join and participate in the Oversight Task Force, which has an awful lot of work to do in a short period of time.

Given that there is some overlap in the content of the two efforts, it has been decided that the Evaluation Task Force members would be more efficiently served to devote their full resources to the oversight charge first and then carry the knowledge gained from that effort on to the new task force. So work will begin on the new priority after the Oversight Task Force completes its work and delivers its report to the Secretary.

One of the things that I think is important to note is just how hard the members of this committee work. I don't think that we probably disclosed to you, when you took on this assignment, that there would be all of these task forces and that people would be on more than one. They would be working all at the same time. But I just want you to know that the hard work is noted and it is appreciated.

On April 27th, we sent a letter to Secretary Leavitt thanking him for his leadership in addressing oversight issues and for directing our inquiry into gaps in the oversight of genetic testing. We also expressed our interest in two Senate bills that had been introduced recently that affect genetic testing: The Laboratory Test Improvement Act, Senate bill 736, and the Genomics and Personalized Medicine Act, Senate bill 976. You can find a copy of our letter in your briefing book.

Hunt Willard can't be here today, but I want to report that he was invited by the Connecticut Department of Health to give a presentation on our large population studies report. Connecticut is examining the feasibility of a statewide biobank to determine genetic and environmental factors involved in preterm births. Although what Connecticut has in mind would be on a much smaller scale than the type of study addressed in our report, given that Connecticut is a state, they wanted to learn more about the policy issues identified in our report, a number of which are relevant to biobanks in general. So we're glad that he's going to do that.

Well, today, since we're meeting just for one day and are on a tight schedule, this time I will forgo an in-depth review of the status of our strategic plan and priority issues, but for those, again, that are new members of the committee, you know that we are pretty fanatical about trying to lay out the overall strategic plan that we have and to keep tracking our progress to make sure that our stuff is just not a bunch of meetings and reports on a shelf, but that we're actually achieving a set of very defined goals. So I will forsake that today, but always we'll make sure that we keep you up to date on our strategic planning.

I do, however, want to make a quick note of developments in Congress related to the Genetic Information Nondiscrimination Act, or GINA. Genetic discrimination, of course, has been our highest priority issue, and we've been keeping close watch on the progress of this legislation since our inception.

The House bill, H.R. 493, did pass 420 to 3 on April 25th, and the Senate bill has been reported out of committee and a vote in that chamber is expected soon. After 12 years of tireless work by its supporters, a law, specifically prohibiting genetic discrimination in health insurance and employment finally seems very close to becoming a reality.

I also want to report that we have received comments from CMS on our 2006 report on coverage and reimbursement of genetic tests and services. You'll recall that we made nine

recommendations in that report and several of them were related to programs and policies administered by CMS. A copy of their letter can be found in your table folders.

It was not that long ago, I guess, that we came in this very building and briefed the leadership of CMS, and we're very appreciative of their careful review and consideration of our recommendations. Marc Williams has volunteered to review these comments and to help us to determine what follow-up or next steps are needed. So if you have any thoughts, after reviewing the letter, please make sure that you work Marc to death and get to him right away.

With that, let me also welcome Dr. Madeline Ulrich from CMS. Thank you, Madeline. Dr. Ulrich is with the Coverage and Analysis Group and is sitting in today for CMS' ex officio, Dr. Barry Straube. Welcome and thank you for your diligent efforts on behalf of the committee.

I also want to report on staffing developments. Since our last meeting, Dr. Cathy Fomous has joined the Office of Biotechnologies as policy analyst, supporting both the work for SACGHS and a program aimed at harmonizing clinical research policy. Cathy has been working intensively since the day she arrived in supporting the Oversight Task Force. So thank you. She comes to us from her position at the National Library of Medicine where she directed content development for the genetics home reference website. She's also worked as a researcher at the German Cancer Research Center in Heidelberg. Cathy is a certified genetic counselor and earned her doctoral degree in genetics from Georgetown University. Did you have anything to do with this, Kevin?

(Laughter.)

DR. TUCKSON: Natalie Vokes has joined the staff for the summer -- Natalie, where are you? Great -- as the famous intern and is working with the committee's gene patent study. We work the interns to death. So thank you, Natalie.

She graduated with a degree in chemistry from Williams College and is the recipient of a two-year fellowship to study the philosophy of science at Cambridge University. Natalie would eventually like to attend medical school and work as a physician scientist. We're happy that she's with us.

I'd like to also quickly provide an overview of today's agenda. We'll begin with an update from the chair of the Pharmacogenomics Task Force, Kevin FitzGerald, who will fill us in on the status of the public comment process. Andrea will then report out -- Marc will then report out on the work of the Oversight Task Force, given that Andrea is in recovery.

A large segment of today's meeting will focus on the work of the Gene Patents and Licensing Task Force, which is chaired by Jim Evans. Jim will provide an update on the task force's work, after which we will hear from Judge Pauline Newman who will speak on pending patent legislation in the U.S. Jim will then facilitate today's international roundtable on gene patents and licensing practices.

We are very pleased to welcome back to the table two honored SACGHS alumni, Debra Leonard and Emily Winn-Deen, who just won't go away, who are now ad hoc -- by the way, let this be a lesson to all of you.

(Laughter.)

DR. TUCKSON: There is no escape. They are now ad hoc members of the Patents Task Force. They will be participating in today's roundtable, and I know Jim will point out the other members of the task force in his remarks.

Finally, I want to welcome all of our invited speakers on gene patents, most of whom have traveled lengthy distances to join us today, and we really do look forward and appreciate your presentations.

After the patent sessions, Dr. Katrina Goddard of CDC will provide an update on public awareness of DTC tests. She'll be presenting the results of a CDC national survey and then an analysis of data from several states.

Well, now let's turn to Sarah Carr for the famous and long-appreciated reminder about the ethics rules. Ta-da.

MS. CARR: Good morning. As you know, you've been appointed to this committee as special government employees in order to serve, and though you're in a special category, you're nonetheless subject to the rules of conduct that apply to government employees. These rules are outlined in a document that you received when you started on the committee, and I'm just going to highlight two, as I do every time.

First, about conflicts of interest. Before every meeting, you provide us with information about your personal, professional, and financial interests. It's information we use to determine whether you have any real, potential, or apparent conflicts of interest that could compromise your ability to be objective in giving advice during committee meetings. While we waive conflicts of interest for general matters because we believe your ability to be objective will not be affected by your interests in such matters, we also rely to a great degree on you to be attentive during our meetings to the possibility that an issue will arise that could affect or appear to affect your interests in a specific way.

In addition, we've provided each of you with a list of your financial interests and covered relationships that would pose a conflict for you if they became a focal point of committee deliberations, and if this happens, we ask you to recuse yourself from the discussion and leave the room.

As government employees, you're also prohibited from lobbying as individuals or as a committee. If you lobby in your professional capacity or as a private citizen, it's important that you keep that activity separate from the activities associated with this committee. Just keep in mind that we're advisory to the Secretary, not to the Congress.

Thank you, as always, for being so attentive to these rules.

DR. TUCKSON: Well, I don't know about you, but I find that to be one of the highlights of every meeting.

(Laughter.)

DR. TUCKSON: Thirteen times now.

So let's now turn to Kevin to give us an update on the status of the committee's work on pharmacogenomics. The public comments were received on our draft report, copies of which

were sent to you. The Pharmacogenomics Task Force plans to review and address the comments and the time line for completion of the report. Take it away, Kevin.