Opening Remarks
Reed V. Tuckson, M.D.

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

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

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

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

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

Let me welcome Ms. Sylvia Au. She joins us from the Hawaii Department of Health, where she is the state genetics coordinator. She is a board-certified genetic counselor and current president of the Coalition of State Genetics Coordinators.

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

We've got one bit of housekeeping that I need to go through formally. At the end of the last meeting, Drs. Joe Boone and Stephen Groft gave us a presentation on ongoing efforts to improve access to quality genetic tests for rare diseases. Unfortunately, there was not a quorum by the time their presentation was given. As such, I need, while all of us are here, for the record to review a couple of points that were made. Here's what they had to say.

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

We were told about a conference that's being planned in September of 2005 in D.C. The goals of the conference are to raise national awareness of the growing public need to improve the availability, quality, and accessibility of genetic testing for rare diseases, and to promote development of multiple processes and models to enhance the translation of genetic tests from research to clinical practice.
The ultimate goals of their efforts are to improve health outcomes for individuals and families through access to quality rare disease tests, ease of access and third-party payment, usefulness of test results, adequate follow-up systems, and education and support after testing is completed.

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

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

(No response.)

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

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

This, again, is our roadmap, and I want to, at least as your chairman, make sure that we are always aware of where we are on the roadmap and whether we are meeting our targets and our deadlines.

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

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

We will start this meeting, our seventh, with an update on the genetic discrimination package that was transmitted to the Secretary and a briefing on the status of pending legislation in Congress. Related materials can be found in Tab 3 of your briefing books.

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

We will consider next steps to be taken with regard to the issue of large population studies. That's going to be a very, very important and interesting conversation. It is unfortunately only a half hour. So one thing I really want to make sure is if any of you have any stuff that you've got, one little small thing that you have to do where you may have to step out or something, don't miss

that half hour. It is a very key one. We are going to need you really focused on that, because we're going to have to be very specific about some guidance, and we don't have a lot of time to give that guidance to our task force. So I want to really highlight this is an important part of this meeting.

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

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

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

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

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

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

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

MS. CARR: Thank you very much for that. I can't take any credit. I don't do any of the work, actually. Amanda Sarata, Suzanne Goodwin, and Fay Shamanski do it all, and this summer we also have a summer intern. Abby Rives is here with us, so we're putting her to work as well. But thank you very much, Reed.

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

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

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

While we waive conflicts of interest for general matters, because we believe your ability to be objective will not be affected by your interests in such matters, we also rely to a great degree on you to be attentive during the meetings to the possibility that an issue will arise that could affect, or appear to affect your interests in a specific way.

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

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

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

The last rule I want to talk about is lobbying. Government employees are prohibited from lobbying, and thus, we may not lobby. Not as individuals, and not as a committee. If you lobby in your professional capacity, or as a private citizen, it is important that you keep this activity separate from the activities associated with our committee.

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

DR. TUCKSON: Great. Thank you.

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

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

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

So there are some very technical parts of this rule, and you've got to be careful about it. Anyway, I just wanted to make sure that you all saw that. Look at it, but not now, because now we are into the heart of the meeting.

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