Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Good morning.

PARTICIPANTS: Good morning.

DR. TUCKSON: We have two very intense days.

Let me thank everybody for being here and all the members who are in the audience. We appreciate your involvement, everyone that's looking in and following this on the Web. It's always good to get these emergency emails on my BlackBerry by somebody out there who says, wait a minute, what about this? So we know that there are people who are extremely attentive.

This is the 12th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. The public was made aware of the meeting through notices in the Federal Register, as well as announcements on the SACGHS website and through our listserv.

I want to welcome all of you again and for everyone's interest in the work.

By the way, any members of the public that would like to testify, we urge you to sign up at the registration desk.

Our committee is a little larger today thanks to the Secretary's appointment of a new member. We are very pleased to introduce Dr. Marc Williams. How are you doing, Marc?

DR. WILLIAMS: Fine, thank you.

DR. TUCKSON: Great. Marc, you happen to know yourself what the rest of us may not know that you are a board certified clinical geneticist.

(Laughter.)

DR. TUCKSON: And if you didn't know, you're the Director of the Intermountain Healthcare Clinical Genetics Institute in Salt Lake City, Utah. In addition to your clinical work, you are an expert on the role of medical genetics and health care delivery. You chair the Committee on the Economics of Genetic Services for the American College of Medical Genetics, and you serve on the Subcommittee of the Health Care Systems of the Section on Genetics of the American Academy of Pediatrics. So all those things, including your editorship in chief of the Manual on Reimbursement for Medical Genetic Services, really makes you and your background extremely important to this committee, and we really thank you.

DR. WILLIAMS: Thank you.

DR. TUCKSON: Terrific.

I also want to welcome back two of Secretary Leavitt's key staff: Sheila Walcoff, Counselor to the Secretary for Science and Public Health; and our friend, Dr. Greg Downing, Program Director of the Secretary's Personalized Health Care Initiative.

You will recall that Sheila met with us in November to tell us about Secretary Leavitt's commitment to improving the safety, quality, and effectiveness of health care by leveraging advances in genomics and health information technology. She told us that accelerating personalized health care is one of the Secretary's top 10 goals and that he felt an urgency to that.

Well, I want to tell you that as of Friday, I saw that urgency in action. The Secretary allowed me to represent you at two extraordinary events, and I will tell you -- and you will hear more about those from Sheila in a moment -- that clearly this is a Secretary who is inspired, who really gets it, who understands this is a historical moment at being able to merge together the benefits of science and health information technology to advance better health care for each individual.

I also want to say that he gets it as far as this committee. In any of the history that I have participated in in this committee or the prior one, I have never seen this committee treated at the level of respect, not to denigrate any other past -- so this is just an extraordinary added attraction in terms of how this Secretary treats this committee. And I think he's listening to us. So the good news is that you're really respected. The bad news is you're going to have to work a lot harder. So we appreciate that. We'll be hearing much more.

Let me just say a quick word about Sheila. And where's Greg. Greg Downing and Sheila are just terrific people. Greg has been behind the scenes just doing so much work for and with us. We have long wanted somebody to represent and carry our issues forward, and we always have wanted a good ear and someone at the level of Sheila. So I just want to say to you publicly that we are extremely pleased by what we are seeing, and it really makes the work that we're putting in seem so much more real and relevant.

Following the comments from Sheila in a few moments, if I ever get done, we'll hear from Robert Kolodner, whom I'm really interested in seeing, the Interim National Coordinator for the Office of Health Information Technology, and Ms. Jodi Daniel, their chief of policy and research, about the role of health information technology and how this will move this agenda forward. I will tell you again that Robert is also just terrific, and I've had a lot of time to work with him in the days past.

Welcome to all of you and thank you very much for coming.

Well, our committee has a very broad charter and mandate. Within that broad charter and scope, our agenda has been guided by a strategic plan, and I want to put that out. Everyone in this committee -- and Marc, you'll catch on -- knows that I will go through a laborious effort at the beginning of every meeting to review this strategy and agenda. I think it is very important that at the end of the day, that we are able to say that we have kept our commitments, that we are moving our committees and our work forward in a logical way designed to produce results. It's too much work to bring you all in here and just have lovely conversations that go up in the ether somewhere.

So let me just remind you quickly of where we are, and you'll see it on the slides. We've identified 12 issues that we thought warranted our attention or in-depth analysis. The topics at the top, access, public awareness, and genetic exceptionalism, are cross-cutting issues that affect all of them. So they are always addressed in our work. The priorities on the left side are checked because we have produced reports and our recommendations on those issues. The priorities on the right are ones that we are currently focusing our analytical efforts on.

As I rip through these quickly, I want you to keep in mind for preparing you for tomorrow afternoon. We're going to relook at these priorities and our status. I want the committee to feel comfortable that there's not a sin of omission or commission up here on this agenda. If you feel that something else is emerging that we should be attending to, that something here is less important than something else, we should be revisiting that to make sure that we are maximally relevant to the events of our times. So I want you to really keep this close in mind.

Genetic discrimination we made as our highest priority. Over the last four years, we've written a number of letters to the Secretary championing the enactment of federal legislation. In 2005, we provided a legal analysis of the adequacy of current law, a compendium of public comments the size of a phone book, and we gave a DVD that documented the public's very real concerns and fears and really compelling public testimonies in front of this committee. We've kept a close watch on congressional developments at every one of our meetings, and in a small way, we have, within the limits of our appropriateness of a committee such as this, tried to bring folk together for common conversation to resolve differences of opinion.

We are thrilled to see how much progress is being made in the current Congress, and we will be looking forward this morning to an update from the HHS Deputy Assistant Secretary for Legislation and several key congressional staff on what's going on with the new GINA, as it's called, bill. So we have great promise for GINA, and I'll leave it to them to update.

In 2004, we made recommendations to the Secretary about the importance of genetic education and training of health professionals and how it should be enhanced. We know that this is largely a public sector responsibility, but government does have a role to play, and we asked the questions: where do genetics education and training stand today; are we in better shape today than three years ago? Well, tomorrow we'll discuss the strategic plan that is being developed and we'll revisit our recommendations in light of this issue.

I want to let you know that there are some developments. The CDC is planning a major initiative called Genetics for Early Disease Detection and Intervention. Like everything, it has an acronym, GEDDI, as in GEDDI knights. I don't know. It sounds pretty cool. It will educate the public and providers about genetically based disorders, whose early detection can lead to interventions that can improve outcomes.

We know too from our last meeting that the CDC/NIH CETT Project, the Collaboration, Education, and Test Translation Project, is working to enhance to communications in genetic testing both between providers and patients and providers and the testing laboratories.

The American Nursing Association to its credit, the International Society of Nurses in Genetics, ISONG, and other nursing groups published an excellent set or core competencies for the nursing community.

The well-respected NCHPEG, the National Coalition for Health Professional Education in Genetics, has continued to advance its hard work. Its latest targets have reached speech language pathologists and audiologists, and new programs for physician assistants and dieticians are on the horizon. They're also developing a database that will deliver concise, clinically relevant genetics information to nongenetics providers at the point of care and are working with the Personalized Medicine Coalition and Feinstein-Keene Healthcare to create a program on pharmacogenomics for health care providers. So that is important.

So we will see whether or not you are comfortable with these things and whether we want to move forward any further on revisiting this important topic.

In 2006, we transmitted a report and recommendation to the Secretary on coverage and reimbursement for genetic tests and services. We highlighted the problems in the system that we thought affected patient access, and we identified nine steps that could be taken to overcome the barriers. These recommendations cover a range of topics, including evidence-based coverage decisionmaking, Medicare coverage of preventive services, adequacy of CPT codes for genetic tests and services, billing by nonphysician genetic counselors, and genetics education for health providers.

Cindy Berry and I had the opportunity in June to brief then-CMS Administrator Mark McClellan and his leadership on the coverage and reimbursement issue. It was a positive meeting, and they expressed a strong interest in the report's recommendations.

We're going to turn to Jim Rollins now -- Jim Rollins isn't here yet. So you're going to hear later from Jim Rollins on an update on where things stand in CMS concerning activity on these recommendations. Let me again say that Mark McClellan was just terrific, and his leaving out does not mean, though, that this just dropped so that there are activities moving forward at CMS and we are well aware of that. So we'll come back at some point and hear from Jim. So whenever that happens, the key emphasis in my comments to you is we have been attentive to making sure that Cindy and I did not just have a nice meeting. So that's the key thing, that we are moving forward.

In '05 and ' 06, we wrote letters to the Secretary on direct-to-consumer marketing of genetic tests. Our efforts in this area led to enhanced collaboration between FDA, CDC, CMS, and NIH, and the Federal Trade Commission. In '06, the FTC issued a consumer alert to warn consumers about using at-home genetic tests that have not been evaluated and to be wary of the claims made by the companies marketing these tests. The alert is a product of interagency collaboration and it is a tremendous accomplishment in that respect, and we commend HHS for its leadership in moving forward in this regard.

But what has been the benefit of the alert in terms of public health? Has it helped? How many people did it reach? Well, I want to thank Matt Daynard, our ex officio, for providing us with some data on how widely the alert has been disseminated. The Web hits on the alert on the FTC website total 6,461 so far. Almost 12,000 copies of the printed brochures have been distributed, which means the total distribution for both print and Web is around 18,000. In addition, the consumer alert has been widely covered in the media, stories in the Wall Street Journal, the New York Times, NPR, U.S. News and World Report, Contra Costa Times, American Healthline, the FDA News, and Medical Device Week. So it is out there and moving forward. If anyone can think of other ways that that alert ought to be disseminated, please let us know.

I'm extremely pleased to say that we completed our report on the policy issues associated with undertaking a new large U.S. population cohort study of genes, the environment, and disease. It was transmitted to the Secretary earlier this month. Copies of the printed version are now publicly available. You each have a copy in your table folder, and copies are available at the registration desk for the public or you can also download the PDF version on our website. I actually handed a copy to the Secretary in a one-on-one meeting in his office Friday. So I know he absolutely has it and we'll quiz him on it later.

(Laughter.)

DR. TUCKSON: On behalf of the entire committee, I want to extend our thanks to Hunt Willard, who will be attending tomorrow's session, and to the Task Force on Large Pop Studies for guiding this effort through a long and difficult fact-finding and consultative process. We are indebted to the many experts who helped us identify the policy issues and broaden our understanding of the challenges and potential benefits of such a study. Our report was also greatly enhanced by the public comment process we carried out last summer.

Let me acknowledge the important role of staff in bringing this report to fruition, particularly Yvette Seger, Betsy Earp, Katie Kohler, and in the early stages our friend Amanda Sarata.

Our draft report and recommendations on pharmacogenomics has also progressed. It was released for public comment this past Friday to coincide with the Secretary's announcement of his Personalized Health Care Initiative at the National Press Club. I want to thank and appreciate our task force, led by Kevin FitzGerald -- Kevin, thank you -- as well as the Office of the Assistant Secretary for Planning and Evaluation, the Lewin Group, and the staff for working so hard to get the draft report ready for release in time. It was a race to the finish, but you couldn't possibly miss the opportunity that the Secretary is going to announce this whole thing, and to be able to have it at his press conference on Friday was pretty terrific. I also handed him a copy of this report personally. I know he has it. We will quiz him later.

We're also making progress on our study on the impact of gene patents and licensing practices on patient access to genetic technologies. You'll recall that at our meeting in November, we approved the study scope and approach developed by the Task Force on Gene Patents and Licensing Practices. Tomorrow our friend, Jim Evans, chair of our study task force, will provide us with some foundational knowledge and prepare us as they move forward with the study. We'll learn about the basics of the patenting system and how licensing of intellectual property works in federal and private sector agreements, and we'll have an in-depth presentation on patent policy issues and developments. We'll be updated on the progress of our study by both Jim and Dr. Robert Cook-Deegan from Duke, who is working closely with us on the information-gathering component of the study.

This slide illustrates, by the way, the structure of our study and the components being carried out by the Duke group. We'll revisit this later in the meeting.

Jim will also be holding -- an announcement, by the way -- a task force meeting tonight. There are no basketball games.

(Laughter.)

DR. TUCKSON: -- with Bob and his collaborators. Committee members who wish to attend, those of you who really are looking for a fun thing to do, should let Jim and Sarah know. We'll be making provisions for overflow seating.

(Laughter.)

DR. TUCKSON: SACGHS has had extensive discussion about the oversight of genetic tests at our last meeting. We heard that CMS will not be moving forward with the notice of proposed rulemaking on a genetic testing specialty under CLIA. After several presentations and much discussion, I think it is fair to say that the committee was left with many questions about the adequacy of the federal oversight framework for genetic tests. Therefore, we decided to engage in further fact-finding at this meeting.

We have since learned that HHS formed an internal working group to examine the roles of federal agencies for both analytical and clinical validity and to determine where problems and gaps lie within the federal government's oversight. This group will be keeping SACGHS apprised of their findings. In a few moments, Sheila will speak to us about a specific charge from the Secretary's office to us related to this.

I will just say this once again. And I don't want to embarrass Sheila or Greg, but I have to say it was very encouraging to me that there's no question that each of you and I personally, at the end of the last meeting, were confused and we were concerned. The responsiveness by HHS and the Secretary's office to that anxiety was palpable. They are on top of their game, and I am personally convinced that this issue is a high priority. I've had several meetings with them, and I will tell you that I understand that they're taking this seriously. So I just want to say to you that while there was a lot of anxiety among the committee at the last meeting, I can at least say to you that those anxieties are being attended to in a professional and responsible manner, and we'll hear more about that as we go forward.

Well tomorrow, finally, we'll be considering whether to take on two new topics, one proposed by our colleague, Steve Teutsch, on the economic consequences of genomic innovations, and another proposed by our ex officios from AHRQ, our good friend, Gurvaneet, and this dude Muin on the evaluation of real-world outcomes of gene-based applications. So we look forward to your terrific ideas. There won't be any time for it, but we'll be happy to have them.

(Laughter.)

DR. TUCKSON: Before we adjourn, we will also have time to discuss whether we need to start developing a new long-range plan. Depending on your decision about the two study proposals and also the oversight issue, we may have to outline new stuff. But as we do this, I think it's useful to keep in mind that as long as it took me to rush through and be out of breath to read all of that, it's important that we have done enough to have to read all of that and rush through it, and it would take that much time. You've been a busy committee, and I hope that when you check off your little form around effectiveness in your annual survey, which is in your packets, that you will be able to grade yourselves pretty highly by saying that you guys don't fool around. All in all, I think we can feel fairly good about what we have accomplished.

Before we go on with the meeting, I want to pause for a moment -- and I will slow down for this -- and acknowledge Joseph Hackett, who died last month. Dr. Hackett participated in a number of our meetings and task forces on behalf of Steve Gutman and the FDA. He was an extraordinary civil servant, dedicating 30 years of his life to carrying out the important mission of the FDA. He was an expert in methods standards and in in vitro diagnostic devices and had many achievements during his long career. He was one of the first scientists at the agency to realize how important genomic and pharmacogenomic testing would become, and he fostered some of the first interactions FDA had with industry on these important topics. These gatherings, I'm told, were affectionately called the Hackett Staff College, undoubtedly a reflection of his appreciation of an openness to new ideas and his dedication to mentoring.

Steve, I know Joe was a valued colleague and friend and that his passing has been a profound professional, as well as personal, loss for you and your colleagues. On behalf of the entire committee, please accept our condolences. Thank you.

Well, since our last meeting, there have been some staff changes. Tara Hurd joined the team in January to help with administrative tasks. Amita Mehrotra took another job, and we want to

thank Amita for everything that she's done. A search is underway for subject matter experts to support the committee's analytical work.

And whoever is responsible for the Reedster bunny joke --

(Laughter.)

DR. TUCKSON: -- we'll be speaking to you at performance appraisal review time.

(Laughter.)

DR. TUCKSON: And finally, some housekeeping matters related to lunch and dinner. To save time at lunch, I want to encourage the committee members to order lunch from the hotel menu. So please fill out the form in front of you, I am told, before 9:30, or else Abbe Smith will hit you in the back of the head.

Also, because of the special task force meeting tonight, the full committee will not be gathering for dinner. There will be a heck of party in room 309. Those of you who have already signed up for the task force meeting and prepaid for dinner will have a dinner buffet during the meeting.

Sarah, time for the official ethics, "scare you to death" comments.

MS. CARR: Right. Conflicts of interest. Before every meeting, you provide us with information about your personal, professional, and financial interests, information that 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 these interests, 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. If this happens, we ask you to recuse yourself from the discussion and leave the room.

I also want to remind you about lobbying. You're special government employees and you're prohibited from lobbying and, thus, we may not lobby, not 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 our activities.

Just keep in mind as well, as Reed has, that SACGHS is advisory to the Secretary of Health and Human Services. We do not advise the Congress.

And I thank you, as I've always thanked you, for being so attentive, as I know you are, to these rules.

DR. TUCKSON: Just remember to go home and tell your families that you are "special."

(Laughter.)

DR. TUCKSON: If you note by your clock, it is actually 8:29. I have gotten through that a minute early, and this is the standard that we want to keep for the rest of the meeting.