Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: We do want to welcome everyone to the 14th 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 website and listserv.

I want to welcome members of the public in attendance, as well as the many viewers who are tuning in throughout the webcast. I do remind the Committee that this is widely viewed on the webcast, and so be on your best behavior.

We encourage any members of the public in attendance who wish to address the Committee to sign up at the registration desk. We are also providing an extended period for public comment tomorrow afternoon specifically to solicit input on the Committee's Draft Report on Oversight of Genetic Testing, which was released for public comment two weeks ago.

Secretary Leavitt has made several new appointments to our Committee. Since we last met, five new experts have joined our ranks. I want to introduce and warmly welcome each one of them.

First, my old friend Mara Aspinall. Mara is president of Genzyme Genetics, where she is responsible for the company's Business Unit, which includes nine laboratories across the United States and operations in Japan that provide diagnostic testing and genetic counseling services worldwide.

Mara earned an M.B.A. from Harvard Business School, and she is not entirely new to SACGHS. She has been serving as an ad hoc member of the Taskforce on Gene Patents and Licensing Practices for the past year. We have appreciated that work very much. Thank you so much, Mara.

Let me also welcome our good friend Paul Billings. Paul is currently a consultant at Lab Corp, where he works on special projects with the company's chief executive officer. Previously, he was Lab Corp's vice president and national director of genetics and genomics. He is also an adjunct professor of anthropology at the University of California, Berkeley. Go Golden Bears. He was a member of the Joint National NIH-DOE Taskforce and the NIH Recombinant DNA Advisory Committee.

Paul earned medical and doctorate degrees from Harvard and completed clinical training in internal medicine and medical genetics at the University of Washington. Thanks so much, Paul.

Paul Miller. Where is Paul? Oh, there you are. Paul, welcome back. Paul is now the Henry M. Jackson Professor of Law and director of the Disability Studies Program at the University of Washington. Before joining the university, Paul was commissioner of the EEOC and, in that capacity, served as the EEOC's ex officio on this Committee. He also served as the White House liaison to the disability community and a deputy director of the Office of Consumer Affairs.

Paul obtained a law degree from Harvard, and I also want to recognize your service on our Oversight Taskforce. Paul, you also have two areas of expertise you are bringing to us. Not only are you our legal eagle on this but you are also our consumer representative as well, and we very much appreciate your involvement.

Paul Wise. Paul, thank you very much, sir. The Richard Behrman Professor of Child Health and Society at Stanford, and a core faculty member at the Center for Health Policy, Center for Primary Care and Outcomes Research. His work is focused on children's health; health outcomes; disparities by race, ethnicity, and socioeconomic status; the interaction of genetics and the environment; and the impact of medical technology on disparities in health outcomes.

I know Paul's work well. He received a medical degree from Cornell and a master's from Harvard School of Public Health. He completed a residency in pediatrics at Children's Hospital Medical Center in Boston. Paul, we really appreciate your being here.

The Secretary also appointed Rochelle Cooper-Dreyfuss to the Committee. Professor Dreyfuss has a longstanding commitment at the National Academies. She is not able to be with us today, but we want you to know that she is the Pauline Newman Professor of Law at New York University School of Law. She serves as a member of two National Academy of Sciences committees, investing intellectual property issues. She is the past chair of the American Association of Law Schools Intellectual Property Committee.

Before earning a law degree from Columbia University School of Law, Professor Dreyfuss earned a master's in chemistry and worked as a research chemist.

Welcome to all of our new members. Let me add that I understand that you are serving today as ad hoc members of the Committee pending the completion of the wonderful appointment process. In that capacity, you are not yet voting members of the Committee. Nonetheless, you are encouraged, and we will be keeping score of whether you comment or not. We want you to comment.

The other thing that you are graded on is whether you have the courage to say, "I'm sorry. I don't understand where you all are in the discussion. Would you mind taking it back and explaining something because I haven't been here for the 13 years that everybody else has." So that is a good thing.

That is a good thing because I hate it when I come to a committee newly and everybody knows everything and I don't know diddly squat and you feel like an idiot. So I urge you to ask as many questions as you want, and you are more than welcome to participate in everything but the vote, and we will be happy there.

Welcome to the new members.

While the appointment of new members is always an occasion to celebrate, it is often accompanied by departures. This meeting is no exception. Tomorrow we will be saying goodbye to three retirees: Cindy Berry, Chira Chen, and Hunt Willard. So we are going to be sad about that, but we will be sad tomorrow. We won't be sad today.

I want to welcome a new ex officio member, the Office of Public Health and Science. Now, Dr. Inyang Isong -- and she will tell me whether I got that right. Where are you? I got it right? I have never gotten it right.

[Laughter.]

DR. TUCKSON: This is the first time in history.

She is a medical officer and a clinical consultant with the Office of Population Affairs on issues relevant to family planning and adolescent family life. The prior ex officio, Dr. Anand Parekh, is acting director, deputy assistant secretary for health, and has assumed the assistant secretary's responsibilities. We appreciated Dr. Parekh's contributions to SACGHS and look forward to working with Dr. Isong.

I'm really happy that Barry Straube is with us today. Barry is a good, valued colleague of mine. He's the chief medical officer at CMS. Barry is taking a much more direct involvement in our work on behalf of CMS. We know that he can't stay the whole day and can't be with us tomorrow, but Barry is making a very conscious decision by his presence to really, really emphasize how important this work is to CMS. So Barry, I really appreciate your being here today.

I want to recognize an ex officio's contributions in a critical area were honored last month. Dr. Robinsue Frohboese, the principal deputy director for the Office of Civil Rights, with responsibility for overseeing all program operations and policy development, received the Secretary's highest recognition award, the Award for Distinguished Service.

Robinsue, we know that you were honored for your commanding leadership in the Office of Civil Rights and deep understanding in ensuring the rights of persons with disabilities nationwide. I want to congratulate you on behalf of the entire Committee for being recognized in this way, and commend you for your dedication to the citizens of this country. You have dedicated your career to upholding civil rights.

She is of course, after doing that, not here yet. But that is fine because it is in the record. We will remind her that we did this when we see her. But Robinsue is just terrific and great.

Now I would like to update you on a few developments regarding the Secretary's Personalized Healthcare Initiative. In September, the Secretary's Office issued a report on the Personalized Healthcare Opportunities, Pathways, and Resources. You may recall that the Secretary's Office was kind enough to send each of us a copy. The report does an excellent job, we think, of describing current activities that are directed toward the achievement of personalized health care as well as the work that lies ahead to bring it to reality. We commend them for that work.

HHS also released a summary of an expert panel meeting on this topic that took place in March. The meeting was sponsored by the Office of the Assistant Secretary for Planning and Evaluation and involved key stakeholder perspectives, such as payers, representatives from industry and government, and patient advocates.

The discussion identified five main issues that need to be addressed to fully realize the potential of personalized health care. These were, and they will sound familiar to all of you, clinical validity and utility, value and cost effectiveness, the need for data to build evidence and informed clinical decisions, impact on health disparities, and education of providers and patients. A copy of that workshop summary is in your table folder. You can of course download it from the HHS website.

There have also been activities within the Personalized Healthcare Working Group of the American Health Information Community related to the Secretary's Personalized Healthcare Initiative. We are staying abreast of that group's work through the participation of Andrea. Thank you, Andrea, for that. Steve as well, and Marc Williams. So to the three of you, thank you so much for your efforts in this important initiative.

I have been tuning into those by telephone and paying attention to those on conference calls, and the work is very, very important and key to what we are trying to do.

At the beginning of each meeting I have established the tradition, and I'm going to continue it, to take a moment to review our strategic plan and the status of our progress in fulfilling each of our study priorities. This gives us an overview of what we have accomplished to date and helps us to stay focused. So if we will put that up.

Again, for the new members of the Committee, this was a plan that we as a collective team developed several years ago. It will be, before very long, time to revisit this again.

This is not one of those government committees that just wanders around aimlessly and bumps into walls. We actually have a plan. We actually have a set of priorities. We actually are implementing them, and we keep track of what we do. So hopefully, we will continue in that vein. We may bump into a wall here and there, but we usually know what walls we're bumping into.

The vision statement describing our priority issues and how we reach them was developed in 2004 and continues to reflect and guide our work as a Committee.

Public concern about the misuse of genetic information and genetic discrimination has been our highest priority issue. Over the last four years we have written a number of letters to the Secretary championing the enactment of federal legislation to prohibit discrimination based on genetic information by health insurers and employers. In 2005, we provided the Secretary with a legal analysis of the adequacy of current law regarding genetic discrimination, a compendium of public comments documenting public fears and concerns about genetic discrimination, and a very, very interesting and compelling 10-minute DVD of testimony we received in the fall from the public in 2004.

We have also strongly supported the Genetic Information Nondiscrimination Act of 2007, HR493, and S358, commonly referred to as GINA, which would protect individuals from discrimination based on their genetic information by health insurers and employers. The legislation has dedicated supporters on both sides of the political aisle, and in April of 2007 it passed the House by a vote of 420 to three.

Secretary Leavitt has voiced support for that legislation, and the President has indicated that he will sign the bill if it is presented to him. However, as many of you know, Senator Tom Coburn has placed a hold on the bill in July and thus has prevented debate and a vote in the Senate. GINA's key supporters are working hard to move the bill forward, and the bill's main sponsor in the House, Representative Louise Slaughter of New York, has set up a petition to persuade Senator Coburn to drop his hold. As of today, there has been no change in the status.

In June 2004, we developed a resolution about the importance of genetics education and training of health professionals and how it could be enhanced. Tomorrow Dr. Barbara Burns McGrath will chair a roundtable on genetics education and training for health professionals. Six expert speakers representing various aspects of health care will report on the progress of genetics education and training activities.

These presentations will be followed by a one-hour discussion of critical needs in education and training and the best approaches to meet those needs. Four additional panelists will join the roundtable to extend the range of perspectives from the healthcare community. Then you will be

deciding what, if anything, we need to do going forward on this topic and whether we will continue to keep it as a priority and move it forward or to let it go and say that the world is safe and you may all return to your homes. That will be your task.

In 2006, we transmitted a report and recommendation to the Secretary on coverage and reimbursement of genetic tests and services highlighting how problems in the system are affecting patient access and identifying nine steps that can be taken to overcome the barriers. These recommendations cover a range of topics, including evidence-based coverage decision-making, Medicare coverage of preventive services, the adequacy of current procedural terminology codes for genetic tests and services, billing by non-physician genetic counseling providers, and genetic education of health providers.

In July, CMS sent feedback on the recommendations. A small group of SACGHS members led by Marc Williams has been reviewing those comments. A copy of their review was shared with you in October. We will be taking to our CMS ex officio, Barry, in December our report. I will report back to you at our next meeting about the outcome of that discussion.

Barry, I think you were at the meeting when we presented this to the head of CMS. It was a terrific discussion we had then. I know that you all are taking this matter very seriously.

In 2005 and 2007, we wrote letters to the Secretary direct-to-consumer marketing of genetic tests. This is one of our successes that I'm particularly pleased about. Our efforts in this area led to enhanced collaboration between the FDA, the CDC, the CMS, NIH, and the FTC. In July of '06, a consumer alert was issued by FTC 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.

In July, we also heard from CDC about their work to measure the public's awareness and use of direct-to-consumer genetic testing. As part of the Personalized Healthcare Initiative, an effort is being made within the Secretary's Office to coordinate relevant agency activities and promote information sharing related to DTC testing. Greg Downing from the Office of the Secretary is leading this coordination effort, and we will keep you updated on their progress.

Greg is actually here. Would you wave? Greg has been and continues to be just terrific. We have enjoyed just such good, close access to the Secretary's Office on a day-by-day basis. Greg is the person behind the curtain to make that happen. We are greatly indebted to Greg and his energy and his commitment to the work of this Committee, and I thank him for it.

Concerning large population studies, the Committee's final report, Policy Issues Associated with Undertaking a New Large U.S. Population Cohort Study of Genes, Environment, and Disease, was completed in March of '07 and transmitted to Secretary Leavitt. A downloadable PDF version is available on our website.

In August, the Secretary sent a letter to us acknowledging receipt of the report and the timeliness of our recommendations. You can find this letter in Tab 6 of your briefing books, and it is posted, again, on our website.

I also want to point out that an article about the LPS report was published in the July issue of the journal Social Science and Medicine. Hunt Willard, who guided the development of this report, and I have written a letter to the editor of the journal to clarify the scope and goals of the report.

You will find a copy of the article and our letter in your table folder. We have given them a what-for.

For more than two years, we have been developing a report on opportunities and challenges to pharmacogenomics research, development of PGx products and their incorporation into clinical and public health practice. In March, the draft report was released for public comment. Public comments were carefully considered, and over the summer and fall, a revised draft has been prepared.

Most of our agenda today will focus on a review of the final draft recommendations. Our goal, and this is absolutely key that all of you get this, our goal is to come to closure on the recommendations and approve the report for submission to the Secretary. No fooling around. We are going to close this out and make a report.

In June 2006, we decided to move forward with a study on the impact of gene patents and licensing practices on patient access to genetic technologies. During our July meeting, the Gene Patents and Licensing Practices Taskforce, chaired by Jim Evans, hosted a roundtable of experts to discuss international perspectives on gene patenting and licensing strategies and clinical access to genetic tests.

Since then, the taskforce has been working with Bob Cook-Deegan and his group at Duke on case studies but evaluating the impact of gene patents and licenses on patient access to genetic tests for hemochromatosis, breast and colon cancer, cystic fibrosis, and hereditary hearing loss. We will continue to meet monthly to begin development through this taskforce of a report on this issue, with a final product expected in 2009.

In March of '07, we were charged by the Office of the Secretary with investigating specific issues related to the adequacy of the oversight system for genetic testing. An extraordinary 33-member taskforce, chaired by Andrea -- 33 members -- was formed to develop a report in response to the Secretary's charge.

Now, for those new members, again, the number one issue for us has always been genetic discrimination. That has always been our number one. The number one historical issue out of which this Committee is the successor of a preexisting committee was this issue of the oversight of genetic testing. So this is really in our -- don't get mad -- in our DNA.

So through dedicated effort and exceptional leadership, the draft report was released for public comment on December 5th, with a December 21 deadline for final comments.

Tomorrow, Andrea will review our effort in this area, and then we will have presentations to gather additional academic and public perspectives. We will be briefed on the international analysis of the oversight of genetic testing. We will learn about the conclusions of the summit meeting held on this topic in September by the Genic Alliance, and we will be providing an opportunity for interested stakeholders and members of the public to share their perspectives on the draft report.

I want to make sure that this is absolutely clear. There is a considerable time period for people to comment. The public comment period does not end until December 21. I'm saying it several times. We are having much opportunity for public input. I am trying to be as transparent as I can to every stakeholder in this process. It is an open process, a transparent process. If you are a consumer, if you are general public, if you are industry, if you are a health professional, whatever

your particular stakeholder view is, this is an open process with lots of time to get your comments in.

I have reasons for why I'm being as emphatic as I am about it. So I would be very disappointed if there are folk who decide not to be participating in the public process of getting all the best ideas so that Andrea and her 33-person committee can duly deliberate over the best ideas. So I think we have been pretty clear about that.

In March, we decided to add a new priority for SACGHS to explore the issue of evaluation of outcomes of gene-based applications. This effort combines two proposals presented to the Committee on the economic consequences of genomic innovation and the evaluation of real-world outcomes on gene-based applications. Work on this issue with Steve Teutsch, who will be leading, is on hold pending the completion of our report on the oversight of genetic testing, which includes some of the same questions and issues involved in evaluating outcomes.

So I want to be real clear that this evaluation of outcomes genes-based applications, we have it identified. It is hanging out there. But quite frankly, as you can tell from this very long introduction, we have a whole lot on our plate. We want to get this other stuff done and then we will decide to move on to that.

The cross-cutting issues of access, public awareness, and genetic exceptionalism we have continued to integrate into all of the other committees' work that you have heard.

With that, I hope that you all get a sense, and for the new folk, I hope you don't get intimidated by the amount of work. But we are a very active, very busy Committee. When it is all said and done, when we get evaluated by the Secretary's Office for committees, I want us to be not only the most prolific but the most productive but the most focused and the most intense. I think we are way out in front on all of those scores, so we are going to keep at that.

Are there any questions from anyone before we get down to the heart of the meeting? Let me just take a moment. We have put a lot in front of you. So let's stop for a moment and ask whether there are any questions.

[No response.]

DR. TUCKSON: Good. Well, that will give me a chance to drink my coffee. So that is perfect.

Now for the serious highlight of the meeting, the Ethics Rules Review by Sarah Carr.

[Laughter.]

MS. CARR: Good morning, everyone. Thank you, Reed. You all have been appointed as special government employees to this Committee. Although you are in a special category, you are nonetheless subject to the rules of conduct that apply to regular government employees. These rules are outlined in a document called "Standards of Ethical Conduct for Employees of the Executive Branch." Each of you received one of these when you were appointed to the Committee. As I usually do, I'm going to highlight two of those rules today.

First, 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 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 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 the Committee's deliberations. If this happens, we ask you to recuse yourself from the discussion and leave the room.

Government employees are also 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 is important for you to keep that activity separate from the activities associated with this Committee. Just keep in mind that we are advisory to the Secretary of Health and Human Services. We don't advise the Congress.

I thank you for being very conscientious about these rules.

DR. TUCKSON: So the idea, by the way, which is important also -- I'm not going to keep embarrassing the new members, but just a reminder to everybody -- is this idea of we are advisory to the Secretary. So as you start to think about what we can do, think about the multiple roles of the Secretary of Health. Those multiple roles are, clearly, in terms of the responsibility for the CEO of all those agencies, but also of course the Secretary has a bully pulpit role.

But our recommendations, though, are within that framework. We are not able, as we have heard, to go out and tell the Congress what to do, even though we think we know. So be careful there.

The other thing is that I want to make sure that we as a Committee are attentive to each other and the hats that we all wear. The reason that you all are on this Committee is because of your expertise and because of the places from which you arise. It is a very considered process to get people from industry here, from academia here, from the genetic counseling community here, from government here, from the payers here. I mean, people are from many different places.

Everyone knows who you are, and people know and they are following this discussion. So you are free to let people know what you think. Let them know where you are and where you are coming from. Conflicts of interest we will always be attentive to and we will be monitoring them. We have all kind of people who are monitoring those sorts of things.

But at the end of the day, you are who you are and you bring your expertise to bear. You shouldn't be shy about that. I just want to make sure that you are comfortable. You are picked because of who you are.

One of the main goals of this meeting is to finish the important work we have been doing on pharmacogenomics. We have allotted most of our agenda today to a review of the final draft recommendations. We need to come to closure on them, and also determine whether we are satisfied with the content of the final draft report.

SACGHS Meeting Transcript
November 19, 2007

The materials for our discussion today are in Tab 3 in your briefing book. So we are going to go through those.

Before I turn to our leader, Kevin FitzGerald, to lead this discussion, I want to express the Committee's appreciation to you, Kevin, for your leadership and your dedication in guiding the development of the report.

I also want to thank Emily Winn-Deen, who chaired the taskforce during her appointment to SACGHS. Emily, you were instrumental in conceptualizing our approach to this issue and getting the initial work off the ground.

I also want to thank all the members of the taskforce, whom Kevin will name in a moment, for their time and effort and many contributions.

Sandra Howard, from the Office of the Assistant Secretary for Planning and Evaluation, deserves our gratitude for providing additional resources for the report's development and in particular the excellent services of Cliff Goodman of the Lewin Group and his team of crack policy analysts.

Last, but by no means least, I want to applaud Suzanne Goodwin of our staff for her excellent work as the staff lead on this project. Anybody who has worked with Suzanne will know that she is a tough, tough taskmaster and she intimidates all of us. So we are grateful for you and your high standards, hard work, and commitment to excellence.

So we are going to go through this in an orderly way, folks. We are going to have a good, far-ranging discussion, but you are going to stay on point because, at the end of the day, we are going to bring this thing in on time today.

Kevin, take us through it.