Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Good morning.

PARTICIPANTS: Good morning.

DR. TUCKSON: Thank you. My gosh, some energy or something. Painful.

We have a terrific agenda, power packed and an awful lot. So I hope the coffee is good and that you're stoked up.

Welcome to the 11th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. The public was made aware of this meeting through the notices in the Federal Register, and also announcements on the SACGHS website and listserv. I want to welcome members of the public in attendance, as well as any viewers who are tuning in through the webcast. We really do thank you for your interest in our work.

Before I begin, I want to make a few introductions. First, we are joined this morning by a special guest and an important member of Secretary Leavitt's staff, Sheila Walcoff. She was council to the Secretary for science and public health programs. Sheila will be saying a few words about the Secretary's personalized health initiative in a few moments.

Thank you very much for taking the time to join us.

Dr. Greg Downing. Is Greg here yet? I just saw you, Greg. I was just talking to Greg. He's the project director of personalized health care initiative and is also here.

Welcome to you both and thank you very much for taking time from your busy schedules to be here. We'll come back to you, Sheila, in a few minutes, but I want to thank you, Greg, for all the efforts that you have done on behalf of this committee. It has been very, very much appreciated.

I also want to thank Debra Leonard and Emily Winn-Deen back to the committee. Debra and Emily rotated off the committee after our last meeting, but we immediately, smartly commissioned them back to serve on our task forces on gene patents and pharmacogenomics.

Debra and Emily, thank you for your continued dedication to advancing the work of our committee on these important topics, and thank you for being here today to participate in the task force recommendations. Where are you? Oh, there they are. You guys are just hiding everywhere. I can't find anyone this morning.

I want to welcome three new ex officios. I've worked on this very hard, so I'm going to do this right. But I want to welcome Gurvaneet Randhawa, and Gurvaneet will correct that, except she's not there, but we are happy when Gurvaneet gets here, who has been with us before. Dr. Randhawa has focused on clinical applications of genetics and genomics and the advancement of evidence-based decisionmaking in the use of genomic technologies. This you will hear in a moment is going to be key to much of what we're going to be doing coming forward.

I also want to welcome Anand Parekh.

Anand, say it again.

DR. PAREKH: That was close, Reed. It's Anand Parekh. Pretty good, though.

DR. TUCKSON: We also practiced that he was going to say that that was close.

(Laughter.)

DR. TUCKSON: Thank you so much. The emphasis, by the way, is on the first syllable, and that's the way you can do it. Even knowing that, I messed it up.

He's the senior medical advisor in the Office of Public Health and Science, where he advises the Assistant Secretary for Health on a variety of medical and public health policy issues.

Thank you very much for being here.

Michael Amos -- I think I got that right -- is representing the Department of Commerce, and you are the biosciences advisor to the director of the Chemical Science and Technology Laboratory at the National Institute of Standards and Technology. Mike, thank you very much.

Bio-sketches for these three outstanding people you will find in your table folders.

I also want to acknowledge new staff member Yvette Seger. I'm sorry, Yvette. To have to work that hard, because the staff here works terrifically hard. Yvette joined the team in August and has been working closely with Hunt Willard and our large population study task force in developing our final report on large population studies. Yvette came to us from Faster Cures, a biomedical research advocacy organization, where she served as research associate. She was also a science and technology policy graduate fellow at the National Academies. Her dissertation research at Cold Spring Harbor Laboratory received her Ph.D. in genetics from SUNY Stony Brook in 2004.

You may recall that in June I met with Dr. Elias Zerhouni, who is Director of NIH and our conduit to the Secretary of Health. I briefed Dr. Zerhouni about the progress of our work, and we discussed the committee's accomplishments and the ways in which SACGHS might enhance our impact and public visibility. I will tell you that meeting with Elias is always a pleasure. He is extremely well aware of what we are doing. He is up on all of the details, and what he really thought that we ought to be thinking more about is how we disseminate the results of our deliberations and of our products. He had a few ideas, in particular thinking that we ought to transform some of our reports and recommendations into manuscripts for journals. We have taken this advice to heart, and we are now working on an article about our recommendations on coverage and reimbursement for genetic tests, and we're talking to some of the people at journals like the Journal of Health Affairs and others. So we're working hard on that, and we want to have you start to think about places in your domain where you have influence or where you think it would be important for us to get our reports and recommendations out. So I'll be very, very eager to see that, and our terrific staff team would be happy to help facilitate that. So bring those ideas forward.

Our community has a very broad mandate and charter. Within that broad scope, our agenda is guided by a strategic plan that we developed as a committee through a systematic priority-setting process in March of '04. As you know, every meeting I would pull out this chart, and I'm going to do it now, because I think it is critical that you keep in front of you what it is that we said we wanted to achieve, and we have to keep checking ourselves to see whether or not we are meeting our expectations for our work.

Importantly also, I think, it's important that we take time to be thinking about whether we want to modify what's up there, what our agenda is. So I want to be pretty rigorous about reviewing with you, but quickly, about what it is that we are doing and where we are in our strategic plan. Again, I remind you, 2004 was a while ago, and so at some point we're going to need to revisit the strategic plan.

First, public concerns about genetic discrimination have been our highest priority issue. You know that we've written three letters to the Secretary championing federal genetic non-discrimination legislation. We commissioned a legal analysis of the adequacy of current law, compiled a significant set of public comments on the issue, almost like a phone book size, and to document public concerns about the issue in a more compelling way we produced a DVD, a 10-minute summary of our public testimonies. We'll be getting an update on the status of Congressional activity in this area tomorrow afternoon.

Number two, we produced a report and nine recommendations on coverage and reimbursement for genetic tests and services, and we've had a very good meeting with CMS as we have looked at the recommendations that apply to them, and they have those recommendations that they are evaluating as we speak.

Number three, we've developed a resolution about the importance of genetics education and training of health professionals and how that should be enhanced. We've written several letters to the Secretary on direct-to-consumer marketing of genetic tests and have prompted several collaborative efforts among relevant agencies. At our last meeting in June we heard updates from the agency's working groups that were formed to address our concerns about direct-to-consumer marketing, and I am very pleased that the working groups have continued to make progress and that in July their efforts culminated in the publication by the Federal Trade Commission on this consumer alert on direct-to-consumer marketing of genetic tests that was produced in cooperation between FDA and CDC. This is just a fantastic example of the agencies working together to solve a problem, and you as a committee should feel good for highlighting it, but our ex officios ought to feel real terrific in making it happen. The alert is aimed at raising consumer awareness of the facts about "at home" genetic tests. It cautions consumers that "at home" genetic tests have not been evaluated by the FDA and urges them to be wary of the claims made by companies marketing such tests. If they're considering using an in-home test, the alert warns them to protect their privacy before doing business with an online company and to, of course, consult a health care provider.

We were enormously pleased by this action and impressed by the collaboration of it all, and I just want to take a moment to applaud Matt Daynard of the FTC and Steve Goodman and his team at FDA, Muin Khoury at CDC and Linda Bradley. The director of CDC, Dr. Julie Gerberding, was clearly very pleased as well, and her letter, which is in Tab 3 of your briefing books, affirms the importance of these efforts.

Earlier this year we wrote to the Secretary to commend his leadership in advancing the health information infrastructure and to urge his attention to the development of standards, common vocabularies and security measures to support the incorporation, interoperability and security of genetic data. I'll say more about the Secretary's efforts in this area in a moment.

Work on a large population studies report will be a major focus of this meeting. The draft report we saw last time went out for public comment this summer, and the task force made extensive revisions based upon feedback that we've received. We'll have an update from task force chairman Hunt Willard on the public comments that came in and how they helped to shape the

development of the report. The goal for that session -- and let me be clear and slow down for a minute -- the goal for that session will be to come to closure on the report so it can be sent to the Secretary in final form.

One thing we're going to be doing in this meeting, again, in introducing every topic area, you're going to be very clear about what it is you're supposed to do today, so that when you ask the great smart questions or put the great input that you do, it's designed to get us to a goal. So the goal on this one is close the report and send it to the Secretary in final form. So we're going to move this today.

Gene patents and licensing. At our last meeting we decided to move forward with a study on the impact of gene patents and licensing practices on patient access to genetic technologies. The committee established a task force to refine the scope and study plan we discussed, and they have a detailed scope, work plan and timetable for us to review today.

Work will also continue on the priority issue of pharmacogenomics. Since our last meeting, the task force has refined the draft report and recommendations, and we will begin an important and very focused discussion about it in just a few minutes.

We'll also be looking closely at the issue of oversight of genetic tests. We will be updated on developments at FDA and CMS, and then we'll have a discussion about whether SACGHS should take on a more analytical role in this area. For those who are new to the committee, we'll be bringing you up to speed about our history. Our committee evolved out of an earlier committee that was very focused on this issue of oversight of genetic tests. We've sort of been able to turn our attention to other issues, and now developments are such that we are bringing that back for a decision about whether or not we need to be more involved or not in this oversight of genetic tests. So this is going to be an extremely important discussion for us in a few minutes.

The cross-cutting issues of access, public awareness and genetic exceptionalism are integrated into all of our other work. So that's where we are with our priority issues. So I ask you to keep that in mind, and always we want to revisit it.

In your briefing books in the left-hand pocket is an annual survey that we're supposed to fill out about your perspectives about our effectiveness and whether we're meeting our goals and priorities. So if you've not done so, then you're supposed to do that and turn it in before we leave.

The thing is, if you don't think we are making the progress we're supposed to make, then you've got to say that, but we've got to then figure out what it is that we're not doing to meet the objectives that we have. But one thing at least we are is focused on what our objectives are supposed to be.

The work we've done in priority areas provides a strong foundation for us to assist HHS in other ways, and I want to talk now about new work that Secretary Leavitt would like us to undertake in the near future.

I have to say something about Secretary Leavitt. I am extremely excited about his leadership. He has been, in a way that we have not experienced before, attentive in an unusual way to the work of this committee, and he's been very receptive to talking to me as your chairman about this, and he has made his key staff available to us. We have an opportunity that we've never had before, which is to really get input and guidance from the Secretary about his agenda and how he wants to see us help to move that agenda forward. So I really want us to spend a minute now, as we pay

attention to that agenda, and understand that what he's really focused on is improving the quality and cost of health care and making that quality and cost transparent to consumers. The President of the United States advanced this agenda not long ago in an executive order that requires agencies administering health care insurance programs to use health information technology as a way of sharing information on the price and quality of services. Some of his other high priorities, of course, include implementing Part D of the Medicare program, that every senior citizen has access to affordable prescription drugs. He's been working hard and I've been in a number of meetings with him on planning and preparing for the potential of an influenza pandemic, and promoting the development of electronic medical records and health information technology.

He is deeply committed to the development of personalized health care through the advancement of medical science and the transformation of the health care system, taking a systems approach. Over the next 10 years he wants to see health care system development that can support new frontiers in medicine, where our ability to exchange information, including genetic testing information, will be applied for clinical decisionmaking. Electronic health records are part of that transformation, part of what will enable health care to become more preventive, predictive, and certainly more personalized.

The Secretary also recognizes that genomics is playing a larger role in medicine and that we need to begin now to address how to incorporate this new information.

Last month I met with, as I mentioned, both Sheila and Greg to discuss our work and how we might be helpful in advancing the Secretary's agenda. The work we are doing to address the challenges of integrating genetics and genomics into health care and public health, particularly in the area of pharmacogenomics, is already well on the Secretary's radar.

Another federal advisory committee that is part of this effort is something that's called the American Health Information Community, or AHIC. This is a public/private partnership that is aimed at getting the best thinkers across health care and those who pay for health care to try to put together a coordinated way of combining performance assessment, consumer decision support, health information technology, and data that allows people to make better choices and decisions, having physicians and health care professionals have access to information so that they can make better choices and decisions, and to do this in a way that protects privacy and security within the confines of an interoperable health care delivery system. So this is right down the middle of the plate for us.

So the last meeting, AHIC formed a working group on personalized health care and are thinking through some of the technological challenges. So it will be very important for us to stay tuned to some of that work.

Finally, the Secretary asked me to make you aware of a request for information that HHS published in the Federal Register November 1. A copy of that document was sent to you last week and another is in your table folders. The Secretary's office and America's Health Information Community are seeking input from the public and private sectors on plans for developing and using health information technology and genetic and molecular medicine for evidence-based clinical practice, health outcome evaluation, and research. HHS is seeking information on a wide range of topics, and we'll be hearing about that in a minute. I encourage you to respond to the RFI and to share the RFI with interested colleagues. Feedback is due by the 1st of next year.

So with that, and again because I think this is a moment of trying to now bring together this health information technology, this ability to have information about personalized genetics combined with enhanced consumer decision making, combined with health providers and hospitals having access to information, all of that coming together now in a new and interesting way, I want to turn to Sheila and see if she can bring us up to date a little bit more on what is going on here and how, from the point of view of the Secretary's office, this committee might be more helpful.

Thank you for joining us.

MS. WALCOFF: Thank you, Reed, for the opportunity to join you and the SACGHS members here today in your important work. As you mentioned, the work of this committee is highly relevant to the Secretary, in particular one of his top-ten initiatives, and that is accelerating personalized health care.

Under the leadership of Secretary Mike Leavitt, the initiative he's undertaken will improve the safety, quality and effectiveness of health care by leveraging advances in genomics and health information technology. The convergence of these will be a powerful force in educating consumers and providers and enabling better clinical outcomes. His focus is primarily on how to improve health in a more patient-centric way.

However, to fully realize the potential of personalized health care, we recognize that we will need input from many important stakeholders, including the science community, the provider and patient community, and the health information technology community.

At your prior meetings you discussed many of the areas of importance related to science and public policy, and we eagerly await the work of this committee. I've briefed the Secretary extensively on the work you have been doing, and I can tell you that he is eager to see the product that you're producing over the next several months, and he appreciates what you've done previously.

Let me share a few other points that I think might add to what Reed has already mentioned in terms of what we're working on in the Secretary's office and across HHS. As Reed mentioned, the Secretary has been highly focused on using information technology to advance health care. At the October 31 meeting of the AHIC, it was recommended that a formal working group be established to address the information technology aspects of personalized health care. Some of the recommendations that you can expect to see from this group include standards on how to incorporate genetic information and genomic test information into a personal electronic health record. Other issues that this working group may address include integrating databases and including genetic and medical test information as part of the analysis for clinical decision support.

In conclusion, I'd like to say that we recognize the many thoughtful hours this committee has devoted to working on these very important issues, and that list that you had up earlier really highlights the focus areas that we have been discussing in the Secretary's office over the last several months. We have a countdown clock. The Secretary feels a great sense of urgency in trying to do as much as he can to accelerate this area during his tenure at HHS, and I have it sitting right on my desk, and I believe we have less than 800 days. We want to focus on what we can accomplish in the near term but, importantly, make sure that we are on the track, and this committee is the perfect forum to continue that work beyond his tenure on this really important public health area.

On behalf of the Secretary and Dr. Greg Downing, I'd like to thank you for having me here today. We'd like to discuss these issues in greater detail at your next meeting, and I hope you will allow us to come and give you a more fuller briefing on where we are in terms of this initiative. I look forward to seeing you again then.

DR. TUCKSON: That's terrific. Again, I want to really acknowledge Greg as well, and I don't know how long Greg will be here. I know the Secretary has asked Sheila to go back downtown, so she's going to have to leave in just a minute. But Greg, I know you've been really attending, so however long you're going to be here, we really want to use you. But I know you'll be following up.

I know we've got a busy agenda, and I want to move us forward, but I just want to make sure if there are any questions you may have of Sheila or Greg, since we have them here. Again, I want to keep center for you that the 800 days -- when they tell me they have a countdown, that's not a countdown to figure out how quick they can go home. The countdown is they're going to make some changes, and I will tell you from where I sit, and you all may have seen what the impact of this is from where you sit, this activity that they are engaged in, both the AHIC, the President's order, the personalized health care agenda, the interoperability of health data and information, the transparency of information about quality and performance being fed into physicians, hospitals and consumers, this stuff is transforming the way in which health care is delivered. It is a sea change. You know that IBM commercial? "This changes everything." This is one of those "this changes everything."

So I just want you to be thinking a lot, especially when this pharmacogenomic stuff, but our work around educating the public, around anything to do with data systems, and the large pops, all of that is connected in here. So you really do want to be making sure that we are in that 800-day agenda.

MS. WALCOFF: Well, thank you very much, and I also want to recognize Dr. Greg Downing. He really is the director of our personalized health care initiative and has done an enormous amount of work in a very, very short period of time and is an incredible force supporting the Secretary in this initiative, and as you said, it's important for us to keep in mind all of the activities that are going on in this area. Close coordination, transparency of activity and the participation, the meaningful participation of these stakeholder groups is going to be essential for us to achieve the objectives that we all share, and I thank you very much for supporting us in that.

DR. TUCKSON: Terrific. They have nailed this pretty well, but I'm just looking to make sure there is no question.

With that, then, Sheila, thank you. I know you've got to get back down the way. Greg, as long as you can stay, you're more than welcome.

MS. WALCOFF: Thank you.

DR. TUCKSON: Thank you so much.

We have a couple of things before we move to our pharmacogenomic session. Didn't we plan this agenda well?

Public comment sessions are scheduled for both days. Individuals who would like to provide testimony and have not already signed up should do so at the registration desk.

Two housekeeping matters related to important topics, lunch and dinner. To save time at lunch, I want to encourage committee members to order a boxed lunch. So please fill out the form in front of you, or else Abbe Smith will be very upset with you.

We will also be having a group dinner tonight. If you can attend, please let Abbe know at our first break.

Now for the technical commercial from our sponsor, Sarah Carr, and all the technical rules about the ethics.

MS. CARR: Well, I won't go over all of them. I just wanted to highlight a couple, and I do this at every meeting, so I know you probably know what I'm going to say by heart. But it's important, so it does bear repeating.

As you know, you've been appointed to the committee as a special government employee in order to serve the Secretary and the public. This is a special category, but you are nonetheless subject to the same rules that apply to regular government employees. These rules are outlined in a large document that you received when you were appointed, and I'm just going to highlight, as I said, two of those rules, first about conflicts of interest. Before every meeting, you provide us with information about your personal, professional and financial interests, and this is 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 our 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. If this happens, we ask you to recuse yourself from the discussion and leave the room.

As government employees, you are also prohibited from lobbying and thus 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 that you 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 and we don't advise the Congress.

As always, I thank you for being attentive to these rules, and we appreciate your conscientiousness very, very much. Thank you.