Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Good morning, everyone, and welcome to the ninth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society.

I know everybody sort of does know everybody, but just for the sake of it, I want to just go around again and have everybody just reintroduce themselves and their organization or affiliation.

I'm Reed Tuckson, a physician and senior vice president of UnitedHealth Group.

Going around to Sarah.

MS. CARR: I'm Sarah Carr. I'm the executive secretary of this committee.

DR. WILLARD: Hunt Willard, director of the Institute for Genome Sciences and Policy at Duke University.

MS. MASNY: I'm Agnes Masny. I'm a nurse practitioner and research assistant at the Fox Chase Cancer Center in Philadelphia.

DR. ROLLINS: Jim Rollins from the Center for Medicare and Medicaid Services.

DR. GUTMAN: I'm Steve Gutman from FDA.

DR. KOCH: William Koch, deputy director of chemical science and technology at NIST, Department of Commerce.

MS. BERRY: Cindy Berry, partner in the law firm of Powell Goldstein.

DR. EVANS: Jim Evans. I'm a medical geneticist at the University of North Carolina at Chapel Hill.

MS. AU: Hi. I'm Sylvia Au. I'm the state genetics coordinator at the Department of Health in Hawaii.

DR. TELFAIR: Joseph Telfair, associate professor, University of Alabama at Birmingham.

MS. CHEN: Chira Chen. I'm a patient advocate and also a researcher at UCSF.

DR. LICINIO: Julio Licinio. I'm the head of the Center for Pharmacogenomics at UCLA, and beginning May 1st, I'll be at the University of Miami.

DR. BRADLEY: I'm Linda Bradley from the CDC.

DR. COLLINS: Francis Collins. I'm the liaison member from NIH.

DR. SCHWETZ: I'm Bernard Schwetz, the director of the Office for Human Research Protections, and I'm also here representing Cristina Beato from the Office of Public Health and Science.

DR. LEONARD: Debra Leonard, vice chair of laboratory medicine at Cornell Medical College.

DR. SHAMANSKI: Fay Shamanski. I'm staff for the committee.

DR. WINN-DEEN: Emily Winn-Deen, vice president for business development and strategic planning for Cepheid.

DR. TUCKSON: Thank you very much, and I'll introduce some of the staff folks in a minute.

Thanks to all the guests who are around the table. I'm sure we'll be hearing from many of you at different points during the day.

Before we begin, let me thank Cindy Berry for serving as acting chair at the October meeting. I understand you've done such a terrific job that nobody likes me anymore. So thank you very much. We had an unexpected death in the family, so I really did appreciate your stepping in at the last second.

The public was made aware of this meeting through notices in the Federal Register, as well as announcements on the SACGHS website and listserv. I want to welcome members of the public who are in attendance, as well as viewers tuning in through the webcast.

By the way, committee, you are on camera and you should be on your best behavior, Joe.

(Laughter.)

DR. TUCKSON: I thank all those who are tuning in for their interest in our work.

As you know, we arrived at our study priorities through a systematic priority-setting process that we completed back in March of 2004. I think Sarah is trying to get those priorities up.

I'm sort of fanatical about starting every meeting with this review of our strategic process. I think that it is important that the committee sort of take a look at this, and it's up on the screen now. At the end of the second day, I want us to sort of relook at this again and revisit this. It is, to me, as your chair, important that I am advocating and pushing hard that your priorities are being addressed. But, of course, from time to time, we need to stop and relook at our priorities and seeing are these the priorities that we want, where are we, is it time to move some things off and some things up. So I think it is very important to take moments to reassess where we're going and how we feel about where we are.

Sarah, would you take us through that?

MS. CARR: Sure. As you said, Reed, in March of 2004, the committee identified 12 high priority issues, and they're listed in the column going down. And, by the way, you went through this fairly extensive and systematic process to get to these 12, and you also organized them into three categories.

The first was issues that you thought required only short-term action or monitoring, and those are the first four listed here because the vision statement is actually just a report of your priorities actually.

And then the second category was high priority issues requiring in-depth study, and they are listed here.

And then the third category was issues that had a more overarching aspect and required sustained action. On these issues, access, public awareness and understanding, and genetic exceptionalism, you have wanted to incorporate those issues in all of the reports and letters that you prepare for the Secretary.

Going across here is time. This sort of represents the life of the committee, really. And after you identified these priorities here, there was a number of things you've done. You sent a letter to the Secretary. Actually, your very first action was a letter on genetic discrimination after your very first meeting. Then you sent another one in March of 2004. And on genetic discrimination, we also did a letter in May of last year, along with a legal analysis, an analysis of the adequacy of current law. You prepared a DVD of personal stories of testimonies you heard in the fall from people who are concerned about genetic discrimination. And we also had done a wider solicitation of public comments, and those were pulled together in a compendium that you sent to the Secretary. So there were three things that went with that letter, the DVD, the compilation of public comments, and the legal analysis.

And after that, we've been having updates, and we'll have another one tomorrow on the status of federal legislation in this area.

On genetic education and training of health professionals, we had a roundtable session in October of 2003, and then you prepared a resolution that made nine recommendations in this area to the Secretary.

On patents and access, once we realized that the National Academy -- and Debra is going to go through all this tomorrow -- was doing a fairly extensive report on this issue, we decided to defer further action until that report was completed. So tomorrow we will be discussing that report and what, if any, steps to be taken by the committee.

On oversight, we had a roundtable in October of '03, and we've been in sort of a monitoring mode. This issue, obviously, also relates to the one on direct-to-consumer marketing. It has an oversight aspect.

I'll move down to the coverage and reimbursement. We had a lot of activity on that, and it has culminated in the issuance of our report today.

Large population studies. We've started work on that in a very serious way in actually, I guess, March of last year. We had a day-long session, an update in June, and then another day-long session in October. I'm just going to go through a lot of that, and today we'll be looking at a draft report and some possible ways to move forward with this.

On pharmacogenomics, we started work on that in June '05 and had a pretty extensive session then and an extensive last October, and we'll be talking about that quite extensively today.

On direct-to-consumer marketing, we wrote a letter in March of '05, another one more recently, and Reed will be talking about that in a moment.

On access, these are the issues that we are trying to touch on in everything we do. We did one letter that sort of relates to the access issue, and that pertains to electronic medical records and the

effort to develop a national infrastructure to facilitate transmission of medical information, and Reed will be talking about that letter in a minute.

Then on public awareness and understanding, we have been trying to incorporate that issue into all of our reports and recommendations, and we wrote a letter about the family health initiative of the Surgeon General in June of last year. We sort of put that in that category.

Then on genetic exceptionalism, we have also been trained to attend to that in everything we do.

DR. TUCKSON: Thank you very much, Sarah.

I think that if you will just take a sober look at our progress here, I think what it shows is that as a committee you have been very focused and you have been very active. You have accomplished a great deal in checking off a number of these boxes. There are some that you will be able to check off, significant work, by the end of these two days. So I do hope that you will feel good about the fact that you don't just come here and have these intense meetings and nothing happens, that you are moving forward.

Now, there are certain things we would like to have more progress about. I think we all would feel better if we could say and point to, because of our efforts, genetic discrimination was resolved and that there was a bill in the Congress. Well, I'm not going to put that as my definer for our committee having scored a touchdown, because we just don't control that. But I think that we have been extremely active and vigorous. I'm not trying to pat ourselves on the back, but I think that we have at least kept to our strategy of trying to do things that are productive and helpful in these areas.

There's one that I would want you all to think about and I want to revisit. I'll just tee it up and we'll discuss it at the end of the session tomorrow. But that is the public understanding.

I'm still not sure I know enough anymore about today's world where the public is in terms of understanding these issues and whether or not there's more that needs to be done, whether we should be the ones to do it. But I've got that high in my mind as an issue for us just to be thinking about. So I'll just put that there for you to think about.

Since our last meeting, the coverage and reimbursement report was finalized and transmitted to the Secretary. Today marks the release of the final report to the members of the public. Give ourselves a round of applause.

(Applause.)

DR. TUCKSON: Because that's actually pretty cool.

We are going to be actively disseminating the report through a number of mechanisms. Can you put that slide forward?

Now, the deal is that we're transmitting it to the Secretary and their senior leadership. We did that in February. It is now posted on the website. E-mail announcements went to our distribution list of approximately 1,000 individuals, individuals who represent organizations, not just Bob Smith at 1309 Maple Street. A targeted mailing to about 150 individuals and organizations, including, as you see, the expert presenters, Genetic Counseling Services Group, public commentators, and key staff. Also key organizations who asked for it have gotten it. The HHS

offices, patient advocacy groups, providers, health plans. AHIP certainly is going to be helpful in that regard. AHIP is the Association of Health Insurance Plans and also Blue Cross/Blue Shield Association. Lab groups, technology assessment groups, and interested academies.

Now, the one thing that's not there is you. So what I need you to be thinking about is who do you think this ought to go to, and you should take certain leadership in making sure that you get this thing out to all the places that you think it needs to go. Don't be shy about calling people up and talking about it because we think it's pretty important.

We are working through the process of a press release to let the world know. That's complex when you deal with government. But I think that we actually may be able to have a press release, and we may even be able to talk about it before we leave here at this meeting. If not, it will happen right after the meeting. We'll keep you informed, but do be aware that we're not taking a passive role. This was a lot of years of our lives to get this darned thing done, and we're not going to just say, okay, we did a report. Which shelf do we file it on? That's not the purpose of this. So it's getting out and we're going to push it very hard. So I urge each of you to become a committee of one and make this important and disseminate it.

Any questions on the dissemination of that report? Yes, Emily.

DR. WINN-DEEN: I noticed on the list of people we're extending this announcement to, a category that said "expert presenters." Is there a thought to preparing a slide set that at least has the recommendations on it?

DR. TUCKSON: That's a great thought.

MS. CARR: Say that again. Sorry.

DR. WINN-DEEN: Well, we have a series of a dozen recommendations. Could we have a set of slides made that has those recommendations?

MS. CARR: Oh, so that you can present. Absolutely, that's a great idea.

DR. WINN-DEEN: And just put it up on the website.

MS. CARR: And then you can use it when you need it. Sure.

DR. WINN-DEEN: Or whoever we're targeting in the "expert presenters" category.

MS. CARR: Oh, I see.

DR. WINN-DEEN: Anything you can do to make things easier for them helps.

MS. CARR: That category represents the people we heard from and consulted with in-depth. But that's a great idea, Emily.

DR. TUCKSON: That's a deliverable.

Any other quick thoughts on that?

DR. LICINIO: Yes, I had a quick thought, which is that can the report in full, or at least parts of it, be available on the website?

DR. TUCKSON: It's on ours. So thank you for that, Julio. It is on our SACGHS website, which anybody can go to to get. So absolutely let people know that.

Yes, please.

DR. LEONARD: Has this been distributed? I didn't see industry like IVD companies. I don't know if BIO is the right group or AdvaMed. They would be interested in this as well probably.

MS. CARR: Susanne, are they on our listserv? They are, aren't they? We'll make sure they get it if we haven't done it.

DR. TUCKSON: That is a great thought. Thank you.

DR. LEONARD: And the second question. The Secretary has vetted this somewhat or got it in February. Do we anticipate when we will be hearing response at each implementation of recommendations or responses to them or anything like that?

MS. CARR: Well, we're aware that the report is being looked at within the Department. We've gotten some calls from some of the staff to the Secretary about it. So we hope to hear soon.

But may I say, I think it's a fairly complex set of recommendations and we don't want to rush them, I don't think, in terms of looking at it. So I think the longer they take -- well, to a point, but clearly they need to think about some of the cost implications and some of the other issues in the report.

DR. TUCKSON: But I think the key thing, Debra, there is that -- and I think it falls in some ways to me -- to make sure that on this and other areas, when we send these things forward, to try to figure out how to make this a higher priority or a priority within what the Secretary is doing. So we know they got it. We know they're looking at it and so forth.

Let me just say we're going to come to that in a second. I'll just go ahead and fast forward to this. One of the things that we are aware of from your evaluation reports is that we sort of felt like you want to know more about is anybody paying attention to these recommendations in the Secretary's office.

I think that Secretary Leavitt has had a chance now to be on the ground and get established. He still is fairly new, even as of our last meeting, and then was hit immediately with not only the ongoing bioterrorism issues, but then with the bird flu challenge, and then also with his own initiative, which is the health information technology initiative, which is occupying a lot of his priority. Those three are pretty big items.

I have had the chance to spend face time with him in actually all three of those areas, and so I've had a chance to see him out and about multiple times. I am going to try to see if I can't have the opportunity to chat with him or somebody on his staff a little more. Every time I see him, I always say, by the way, I bring you greetings from your advisory committee. So every time he sees me, I think he knows I'm going to say something about the Secretary's Advisory Committee on Genetics.

But I have not had a chance to sit down with him in any depth to go over all of our portfolio, and I don't know if any advisory committee chairman does get a chance to go over their portfolio in any depth with the Secretary. But I'm going to try to do that.

We got into the same issue with Secretary Thompson, and we were even trying to think about should we create or urge there be some coordinating person within his office. And that got us into all kinds of entanglements as it looked like we were potentially creating more favored nation status for one agency over another or trying to create an intermediary genetics czar between some of the agencies and the Secretary. So that probably didn't turn out to be too good of an idea, and none of our ex officios liked that a whole lot.

So we're going to try to figure out some kind of what to get somebody to make sure, you know, the chief of staff or somebody that knows us and can shepherd our stuff through without creating an unnecessary bureaucratic hurdle. So that's the challenge.

I guess I'm reporting to the committee. I am aware of your concerns in this regard and hold myself personally accountable to try to do something to bring us to attention. So we may have to stage maybe a parade in front of HHS saying, "Yea, Genetics," or something, but we'll figure it out.

We also sent the Secretary two letters, one on the incorporation of genetics, genomics, and family history, as Sarah mentioned, into the electronic health information infrastructure and another on direct-to-consumer marketing of genetic tests. Copies of these letters are in your tab 3. In the DTC letter, we recommended that FTC and FDA consider using a joint statement about genetic tests marketed directly to consumers.

Let me just say, as we turn to Dr. Gutman to give us an update, we said in our letter to the Secretary -- and I think we felt good about it -- there was really great collaboration between FDA and FTC on this issue. This was a good example of government working together and working well, and I think it's something that should be noted and applauded, celebrated, modeled.

Steve, where are we on this now?

DR. GUTMAN: Yes. We actually are working on a final work product to produce some consumer information that we think would be very helpful, very clarifying. We hope it would be a strong statement. We are doing that collaboratively with FDA, FTC, and CDC. There has been a lot of recent interest.

As you remember, historically we had actually hoped that one of the agencies might be able to identify a target that might produce the response that would be more than sort of general advice, that might FTC might actually be able to take some action. We actually continued to survey the environment to look for targets where they may have crossed the line and actually violated and deserved some more specific action. I again urge the committee, as I did before, to please keep your eyes and ears open. If you do identify outrageous outliers, I'm certain I would like to know. I suspect Matt would like to know about them.

This is not intended to actually create a solution to a particular problem. It is a general public health notice. It is in final form. Because you are coordinating across three agencies, it probably won't come out like lightning, but I am certainly hopeful it will come out with reasonable speed.

DR. TUCKSON: Again, Steve, if you would take back to the interagency work group that the committee acknowledged with applause the coordinated efforts there and, within that context, would urge more of the light speed than the reasonable.

DR. GUTMAN: I will try.

DR. TUCKSON: We'd like a real victory on this one. I mean, we've got it now.

On the incorporation of the genetics and family history electronic health record, health information, Sarah, if you would, after this meeting, cause me to call David Brailer. I think we want to really, really make sure that we are personally engaged with David Brailer on this issue. This is a win. I mean, I can feel it. This is low-hanging fruit. We should be able to get this done, and so I want to call him directly.

Today we will continue to develop our reports and recommendations on the large population studies and pharmacogenomics. Tomorrow we will be briefed about the report issued last fall by the National Academy of Sciences on the impact of genomic and proteomic patents and licensing practices on innovation in public health. We'll hear the conclusions of the SACGHS Task Force on Patents and Access about the report and their recommendations for next steps we should take. So those are those two big items on our strategic plan that we will substantively move forward with by the end of this meeting, both large pop and on patents.

We will also be updated on the status of federal genetic nondiscrimination legislation and hear about a new survey of public attitudes that is now available.

Public comments sessions, as always, are scheduled for both days and individuals who would like to provide testimony and have not already signed up should do so at the registration desk.

In order to enhance our currency and ability to stay abreast of developments, the ex officio agencies were asked to provide updates on relevant activities in their agencies and Departments. These updates can be found on tab 4.

Let me just say to the ex officios, we really, really appreciate your involvement on this, and I think it's very good to have those updates to let us know what's going on and to find ways in which we can see more about how we can support and encourage those good activities. We'll hear more about several of these activities during the large population studies, the pharmacogenomics, and patent and access sessions later today and tomorrow.

At the last meeting, you completed a survey about the effectiveness of the committee's activities. The results of that survey are in your table folders, in the folders here. In general, our responses suggest that we think the committee is effective. However, there is room for improvement in some areas, and in particular, some of us would like to see more feedback from HHS about our work and priorities. I know the ex officios have taken this concern to heart and are going to be considering it and other suggestions very carefully. And I mentioned earlier this business about trying to see if we can't find out a little more from how what we do connects to the Secretary's office.

Joseph, thank you for your liaison activity to the HHS Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. You've held your seventh meeting in February, and the highlights of Dr. Telfair's meeting minutes can be found, again, in your table

folders. We won't have a chance to go through that today, but Joe, thank you for making that available.

Yes.

DR. TELFAIR: I just had one minor correction that I need to make to the report. It's on the very last page. It's under G. It's an editing comment. It's because I tried to use the same format. At the top, it should say "Final Presentation or Comments on Tuesday, February 14, 2006," instead of "October 2005." Sorry about that.

DR. TUCKSON: Joe, you are on the case as always. Thank you, sir.

DR. TELFAIR: Okay. You're welcome.

DR. TUCKSON: With that correction noted. Again, nobody needs an extra meeting to go to, but thank you for doing it.

DR. TELFAIR: It's my pleasure. Thanks.

DR. TUCKSON: Thank you.

Debra, you are the liaison to the CDC EGAPP Working Group. The working group held their fourth meeting in February. Highlights of that meeting can also be found in your table folders. Any comment?

DR. LEONARD: No. Last time I must have said something I shouldn't have said. So this time Linda provided the update so that I couldn't say anything that I wasn't supposed to say.

But if anybody wants to know how interesting the EGAPP work is, it's really intriguing and they're finally going to be getting to some data and so it's getting very, very exciting.

DR. TUCKSON: Oh, it is. Oh, great. Well, thank you very much.

We've had a change in our membership. Regrettably, Dr. Christopher Hook made the very difficult decision to resign from the committee due to family and professional obligations. I know that Chris was immensely honored to be appointed to this committee and to serve with all of you. He greatly regrets having to step down, and he asked me to extend his heartfelt thanks and warmest regards to each one of you. The Secretary is expected to fill Chris' seat in the very near future.

Two ex officio positions have also changed. Dr. Cristina Beato, Principal Deputy Assistant Secretary of Health, has been appointed to serve as the ex officio for the HHS Office of Public Health and Science. I know Cris really well. She is a terrific colleague and she will serve our committee very well. She couldn't be here today, but thank you very much, Bernard, for sitting in and I appreciate your involvement today. Please tell Cris I said hello.

The Department of Defense will now be represented by Lieutenant Colonel Scott McLean, Chief of Medical Genetics at Lackland Air Force Base in Texas. Dr. McLean could not attend this meeting due to a longstanding commitment, but we look forward to his participation.

Also, we're joined by Linda Johnston-Lloyd, Acting Director of HRSA's Center for Quality. Linda, are you here?

MS. JOHNSTON-LLOYD: I'm right here. Good morning.

DR. TUCKSON: How did you get there? You just snuck in. How are you doing today?

MS. JOHNSTON-LLOYD: I'm fine.

DR. TUCKSON: Great. We're very glad to have you here. You're sitting in for my old friend, Sam Shekar, and again, we're happy to have you involved.

We're also joined by Dr. William Koch. See, I did it right this time, William. He is the Deputy Director of the Chemical Science and Technology Laboratory at NIH Standards and Technology, sitting in for Willie May, our ex officio from the Department of Commerce.

There's also been a transition in SACGHS staff. Our old and good friend -- I guess she's too young to be old because she's still just so young -- Amanda Sarata took another job in December with the American Society for Therapeutic Radiology and Oncology. She was, I mean really, just a terrific staff person to our committee.

But we're real pleased that Amita Mehrotra has now been hired to fill Amanda's slot. Amita earned a masters degree in public health from GW and an undergraduate degree in molecular genetics from Ohio State. So we are very pleased and we're going to work you to death. It will be just terrific. You'll love every minute of it.

Also, Kathi Hanna, a science policy writer, well-known to many of us, has been tapped to help develop our report on the large population study. How are you doing? Good to see you.

I'll now turn to Sarah Carr for her very serious, sober, scary reminders about ethics rules.

MS. CARR: Thank you. As you know, you've been appointed to this committee as special government employees in order to serve. This is a special category of government employees, but you're, nonetheless, required to follow the rules that we must follow. Those rules are outlined in a document called Standards of Ethical Conduct for Employees of the Executive Branch. Each of you received this document when you were appointed.

There are many rules in the document that you are aware of, I know, and I'm just going to highlight two today.

The first one is about conflict of interest, as Reed said. 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 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 could arise that would affect or appear to affect your interest 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 if they became a focal point of committee deliberations. And if this happens, we would ask you to recuse yourself.

Let me remind you that you are also prohibited from lobbying. If you lobby in your professional capacity or as a private citizen, it's important for you to keep that activity separate from the activities of this committee. Just keep in mind that we are advisory to the Secretary and not to Congress.

Thank you.

DR. TUCKSON: Thank you.

With that last comment being who we are advisory to, as we turn now to the large population study -- and I'm getting ready to turn to Huntington in just a moment.

By the way, the latest draft report was e-mailed and FedExed to the full committee on March 20, but also copies are in the table folders. Does everybody have a copy? All right.

Let me just say, as I turn to Hunt, everybody makes this committee a priority for them, and we appreciate it. Joe Telfair just got off a plane from Uganda. So when he goes "pow," it's not that he's not happy. I can't believe he's done it. I'd say that also to introduce Hunt who is on his way in 8 hours to China. So he's here and that's the kind of commitment that people on this committee have, and I just really want to acknowledge the extra effort that people make to get here.

Before Hunt takes us through that, there's one small correction that I just want to handle in the materials. You will see there's an RFA announcement about this from our colleagues at NIH, and in there is a slight sentence that gets at the idea that in the RFA, that they sort of allude to a recommendation that the committee might have made in this regard of sort of supporting this study at the last conversation. A small technicality in that we don't actually recommend these sort of things to the agencies, but to the Secretary.

It means that we will have to work with NIH, and I've talk with the folks with NIH. A slight modification, just a very subtle modification of that language. It's not a real big deal, and I don't want to make it a big deal, but just a matter that we can't quite recommend in that regard. Just a little caution there.

But be that as it may, I think we're all on the same page, that we do want to emphasize how important it is to get the input of the public going forward. So there will be a slight modification of that. But the spirit is the main thing. We're all on the same page in terms of the spirit of what we're trying to achieve here, and so we'll just technically resolve that and be done with it.

With that, Hunt.