Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Well, good morning, everybody. Do we have everybody out of the super duper breakfast room? I really want to thank all of you. I am sure that we could spend a lot of our time doing travel nightmare stories for yesterday and I'll just sort of say that when my cab sunk on the GW Parkway, I knew that this was going to be an interesting experience, and that was fun to paddle the cab out of the muck there.

I'm actually very happy that we are here at this facility and I really appreciate and I really hope that somebody will be able to transmit our appreciation to the NIH staff and team for allowing us to be here. It is very, very difficult to get a meeting at NIH nowadays and we really appreciate all the extra effort and security, the folks that come out, the dog sniffing guy standing by the van is always impressive. It always makes me want to come here.

(Laughter.)

But the problem is—I'm sort of giving you a segue for the next meeting—we're going to be out east hell somewhere—

(Laughter.)

--which is actually very nice, College Park, but we're going to be a long way from here. The problem is that we're not big enough for hotels to love us because we don't use enough rooms and so we—apparently, unless you have enough rooms they don't care about your staying in their ballroom or their meeting room so they're mean and we hate the hotel industry in Washington a whole lot.

(Laughter.)

And I'm very upset but—anyway, so we're going to be out in wonderful College Park, though, and I joke but it's a lovely place and we're happy that somebody wants us but anyway—so, with that, can you believe this is the tenth meeting of the Secretary's Advisory Committee on Genetics, Health and Society. I mean this has been a real effort and we've been around a good while now, and I think that that sort of is its own challenge is to ensure that we're making a difference. So being also the second committee—it's really our legacy is much longer than ten meetings and so we really do have the challenge of focusing in on making a difference, and I think that's the watch word for what we do today.

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 to the webcast, and we thank you for your interest in our work and thank all of you who joined us.

Before we begin, I'd like to let you know that we have some new members and I want to do a warm welcome of them.

First, let me ask, Barbara, could you—Barbara Burns McGrath, could you just give us a one sentence of who you are and where you are, and welcome aboard? You have to push the button right there.

DR. McGRATH: There.

DR. TUCKSON: You got it.

DR. McGRATH: I just flew in from Seattle moments ago so I'm delighted to be here. I'm Barbara Burns McGrath from the University of Washington and I'm a nurse and a medical anthropologist.

DR. TUCKSON: Terrific. Well, we're very glad. And let me also introduce—allow her to introduce herself, Andrea Ferriera-Gonzalez if I said that right.

DR. FERREIRA-GONZALEZ: Actually you are really close.

(Laughter.)

DR. TUCKSON: Now this is a diplomat.

(Laughter.)

Somehow or another I have made an error and I don't feel bad about it.

DR. FERREIRA-GONZALEZ: Gonzalaz will be fine to make your life easy. I'm Andrea Ferreira-Gonzalez. I'm a professor of pathology at Virginia Commonwealth University and also the Director of the Molecular Diagnostics Laboratory there. Thank you.

DR. TUCKSON: Thank you so much.

Also, let me welcome Steven—well, Steven, I'm going to let you say your name, too.

DR. TEUTSCH: After all the times we've been together.

DR. TUCKSON: I'm just trying to be cautious.

(Laughter.)

DR. TEUTSCH: I'm Steve Teutsch. I'm a medical epidemiologist at Merck, retired from CDC, and now I do a lot of work on evidence-based medicine and evidence-based public health.

DR. TUCKSON: I know that Steve is a good person and we have been around a lot together. So thanks for letting me have fun at your expense.

I want the new members of the committee to feel comfortable and I want you to feel at home. This is a complex committee and so we're going to do everything we can to try to give you a sense of catch up quick. I would urge you, though—and, unfortunately, I'm the kind of person who is shy and so—

(Laughter.)

--I tend not to ask very basic questions and be afraid that if it's a too basic a question for something I'm trying to catch on, and then I sit there and I'm completely lost for the next three

years. So I would urge you to really just ask whatever you need to ask and catch up but we want this to be a comfortable and a fun experience for you.

To help make sure of that, let me just ask the other members of the committee if they would very briefly give a one sentence introduction of themselves so you'll know some of the people who are the actual members of the committee. I appreciate the ex officios, by the way, but I'm just going to do this fast for the members of the committee just to run around real quick.

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

MS. AU: I'm Sylvia Au and I'm the State Genetics Coordinator in Hawaii.

DR. FITZGERALD: Kevin Fitzgerald. I'm at Georgetown University in the Department of Oncology and also the Center for Clinical Biologics.

DR. TELFAIR: I'm Joseph Telfair. I'm at the University of North Carolina, Greensboro, in Public Health.

MS. C. CHEN: I'm Chira Chen. I'm a patient advocate and I also work at University of California, San Francisco.

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

DR. LICINIO: I am Julio Licinio and Chairman of the Department of Psychiatry at the University of Miami.

DR. LEONARD: Debra Leonard, Vice Chair of Laboratory Medicine at Cornell, Wilde-Cornell Medical College.

DR. WINN-DEEN: Emily Winn-Deen. I work for a molecular diagnostics company called Cepheid.

MS. CARR: We also have two other members, Cynthia Berry, who unfortunately has a flooded basement, but Cindy is a partner at Powell Goldstein in Washington, D.C., a law firm, and she's an attorney.

And then also Hunt Willard, Director of the Institute of Genome Sciences and Policy at Duke University couldn't be with us today but he has also been working very hard on one of the issues of the committee's, the draft report on large population studies. So he is a big contributor to the committee as well.

DR. TUCKSON: And just real quick on the ex officios, I want to start with Lieutenant Colonel Scott McLean. Is that right, Scott?

DR. McLEAN: Yes.

DR. TUCKSON: Please let us know where you are.

DR. McLEAN: I'm a clinical geneticist stationed in San Antonio and I represent the Department of Defense.

DR. TUCKSON: Terrific. Steve, do you want to go around and do you and the rest now?

DR. GUTMAN: I'm Steve Gutman. I'm with the FDA in the Office of In Vitro Diagnostics.

DR. COLLINS: Francis Collins, Director of the National Human Genome Research Institute here at NIH and I am the NIH liaison member.

DR. TUCKSON: Good.

DR. ROLLINS: Jim Rollins, one of the medical officers at CMS. I work for the Coverage and Analysis Group.

DR. CAROME: Michael Carome. I'm the Associate Director for Regulatory Affairs in the Office for Human Research Protections.

DR. TUCKSON: Great. And we have a new member. Denise?

DR. GEOLOT: Denise Geolot, Director of the Center for Quality at the Health Resources Services Administration.

DR. TUCKSON: Great. Did I miss any of the ex officios?

For the committee members again, the ex officios from the agencies are exceedingly important to us, especially as we—again the watch word for this meeting is "let's get stuff done." Let's move this ball forward. And the ex officios are absolutely essential to that and that's why I wanted to highlight them, and we appreciate everything that you all do for us.

Well, this is also a time of transition in the staff. The wonderful Fay Shamanski has gone to a new position at the American College of Pathologists. We would like to make sure, Sarah, that we thank her and that she gets a note that says that we mentioned her and we appreciate everything that she has done for us.

There's recruitment underway to fill the position. In the interim we're also benefiting from the wonderful services of a really special HHS program called the "Emerging Leader Interns Program." They're doing rotations with our staff. Dr. Kathryn Kolor, who is based at CDC in the Office of Genomics and Disease Prevention, has been working on the large pop studies draft report and public comments.

Kathy?

DR. : There she is.

DR. TUCKSON: Hey! Thank you.

And then we also are pleased that Dr. Joseph Malone, who is based at FDA in the Office of Policy and Planning, has been assisting with the pharmacogenomics draft recommendations.

Thank you, both, very much.

Well, since our last meeting in March, we received responses from the Secretary on the coverage and reimbursement report that is in your tab and essentially it indicates that he's obviously in

receipt of it and that they are in the process of working through the recommendations. It pretty much is a very early statement of response and I don't have anything—there's nothing more definitive than that.

We also have a response on our letter on the incorporation of genetics, genomics and family history into the electronic health infrastructure. Both of those are in tab 3 of your briefing book.

We also just received a response to our letter on directed consumer marketing of genetic tests and a copy of this letter is located in your table folders. You'll be hearing more about that tomorrow.

Regarding the coverage and reimbursement report, I'm pleased to report that Cindy Berry and I met with the CMS administrator and their staff, and Mark McClellan, a couple of weeks ago on the committee's recommendations. In particular, we focused on the five recommendations that are directed at the Medicare and Medicaid programs.

I will say that Dr. McClellan was having an extremely intense day that day. It was very clear that something extraordinarily important was going on. He made very great efforts to have not only himself but his senior leadership team in the room with us.

And I want to note, James, if you would pass to them that it was very much noted and appreciated the priority that Mark McClellan placed on our meeting. Despite whatever the challenges were at the moment, we had his undivided attention for as long as we needed it and they took our report very seriously.

Our recommendations specifically regarding the screening exclusion, billing and reimbursement of genetic counseling services, national versus local coverage decisions were of particular interest, and so he has assigned—he assigned out follow up work to the appropriate people on his staff, including his legal team and he assigned a coordinator, Mary Lacey Rather, as the point of contact to follow up so there's a clear way of process and going forward. So I think the committee, again back to our mantra of trying to move things along, that was a very important meeting for us and we are pleased about it so we will follow up.

Similarly, we have a meeting or I have a meeting tomorrow afternoon. I will have to break away from our conversation to meet with Elias Zerhouni tomorrow, the NIH Director, so I will have a chance. I love our staff and our team. Apparently I'm to memorize this briefing booklet here and do this meeting with Elias so I will be staying up tonight doing that but I'm actually looking forward to that and I think we have a lot of issues. Again, this is important because I think the Director of NIH is taking our work seriously and wants this time to sit down and go through some level of detail so I'm pretty pleased about that meeting and we will talk to you.

I think the key thing is to continue to maximize the visibility of our work not only within NIH, within HHS, both of those together, I think that's really the challenge.

For the new members of the committee, we've been always struggling with how do you make that happen, particularly at the level of the Secretary of Health, given all the things that are on his or her plate at the time. I think we're just going to keep pushing and being very, very aggressive about it.

Now if I could put the slide up.

(Slide.)

We have a very broad charter and mandate. Within that broad scope, our agenda has been guided by a strategic plan that we developed collectively through a systematic priority setting process in March of '04. At the beginning of each of our meetings, I always try to take a moment to review our priorities because I think the committee has to always be focused on what is our focus, what are our priorities, and where are we in implementing our strategic plan. It's easy to get lost in the woods and not keep a high level view of where we are.

So do you have the slide there? Oh, okay. I wasn't seeing anything. So she's got it all under control. They're so good.

First of all, we did a vision statement describing our priority issues and how we reached them. We did that in 2004 and for the most part it continues to reflect and guide our work as a committee. So the checkmark is there because, in fact, we have done that.

The second priority that we had was genetic discrimination. It's our highest priority issue and to date we have developed three letters, commissioned a legal analysis of the adequacy of current law, compiled a phone book sized document of public comments that the committee has very laboriously collected as we really pulled together a significant amount of comment from all the major stakeholders in this drama, both the public as well as industry, health plans, et cetera. So we've pulled together these comments to document public concerns about this issue in a compelling way and produced a ten minute DVD of public testimonies.

We produced a report and nine recommendations on coverage reimbursement of genetic tests and services, and so we have attended to that. By the way, the genetic discrimination, while we have a check on it, it is a—we have done what we were supposed—we have done a lot of stuff there. We are very proud of what we've done but that issue is still an ongoing issue for us and I want to make sure that by putting the checkmark there, I want to indicate that we have performed but this will always be a continuing drama.

The coverage and reimbursement recommendation—we produced a—it has nine recommendations and those we have sent forward to the appropriate—to the Secretary and, again, mentioning we've gone to CMS. It has been out in the public and the private sector health care world, and we will need to be attentive again towards making sure that we drive that forward.

Next is regarding education and training. We have written a resolution about the importance of genetics education and training of health professionals and how that can be enhanced. Again I think we need to be always thinking about what if anything is the next step on this, and you want to keep that sort of in your mind.

On direct to consumer we've written two letters on direct to consumer marketing of genetic tests. We are—at the last meeting we had a good report about the collegial interaction between FDA and FTC and how they are moving forward on that, and so we'll be monitoring that as we go forward.

On the issue of pharmacogenomics, this—then we also—so pharmacogenomics was another major priority. The next issue that we have, of course, is large population studies and then gene patents. These three are going to be discussed at this meeting and so you'll get a sense that we're going to be really drilling into these as well.

Today we will also be advancing further our issues on genetic discrimination, direct to consumer marketing and oversight.

The issues of access, public awareness and genetic exceptionalism transcend all the other issues and are integrated into our work. So just again for the newcomers to make sure you get a sense, genetic exceptionalism is one that we have sort of been struggling with from the very beginning in terms of how much of our efforts are this is genetics outside of everything else versus genetics being integrated across a broad panoply. So we sort of see that as woven in so there's probably not going to be much that we see right now as a discrete project like the other ones.

Public awareness and how do we educate the public about being prepared for the genetic revolution and all the things that come with that is something that we try also to think about it in context with other things but we haven't addressed that as a specific initiative as such and that's something that we need to keep in mind.

The access issue was very much connected to the coverage and reimbursement report, and that was really the first effort to sort of make sure that we looked at that, at the access issue, as an important kind of deal so genetic discrimination again being work that we're going to continue to focus on.

So, hopefully, this gives you a sense of where we sort of are in our strategic plan that was developed in 2004. I emphasize 2004. This is now 2006 and so at some point we made decide, and you will be the ones to decide, whether or not we need to make some shuffle in this and whether or not there's something that's not there that ought be. Should we be giving more priority to something else, go back to things that we've done work in the past and push that forward? I want to just keep those things in the committee's mind and at some point maybe we will have a chance to revisit this and talk about it.

So giving you a sense of where we are: The agenda I'm going to through in a minute but actually we're going to actually jump into the meeting for a moment. We've got a presentation from Judy Yost who is going to give us an update on the Notice of Proposed Rule Making on a Genetics Specialty for the CLIA Program. The reason we're going to go to this first is Judy may well be called away back to CMS for something that she has to do in Baltimore.

Judy, by the way of travel stories, apparently got up at like 2:00 or 3:00 o'clock in the morning to drive down from outside of Philly, I think it is, to get here for this presentation and so that's just commendable that she would give this committee that kind of respect to make sure that she was on time. So I'm going to give her the opportunity to make her presentation.

As I mentioned, she is the Director of the Division of Laboratories and Acute Care at CMS. She's here to provide an update on the status of the CMS plan to augment clinical laboratory improvement amendments or CLIA program with a genetic specialty, which has been in development for a number of years. Tab 5 provides some background on this issue as well as a timeline of developments related to the oversight of genetic tests, specifically with regard to both CLIA and FDA oversight.

CMS has worked closely with CDC in developing a genetics specialty proposal for the CLIA program and Dr. Joe Boone, Associate Director for Science in CDC's Division of Laboratory Systems, is joining us today by Phone.

Joe, are you there?

DR. B. CHEN: Hi. This is Bin Chen from CDC. Dr. Boone is delayed on his way back home so he cannot join this meeting today. I'm sitting in for him.

DR. TUCKSON: Okay. Well, thank you. And your name?

DR. B. CHEN: Bin Chen.

DR. TUCKSON: Okay. Thank you so much. With that, let me just thank Judy for the presentation and after Judy's presentation and a couple of questions for her, I'll come back and we'll restate the deck in terms of the order of events and what you can expect over the next two days.

Thank you, Judy.