Overview of Session
Andrea Ferreira-Gonzalez, Ph.D.

DR. TUCKSON: Thank you all very much. As always, we start on time. We have a power-packed afternoon, on top of a very power-packed morning, but we are going to pause for just 10 seconds and introduce a very special new friend of the Committee.

Rick Campanelli is the Secretary's counselor for science and public health. He has been an integral part of the Secretary's leadership team since 2002, when he was appointed director of the Office of Civil Rights, and led the significant effort under former Secretary Thompson to finalize the HIPA privacy rule and spearhead OCR's HIPA enforcement program.

When Mike Leavitt became Secretary, he was asked to serve as the first counselor for human services and then as his counselor for science and public health.

Now, I will tell you that Rick has had a rich and varied legal career even before joining HHS, both in the private sector, representing nonprofit organizations, and in the Justice Department as a litigant fighting against unconstitutional conditions in mental health institutions and race-based segregation in state prison systems. Later, in the State Department, he worked on U.S. initiatives to end apartheid. A terrific career.

We appreciate the interest and support that you have shown in our committee since taking Sheila Walcoff's place as counselor a few months ago. You took the time to meet with our Oversight Taskforce in September and just a week ago were briefed by our superstar, Andrea, by Steve, and Marc about the draft Oversight Report that we released for public comment earlier this month.

With that, I just really want to say, also -- I'm sorry, Greg, but you are going to get it again -- Greg Downing is just terrific. We have enjoyed unprecedented relationships with this administration and this Secretary. Not to say anything bad about the fine ones that came before. Lord knows they were all wonderful as well. But you have been super-wonderful this time around.

So with that, Rick, let me welcome you to the Committee.

MR. CAMPANELLI: Thank you very much, Reed. It is great to be with you all. I see around the table friends from various parts of my life, and I'm grateful to be here. When you talk about that varied legal career, my kids refer to it as my checkered legal career.

[Laughter.]

MR. CAMPANELLI: But it has been a privilege to serve since coming to work for Secretary Thompson and Secretary Leavitt.

Secretary Leavitt extends his greetings to you. He is traveling, as I was with him in the last couple of days, on import safety and food safety just before the Thanksgiving holiday here.

But I just want to say that he is so appreciative, as of course am I, for the very hard work that has continuously gone on with this Committee over the year. With that, in this time of Thanksgiving, the only thing I want to say is I'm really looking forward to just being with you. As Reed mentioned, Andrea has been very kind. We had a good talk about the report of the taskforce, and I'm looking forward to hearing more discussion today.

What I just want to say as we approach Thanksgiving, thanks to a few people who are going off. Two of them aren't here, but Chira Chen is down there. We just got to visit. I just wanted to say thank you for your great work on this Committee. Since 2005, right, Chira? The Committee has had the benefit of your participation, your perspective, and orientation for consumers in making sure that these matters are things that get right to where they are supposed to get, to the bedside, and your participation in the Large Population Studies and also on gene patent and licensing studies.

So I just want to say thank you to you for your service. I know that I say to everybody in this room at the same time that it is a wonderful thing to participate in these things and a sacrifice. It is a very high calling, and we appreciate it.

I also want to say thanks to those who aren't here with us right now, to Cynthia Berry, who was with us with the original Committee and helped in the transition, and also Dr. Hunt Willard, chair of the Large Population Studies Taskforce and the Pharmacologics Taskforce. Just thanks to them for their excellent service on behalf of the Secretary and the Department. Thank you very much.

DR. TUCKSON: Thank you.

[Applause.]

DR. TUCKSON: We know that your schedule is very busy today, and obviously at some point I know you will have to leave us. But please stay as long as possible and don't be shy. When you have to go, we understand.

We have to say one thing to the troubadour.

[Laughter.]

DR. TUCKSON: You cannot get the Presidential Medal of Freedom, the nation's highest civil award, and not be noticed by your colleagues around this table. Now, I know that you are turning red. I don't have to look.

But everyone around this table understands that that is awarded to those who have made especially meritorious contributions to the country, that you got it for your leadership in the Human Genome Project, which obviously revolutionized genetic research, and for paving the way for applications that will greatly expand our ability to diagnose, predict, and treat disease at the individual level.

You got this thing on November 5th at a major White House ceremony, and you were praised for your relentless pursuit of knowledge and your extraordinary intellect. By the way, I did notice with some interest that the President did liken the Human Genome Project to the Apollo project in scope and in the long-term potential that it will have, and that Americans are proud of this wise and humane American scientist who is behind our national scientific effort and achievements in genetics.

So not only that, but Francis, you are not only smart and brilliant but you are collegial. It is a rare gift for a committee like us to have someone who is not only very, very smart but who knows how to play nice with the other boys and girls, who can actually work with other people, not have

a massive ego to the point where you can't sit down and have discourse and dialogue, and come up with shared accomplishments.

I think that you have always prided yourself in the way you have demonstrated here as being a member of the team and a member of sharing. But dear Dr. Troubadour, we really do honor you.

[Applause.]

DR. COLLINS: I have to say thank you so much to my dear colleagues for that. That means a lot. I really value the collegiality on this group as it has wrestled with so many difficult issues. I gather you were exposed to another facet of me earlier today.

[Laughter.]

DR. COLLINS: I will have to tell you one slightly funny aspect of what happened in the Medal of Freedom run-up. When I got the call from the White House, which was a stunning call, to say that this was going to happen, the person who called, someone on the White House staff who I had not met before, described the event. I was of course by that time lying on the floor. At the end of all this presentation about the circumstances and the logistics and what to wear and where to show up and which kind of security issues to worry about, he said, "Oh yes, there is one more thing I was asked to tell you. There will be no singing."

[Laughter.]

DR. COLLINS: To which I guess I would have to assume my reputation had preceded me. The President wanted to be quite clear this was going to be a dignified occasion.

When I did get the award and the President put the medal around my neck, I was feeling pretty inspired. So I turned to him and said, "Mr. President, I feel like singing."

[Laughter.]

DR. COLLINS: And he gave me a very warning sort of look, and I said, "Just kidding."

DR. TUCKSON: Pushing the envelope again.

That really is fun. I think the spirit of collegiality and so forth is very important.

So here we go into this very complicated session. Now, we have rehearsed this a number of times, so all of the five new members of the Committee understand that this is a part of our DNA. We have inherited this issue of oversight. Andrea is going to take us through this.

I want to, again, ask Andrea to emphasize, and I want you to pay attention, to the process that we are under. We have already put forth a draft, a very early draft document, into the public discourse. So the Committee has put forward a draft into the public discourse.

We are soliciting responses from the public through December 21. We are soliciting responses from the public, comprehensively described, through the 21st. Then, with their input and our own new members' and others' review of this, informed legitimately by the public comments as well as our own -- but I'm being very explicit here -- respecting and listening and reacting and responding to the public input, which is what we asked them to do, we will then engage in a

second process to deliberate and to determine what it is in fact that we believe. Do you understand what I'm saying?

So we are here today to listen to more public comment, other examples of other experience, that we will then use in its combined wisdom to redeliberate it as a Committee.

So I don't want the Committee today to get caught up in redebating the report, a report that is already in the public discourse asking for comment. It is not appropriate. What you want to do is you want to listen today, you want to raise issues, you want to ask questions, you want to discuss. Then you are going to have a whole lot of energy and time where you are going to grapple with this thing anew. You are going to grapple with it anew after this meeting, or after the 21st when you get the public comment.

With that, we are going to march through this, and then we will have our conversation.

Andrea.

DR. FERREIRA-GONZALEZ: Thank you, Reed. I think we are waiting a little bit more for the presentation.

DR. TUCKSON: While we are going to reboot the computer, we are going to remind you also, and I think that we got into this wonderful issue the last end of the session, so let's try to lock it in.

We had this notion around the genetic training issues. Francis, you weren't here, but it is an old conversation. We had a whole bunch of stuff on who is qualified to do what and who gets reimbursed to do what. That is a big part of this Oversight Committee conversation.

So one of the things that we have to finish today, if we can, the one deliberative action that we are going to take today, hopefully, is to try to empower a committee that is going to look at the training and education issue within the context of all of this. That might be one thing that we will get closure on before we leave today, at least trying to empower them with a task. The charge will be probably to go and create its parameters, its context.

The Committee will probably have to invent its own priorities, but I think we laid out three at the end of the meeting.

I think that I am certainly going to look for those who want to be a part of that effort to start thinking about self-assigning themselves. Barbara hasn't escaped yet, so as soon she leaves the room I will appoint her chair.

DR. FERREIRA-GONZALEZ: One thing we can do is, everybody has their handouts in their folder. We can pull the handouts and maybe start, and then they can catch up with the different slides so we can keep moving and leave at a decent time.

Thank you, Reed, and good afternoon, everyone. As Reed said, we have been working diligently over the summer and fall to consider the questions posed by the Secretary. Part of our work is now in the critical stage of undergoing public review, and we are looking forward to the input we receive to help us ensure that the advice we give ultimately to the Secretary is sound, forward-looking, and in the public interest.

We are going to be receiving public comments until December 21st, and our session today is part of that process. We are seeking public comment.

Today we will begin with an academic analysis of regulatory gaps in the oversight of genetic testing and models to address these gaps. We will have about 20 minutes to discuss the findings of these analyses. We will also hear from various stakeholders regarding the oversight of genetic testing.

Sharon Terry, a dear friend to our Committee, will describe the key points that emerged from a summit meeting held in September by the Genetic Alliance. David Mongillo will comment on behalf of the American Clinical Laboratory Association. Patricia Goldberg will present on behalf of ISONG, and Dr. Patrick Terry will also report from the Coalition for 21st Century Medicine.

Before I begin, I want to take a moment to review the Secretary's charge and main elements of our draft report. The draft report is a comprehensive map of the steps needed for the evidence development and oversight for genetic testing. The charge included eight questions about key measures of validity and quality of genetic testing technologies and processes in place to assure their safety and effectiveness.

The Secretary also asked the Committee to consider government and private sector solutions to gaps in oversight and advised us to focus on the future so our recommendations will be relevant and forward-looking. The Secretary has asked for recommendations by February 2008.

The report was developed by a taskforce comprised of SACGHS members and experts that we have recruited from the federal agencies and the private sector. As you can see here on the slides, there are 33 members. As was commented yesterday, it takes a village.

The taskforce interpreted oversight in broad terms, and I think this is very important, to demonstrate that formal regulatory mechanisms are not the only components of the system. The report frames oversight in a very inclusive and comprehensive way, to include federal and state governments and regulatory agencies, standard-setting organizations, knowledge-generating organizations, private and public sector health care payers, professional societies, health providers, and patients and consumers.

The report was organized in seven chapters and makes 16 recommendations, a little bit fewer than the PGx, that address a number of gaps in the oversight of genetic tests.

The report was released for public comment on November 5th, and this comment period will end on December 21st. To encourage broad input from a wide range of stakeholders, we used several outreach mechanisms, including the federal registry, our website, and a targeted mailing of about 2,000 individuals and organizations. We have also encouraged a number of organizations to inform their members on the opportunities to comment on the report.

This is a snapshot of the website where the report can be downloaded. I will show you the URL in a moment.

We reached out to many stakeholders, including representative nonprofit organizations, advocacy groups, professional organizations, policy groups, healthcare providers, industry, laboratories, government agencies, and other advisory committees. We want to be very inclusive of trying to get public comments back to us.

After the comment period ends, our work will intensify in order to meet the Secretary's request for recommendations by February. The comments will be analyzed and summarized. A lead for each chapter of the report will be tasked with considering the comments and making revisions. As needed, they will call on taskforce members for their expertise.

The steering group, which is five members of the SACGHS members and the taskforce, will have weekly conference calls in January to assess the progress. On January 23rd, the entire taskforce, with the 33 members, will discuss revisions to the recommendations.

At the end of January, we have planned a conference call for the steering group to brief the full Committee on revisions to the recommendations in preparation for discussions of the February meeting. Following the February meeting, we will make revisions to the recommendations to reflect the Committee's input and submit the final recommendations to the Office of the Secretary by the end of February. The final report will be formally submitted in April.

This is the report URL. It is available for downloading.

DR. TUCKSON: Andrea, you have laid it out very nicely. I just want to make sure that in terms of your guidance to your colleagues around the table, once they have had a chance to see the public input at the end of December and have their own reactions and ideas based on that, and revisions to the report that the Committee has put out there, are they encouraged or will they have an opportunity to submit or participate in the taskforce's deliberations in early January so that their thoughts can be considered in that process prior to it coming for final deliberation to the full Committee?

DR. FERREIRA-GONZALEZ: That's correct. We are very keen on those two particular events. The full taskforce with the 33 members will have a discussion of what we come up with, and then we will bring the SACGHS members, again through another conference call, to tell them where we are with changes to the recommendations to start engaging them and just putting them in the mind frame for the further deliberations that will occur in our February meeting.

DR. TUCKSON: Just to be clear, and you are being responsive, and I appreciate it, because I have a suspicion that certain members of the Committee will be provoked at one point or another to either modify some thinking that they may have had, or had new insights, or we have new members of the Committee, so that they aren't in a position of only being reactive downstream, I think what you have said is that they have mechanisms by which they can get their comments in as the river is flowing, even as they, of course, reserve their right to comment on it once it is more set.

So it is a fluid process. I just want to absolutely emphasize it is a fluid process and you are encouraged to participate in the fluidity of it even though you are going to have some formal deliberations and react to it once it is more gelled.

DR. FERREIRA-GONZALEZ: Thank you, Reed.

DR. TUCKSON: Francis, you had a quick question?

DR. COLLINS: I really appreciate your clarifying that, because we are doing this in a somewhat different process than we have sometimes followed for these reports, by getting the public comment at this point. It is very important to find out what the public thinks. In some instances,

that might imply we were already at the penultimate stage where the Committee had essentially already achieved consensus.

I think in this instance the Committee is still wrestling with some of those issues, and I'm glad to hear you endorse the fact that there is still plenty of opportunity here to reconsider what the final product might look like. We should not consider that we have already passed that point.

DR. TUCKSON: I think that is important. What we would say is that we have put forward some considered ideas and thoughts for the public to respond to. We tried to be respectful of the public by giving them something that was legitimate to consider but not so far along the road as to make their input not substantive and meaningful.

So we have tried to strike a very real balance. We gave out something that was serious for people to think about, which we believe we have done, and now we will undertake the process that we have outlined. So we believe we have struck a pretty good balance in all of that.

I'm glad that we have gotten that issue and clarified. I urge you all to participate to the degree that you would like as this stream flows, even though you will still get a chance to respond reactively once it has completely gelled in late January.

DR. FERREIRA-GONZALEZ: Great. Thank you. Let us now turn our attention to Mr. Stuart Hogarth and Dr. David Melzer, who will provide analyses of the oversight of genetic testing.

Mr. Hogarth is a visiting research fellow at the Institute for Science and Society at the University of Nottingham. Dr. Melzer is a professor of epidemiology and public health at the Peninsula Medical School in Exeter, England.

We will have 40-minute presentations, followed up with a 20-minute discussion.