

Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Good morning. I was not worried about there being snow, and then I checked with Francis. Francis gave me the thing again, because he's got a computer with the weather thing on it. But we're going to press through today because we really do have an awful lot to accomplish over the next two days, so we'll do our best. If it looks like tomorrow is going to be bad, we'll worry about that as we go along and try to be sensitive to people. But right now I think we'll put that out of our mind and focus on the agenda as it's before us.

Let me just say that the public has been made aware of this meeting through notices in the Federal Register, as well as announcements on the SACGHS website and listserv. I really want to thank everybody that is here in person, but also I do want to make sure the committee members are aware and are appreciative of the webcast.

I didn't realize this, Ed, you didn't warn me, but emails come in during the process of the meeting. So there are a lot of people out there who are actually paying very close attention to what you say. They're okay with me, but apparently it's you. So just be aware that there's a lovely interaction from people back and forth, and we appreciate that.

Also, for those who have sent emails asking about the meeting minutes from October, those will be up shortly. We do know that those hadn't gotten up from our last meeting, but they will be, I'm assured. So I just want to make sure that those who have asked about that are aware.

I want to welcome two new people to the committee. We are very pleased that Dr. Joseph Telfair has joined us from the Department of Maternal and Child Health, the School of Public Health at the University of Alabama at Birmingham, where he is an associate professor. He holds a Doctorate of Public Health from Johns Hopkins and an M.S.W. and M.P.H. from the University of California at Berkeley. His work is focused on health care access issues for the poor, rural, multicultural, multiethnic populations, as well as has been a very strong advocate for patients with chronic diseases, particularly those with sickle cell disease.

Dr. Telfair is also serving as the SACGHS liaison to the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. We thank you for taking on that role. We will hear about that committee's work some more today, so we are very appreciative of that. Joe or Joseph? How would you like to be called?

DR. TELFAIR: Either one is fine.

DR. TUCKSON: Well, Joe, welcome aboard and we thank you for being part of this. We are also pleased to welcome Father Kevin Fitzgerald, who joins us from the Department of Oncology at Georgetown University Medical Center, where he is the Doctor David Lauer Chair in Catholic Health Care Ethics, as well as a research associate professor. Father Fitzgerald received dual Ph.D.s in both philosophy and molecular biology from Georgetown University. His research on oncogenes has most recently focused on tumorogenesis of the MLL and the MLL2 genes. Father Fitzgerald will be participating in this meeting as an ad hoc member while the processing of his appointment papers is completed.

But, Kevin, you are fully on board here and we're going to expect you to work just as hard as Ed McCabe. There is no grace period.

We are pleased that Dr. James Rollins will represent the Centers for Medicare and Medicaid Services. Thanks a lot, Dr. Rollins. As well as Dr. Willie May, who is representing the Department of Commerce for Dr. Semerjian.

Dr. Melissa Fries will represent the Department of Defense for Colonel Martha Turner. I think she must be on her way.

Kim Zellmer will be joining us later today. Chris Hook can't be in person but will be participating by teleconference later this morning and tomorrow morning, and Joan Reede is, unfortunately, unable to attend this meeting.

Well, as you know, Mike Leavitt was approved as the new Secretary of Health and Human Services, sworn in on February 11th, 2005. Let me just say that I want to express my own appreciation for former Secretary, Tommy Thompson, who was very gracious and very helpful and received our committee's reports I think with great interest and responsibility, and we hope that he is doing well. But we are very pleased now to welcome the new Secretary of Health, Michael Leavitt.

As you know, he's former governor of Utah and served most recently as the administrator of the Environmental Protection Agency. We're trying to go through the process of getting on his schedule. It hasn't happened yet but I'm sure it will soon, and we'll have an opportunity to update the Secretary on the work of this committee.

Well, behind you on the chart is the strategic plan and our study priorities. I put that up there again just to remind you that this committee is very focused on its agenda. Once again, I have to give acknowledgement to the leadership of Ed McCabe, and as I take over now and continue the stream of activity, I want to make sure that we keep in front of us what we have agreed to do and we always understand what it is we are responsible for trying to complete.

Last March we did identify these 12 issues that we thought warranted various levels of attention by the committee. In August of 2004, we did submit a resolution to Secretary Thompson on genetic education and training, which is the second dot there. By the way, genetic discrimination, the number-one item on the list, we will of course be spending a great deal of time with today, and we'll talk a little bit more about that. But we did submit the resolution on genetic education and training which made nine recommendations aimed at ensuring the adequacy of genetics and genomics education for all health care and public health professionals.

The next one on our list is patents and access, and as you know, we received an extensive report on that at the last meeting and we are awaiting the latest developments from the National Academy of Science and their work, and I think we left that last discussion assured that this is moving forward with thoroughness and deliberateness, and I think we need to see what they deliver back to the process.

The overall oversight by the federal agencies stays on our minds, and that is one that we track regularly and consistently. Then there is the vision statement report, which of course we have also submitted to the Secretary, and it will be one of the main items on the agenda when we have the opportunity to meet with Secretary Leavitt.

In 2004 we sent a letter to the Secretary expressing concern about the potential harm to consumers from direct-to-consumer marketing of genetic tests and services, requesting HHS to collect data on the public health impact of the DTC marketing, and to collaborate with the Federal

Trade Commission on the monitoring of such advertising. We have sent this forward to the Secretary as well. That is in your briefing books. I believe that letter is there. For those who are monitoring us through the Web, you can find that report on the website.

Let me just see what else we have on the list. The coverage and reimbursement is obviously the subject of today, large population studies tomorrow. Pharmacogenomics, we have a task force. Emily Winn-Dean chairs that, and we will be coming to that. We didn't have time in the agenda for today and tomorrow, so that is an issue we'll be coming back to visit very soon. I mentioned the direct-to-consumer.

Access is an issue that cross-cuts all of the other issues, and I think that we view the coverage and reimbursement issue to be a key issue for access. So we will be hitting that mark as we do the coverage and reimbursement discussion.

The public awareness and understanding issue is one that I would like just to take 10 seconds to put in front of the committee. I still, at least as one observer, am concerned about how well the public is prepared to understand the issues that are before them with this new revolution, integrating it into the personal health care decision-making, the counseling activities and so forth. I'm not going to ask for any action on that issue today, but maybe by tomorrow we might think about whether or not we need to convene at least some kind of a discussion with the best folks in the country and in the government who are thinking about this issue of what are we doing to educate the public.

I just know every single day in terms of the world in which I'm working and living that the individual American is expected to integrate extraordinary amounts of information as they take on more responsibility for their health care decisions. The last item on that agenda says "genetic exceptionalism," and clearly the issues of genetics are so intertwined now with so much of the health care system, and whether or not the public is adequately being prepared or other steps can be done, whether through elementary school, junior high school, high school education, whether it is through the kind of pamphlets and education that the government puts out as a normal course of what it does, I'm not sure, but I just think we need to start thinking about that as an issue. But at the end of the day, we've got to stay focused on what we have in front of us, and I don't want to take us too far afield. So I will leave that there and see if, at the end of the meeting, people have any thoughts.

Well, let's go straight to the agenda that we now have, and you will see that at the very beginning of your booklets. We will start the meeting with an update on our efforts on genetic discrimination and what has occurred since October. As you are, I'm sure, all aware, there have been a great deal of activities since October. So there will be a full committee discussion in light of those activities on our next steps, keeping in mind that the goal of our discussion is to determine what is the appropriate steps that we should take as a committee to push forward and add our own unique opportunities to add value to protecting against genetic discrimination, or in this case as we also understand, equally important, the fear of genetic discrimination in employment and health insurance through federal legislation.

We will spend this afternoon considering coverage and reimbursement, the in-depth high-priority issue that we ranked the highest, which has been the focus of much of our work over the past year. We will review a revised draft report on the issue, developing a consensus on 12 recommendations that have been made and discussing strategies for gathering public comments on the draft report. During our deliberations we will be briefed by the Genetic Counseling

Services Work Group, which was formed after our October meeting to respond to our request for evidence supporting the value and effectiveness of genetic counseling services.

We also classified large population studies as an issue warranting in-depth study. We need to learn more about large population studies and what scientific, public health, ethical and policy issues they raise. We're devoting five hours tomorrow to an exploration of the issues associated with such studies. By the end of the 10 presentations we have organized on this topic, we will need to determine what next steps, if any, we wish to take. So again, we'll need to determine what next steps, if any, we need to take.

In addition, as we agreed at the last meeting, we'll begin hearing updates and briefings on three other important issues that we need to be aware of. First, following the genetic discrimination update this morning, we will be briefed about the National Health Informatics Initiative. This topic was introduced during our discussion of the Surgeon General's Family History Initiative at the October meeting, and we want to consider how genetics, genomics, and family history information will be incorporated into this broad initiative. While we certainly did focus this and got into this through the Family History Initiative, I think that the events are moving so rapidly now in the area of health information integration that it will have very broad implications for every part of health care, and I think it is important for many reasons that we hear and listen carefully to that report.

After the NHII briefing we will hear a report on the newborn screening recommendations that have been made by the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children, which is a report that has been of great interest to many.

Tomorrow afternoon we will be briefed about a collaborative public/private effort to promote quality laboratory testing for rare diseases. This briefing resulted from a specific request by CDC for feedback from our committee on their efforts. So due to this very full agenda, as I mentioned, we will not be having a session on pharmacogenomics at this time, but we will be looking forward to that coming forward.

Public comments sessions are always appreciated. This committee is committed to great respect for listening to the public, and as such as we have public comment on both days of our meeting. Seven individuals so far have signed up to provide testimony, so that is just terrific and we're pleased about it.

Finally, I'd like now, in closing out this part of the meeting, to have Sarah Carr give us the reminders of all of the very serious rules that you are under. You can barely breathe without being in trouble, so watch out.

MS. CARR: Thank you, and good morning, everyone. I'm actually only going to talk about two of the rules today. One is the conflicts of interest screening process and the need to be attentive to conflicts of interest during the meeting.

As you know, before every meeting you provide us with information about your personal, professional, and financial interests. It's 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 interest 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.

Lobbying. Since we're going to be talking about congressional affairs and legislation in a minute, I did want to remind the committee that as government employees, and you're special government employees, we're prohibited from lobbying, and thus we cannot lobby, not as individuals or as a committee. If you lobby in your professional capacity or as a private citizen, it's important that you keep that activity separate from the activities associated with this committee. Just remember that this committee is advisory to the Secretary of Health and Human Services. We don't advise the Congress.

We appreciate your attentiveness to these two rules and all the others that apply to you, and we appreciate how conscientious you are about them.

DR. TUCKSON: Well, with that admonition to be attentive, and with the reassurance that we're all special –

(Laughter.)

DR. TUCKSON: By the way, let me just ask, does anybody on the committee have any opening issues, anything you want to put on the table early or anything before we launch into the agenda?

(No response)