

Opening Remarks
Reed V. Tuckson, M.D.

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

A couple of quick housekeeping notes so that you all are aware. Your Blackberries, when they get information, the electrical pulse at 18.7 megahertz -- I made that part up -- goes right into the speakers and we get that [static] sound. So move your doggone Blackberries way the heck away from the thing or turn them off. The same, by the way, for your cell phones. So the first person that [causes static], we are going to make you feel badly.

The other thing is to turn the mics on, you push the button. You will see a light. That way you will be heard.

The other thing is, right now the webcast video is not on yet, through some technical issues unrelated to our crack team of dedicated folk in the back there, who are wonderful by the way and whose work we really appreciate. So the audio is on through the Internet but not the video, so you have that.

The public was made aware of this meeting through notices in the Federal Register as well as announcements on our SACGHS website and listserv. I want to welcome members of the public who are in attendance as well as the many listeners tuning in via the webcast. Thank you all for your interest in our work.

Before I get into the substance of my opening remarks, I do want to point out, to the Committee's great joy and happiness, that my term on the Committee is ending with this meeting.

[Laughter.]

DR. TUCKSON: The Secretary has made a very wise choice, and that is that Steve Teutsch will now be your new chair. We decided that it would be fitting to make the transition on day two of the meeting, and so as of tomorrow morning the gavel will pass to Steve. I am absolutely pleased that the Secretary has made a tremendous choice, and good luck to you.

At the beginning of each meeting I take a moment to review our strategic plan and the status of our progress in fulfilling each of our study priorities. This gives us an overview of what we have accomplished to date. Today I need to really ask for your forgiveness because I'm going to go through this in some great detail today.

I think it is very important that this Committee, especially [because of] the fact that we have so many wonderful new members to the Committee, that you have a real sense of what we have done and where we are in our process because we are going to, at the end of the day tomorrow, have a priority-setting review process in which will have a much more in-depth discussion of where you are headed for the future. So tomorrow we will kick off a process of brainstorming about the issues that may warrant the Committee's attention.

With that, if you will look at the slides that are available, let me just start with the vision statement.

[PowerPoint presentation.]

DR. TUCKSON: That vision statement, which described our priority issues and how we reach them, was developed in 2004 and has consistently guided our work as a Committee since then. So one of the things that you may wind doing at the end of the day is to revisit that vision statement.

But ultimately, as you see the timeline, we began in October 2003. In March of '04 we did the priority-setting, the discussion, and then in December '04 the report.

Public concern about the misuse of genetic information and genetic discrimination has always been our highest priority issue. We have written three letters to the Secretary championing the enactment of federal legislation to prohibit discrimination based on genetic information by both health insurers and employers.

In early 2005, we provided the Secretary with a legal analysis of the adequacy of current law regarding genetic discrimination. We provided him with a compendium of public comments documenting public fears about genetic discrimination and a compelling 10-minute DVD of compelling testimonies we received from the public in the fall of 2004.

We strongly support genetic information non-discrimination and the Genetic Non-Discrimination Act of 2007, commonly referred to as GINA, which would protect individuals from discrimination based on their genetic information, including their family history information, by employers and insurers.

GINA has dedicated supporters on both sides of the political aisle, and in April of '07 it passed the House by a vote of 420 to three. Secretary Leavitt voiced support of legislation, and the President is also on record as supporting such legislation.

However, last July, Senator Tom Coburn placed a hold on the bill. In the last few days of '07, Senate leaders attempted to attach GINA to the Fiscal '08 Omnibus Spending bill but were unsuccessful. An article from the January 14 issue of Congressional Quarterly, which is in your table folders, provides more background on the current situation.

Proponents of the bill who are in dialogue with congressional leadership are hopeful that the procedural hold will be dropped and that GINA will be brought to the Senate for a vote early this legislative session.

In June of '04, we developed a resolution about the importance of educating and training health professionals in genetics and how these efforts could be enhanced. At our last meeting, we convened a roundtable on this topic, during which it became apparent to us that there still are critical needs in education and training.

As such, we created the Genetics Education and Training Taskforce, which is chaired by Barbara Burns McGrath. Tomorrow Barbara will present the charge of that taskforce and we will discuss and finalize that charge so that this important taskforce can then proceed with its work.

In '06, we transmitted a report and recommendations to the Secretary on coverage and reimbursement of genetic tests and services. The report highlights limitations of the healthcare system that are affecting patient access to genetic tests and services and identifies nine steps that can be taken to overcome these limitations.

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The recommendations cover a range of topics, including evidence-based coverage decision-making, Medicare coverage of preventive services, the adequacy of billing codes for genetic tests and services, billing by non-physician genetic counseling providers, and genetics education of health professionals.

In July of '07, CMS sent feedback to us on our recommendations. A small group of our committee led by the terrific Marc Williams reviewed CMS's comments and found several areas that required follow-up with CMS.

In December, we had a very encouraging call with CMS leadership, and Dr. Barry Straube in particular and his staff. A summary of that call can be found also in your table folders.

There are two important messages that we want to emphasize that we took away from that call. Number one, the eagerness on the part of CMS to learn more about and be more actively involved in various genetics-focused initiatives within HHS and its agencies, particularly in the area of family history initiatives and CDC's EGAPP program.

Second, we were impressed by CMS's eagerness in taking and in continuing to move forward in how personalized medicine, genetics, and genomics are transforming the modern healthcare delivery system. Their eagerness was clear in wanting to explore how the Medicare program can take advantage of the opportunities and benefits that genetics has to offer while also, of course, being fiscally responsible.

We provided Dr. Straube and his team with information that will help them pursue these goals, and we identified for them some areas that we think they should take a closer look at as they proceed with their self-examination.

Two years have passed since we transmitted our recommendations to the Secretary, and while we are excited by the leadership of the CMS team in taking action on our recommendations, we have also been clearly impressed that some of our recommendations, in the opinion of CMS, will require legislative authority that they currently do not have if they are to act on at least one of our key recommendations, particularly the one that is involved with urging Medicare to cover services indicated by a family history of disease.

This is so important to us that I recommend that we write the Secretary calling for legislation or asking the administration to push for legislation to give them the authority to act.

Also, since the coverage report was written, there have been some developments related to billing for genetic counseling services. These developments are technical in nature, and I won't review them here, but they essentially affect genetic counselors' options when billing Medicare for their services.

In light of these developments, I think we should also ask the Secretary to clarify genetic counselors' billing options. Some legislative action may be needed to remedy the situation depending on the nature of the response.

Although it was not part of our '06 coverage report, I believe this new recommendation is consistent with the spirit of the report. A draft letter addressing these two issues will be distributed to you later today.

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I want the Committee to take a look at the letter and let Suzanne Goodwin know if you have any changes to suggest.

They will be distributed later. You will get them today. If you have any questions about it, let Suzanne know that you have issues off to the side. Then we will take a sense of it and, if necessary, we will have a discussion about it. If it is straightforward, then we want to get it into the hands of the Secretary as quickly as possible.

I think the Committee all know and understand that we cannot ourselves push for legislation. It has to go through the Secretary. That is why we are taking this step.

In '05 and '07, we wrote two letters to the Secretary on the issue of direct-to-consumer marketing of genetic tests. Our efforts in this area led to enhanced collaboration among FDA, CDC, CMS, NIH, and FTC. In '06, a consumer alert was issued by the FTC to warn consumers about using at-home genetic tests that have not been evaluated and to be wary of the claims made by companies marketing these tests.

As part of the Personalized Healthcare Initiative, the Secretary's Office is organizing an informal workgroup that includes various HHS agencies and FTC to explore direct-to-consumer genetic testing services.

This Personalized Healthcare Initiative Workgroup will be discussing the roles and responsibilities of federal agencies in direct-to-consumer marketing and performance of genetic tests, challenges associated with communication of complex genetic information to the public, and assessment of the services offered by various companies engaged in direct-to-consumer marketing, including the quality of information provided and confidentiality provisions. We are actually very pleased by the push that we have done and the response that is occurring.

Regarding the issue of large population studies, the Committee's final report, Policy Issues Associated with Undertaking a New Large U.S. Population Cohort Study of Genes, Environment, and Disease, which we need an acronym for because no human being can say that again in one breath, was completed in March 2007 and transmitted to Secretary Leavitt. A downloadable PDF version is available on the SACGHS website. We will be looking further into the status of the Secretary's response to the report and recommendations.

In November I mentioned that there was an article in the journal Social Science and Medicine about the report. We drafted a letter to the editor of the journal that clarifies the scope and goals of the report, which you had an opportunity to review and comment on in the November meeting. That letter is now going, we understand, through the journal's review process. A copy of the final letter is provided at your table folders.

For more than two years we have been developing a report on the opportunities and challenges associated with pharmacogenomics research, development of pharmacogenomics products, and their incorporation into clinical practice and public health.

In March, the draft report was released for public comment. These comments were carefully considered over the summer and the fall. In November we finalized the recommendations. The final report and recommendations will be delivered to the Secretary in March, after copy-editing and printing are completed. The report will be made available to the public 30 days after we give it to the Secretary, which is provided, of course, as a courtesy to the Secretary to give him and his staff time to review it.

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Although the report has not yet been formally transmitted to the Secretary, we do note that the America's Health Information Community, AHIC's, Personalized Healthcare Workgroup, is actually already reviewing our pharmacogenomics recommendations in the areas of electronic health records, clinical decision support tools, data sharing, and database interoperability as they begin to explore how pharmacogenomics test information can be used for disease management.

There is additional information about the Personalized Healthcare Workgroup's activities on pharmacogenomics, family history, genetic tests, and newborn screening in your table folders.

We have been monitoring the work of this group closely through our liaisons, Steve, Andrea, and Marc.

Marc, let me just ask you, is there anything specific that you would like to mention about the work underway by AHIC or its PHC workgroup?

DR. WILLIAMS: Just to mention that it is moving very quickly. Again, there is a lot of energy behind this and the recommendations that have come through relating to the use case.

The use cases are the things that the AHIC workgroup has developed to basically lay out the landscape and allow the Office of the National Coordinator of Health IT to be able to say what do we have in terms of available standards and what gaps are there that need to be filled with additional coding standards.

That is moving very quickly. Our use case is out for public comment I think for another two days. Then we will go into final form, which will allow it then to move, by the end of the year, through the standards analysis.

So this is an exciting time. Those of you who have read the entire report on oversight will also recognize that there are references to the AHIC there. I think it will be incumbent on this group to work very closely with the AHIC and particularly the Personalized Healthcare Workgroup because a lot of the problems and gaps we are identifying are ones where potential solutions reside within that group.

DR. TUCKSON: Of course, everyone has read that report cover to cover.

DR. WILLIAMS: I have read it about five times, so those that are slacking off --

[Laughter.]

DR. TUCKSON: You bring the curve up.

The work with AHIC is absolutely transformative for the future of American medicine. So I think that everybody really needs to continue to focus in on this as the Committee moves forward in the months and years to come.

In June of '06 we decided to move forward with the study on the impact of gene patents and licensing practices on patient access to genetic technologies. Since then, the taskforce hosted a progress session on this issue and a roundtable focusing on international perspectives.

You will recall that we have been working with Dr. Bob Cook Degan and his group at Duke on case studies that evaluate the impact of gene patents and licenses on patient access to genetic tests

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for hemochromatosis, breast and colon cancer, cystic fibrosis, congenital hearing loss, Alzheimer's disease, and Tay-Sachs disease. These case studies will illustrate lessons learned in diagnostic development, commercialization, and adoption of patented versus unpatented genetic tests.

We expect these case studies to be completed within the next few weeks. Once we receive them from Duke, they will be used in the development of a draft report and recommendations on gene patents and licensing. Report development will occur during the spring and summer of '08. The taskforce anticipates releasing a draft report for public comment by the early fall, with a final report targeted for mid to late 2009.

Jim Evans, chair of our Patents Taskforce, recently presented an overview of our work on gene patents to another HHS advisory committee, that being called the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborn and Children. That committee is interested in this because many newborn screening tests are administered as panels and patchy intellectual property protections may limit access to these tests.

Jim's presentation, as always, was well received, and audience members offered advice on additional areas to explore as the Patents Taskforce moves forward with its work.

Some issues of mutual interest to our Committee and the Advisory Committee on Heritable Disorders include informed consent, mechanisms to assess clinical utility evidence, and education of healthcare workers and families.

In March of '07, we were asked to respond to a series of questions posed by the Office of the Secretary on the adequacy of the oversight system for genetic testing. An extraordinary 33-member taskforce, chaired by Andrea, was formed to develop a report in response to the Secretary's charge.

Through the dedicated efforts of the Oversight Taskforce, the draft report was released for public comment November 5th through December 21. In response, we received 64 sets of public comments that have been carefully reviewed and considered by members of the taskforce and staff. A summary of these comments is included under Tab 3 in your briefing booklet.

Most of our agenda today and part of tomorrow will focus on a review of the draft recommendations that have been revised in response to the comments received.

Our first goal for this session, and let me be very clear, is to finalize the recommendations for submission to the Secretary by the end of February. Our second goal is to receive approval on the spirit of the final report so that it can go through final editing and be transmitted to the Secretary in April.

Our commitment to the Secretary based on the charge to us, his Advisory Committee, is that we have to get this to him by April.

I want to be real clear again. We have been asked by the Secretary to do this work. We have responded as urgently as we can. We have been extremely diligent about the process, but we have to bring it in by April.

I also want to just make sure that everybody also appreciates the amount of public comment that we have received and, I will tell you, the diligence with which we have gone to every stakeholder

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organization that we can find out there in the country to give us their comments. We have just beaten the bushes on this thing. So I just wanted you all to understand how seriously we have taken this process.

Finally, you will notice that when we start this discussion in today's meeting, the public comment will be first. That is to make sure again that we get as much public comment before we start our deliberations. I am extremely focused on the meticulousness of the process here as we go forward.

You may recall that in March of '07 we decided to take up a new priority based on two proposals that we heard: one, the economic consequences of genomic innovations, and second, the evaluation of the impact of gene-based applications on real-world outcomes. We integrated these two together into one topic that would explore what we call the translational analysis for public health and clinical care and a viable economic model that could sustain the work. The taskforce appointed to lead this effort was given the shorthand title of the Evaluation Taskforce.

Because of potential overlap with the Oversight Report, work on this new issue was put on hold. So during the priority session in July you will have the opportunity to revisit this topic, along with any other new issues that you have identified or will identify.

Finally, the cross-cutting issues of access, public awareness, and genetic exceptionalism have been integrated into all of the work that we have been doing. So those have served as a foundational commonality of everything else that we have done.

Well, that took a while. Quite frankly, I'm kind of proud that it took a while. This is one heck of a Committee.

[Applause.]

DR. TUCKSON: I think you all understand that you all are not lazy. The staff is definitely not lazy.

We have a legacy of work here. I'm also thinking, though, that it is absolutely time and appropriate to revisit where we are now with this template. As we, I think, are at a nice transition point by tomorrow, not only do we have a new leader but also so many wonderful new voices on the Committee, it is a real nice time to take stock of everything that we have done, where we are in the middle, and then figure out where do we need to be to continue to be relevant for the future. So I'm excited.

Now we are going to turn to Sarah about a reminder about ethics rules.

Let me say that I sometimes, in addition to being light-hearted about mangling names -- "Gubernot" --

[Laughter.]

DR. TUCKSON: I actually can do it when I want to.

I also sometimes sort of joke about the theologic tone of what we want Sarah to do when it comes to the conflict thing. Today I'm going to be, actually, very serious and somber about it because I'm emphasizing two things in today's meeting. Number one is, again, the absolute

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sacrosanctness of the public comment process and getting that input. Secondly is a meticulousness that we always have had and will continue to have around conflict of interest.

I think this is very important, so this time I'm not going to actually tease Sarah about this because I really do want to bring a certain gravitas to her comments. Sarah.

MS. CARR: Thank you, Reed. As you all know, you are special government employees when you serve on this Committee. As such, you have to follow the rules that apply to regular government employees. I'm going to highlight two of those rules today, the rule about conflicts of interest, and because we are so close to the Capitol, the rule about lobbying.

Conflicts of interest. Before every meeting you provide us with information about your personal, professional, and financial interests. 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 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 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 have 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.

Government employees are also prohibited from lobbying, and thus we 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 activities associated with this Committee. Just keep in mind that we are advisory to the Secretary of Health and Human Services. We don't advise the Congress.

As always, I thank you for being so attentive to the rules of conduct. Thank you.

DR. TUCKSON: Thank you very much, Sarah. Again, I think the hallmark word of everything that this Committee has been about and will continue to be about is transparency. This is all extremely transparent, and we actually will keep to that.