

***Opening Remarks***  
**Ed R.B. McCabe, M.D., Ph.D.**

---

DR. McCABE: Well, good morning, everyone, and welcome to the fourth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. The public was made aware of this meeting through notices in the Federal Register, as well as announcements on the SACGHS website and listserv.

First, I want to begin by taking note of some changes in our membership. We are very pleased to welcome a new ex officio member, Dr. Howard Zucker, who is the Deputy Assistant Secretary for Health and is representing the Assistant Secretary for Health in the Department of Health and Human Services.

Dr. Zucker trained in pediatrics and has held faculty appointments at Yale University School of Medicine, Columbia University College of Physicians and Surgeons, Cornell University Wyle College of Medicine, and the National Institutes of Health. Dr. Zucker also served as a White House fellow and worked at the Center for Space Research at MIT. Welcome.

Dr. Steven Gutman, Director of the Office for In Vitro Diagnostics Evaluation and Safety, has been named as the new ex officio for FDA, replacing David Feigal, who recently accepted a position at NDA Partners, a product development consultancy to the biopharmaceutical and medical device industries.

In addition, we welcome Joe Hackett from the Food and Drug Administration, filling in for Dr. Gutman this morning, and Dr. Hratch Semerjian, Acting Director for the National Institute of Standards and Technology, will be representing the Department of Commerce for Arden Bement, who is currently Acting Director of the National Science Foundation.

Also, Dr. Steve Phurrough will be substituting for Sean Tunis today. Dr. Phurrough is Director of the Coverage Analysis Group at the Centers for Medicare and Medicaid Services. Judy Yost will be here tomorrow representing CMS.

Dr. Sherrie Hans will represent the Department of Veteran Affairs for Ellen Fox. Ms. Amy Turner is here representing the Department of Labor for Tom Alexander. Welcome to everyone.

I also want to explain a couple of absences in the membership. Christopher Hook will be joining us later today. Hunt Willard will join us tomorrow, and may be able to participate for part of today's meeting by phone. Reed Tuckson will be joining us by phone this morning for the remainder of the day.

Eric Lander is also not present. Last week, with great regret, Eric resigned from the committee, due to extensive commitments and responsibilities as Director of the new Broad Institute of MIT and Harvard that prevents him from having a more active role in the committee's activities. Eric told me that he very much wishes to stay involved in the committee's work, and I promised him that he would become a distinguished member emeritus and that we would feel free to tap his expertise as needed. The Secretary will be appointing a new member to take Eric's place in the very near future.

Before I review today's agenda, I would like to remind everyone that at the end of the March meeting, we set some extremely ambitious goals in preparation for this meeting. We planned a

*SACGHS June 2004  
Meeting Transcript*

number of short-term actions, including sending a second letter to the Secretary in support of federal genetic nondiscrimination legislation.

We decided that education and training of health professionals in genetics was a high priority issue, and that after additional fact-finding on genetics education efforts, we would be equipped to consider a resolution regarding these efforts at this meeting.

An Education Task Force chaired by Joan Reede has been hard at work gathering data and drafting a resolution for our consideration today. The committee also decided to prepare a report describing SACGHS' mandate and priorities, and providing background information policy considerations on priority issues.

Sarah Carr and her staff, with the assistance of Emily Winn-Deen, prepared a draft vision report for our consideration. In March, we also identified high priority issues that require more in-depth study. Coverage and reimbursement of genetic technologies and services was identified as the first topic on which we would focus our efforts.

Staff, with the assistance of Cindy Berry, carried out additional data and information gathering, and prepared a draft report for our consideration. This afternoon, we will be discussing the draft, and developing recommendations for the Secretary.

Three other issues were also identified as warranting in-depth study. Large population studies, pharmacogenomics, and direct-to-consumer marketing. Our in-depth work on these three issues will begin at future meetings. With regard to the direct-to-consumer marketing issue, we also decided to take a short-term step by drafting a resolution expressing concern about the proliferation of direct-to-consumer advertising of genetic tests.

A task force chaired by Chris Hook accomplished that short-term goal, and we will be considering the draft resolution tomorrow. For this meeting, we hope to finalize the two resolutions on education, direct-to-consumer marketing, and the report on our priority-setting process. Given the length and complexity of the coverage and reimbursement report, and the work that needs to be done to develop consensus recommendations, Cindy and I expect that we will want to continue refining the report and gathering additional public comment after this meeting.

We will begin the meeting with an update on the status of federal genetic nondiscrimination legislation by Dr. Joann Boughman. Following our discussions on genetic nondiscrimination, we will engage in a roundtable discussion on educational issues with involved professional organizations, and consider the draft resolution on education. The afternoon is dedicated to discussions of coverage and reimbursement of genetic technologies and services. Tomorrow we will hear a presentation from Dr. Muin Khoury about CDC's public health approaches to genomics, and deliberate on the vision report and direct-to-consumer marketing resolution.

Finally, we have allowed time to discuss the other issues we prioritized at the March meeting, and identify next steps. Let me also point out that we have public comment sessions scheduled for both days. We will hear comments immediately following lunch today, and tomorrow morning. Thus far, five individuals have registered to provide testimony. If there are others who wish to give public comments today or tomorrow, please sign up at the registration desk.

*SACGHS June 2004  
Meeting Transcript*

We have received a considerable number of written public comments on the draft documents as well, including requests that we provide additional time for the public to comment. The comments can be found in your table folders. As our deliberations on the draft documents proceed throughout the next few days, we will take careful account of the comments on each document.

At this time, we'll hear from Sarah Carr regarding conflicts of interest.

MS. CARR: Good morning. Being a member of this committee makes you a special government employee, and thereby subject to rules of conduct that apply to government employees. The rules and regulations are explained in a report called "Standards of Ethical Conduct For Employees of the Executive Branch." You each received a copy of this document when you were appointed to the committee, and I'm going to review one of the rules in that document.

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 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.

Let me add a sincere thank you to all of you for being so attentive to these rules. We know that the reporting process is time consuming, and we very much appreciate how conscientious all of you are about fulfilling your duties.

Thank you.

DR. McCABE: Thank you, Sarah.