

Opening Remarks
Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: Good morning, everyone. Thanks to all of you who fought the traffic and dealt with the airlines and the weather and assorted other travails of travel yesterday. Hopefully you had a great Thanksgiving. I appreciate everyone taking the end of their weekend to get here and be with us.

This is the 17th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. Just as a matter of record, 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 in attendance as well as viewers tuned in via webcast. Thanks so much for your interest in our work.

Please note that we have scheduled public comment sessions for this afternoon at 1 o'clock and again tomorrow morning at 10:15. We have several of you already registered to make comments, but there is room for others of you to do so. If you would like to make comments, please sign up at the registration desk just outside of the meeting hall so that we can get you on the list.

We have an interesting agenda. There are four main goals for this meeting. First, we are going to be reviewing a draft report that explores the question of whether gene patenting and licensing practices are having effects on patient access to genetic tests and determining whether the report is ready to be released for public comment.

Later today, as a follow-up to some of the issues discussed in our Oversight Report, we will take an in-depth look at some of the important federal initiatives to enhance quality and innovation of genetic technologies through standards development. Tomorrow we are going to continue to discuss and refine our future study priorities and plans. Finally, we will also discuss a draft progress report for the new administration.

At our last meeting, which was in July, in addition to preparing a progress report for the incoming Secretary, we decided to write a letter to Secretary Leavitt. We sketched out the main points of the letter during our meeting and finalized the text via Email after the meeting.

In addition to thanking the Secretary for the high priority he has given to effecting innovative policy strategies that harness public and private sector solutions and resources to address the policy challenges associated with the development of genetic technologies, we also took the opportunity to highlight several issues that we thought were in need of critical attention over the remainder of his tenure.

We urged the Secretary to move forward on one of our oversight recommendations by beginning to address the practical and legal questions surrounding the establishment of a national registry of laboratory tests, and taking steps to create incentives for laboratories to make their test menus and analytical and clinical validity data for these tests publicly available through gene tests, or at least post them on their own websites.

In the area of pharmacogenomics, we highlighted the importance of the FDA issuing draft guidance on the co-development of pharmacogenomic drugs and diagnostics. We also reiterated the need for changes in Medicare coverage and billing policies to facilitate the integration of genetic technologies based on family history of disease and to enhance patient access to genetic counseling services.

SACGHS Meeting Transcript
December 1, 2008

A hard copy of that letter is in Tab 7 of your briefing books. We have also made it available to those in attendance, as well as to the public generally through our website.

With regard to the FDA co-development guidance for pharmacogenomic drugs and diagnostics, we understand that there have been a series of meetings over the fall on the guidance and that work continues on that.

With regard to the other issues we have raised regarding coverage and reimbursement, I'm told we can expect to receive a letter from the Secretary addressing some of those issues as well.

I also want to take note of the report, which you see here on the screen, that Secretary Leavitt released about two weeks ago to provide an update on HHS efforts to advance personalized health care. The report discusses many of the issues that we have been addressing as a committee. It outlines some of the important steps that have been taken to advance personalized medicine, but also offers a frank account of how much more will need to be done before personalized health care is a fully developed and fully applied system.

The report contains case studies and commissioned papers that are very relevant to a number of the issues that we are likely to take up in the years ahead. It is available on the HHS website at the URL that you see on the screen. Those of you who are on the Committee should have received copies of that as well.

We have also seen significant progress on the family history front. A demonstration of the Secretary General's Family History Tool was shown on November 25th. Marc Williams was there and can regale us with stories of that. It is to be released in late December.

Several agencies -- CDC, HRSA, and AHRQ -- are supporting research and development through contracts and cooperative agreements to enhance the utility of family history in electronic health information to support risk assessment and prevention.

At our last meeting we not only acknowledged but we celebrated the signing of GINA, the Genetic Information Nondiscrimination Act, of 2008. The provisions of the Act do not take effect until next year. There is a great deal of focus on the implementing regulations that need to be developed. Rulemaking processes are underway throughout HHS and the Departments of Labor and Treasury and the EEOC.

We understand that a proposed rule will be issued soon by the EEOC on the employment provisions of the law. There are multiple teams working across the agencies on the health insurance provisions. The health insurance provisions take effect in May of 2009. The employer provisions start in November of 2009.

Guidance is also being developed for researchers and research oversight agencies. These are in clearance and we expect them before year's end.

I would also like to note that since our last meeting the work of the SACGHS Genetics Education and Training Task Force has proceeded under the dedicated leadership of Dr. Barbara Burns McGrath. The task force has formed three workgroups to examine the educational needs of healthcare professionals, public health providers, patients, and consumers. They are currently in a data-collecting phase and plan to begin drafting the report in February.

SACGHS Meeting Transcript
December 1, 2008

As part of this effort I would like to alert our ex officio representatives that they will receive a survey later this month from the task force. The survey will inquire about genetics education activities within your agencies. I hope you or your colleagues will take time to complete the survey, which should be returned by the end of January.

Also, during the course of information gathering, the task force learned that the Council on Linkages Between Academia and Public Health Practice was revising its core competencies for public health practitioners and academicians. Since competency in genetics is not currently addressed, the task force would like SACGHS to submit a competency that emphasizes the importance of understanding genetics and genomics as they relate broadly to public health.

The proposed comments are the first item under Tab 7. The council is accepting comments until December 15th. We would like you to review the proposal over the next two days and let Cathy Fomous know if you have any suggested edits.

In particular, I want to thank Sylvia Au and Joseph Telfair for really spearheading this and making sure that this gets in here. Thanks to you both.

Tomorrow we will be delving back into our discussion of future study priorities. You will recall that in July we came to preliminary conclusions about the issue areas that we thought needed to be pursued. Our goal at this meeting will be to come to a final consensus on the issues and agree on a work plan for addressing them. As we do this, we will be mindful of the need to factor the priorities of the new administration into our ultimate work plan.

To this end, we will also be discussing a draft report to the new administration. In July we agreed that this report should take the form of a concise summary and that it should discuss the growing importance of personalized medicine and the complex issues it raises. It should sum up our work and key recommendations over the past six years and outline the issues that will need attention going forward.

The report should also serve as a vehicle for ascertaining how we can be most helpful to the new Secretary and make clear that we are ready to adjust our priorities as needed.

We are in a time of transition in more ways than one. This will be the last SACGHS meeting for several of our ex officio members: Scott McLean, Matt Daynard, who will be joining us tomorrow, and Steve Gutman, who will be retiring from federal service at the end of the year.

Let me say we deeply appreciate your service on this Committee and your many contributions to our work. We have admired your commitment to public and military service and your dedication to fulfilling your agencies' important missions.

Steve, I know you were involved in SACGHS's predecessor, the Secretary's Advisory Committee on Genetic Testing. All told, you are probably among the longest-serving ex officios. For that you deserve special recognition and an extra measure of our regard and appreciation.

To all of you, we wish you the best in all your new endeavors.

[Applause.]

DR. TEUTSCH: We know that FDA and DOD will be appointing new ex officios, and we will look forward to seeing those new faces and working with them.

SACGHS Meeting Transcript
December 1, 2008

Matt Daynard's replacement at the FTC will be Sarah Botha, an attorney in the Division of Advertising Practices. She should be here tomorrow and we will meet her then.

I also want to take this opportunity to thank Joe Boone, who I don't believe is here, and who is the associate director for science in the Division of Laboratory Systems at CDC, for his contributions to SACGHS and SACGT over these last 10 years. Joe is also retiring at the end of the year. I have known Joe since my CDC days, so I have known him for about 30 years.

There has also been a transition at the EEOC. Peter Gray, who served as Commissioner Earp's alternate for a number of years, has moved to the Civil Rights Division of the Department of Justice. We have appreciated Peter's dedication very much and know that before he left EEOC he was working on the development of the regs implementing the employment provisions of GINA.

EEOC will now be represented at the staff level by Kerry Leibig, a senior attorney advisor in the EEOC's Office of Legal Counsel. Kerry will be joining us tomorrow as well. We welcome her to the SACGHS.

Thanks to all of you for your service and advice.

I also want to welcome Dr. Doug Olsen, a senior nurse ethicist at the National Center for Ethics and Health Care at the VA. He is serving as the alternate ex officio today. Dr. Fox will be here tomorrow.

We have a new member of SACGHS to welcome. Darren Greninger joined the team in August and was put to immediate work. He has an undergraduate degree in biology and a law degree, and has worked as a science writer and journalist. Welcome, Darren. I'm glad to see that all the work didn't dissuade you from coming.

I also have a personal transition. This is my first day of retirement from Merck. I am leaving the private sector and will be rejoining the public health community as chief science officer at the L.A. County Health Department, so I will be here in a different capacity.

I would also like to call your attention to the fact that, like all federal advisory committees, SACGHS has a two-year charter. In September our charter was extended for another two years, so that is good news.

We also wanted to point out that SACGHS has a new Web address and a new site. You will see on the screen the new URL, which is shown here. There is also a handout at the registration desk. Hopefully we will find people finding our materials even more accessible than they have been up until now.

Sarah, this is the time that we all know and love when we get together, the important reminder about the ethics rules, which are clearly important.

MS. CARR: Very important. As you know, you have been appointed to this Committee as a special government employee. Although you are in this special category, you are nonetheless subject to the rules of conduct that apply to regular government employees. I'm going to highlight two of those rules today: the rule about conflicts of interest and the rule about lobbying.

First, conflicts of interest. Before every meeting you provide us with information about your personal, professional, and financial interests, which is information that we use to determine

SACGHS Meeting Transcript
December 1, 2008

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.

Government employees are 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 SACGHS is an advisory committee to the Secretary of Health and Human Services. It does not advise the Congress.

As always, I thank you for being attentive to these rules of conduct. We appreciate how conscientious you all are. Thank you.