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

DR. TEUTSCH: Good morning, everyone, and welcome to an early Monday morning here in Washington. I hope everybody had a good holiday. Thanks to everybody for making the extra effort to travel here. I'm sure many of you had to give up part of your weekend to make it and battle the weather last night. So, many thanks to everyone.

This is the 16th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. I'm Steve Teutsch.

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 any viewers tuning in via Webcast. Thank you for your interest in our work. As you will hear later from Paul Wise, many of you have provided important comments which have been informing our work. We certainly appreciate that.

Tomorrow we will have a public comment session at 1:15. We encourage any of the public who wish to address the Committee to sign up at the registration desk, if you haven't let us know already.

I would now like to welcome Rochelle Cooper Dreyfuss, who is a new member of the Committee and is attending her first meeting. Professor Dreyfuss is the Pauline Newman Professor of Law at the New York University School of Law and has also served as a member of two National Academy of Sciences committees investigating intellectual property issues and is past chair of the American Association of Law Schools' Intellectual Property Committee.

Before earning a law degree from Columbia Professor Dreyfuss earned a master's degree in chemistry and worked as a research chemist. So, welcome, Rochelle.

I want you also to know that last summer we had the pleasure of welcoming Judge Pauline Newman here. She shared her perspectives on patent reform legislation as part of our International Patents Roundtable. That was terrific.

A couple of our members are unable to be here in person today. Andrea Ferreira-Gonzalez is, I believe, in Europe, and Marc Williams won't be in attendance though Marc is hoping to join us later by teleconference. I believe he had his daughter's wedding this weekend, so I guess he gets some dispensation for that.

We are also welcoming Charles Keckler, deputy assistant secretary for policy in the Administration for Children and Families, ACF, as the new ACF ex officio. Martin Dannenfelser left ACF in May to become staff director of the U.S. Commission on Civil Rights. We wish Martin the best in his new position, and Charles, we look forward to working with you as well.

We have also had a change in representation from the Office of Public Health and Science. Dr. Inyang Isong left this month for Harvard, where she is pursuing post doctoral training in genomics and primary care through a pediatric health services research fellowship. Hopefully she will be carrying flag in that field as well.

Until an ex officio is named, Dr. Mike Carome, who we know well, will be serving as ex officio from OPHS as well as OHRP. Mike, thanks very much for filling both those roles.

I think this has actually been a rather momentous few months since we last met. Before we go any further, I want to at least take a moment to identify a few of those things.

First, as I think all of you know, we need to salute the enactment on May 21, 2008, of the Genetics Information Non-Discrimination Act, GINA. Really, we need to sincerely commend all of the many advocates who worked so hard and for so long to bring this law to fruition. I know a large number of you are actually in the room today. Thank you very much.

Our nation now has a federal law to protect consumers from discrimination in health insurance and employment on the basis of genetic information.

We know from our own work on this issue, which included analysis of current law and a compendium of public comments documenting the public fears and concerns about the misuse of genetic information, that federal legislation is needed, and we made the legislation our highest priority.

At the same time we know that there is still much work to be done to implement the protections afforded by the law which do not actually take effect until June 2009 for the health insurance provisions and December of next year for the employment provisions. We also know that, as important as GINA is, it does not cover all types of insurance, including life, disability, and long-term care, or prevent all possible misuses.

For today we will celebrate this achievement, salute the President and Congress, and laud everyone who played a role in making GINA a reality. So, congratulations to all of you who played a role in bringing this to fruition.

We have a large agenda. In the interest of time and given our focus this morning on the development of future priorities, I won't review the status of our other current priority issues except to say that in April and May our reports on oversight and pharmacogenomics were formally transmitted to Secretary Leavitt, I'm sure to the relief of many of us who have labored overtime on those reports.

We are aware that careful consideration is being given to both reports and the recommendations that we put forward.

In April, Dr. Gonzalez, Dr. Williams, and I had a very productive conversation with Greg Downing on the Secretary's staff about the oversight report. We know from the discussion that our recommendations in that area were much anticipated -- probably more than much anticipated. They had asked us to deliver them -- and appreciated, and are now being actively reviewed and discussed.

The Secretary's office has also undertaken a close assessment of the 14 recommendations that we made on pharmacogenomics. In your table folders you will find a list of HHS actions provided to us by the Secretary's staff that relate to some of those recommendations. We look forward to receiving additional reports in the future on the Department's progress and in addressing policy and programmatic gaps in these two areas.

Mara, you look puzzled.

MS. ASPINALL: Thank you. I'm just trying to understand the next steps in terms of comments on the report.

DR. TEUTSCH: We are of course waiting to hear back a bit more from the Secretary's office, but I think we will make it a point, too, to do follow-up with them along the way to see what the progress is, what additional things they could use from us, and to try and make sure that there is an orderly transition in these recommendations over the next few months as we get a new administration.

MS. ASPINALL: Thank you. Because there was, I think, at least one recommendation that had a time sensitivity to it where we talked about convening a group of people within HHS sometime in the fall.

DR. TEUTSCH: That was basically to help shape the registry.

MS. ASPINALL: Yes, yes.

DR. TEUTSCH: I am not aware if that has been scheduled. As you know, one of the things that probably could happen here is to bring the agencies together not only for that issue but to look at implementation. I think those are the kind of discussions we need to continue to have with Greg and the Secretary. Obviously, they wanted these. Hopefully they will take action on them and carefully consider each of them.

MS. ASPINALL: Yes. It is super how they acknowledged the report and spent so much time going through it. Thank you.

DR. TEUTSCH: There are three main agenda items for us to cover over the next two days: deliberation on our new study priorities, an exploration of marketing of personal genome information and services directly to consumers, and third, our proposed action plan for issues associated with genetics education and training of health professionals.

Our morning will be focused on a discussion of the highest priority issues that were identified in the scoring process that took place in June. Paul Wise, who has been chairing the Priority Setting Taskforce, will present background information on the work and then lead our discussion concerning those priorities.

Our goal for this session is really to develop a shorter and more refined list of issues that can be researched further. Then we will look to finalizing that list at our meeting in December.

Tomorrow we will focus on personal genome services, including the state of the science, consumer perspectives, and public policy considerations. Representatives from several companies have agreed to come and talk with us and are going to participate in a roundtable that will explore the information provided by these services as well as the companies' plans for helping consumers interpret and use the results in healthcare decision-making.

As part of our exploration of personal genome services we have a great opportunity. We will be participating in a workshop this afternoon sponsored by Secretary Leavitt's Personalized Healthcare Initiative on understanding the needs of consumers in the use of genomic-based health information services.

The workshop will focus on three topics: what is known about consumer interest in consumer-oriented, genome-based health information services, CGHIS, and the consumer's understanding of what is being offered; what information is needed by consumers to make use of these services

to maximize health benefits and minimize harms; and what consideration should be made by the CGHIS organizations for privacy protections and informed consent procedures.

We really do appreciate the Office of the Secretary providing us this opportunity to coordinate these two meetings. As you might expect, it has been a major effort on both parts, and we sincerely appreciate all their efforts to accommodate us.

A bus will be waiting outside this building at 11:30 to take us to, it says Reagan Building here but I think it is the World Trade Center, for the workshop. If you ordered a boxed lunch, please pick it up from Abbe and go directly to the bus. If you haven't, you can go to the cafeteria in the Reagan Trade Center and bring your lunch into the workshop.

Tomorrow afternoon we will be hearing from Barbara Burns McGrath, chair of the Genetics Education and Training Taskforce that was created in November. Barbara will provide an update on two taskforce products: the revised taskforce charge that was modified based on our discussions in February, and a proposed action plan for this group.

There are two SACGHS staffing developments that I want to mention. I think many of you are aware Suzanne Goodwin left the SACGHS staff in May to pursue her doctoral degree on a full-time basis. She was a pivotal member of the SACGHS team and served on the staff of our predecessor committee, so she had a lot of perspective on the work of what we are doing and part of the historical memory of our group.

She was tremendously dedicated to her work. Her writing and analytic skills were exceptional. She was the lead staff person for our Coverage and Reimbursement Taskforce Report and the Pharmacogenomics Report, and played an important cross-cutting role in issue identification and helping plan and manage the Committee's work.

It is really gratifying to see that her interest in genetics policy goes very deep. She will be focusing on that in her doctoral work. So we hope and expect that we will see her again, putting her talents to work in the genomics area. I guess she is done next year, right? She hopes. Maybe we can recruit her back.

Anyway, recruitment is underway to fill Suzanne's position. Hopefully that will be done soon.

I would also like to introduce David Slade, who I think is here somewhere. Over here at the table. David has been interning on the SACGHS staff this summer. He is an M.D., J.D. candidate at Southern Illinois University. His studies are focused on health law, bioethics, and administrative law, and he has been working very closely with Paul Wise and the Priority Setting Taskforce. You will see the results of some of his labors this morning.

David, we thank you for spending your summer and helping us with our work. Clearly, we need all your assistance.

Now for the highlight of the morning. Sarah helps us understand the rules of the road.

MS. CARR: Right. Good morning, everybody. As you know, you have been appointed as a special government employee to serve on this Committee. You are subject to rules of conduct that apply to regular government employees. These rules are outlined in a document called Standards of Ethical Conduct for Employees of the Executive Branch that each of you received

when you were appointed to the Committee. I'm going to highlight two of the rules that we expect you to follow.

One is on conflicts of interest. 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 our 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 interest 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 the activities associated with this Committee. Just keep in mind that we are advisory to the Secretary of Health and Human Services. The Committee does not advise the Congress.

As always, we thank you for being so attentive to these rules and all the others that you are obliged to follow. We appreciate your conscientiousness very much.

DR. TEUTSCH: Thank you, Sarah. Wise words.

Before I turn the agenda over to Paul Wise, any items of a general nature?

[No response.]