

Opening Comments
Ed McCabe, M.D., Ph.D.
SACGHS Chair

P R O C E E D I N G S

(9:02 a.m.)

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

A couple of announcements. For those of you with microphones, you have to press the button in order to speak or you will not be picked up. I'll try and remind you, but the red light will go on when you can speak, so please do that. We've also had requests from the press and from our transcription service to please state your name as you're beginning to make a statement so that it's clear who you are for the record.

At our inaugural meeting in June, we had a number of presentations on the scope of issues encompassed by the SACGHS charter. We heard about the work of our predecessor committee, the Secretary's Advisory Committee on Genetic Testing, or SACGT, and were informed of the issues that our ex officio agencies think should be our top priorities. We identified several issues to explore in further detail. Two sessions today and tomorrow are in response to a request at the first meeting to be briefed on two of these issues. First is the status of federal efforts to enhance the oversight of genetic tests; and the second is genetics education and training and genetics workforce issues. With that information, we feel that we can make an informed decision about whether any further attention on our part is warranted on these issues.

Before reviewing the agenda for this meeting, I would like to turn our attention for a moment to the draft minutes of the June meeting. This is at Tab 2 of your briefing books. Before approving the minutes, I'd like to have a sense of the committee that the draft minutes are a fair and accurate representation of our June meeting. Do members have any comments or suggested changes to that document? I'm sure you've all memorized these minutes.

(No response.)

DR. McCABE: Any concerns, issues about those?

(No response.)

DR. McCABE: If there are no substantive concerns, then we will approve the minutes. Is anyone concerned about that?

(No response.)

DR. McCABE: Okay. So then let's move ahead.

The other thing about the minutes, I'd like to ask the committee to be thinking about whether or not we might want to rework them into a formal report to the Secretary. These reports are our means of communication with the Secretary and we provide the Secretary with an overview of the current status and future directions in genetic technology, the issues associated with them, and

the determinations we made about which issues we think are of highest priority. So I'd like you to think about that and we'll revisit this idea later in the meeting and ask that you give some thought to it in the meantime, and you might want to look over those minutes with that as an idea.

You'll recall that in June we had an extensive briefing from Kim Monk from the Senate Health, Education, Labor and Pensions Committee, the Senate HELP Committee, about the Committee's passage of Senate 1053, the Genetic Information and Non-Discrimination Act of 2003, and the prospects for further development of this issue in the Senate and the House. After Ms. Monk's presentation, we agreed to send a letter to the Secretary commending the administration for supporting S. 1053 and urging the Secretary to continue pressing for passage of legislation in the full Senate and House.

I'd also like to comment that I think it's important to note that the first action of the Secretary's Advisory Committee on Genetic Testing with both administrations -- so with Secretary Shalala and then with Secretary Thompson when the new administration came in -- was to write a letter supporting genetic non-discrimination, and the first action of this committee, the first correspondence of this committee with Secretary Thompson was in support of genetic non-discrimination, and I think that is a measure of the public's concern about this issue.

A copy of the Secretary's very positive response is in your table folders. Naturally, we were all delighted with the Senate's unanimous approval of the bill last week. That was very welcome news indeed because of our support that we've given it over the course of these two committees.

Now, of course, the focus shifts to the other chamber. Later today we will be briefed by Kristin Fitzgerald from the House Committee on Education and the Workforce, one of the three House committees with jurisdiction over this issue, about prospects for passage of genetic anti-discrimination legislation by the House of Representatives. Most of our agenda today will be devoted to a series of briefings by the federal regulatory agencies on the roles, activities and plans with regard to the oversight of genetic technologies, marketing and laboratories. This issue was a major focus of the work of SACGT, which made a number of recommendations about how oversight might be enhanced. Our briefings today will review how the agencies carry out this information and provide an update on their future directions and plans.

We will start tomorrow with a look at how other nations are addressing issues raised by advances in genetics research and genetic technologies. We will hear presentations from Philip Webb of the UK Human Genetics Commission and David Weisbrot of the Australian Law Reform Commission about recent reports of their commissions and relevant policy developments in their countries. Following their presentations, we will engage with them in a roundtable discussion of the issues.

The remainder of tomorrow will be spent hearing about federal and private sector efforts to enhance the education and training of professionals in genetics. You'll recall that at our June meeting, one of the issues we discussed was the importance of ensuring that our health professions workforce is well prepared to apply genetic knowledge, services and technology, and we decided that we should learn more about what federal agencies in the private sector, where most of the responsibility lies, are doing to address this issue. A series of presentations are scheduled on these important activities.

Let me also point out that we have public comment sessions each day. I am pleased thus far that 10 individuals have registered to make public comments during these periods. We're extremely happy that the public is interested in and wishes to contribute to the committee proceedings. If

there are others here who wish to make comments, please let us know by signing up at the registration desk. We also have received written comments from a number of individuals. At latest count, 20 individuals or groups have sent us comments. These are in your briefing books at Tab 1.

So with that as an introduction to this meeting, let's proceed. Bio sketches for all of our presenters are at Tab 1, and in the interest of time we will forego formal introductions for most of our presenters. Background materials for oversight sessions are at Tab 4 of the briefing book, and presenter slides are in your table folders.