Public Comments
Day 2

DR. McCABE: Good morning, everyone. We're going to start off the morning with public comment. We're extremely pleased that we've had public comment both yesterday and today. If anyone wishes to sign up for public comment and is not signed up, please do so.

I have three individuals signed up at this time, Robin Bennett, David Sundwall, and Joann Boughman. If anyone else wishes to, please sign up at the registration desk.

So we'll lead off with Robin Bennett, representing the National Society of Genetic Counselors, and if you could come to the podium. Thank you, Robin, for doing that.

I should comment that just in terms of history and to maintain this, I think the National Society of Genetic Counselors made a commentary at every one of the Secretary's Advisory Committee on Genetic Testing meetings. So I'm glad that you're continuing that tradition.

MS. BENNETT: Thank you, and good morning.

The National Society of Genetic Counselors represents over 2,000 genetic counselors with specialized education, training and experience in medical genetics and counseling in an array of medical specialties. We are the leading voice, authority and advocate of the genetic counseling profession.

Genetic counselors are uniquely qualified to provide quality genetic services to the public throughout the life span, from newborns to elderly individuals. We have the skills and resources to answer research questions related to genetic services, counseling and testing.

The NSGC would like to assure that the following areas of concern are addressed by the SACGHS: prevention of harm from genetic testing, support for clinical genetics research, and access to genetic services.

Genetic testing is part of the process that must involve pre- and post-test counseling to enable consumers to make well-informed decisions. Consumers and their families have the right to expect that the correct genetic tests have been ordered, that specimens have been sent to a CLIA-certified laboratory, that costs of genetic testing are known, and that the test results have been interpreted correctly.

The nuances of reduced penetrance and variable expressivity complicate the clinical implications of positive or negative test results. Genetic test results are frequently used by patients and their family members to make complicated medical decisions about pregnancy outcome, medical treatment or disease prevention.

In the area of cancer predisposition testing, for example, a positive test result could lead to increased monitoring, chemoprevention, and in some cases prophylactic surgery. Genetic testing should be voluntary, accompanied by pre- and post-test counseling. The SACGHS should advocate for genetic counseling as an important component of genetic testing, including presymptomatic testing for conditions with no treatment.

When is a genetic test ready for application to the public? There should be oversight of a genetic test as it moves from research to clinical practice. There are even web-based companies offering genetic tests with no clinical validity or utility. It is as equally important for quality assurance measures to be enforced for laboratory analysis as it is to ensure high-quality pre- and post-analytical phase of testing.

The SACGHS should support education of health professionals, insurance companies, judicial systems, lawmakers and consumers about appropriate uses of genetic testing. This should include the differences between diagnostic, presymptomatic and pharmacogenomic profiling and the availability of genetic services.

Strong antigenetic discrimination laws for insurance and employment must be enacted and enforced. Fear of genetic discrimination is pervasive in the community, despite limited documentation that genetic discrimination is indeed occurring. Fear of genetic discrimination causes underutilization of genetic services and inhibits individuals who would benefit from genetic testing from using this technology.

As a final area of protecting the public from harm from inappropriate uses of genetic testing, licensure of genetic counselors would help assure that consumers receive quality genetic services from individuals with appropriate training.

There needs to be increased support for clinical genetics research. Individuals found to carry germline mutations invariably ask their clinician what does this result mean? The only way to truly answer questions about genotype/phenotype correlations as well as appropriate management is through large-scale cooperative research studies. The NSGC strongly supports thorough large-scale cooperative research studies and believes that such studies will provide valuable information to our patients and their families. Genetic research projects should continue being encouraged and supported, including studies on ethical, legal, social and financial implications of testing.

The American public deserves access to quality genetic services, regardless of socioeconomic status, racial, ethnic or educational background, disability, ability to pay for services, method of payment, or geographic location. To meet the exponential demands of the public for genetic service providers, there needs to be an increased training of a culturally competent family-centered genetic workforce of genetic counselors and medical geneticists. Currently, there are 26 programs accredited by the American Board of Genetic Counseling. Each program receives 75 to 100 qualified applicants. There are about five qualified applicants for every available training slot. Genetic counseling should be recognized as a specific allied health profession with access to federal support for training programs similar to other allied health professions.

To assure uniform access to genetic services, there must be improved insurance reimbursement for genetic services. Many insurance companies do not cover the cost of genetic services or these services are limited to coverage during pregnancy. Coverage may only include genetic testing of a pregnant woman but not the necessary genetic testing of her partner. Few plans cover genetic counseling in the setting of prevention. For example, genetic risk assessment for individuals at high risk to develop cancer.

As President of the National Society of Genetic Counselors, as a genetic counselor with over 20 years of clinical experience, having personal experience with over 10,000 patients, and as a consumer of genetic services who has watched cancer tatter three generations of my family tapestry, I am here to extend the services of the NSGC to the efforts of the SACGHS. We look forward to working with you.

Thank you for your attention.

DR. McCABE: Thank you very much.

Any questions or comments from any of the Committee?

DR. LEONARD: Could I ask a question? As we move from a paradigm of genetics being involved in relatively rarer diseases to being involved in basically all of medical practice, how do you see the integration of genetic counseling services versus counseling by the physician themselves evolving?

MS. BENNETT: Well, I would advocate that just because genetic services become more common in the public, it doesn't become any less complicated, and actually when you move into common disorders, you have a much harder time sorting out the true meaning of a negative test result versus a positive test result. So instead of saying there's not enough genetic counselors, I would advocate that there needs to be an increased workforce and a lot of effort put into funding for training and making sure that workforce is culturally diverse and cover geographic areas around the country.

DR. WINN-DEEN: I had one more question. You said that there's five qualified applicants for every slot. Do you have a specific proposal for how to increase the number of slots?

MS. BENNETT: I think there needs to be increased funding for genetic counseling training programs because there's definitely an interest in students who want to become genetic counselors that increases every year and there's very little funding. There are few scholarships for genetic counselors, no initiatives for minority development for genetic counseling students, and I think that has to go with medical geneticists also. It's not just genetic counselors. I'm just speaking because that's where my training is.

DR. LANDER: Can you tell us a bit more about the funding for genetic counselors? Do we need more resources at the universities to pay for these programs, more scholarships for people to make it affordable to do it?

MS. BENNETT: I think all of those things are true, and I think that having genetic counselors recognized by HRSA as a specific allied health profession would improve that because right now, it's not recognized as a separate allied health profession in any of those programs, so that the programs aren't eligible to apply for those grants.

DR. LANDER: So do you guys have a specific recommendation that would include the finances of it, to say this much money would be needed to launch the right number of programs, this much would go to scholarships, these are the HRSA recognition --

MS. BENNETT: We could certainly come up with that number. I'm not prepared to come up with it right now.

DR. LANDER: No, I wasn't meaning to put you on the spot, and I think I've heard it said many times that we don't have enough. We're clearly not going to be able to meet the demand, and I think it's time to come down to very specific proposals because my guess is that the amount of money needed to do it is really quite small relative to almost any of the other costs running around here.

MS. BENNETT: Right.

DR. LANDER: But having something concrete to get people to focus on it might help advance the cause some.

MS. BENNETT: I agree, yes, and I think there is the workforce to meet the demand. There just needs to be increased training programs.

DR. LANDER: So you'll come back to us with a proposal?

MS. BENNETT: Sure. I'd be happy to, and I think the other issue that comes along hand in hand with that is billing and reimbursement because that's an area that the demand is there but the hospitals can't fund the genetic counselors because they're not getting reimbursed.

DR. McCABE: Great. Robin, could you have something back to us in a month? I know one of the things that I've heard discussed is the need for diversity among genetic counselors and so the scholarship idea might play into that. So could you get something back to Sarah Carr within the next month, please?

MS. BENNETT: I'd be delighted to.

MR. MARGUS: So my quick question was how many men are among those 2,000?

MS. BENNETT: I think there's about 10 percent are men.

MR. MARGUS: Ten percent. Does that matter at all?

MS. BENNETT: Well, I am involved in social work training and there doesn't seem to be a problem with diversity in that field. I think that it is a problem.

MR. MARGUS: Are there ever counselees who would prefer to be counseled by a same sex or does it really matter in genetic counseling?

MS. BENNETT: I think that improving the number of men in the field would definitely be a service to the public. I would consider that part of the diversity of the profession.

DR. McCABE: And probably to some extent tied to the reimbursement, I would guess, because we've seen that in other disciplines as well.

MS. MASNY: I just wanted to mention as a comment and then a question, is that, we have an initiative from the Oncology Nursing Society Cancer Genetics Special Interest Group, along with the National Society of Genetic Counselors Cancer Genetics Special Interest Group, to do some collaborative work, so that each group could gain from the expertise of the other, and my question would be that in other areas of genetic counseling, could there be similar types of collaborations with other health professionals?

MS. BENNETT: I think absolutely.

DR. McCABE: Other comments or questions?

(No response.)

DR. McCABE: Thank you very much for speaking to us.

MS. BENNETT: Thank you.

DR. McCABE: And we look forward to receiving your written proposal to us, your recommendations. Thank you, Robin.

Our next speaker is Dr. David Sundwall, who is representing the American Clinical Laboratory Association.

DR. SUNDWALL: Good morning.

In order to be brief, I'm going to stick to a script here. I'm very pleased to be here to make a few comments on behalf of the American Clinical Laboratory Association, ACLA as we call it, a not-for-profit organization representing the nation's leading independent clinical laboratories.

ACLA member companies provide services in every state of the Union and provide the majority of lab testing done by commercial laboratories nationwide. I am pleased to have been invited here to make a statement at this inaugural meeting of the -- you know what you are. Secretary's blah, blah, blah.

(Laughter.)

DR. SUNDWALL: It's getting long. It's kind of hard to say. By the way, what is the acronym? It's not quite as easy as SACGT.
I want to compliment those of you who have accepted this invitation to serve on this important Committee. You now have the responsibility to carefully consider and wrestle with complex issues that will undoubtedly impact health care in many ways. Genetic testing is likely to be an increasingly important component of preventive medicine and enhance the ability of clinicians to make accurate diagnoses, to tailor treatments, and to make them more effective. Furthermore, the development of new genetic tests will likely be the focus of a significant amount of biomedical research.

Because the charter of this Committee is broader than its predecessor, the SACGT, you will also likely address more challenging issues related to ethics and social concerns. I personally commend each of you who have accepted this appointment for your time commitment to contribute to this very important advisory body. As you embark on your duties to advise the Secretary on genetic testing and its potential impact on the health of individuals in society, I want to leave you with just two points on behalf of ACLA.

Number 1 is the importance of appropriate and feasible regulation of diagnostic testing. ACLA understands that the government has to provide some oversight of genetic testing. Such tests have enormous potential to prevent and treat disease and the federal government has a role in ensuring that such tests are valid and appropriately used. However, we believe there is a significant risk to overregulation. For example, on January 9, 2001, Secretary Donna Shalala wrote Dr. Ed McCabe, then chair of the SACGT, and recommended that "oversight of clinical genetic testing services (so-called homebrews) as well as genetic testkits would be undertaken by HHS to fulfill their regulatory responsibilities."

ACLA, along with five other scientific medical professional organizations responded in a letter to Secretary Tommy G. Thompson on May 16th, 2001, expressing our concern that the January 9 directive may "hinder the development and dissemination of genetic testing advances by significantly expanding federal involvement in the clinical laboratory."

We remain of this opinion and believe that whatever regulatory mechanism is imposed by the department should be carefully considered and should take into account the well-acknowledged and medically

accepted role of clinical laboratories in fostering genetic testing advances. We do not think such regulation should be generally applicable to clinical laboratory science and services. Having said that, we understand that it will be challenging for you to determine how best to focus federal regulatory efforts without risking public health by hindering access to new technology.

The second point I'd like to leave you is simply an offer that the considerable experience and expertise of representatives of ACLA member companies is at your disposal. Collectively, our member companies do considerable research, provide a very high volume of testing and have years of experience in complying with quality control and regulations currently imposed on laboratories. We would be pleased to work with you to help you in fulfilling your responsibilities.

Now let me just insert a paragraph here that isn't in my written statement, and I'm now speaking as a member of the Clinical Laboratory Improvement Act Advisory Committee, known as CLIAC. It wasn't mentioned yesterday, but the Centers for Disease Control also has a very important role in implementation of this law. At our September meeting, I'm given permission to announce that the CLIAC will revisit our role in the regulation or oversight of genetic testing, and I want you to be fully aware of that just because there would be a risk of overlap or redundancy, and they have done this before but nothing was forthcoming. So we're going to put that back clearly on our agenda and will be working to figure out what is the proper way for us to assure validity and reliability through the CLIA mechanism. I've already spoken with Steve Gutman at the FDA and we clearly want to work together to make sure that there's cooperation and not redundancy.

The second point is that the CLIAC will be following up on our presentation at our last meeting on direct access testing which was discussed yesterday. We also are very concerned about this. We don't know a proper role of regulation and limiting access to patients to testing, but we are very concerned about what many would consider unethical promotion of such testing and their non-medical necessity use.

So with that, I'll just tell you again we look forward to working with you and compliment you on your efforts.

Thank you.

DR. McCABE: Thank you, David.

DR. TUCKSON: David, it's always a pleasure to hear from you, and I appreciate your comments.

I would sure appreciate maybe if you could supplement your comments back to us after this meeting with a sense of while we know that this Committee is not a direct pass-off of the earlier Committee to which you referred, there is a relationship, and you know that we struggled mightily in those last meetings around the appropriateness of defining criteria for appropriateness for release of tests.

A lot of time has gone by since then, and it would be important, I think, for us to know what progress has been made. How well does what exists today work? Do we feel like now that the private sector, through organizations such as yours and CLIA, have got this problem solved? Do we have anything to worry about? What's missing? Because at the end of the day, I think many of us might be well persuaded to say let the private sector do it. The government regulations are in place. The right balance. If it ain't broke, don't fix it.

But I think we would need to sort of know from you how well is the system regulated, how appropriate is it, and maybe others may have a different point of view, but I think that's a data point that I would sure like to see early on.

DR. SUNDWALL: Fine. I just need some help with you, Reed, on, do you mean the quality assurance efforts or are you talking about privacy of data?

DR. TUCKSON: The quality assurance effort, the appropriateness of the criteria that is used to ensure that the test before it's released to the public meets sensitivity and specificity.

DR. SUNDWALL: I see.

DR. TUCKSON: Clinical validity measures. I mean, all the technical stuff that says crap is not being sent out to be used on the American people.

DR. SUNDWALL: Right.

DR. TUCKSON: And what I think I hear you saying, I don't want to belabor it now because we don't have time, but what I hear you saying, I think, is the private sector feels that you all don't want government all over you with unreasonable regulations.

DR. SUNDWALL: They already are.

DR. TUCKSON: So at the end of the day, we need a sober, cold-blooded assessment from your point of view as to whether or not what the state of the situation is and then let's see how others may feel about it.

DR. SUNDWALL: I'd be happy to provide that.

DR. LANDER: I think that's just great. I very much agree that hearing that very concretely would be very valuable, and I wonder if you could also fill in a bit for me at least who sort of vaguely knows about CLIA but doesn't quite understand all of the range of things that have been considered there.

I know that CLIA has a lot of experience in making sure that a well-defined test is practiced at a high standard, that when somebody says that person is Apo E4, CLIA has all the right kind of procedures in place to be sure that they are really Apo E4, that QC's been done, et cetera. But what I wonder about with respect to the genetic testing is it's less whether the genotype is done correctly than whether the interpretation is valid in a world where this is just radically changing all over the place.

Can you give us examples of the experience of the CLIA process in dealing with the validity of interpretation of testing as opposed to simply the laboratory process?

DR. SUNDWALL: Right. Well, I'm glad you make that distinction because at Reed's request, I think I can provide a wealth of data to give you confidence that the lab data result is good. I think that as CLIA does its job, we wrestle with the same thing. The most difficult component of lab testing, as I understand, is not getting an analyte you can trust, it's the pre- and post-analytic phase.

DR. LANDER: Yes.

DR. SUNDWALL: Was it ordered necessarily in the first place? Then is it interpreted or used appropriately? That goes hands-down for genetic testing even more so. So I think that as we meet in September, these would be the very issues that we're going to focus on, the pre- and post-analytic phase.

It's a challenge, and I think we're kind of pioneering in this effort, but I'm very pleased to hear this presentation on the genetic workforce and counselors because that's an important component of it, too. But let me just agree to provide for the Committee what CLIA does in their performance testing, their oversight of labs. I think you can be assured the labs that are CLIA-certified and CAP-certified are pretty good trustworthy operations, but that doesn't mean there isn't room for improvement.

DR. LANDER: But you would say this is relatively new ground with respect to the nature of the interpretation of information, not the analytes.

DR. SUNDWALL: Right.

DR. LANDER: Because I have that sense, too, and that's where I wonder whether -- I'm very much in favor of seeing the private sector take major responsibility in this.

DR. SUNDWALL: Right.

DR. LANDER: But I think it's probably fair to say there isn't that much experience anywhere, private sector or public sector, with regard to these questions, and so simply leaving it to the private sector may be difficult. So it would be interesting to hear from the private sector and from the laboratories what are the things you're most worried about? What are the failure scenarios you guys see? Because since I don't think there are very large numbers of existing failures, we're looking ahead. We're all on the same side on this, but hearing you say very specifically what could go on that would not currently be caught by the system, that would not currently be caught by existing practices would be helpful, too.

DR. TUCKSON: So less on the background, less on the background of CLIA and more on the interpretation of what does it all mean in the current time today?

DR. SUNDWALL: Well, let me just have a note of caution here. I think I can speak on behalf of the labs. One thing about independent commercial laboratories is they don't see the patient, and I am afraid that there may be some expectation put on labs they can't meet. In other words, if you don't have that relationship with the patient, you do the test on behalf of your physician client or sometimes the patient who requests the test to a lesser degree, but that's a significant minority of our business. It's primarily for the physician, although I think we should foster this kind of improved follow-up and we have a role in interpretation.

I'm a primary care physician in my other life, and when I see patients, I'm grateful for the laboratories that provide for me not just reference ranges but some education at the bottom of the page, and I think that's very helpful.

DR. LANDER: So if I'm hearing you right, you're pointing out the need for or the potential need for thinking about regulations in two parts. One is of the laboratory.

DR. SUNDWALL: Right.

DR. LANDER: And the other may be a very different structure, not so much affecting the clinical laboratory but that interpretation and that's a very helpful distinction.

Thank you.

DR. SUNDWALL: I think you all need to pay attention to that. What is the role of the lab versus the clinicians or the counselors or the institution that's doing this testing?

DR. McCABE: So David, could you get back to us with that information?

Arden, and then Debra briefly, please, so we can move on.

DR. BEMENT: I think I may know the answer you've been searching for in the dialogue that took place, but I take it when you talk about regulation, you're talking about laboratory certification. You're talking about quality assurance. You're talking about instrument calibration. You're talking about chain of conformity to higher-level standards.

DR. SUNDWALL: Right.

DR. BEMENT: All those things.

DR. SUNDWALL: Indeed.

DR. LEONARD: I think that Eric has basically made a very important distinction, and I'd like to re-emphasize it, that the clinical laboratories are regulated by professional organizations, by the government, by a lot of different levels. Concern is raised by those laboratories doing testing that are not CLIA-certified, and I think that is an area that we need to think about and maybe those are the enhancement laboratories, but there may be clinical laboratories functioning out there, also, that aren't following appropriate regulations. So operating outside that window is of great concern, and then I think the whole health care professional education piece addresses this post-analytical use of test results. The test results may be done accurately, but the laboratorian -- I mean, I am a physician, and I do interpretation of results, but I can't control the physician-patient interaction if it fails, and I think that's where there's a great deal of concern.

DR. SUNDWALL: My last word, Ed, one suggestion is that you focus -- I base this on our last CLIAC meeting -- on grave concern about the inappropriate marketing of these tests, and I think, who knows, is that the FTC or who does that? I'm not sure. But I don't think it'd be necessarily CLIAC or customary bodies.

Thank you.

DR. McCABE: We took this up in the Secretary's Advisory Committee on Genetic Testing, and it does get very complex because it's multiple agencies that are involved in that. So it's Commerce. It's FTC. So it's a number of areas.

And lastly, thank you very much, David, and we look forward to having your written responses to that discussion.

Dr. Boughman is Executive Vice President for the American Society of Human Genetics and was a member of the SACGT, and I want to thank you, Joann, for being flexible in allowing us to move you to your presentation today.

DR. BOUGHMAN: Well, thank you very much, Ed, and today, it will sound like refreshing the agenda rather than just hashing it over one more time yesterday.

The American Society of Human Genetics, for those of you who don't know, is the primary professional organization for human geneticists with nearly 8,000 members. It includes researchers, academicians, clinicians, laboratorians, genetic counselors, nurses, a variety of other people involved in or with special interest in genetics. Our mission is clearly stated to, one, promote and expand research; two, to apply the knowledge to enhance health care; three, to train the next generation of geneticist professionals; and four, to educate and inform other health professionals, the public, lawmakers, policymakers, and so forth.

We take our mission very seriously, and I'm pleased to say that sitting among you on the Committee are five members of our society, so that we understand that the viewpoint of the genetics community will clearly be heard here. But today, on behalf of the Board of Directors, I'm here to do two things, just point out a few of the issues that we see as the most urgent and most important, and secondly, to offer our services in any way of the 8,000 or so of us out there that are working in the area.

Let me make just a few points. In the area of research, we know that the basic science research is moving very rapidly, and we know that translational research is also moving rapidly but that we need in fact more focus on that translational research and the transition into clinical practice, and in fact those areas are broadening as we heard yesterday into the area of human genetics and bacterial genetics and the interactions between the two.

We also recognize that the more traditional academic model of publish or perish must be adapted in this rapidly changing environment to serve new and very exciting public/private partnership models without overreacting and making it simply a protect and profit model. We've got to come out somewhere in between. But in that vein, we have pride in the fact that we think the genetics community in general has demonstrated significant leadership in the sharing of research findings and the making of our research findings public.

Conversely, industry-based researchers as well as academicians who develop marketable intellectual property must also obtain and protect that intellectual property. Securing that balance between the protection of intellectual property and public access and patient access to the results of that is of great concern and we seek that balance. We encourage this group to further engage in substantive discussions around some of these issues, patenting, licensing. In fact, as suggested by Professor Sung yesterday, that there may be some ways, some new points that could be made and taken up by the Patent and Trademark Office in ways that biotechnology is different and encouraging some of those discussions may be extremely valuable.

We also are dealing with the new privacy rule, and we have found in the area of research that barriers, whether real or just perceived, to research participation by volunteers are also of some concern. We have new challenges in the interpretation of compliance with the HIPAA privacy rule and we have a new ad hoc Committee in ASHG that is looking at some of these issues directly related to genetics.

We obviously maintain the highest regard for privacy, but we are concerned about the lack of understanding and interpretation and possible over-interpretation of the HIPAA rules. We also have some concern about consistent interpretation by IRBs and privacy boards and the inconsistencies that may arise institution-by-institution.

ASHG is the large umbrella organization, and in certain situations with regard to health care, in fact, it may be the American College of Medical Genetics or some of the boards that may be more specifically

interested in that, but under our umbrella, I'll go ahead and make a few comments about health care issues as well.

As we have already heard, access and cost of testing and access for patients to services as well as cost recovery is, of course, of primary interest and a topic of importance and urgency. As has been mentioned several times, quality of service is a basic tenet of clinical practice, but in this emerging and expanding field of genetic testing and services, systematic and systemic quality control mechanisms are not yet fully in place as we know.

Because the term "genetic testing" covers such a wide variety of services, from newborn screening, diagnostic confirmation, and now more into the areas of predictive testing and risk assessment, as well as from identifying the common rare disorders to moving into the common disorders, we also urge you to think about the issues of the complexity of multiplex testing and now as we move forward into the concept of genome scanning. These will present us new challenges, we believe.

Adequate interpretation of the results is obviously essential, and we think that you've just reiterated the gap that may exist between the laboratory, the laboratorians, the oversight of their practices within the laboratories, and the translation and interpretation of that information to the patient and the possibility of information loss along that trail, if you will.

This is getting, of course, more complicated as the interpretation becomes probabilistic, not inevitable, in its interpretation, not just are you a carrier, are you not a carrier, but what is the probability that this allele or this gene may increase your risk for a predisposition to a disorder? We have concerns about that. Our collective concern is heightened when even the best lab reports go to unprepared clinicians to translate that information, and we move from concern to anxiety when we talk about some of the direct consumer testing, and I would remind us that while we in the professional community may clearly understand the difference between a CLIA-certified laboratory and some of the other end of the spectrum that we saw yesterday with the ego-genomics, that there is a very large area that's somewhat fuzzy in between and even if we clearly know the difference between those, the public may not know.

We also are interested in the protection of research subjects obviously, and we are very pleased with the Senate HELP Committee moving the Genetic Information Nondiscrimination Act from the Committee to the agenda of the Senate. We know that there may have been only a very few cases documented of discrimination in insurance eligibility and/or employment, but the perceived deterrent has been very important to us. We will be active in the support and interaction with members on the Hill, and I think if there was a message that I heard yesterday, certainly from Dr. Zerhouni, he gave a very clear message to this group that a comment from this Committee would be welcomed on the importance of the Genetic Nondiscrimination Act.

The last point that I'd like to make is about preparing future professionals. That's really a growing challenge for us as geneticists. We have a limited workforce of trained geneticists, and we are now in the area of trying not only to train the next generation, we're doing the research, we're providing the services, and now we have the challenge of sharing our information and training all of the other health professionals as well.

I think Robin Bennett made a very good point about the support of training programs in genetic counseling that has not been on the agenda of the nation recently.

We also are participating in and very supportive of many of the efforts of NCHPEG and other outreach efforts, but the resources remain limited. There have been some wonderful model programs, like the

Genetics and Primary Care, that in fact are seeing fruits from their labors, but once again, unless we have more trained geneticists, we don't have enough of us to do all of that interacting.

We also have a long tradition of activities to inform the public and we're very active in that area now with the Mentor Network that we have developed with NHGRI. We have 900 of our members out there who have volunteered in their local communities to be mentors either in the public schools, K through 12, all the way through graduate school. In fact, in the week of the 50th anniversary celebration, we know of 60 activities in 27 states with almost 3,000 people in the audiences with geneticists in the community. I think this is a huge effort but once more, we can only be in one place at a time.

We would encourage this group to support those outreach activities in any way that they can and encourage these interactions between the professions to enhance this. We'll do our best as a group of geneticists to get the kids young and bring them up right, if you will, but in fact we need to have more focus and support for those activities.

And finally, with regard to what Dr. McCabe said yesterday, should this Committee be thinking very long term or immediate, I was immediately reminded of the think globally, act locally rule which I would encourage you to think long term but in fact focus initially on some actions that could make some immediate effect and in setting of the agenda for further conversations, and once again, the American Society of Human Genetics would be happy to help in any way we can. Please call on us for anything we can do to help.

DR. McCABE: Thank you very much.

DR. LEONARD: I would like to make a proposal or ask your opinion on an issue.

DR. BOUGHMAN: Sure.

DR. LEONARD: Which is it's my feeling that my 14-year-old probably knows more about genetics than does a 50-year-old physician, primary care physician. So focusing efforts on current training is not so much of an issue as figuring out how to reach the practicing physicians that are out there and this Genetics and Primary Care Initiative, those types of things, I think, need to be more the focus of initiatives because maybe in 30 years, we won't be having this problem anymore, but we have to get to that point.

So do you have any suggestions on how you get the practicing physicians trained?

DR. BOUGHMAN: Well, I would suggest that there are many of those activities going on and this interfaces with the Society of the American College of Genetics and the American Board of Medical Genetics and its relationship with the other boards and certification of physicians and the development of proposed curricula for a variety of current training programs in pediatrics, internal medicine, and so on, but even more so as the professional boards move to a climate of maintenance of certification, where in fact physicians are recertifying and the development of materials and curricula that can be moved into those other areas, that is one of the systematic ways that we can do it as well as doing it the best we can on a day-to-day basis with all of the grand rounds and other things that we might do in not only medical centers but general hospitals and such.

DR. LEONARD: I think your point is excellent, that we have moved to limited licenses for physicians, and so the recertification process may be a window of opportunity.

DR. BOUGHMAN: Yes.

DR. LEONARD: If those training materials or informational materials are out there, to at least get to them the basics of what does it mean if a disease is recessive or dominant or when are you in over your head and who should you refer to and things like that.

DR. BOUGHMAN: Yes, and Dr. Leonard, I think you just made a perfect point. I think as geneticists, we have not been good enough at defining who we are, what we do, and when you should refer to us, when in fact the information can be assimilated and truly used by the generalists and when the genetic counselor can be a part of the team that bridges some of those gaps in very important ways. But that's one of the systematic ways that we are trying to do it and developing curricula right now as quickly as we can in a variety of forms.

DR. LEONARD: Could we get information on their efforts?

DR. McCABE: Could you get us information on the efforts that you're putting together?

DR. BOUGHMAN: Certainly, and I will talk to Mike Watson over at the College and the folks at the American Board of Medical Genetics and get that list to you and also with NCHPEG and the development of some of their curricula in a variety of areas.

DR. McCABE: And NSGC also, because I think they're doing some efforts in this area.

I would just comment that I'm glad you're so optimistic about the physicians we're training now, Debra. Dr. Linda McCabe and I were asked by the Macy Foundation to put together a paper for a meeting they're having on how do we educate physicians for the future, for both the clinical future as well as educating them, and I think it goes back. It's not just problems in medical school but it's premedical education.

We're still requiring organic chemistry but we don't compound our drugs anymore. That's really just a memorization barrier that we put up for testing, and we still approach medical education as if we can teach a physician everything they're going to need to know for the rest of their career. I think we really need to revisit how we prepare for medical school as well as how we pursue medical school and really need to train people to be lifelong learners. We pay lip service to that, but we don't select for that. So there are a lot of issues here. Genetics is only one in terms of the technology.

DR. LEONARD: Well, that's why I went back to my 14-year-old because they just learned genetics and probably learned a lot of what medical students are currently learning.

DR. McCABE: Thank you.

DR. FEETHAM: As another source of information on the training of health professionals, again I have some information that I was going to distribute today, but HRSA in partnership with NIH, CDC, and other colleagues, we've done several programs focusing on the education of health professionals, and the Genetics and Primary Care that's been mentioned was under the initiative of Dr. Michele Puryear who's here who nudged us all to move forward in that. So we can add that to the information that you have. All the numbers of grants that have been funded in that area of education and those are often interdisciplinary education of health professionals.

DR. McCABE: This would be a big help to us since one of our issues really has to do with education and anyone else from any of the other agencies, anyone in the audience here, where there are activities going

on in this area, if you could communicate with Dr. Boughman or, if you wish, directly with Sarah Carr, so we can begin to put these efforts together.

DR. BOUGHMAN: Yes, Dr. McCabe, if I could just make one more comment on taking advantage of every teachable moment, if you will. In one of the comments that Dr. Lander made earlier in part of this discussion about laboratory results and the difficulty in interpretation and the agencies involved, in the SACGT and in other areas, one of the points of discussion is the transition from the trial process and the FDA approval process and in postmarket data follow-up that might come under the area of CDC and others, and in fact, what parts of those processes within the laboratory and beyond could be handled under the very broad category of labeling or information processes that go along with the test and the guidelines on the way the results should be delivered to the care provider.

This is something that we would not have concerns about with the large academically-based laboratories that do this on a routine basis but once again, as these genetic tests move out into the public sector and are being done by small hospitals or other small private laboratories that do not have this academic tradition, that in fact guidelines on the way those test results need to be communicated can in fact be a teaching process and a learning process if the guidelines are done correctly.

DR. McCABE: Thank you very much.

We're now prepared to move on. I don't think there are any other individuals who have registered for public comment. If there are none, then we will move on.