Public Comment Session
October 23, 2003

DR. McCABE: We're going to begin our afternoon session. We have seven speakers, as I mentioned before the lunch break. I would encourage the speakers to please try and cut their presentations. If it stretches into a four- or five-minute presentation, there will be no time for questions, and I would encourage you to turn in your items in writing and permit the committee to have time to discuss them with you.

Our first speaker is Dr. Paul Billings, who is speaking for the Laboratory Corporation of America. Thank you.

DR. BILLINGS: Thank you, Chairman McCabe, distinguished committee members, friends, and guests.

I'm Paul Billings. I'm an internist, a medical geneticist, a professor of anthropology at the University of California at Berkeley, I'm the co-founder of GeneSage & Company, and for many years I've conducted research on the translation of biotechnology from lab to clinical care and in consumer issues in genomic medicine.

For instance, and this may be of interest to the Chair, given comments he expressed yesterday, I'm currently the PI on a grant funded by the Robert Wood Johnson Foundation that seeks to document and analyze legal and policy precedents affecting standards of care in genomic medicine. An initial database and draft analytic summaries are complete and I would be happy to give the committee, its members, and staff access to this project's initial results. The work will be reached at www.genewatch.org., a site sponsored by the Council for Responsible Genetics, and it is produced with the help of the National Council of State Legislatures and distinguished legal scholars.

I've also recently completed a large project considering the potential use in non-insurance health markets of genetic testing.

But I'm here today having recently become vice president and national director for genetics and genomics at Lab Corp. As you know, Lab Corp is one of the largest clinical reference labs in the country and is the provider of the highest-quality molecular and genetic tests and services nationwide. I'm pleased to be a part of such an excellent group of laboratorians.

I would like to make three brief comments, primarily in response to the discussions yesterday and the characteristic incisive comments by Reed Tuckson and Huntington Willard. It has been over 10 years since I testified before a subcommittee of the House of Representatives on genetic testing and the then-current ClIA-associated oversight practices.

First, the actors in genetic testing now -- consumers, patients, providers, payers, producers of technology, labs, standard setters, lawyers, and others -- are all generally united in the intent to provide safe, valid, and information-rich testing in the United States. While variance in quality of testing practices will always occur and a few enterprises may need to be curtailed, the system with its current mission standards and checks is working. I have seen no convincing data that documents current systematic harms or end user dissatisfaction with how genetic testing is now delivered.

Rather, demand for more products seems apparent, even with well-known public concerns about the uses of genetic information by third parties and privacy. Attention rightly ought to be paid to the needs of informed and, therefore, empowered consumers and patients who are changing the balance of power in

demand and decisionmaking and who will be significant determiners of the market for tests and its qualities in the coming days. The role will likely be more important than some experts now feel comfortable with.

Second, clarification of nationally enforceable standards, oversight, and appropriate regulation is desirable. The issue has always been neither doing too much nor too little given this rapidly changing field, its evolving methods, and the wishes of components of the health care system. There are significant problems in the payment and coverage systems in our country that do not promote equitable access to the benefits of genomic medicine and sometimes contentious issues related to intellectual property ownership and policies currently affect which genetic and genomic tests are being delivered and their cost. As with regulation, these topics are relevant to your work as well.

Finally, I first took part in a debate about the special nature of genetic testing for policy purposes here in Washington many years ago as part of the Joint NIH/DOE Committee on Genetic Information and Insurance, which was chaired by Tom Murray. At that time, I argued that there are unique qualities of genetic tests and information, fully aware that this smacked of the so-called genetic exceptionalism and essentialism and that genetic data can be part of medical information generally.

Discriminatory practices using health-related, disability, or genetic information can be wrong and, if so, ought to be prevented. Pertaining to genetic information, the so-called laboratory of the states has legislated for years in this area and now developments at the federal level are occurring.

For the purposes of this committee's work, clarity about what, if anything, is special about genetic testing remains a challenge. As mentioned yesterday, the fact is that practices of those developing and delivering new imaging modalities are relevant and examination might cast light on non-unique aspects of the expansion in genetic services in this country. The need to collect data on the special aspects of genetic testing practices now and to let the information direct new policy and regulation is prudent conduct.

While new regulation and law can precede large-scale problems -- for instance, the banning of human reproductive cloning on primarily current safety grounds or the outlawing of certain discriminatory practices arise from genetic information simply because it violates basic American principles of fairness -- policy made anticipating problems or without enough data to direct it usually is fraught with folly.

Thank you for your time and attention. I would be happy to supply the committee with my comments in writing if you wish. Thank you.

DR. McCABE: Thank you, Dr. Billings, and we would appreciate it if you could supply your comments to us in writing. You can provide them to Sarah Carr. Thank you.

Our next speaker is Dr. Chin-To Fong from the University of Rochester School of Medicine and Dentistry.

DR. FONG: Well, I thank the committee for giving me the opportunity for a few comments to give some perspective. As a person that's spent a fair bit of time on what I call the front line of some of the teaching efforts, I spend about 50 percent of my efforts in medical education, and I'd just like to share a couple of points with you.

One is, to sort of put into perspective our programs, what I thought of is this hierarchy of interest. If you take this triangle as the pyramid of the general public, with sort of increasing degree of interest in genetics, this is probably, in Dr. Willard's analogy this morning, the iceberg, and somewhere in the top half are folks who are highly more interested in genetics. This is the informed public that is interested in

genetic issues, and somewhere in that upper group would be professionals that have to deal with genetic issues. At the topmost of this hierarchy are genetic professionals, who need to be interested in genetic issues. This is how we make a living in some ways.

So the amount of training needed to reach the top of the pyramid certainly increases the further you go, and what I really perceive as our real important agenda is to prevent the knowledge gap from the top and bottom of this pyramid to be widened as genetic technology becomes more and more advanced. In other words, if you don't watch it, this pyramid is going to get more and more elongated and we're going to fall further and further behind.

We take the current high school student as an example, as an approximation of the future public, and to think about high school education particularly. One of the issues that deal with high school education is that many of the existing programs that encourage genetic education turns out benefit kids who are already interested in genetics.

Secondly, professional development of the teachers is sorely needed, and thirdly, we need to really watch out to adhere to current state science curriculum standards, because this is what teachers have to deal with. Fourthly, we need to watch for availability of laboratory equipment to all school districts, which is easier said than done.

Fifthly, while we're interested in genetics, the current vogue in education in general at the school level is to develop student-centered education approaches that encourage critical thinking and problem-solving, and we think genetics teaching fits very well into that model.

So in Rochester, we have a new project called Project BEGIN. It takes advantage of an infrastructure in the New York State teachers. This is called the New York State Chemistry and Biology Mentor Network.

In deference to Dr. McCabe's call for brevity, I will skip through some of these specific items, but basically there is a hierarchy among the teachers in New York State that starts in the top with the highly motivated, so-called coordinating mentor teachers that would then evolve the curriculum development and teacher training. They work with the regional mentors and the regional mentors also work with local teachers. So this is the network of instructors within New York State that we capitalize on.

We take advantage of this network by bringing the mentors to the university and to summer workshops. We've developed a problem-based case that is very rich in ELSI issues that adheres to certain parts of the New York State science curriculum standard and that the coordinating mentors then take back to the regions to implement in the schools. So the mentors would disseminate these curriculum into the schools.

We also supply the participating schools with laboratory equipment to support some of these lab activities.

DR. McCABE: If you could wrap up in the next 30 seconds, please.

DR. FONG: I would refer you to the handout on the efforts we're doing with the medical education. So I'll probably quit here.

DR. McCABE: Thank you very much, and I would refer the committee to the handout. Thank you very much, Dr. Fong.

The next is from Ms. Dawn Allain, National Society of Genetic Counselors.

MS. ALLAIN: Good afternoon. Again, my name is Dawn Allain, and I'm the current president of the National Society of Genetic Counselors. It's my pleasure to speak on behalf of NSGC, which represents genetic counselors worldwide and is the leading voice, authority, and advocate for the genetic counseling profession.

Like others, NSGC recognizes we are entering an era where genetic services will increasingly have a significant impact on health care. Although genetic advances will benefit health care services, they will also pose challenges, particularly as they relate to access to genetic care. Specifically, many areas of the country have few or no geneticists or genetic counselors and many non-genetic health care professionals have minimal training in basic genetics. NSGC supports the expansion of not only the genetic counselor workforce, but also all genetic professionals. We also support increased training and education of health care providers.

I would like to highlight some key areas which NSGC believes could increase the genetic counselor workforce, as well as access to genetic services.

In regards to increasing the genetic counselor workforce, NSGC proposes three areas for consideration. First, we encourage SACGHS to support the renewed passage of and appropriations for the Allied Health Reinvestment Act. If this act is renewed and budgeted for and HRSA develops grants targeted specifically for genetic counselors, genetic counseling training programs could be eligible for grants promoting recruitment of minorities, development of didactic education and clinical internships, and programs for faculty development.

Second, NSGC recognizes that access to genetic counseling and testing services requires genetic specialists to practice in underserved patient populations and/or geographical areas. Inclusion of genetic providers into federal acts and programs would enable expansion of genetic services into these areas. For example, while federal programs, such as HRSA's National Health Service Corps, specifically aim to increase access to primary care physicians into underserved populations through scholarship and loan repayment programs, there are no programs specifically targeted for genetic providers.

NSGC would like SACGHS to support the development of federally-funded mechanisms for enhancing clinical genetic services in underserved populations. We also urge SACGHS to promote developing network infrastructures which will allow the provision of genetic services through telegenetics and web-based modalities to enhance access to genetic services in these areas.

Third, employability of an increased genetic counselor workforce and improved access to genetic health care is directly tied to reimbursement for genetic services. According to preliminary data obtained by NSGC, many medical centers subsidize genetic counseling services because there is no CPT code for genetic counseling services and there is no manner in which genetic counselors can bill.

The NSGC is committed to obtaining more comprehensive coverage for genetic counseling and testing services. We encourage SACGHS to make appropriate agencies aware of the current problems of billing and reimbursement and support state-based licensure for genetic counselors, the lack of which limits patients' access to genetic health care.

Separate from services provided by the clinical genetic workforce, it is clear that non-genetic health care providers are already providing some level of genetic services, including ordering and interpreting genetic tests.

NSGC strongly believes a well-informed and prepared health care workforce will lead to appropriate utilization of genetic services. We have and will continue to play an active role in educating health care

professionals about genetic counseling and testing services through the development of professional guidelines and genetic education programs.

Based on our experience, NSGC believes that development of genetic curriculum or educational programs should be tailored to each medical specialty to ensure that each health care provider understands the immediacy and relevance to their patient populations. Education must also stress the underlying genetic component in common complex disorders, as well as single-gene disorders. In education, educational programs must incorporate mechanisms for distance learning to help meet the needs of educating non-genetic health care providers. NSGC requests that SACGHS support the development and implementation of model educational programs.

In conclusion, genetic counselors currently provide a large percentage of direct patient care, genetic services, and education of health care professionals. Therefore, increasing the genetic counselor workforce will be critical to continuing translation and integration of genetics into routine health care. We encourage SACGHS, in conjunction with professional and consumer organizations, to continue to develop thoughtful yet practical strategies addressing the issues regarding oversight for genetic testing, education of health care professionals, and an increased workforce.

The NSGC membership has vast experience and expertise in direct patient care, laboratory services, research, public policy, and industry-based genetic services. We are available to work closely with SACGHS as you continue to address your important mandate.

DR. McCABE: Thank you very much, Ms. Allain, and while Dr. Lawrence O'Connor from the AMA comes forward for his presentation, I just want to make a comment that the NSGC has presented in public comment at every one of the meetings of the Secretary's Advisory Committee on Genetic Testing and now the Secretary's Advisory Committee on Genetics, Health, and Society. We appreciate your coming and commenting.

Dr. O'Connor.

DR. O'CONNOR: Thank you, Dr. McCabe.

My name is Larry O'Connor and I represent the American Medical Association. Now, the mission statement of AMA is to promote the science and art of medicine and the betterment of public health. With regard to genetics, we at the AMA are committed to providing educational tools that will enable physicians to better understand and incorporate medical genetics in their clinical practice.

This commitment is perhaps best illustrated in our genetics and molecular medicine website, which is shown here, the front page. This site is intended to serve as a portal by which physicians, as well as the general public, can obtain information on and links to the most current information in genetics.

Now, briefly, I'd just like to point out a few highlights that we have on our website here. For example, within our website we have a series of short educational primers that appear under the Number 1 heading there on various topics related to medical genetics, including gene therapy, stem cells, gene testing, and pharmacogenomics. These primers provide a brief summary of the subject matter and links to other sites where additional information can be obtained.

Now, we also have sections that are updated regularly listing recent advances in the field of medical genetics. These advances include not only research in clinical breakthroughs, but also news stories highlighting the social, economic, and legal implications of genetics.

In addition, there is always a special section within our website that provides more detailed analysis of current topics in genetics. As shown here, one such example is a topic on the recent anniversary of the double helix structure of DNA.

Now, the AMA also has a number of collaborations with a variety of national organizations to improve physician understanding of medical genetics. For example, we have recently co-sponsored a two-day seminar with the American Bar Association and the American Association for the Advancement of Science on applications of the human genome in clinical medicine.

Now, for physicians, we also have available a number of CME programs available online that can be used to better understand not only the science, but also ethical issues relating to the genetics, in this particular case shown here, of ovarian and breast cancer.

Now, the AMA continues to seek out new collaborations with federal, non-profit, and private organizations to develop new educational tools on genetic medicine. Currently, we are partnering with a number of organizations to help develop and disseminate educational programs in medical genetics.

Now, two examples shown here on our website -- actually, they're not on our website yet. They'll soon be posted on our website -- include a collaboration we have with the Dartmouth Medical School and the CDC to promote and distribute their educational program called "Genetics and Clinical Medicine." In addition, we're also working with the March of Dimes to promote their new education program called "Genetics and Your Clinical Practice."

Now, in the interest of time, I won't go into what each of these programs covers, but suffice it to say that each of these are intended for the primary care physician and are intended to provide tools and guidance to assist them in integrating genetics into their patient services.

Now, in conclusion, we at the AMA feel that our access to our physician members places us in a unique position to help increase awareness of how genetics can be integrated into clinical practice. We welcome the opportunity to collaborate with other organizations to create new educational tools or to assist in publicizing existing educational tools that may already be out there.

Thank you.

DR. McCABE: Thank you very much, Dr. O'Connor.

We'll now move on to Ms. Sharon Olsen from the Oncology Nursing Society.

MS. OLSEN: Thank you, Dr. McCabe.

Dr. McCabe and committee members, thank you very much for having us here. My name is Sharon Olsen. I'm an oncology nurse. I've been in oncology since 1969 and I've very proud of it. I'm here on behalf of the Oncology Nursing Society.

ONS is one of the largest professional organizations in the world. It's composed of over 30,000 members. These are registered nurses and other health care providers. All are dedicated to excellence in patient care, education, research, and administration in oncology nursing. We'd like to thank the advisory committee for this opportunity to provide testimony on workforce issues regarding genetic testing and counseling.

The Human Genome Project accomplishments have made it very clear that in the genomic era health

professionals in every medical specialty will utilize genetic technologies and genomic information in the prevention, diagnosis, and treatment of disease. Oncology nurses are pivotal to the interface between genetic technologies and the patient. As such, in 1995, the Oncology Nursing Society put together a strategic plan that set as a priority the integration of genetics into its educational and practice initiatives.

You have in your packet our written testimony. There is also testimony available at the table outside. I will highlight here only a couple of our accomplishments and outcomes to date.

In 1996, a Cancer Genetics Special Interest Group was formed for nurses working in cancer genetics to provide a forum for networking, education, and professional growth so as to improve our genetic services provided to our patients. As a member of this group, we are spearheading efforts to help all oncology nurses recognize the relevance of genetics for their practice.

With the support of a five-year grant from the National Cancer Institute, the Oncology Nursing Society offers a three-day continuing education accredited course that is entitled "Genetics Short Course for Nurses." It provides basic genetics education for nurse clinicians.

Third, with the support of ELSI funds from the Human Genome Institute, a bench-to-bedside science lecture series has been offered at the Oncology Nursing Society Congress for the last three years. Typically, we have over 3,000 individuals attending this session each year.

Just this year, the Oncology Nursing Society released a practice and education-based genetics tool kit for oncology care for our members, and lastly, the Oncology Nursing Society has collaborated with our colleagues at the International Society of Nurses in Genetics and with the American Society of Clinical Oncologists on the publication of position papers and standards of practice.

While the Oncology Nursing Society has played and will continue to play a key role in educating and training oncology nurses in the provision of quality genetics care, ONS maintains that these issues cannot be addressed solely by private and non-profit sector entities. The federal government must contribute in these critical public efforts.

To that end, the Oncology Nursing Society advocates the following. Full support and sustained funding for the efforts of HRSA and the Human Genome Institute's ELSI program project that is entitled "Assessing Genetic Services and the Health Workforce." This is a project in which ONS will be actively participating.

Second, sufficient funding is needed to model interdisciplinary educational efforts that will facilitate the rapid and the safe transfer of genetic technologies and therapies to the service arena.

Third, federal support is needed for efforts to educate nurses and to encourage collaboration between the myriad of stakeholders in patient care for purposes of developing and advancing initiatives to integrate genetics and genomics into health care.

Lastly, provision of scholarships, loan forgiveness, and other incentives are needed to recruit and retain nurses practicing in the area of genetics.

As many of you probably know, we are expecting in the next 10 years a shortfall of 800,000 nurses in the United States. This is not just a U.S. problem. This is an international problem. The Oncology Nursing Society urges Congress to provide a minimum fiscal year '04 allocation of $163 million for the Nurse Reinvestment Act and other federal nursing workforce programs that are housed at HRSA.

The Oncology Nursing Society respectfully requests that the committee recommend to the administration as well as to Congress that they support a significant increase in funding for these programs in fiscal year '05, as educating and training nurses takes time and insufficient investment today will leave our nation without the care and the genetics workforce that it needs.

In conclusion, the Oncology Nursing Society very much appreciates this opportunity to discuss workforce issues pertaining to genetic testing and counseling. Please know that the Oncology Nursing Society maintains a strong commitment to working with this committee, and also the administration, members of Congress, other nursing and genetics-related societies, patient organizations, and other stakeholders to reduce and prevent suffering from cancer and to ensure that all people and their family members have access to quality genetic testing and the counseling that they need as well as deserve.

Thank you very much.

DR. McCABE: Thank you very much, Ms. Olsen.

Our next speaker is Mr. Michael Rackover from the American Academy of Physician Assistants.

MR. RACKOVER: Good afternoon. I represent the American Academy of Physician Assistants, and it is the only national organization that represents physician assistants in all specialties and all employment settings.

While PAs practice in at least 61 specialty fields, 44 percent of this year's respondents to our national survey reported that their primary specialty was in one of the primary care fields: family general medical practice, general internal medicine, OB/GYN, general pediatrics. The other prevailing areas that PAs practice in are surgery and their subspecialties, emergency medicine, and the subspecialties of internal medicine.

As a university professor at a PA program, I make recommendations to the Association of Physician Assistant Programs, which is called APAP, established in 1972, and this is the national association representing physician assistant education programs in the United States.

The Accreditation Review Commission on the Education for Physician Assistants is the accrediting agency that protects the interests of the public and the PA profession by defining the standards for PA education and evaluating PA educational programs within the territorial United States. This organization is beginning the standards review process from this day until December 1st, 2003, and it is soliciting comments or suggested changes regarding the current standards.

I will try to make the appropriate recommendations, as my role is in physician assistant education and nationally is genetic literacy, to improve the education of PA students and postgraduate physician assistants in clinical practice with respect to the integration of genomic medicine. My concern is that we are having a difficulty as the students are coming out. There are no mentors to help them take what we are training to apply it to practice.

My other concern here is that when we talk about family history-taking and family practice, it should be synonymous. The correlation I present to you as a former x-ray technologist in diagnostic radiology, because of the shortage of radiologic technologists, you wouldn't expect a mammography to be done onsite. So it should be synonymous that in family history, the public assumes that the practitioners will understand their family history to be able to make applicable testing and to be able to take care of preventive medicine for themselves.

Thank you.

DR. McCABE: Thank you very much, Mr. Rackover.

Our final speaker from the public comment session is Dr. Fred Ledley from Mygenome.

DR. LEDLEY: Hi. Thank you for having me, and my apologies for not being here yesterday. I had the same choice most physicians have in practice, whether you pay attention to the 16-year-old who crashes into the goalie and doesn't think she can walk or whether you spend time talking about genetics, and I chose the same thing most health care providers choose.

I want to take the first 10 seconds and congratulate the committee and the people here on the work that was done to get the Senate to approve legislation on genetic privacy. Hopefully, this will go through the House and this will be a landmark, if it passes, in reducing one of the great barriers that has prevented consumers from having access to genetic testing.

My message to the committee is that this is only one barrier of many which prevent the health care system today from playing a proactive role in meeting consumer interest in predictive genetic tests, and I will restrict my comments today to predictive testing and not prenatal or genetic disease testing.

In addition to the inadequate training of professionals, there is the issue of the interest of the health care providers, many of whom are also contributing to meetings about the need for increased emphasis on social and behavioral causes of disease, increased recognition of spousal abuse, and of course, in pediatrics, where I trained, injuries and family issues.

The demographics of health care utilization is a critical issue, I believe, for this committee. Even if every physician was providing adequate genetic services, CDC data says that only 37 out of 100 people in our society go to a health care provider for preventive medicine in any given year. You can multiply it out. In your lifetime, that gives you about 15 hours of preventive care. There are not that many hours in that for in-depth genetic background and training.

This is particularly acute for young adults. For women, the number is a little bit higher, but they're using their OB/GYNs for practice, and in the period of time in which predictive testing would be most useful and most important, few of us, few in the 15 to 44 demographic, go to health care providers. More of us, ironically, in our society are going to alternative providers for health and wellness care.

There has been very little incentive for payers or providers to build the infrastructure for genetics. I think there are a number of academic centers that have shown how outstanding that can be when that investment is made, but it's expensive. Forrester Research has identified fear of the cost of genetics as one of the things that's inhibiting growth of genetics.

Consumers have an enormous lack of trust in the health care system with genetic data. The genetic privacy legislation is useful, but I believe that consumer concerns for privacy are primarily emotive and not practical, and that family history is traditionally something that's out there. In our surveys of consumers, there is enormous fear of this in the hands -- they trust their provider. They don't trust the HMO, the PPO, the employer, and, very importantly for people at this table, the government is not a good guy in the eyes of many consumers when it comes to privacy.

Consumers believe that genetic history is very important. It's something they want to do, but the same disparities in health care that plague everything else in our system are even more profound for new technologies like genomics.

The cost, the reimbursement, education, literacy. We did a quick survey of all of the documents on the web related to cystic fibrosis and only one tests out at a readability level appropriate for consumers, and I congratulate anyone who is here from ACOG that they wrote the one that in fact passed.

Race is a big issue. Geography is a big issue. Trust of the local resources is a big issue.

This problem that we're discussing today -- I believe we already have inadequate resources -- potentially is only 1 percent of the demand for genetic services that we will have within a decade.

Let me give you some context. The Kaiser Family Foundation on their website lists all the public opinion polls that have been done over the last 10 or 15 years in health. In every one of them, more than half of the people asked say they would have genetic tests to know what diseases they'd have later in life, whether or not it's treatable, whether it's curable, whether it's fatal. No matter what adjectives you put in front of it, it's over 50 percent. Our data suggests that when you actually put a specific disease in front of people which runs in their family, acceptance would be in the 85 to 90 percent range, and this includes things like drug sensitivity.

Privacy concerns are so profound that in some studies we and others have done, people say they would not do genetic testing if it's reimbursed, only if it's self-pay. We see a 2 to 1 preference for self-pay if it's associated with the ability to decide and have control over where that information goes and who sees it. As I said, this is largely personal.

We find that consumers are smart. I had a professor in medical school who said, "When in doubt and you don't know what's going on, ask the patient," and what we see is that consumers have an awful lot to say. They want control. Autonomy is very important. Access is very important. Quality information, knowing the laboratory provides quality results.

Consumers want to provide informed consent. I think it would be a shame if this is something that's passed away as too complex. Even for simple tests, things in pharmacogenomics, I think consent is something consumers want to be asked for and want to provide.

Counseling, follow-up. The follow-up issue is an extremely important one, as Neil Holtzman and many others have pointed out.

DR. McCABE: Please finish up in the next 30 seconds.

DR. LEDLEY: So my charge to this committee is that we're looking at the tip of the iceberg here, that the solutions perhaps aren't even on the table yet, and that it's very important that the policies that are established do not, even accidentally, create any barriers. I think that there needs to be tremendous innovation and open-ended innovation, not only in clinical practice and training, but in information sciences and the application of expert systems, in business practices.

There needs to be partnerships with the market to bring investment to bear to support the kind of works that need to be done. One needs to look at the financial incentives and disincentives very carefully. There is some troubling language in the Senate law that could actually prohibit financial incentives for patients to have genetic testing, and we need to be very careful that no accidents are made in the future about things like this.

So we believe the consumer has a lot to say. I think they're going to be in the center of it. They're facing a health care system that today is not providing what really any of us here are saying are adequate

services, and today's consumer is only about 1 percent of the people who we're going to be facing in the next decade.

I think the success of this committee is not going to be decided -- the question was asked before, how do you define success? I think success is not how do you prepare the health care system for genomics. It's in 10 years have we delivered the health benefits of genomics to the maximum number of consumers?

Thank you very much for the opportunity to talk.

DR. McCABE: Thank you, Dr. Ledley.

With that, that concludes the public comment. We appreciate all of the presenters from the public.