Public Comments
Susan Manley, M.S., C.G.C., Stephanie Mensh, Marueen Smith, M.S., C.G.C., and Mary Steele Williams

DR. TUCKSON: Public comment -- speaking of democracy -- Susan Manley, National Society of Genetic Counselors. I want you to sit right there. Head of the table. They'll make the microphone work.

MS. MANLEY: I thought this would be good timing. Good afternoon. I'm Susan Manley, Chair of the Professional Issues Committee within the National Society of Genetic Counselors.

As you know, NSGC represents over 2,000 member genetic counselors practicing in a variety of medical specialties, providing genetic counseling in prenatal, pediatric, and adult settings, as well as working in academia, research, and biotechnology companies.

NSGC would like to thank this committee for taking our previous testimonies and information into account when developing draft resolutions and reports, and we would like to continue to have input where appropriate as SACGHS moves forward with the important issues discussed at this meeting. Primarily billing and reimbursement for genetic counseling services and the development of population-based genetic databases.

With regards to reimbursement and coverage issues, as you heard yesterday, genetic counselors are uniquely qualified to provide genetic counseling services. But without reimbursement for these services, the public's access to appropriate genetic services faces a limited future.

It is critical to note that Masters trained genetic counselors currently make up over 50 percent of practicing genetic specialists, which means that genetic counselors are currently providing the majority of genetic counseling services, and will likely continue to do so in the future.

Although additional studies must be done to clearly define the value and cost-effectiveness of genetic counseling services as conducted by specific providers, there are already many examples cited by the working group on genetic counseling services through invited testimony yesterday.

The issue of reimbursement for genetic counseling services and in particular, those provided by Masters level genetic counselors, is critical when we consider the impact on the genetics workforce. Specifically, if genetic counseling services provided by genetic counselors and other non-physician service providers are not reimbursed, it will continue to impact access to quality services nationally.

This committee is in the position to make recommendations regarding the future of genetic services in health care. Currently, the educational and credentialing structure exists to produce quality, certified genetics professionals. However, without adequate reimbursement, public health could be compromised by the provision of increasingly available genetic services by uninformed health care providers without specialized training.

As was proposed yesterday by the working group, the NSGC appreciates the support of this committee, and strongly encourages you to continue to develop recommendations that explicitly support the recognition of non-physician genetic services providers, specifically including Masters trained genetic counselors who hold credentials that document knowledge in human genetics and clinical genetics expertise.

We also hope that SACGHS will advocate in all matters appropriate for the development of CPT coding that is specific to credentialed genetic counseling service providers, and for both third party payers and CMS to recognize the importance of reimbursement and coverage for genetic counseling services by appropriate providers.

Lastly, SACGHS can recommend that studies be funded to continue to assess the value and cost-effectiveness of genetic counseling provided by
non-physicians.

With reimbursement, qualified genetic counseling providers can become even more valuable in the financial realm of U.S. health care, and allow more medical facilities to offer quality genetic services to the public.

Finally, the National Society of Genetic Counselors applauds SACGHS for considering the logistical and ethical issues associated with large population-based genetic studies. Many of our members work in research genetic settings, functioning as research coordinators, including the provision of informed consent.

NSGC members recognize that the scientific data that arises from population-based studies will have a powerful impact on the data that is available to provide clinical information to patients in the future.

DR. TUCKSON: Thank you. Susan, that's terrific. I just would say that that's a very important statement. So now given where the committee is, I really, really hope, at least as the Chair of the committee, that your community now will take the initiative and really move forward and provide very detailed and very explicit suggestions into the public discourse around how you actually now accomplish this certification.

Not just for the small groups that have it. You've got to really figure out how that is going to work. You have heard us about 12 times say that there are some fundamental questions that need to be dealt with and answered. You guys have opinions about it, and you probably know others, but I think the ball is really now back in your court in your community to respect the professionalism of what you do and figure this thing out and make those suggestions.

I really appreciate your comments. As I say, now you threw it at us, and we ran with it. Now the question is you all are going to have a lot of work to do. I know that is what you wanted.

MS. MANLEY: And we know that already as well.

DR. TUCKSON: I figured that. Susan, you have been terrific. Thank you so much.

MS. MANLEY: Thank you.

DR. TUCKSON: Greg Rapp? Greg? I'm sorry. Please come right in and introduce yourself for the record.

MS. MENSH: My name is Stephanie Mensh. I'm a consultant to AdvaMed, the Advanced Medical Technology Association. AdvaMed represents manufacturers of diagnostic and genetic tests, among other medical devices, which is why we are interested in the activities of this committee.

We'd like to thank you first for the opportunity to make comments during this session. We're very pleased with the amount of time that you've spent deliberating on issues that our members consider to be very important relating to the coverage and reimbursement of genetic tests.

We do believe that for the tests themselves, how Medicare treats them will have an impact on access. We understand that there are certain limitations in terms of prevention and information in how the agency views these tests, and what they are used for.

We do appreciate the amount of time and effort that this committee has put into understanding the issues. Hopefully your report will be a major source of support to move this forward through Medicare and other agencies that are related.

We did submit specific comments, almost line by line comments in September, and appreciate how much work has been done since then on the draft. We do look forward to doing a very careful review of the report when it comes out for public comment in the next few months.

What I passed around is AdvaMed's policy statement on another section of the Medicare Modernization Act, which we hope that you'll also address in your report, even if it is just to acknowledge to CMS that you are interested in how they are implementing this section of the report. It has to do with how new tests are paid under the clinical lab fee schedule.

You did mention the MMA provision having to do with coverage in the report, but this is Section 942. It also talks about the disposition of new tests. It puts into place a very thoughtful process. A public, open, transparent process. We think this is important because we would like to be sure that the agency and the contractors in the field who may be doing gap filling understand completely what is required of them to develop cost data for new tests, and that this information, the data is made public.

AdvaMed has summarized what is in the law itself at the beginning of the policy statement, but also because the statute is fairly broad as it is written, we have offered our suggestions for additional regulatory provisions that we believe can be implemented on the regulatory level.

There was an open meeting, a town hall meeting, that CMS held in January to take comments. We provided our comments to CMS at that time on new tests, on implementing this section. It is our understanding that a notice of proposed regulation will come out in late spring or early summer to implement these provisions. So the timing of your final report will be right on time if you were to just mention that you are interested in how CMS is carrying out this provision of the law.

I think that that is pretty much what we're asking for, is to just have your recognition that these provisions are important, and that some stakeholders, like AdvaMed and others, in the lab community are very interested in being able to have the best that we can get for new tests, understanding the limits of the current Medicare fee schedule.

Again, thank you for this opportunity to comment. We hope that you will consider making a recommendation in your final report that relates to implementing the new test section as well.

Thank you.

DR. TUCKSON: Thank you very much. Let me also thank you all for a very well done briefing paper. One page, front and back. Very specific, absolutely right to the point on every point

you're making. We understand the point that you're making very clearly. Obviously a lot of work went into this. I think it stands on its own. We have this, and we will certainly study it.

Does anybody have a question?

(No response.)

DR. TUCKSON: Again, very well done. Thank you very much.

MS. MENSH: Thank you.

DR. TUCKSON: Maureen Smith from NUgene Project, Center for Genetic Medicine, Northwestern University.

MS. SMITH: Good afternoon. I'd like to take us back to the topic from this morning on large population studies. I represent the NUgene project, which is a genetic banking study conducted at Northwestern University in Chicago, Illinois. The NUgene project is a population-based initiative whose purpose is to develop a diverse collection of samples and information that will facilitate biomedical research on the genetic and environmental factors contributing to health and disease.

NUgene currently combines a centralized genomic DNA sample collection and storage system with the ability to regularly update participant's health status and retrospective and prospective data from electronic medical records. The project received initial seed funding from the Northwestern University and its health care partners.

I will shorten my statements, as this has been fairly extensively discussed this morning. I just wanted to make a few points.

One is the NUgene study is conducted throughout the Northwestern Health Care System, which includes five hospitals and numerous outpatient clinical sites throughout the Chicago area. We are an approved IRB study through the Northwestern University IRB, and we have a certificate of confidentiality from the NIH.

I did want to point out that we have spent time since the inception of this study in early 2002, up until the present time, and continue to work very closely with our IRB. It has been a very lengthy process of education and work, so I wanted to point out that I think it does take a huge effort to educate IRBs about this type of research.

Our recruitment began in late November 2002, and we had very modest initial accrual goals so that we might better understand how to best educate and work with our physician and participant populations, as well as to evaluate how to improve recruitment in our informed consenting processes.

We have found people to be responsive to learning about the study, and agreeing to participate. However, that certainly does vary given the situation in which participants are approached. But while the public appears interested in participation in studies of this type, we are aware of the need to continuously examine the ethical, legal, and social issues associated with acquiring, maintaining, and managing personal health and genetic information as a large resource.

Therefore, we recently served as the site for the Department of Energy-funded ELSI study of informed consent for population-based genetic research. This project assessed the participant knowledge of our study with the goal of improving the informed consent process for large population research. Results of this study have been presented at scientific meetings, and we are in the process of publishing that data.

The longitudinal and population-based design of this study positions NUgene, as well as similar studies, to be a resource for a breadth of studies, and I won't go into those, as they were extensively discussed this morning.

We believe that our project has begun to demonstrate the value of such collections for research, as over the past six months, being even a small population study, we have distributed samples for three different research studies within our university. These investigations included such varied and common conditions as aneurisms, neural tube defects, and head, neck, and lung cancer.

In conclusion, we believe that large population studies will offer great benefits to society, and will enhance our understanding of how environment, lifestyle, genetic, and other factors contribute to health and disease. The experiences and expertise of existing population studies in the U.S., particularly in the areas of informed consent, building sophisticated data management, and sample storage systems, developing privacy policies, and establishing community trust can be leveraged to provide a framework and guidelines for further studies.

As others in the international community work to create country-specific, longitudinal population cohorts, we believe that preexisting U.S.-based population repositories should be further developed into a national, not-for-profit consortium.

DR. TUCKSON: Well, thank you very much, Maureen, for that. Also thank you for letting us know that the NUgene project is available as a resource as we look forward to these issues going forward. I know several of us will probably try to take advantage of that. Thanks for taking the time to make sure that we know what you are doing.

MS. SMITH: Thank you.

DR. TUCKSON: We appreciate it.

Finally, Mary Steele Williams, the Association of Molecular Pathology. Welcome.

MS. WILLIAMS: Thank you. I'll need to provide a new written document to Sarah based on yesterday's discussions. The verbal comments are a little bit different from the document that I provided you with earlier.

Dr. Tuckson, members of the committee, good afternoon. My name is Mary Williams, and I am the Director of Scientific Programs of the Association for Molecular Pathology. I speak to you today as a representative of AMP.

The Association for Molecular Pathology is an international not-for-profit educational society representing over 1,200 physicians, doctoral scientists, and other professionals who perform molecular and genetic testing, as well as other tests based on nucleic acid technology.

The AMP membership is from a wide variety of health care settings, both public and private, as well as from the IVD industry. AMP members are involved in every aspect of genetic testing, research, and education.

My purpose today is to provide comments on several issues currently under consideration by the SACGHS. First, review of molecular CPT code reimbursement. AMP strongly supports the proposal in the coverage and reimbursement document to request CMS to review and revise reimbursement for molecular CPT codes.

As the number of available genetic tests and their use in routine diagnostics grows, laboratories will not be able to continue absorbing the losses associated with genetic testing as they do today. We strongly support the SACGHS recommendation for CMS to review and revise reimbursement for molecular CPT codes. AMP, through its resources and knowledge of this subject, stands ready to assist CMS in carrying out this recommendation.

Second, change in the definition of a genetic test. AMP's position remains in strong support of the limitation in the definition of a genetic test to inheritable germline variations, and not including somatic variations. If a genetic test is more broadly defined as any molecular biology-based test, then there needs to be a distinction that allows for the discussion of the ethical, social, and regulatory issues to inheritable genetic tests separate from testing for somatic mutations.

This distinction is not relevant to the coverage and reimbursement report, but may be relevant to future reports of the SACGHS.

Third, better coverage and reimbursement for genetic counseling services. AMP in performing genetic tests works closely with genetic counselors and medical geneticists. These professionals provide essential genetic services to patients and their families that are time intensive, and are not adequately reimbursed. AMP strongly supports a recommendation to define genetic counselors as allied health professionals allowed to direct bill, and to review the billing codes associated with genetic counseling services.

Last, gene patents. AMP asks that SACGHS give full consideration the negative impact of exclusive licensing and enforcement practices for gene patents on the future of genetic testing. We understand that SACGHS has set this as a high priority, but has decided to wait for the National Academy of Sciences' study of intellectual property related to genomics and proteomics.

We urge you to promptly set this as an agenda for the SACGHS as soon as the report is available. On behalf of AMP, I thank you for the opportunity to speak with you today. AMP remains available to the SACGHS to assist with or provide information for your thoughtful deliberations and important work.

DR. TUCKSON: Mary, thank you very much. Thanks for making sure that we are staying closely connected with the association. That's important that you are clearly with us as we go forward.

The patent thing we talked about yesterday, and we are right on board there. We are waiting for the NAS report as well.

We don't have a lot of time, but I just wanted to note in terms of I appreciated the guidance around the laboratory testing thing. I'm not sure what we might do with that comment right now, other than we'll take it as

you've made a point. We have to deal with it at some point. So we'll probably get back to it.

Thank you. Good job.