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**Public Comments**

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DR. TEUTSCH: Good afternoon. We have come to the public comment part of our meeting. This is, as all of you know, one of the critical things that we do at every meeting. The Committee uses this as an opportunity to obtain input from the public and get their suggestions so that they can inform our deliberations on a wide variety of health and societal issues.

We, as always, greatly value the input that we get from the public. As you can see from our earlier discussion yesterday, we received an enormous number of comments which were extremely helpful in shaping our priorities, so we will get back to that.

We have four individuals who have indicated that they plan to speak. We will take them one at a time. Each of them will be speaking for five minutes. We very much appreciate all of your thoughts and input, and I think we have copies of your full statements which will be made part of the meeting record.

Let's start with Michele Schoonmaker, who is the director of government affairs of Cepheid and representing the Association for Molecular Pathology. Michele, we have appreciated your input in the past and look forward to your comments.

DR. SCHOONMAKER: Great. Thank you. Good afternoon, Mr. Chairman and members of the Committee. Thank you for the opportunity to speak with you. I am Michele Schoonmaker, representing the Association for Molecular Pathology.

AMP is an international medical professional association representing approximately 1,500 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on the knowledge derived from molecular biology, genetics, and genomics.

I will be providing comments on high priority areas of focus for consideration by the Committee in the coming year. My comments today will briefly summarize the more detailed written statement that we have submitted for your review.

AMP recommends that the following topics be considered for Committee review with development of recommendations. First, we encourage the Committee to investigate the current mechanisms for funding outcomes research for clinical diagnostic tests. Specific areas to consider include implementation and performance of tests in clinical practice settings, the impact of the physician ordering practices and patient decision-making on test utilization, and the impact of test interpretation on patient management and family decision-making.

Second, coverage and reimbursement decisions are increasingly made based on the comparative effectiveness of various treatments. Genomic information may identify population subgroups that contradict aggregate population study findings and challenge population-based treatment decisions. The Committee should explore the role genomics will play in this emerging trend in health policy research.

Third, we recommend that the Committee survey the clinical decision support tools currently under development and explore future needs for the integration of genomic information into the clinical decision support tools, including the development of standards and specific clinical services.

In addition, the Committee should evaluate the current oversight and policy needs to overcome systematic barriers and challenges for the integration of these tools into the patient care setting.

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Fourth, we request that the Committee continue to examine the structure and consequences of non-traditional genetic testing. Important aspects include an understanding of how non-traditional genetic testing will be used by the lay public and an understanding of how these test results will be interfaced with traditional genetic medical practice.

The development of appropriate quality assurance measures and practices to validate the quality of non-traditional laboratory test results or integration of these laboratories into the current regulatory oversight is critical to the utilization of this information in conventional clinical evaluations and treatment decisions.

Finally, we request that the Committee continue monitoring oversight efforts in reimbursement and coverage for genetic tests. SACGHS has released several influential and important reports on both of these issues, and we encourage continued efforts to work with stakeholders within and outside of HHS to implement your recommendations to improve the quality of genetic tests and to achieve appropriate reimbursements for providers of the genetic tests.

On behalf of AMP, I would like to thank the members of the Committee for their time and attention.

DR. TEUTSCH: Thank you, Michele. Any questions or comments for Michele?

[No response.]

DR. TEUTSCH: That is great. As you know, we take all those issues very seriously and look forward to seeing how we can help move some of those agendas forward. Thank you for your input.

DR. SCHOONMAKER: Great. Thanks.

DR. TEUTSCH: Our next presenter is Amy Miller. Great. Welcome. Amy is the public policy director for the Personalized Medicine Coalition. We look forward to what you have to say. Good afternoon.

DR. A. MILLER: Thank you, Chair and members of the Committee. I am Amy Miller, public policy director for the Personalized Medicine Coalition. PMC represents all stakeholders in personalized medicine, from the academics who do the research to the medical institutions that put it into practice, to diagnostic companies, pharmaceutical companies, insurance companies, and we even have among our members ex officio government officials who work with us to make good policy happen.

We are a consensus-reaching organization. We don't vote. That gives us a unique place in the world of personalized medicine. Much like this group, we have all the stakeholders coming together to talk.

Although PMC has submitted to SACGHS where we think your priorities should go, what I wanted to talk today with you about was the space of consumer genomics. As a couple of the speakers have already mentioned, PMC met with the leading companies to discuss the possibility of working together towards standards of operation and basic guidelines about how these companies should act.

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There are a number of issues that need to be discussed. We feel that we are at the very beginning of this conversation. Yesterday and today and the previous SACGHS meeting in particular have started to air a number of questions that go unanswered or that we need to have answered by all the different constituents in personalized medicine. PMC has agreed to work with the companies on convening the stakeholders in personalized medicine to talk about consumer genomics and to build on the work that HHS began yesterday and that this group is continuing today and move it forward, possibly.

We see the output of that effort as possibly being some basic guidelines for operating in this space. We see the possibility of a consumer guide in selecting these services, and we see the possibility of a physician education tool, be it as simple as a brochure or as complex as a report.

We are at the beginning, as I mentioned, of this conversation. We are also at the beginning of what PMC is looking to do in fostering this conversation and coming to a consensus around this issue. So, thank you.

Also, I should mention we will keep the SACGHS apprised of what we are doing, of course.

DR. TEUTSCH: Thank you. Any comments or questions for Amy? I have a question for you. Since there is a clear interest on the part of advising the Secretary on these issues, how do you see what PMC is trying to do to integrate with the more public and governmental functions so that there is some common set of guidance?

DR. A. MILLER: PMC does have ex officio government people on our committees, so we do have representation in our organization. We will work with those members and possibly reach out to some other government members who don't often participate in the PMC process.

We will work with the Secretary's Personalized Healthcare Initiative to make sure that the work that began yesterday moves forward. We will revisit what is written in the report that you recently published and revisit this conversation to make sure that all the questions raised here today are part of our deliberations moving forward.

We are also open to, in answer to your question, any government official as well.

DR. TEUTSCH: Mara.

MS. ASPINALL: I'm involved in the PMC, but it sounded like several of the panelists earlier talked about working with PMC and getting a number of groups together. Is it time to describe what that is and what role you anticipate that playing?

DR. A. MILLER: We are at the beginning of the conversation, actually, in terms of planning what we are thinking about doing. I think our goal is to bring together all the constituents around this issue and do a PMC-type event. What we have done in the past is issue a brief on a topic, convene everybody in a conference, talk about it, and then do some sort of post-meeting product. In this case, it could take a number of forms: a consumer education guide, an M.D. education guide, and guidance for the industry on operation.

But we are at the beginning of the conversation.

DR. TEUTSCH: Thank you very much.

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DR. A. MILLER: Thank you for your time.

DR. TEUTSCH: We appreciate your suggestions. Our next speaker is Rick Carlson. Rick, are you here? I didn't think I saw you. Is someone here representing Rick?

[No response.]

DR. TEUTSCH: Taking that as a no, then we will move on to another friend of the Committee, Ann Willey, who is the director of the Office of Laboratory Policy and Planning at the Wadsworth Center at the New York State Department of Health.

DR. WILLEY: First, I want to thank the Committee for this opportunity. Some of what I'm going to say is known to the Committee but I wanted to put it in the context of speaking to the issue of these entities that are now marketing direct-to-consumer marketing and/or direct-to-consumer access of whole genome profiling of some kind, and the relation to the New York State regulatory program.

New York has been mentioned several times over the last couple of days, some of it correctly, some of it with some perhaps erroneous implications.

The New York State Clinical Laboratory Reference System has been responsible for the oversight of clinical laboratories performing analytical testing on specimens collected in the State of New York since 1964. The categories of testing covered are specified either in the enabling statute or in its implementing regulations.

The clinical laboratory permit requirements include personnel standards, credentialing of the laboratory director, physical facility inspection, proficiency testing, test authorization requirements and result reporting standards, and business practice requirements, among others.

Category-specific standards are stated in our regulations and/or in our interpretive standards, which are issued by the program. Standards for genetic testing related to cytogenetics were first added in 1972 for genetic testing, including biochemical genetics and molecular or DNA-based genetic testing in 1990. Other genomic types of testing, which might include nuclear DNA, RNA, or gene expression profiles, are also covered in other categories such as molecular oncology.

Key elements of the oversight of our genetic testing labs include the training and experience of the responsible laboratory director in the relevant areas of genetics and the performance of tests that are generally accepted in laboratory medicine -- these are tests which were in general use prior to 1976, clearly not those we are talking about today -- or approved by the FDA as cleared or approved in vitro diagnostic devices, also not the kinds of tests we are talking about today.

The only other alternative is that the assay must be approved by the department.

Since 1990 the department has reviewed all laboratory-developed genetic tests as to their analytical validity and clinical validity prior to their approval for addition to the test menu of any permitted lab.

Genetic testing based on a single genome sequence or gene product detection or multiplexed assays detecting multiple targets concurrently, including those used in the various genome profiles, are all subject to similar review standards.

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The recent explosion of Internet marketing of various genetic profiling assays for individualized genome information systems have raised new paradigms for patient or consumer access to such lab analysis. The Department routinely monitors the Internet for entities purporting to offer laboratory services of any kind. Lab services in our system are defined as the performance of an analytical analysis on specimens derived from the human body and the reporting of individualized results for almost any purpose.

We don't limit it to diagnosis of disease and health assessment. The measurement of any component in a biological specimen gets defined as a lab test.

All such entities that we identify on the Internet are routinely notified that in order to offer their services in New York the testing entity must seek and obtain a clinical laboratory permit from the Department and meet all relevant requirements and standards. Just as an aside, these requirements apply regardless of the physical location of that entity anywhere in the world. If they receive a specimen from the State of New York, they are subject to New York requirements.

We have sent 31 entities purporting to offer some type of genetic testing services notices that they must seek permits in the last year. These letters indicate that in the absence of such a permit the service cannot be offered in New York. It is slightly different than the cease and desist type of letter that was sent by California.

That is 31 labs offering genetic tests. We send hundreds of these warning letters with the new age of the Internet.

I do have the list of the 31 entities with me. I thank Kathy Hudson for reminding us that the major entities we have heard from in the last two days are not the major problem in this arena. There are a huge number, and I'm going to go home and add two more tomorrow.

[Laughter.]

DR. WILLEY: There are more and more of these entities purporting to offer some kind of genomic profiling.

Unfortunately for the major players that we have been hearing from today, all of whom have indicated their full intent to comply with whatever requirements and regulations that are put forth, there are many that have no intention of complying. The only way a regulatory program can make the distinction is by forcing all players through the same keyhole, if you will. It is a process that has some burden and delays and problems with it.

Although over 150 laboratories hold New York State permits for various genetic testing menus, none of the major entities marketing consumer access to genetic profiling or their contract laboratories currently hold New York State permits for that purpose.

The Department is in discussions with several of the entities that wish to offer these services in New York, and the issues under discussion include the requirement for the submission by the testing laboratory of the necessary assay descriptions, analytical validation data, and documentation of the clinical validity for the use of these genetic markers in advising the client about health issues. This may be the easiest issue to resolve, depending on the variety of marker to be tested and the known clinical associations for those markers.

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The second item is the resolution of the business relationship between the marketing entity, the data management and interpretation process provider, and the testing laboratory. Within the constraints of New York law related to corporate practice of medicine, which is prohibited, direct billing requirements for laboratories -- the lab that does the test bills the patient -- and inducements, those between the laboratory and the ordering entity, there can be no inducement, no payment, no contractual arrangement between the individual requesting the test and the laboratory. These are complex and often circular issues and have not yet been easy to resolve.

The third item is the physician-patient relationship between the person authorized to order the test and the person tested, and the relationship of that provider with the marketing entity, the data management and interpretation entity, and the laboratory. Laboratories, under New York State permit, are prohibited from performing testing on New York residents except as requested by a person authorized by law to use those test results. For those kinds of tests, that is generally a healthcare provider with an established provider-patient relationship with the tested individual.

The New York program views these genome profiling scenarios as no different than any other clinical laboratory genetic testing menu and expects the providers to comply with all applicable permit and business model requirements. We remain open to working with all interested providers of such services through the permitting process. Thank you.

DR. TEUTSCH: Thank you, Ann. Any comments or questions for Ann? Obviously a topic of considerable interest.

DR. FITZGERALD: Ann, just one quick clarification. Thanks again for updating us on things. So, is it the case that in New York right now there are no direct-to-consumer organizations that have made these arrangements yet with New York State? Did I hear you correctly?

DR. WILLEY: There are entities which market direct-to-consumer marketing that are not providing direct access testing. DNA Direct offers its services in New York. They are not a laboratory, but all of the laboratories that they use for their monogenic gene, disease-specific testing for a New York resident must be New York-permitted, and they are.

But for genome profiling -- they all know it -- Navigenics, deCODE, and 23andMe do not yet hold permit. Some of their contract laboratories where that is the mode of testing have submitted. We haven't finished the review process for the analytical and clinical validity of the assays that they intend to include in those profiles.

But the biggest stumbling block at the moment are the business relationships between these intermediaries and the laboratory: who is collecting the money; who is paying the lab; who is providing the counseling; who is a physician; who is a counselor; what are all these relationships. That is the biggest stumbling block at the moment.

DR. FITZGERALD: Excellent. Thank you.

DR. TEUTSCH: Thank you, Ann. We will look forward to hearing how all of this proceeds in New York and in California.

Thanks to all of you. I think the Committee should all have your comments in their folders. We appreciate all of the public input each time.