Disparities in Access to Genetic Services

A Town Meeting with Members of the
Secretary's Advisory Committee on Genetic Testing
Held in Conjunction with the
National Leadership Summit on Eliminating Racial and Ethnic Disparities in Health
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DR. JUDITH LEWIS: On behalf of the Secretary's Advisory Committee on Genetic Testing, I'd like to welcome you to our town meeting. What we really want to do this afternoon is spend some time having a conversation with all of you. My name is Judy Lewis and I'm a women's health nurse practitioner. I am a member of the Secretary's Advisory Committee on Genetic Testing, and I have the privilege of chairing our Access Working Group. My colleagues with me, Victor Penchaszadeh and Vence Bonham, are also members of the Secretary's Advisory Committee and also members of the Access Working Group. We thought we'd just spend a few minutes at the beginning of the session giving you a little bit of a sense of where we're at, but basically what we are here for is that we want to hear from you.

Just for those of you who don't know, basically when we are talking about genetic testing, we are talking about the analysis of any human DNA, RNA, genes or gene products, for the purposes of doing prenatal testing, newborn screening, testing people for carrier status, doing diagnostic tests, doing predictive genetic tests, both presymptomatic and risk assessment, and also using genetic tests in the area of pharmacogenetics and medication and genetic effects of medication. Genetic services include a wide variety of issues including family and medical history taking, patient education and counseling, management and treatment, and actually genetic testing itself. The Secretary's Advisory Committee on Genetic Testing was formed with the purpose of addressing medical, ethical, legal and social issues raised by the development and use of genetic tests. Our goal is to ensure the safe and effective incorporation of genetic technologies into health care and to identify other research needs related to our mission. Basically, the way we work is that we make policy recommendations to the Secretary of Health and Human Services. Our reporting stream is through the Assistant Secretary of Health. The Committee is composed of thirteen voting members - and you see three of us here - and we represent a wide variety of perspectives in terms of health care advocacy, industry, genetic counseling – all sorts of spectra. We also have seven non-voting members who represent the various agencies within Health and Human Services. One of our representatives is here today, Michele Lloyd-Puryear, who is one of the ex-officio members of our Committee. So, we work together, and the goal is for all of us –. We have felt public input has been a very, very important part of the policy development process. We have used many, many mechanisms for public access and for getting public comment. We have public consultation and we have public testimony at our meetings. For some of our work, we set up an interactive web site. We actually had a public consultation meeting a couple of years ago – January, in the middle of Baltimore's very last, very big snow storm, which was also a challenge. We've done lots of outreach to organizations and we're very pleased to be here today.

One of the things that's been very important to us throughout is to make sure that we have targeted efforts, to make sure that we get a diverse group of perspectives. At several times as we have done outreach meetings, we have worked really hard to have steering committees that represent diverse

perspectives to help us plan the meetings to make sure that we are capturing a wide variety of perspectives, and not necessarily a single or unilateral perspective. Just to give you a sense of some of the work we've done to date: We've done – our first report was to the Secretary – our very first assignment was to advise the Secretary on whether or not there should be a need for additional federal oversight in the area of genetic testing. So we did lots of public consultation, and as a result, we came out with major oversight recommendations, including the fact that we believe all new genetic tests should be reviewed by the Food and Drug Administration prior to marketing to ensure safety and effectiveness. This includes commercially prepared as well as what's called "home brew" tests. We believe there should be federal regulations for ensuring the quality of testing laboratories and that these should be augmented to include specifications that are unique to genetic tests. We believe that all genetic tests that are investigational, that use identifiable samples, should undergo review by Institutional Review Boards and that enhanced data collection and dissemination efforts are needed once genetic tests have been marketed to the public.

We've worked on issues also of genetic discrimination. We've advised the Secretary about our concerns about genetic discrimination in health insurance and employment; in issues relating to gene patenting and licensing; and issues relating to informed consent of third parties in research. Right now, we have five Working Groups that are dealing with issues that we work with in small groups, such as our Access Working Group; and then each of these groups formulates recommendations and we present them in our public meetings that are held four times a year.

In addition to access, we continue to work on oversight. One of our issues is educating what is the appropriate role of the federal government in insuring education of healthcare professionals and the public. We had a major educational summit in conjunction with our last meeting. We're working on issues related to informed consent and issues of rare disease testing. The Access Work Group is specifically looking at issues related to coverage and reimbursement, to healthcare disparities, such as differences in health and disease and differences in access to and quality of health care. So that's just to give you a broad background of where we're at, and now I'm going to turn to Victor to say a few words and share with you his perspective, and then to Vence. Yes, ma'am.

DORTICIA MCNEIL: In the handout you mentioned that seven governmental agencies that are within the HHS are on the Committee. I'm with the Office for Civil Rights and I'd like to make a recommendation that the Office of Civil Rights be included on the Committee since you are looking at discrimination and you're also looking at disparities issues. One of the problems that we have is that we are not involved until too late. So if you're developing policy and making recommendations, I think it would be critical for us to be a part of that.

DR. LEWIS: Well, thank you, and I really appreciate that. Are we going to be able to capture that comment without a microphone? Okay. I just want to make sure, because I know we have the hand-held mike going around.

JENNIFER JOHNSON: I won't need a mike. Okay. Hi, how are you? I'm Jennifer Johnson. I came all the way down from New York Methodist Hospital. I'm the new genetic counselor, and facing off of her comment, I'm noticing that the National Society of Genetic Counselors is not on this group here. I think that they would also be an important group to include because the genetic counselors, we're the ones who are counseling the patients about the genetic testing, pre- and post-counseling.

DR. LEWIS: Thank you. Yes, and we have had Ann Happ-Boldt who is a past president of the National Society of Genetic Counselors (NSGC) as a voting member of the Committee. She rotated off last

February. We also have several members of the NSGC who are on some of our Working Groups and your current president is always present and testifies at just about every meeting. I really appreciate that, and we do appreciate the perspective. Maybe Victor would like to say a few words, and Vence, and then we'll go ahead and start the discussion. Victor.

DR.VICTOR PENCHASZADEH: I'm Victor Penchaszadeh. I'm a medical geneticist. What brought me to the Committee has been essentially; rather what I brought to the Committee – I don't know what brought me to it - is my concern for equity in health care in general, particularly in genetic services and genetic testing. The concern that misconceptions on genetics don't affect, are not part of the discrimination against people, and basically the need for proper education and counseling before, during and after the genetic testing process. As you heard from Judy, one of the main recommendations that the Committee has already proposed is the fact that all genetic testing should require informed consent. I am chairing one of the subgroups within the Committee which is the Informed Consent Working Group. We are currently working on all these complex issues of how to implement informed consent for all genetic testing. I'll be very happy to answer any questions regarding all these issues and whatever you may have in your minds to ask. Thank you.

MR. VENCE BONHAM: My name is Vence Bonham. Good afternoon. I am an associate professor in the Department of Medicine at Michigan State University and a lawyer by training. I am one of the four newest members of the committee. My particular area of work and research is involving issues with regards to some of the legal, social, and ethical issues related to genetics and genetic testing, as well as work related to health disparities, where I am also involved in work looking at a number of different issues with regards to treatment and services disparities of different racial and ethnic groups.

We are here this afternoon to learn from you. So that gives you a context of our background and a little bit about the Committee and the mission and purpose of the group. But we really want to hear from you. I was asked by my colleagues to moderate this afternoon, and I really kind of want us to lead into that at this point in time.

I would like to set several ground rules. One ground rule is that we would like everyone to speak in the mike because we are recording this, and we are going to provide it back to the members of the Committee so that each member will get a transcript of what was said - what are the comments, some of the concerns, the issues that are raised, and they'll be shared and discussed at the next meeting of the committee in August. The second issue is we would like for you to identify yourself by name and affiliation so that we have a context for the comments that are coming. The final ground rule that I would just like to give is just kind of respect of each other that we don't take too long with our comments. I'm not going to set a specific kind of time limit because we are a fairly small group, but we really would like to make sure that everyone has an opportunity to be heard. So as you share your comments or your questions that you respect everyone in the room and their time. Fair? I guess I would like to go back and start with the member from the Office of Civil Rights to just share her comments on the microphone as someone who has already raised a comment.

DORTICIA McNEIL: Hello. I'm Dorticia McNeil. I'm with the Office for Civil Rights. I'm actually out of the Philadelphia, Region III Office. Just to repeat what I said earlier is that I noticed that the seven divisions of HHS that are included in the committee do not include the Office for Civil Rights (OCR). The fact that you are dealing with policy formation and recommendations, you're dealing with issues of discrimination and health disparities, I think it would be very important to include OCR on the Committee. One of the problems that we have is that often we're brought to the table too late. When we

are trying to do civil rights enforcements, a lot of times there aren't policies that the recipients have to adhere to that help to make our job easier. So, I would strongly suggest that OCR be included, and I would even like to specifically recommend Lisa Evans, who is the Senior Civil Rights Analyst out of our headquarters office. Sshe also has the lead responsibility for health disparities and coordinating that initiative throughout the ten regions.

FRANKLIN ZAVALA VELEZ: My name is Franklin Zavala Velez, Chairman of the Board of Directors for the Center for Independent Living of South Florida. I represent the people with disabilities, multiple disabilities. When you are concerned about civil rights or American disability it had been a lot of problem in term of how health professionals discriminate or stereotype people with disabilities because based on communication. Being hearing impaired - you can see I have a sign language interpreter - and you can see that it is very difficult for persons who are deaf who are being discriminated in terms of many of the health professionals because they did not want to hire an interpreter. In order to comprehend the language to understand and to find out its because English language is one language; American sign language a totally different language. Yet the health community of the deaf are being neglected, are being treated like third-class citizens - not second-class - third-class citizens, unable to get access to health care or everything else, yet, as equally as everybody else. I strongly would have the Federal Independent Living Council which was established by Congress in 1975. It was a Washington member of Congress at that time who established it. Centers of Independent Living are all over the state and different parts of the county never have been approached by health professionals as to how can we improve quality and quantity care for people with disabilities who are blind, who are deaf, who have multiple disabilities. And that we are just dropped off the face of the earth. When anything that comes to health, we are just dropped off the face of the earth. I made a point already that the Health and Human Services already violated the ADA law by not even having a TTY number on their posters. Just to give you an example of how hard it is to get information. You can get information by 1-800 number when you put that out in the street of any type of information you wish to reach to the community; you always never put a TTY phone number. What, you think twenty-six million Americans who are hearing impaired are not citizens of the United States? Here you have Gallaudet University located in Washington, DC on Florida Avenue. There you will see they have over twenty thousand students from all over the country. If you could just go over there and visit that particular institution you could see for yourself – you are a minority once you go in to that campus; we are the majority. But we never, ever get information on health care, health access, anything. We just dropped off the face of the earth. I strongly urge for you to get in touch with the president of the university at Gallaudet, Jordan King, and establish a relationship with the deaf community also. I know you guys are not blind; they are all over Washington, DC when they take a break. We demonstrated for a deaf president in 1988 and closed down the Capitol with five thousand deaf, if you remember. I'm one of them. I asked a police officer, "Do you have the sign language I would like in case you have to arrest us?" and they lost right there. They couldn't even touch us. But we got what we wanted. How come we're never involved, working together in partnership to reach out to the deaf community? I appreciate you start thinking about us because next time we'll meet the next Supreme Court or federal court to discuss about this.

MR. BONHAM: Thank you for your comments. Next comments.

AGNES MASNY: I'm Agnes Masny and I represent the Oncology Nursing Society. As a follow up to a comment about translation, I wanted to mention that we commend all your efforts that you've done regarding making recommendations for education, but we know that it's going to take a while for healthcare providers to get up to speed in this whole genetics area. In the meantime, for people to have

access to genetic counseling or to any of the genetic services that should be available to a variety of populations, we'll have to pay special attention to make competent translators in this whole genetics area, because sometimes there is a difference between just translating and translating appropriately. I think this whole genetics area is going to bring up many, many challenges.

MR. BONHAM: Thank you. I also want to highlight the questions that we included in your power point presentation. So as you share your comments, these are some of the questions we had identified as some of the things that we wanted to make sure that we are getting information from the public as well as we clearly want to hear other concerns and issues that are not identified in our questions. So, I want to just focus you to those questions and also as you provide your comments. The first question was, "Of all the issues concerning genetics and health disparities, which ones should the Secretary's Advisory Committee on Genetic Testing focus on? Are there issues that the Secretary's Advisory Committee on Genetic Testing should not address?" The second question: "What should the Department of Health and Human Services be doing to address disparities in access to genetic services? What should the Secretary's Advisory Committee on Genetic Testing consider recommending to the Secretary? How can the Department of Health and Human Services help to promote the successful efforts? How can the Department of Health and Human Services ensure that genetic services are tailored to the community being served?" So those are some of the questions. There are other questions in the next two slides. I'm not going to read all the questions, but again, I would also encourage you to look at those questions as you provide us comments.

DORTICIA McNEIL: One of the questions mentioned on the Power Point is "Are there other issues that might deter people from genetic testing?" One of the issues I think might be a concern for people is privacy and what's going to happen with the information once it's collected. I don't know how you all are addressing that but that's something that definitely needs to be considered.

MR. BONHAM: Could you identify yourself again?

DORTICIA McNEIL: Dorticia McNeil, Office for Civil Rights.

ANN RECCHIE: I am Ann Recchie. I am Executive Director of the Aegis Initiative Foundation. My question really is in regard to BRCAnalysis, something that we are doing for Myriad Genetics . I am a little concerned that Myriad is starting a campaign in the fall advertising print and TV to get the word out to everyone, and concerned furthermore that Myriad – their only requirement right now is that someone have MD after their name in order to order that test. And while they have a physician of excellence program where they are taking time out to train doctors and nurses, since we will be dealing with oncology-related diseases, not necessarily oncology doctors or hemotologists, per se. But in the health care industry, as you are well aware, everything in the name of the game is profit. And you have to see four to six people an hour to make your private clinic profitable, I'm concerned about what kind of genetic counseling people are going to get from those who are not genetic counselors. When I asked Myriad – I called Myriad yesterday and just flat out asked them – they said, "Well, we are hoping that someone, a nurse, may take maybe a Wednesday afternoon once a month to talk to the people that test positively." As any genetic counselor knows, it's one and a half to two hours to answer all of those questions. I'm curious. Are you concerned about what they are doing, and are you concerned enough to do something about it or address it? Thank you.

MR. BONHAM: Questions?

DR. LEWIS: Let me take that on. One of the things we have spent a lot of time talking about at the Committee is the appropriate use of genetic testing and recognizing the fact that genetic testing is more than giving a test and getting a result, but there's a whole process that goes on from the validity of the test in the laboratory to the pre-test counseling process. Does somebody actually even - is the test appropriate for the patient, and then after the test, if the test is appropriate and it's ordered, and issues of access to make sure that those who need to get it and those who don't necessarily need the test aren't given the testbecause of some of the issues that you have raised, and then the post-test counseling. We see the whole thing as a process. One of the things that we are very concerned about and why, I think, one of the reasons, maybe, we were formed, was the whole idea that public policy goes along with the development of science and that the policy piece is an important part of it, looking at the whole broad range of services. So, I would say that the issues you have raised would be issues that would be of concern to the Committee, and I really appreciate your raising them.

DR. PENCHASZADEH: If I may complement what Judy just said. If the Committee had been in existence by the time the BRCA 1/2 were discovered, and if our recommendations had been implemented by the powers that be, Myriad would not have their way as they have had so far. First of all, because one of the essential recommendations, after lengthy discussions, that we enacted, or we promulgated, is that first of all you have to demonstrate clinical validity and clinical utility of a test. Not only how it performs in the lab, but what it means in terms of health outcomes, and particularly what it means for individuals having a positive or negative test. Predictive testing of conditions such as breast cancer is a very complicated issue, because we all know that breast cancer is due to a multitude of factors and BRCA 1/2 are only five or ten percent of the total, which means that we are interested in the government playing an important role in ensuring that before any tests such as BRCA 1/2 are introduced into the market there is some information about the clinical validity and clinical utility of the test. I think that this is probably one of the most important safety concerns that we have about genetic tests in general. Of course, the other issues are the ones that you raised. Once the test has proven clinical utility and clinical validity, how to make sure, first of all, that the proper indications are followed, number one. Number two, that people have appropriate informed consent. Informed consent, as far as genetic testing is concerned, means proper counseling and education before, during, and after the process of genetic testing. We definitely share your concern. That concern already has been elevated to the Secretary of Health in our first set of recommendations about oversight and now we are working on these issues of proper consent and proper education and counseling surrounding testing. Regarding the question of privacy that was raised earlier, it is also a major issue of genetic testing and could become a major barrier, also, for people to avail themselves for testing. We are working on that following many of the recommendations that have been put forth by a number of national and international bodies: that genetic testing should be private and should not be used to discriminate against people either in the health insurance or in the labor force, etc.

MR. BONHAM: Comments.

PARTICIPANT: I just had a comment since Myriad . . .

BONHAM: Could you give your name and affiliation?

EVELYN CHURCHVILLE-LETARTE: I was invited by the Oncology Nursing Society and Agnes Masny. I just had a comment since Myriad Genetics was mentioned. I did have genetic testing for BRCA 1 and BRCA 2, and at the time, I worked for a healthcare agency. If it wasn't for that being involved, the cost from Myriad Genetics would have been prohibitive. At that time it was twenty-six hundred dollars to have the test done. As a minority, having it done, if I didn't work in that hospital at that time, there is no

way that my insurance would have covered it. I just find that at that time Myriad was the only lab that is specifically for genetic testing, and I would really like to see other labs afforded that opportunity. Maybe the cost would come down at that time. I know as a minority, I probably wouldn't be able to have it done if it wasn't for working at that hospital.

MR. BONHAM: Thank you for your comment.

DR. PENCHASZADEH: If I may comment on that. The main reason why the test was so expensive initially, and still is very expensive, is because Myriad has a monopoly on the test. This is another issue through patenting and licensing. This is another issue that we have started to look at in terms of the ethical issues surrounding patenting.

JUDITH BENKENDORF: Good afternoon. I'm Judith Benkendorf. I'm a board certified genetic counselor. I guess I've worn many different hats over the years, but I'm a genetics and public policy consultant right now with the Center for Genetic Services and Health Workforce Research through the University of Maryland - Baltimore. I just wanted to say for the record, and I know this is an issue that SACGT has grappled with since its inception, and that is, I think, classically in medicine, when we think of risk and benefit, and we think of informed consent, we obviously do go through the whole validity and utility of tests as well as medical risks and benefits. But I think, in genetics, a big part of the education and counseling are the social or non-physical risks. I just wanted to make sure that gets on the record, because I have a lot of concerns from back in my days of prenatal counseling that those technologies that have no physical risks, like ultrasound and maternal serum marker screening, have no informed consent and no education. And they give vast amounts of information – predictive information - that people are not always prepared to handle medically, emotionally, from a religious standpoint, and then the counseling becomes crisis management, rather than up front doing some values clarification before the test is done.

DR. LEWIS: Thank you for bringing that up for the record. As you know, from having been to several of our meetings, there are issues that we have grappled with, and there are issues that we will continue to grapple with, which is what is the value of information.

MR. BONHAM: Comment in the back.

JENNIFER JOHNSON: I was just going to add to what you - I'm sorry, I don't know how to pronounce your last name.

DR. PENCHASZADEH: Penchaszadeh.

MR. BONHAM: And you can give out your name and affiliation.

JENNIFER JOHNSON: Jennifer Johnson. I'm a new genetic counselor at New York Methodist Hospital, and I just wanted to add to what you said. The BRCA – Myriad has the patent on the BRCA gene, if I believe, and that's why they're pretty much the only way to get our BRCA tests, so that leads into also the issue of gene patenting. Where is that going to go? Because once a company owns the patent on that gene, it prevents other companies and other laboratories from maybe doing a better or even more affordable test. That's also an issue that goes into advocacy as well as the genetics. I just wanted to add to that.

DR. LEWIS: And we actually have written to the Secretary, sharing our concerns on that issue. That is something that we did , what, about a year and a half ago, Suzanne?

AGNES MASNY: I'm Agnes Masny from the Oncology Nursing Society. This is a question that I have just in looking at some of the areas that you were looking at, and on the slide that you have about what is a genetic test. Aren't you going to be also considering the microchip technology that is very rapidly advancing now into practice?

DR. LEWIS: That is something that has come up and as we have been talking about looking at bringing tests into practice. One of the comments that we had was that basically, the challenge of that is if there are a hundred tests, does that mean that you have to go ahead and do informed consent for one hundred different tests as you are doing the microchip? So, it certainly is something that we have been addressing.

DR. PENCHASZADEH: That is something that we haven't gone to much depth so far, but it's something certainly on the horizon. We have raised the issue of multiplex testing, which is part of the microchip technology.

MR. BONHAM: There have been several comments related to access that have been raised. I want to more formally raise the question with regards to access issues. We have a working group that is focused on that, but as we are here in a meeting that is focused on issues around racial and ethnic disparities and health, I want to raise the question related to access to services based on racial and ethnic background. Are there any comments related to that, that people would like to share?

ANN RECCHIE: Anne Recchie, again, with the Aegis Initiative. First of all, I want to commend you about the brochure. It was given to me, I think, in June, so it was a little late for comment, which was due in April. But you did the brochure, and I thought that it was very well written and would like to see a Spanish version. I also wanted you to know, and anyone here, if you are interested, I have in my possession all of the insurance companies that cover BRCAnalysis for breast and ovarian cancer as well as Colaris for endometrial and colorectal cancers – all of the insurance companies that would cover that from Myriad. So, if anybody would like that, I'd be happy to send it to them.

FRANK ZAVALA-VELEZ: My name is Frank Zavala from the Center for Independent Living of South Florida. I have been working on disparity for a very long time. All different kinds of brochures on cancer, cardiovascular and everything. In Miami, I have translated not only in American Sign Language at the expense of foundations, not by federal government. I always get in that beautiful letter saying that my proposal is so unique but we cannot fund your program. That's a nice letter to get for a person who is disabled or an organization. But I'm also looking at the Haitian community. I live in the Haitian community in North Miami. The mayor of North Miami happens to be a Haitian-American. I'd like to see material in Creole to read because the Haitian community or race are not being addressed, immigration and all sort that is coming in. Also, I have Russian migration coming into Miami and information in the Russian language is not available. As many languages not available whatsoever in any type in the health disparities, and yet what are you going to do about it? I mean you're going to hear it and you are going to make recommendations, but yet I spent ten years fighting with Health and Human Services about this. Still, it's not being done. Ten years is a long time fighting this and still not being done. That is a violation of civil rights of the Rehabilitation Education [Act] of 1973, for God sake! We're not talking about ADA now. I'm talking about laws that existed in 1973 are not being enforced. What are you going to do about it – a law that is almost thirty years old. That needs to be addressed immediately. A thirty-years-old law have not been addressed.

MR. BONHAM: And thank you for your comments. They will be part of the record. I want to remind everyone that our charge as a Committee is really focused on the issue around genetic testing and genetic services. So, we will be providing recommendations and comments to the Secretary related to those issues. We have, I think, a broad range of people here as well as they will receive the transcript. So I appreciate your comments.

EVELYN CHURCHVILLE-LETARTE: My name is Evelyn Churchville-Letarte and, again, I was invited here by the Oncology Nursing Society. I worked for a hospital in an underserved community and predominantly with a breast cancer program. I did find, since that was rather close to me, that in the minority areas or underserved areas, there is not enough focus on getting the word out about genetic testing to our breast cancer patients. I also found that there is a lot of stigma involved, or stigma still attached, when you talk about genetic testing. I think it's because of probably literature, or because the literature isn't geared to that population. I'm just hoping that you would take that comment and make literature that would be geared to the minority or underserved population that genetic testing for breast cancer is available, or more studies, or more programs. I guess what I am trying to say is I know there's grants. if you would make it more accessible for grants for genetic testing without going through a lab like Myriad. I would like to see that put in place.

MR. BONHAM: Thank you.

JENNIFER JOHNSON: Do I have to say my name again?

MR. BONHAM: You can give your name; you don't have to give your affiliation.

JENNIFER JOHNSON: I'm Jennifer Johnson. Just to back up with your comment. I'm wondering exactly what kind of research your facility is involved in, because I know I've been doing - I just finished graduate school and I got a dual masters in health advocacy and in human genetics, and I have been trying to recruit African-American women into breast cancer research studies for years. I'm African-American, I try to get in there. I talk the language. You know, "How you doin' girl?" – the whole bit. I try to get in there and sound like I'm somebody that they'll listen to, and a lot of Aftican-Americans are very, very scared of genetic testing. So, it's not even a matter of is it Myriad, is it not Myriad, is it the language. You have a problem with the culture that is scared of genetics. And when you have all of one percent of African-American genetic counselors, we can't do it by ourselves. So, I think we have to look at the broader issue. I also speak Spanish, and it's hard to get that community also. I think people aren't focusing on the larger issue. Because it's not just is there money or is there not money, it's how do you get genetics out there. I have women who have been to genetic counselors for AMA, risk of Down's syndrome as you get older when you are pregnant. They don't really know that they have been to a genetic counselor. All they remember is looking at pictures of the chromosome. So, you really got to get genetics out there, I think.

MR. BONHAM: There were a number of people that nodded heads and raised as you made your comments, and the broader social issues. We decided not to do our presentations that we originally had prepared, but raising a number of the kinds of issues of concern. We would like to hear from the group here with regards to what are some of the issues, maybe ways to address some of the issues, but clearly putting on the table concerns that may have an impact on why certain groups may not want genetic services or consider participating in genetic research.

ANN RECCHIE: Hi. Ann Recchie again. What I found in the Hispanic community in North Carolina – we have a tremendously large Mexican population. And we find, by and large, there are several reasons why they don't want to be tested, and it's not just for oncology related diseases. First of all, there is the illiteracy factor; perhaps most of them have a sixth grade level education in Mexico. So when they come here and trying to ascertain information and learn in English, it's extremely difficult for them. Secondly, they are very religious as a whole – Catholic - and believe that many things are God's will. So you are also battling that. They are very family oriented; they think that many things are preordained. These are just the conversations that we have had with them. Oftentimes, they will agree to show up for the appointment, or to come in. And we are in a particularly unique situation because this foundation is the first in the country to help people – the underserved population – gain access to those tests that are so expensive. That's really the whole mission of our organization. So we are constantly going out and talking with them, and it's falling on deaf ears. The Hispanic population in North Carolina, they are very cordial, very sweet, they don't want to disappoint, so they'll tend to say, "Oh yes, I'll be there for that appointment," or "I'll come back," and then they never show.

As far as the African-American community, what we have found is there are -. Remember that African-Americans, traditionally when there have been needs assessed-base studies done, everyone runs to the African-American community, and when those test results are in or those assessments, do they really benefit from anything? Largely, many times, sadly they don't. It's somebodies PhD dissertation or a thesis, and that's all the far that it gets, or it's used to help get money that's never used where it should be. That, and I found also the Tuskegee legacy. Every once in a while when talking to people that will come up, "What are you going to do with this information?", "What guarantee do we have that it won't be used against us?" I explain that to the best of my knowledge to date no one has been turned down for health care. However, for life insurance, that's a different matter. Those are really the primary issues that we are dealing with with the Hispanic and African-American communities. I'm out there talking, and I find, as with so many things in the African-American community, if you really want to reach the most people, get into the churches, get involved in talking to those groups. And it is so well received, what we talked about. I give away more brochures than you can imagine and business cards, but when push comes to shove, that last step across the threshold isn't always there and it's very frustrating.

MR. BONHAM: Any comments?

DR. PENCHASZEDEH: I just wanted to follow up on what she just said, and I would like to put things into perspective also because suddenly we have to acknowledge that genetic testing is very imperfect yet. There are three main goals: you can do genetic testing to diagnose a particular disease in an individual who has symptoms of a particular condition; you can do genetic testing for prenatal testing, or for predictive testing in adult diseases like cancer or something like that. If you take out the diagnostic use of testing, which is, I would call it, mainstream medicine, where the value of the diagnostics may be followed by a particular treatment of an individual with a disease, and so on and so forth. So if you take that out, prenatal testing and predictive testing are the most likely to collide with some of those cultural factors that you have mentioned. Medicine doesn't have so much to offer yet. Prenatal testing is essentially interrupting a pregnancy or will affect the fetus. Of course, in this audience I don't have to say all the collisions that can occur with religion, with social, with culture. For predictive testing, there is only one or two examples of conditions for which medicine today has something to offer to those who test positive. Genetic testing is no panacea. It's not that we have an accepted, wonderful medical technology that will save our lives and improve our health and some people don't have access to it. Sometimes having excess access may be detrimental because if you have the means, you rush to have predictive testing, which may eventually backfire or become counterproductive for your own health or

well-being. I agree that we are actually striving against all those barriers, and we would like to have a health care system that would be equitable and have no financial barriers nor any other type of barriers to testing. We have to keep in mind the most important factor here is to assure that they are safe and that they are effective in the roles of medicine. We are only at the beginning.

JUDITH BENKENDORF: Judith Benkendorf again. Victor, I think I want to piggyback onto your comments. I think we have two different issues here. One is access to information about genetic services and testing, and the other is uptake of testing and testing decisions. I would wholeheartedly agree that there is still a great deal of work to be done to get culturally appropriate, sensitive information at the right literacy level to underserved and minority communities. If we take a look at the demographics of the genetics workforce, it does not at all reflect the demographics of the United States or the communities that we are serving. It is a problem. I can say that as the white upper class female that was sent into the only public prenatal substance abuse clinic in the District of Columbia and to the jail and it took me quite a while to become accepted there. So I certainly know about some of those hurdles. We need to work from the grassroots up with communities to get information to them in a way that they can make the best possible decision. Genetic testing, when it comes to, as Victor said, prenatal diagnosis and predisposition testing, is really about choices. Few people would deny their child a chromosome study for Down's syndrome or a newborn screen. I don't think that's what we're talking about. But I'm not upset when a person really has thought about the issues, has all of the information, understands the facts, and then decides the test is not for them. We are going to see communities that are more amenable to technology where there is going to be a higher uptake of testing. Reimbursement may not even be the whole issue for that. I think it's okay for us to be a society where the uptake of testing is different in different communities. The question is, "Is there the opportunity to get testing equal?" I think that's our goal.

DORTICIA McNEIL: Dorticia McNeil. I would just like to say a couple of other issues that I think are relevant are the lack of trustworthiness and the lack of enforcement. I keep hearing people talk about literacy and education levels. I am a college graduate and I have had instances where I have asked doctors about what are the associated risks and they will tell me there are none. But because of my own research and studies that I've done, I know that's not correct. I've had doctors who get offended because you ask questions about the treatment that's being provided. Almost as if, "What are you asking? Why are you questioning me? Who are you to question me?" I'm not denying that literacy and education is not an issue. I know it is an issue, but there are other factors as well. You hear people talk about Tuskegee all the time. There are probably other incidents that occurred similar to Tuskegee; Tuskegee is just one that is very publicized that we know of. Look at how long it took for the government to address Tuskegee. So, when you look at minority communities and you talk as if there is something wrong with them because they remember Tuskegee, there are incidents that people have experienced that we just don't know about. To say there is something wrong with them because they are not willing to have genetic testing or they are not willing to be in clinical trials. We've got to remember there are things that are going on. If the attitude is let's pretend that this didn't happen, let's not acknowledge this, well, why should you trust someone that you know has done wrong to you in the past and they don't even want to admit that it happened? Why should I say, "Okay, I'm going to forget about that and I'm going to trust you now when you are not even willing to admit the wrongs that have been done to the communities and the people." So, a big factor is trustworthiness and to just pretend that things did not happen is not going to cut it.

The other thing is enforcement. We're talking about privacy issues. We're talking about what is going to happen to the information once it is collected. If there is no legislation or policies to address this, then we really cannot tell people, "Well, your information is going to be protected." If we do develop policies and legislation, but there is no funding for enforcement, and there are no human resources to enforce these

legislations, then we still have a problem. Those are two things that we need to look at. If we are not going to have human resources and funding to enforce the legislation and the policies, and if we are not going to address the idea of trustworthiness, then we still are going to have a problem getting minorities to participate.

MR. BONHAM: Can I ask you a follow-up question to your comments? Related to thinking of the role of the Secretary's Advisory Committee, what do you see as some of the things that the Committee can do to address some of the issues that you have just identified?

DORTICIA McNEIL: Particularly with legislation, like I mentioned earlier, involving OCR, so that when policies are developed we are looking at issues of discrimination, and it's not an afterthought. It's not that we have done everything, we have developed our policies, and now since we are getting complaints, now OCR is trying to figure how we are going to deal with this. Bring OCR to the table in the beginning so that when policies and legislation are developed, we have already looked at the issues of discrimination and differential treatment and we have shaped the policies in such a way that health care providers, genetic testers, and healthcare institutions that are going to do this have to address those issues and how they are conducting the testing, how they are providing counseling, and what they are doing with the information, how the information is being stored, who has access to that information. We are already looking at issues of discrimination and differential treatment.

Also, making recommendations to HHS and government officials that we provide funding so that the policies and the legislation that is developed will be enforceable. Some of these issues came up in earlier workshops and they were talking about the fact that OCR does not have enough resources to do what we are supposed to do. Well, if we are not going to increase the staff of OCR and we are not going to increase the budget of OCR but you are increasing the responsibilities, how do you really expect us to successfully carry out those responsibilities? One of the things that you can do is make those recommendations to support us.

MR. BONHAM: Thank you.

SHARON MARABLE: Hi, my name is Sharon Marable. I think it would be a lot safer if I spoke as a private citizen. I do work for a state government, but I think that I can be more candid and more loose if I would talk as a private citizen from Massachusetts, so that's how I would like to be on the record.

MR. BONHAM: Okay.

SHARON MARABLE: Dr. Sharon Marable, Sharon, Massachusetts. Okay. Being that as it may, what this Committee needs to do is look within its own shop and make changes. For example, you have on your advisory committee members from CMS and CDC. Let's talk about CDC. CDC has a national breast and cervical cancer initiative, which I hold PI in my state. There is no official genetics component in that program, and we don't have a sense, we're not asked to evaluate or get any type of sense of how many women in that program have BRCA 1/2. So if you want to integrate genetics, look into your own shop and see where there's a correlation with what you want to do. Make sure that the state agencies that have these things that you want do what you want. So basically, clean up your own house, your own garden, first of all.

The second thing is reimburse the healthcare system properly for testing and make sure that all the people who need the services, particularly people of certain race and ethnic groups, get the reimbursement and

get the access. For example, in one state, and this is the state where I work, we have a program called Right Care. Right Care is Medicaid health insurance for pregnant and parenting women and children, not the fathers. If a child has sickle cell anemia and you want to test that line, we can test the mother because it is covered with Medicaid/CMS/Health and Human Services. However, in our state, the father is not covered. What ends up happening is that mother and that child get tested and the father does not, not because he does not want to get tested and in this case not because he is feared of Tuskegee, but just because he simply cannot afford that test.

Those are two salient, clear examples regarding what's happening in the nation, in things that you can do. Again, my recommendation is to water your own garden, and clean up your own house. Thank you very much.

MR. BONHAM: Thank you.

LAURIE NSIAH-JEFFERSON: Hi, I'm Laurie Nsiah-Jefferson. I'm a Kellogg Fellow, and I've also done a lot of work around genetics and culturally competent populations. Currently, I am working on a project with the New England Collaborative for Managed Care and Public Health. We recently put together a survey in reference to how states can begin to address collaboratively with managed care around genetics. We did ask some questions around culturally competent care. Interestingly enough, almost all of the states said that this is a very, very high priority, but past being able to say that it was a high priority, there really weren't any specifics in terms of what they were doing. There seems to be an awful lot of it – like it's politically correct to say this is what we want to do. I do believe that the states were interested in the areas, but they really seemed to have very, very few tools at their disposal in order to do the work that needs to be done in reference to cultural competency. Of course, some states have culturally competent initiatives going on and they can integrate with those particular states and what they are doing. What they were really saying was that we know that it's an issue for our communities. There were a few very forthcoming and very forward thinking commissioners who were saying that we do have large health disparities in our communities and between our communities, and we can begin to look at things like predictive testing, we can begin to educate around a number of different areas that would potentially have a good impact on some of these disparities in the long run. But they, again, don't have the tools.

The first message in reference to that is that states need the tools, generally speaking, around genetics. Because this survey was around genetics in general, people – outside of newborn screening – were really at a loss of what to do and how to think about this. You had the problem at the level of genetics overall in terms of managed care and public health, and then the next level was looking at it in reference to communities of color. So, you could imagine where people are in states on this issue. That was one piece of it. In addition to that, another piece came up and that related to being able to collaborate, because managed care is who is providing our care now. We in states probably have a better idea how to work with underserved communities. The managed care organizations don't necessarily have a clue in that area, or they are learning and they are growing. So we do need to collaborate between the two. And as we know, how is managed care working around issues relating to communities of color in general. I'm saying there is a learning curve and on the basic issues we have a problem. Then we have to take it to the next level.

I'm also working on a project in reference to pharmacogenomics– it's a NIH study – and put together a piece on communities of color in pharmacogenomics. That, of course, again, is a forthcoming issue, but there are things in reference to pharmacogenomics that we can look at right now in terms of communities

of color. One of the questions I wanted to ask is whether pharmacogenomics is something that's even on the board in reference to that issue.

Lastly, when we are thinking about genetics and how do we spark communities of color and professionals from across the board to look at this, I always have to look at something in its full context. As you were talking about this before, we have disparities in care and disparities in treatment. Whatever we are doing, we need to begin to pull the resources together that are working on issues around disparities of care, disparities in health status, and apply that to genetics instead of trying to start all over again, because I think there has been an awful lot of learning in the area. Those are some of the comments I have.

DR. LEWIS: Just to answer your question directly. Yes, pharmacogenomics is on the table. It's something we have been talking about from the very beginning, we've been educated by, and it's certainly one of the areas that we have on our plate.

LAURIE NSIAH-JEFFERSON: In terms of putting together that piece around communities of color, it's an extraordinarily complicated issue. There are some definite pluses
for communities of color around pharmacogenomics, but there are a lot of challenges and cautions as well in that area.

DR. LEWIS: Absolutely.

MR. BONHAM: Thank you for your comments.

DEREK ROBERTSON: My name is Derek Robertson. I am a consumer and I am also here representing the National Hemophilia Foundation. My comments won't necessarily reflect that, but I thought I needed to acknowledge that. I just wanted to reemphasize what has been said before. I want to disagree with a colleague of mine in saying that it is acceptable in some ways that some communities may not take to genetic testing, or words to that effect. I don't feel that is something we want to accept. We have to accept the challenge. We know what some of the barriers are and that is why a conference like this is so important. In terms of what specifically can the Committee do, just within your recommendations make sure that culturally appropriate materials, culturally appropriate education is something that is not going to be left behind when it comes to genetic testing. Even if we focus on what is already available in terms of genetic counseling related to issues like sickle cell, for example, that's something that has a real impact today; that's not something we have to wait for some more medical advances tomorrow. Those are issues that we have to really address now.

Another recommendation could be to have more seminars, educational sessions. Not necessarily to this scale – this is a huge conference. Much smaller, targeted educational seminars that can bring people in to discover how we can overcome these barriers. Just as a comment to some of the reaction that we saw, we heard, some of the comments that were made initially could probably give a sense of some of the reaction that some of the communities are also getting when they are approached. A lot of it has to do with how it is approached and the mechanisms. What the beauty of this conference has been is that I've seen so much expertise in various communities. That's why it's important, so we can tap into those resources, so that we can eventually overcome the barriers, and not accept that, well, this community is just resistant for a-b-c. We have to overcome that.

ROBERT YAMASHITA: Bob Yamashita, California State University-San Marcos. One of the critical

issues which Committee really needs to focus on is to look at the old diseases and not just focus on the new stuff that is coming out. Around the communities of color, hemoglobinopathies, sickle cell, thalassemia, provide key examples of failure of genetic education, genetic knowledge, dissemination, and also, around newborn screening programs, follow-up – what happens. It becomes critically important as many newborn screening programs are wrapping up for more testing, not less. What do you do when you diagnose cases? They have a clear strategy. What about trait? Given the failures within sickle cell trait follow-up. Let's go to the National Sickle Cell Disease Program. There's tons of evidence there. There is a complete retreat in California of doing any follow-up for identified trait cases, saying those programs don't work. They have never bothered to try to understand why, in the case of sickle cell, as a program which did have funded mandates, like trait follow-up for example, community education, they have never bothered to go back and say what happened here. To some extent those programs have shown signs of success that the point of time in which it was potentially becoming an area in which trait follow-up education, community education programs were about to happen, interest, funding, etc., dried up, disappeared. Perhaps it's good to review history, otherwise you are bound to repeat the failures.

DORTICIA McNEIL: Dorticia McNeil. Another issue that you should consider is reporting requirements. That has double sides to it. One thing is the idea of maintaining baseline data to determine whether there are disparities so that we can see who is getting the tests, who is getting counseling, and what type of follow-up treatment is being given to those who are diagnosed with certain diseases. The other thing that you need to consider when you are developing reporting requirements is the chilling effect of mandatory, named reporting. I know that's one of the problems with HIV testing. In some cases where there was anonymous testing allowed, it can be very successful, but in states or cities where they required names reporting of HIV tests, it has had a chilling effect. People don't want to get the test because of what may happen afterwards. But reporting is very important for places like OCR, if we are trying to make a case.

PARTICIPANT: I recommend providing funding for more people to become genetic counselors. Getting the word out in colleges or just like they had the big thing for teacher education. The state paid for it if you stayed with a certain place for so many years. That is what we need - more minority genetic counselors.

SHARON MARABLE: Hi. Sharon Marable, private citizen, again, Massachusetts. I work for Rhode Island Department of Health, but I am a private citizen right now. The other thing that you need to think about – back to the access piece, which is also disparities, is, within your rubric of the Department of Health and Human Services, you have a consolidated health center initiative. These health centers, as you probably know, serve many, many people of different race and ethnic minority groups who speak different languages, of different incomes, etc. We know that President Bush has a health center initiative, along with Secretary Thompson. If health centers are now on the table, maybe it would be prudent to some how integrate a line item for genetic services into that component, whether or not there be counselors. For example, they are already getting their physical exams, anyway. And you already have family planning money there, so, if they are getting counseling for contraception, why not have other counselors there, too, that can help them with this type of testing. Again, look at your infrastructure to see how you can dovetail your efforts into what you really want, and the states can really help you out. That's it.

MR. BONHAM: Thank you.

PARTICIPANT: Yeah, I wanted to say what I was thinking. The other thing is that what I have noticed is

another way to influence this policy is encourage CDC, when they write their RFPs for things like diabetes, to have a genetic component. Or obesity or the breast cancer detection programs, to integrate into their RFPs some type of genetic component because many of these programs nationally serve people from race and ethnic minority groups of different languages. If you make CDC put it into their RFP, therefore, it makes the states and the cities who respond to their RFP automatically do what they are supposed to do. Because when CDC says something, we jump. If they don't say something, we don't jump, even though it may be important. So dovetail your efforts with the heavy hitters in the federal government. I'm not saying that you are not a heavy hitter, with all due respect, but basically, the people that really have the money to make people do stuff. Think about that.

MARTIN RAYNER: My name is Martin Rayner. I'm from Honolulu, Hawaii. If I had any sense at all, I wouldn't tell you my name. What I want to tell you about is a horror story, a situation in which essentially everything went wrong. With some good outcomes, but everything went wrong. In 1846 a Belgian seaman swam ashore from the ship and decided he wasn't going back on that damn boat. He settled down with a native Hawaiian woman and now has had some 350 to 400 descendants – 350 now living. He carried a dominant genetic disease, which produced stroke and cardiovascular problems for people in their thirties and forties. This was considered by the family to be a curse, a problem that they should not have had anything to do with this guy. There was a lot of moral stigma going on in the family about this for generations and generations. About four or five years ago, people at the university decided that this was something they would really like to get their hands on in the sense of trying to find out what the mutation was, where it was, what was being affected, and particularly, since there were no symptoms to this problem until the people started to get their strokes in their 30s and 40s. If you could do the genetic testing early, then you could at least suggest who might be better off, perhaps, not having kids. And so there would be many people in these families who would benefit from some basic testing. Unfortunately, the study that was initiated was not funded. However, in order to get the grant approved, you have to have an IRB approval. Somebody else came along and rather fancied himself and went off thinking, "Well, I was kind of connected to that study, and that study got IRB approval, so I'm going to go over and interview these families and try and get some blood from them," which he did. He talked to them for some time about the values of genetic testing and at a series of family events was able to get blood from approximately eighty people. He then went off and of course, actually, he was going to send the blood for analysis to Duke, at the time when Duke was closed for problems with their IRB. So he never got that working. He sat for some eighteen months or so without getting back to the family and without being able to tell them anything about what he got. During that 18 months, the disease was identified, the site of the mutation was known. He could then send one patient's blood, which he did, to the Netherlands where it was tested and found that, indeed, this family did have a classic mutation. About this time, the family heard about it by roundabout routes because he did not know what to do. He had no funding, no money, he had no IRB approval, and he had come across a piece of information which was of considerable importance. The family heard about it, they got mad, they started raising a ruckus – very rightly, as they should have done. At that point, I became involved because I was the Chair of the Ethics Committee at the University of Hawaii. The subsequent ethics investigation showed that the IRB had made major faults. The university's IRB had missed – I won't go into it – they did a bunch wrong. The positive that had come from all this was the IRB was completely reformalized at the University of Hawaii by our action, without having to go outside. That was the only positive thing, as far as I can see, that happened from this bad incident.

The other outcome was tragic. The family got nowhere - they've had no genetic testing; they've had no genetic counseling, as far as I know. We have a frightened group of hospitals because the investigator concerned should have passed his project through the hospital IRBs as well as the university because he

was both employed by a hospital and the university – two different hospitals in the community. We now have hospitals that are frightened to do anything. We have a university that is scared that it will one day be sued for some of this, and we have a family that's got nowhere, and no help has been provided. This is how bad a thing can go wrong when dealing with a small, minority population in a distant place.

I'm telling this story because I lived through it, I'm a survivor of it in a sense. Yet, I don't think that the outcome has been good. The outcome has been nothing short of sad, all way round. While we have tried to get some genetic counseling to the family, no testing, as far as I know, has been carried out.

MR. BONHAM: Thank you very much for the comment relating an actual situation.

JENNIFER JOHNSON: It's me, again, Jennifer Johnson. I just wanted to touch on a couple of things that a couple of other people said. To the oncology nurse in the front on her suggestion to recruit more people into genetic counseling. If anybody has any ideas on how to do that, please let me know. I was the only African-American student who graduated from my school in May in the class of genetic counselors. The numbers, according to my thesis which I did on advocacy for sickle cell disease, according to 2000 data, ninety-three percent of genetic counselors are Caucasian, three percent Asian, one percent African-American, one percent Hispanic, and the other percent – just put other; it's a very small percentage, of course. We definitely need ideas in that area as far as recruiting more people of color into that field.

To the comment that the young man on my right made regarding hemoglobinopathies. That is a direction we can take. I'm not sure the age range of the people in the room, but in 1973, we did have the national Sickle Cell Anemia Act, which did legislate money for genetic counseling for the population at risk for sickle cell disease. Unfortunately, it did not go very well. A lot of African-Americans had a lot of backlash to it. They felt it was a lot of genocide regarding genetics and things like that. The timing as far as the civil rights issue and the lack of genetic counselors at that time contributed to the failure of it. Maybe if we revisited that issue because hemoglobinopathies are very important. You have the sickle cell carrier frequency in the African-American community being one in ten. In Africans from West Africa, you have it being one in four. That's huge. As a result of what happened with that act, a lot of medical professionals are still afraid to talk about sickle cell. That is evidenced by the fact that, according to the American College of Obstetricians and Gynecologists, their guidelines for screening for sickle cell and hemoglobinopathies is that physicians are told to test patients who they feel are in an at-risk group. Whereas this same group just recently made a recommendation that all Caucasian women should be directly offered testing for CF. Now, the carrier frequency for CF is one in twenty-five. The sickle cell frequency is two times higher but the recommendation is vastly different. We need to directly revisit that. My focus is sickle cell counseling. I genetic counsel everything. That's a direct path we could take. It's a great way to introduce genetics. There are a lot of famous African-Americans who I think would give support for it. They gave support for it in the seventies. You had people like Bill Cosby, Sidney Poitier. Now you have T-Boz, the girl from that rap group. It's a direct way to get involved. Destiny's Child is doing it.

MR. BONHAM: Thank you for your comments.

TRACI POWELL: Hi. My name is Traci Powell. I'm currently at the National Academies of Science. I just wanted to say that I believe there should be some focus on genetic education at the secondary school level. My research at Stanford, my study indicated – it was on genetic testing issues in breast cancer – there would be a benefit if minority communities and Caucasian communities were educated earlier on so that they grow up knowing something about genetics. With that being such a complicated issue or

complicated thing to study, they would not be so afraid or put off by the word genetic. They would know what that meant. Even if they don't go off to become scientists, I believe there should be more public education at an early age so they would be more informed, so when you do have the issue of testing for Tay-Sachs or some other prenatal or carrier testing, they would have some way of referencing what the genetic counselor is saying or what their physician is saying or what they read in the newspaper and magazines.

MR. BONHAM: Thank you. It's 5:15 p.m. We are coming to a close. Are there any last comments from the public here? Then I'm going to give my colleagues an opportunity to make any comments.

SHARON MARABLE: Well, as people were talking, as Sharon Marable. One thing that keeps coming up over and over and over is how are we going to build a health care workforce for genetics? Looking at the people on your Committee, you have a representative from HRSA. HRSA supposedly has initiatives on building health care workforce on many levels. Has there been any discussion regarding dovetailing some of these initiatives within HRSA? That's just a question, food for thought. Thank you.

DR. LEWIS: I can answer that directly, and tell you that, yes, there have been several grants that have been funded by HRSA that are looking at genetics workforce. Several of them are looking at mid-level providers as well as this issue. So, yes, HRSA is doing some work in that area. Michele maybe can talk to you afterwards.

SHARON MARABLE: Thank you.

DR. LEWIS: Does that make sense? Unless you want to say something on the record, Michele.

MICHELE PURYEAR: I'm Michele Puryear from HRSA. Actually, HRSA is an agency that has identified genetics training and education as a priority. However, there has been zero funding for that initiative. We have done some stuff with genetics and primary care initiatives, and as Judy said, we're doing a large workforce study in five centers. Except for small, isolated initiatives, there has not been a national program. So, your need you are pointing to is real.

MR. BONHAM: Well, Victor and Judy, any last comments?

DR. PENCHASZADEH: One comment certainly is that we will look very carefully to all your comments and recommendations and will try to put them forward and bring them to full discussion in the Committee.

With respect to the last issue about the genetics workforce. We also have very clear in our minds that medicine in general is being geneticized. In the sense there is no such thing and there will probably not be such a thing, at least in a wide spread way, of genetic services the way we conceive them today. There are a number of initiatives – Michele just outlined some of them - that call for education in genetics to all the healthcare force. I think this is the direction we have to go. The Committee, as such, has education as one of its main topics. I'm sure we will make recommendations in that regard. Thank you very much for being here with us.

MR. BONHAM: I'm going to make just a couple of brief comments and let Judy close. Your comments are important. They will help us in saying we have had opportunities to talk to people, and some of the concerns that members of the Committee have we are hearing from the public. I just want to thank you

very much and look forward to having you follow the work of the Committee. There is a website within your Power Point presentation that identifies the website, the phone number, how to get in contact with us. I encourage you to watch the work of the Committee. Again, thank you.

DR. LEWIS: My closing was going to be to tell you we are there to do work that we really believe is important for all the citizens. We've heard that loud and clear continuously. Please continue to look at our website. Everything that we do is there. Our meetings are all open. We invite you to come to our meetings. Our next meeting is August 15th and 16th at the Pooks Hill Marriott here in DC. Feel free to come to meetings. Feel free to email us. Feel free to testify at our meetings. Feel free to stay in touch with the issues. Continue to let us know how we are doing. It's really important to us that we do work that helps create policy that is good for all the citizens of this country, and that make sure that --. Our charge is specifically genetic testing, so some of the areas are outside of our purview. In the area of genetics, it's a microcosm of a lot of things. The recommendations that come forth in the service of genetics many times have brought applicability. We keep struggling with our charge. We need you to keep us on task.

So, again, thank everybody very much for being here.

I'd also like to acknowledge, when you do emails or if you do telephone, in the back of the room, Sarah Carr and Suzanne Goodwin, who are our staff, who do all of the work and who really need to be commended for all of the work they do on our behalf, as well. Thank you.